Quality, Patient Safety, and the Cardiac Surgical Team

Elizabeth A. Martinez, MD, MHS

BACKGROUND

The need for quality improvement (QI), coupled with increased safety and efficiency, continues to be at the forefront of health care discussions. To accomplish these goals, clinical leaders need to be proficient in the principles of QI, identification and mitigation of hazards, and redesign of care process. The practice of quality evaluation has evolved from primarily an external review of practice (such as accreditation, board certification, and licensing) to an internalized process of ensuring QI, and an increasing focus on outcomes. This evolution denotes the growing (and arguably obvious) recognition that quality cannot be improved by focusing on structure, process, or outcomes independently; rather, the entire continuum of care must be considered. Recent efforts to infuse industrial process innovations into health care, coupled with a national

KEYWORDS

- Quality
- Patient safety
- Cardiac surgery
- Continuous quality improvement
- Registries
- System redesign
- Collaboratives
- Interventions

KEY POINTS

- The patient safety literature has evolved from a quality-assurance focus to quality improvement using multidisciplinary teams that review the continuum of care: structure, process, and outcomes.
- Recent publications regarding patient safety in cardiac surgery consider teamwork and collaboration to be integral to improving patient safety.
- Cardiac surgery has a rich history in patient safety, including the use of benchmarking, public reporting, collaboratives, and systems redesign.
- Effective interventions use tools to ensure collaboration, such as briefings, checklists, and handoff protocols.

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Department of Anesthesia, Critical Care and Pain Medicine, Massachusetts General Hospital, Harvard Medical School, GRB 444, 55 Fruit Street, Boston, MA 02114, USA

E-mail address: Martinez.Elizabeth@mgh.harvard.edu

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agenda to improve the quality of care and reduce costs, have solidified a commitment to continuous QI (CQI). The trend towards more intensive self-evaluation is supported by partnerships with physicians to conduct QI, which is now a required element by licensing and accreditation bodies.

Cardiac surgery remains an area of focus for quality and safety efforts, because of its prevalence, high cost, and high-risk nature. There is a long history of quality work in cardiac surgery, but there is residual room for improvement. Early research seemed to indicate that volume was inversely correlated with outcomes: surgeons and centers that performed more operations tended to have lower mortality. Volume was initially accepted as a surrogate for quality and was adopted as a quality measure by the Leapfrog group.¹ However, it has since been shown that volume, when appropriately risk adjusted, is not the most important driver, or even a proxy for, quality in cardiac surgery. Thus, although practice (high volume) is important, other factors are amenable to improvements that influence patient safety, such as better teamwork and collaboration combined with a systems approach to proactively identify hazards and near-misses to correct or mitigate them.

This review introduces the reader to the principles of research in QI and the science of safety, followed by a targeted review of several decades of discussion surrounding quality and safety issues in medicine, and then presents a focused review of efforts to improve quality and safety in cardiac surgery, specifically. The review concludes with recommendations for future research regarding effective interventions to improve quality and safety of cardiac surgery.

INTRODUCTION TO QUALITY AND SAFETY
Perceptions of Quality and Safety

Patients and clinicians tend to agree that patient safety and health care quality are not yet where they need to be. In 1999, the Institute of Medicine’s (IOM’s) report To Err is Human² reinvigorated the focus on the state of patient safety in US medicine. Although this oft-cited report got the nation’s attention, the problem was not new. The practice of assessing quality began more than 4 decades ago with the publication in 1966 of Avedis Donabedian’s³ article on the evaluation of quality in health care. One of the concepts introduced in this seminal work is the notion of assessing quality from 3 vantage points: (1) structure (staffing patterns, personnel training, organization, tools, and technology), (2) process (the degree to which care practices are evidence-based, timely, safe, and followed), and (3) outcomes (such as mortality, functional improvement, and patient satisfaction).⁴ Donabedian’s framework reflects the interrelatedness of these concepts (Fig. 1). Furthermore, in 1991, Brennan and Leape⁵ noted that approximately 3% of hospitalized patients suffered a medical error, resulting in 44,000 to 98,000 deaths per year and billions in excess costs.

Several years later, a 1997 survey by the National Patient Safety Foundation found that 1 in 3 US adults have reported that they have been personally involved with a medical mistake with a permanent negative effect on health, and only half reported being very satisfied with their latest experience with a health care professional.⁶,⁷ In the intervening years, opinion has not improved measurably, even among clinicians. In a nationwide survey in 2001 of health professionals,⁸ 58% reported that health care in the United States was not very good, with as many as 95% of physicians reporting that they had witnessed a serious medical error. Four of 5 professionals stated that they believed that fundamental changes were needed in the American health care system. The problem continues to be grave. In a recent survey of 1034 Americans, 66% gave “the quality of health care in the country as a whole” a grade of C or lower.⁹
Improving patient safety is important, because it is the right thing to do. But there are economic imperatives as well; mistakes are costly. Purchasers and insurers are keen on making value-based decisions. Regulators, both governmental agencies and not-for-profit accreditation organizations, have developed improvement projects with built-in incentives for adoption, some of which may result in improved reimbursement, and others that are linked to a disincentive, such as nonpayment for certain hospital-acquired conditions (e.g., development of a pressure ulcer or a nosocomial infection). To this end, safety data have been collected and analyzed to identify trends, compare and reward institutions, and promote accountability.

Twelve-year trend analysis of patient perception of health care quality shows that patients are increasingly aware of the existence of such reports, and are taking an active role in ensuring quality and coordination of care. Health care decisions are more likely to be based on information about provider quality, such as expert ratings, than in previous years. Most (70%) patients double-check prescriptions for accuracy, and 2 in 3 call to follow up on tests. However, hospital decisions continue to be primarily driven by referrals from family and friends, and more than 90% of respondents were unaware of a new government Web site providing hospital comparison data (http://www.hospitalcompare.hhs.gov/). These data suggest that patients and providers are beginning to accept their joint role in monitoring and improving quality and safety. Yet these data raise as many questions as they answer. With continued vigilance on safety and ever-more information about inherent risks, why are there still safety issues? And what can be done about them?

Why Are Quality and Safety Poor?
Although this progress toward a more vigilant public and provider community is encouraging, some experts contend that the decade that has elapsed since the IOM report has not seen enough improvement in the quality and safety of clinical care. Adverse events continue to happen, many of which are deemed preventable, and this may be particularly true for cardiovascular procedures, which are inherently complex and multidisciplinary, requiring attention to detail, adherence to
protocols, and careful coordination. Yet such adherence is difficult to establish and sustain. In 2 evaluations of 12 different geographically located communities, McGlynn and colleagues\textsuperscript{12,13} reported that although some disparities in quality of care exist between regions and demographic subgroups, none of the gaps in care was as large as the deviations from standards of care. These investigators identified that, on average, patients are receiving the recommended practices only 54.9\% (95\% confidence interval [CI] 54.3\%-55.5\%) of the time, and 60\% (95\% CI 64.2\%-71.8\%) for coronary artery disease.\textsuperscript{12} Such systemic deficiencies in safety and quality indicate that attention needs to be directed toward errors of omission. This strategy may be particularly relevant to those working to improve quality and safety in cardiac surgery, in which adherence to standards of care and streamlining operating room (OR) procedures can have a real impact on patient safety, every day. In the highly technical and demanding surgical suite, attention should remain focused on identifying latent hazards that contribute to errors and adverse events.

\textbf{Types of Errors and How They Jeopardize Safety}

Although the patient safety literature has expanded since the IOM report, with nearly 3 times\textsuperscript{14} as many articles published and research awards granted in subsequent years, it is unclear whether this proliferation of attention in the journals came with any attendant change in frontline provider awareness or modifications to basic processes. Stelfox and colleagues\textsuperscript{14} suggest that despite the popularity of Reason’s Swiss cheese paradigm\textsuperscript{15,16} of latent and active failures in complex systems (\textbf{Fig. 2}), many providers cannot accurately describe what the model means. For many providers, the holes in the cheese are perceived to be caused solely by systems issues (latent failures), not potentially active failures (or departures from standards of care) by an individual.

In Reason’s model, the vulnerable system syndrome is created by the inadvertent alignment of both active and latent failures. Active failures have an immediate and adverse effect. Latent errors arise from managerial and organizational decisions (or the lack thereof) that shape working conditions. These latent errors often result from production pressures. Damaging consequences may not be evident until a triggering event occurs. Thus, the perception may be that chance is still largely responsible for adverse events. In the cycle of blame and denial typical of a vulnerable system, Reason argued, individual workers cannot be expected to pursue excellence. To

\textbf{Fig. 2.} James Reason’s Swiss cheese model of latent and active failures. (Reproduced from Reason J. Human error: models and management. BMJ 2000;320(7237):768–70; with permission.)
combat this perception, a culture of safety must be created by implementing systems to identify hazards and the structural issues that contribute to them, as opposed to blaming individuals after the fact. Perhaps the emerging recognition that teamwork and good communication are central to improving quality and safety will galvanize efforts to create systems that better support the humans performing difficult tasks under intense conditions.

**IMPROVING QUALITY AND SAFETY**

Creating a viable safety culture requires cognizance of both the inherent hazards in processes of care as well as structural adaptations to prevent or minimize risk. In its continued effort to provide guidance to hospitals, 4 of the 6 2013 Joint Commission National Patient Safety Goals\(^\text{17}\) are aimed at reducing errors (medication, patient identification, surgical mistakes, and infection); the remaining 2 are to improve communication and to identify patient safety risks (eg, reducing suicide). The last decade has seen more robust and multidisciplinary examinations of both structural and process-related factors with respect to their impact on outcomes. These efforts are reviewed in the next section.

**Evolution of QI Methods in Medicine**

Goal setting starts with definition. What is good quality of care? “Quality of care is the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge.”\(^\text{18}\) In 2001, 2 years after its initial report, the IOM developed a 4-tiered approach to improving quality and safety by: (1) establishing a national focus on safety leadership and knowledge; (2) identifying and learning from errors; (3) setting performance standards and expectations for safety; (4) implementing safety systems in health care organizations. Six specific aims for improving quality were developed (Box 1):

The quality literature has evolved, as have quality efforts. The term quality assurance (QA) was first used to describe quality initiatives. However, QA derives from a regulatory perspective: assurance that organizations or products and services are meeting minimum standards. The use of the term QA has since fallen out of favor, because it has traditionally been linked to just meeting the minimum standard. QI, on the other hand, invokes movement toward a goal. Accreditation bodies, such as The Joint Commission, seek to merge the 2 philosophies by both measuring quality and promoting standards of care delivery.

<table>
<thead>
<tr>
<th>Box 1</th>
<th>The 6 IOM aims for quality</th>
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<tbody>
<tr>
<td>1. Safe: avoids injuries to patients from the care that is intended to help them</td>
<td></td>
</tr>
<tr>
<td>2. Effective: provides services based on scientific knowledge to all who could benefit, and refrains from providing services to those not likely to benefit</td>
<td></td>
</tr>
<tr>
<td>3. Patient-centered: provides care that is respectful of and responsive to individual patient preferences, needs, and values</td>
<td></td>
</tr>
<tr>
<td>4. Timely: minimizes waits and sometimes harmful delays</td>
<td></td>
</tr>
<tr>
<td>5. Efficient: avoids waste</td>
<td></td>
</tr>
<tr>
<td>6. Equitable: provides care that does not vary in quality because of personal characteristics such as gender, ethnicity, geographic location, and socioeconomic status</td>
<td></td>
</tr>
</tbody>
</table>

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Numerous frameworks for assessing and improving quality have been proposed. Donabedian’s structure/process/outcome model (see Fig. 1) is still relevant more than 4 decades later. Structure comprises the stable elements of a system in which care is delivered via certain processes and interactions, which result in an outcome. Although both are useful and informative, there are important differences between process measures and outcome measures.

Process measures may be collected quickly and provide immediate feedback on how well the system is working to deliver care according to prescribed standards. Outcome measures are more meaningful to patients, clinicians, and insurers, but they are more difficult to measure and require risk-adjustment methods to adequately control for differences in the health status of patients. When selecting process measures, strong evidence must be available that shows that the process is linked to the desired outcome. Outcome measures are important to patients, physicians, and insurers, but they are imprecise. In a recent study, Shahian and colleagues reported that when comparing 4 different methods of assessing hospital mortality, 4 different rates were calculated. However, when outcomes are appropriately and accurately measured, comparing them can drive QI efforts by identifying differences that illuminate the complex interaction between structure and process and suggest problems in the implementation of care processes.

Once these hazards are identified, implementing improvements based on the principles of QI and patient safety are imperative. Such principles include the use of CQI methods, which includes plan-do-study-act (PDSA) cycles or similar rapid-cycle approaches to change, standardization of care, use of checklists, and other measures to introduce redundancy (reminders) into the system. Because cardiac surgery is one of the most prevalent surgical procedures in the United States, it provides an excellent proving ground for putting these principles into action. The impact of care redesign can be seen readily, and performance against recommendations can be compared across institutions to further motivate improvement.

Safety in Cardiac Surgery

Of the 357,000 patients undergoing a coronary artery bypass graft (CABG) or valve procedure in the United States each year, nearly 8% experience an adverse event; half of these events may be preventable, and 1 in 3 deaths may be avoidable. A recent focused literature review performed by the LENS (Locating Errors Through Networked Surveillance) research team supported by the Society of Cardiovascular Anesthesiologists Foundation (SCAF) synthesized nearly 4 dozen studies of such events to gain insights into hazards in cardiac surgery. The investigators found that most of the studies published were retrospective; only 3 identified at that time investigational interventions aimed at improving safety. One recently published study attempted to prospectively gather data on hazards using direct observation and contextual inquiry. More than 160 hours and 20 cardiac surgeries were observed and 84 contextual inquiries were captured. The team identified 59 hazard categories and grouped these according to the following system: care providers, tasks, tools and technologies, physical environment, organization, and processes (Box 2). This multicenter observational study provides numerous contemporary examples of hazards in cardiac surgery. The direct observational nature of the study afforded the investigators rich detail, making their findings actionable.

Among the latent failures identified by Martinez and colleagues, lack of a vigorous QA program to monitor and detect problems stands out as a key organizational deficiency exemplified in 2 pediatric cardiac mortality series that gained widespread attention in the late 1980s. The first was at Bristol Infirmary (Bristol, UK) and the
Box 2
Direct observation of hazards in the cardiac OR

- Care provider
  - Inadequate/insufficient knowledge or skills
  - Inadequate/lack of professionalism such as not respecting other providers
  - Nonstandardized approach to care delivery or task performance caused by habits, preferences, education, and previous experiences of individual care providers, which may not be based on the current evidence

- Task
  - Avoidable time pressure and unexpected changes
  - Ambiguities caused by different preferences of care providers
  - Nonvalue adding tasks

- Tools and technologies
  - Poor usability (eg, nonintuitive interface design, inconsistency in design, poor visibility of system status)
  - Poor fit or misalignment of safety features with users' needs or work as intended (eg, too many alarms without prioritization)
  - Use of tools, technologies, and supplies with different design characteristics and brands across different sectors of the work environment (eg, ORs and intensive care units [ICUs])
  - Delay in availability of tool and technology at the point and time of need (such as surgical equipment not sterilized in a timely manner)

- Physical environment
  - Poor planning and design of work area in relation to other parts of the OR suite and the hospital (proximity of OR suites to each other, to the storage areas and laboratories, and to the ICU)
  - Insufficiency of size and poor layout design of the ORs
  - Nonstandardization of work-space designs across different ORs
  - Poor configuration of work spaces leading to clutter, inadequate storage, and poor organization of tools, equipment, furniture, and cables

- Organization
  - Focus on productivity in expense of patient safety
  - Lack of or poorly organized policies and protocols for care and other processes
  - Inadequate discussion, training, and dissemination of protocol and policy changes
  - Exclusion of frontline providers' input to purchasing decisions that can potentially affect safety of care
  - Lack of or insufficient reinforcement of policies and protocols

- Care processes
  - Noncompliance with the recommended guidelines and practices
  - Lack of standardization in care processes

- Other processes
  - Ineffective supply chain management processes, resulting in unavailability of supplies and equipment in a timely manner

second was in Winnipeg, Canada.\textsuperscript{30–32} During a 6-year period (1988–1994), Bristol Infirmary providers’ concerns about 29 pediatric deaths initially went unheeded. Eventually, public outcry resulted in a moratorium on pediatric cardiac surgery while a full investigation was conducted. The investigators recommended systemic organizational changes to place a priority on QA, including feedback from patients and families. The investigators specifically recommended a centralized quality department with an audit function\textsuperscript{28,29,33} to detect issues and monitor progress after interventions. In Winnipeg, the pediatric cardiac surgery service experienced 12 deaths over the course of a year (1994). On investigation, issues with the QA program of the organization were again identified as contributors. In addition, the low volume of cases was implicated as a contributor to the clinicians’ lack of expertise in both series.

Just more than a decade after these 2 important cases occurred, enough evidence has accumulated to refine our understanding of other contributors, such as organizational issues, poorly designed tools and technology, and teamwork and communication. In a study by Weigmann and colleagues,\textsuperscript{34} poor teamwork and communication were found to be the only significant predictors of surgical errors (Fig. 3). Similar results have been found in studies by Hazelhurst and colleagues,\textsuperscript{35} Wong and colleagues,\textsuperscript{36,37} and others. Communication issues can be symptomatic of a hierarchical atmosphere in the cardiac OR. In an atmosphere that is not conducive to speaking up, small errors can compound, resulting in an inability of the team to compensate for major errors (Fig. 4).\textsuperscript{38} These studies provide real-world perspective on the hazards inherent in cardiac surgery and the numerous opportunities to improve safety with relatively simple changes.

A HISTORY OF IMPROVING OUTCOMES IN CARDIAC SURGERY

Cardiac surgery has a rich history of QI. Despite older and more ill patients presenting for surgery, mortality has decreased significantly over time. In this next section, some

\begin{figure}[h]
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\end{figure}
of the major efforts to improve cardiac surgical care and some recent examples of focused QI efforts are reviewed.

**Registries**

The Society of Thoracic Surgeons (STS) developed a national registry to capture important risk factors, processes of care, and outcomes. The STS database was introduced more than 20 years ago and has served as a source for national benchmarking and identification of variations in care processes. The results of findings from studies using the STS database have driven important QI efforts. Furthermore, the database and its risk models serve as a gold standard for other registries in health care. Nearly all cardiac surgical centers submit data to the STS or a state level registry (e.g., New York State CABG Surgery Reporting System) and receive data reports that show their performance in relation to national peers. This feedback loop has served as a powerful impetus for both local and national improvement efforts. Development of credible reporting tools is an important component of improving quality; understanding current performance is integral to priority setting.

**Report Cards and Public Reporting**

Early in the 1990s, the states of New York and Pennsylvania began to publicly report surgeon and hospital outcomes in cardiac surgery. The goal of this public reporting was to help cardiac surgeons improve the quality of care they deliver and to allow patients to select care from high-performing surgeons. Although cardiac surgical outcomes improved during the 1990s, controversy remains as to the impact, if any, this reporting had. However, it began to set the stage for transparency in health care and currently cardiac surgical outcomes are publicly reported nationally; some centers have even been ranked in an article in *Consumer Reports* (Consumer Reports home page (http://www.consumerreports.org/health/home.htm)).
Collaboratives

In addition to report cards, there is a long history of collaboratives for continuous QI, of which are presented here. The first large collaborative was the Northern New England Cardiovascular Disease Study Group, which consisted of 23 surgeons, representing 5 hospitals from Maine, New Hampshire, and Vermont. These surgeons performed a pre-post analysis after implementation of a program designed to help the cardiac surgical centers learn from each other. The interventions consisted of 3 key elements: (1) feedback on outcome data, (2) CQI training, and (3) site visits. Beginning in 1990, each surgeon in the collaborative received a report on their data in addition to a report on the performance of their hospital and the regional data, to which the surgeons remained blind. These reports were distributed 3 times a year and were timed with regional face-to-face meetings to discuss the reports. All members of the group were exposed to CQI training at the start of the intervention period so that they could participate in local improvement initiatives. Multidisciplinary teams, which included an industrial engineer in addition to clinical staff, were invited to visit another site. During these site visits, teams would observe practices throughout the course of the CABG procedure, including preoperative catheterizations through postoperative care. The teams returned with lessons learned and some of the findings inspired local QI projects.

After the intervention, which took place over 1 year, the collaborative team showed a 24% reduction in hospital mortality ($P = .001$), despite an increased complexity of the patient population. In an attempt to understand the drivers of this improvement, interviews with the management team at each center were conducted to identify what had changed. The list included modifications in technical aspects of care, the processes and organization of in-hospital care, personnel organization and training, and methods of evaluating care and in making treatment decisions. This group has remained intact with varying membership and has maintained its CQI framework to achieve successful data-driven improvements.

Another well-known collaborative in Alabama involved the state peer review organizations (PROs) as well as CABG practitioners and administrators from the 20 Alabama hospitals in which cardiac surgery was being performed at the time of the study. This collaborative intervention focused on 7 quality indicators (Table 1). Similar to the Northern New England collaborative, beginning in 1997 they included face-to-face meetings to introduce the project, its objectives, and baseline (preintervention)

<table>
<thead>
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<th>Table 1</th>
<th>Alabama standardized care processes</th>
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<tr>
<td><strong>Care Process</strong></td>
<td><strong>Standardized Approach</strong></td>
</tr>
<tr>
<td>Timing of operation</td>
<td>No elective patient is to be scheduled for surgery the day after cardiac catheterization</td>
</tr>
<tr>
<td>Preoperative briefing</td>
<td>Use of a robust checklist to review the care plan for the OR</td>
</tr>
<tr>
<td>Stroke prevention</td>
<td>Aortic imaging and cerebral oximetry were to be used in all cases</td>
</tr>
<tr>
<td>Prevention of atrial fibrillation</td>
<td>Standardized amiodarone and β-blocker protocol</td>
</tr>
<tr>
<td>Glycemic control</td>
<td>Use of standardized glycemic control protocol with clear glucose goals</td>
</tr>
<tr>
<td>Appropriate referral</td>
<td>Predetermined complex cases were to be referred out</td>
</tr>
</tbody>
</table>

data. In addition, a representative from the Northern New England Cardiovascular Disease Study Group met the teams to review their implementation process and provide a forum for questions. The Alabama teams also held a teleconference in 1999 to discuss progress, and a member of the state PRO visited each of the sites to check in on the progress they were making. Similar to the Northern New England collaborative, teams were invited to carry out reciprocal site visits. If a site visit took place, each hospital received a written report of the assessment by their peer highlighting similarities and differences between the sites. The collaborative showed that risk-adjusted mortality decreased in Alabama by 2% (4.9%–2.9%, \( P < .01 \)). The collaborative also showed improvements in many of the targeted indicators; those that achieved statistical significance are highlighted in Table 1.

A third quality collaborative was developed by the Michigan Society of Thoracic and Cardiovascular Surgeons. This group partnered with the state’s largest payer group (Blue Cross/Blue Shield of Michigan) to expand their quality work. The group comprised all of the cardiac surgical services in the state, and the funding by the payer group allowed for a more robust infrastructure, which helped support the efforts of the teams and facilitated opportunities to communicate, share data, and implement improvements. Improvement targets included: (1) internal mammary artery (IMA) usage, (2) preoperative intra-aortic balloon pump usage, (3) prolonged ventilation, (4) postoperative atrial fibrillation, and (5) CABG crude and risk-adjusted mortality. The teams met quarterly and reviewed their own performance in the context of the Michigan and national STS averages on the performance targets. IMA usage was targeted early because of the wide variation within the cohort and 7 notable outliers. As part of the improvement phase, surgeons were required to complete a form explaining why they did not use an IMA and fax it to the collaborative coordinating center; these were then shared with the teams at the next face-to-face meeting. Using this process, the 7 outliers improved their performance (Fig. 5), and the state’s performance on this metric improved. Similar successes in reducing variation and rates of prolonged ventilation were achieved. Site visits were also conducted at hospitals with risk-adjusted mortality that was consistently higher than the Michigan average. The visiting team then reported back to the site with an analysis of their findings and suggested opportunities for improvement. This collaborative continues to be active and has since developed a focused review of all deaths in the state to continue the momentum.

The Cardiac Surgical Translational Study is a fourth collaborative, which incorporates the Comprehensive Unit-Based Safety Program \(^47\) and evidence-based practices to reduce perioperative infections in a national cohort of cardiac surgical centers. Principal investigator Peter Pronovost plans to implement the same intervention design.

Fig. 5. Improvements in IMA use in Michigan. (Reproduced from Prager RL, Armenti FR, Bassett JS, et al. Cardiac surgeons and the quality movement: the Michigan experience. Semin Thorac Cardiovasc Surg 2009;21(1):24; with permission.)
that improved the rate of catheter-related blood steam infections in Michigan. This study, supported by the Agency for Healthcare Research and Quality, and in collaboration with national professional societies including the SCAF, is under way and results are not yet available.

SCAF (http://scahqgive.org; accessed January 13, 2013) has implemented the FOCUS (Flawless Operative Cardiovascular Unified Systems) project, with the goal of eliminating systems-based failures in cardiac surgical care. SCAF partnered with researchers from Johns Hopkins University to identify hazards in cardiac surgery and continues to serve as a member of the CSTS Collaborative. These investigators are working to build and solidify bridges between the national societies representing all of those individuals who care for cardiac surgical patients, including the American Society of Extracorporeal Technology, Association of Operating Room Nurses, National Center for Human Factors Engineering in Healthcare, and the STS. Only through unified approaches such as these can we make important and long-standing improvements in cardiac surgical care.

Process Redesign

The literature provides 2 good examples of a process redesign in cardiac surgical service to guide improvements in the care delivery process. The first implemented process improvement within a long-standing clinical program, and the second incorporated quality and safety principles into plans for a new cardiovascular center.

The first, a program called ProvenCare, was implemented at Geisinger Health System, which is a large integrated health system in Pennsylvania. In 2005, the cardiac surgical service team set out to update the delivery of evidence-based care in cardiac surgery by implementing a program in 3 phases: (1) review and validate best practice evidence, (2) redesign the process (of delivery), and (3) implement the new process. To accomplish phase 1, the team reviewed the literature, with a focus on the American College of Cardiology/American Heart Association class I and IIa recommendations for patients with CABG. A leadership team distilled this information and presented it to the cardiac surgeons at Geisinger. Through discussions and consensus, 19 recommendations (which consisted of 40 process elements) were agreed on and standardized for inclusion in the program. During the redesign phase, the team identified the process flows for each surgeon so that they could identify local variation in care delivery and begin to formulate a new process flow that would be used to anchor their redesign efforts (Fig. 6). This process map identified the points at which the

Fig. 6. Process map for care of the cardiac surgical patient. (Reproduced from Berry SA, Doll MC, McKinley KE, et al. ProvenCare: quality improvement model for designing highly reliable care in cardiac surgery. Qual Saf Health Care 2009;18(5):363; with permission.)
best practices should be integrated in the care delivery continuum. Integral to this process was a review of ways to leverage the electronic health record to facilitate the adoption of the 40 evidence-based processes. The teams undertook several PDSA cycles to settle on the ideal processes to incorporate standards and reduce redundancy.

Six months after the initiative began, ProvenCare was implemented. In the overall analysis, the investigators reported that performance improved on the 40 measures by 41%: at baseline, 59% of patients with elective CABG received all 40 elements compared with 100% during the last 6 months of the data collection period. Outcomes at 30 days are shown in Table 2 and represent 137 patients in the preintervention phase and 117 in the postintervention phase. Although provable trends toward improvement were noted for many of the outcomes evaluated, the only statistically significant difference was the number of patients discharged home.50

The second example of a process redesign is reported by Culig and colleagues.51 In this unique example of a proactive process design evaluation, the team reviewed all aspects of the cardiac service line before the introduction of a new cardiac service. The Toyota production system-based methodology (operational excellence) was used to inform the evaluation. The team began the training 2 months before a patient was treated, and the work continued for 2 years. The entire team (both clinical and administrative) was educated on the plans and methodology. A key to the redesign in this system was real-time problem solving: problems were identified daily and addressed by the team during daily reviews of the previous 24 hours. Plans for process changes were initiated immediately on review. In addition, the team standardized 6 care processes (Box 3). Other standardized protocols were implemented based on daily hazard identification.

Because a new service was being redesigned, baseline data were not available. However, the team did compare results with like patients within the same geographic region using the STS database. Reported mortality and complications rates were 61% and 57% lower than the comparator group, respectively. The team addressed more

<table>
<thead>
<tr>
<th>Outcome Variable</th>
<th>Before ProvenCare</th>
<th>With ProvenCare</th>
<th>Improvement/Reduction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Average total length of stay (days)</td>
<td>6.2</td>
<td>5.7</td>
<td>–</td>
</tr>
<tr>
<td>30-d readmission rate (%)</td>
<td>6.9</td>
<td>3.8</td>
<td>↓44</td>
</tr>
<tr>
<td>Discharged home (%)</td>
<td>80</td>
<td>91</td>
<td>↑11b</td>
</tr>
<tr>
<td>Patients with any complication (%)</td>
<td>38</td>
<td>30</td>
<td>↓21</td>
</tr>
<tr>
<td>Patients with less than 1 complication (%)</td>
<td>7.6</td>
<td>5.5</td>
<td>↓28</td>
</tr>
<tr>
<td>Incidence of atrial fibrillation (%)</td>
<td>23</td>
<td>19</td>
<td>↓17</td>
</tr>
<tr>
<td>Neurologic complication (%)</td>
<td>1.5</td>
<td>0.6</td>
<td>↓60</td>
</tr>
<tr>
<td>Any pulmonary complication (%)</td>
<td>7</td>
<td>4</td>
<td>↓43</td>
</tr>
<tr>
<td>Received blood products (%)</td>
<td>23</td>
<td>18</td>
<td>↓22</td>
</tr>
<tr>
<td>Reoperation for bleeding (%)</td>
<td>3.8</td>
<td>1.7</td>
<td>↓55</td>
</tr>
<tr>
<td>Deep sternal wound infection (%)</td>
<td>0.8</td>
<td>0.6</td>
<td>↓25</td>
</tr>
</tbody>
</table>

* At 18 months.
* P = .03; the only statistically significant outcome.

than 900 perioperative issues identified by frontline staff at an estimated cost savings of greater than $884,900.\textsuperscript{51} One of the limitations of this study is that 83\% of the cases were performed by a single surgeon, making it potentially more difficult to generalize the effect of changes to a broader population of clinicians.

**Teamwork, Communication, and Culture Change**

Communication difficulties are consistently identified as the root cause of errors. According to data gathered by The Joint Commission, which monitors all reported sentinel events, communication breakdowns contribute to more than 60\% of all sentinel events.\textsuperscript{54} Several strategies can provide a way to structure communication such that oversights are not so common. Briefings are 1 way to provide information to all team members at the beginning of surgical cases, and have been shown to affect outcomes among general surgical cases.\textsuperscript{55} In the cardiac surgical literature, Henrickson and colleagues\textsuperscript{56} pilot-tested the impact of a cardiac surgery-specific briefing tool (Fig. 7), which was developed based on input from focus groups and survey data.

The new briefing tool was implemented by a single surgeon at the institution and observational data were collected before intervention (10 operations) and after intervention (6 cases). Observations were made by a single individual to identify surgical flow disruptions, the number of trips made by the circulating nurse to the central core for equipment or other issues, and the time spent in the core.

After implementation of the tool, there was a statistically significant reduction in surgical flow disruptions (4.1–2.7 per case), procedural knowledge disruptions (4.1–2.17 per case), miscommunication events (2.5–1.17 per case), number of trips to the core (10–4.7 per case), and time spent in the core (397.4–172.3 seconds). Minimizing disruption is important because it has been shown to affect outcomes: disruption reduces the team’s ability to compensate for minor errors and predisposes the surgical team to experiencing a major event.

There are multiple examples of interventions to improve teamwork and communication during transitions of care. Two are highlighted in this section: 1 for pediatrics and 1 for adult cardiovascular patients. Among pediatric patients, Catchpole and colleagues implemented a Formula 1 pit-stop model to reduce technical errors and omissions during handoffs to the ICU. Their model was successful, and did not increase handoff duration (Fig. 8). Petrovic and colleagues performed a pre-post study of a handoff protocol from the OR to the cardiac surgical ICU. These investigators introduced a standardized template and required that all caregivers be present at the patient’s bedside and focused on the patient with only 1 person speaking at a time. A decrease in the percentage of missed information in the surgical team’s report

<table>
<thead>
<tr>
<th>Summary of the new handover protocol</th>
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<tbody>
<tr>
<td><strong>Phase 0: prehandover</strong></td>
</tr>
<tr>
<td>The Patient Transfer Form is completed by the anesthetist and collected from theater at least 30 min before the patient is transferred to the ICU.</td>
</tr>
<tr>
<td>The receiving doctor ensures that all appropriate paperwork is ready.</td>
</tr>
<tr>
<td><strong>Phase 1: equipment and technology handover</strong></td>
</tr>
<tr>
<td>On arrival the team transfers the patient ventilation, monitoring and support from portable systems used during the transfer to the ICU system.</td>
</tr>
</tbody>
</table>

![Fig. 8. Formula 1 pit-stop handover protocol. (Reproduced from Catchpole KR, de Leval MR, McEwan A, et al. Patient handover from surgery to intensive care: using Formula 1 pit-stop and aviation models to improve safety and quality. Paediatr Anaesth 2007;17(5):473; with permission.)](image)
to the ICU from 26% to 16% \((P = .03)\) was reported, and the percentage of ICU nurses who reported being satisfied with the report increased from 61% to 81% (Fig. 9).

A third example of improved teamwork and communication can be found in work carried out by the Concord Hospital in Concord, New Hampshire. This intervention focused on the ICU and introduced team-based, daily collaborative rounds using a structured communications protocol (Collaborative Care Model). These investigators also introduced a biweekly forum to discuss the progress to date and address systems-level concerns. Key elements in the new process included rounds led by the nurse practitioner instead of the surgeon, dramatically changing the hierarchical playing field. Also novel is the fact that the patient and family members were invited to participate and share with the team anything that had not gone well ("system glitches", in the team’s parlance) during the episode of care. The researchers evaluated the impact of the intervention on mortality and staff quality of life, and reported improvements in both, with a decrease in the observed mortality compared with the expected mortality and an increase in scores on the staff quality of life survey.

In all these interventions, communications were standardized using new tools and processes that made the communication process more collaborative and less hierarchical, showing improved patient outcomes and staff satisfaction. These processes recognize the fallibility of the human element in communication and provide the tools (checklists, standardization) to guide the conversations and support good communication. With improved communication, the culture changes from fear of failure to a more progressive stance that promotes patient safety.

![The Perioperative Hand Off Protocol](image)

Fig. 9. Johns Hopkins medicine perioperative handoff protocol. (Copyright © 2009 The Johns Hopkins University. All rights reserved.)
SUMMARY

The literature shows how structural and process factors can predispose the cardiothoracic surgical team to experience errors while completing the complex series of tasks during the perioperative period. Successful completion of these tasks hinges on both technical work (completion of tasks in compliance with recommended standards) and adaptive work (organizational culture, teamwork, and provider characteristics). A culture of collaboration is essential to ensuring that both the technical and adaptive work are performed in a manner conducive to safety. Good teamwork and communication are at the epicenter of patient safety reforms, because they create a culture of safety and collaboration.

Relatively simple tactics can deliver big gains in patient safety, such as those described in this review. Other industries, such as aviation and nuclear power, rely on systems approaches to optimize communication and prevent human error. Processes to standardize care, provide feedback on performance, and add redundancies as safety checks provide similar supports in medicine. High reliability depends on vigilance at every level and at every step in the care process. Martinez and colleagues suggest 3 strategies to create such an environment: transparency (reporting systems and an atmosphere conducive to speaking up); teamwork (train team members in constructive communication skills to deconstruct the hierarchical nature of the OR); and task performance (keeping skills up to date and identifying weaknesses in tools and technology that compromise task performance). Individuals must share a mental model of the goals and methods for care, and this distributed cognition should extend to training in tools and technology. It is imperative that strategies that improve the safety and quality of care of the cardiac surgical patient population continue to be identified and quantified.

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REFERENCES


