Leadership Oversight for Patient Safety Programs: An Essential Element

Susan Moffatt-Bruce, MD, PhD, Stephen Clark, MBBS, FRCS, Michael DiMaio, MD, and James Fann, MD

Department of Surgery, Ohio State University, Columbus, Ohio; Freeman Hospital, Newcastle upon Tyne Hospitals NHS Foundation Trust, Newcastle, United Kingdom; Department of Cardiothoracic Surgery, Baylor University Medical Center, Dallas, Texas; and Department of Cardiothoracic Surgery, Stanford University, Stanford, California

Leadership in the realm of quality oversight and endorsing a culture of safety is paramount. The stakeholders, ranging from the surgeons to the Chair of the Board have to be engaged and really understand the importance of leadership support. Clarity of leadership support, innovation in process improvement as well as performance management and accountability are the foundational components of a strong culture of safety. Alignment of all stakeholders and continuous improvement that is supported by leadership will ensure the best outcomes for surgical patients.

More than a decade ago, the Institute of Medicine Quality of Health Care in America Committee released a comprehensive report, “To Err Is Human: Building a Safer Health System,” addressing issues related to patient safety and laying out an ambitious national agenda for reducing errors in health care and improving patient safety [1]. Subsequently in 2005, the Patient Safety and Quality Improvement Act was signed into law to promote voluntary and confidential reporting of adverse events and improved communication among providers to improve patient safety [2]. Not long before that, the Medicare Prescription Drug, Improvement, and Modernization Act introduced the Acute Care Episode Demonstration, which aimed to shift the health care focus from quantity of care to quality of care [3].

The initiatives resulted in millions of dollars saved without negatively affecting patient safety [4, 5]. The most significant regulatory overhaul, however, was in 2010 when the Patient Protection and Affordable Care Act was signed into place. Under this Act, the Centers for Medicare and Medicaid Innovation was established to improve quality of care and reduce the rate of growth in health care costs [6]. This legislation resulted in further expansion of bundled payments and reimbursement shifts laid out by the Centers for Medicare and Medicaid with Innovation’s Bundled Payments for Care Improvement Initiative as the most recent nationwide project [7]. With the current administration, the fate of the Patient Protection and Affordable Care Act is yet to be defined and determined.

In Europe these initiatives have been mirrored. Taking the United Kingdom National Health Service as an example, where 1 million people use health care services every 36 hours, recent high profile cases, such as the neglect of patients at Stafford Hospital, prompted the regular review of patient safety incidents and health care associated infections (to demonstrate that the National Health Service is open and learns from mistakes) and led to the introduction of a list of 25 “never events”—incidents that can cause severe harm or death and that should never happen because guidance and tools exist to prevent them (eg, wrong site surgery or retained instruments).

Such an effort was supported by a system of giving all doctors regular assessments (revalidation) to ensure that their training and expertise are up to date and they are still able to provide high-quality care for patients; introducing a “duty of candor” so patients must be told if their safety has been compromised, to apologize, and to make sure that they learn lessons so that mistakes do not happen again; and a new system to allow staff to raise concerns without risk about issues that are in the public interest. Patient safety has also become a major focus in Germany, with efforts to improve patient safety involving all stakeholders in their national health care system. Initiatives to raise the quality of health care services also strengthen patient power and participation in decision making through mandatory and voluntary programs focused on quality of care and safety.

Improving our global health care processes to ensure safe and high-quality care is not only what the public demands, but it is also now tied to our reimbursement and will likely continue to be so. Authorized by the Affordable Care Act, the hospital value-based purchasing program is the beginning of a historic change in how Medicare pays health care providers and facilities—for the first time, hospitals will be paid for inpatient acute care services based on care quality, not just on the quantity of the services provided.
sustain gains in reducing care-associated adverse events while continuing to fund our mission to provide high-quality care, health care institutions have welcomed standardized, evidence-based practices as well as purposeful engagement of the entire health care team.

In England, the Care Quality Commission inspects health care institutions to rate their safety, effectiveness, and leadership publishing ratings for patients to directly compare hospital standards. The National Institute for Health and Care Excellence provides a repository of evidence-based guidance and cost-effectiveness information across the breadth of health care with which institutions are expected to comply.

Amid the political climate, patient safety is clearly a priority in health care, and the success of our industry will be completely dependent on measured outcomes. To that end, we, as surgeons and care providers, need to be leaders to ensure that a robust platform around patient safety is created, the tools for success are available, and the outcomes are collected and reported back to all stakeholders.

**Role and Responsibilities for Successful Oversight**

Health care and the provisions thereof require a combination of clinical skill, judgment, and teamwork. Providers are privileged to be a part of a system focused on treating the ill, reducing suffering, and sometimes simply supporting the patient and family. However, there are times when our care, despite our best intentions, does not produce the outcomes intended or cause harm to the patient. Although teamwork is essential for the provision of safe care, there are a several key roles within an organization that can serve to establish the culture and expectation that patient safety is a fundamental priority for the institution. These roles include that of the chief quality officer, the chief executive officer, and the chairperson of the board.

**Chief Quality Officer**
The “call to arms” that started more than a decade ago has as a goal of creating a culture of safety and accountability; this effort to a large degree has been effectively delegated to key persons within an organization. Changing culture can be difficult, and it takes more than a checklist to achieve a safe environment for our patients and surgical teams. Creating a culture of safety means ensuring that the highest quality of care is not just a theme or a series of memos, but rather is at the core of care provided for every patient and is embedded in everything we do. Creating this environment is often the responsibility of the chief quality officer (CQO). Although no one person can be responsible for all patients and outcomes, the CQO has the privilege and responsibility of encouraging and supporting every provider in his or her efforts to ensure the best outcomes for all patients. The entire field of quality and patient safety has become, out of necessity, a discipline or area of expertise in how to effectively engage with organizational culture to translate quality and patient safety goals and objectives into concrete aims and metrics that can be tracked, measured, and communicated to other organizations to ensure the learning is shared.

Traditionally, the responsibilities of a CQO were part of those of the chief medical officer in smaller hospitals; often the role of the CQO was perceived as something “extra” or as a compliance requirement to supplement the “real work” of patient care. Not uncommonly, the “safety officer” or “quality assurance person” received little respect, whose efforts were not heeded. In today’s health care environment, with public reporting of medical errors and recognition of and support for the concept that adverse events frequently are a result of system failures and not solely provider error, the role of the CQO has become critical to the entire enterprise [8–10]. The CQO must have the ability and skills set to acknowledge root causes of system failures, develop countermeasures, and impact change. Ideally, requisite traits of a CQO are essential leadership skills, including the ability to assess clinical practice gaps, understand the science of improvement and reliability, foster transparency, engage other physicians and nurses, and set clear outcomes and metrics [11–13].

Identifying an effective CQO requires finding a person who embraces change and values continuous performance improvement. The CQO must be able to lead initiatives, address issues, generate support from clinicians, and create and engage the health care team. Often, as talented as they are, these leaders will likely need training in process improvement, conflict resolution, and group negotiations. In addition, every CQO needs dedicated time to network with peers, attend national conferences, conduct meaningful hospital rounds, and actively work with other team members on projects and rapid cycle improvement. Experience with administrative issues such as resource allocation, contracting, budgeting, and strategic planning is very helpful for a CQO as these administrative skills may facilitate goal setting and outcomes measurement [14, 15].

Lastly, the ideal CQO should have sufficient clinical experience and expertise that are recognized and respected by providers. The CQO should be at a career stage whereby he or she can maintain clinical credibility and yet have administrative support and time to promote and effect change in the organization. It is unlikely that a junior physician in a community-based practice or an assistant professor in the academic environment—or for that matter, a physician nearing the end of his or her career—would command sufficient support to effectively impact hospital policies.

**Chief Executive Officer**
The chief executive officer (CEO) of any health care organization is key to the success of a patient safety program. Whether the CQO reports directly to the CEO is perhaps less important as long as the CEO endorses and openly supports the programs put forward. Whereas the CEO does not need to be entirely immersed in the details of the programs, he or she should be able to speak to how
goals are set, articulate the important strategic initiatives that are under way to ensure patient safety, and be willing to assign necessary resources to the projects. Engaging the CEO to participate in hospital rounds will engender a sense of importance and organizational commitment to patient safety among the front line staff. In addition, the CEO should be made aware of significant patient safety events and initiatives so that he or she can inform the board or other key administrative stakeholders. The CEO should always be aware of and never be surprised by what is happening—good or bad—within the organization.

In the United Kingdom, CEOs (with their management teams) are assessed and rated by the Care Quality Commission on the quality of their leadership, and there is a focus on commitment to patient safety and quality. These assessments are published and available to any member of the public.

**Chairperson of the Board**

The chairperson of the board is a key figure in setting the tone regarding the importance of patient safety to the organization and all those that are responsible for it. A key indicator is where the quality and patient safety report falls on the agenda of board meetings. If the report is relegated to a 10-minute briefing at the end of the meeting, the message delivered to the providers and staff is that it is of lesser importance to the hospital leadership. Instead, if the quality and patient safety report is early on the agenda with ample time for discussion and feedback, the clear message is that this issue is one of priority. It must be recognized that the chairperson may need additional time before the board meeting to fully understand the details of the report, which is an opportunity for meaningful interchange and engagement. The board and its chairperson are ultimately responsible for the highest quality and safest care possible within an institution. Leveraging their enthusiasm, interest, and stature will be key to a successful patient safety program.

**Reporting Structure and Administrative Committee Support**

Every health care institution, big and small, is structured a little differently. Nonetheless, some form of institutional Quality and Patient Safety Committee is essential. The mission for such a committee should be providing the highest quality of care for all surgical patients, which implies care that is safe, efficient, effective, patient-centered, timely, and equitable. The Quality and Patient Safety Committee should have diverse and appropriate representation from across the institution and should comprise physicians, nurses, administrators, and staff. The goals and agendas of such committees should be transparent and the accountability real. Trainee, staff, and student representation should be encouraged where appropriate. The reporting and accountability of departmental and programmatic committees on quality and patient safety should be to the hospital or system level Quality and Patient Safety Committee; ideally, the CQO should be an active member of the hospital oversight committee. Having patient participation on such committees is emphasized and will serve to establish a level of trust and openness across the care continuum. Data transparency and defining the level of data sharing are within the purview of this committee to provide feedback to the institutional care providers and to allow for implementation of performance improvement strategies.

**Culture of Safety and High Reliability at All Levels**

The root causes for most serious adverse events often include deficiency in or lack of communication, teamwork, patient involvement, reliable processes, and organizational emphasis on safety and reliability; also troublesome is the inability of the department or organization to learn from its mistakes. Understanding that a just culture is one of trust is essential. A just culture is not only a culture in which people are encouraged to provide essential safety-related information; it is also a culture in which the line can be drawn between acceptable and unacceptable behavior as defined by James Reason’s five-part algorithm for creating accountability [16].

Importantly, there are several examples of measurable advances in patient safety in health care systems [17–19]. A number of notable organizations and programs are able to achieve and sustain significant reductions in preventable adverse events and hospital-acquired infections with a reduction in sentinel events and risk-adjusted death rates, improvement in safety attitude and culture, and increased reporting with more effective investigation of patient safety incidents [18, 19]. The common theme among all of these successes is that improved patient safety metrics have translated into improved staff morale and reduced costs resulting from shorter hospital lengths of stay. These findings resonate with leadership of all levels.

The most significant characteristic shared by organizations that have made progress in patient safety with good outcomes has been consistent and genuine engagement by leadership [20]. This focus on the importance of leadership, specifically with regard to physician education and awareness, has been reflected in new requirements and guidance of the Accreditation Council for Graduate Medical Education (ACGME) [21]. The ACGME has established the Clinical Learning Environment Review program as a key component of the Next GME Accreditation System with the aim to promote safety and quality of care by focusing on six areas important to patient care in teaching hospitals and to the care residents will provide during a lifetime of practice after completion of training. The six areas encompass engagement of residents in patient safety, quality improvement and care transitions, promoting appropriate resident supervision, duty hour oversight and fatigue management, and enhancing professionalism [21, 22]. This is mirrored by the General Medical Council Good Medical Practice guidelines in Great Britain.

These new sets of criteria and expectations have proven to be a tipping point for establishing the importance of patient safety for all care providers, regardless of their level of training. Nursing leadership has also been
highlighted for its critical role in establishing a culture of safety and improving clinical outcomes by directly addressing clinical workflow and patient-care processes at the bedside [22, 23].

What does a “culture of patient safety” actually mean and what does it entail? A comprehensive survey of California hospitals found seven key characteristics: (1) commitment to safety at the highest level; (2) necessary resources for safety are provided; (3) safety is the highest priority; (4) all coworkers communicate effectively about safety concerns; (5) hazardous acts are rare; (6) there is transparency in reporting and discussing errors; and (7) safety solutions focus on system improvement, not individual blame [17]. To improve a culture of patient safety, it is essential to first accurately measure the safety culture, thereby providing baseline data important in assessing the impact of any intervention. The survey most frequently used is the Hospital Survey on Patient Safety Culture that was developed by the federal Agency for Healthcare Research and Quality. This tool has been used extensively to develop patient safety programs in hospitals across the country, and the Agency for Healthcare Research and Quality now publishes comparative data to support continuous improvement and collaboration [22, 24]. Another powerful leadership tool in the hospital setting is Patient Safety Leadership WalkRounds, in which a senior leader undertakes walking rounds to discuss patient safety with staff and patients and their families. Safety issues are recorded, prioritized, and addressed with system wide changes at subsequent meetings. This has been an effective tool in demonstrating that senior leadership value patient safety and will address adverse events and vulnerable systems in a nonpunitive manner [25].

The use of crew resource management across entire departments and hospitals has been part of a culture transformation and recognizes the importance of human factors in safety and prevention of errors [26]. Team training uses crew resource management theory from aviation that has been adapted for health care [26, 27]. Team training, as it currently exists in our operating rooms, relies heavily on checklists and effective care transition communications. The use of these checklists has been shown to globally reduce morbidity and mortality as made evident by the World Health Organization’s Safe Surgery Saves Lives program [15]. Since this seminal publication, the Safe Surgery Checklist, as popularized by Dr Atul Gawande, has spread from the operating room to every aspect of patient care. In Europe, the publication and use of subspecialty checklists for cardiac, thoracic, and transcatheter aortic valve implantation procedures has increased further the specificity and usefulness of this process [28].

The investment, both in terms of time and money, in such programs is real but the results can be impressive [26]. Lastly, the Lucian Leape Institute at the National Patient Safety Foundation has endorsed five overarching principles for transforming hospitals and clinics into high-reliability organizations. These include transparency in disclosing errors and quality problems, integration of care across teams and disciplines, engaging patients in safety, restoring joy and meaning in work, and reforming medical education to focus on quality and safety [9, 19].

Innovation in Process Improvement: Engaging the Team
In traditional health care organizations, responsibility and accountability for patient safety, patient satisfaction, staff satisfaction, and operational efficiency have resided with senior leaders who are not clinically responsible for the patients. What is needed, in most instances, is a more grass roots approach that engages those on the front lines of health care to identify challenges, and that is embraced by leadership. This path allows the care providers to implement solutions and sustain change in the areas of quality, patient safety, resource utilization, patient experience, and financial responsibility. Because the traditional model of rapid cycle improvement addresses one issue at a time, teams outside the clinical area are likely to be less engaged. We have previously proposed a more bottom-up, grass roots approach that directly involves those on the front lines of health care to identify challenges, implement solutions, and sustain change in the areas of quality, patient safety, resource utilization, patient experience, and financial responsibility.

As performance and quality improvement are critical elements of all population health management approaches, one approach is to explore how a performance improvement strategy focused on patient safety improvement can be developed and deployed in a large academic medical center. Operations Councils are an example of where an extension of the process improvement models, including Lean and Six Sigma, use traditional process improvement techniques with a focus on building a collaborative culture that incorporates front line staff in the process. Each Operations Council identified a facilitator who was part of the front line staff who could dedicate time to being trained as a “Yellow Belt Lean Six Sigma” facilitator while still staying clinically active. The facilitators can be nurses, pharmacists, and technicians who completed Yellow Belt Lean Six Sigma in the first year of Operations Council deployment. All process improvement projects had to be in alignment with the health system key result areas of innovation and strategic growth, productivity and efficiency, quality, and service and reputation. Overall, Operations Councils have been shown to reduce medication harm events, mortality, and patient safety events among patients who arrive with life-threatening and difficult care issues [29].

In European practice, hospital committees comprising senior clinically active clinicians and nursing staff alongside administrators regularly review safety incidents to analyze causative factors and widely share learning within and outside the organization. This regular overview permits trend analysis and prevention and ensures that safety issues are dealt with fairly and without blame. Furthermore, it acts to ensure that patients are informed of safety issues that have affected the outcome of their care (a statutory requirement in the United Kingdom) and communicate the results of any investigation directly to them.
Performance Management and Accountability
Managing Tension Between Quality, Efficiency, and Patient Satisfaction

With the pressures of the hospital value-based purchasing program and similar performance-based reimbursement worldwide, tension has been created within organizations relative to priorities of safety, efficiency, and patient satisfaction. We propose that the solution to this problem is to incentivize a cultural shift within healthcare systems toward patient-centered care, possibly through including patient-centered care metrics in the Centers for Medicare and Medicaid hospital value-based purchasing formula. There is evidence that patient-centered care improves clinical outcomes and patient experiences; also, it can be justified on the basis of a business case [4]. Yet patient-centered care requires a change in organizational culture from being “provider focused” or “reimbursement focused” to being “patient focused,” and this can only occur with the engagement of top leadership and a strategic vision that prioritizes patient-centered care [5]. To make this change within their organizations, health system managers should focus on improving meaningful communication between patients and hospital staff, including requiring staff training in patient-centered care and communication skills. Moreover, within the healthcare delivery system there is an opportunity and need to establish patient expectations. As healthcare organizations make the transition to value from volume considerations, leaders of all levels must stay true to the core mission—patient care—and consider all the aspects of patient experience including patient safety, satisfaction, and quality. By integrating and not segregating these elements, we can keep in mind the true, multidimensional experience of patients.

Incentives and Compensation Aligned With Outcomes

Many incentive and compensation models exist among many institutions. Although the incentive model has long been used, the leadership at many institutions are moving toward at-risk dollars that are only captured with successful attainment of goals [30]. At some major health care institutions, performance-based pay is more prevalent in primary care than in the subspecialties, and the most consistently identified performance domains are quality, service, productivity, and citizenship. Interviewed organizations tie or link a relatively low percentage of total compensation to performance. Procedural specialties often remain relative value unit or adjusted relative value unit based for all forms of compensation. At the Cleveland Clinic, Mayo Clinic, and Iowa Health, for example, physicians are 100% salaried. At Group Health and Kaiser Permanente (Southern California) more than 90% of total physician compensation is salary. Importantly, even organizations that tie little or no compensation to performance attempted to track and encourage performance on a variety of metrics by conducting internal performance reviews. Furthermore, performance data for individual physicians is transparent in most systems; physicians are able to see their own performance and rank, as well as that of their colleagues.

In the United Kingdom, individual surgeon mortality data are in the public domain showing performance over the previous year and 3 years for key operations such as coronary revascularization and aortic valve replacement and also for all operations performed. This transparency, however, has some negative effects such as risk adverse behaviors and an impact on training [31]. Performance is not specifically rewarded, however, and all physicians are salaried within the National Health Service. At most organizations, senior leaders set overarching strategic aims and then work closely with frontline physicians and department chiefs to develop fair and meaningful performance metrics. Most organizations use a combination of group and individual metrics to make allocation decisions about compensation. Across large systems, the most consistent performance domains are quality, service, productivity (generally measured by relative value units), and teamwork or citizenship. Most organizations have less than 10% of total compensation at risk, with payments distributed across three to five different domains, each containing several metrics but that consistently approaches with many metrics—and little at-risk compensation for each metric offers weak incentive to achieve any particular goal [30].

Future Leadership Needs
Academic Development of Administrative Roles and Outcome Researchers

Surgeons and physicians have the unique ability to influence health care delivery. As clinicians, innovators, and researchers, we can help to formulate how we will be measured and set forward standards to which we need to adhere. Leadership of all levels of health care institutions are necessary and critical to successfully influencing the safe care of patients and how we are perceived by our patients. To that end, it is possible that we as surgeons need to take on more administrative roles, both large and small, in hospitals and health care systems [32]. Although we may be excellent clinicians, we are often “novice administrators” and will need basic training in management techniques and tools, as well as the support of existing leadership to enable us to succeed. The time spent in administrative roles must be seen as important as time spent in the operating room for surgeon-administrators to influence the outcomes and efficiencies of a health care environment. With the current value-based care transformation paradigm, the time for change is upon us, and we must educate and enable our peers and future surgeons not only to understand the changing landscape but also to be able to influence it. In addition to leadership support, there must be in place a basic infrastructure to support and endorse patient safety programs for every patient across the entire continuum of care. As surgical leaders we can only influence what we can measure, and measurement and change remain our perpetual responsibility.
References


12. Frankel AS, Leonard MW, Denham CR. Fair and just culture, team behavior, and leadership engagement: the tools to achieve high reliability. Health Serv Res 2006;41:1690–709.


