Chapter 9
Surgical Quality and Safety: Current Initiatives and Future Directions

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Key Points

- Despite improved therapies and technology, preventable medical errors and adverse events in surgery continue to occur.
- Error can be classified into four groups: diagnostic, treatment, preventative, or other errors.
- Several initiatives have been implemented to improve patient safety: (1) Patient Safety and Quality Improvement Act, (2) Medicare Prescription Drug, Improvement, and Modernization Act, and (3) Bundled Payments for Care Improvement Initiative.
- Pressures for improving value-based care have led to the linkage of quality to reimbursements implemented by the Hospital Readmissions Reduction

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Program, Hospital Value-Based Purchasing Program, and the Hospital-Acquired Condition Program.
- Established quality improvement programs such as the Agency for Healthcare and Research Quality, The American College of Surgeons National Surgical Quality Improvement Program, and University HealthSystem Consortium provide risk-adjusted quality data to participating hospitals to benchmark performance.
- Human error is inevitable, but defective systems can be fixed to detect and prevent errors. The use of Crew Resource Management and Surgical Checklists are methods to reduce systemic error
- Resident duty hours and physician burnout can impact patient safety and quality. Addressing the problem of physician burnout is the shared responsibility of individual physicians and the organizations in which they work.

Adverse Events in Surgery

Over 51 million surgical procedures and operations were performed in the US in 2010 and the numbers are increasing each year [1]. Because of the critical and dynamic nature of many operative interventions, surgery accounts for a large number of the medical errors that occur every year. Despite improved therapies and technology, preventable medical errors and adverse events in surgery continue to occur and much interest is invested in this area to guide quality improvement efforts. Because reimbursements are being tied to quality outcomes in hospitals, these errors affect the income of the hospital and providers.

Research into iatrogenic injury over the last 3 decades has shed light on the rates of adverse events, characteristics, failure modes, and their sequelae. The California Medical

Association conducted the first large-scale study of adverse events in the 1970s when they reviewed the histories of 21,000 admissions and reported found that adverse events occurred in 4.6% [2]. The first study of surgical adverse events was performed by Couch et al. in 1981 who found that avoidable surgical errors occurred in more than 0.6% of their admissions to their academic general surgery service; 55% of these complications resulted in death [3]. In 1991, the Harvard Medical Practice Study published their retrospective analysis of 30,000 randomly selected patients and found an adverse event rate of 3.7%, many of which were a result of substandard care [4]. Since then, multiple studies have attempted to characterize these adverse events in an attempt to reduce the incidence of error. Gawande et al. analyzed the incidence and nature of adverse events in 15,000 patients in Colorado and Utah, finding that 66% of all adverse events were surgical, 54% were preventable, and 5.6% resulted in death. Technique-related complications, wound infections, and postoperative bleeding produced nearly half of all surgical adverse events [5]. Shortly after, a review of records from a population-based study in New York revealed that nearly 4% of hospitalized patients suffered adverse events. Two thirds of those events were considered to be caused by errors in management, most of which were not because of negligence [6].

Types of Surgical Errors

Patient safety problems of many kinds occur during the course of providing health care. They include transfusion errors, adverse drug events, wrong-site surgery, surgical injuries, hospital-acquired or other treatment-related infections, falls, burns, and pressure ulcers. Leap et al. characterized the kinds of errors that resulted in medical injury in the Medical Practice Study into groups including diagnostic, treatment, preventative, or other errors (Fig. 9.1) [6].

In any given patient, some or all of the types of errors can occur in a single hospitalization. A significant reason why adverse events occur in today's advanced medical system is

Diagnostic
- Error or delay in diagnosis
- Failure to employ indicated tests
- Use of outmoded tests or therapy
- Failure to act on results of monitoring or testing

Treatment
- Error in the performance of an operation, procedure, or test
- Error in administering the treatment
- Error in the dose or method of using a drug
- Avoidable delay in treatment or in responding to an abnormal test
- Inappropriate (not indicated) care

Preventative
- Failure to provide prophylactic treatment
- Inadequate monitoring or follow-up of treatment

Other
- Failure of communication
- Equipment failure
- Other system failure

FIG. 9.1 Types of surgical errors

that medical care is extremely complex and variable, involving a variety of personnel, equipment, and procedures [6]. Systems-based programs and solutions have been created and implemented and continuing efforts are in place to improve these approaches. These errors are being followed and reported by Hospital Systems. This chapter discusses the current topics around patient safety including government initiatives, public reporting, human factors in surgery, and surgery checklists, crew resource management, and resident duty hours, and physician burnout.

Initiatives around Patient Safety and Quality

More than a decade ago, the Institute of Medicine Quality of Healthcare in America Committee was formed to develop a strategy to improve quality. They 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 [7]. 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 between providers to improve patient safety [8]. 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 [9]. The initiative resulted in millions of dollars saved without negatively impacting the patient safety [10, 11]. The most significant regulatory overhaul, however, was in 2010 when the Patient Protection and Affordable Care Act (PPACA) was signed into place. Under this act, the Center for Medicare and Medicaid (CMS) Innovation was established to improve quality of care and reduce the rate of growth in healthcare costs [12]. This resulted in further expansions of bundled payments and reimbursement shifts laid out by the CMS with the Innovation's Bundled Payments for Care Improvement Initiative (BPCI) as the most recent nation-wide project [13].

Linking Quality to Payment

The BPCI initiative links payments for multiple services received during a single episode of care with financial incentives for improved performance. The anticipation is that this model will lead to higher health care quality and more coordinated care at a lower cost. Traditionally, payments were made based on the fee-for-service (FFS) model, where institutions and providers were reimbursed for each individual service furnished to beneficiaries for a course of treatment. This resulted in fragmented care with minimal coordination between multidisciplinary providers, which led to a decrease in health care value; higher cost without improvement in patient outcomes. In 2013, the CMS announced their new shift in reimbursement mechanisms from the traditional FFS to the current proposed BPCI model with payment shifts based on the BPCI model to 30% by 2016 and to 50% by 2018, with the remaining FFS payments linked to institutions quality data to 90% by 2018 [13].

What is meant by quality data? Currently, three main programs exist to reward hospitals for delivering services of higher quality while penalizing those who do not meet performance benchmarks: The Hospital Readmissions Program, Hospital Value-Based Purchasing (HVBP) program, and Hospital Acquired Conditions (HAC). Since 2012, the Hospital Readmissions Reduction Program reduces payments to acute care hospitals with excess readmissions that are paid under the CMS's Inpatient Prospective Payment System. The excess readmission ratio is defined as the risk-adjusted predicted readmissions divided by the risk-adjusted expected readmissions. The payment adjustment amount is determined based on specific formulas based on DRGs and indirect costs [14]. The HVBP, also established by the Affordable Care Act, implements a pay-for-performance (P4P) approach to the payment system that accounts for the largest share of Medicare spending. Under the HVBP, Medicare adjusts a portion of payments to hospitals based on how well they perform on specific measures compared to other hospitals and how much they improve their own performance on those measures compared to their performance during a prior baseline period. The HVBP score is derived from The Total Performance Score (TPS), which consists of four domains—Clinical Process of Care, Patient Experience of Care, Outcome, and Efficiency domains (Table 9.1) [15]. The HVBP is designed to promote better clinical outcomes for hospitalized patients and improve their experience of care during hospital stays. Note that patient satisfaction is part of this composite and is becoming an ever larger part of the P4P picture and should be taken into account by the practitioner and the hospital.

The HAC Program reduces payments to hospitals that rank in the worst performing quartile. The worst performing quartile is identified by calculating the Total HAC score which is based on the hospital's performance on four risk-

Table 9.1 Domains of TPS for VBP

Domains of TPS for VBP	Composites	% of TPS
Clinical process of care domain	12 clinical process measures	10
Patient experience of care domain	8 dimensions of HCAHPS Survey	25
Outcome domain	3 mortality, 1 AHRQ, 1 HAI measure	40
Efficiency domain	1 Medicare Spending per Beneficiary	25

HCAHPS Hospital Consumer Assessment of Healthcare Providers and Systems, *HAI* Healthcare Associated Infection

adjusted quality measures (Patient Safety Indicator 90 composite, central-line-associated bloodstream infection (CLABSI), catheter-associated urinary tract infection (CAUTI), and surgical site infection (SSI) for colon surgery and hysterectomy). Hospitals with a total HAC score above 75th percentile of the Total HAC Score distribution may be subject to payment reduction [16].

Quality Improvement Programs

Several surgical quality improvement programs have been formed as a result of the increasing pressures and demands for improved patient safety and outcome in the health care environment. The Agency for Healthcare Research and Quality (AHRQ) developed four modules of Quality Indicators (QIs) to gauge performance in health care: the Prevention Quality Indicators (PQIs) [17], the Inpatient Quality Indicators (IQIs) [18], the Patient Safety Indicators (PSIs) [19], and the Pediatric Quality Indicators (PDIs)™. This chapter will focus on PSIs, which are quality measures that use administrative data based on the ICD-9-CM coding system found in discharge records. PSIs were developed to help hospitals identify potential adverse events to provide opportunity to assess incidences of adverse events and hospital complications [20]. There are currently 27 PSIs: 20 on the provider-level and 7 on the area-level. At the provider-level, the PSIs provide information about the potentially preventable complication patients experienced during their initial hospitalization (Table 9.2). The area-level PSIs capture all cases of potentially preventable complications that occur in a given geographical area (e.g. metropolitan service area or

Table 9.2 Patient Safety Indicators

Patient safety indicator: provider—level	PSI Number
Complications of anesthesia	1
Death in low-mortality DRGs	2
Decubitus ulcer	3
Failure to rescue	4
Foreign body left during procedure	5
Iatrogenic pneumothorax	6
Selected infections due to medical care	7
Postoperative hip fracture	8
Postoperative hemorrhage or hematoma	9
Postoperative physiologic and metabolic derangements	10
Postoperative respiratory failure	11
Postoperative pulmonary embolism or deep vein thrombosis	12
Postoperative sepsis	13
Postoperative wound dehiscence	14
Accidental puncture or laceration	15
Transfusion reaction	16
Birth trauma—injury to neonate	17
Obstetric trauma—vaginal with instrument	18
Obstetric trauma—vaginal without instrument	19
Obstetric trauma—cesarean delivery	20
Foreign body left during procedure	21
Iatrogenic pneumothorax	22
Selected infections due to medical care	23
Postoperative wound dehiscence	24
Accidental puncture or laceration	25
Transfusion reaction	26
Postoperative hemorrhage or hematoma	27

county) either during hospitalization or resulting in subsequent hospitalizations [19].

The AHRQ PSIs were initially designed as an internal quality improvement tool, but their use now ranges from public reporting to P4P initiatives. These indicators must be used with care as these are associated with limitations including coding inconsistencies, clinical vagueness in description of code, heterogeneity of clinical conditions, and incomplete or inaccurate administrative data. Many research efforts have been undertaken to validate the effectiveness in PSI's ability to capture potentially preventable patient safety events. While many PSIs have been shown to be unreliable as a detector of adverse events and a measure of quality performance, they are currently being used to present a picture of patient safety within all hospitals [21–25].

The American College of Surgeons National Surgical Quality Improvement Program (ACS NSQIP) is a nationally validated, risk-adjusted database tracking surgical outcomes. The program reports on a number of general surgical complications across multiple specialties and procedure-specific outcomes for a variety of individual procedures. The program allows participating institutions to view their benchmarked risk-adjusted parameters in order to develop goals and targets to decrease complications and mortalities. Similarly, the University HealthSystem Consortium (UHC) is another database available to subscribers, which provides benchmarked data comparative to other academic medical centers on safety, quality, and performance. Other available discipline-specific national outcomes databases include the Society for Thoracic Surgeons (STS) National Database, Tracking Operations Outcomes for Plastic Surgeons (TOPS) [26], and National Cancer Database (NCDB) [27] to name a few. All these tools will continue to be developed with the goal of providing sources for institutional improvements in patient safety while increasing transparency [27, 28].

Despite the advances in quality reporting, participation in nationally validated databases alone does not improve surgical outcomes. This was shown in a study conducted by Osborne et al. where they set out to evaluate the association of enrollment in participation in the ACS NSQIP with outcomes. They found that after accounting for patient factors and time trends toward improved outcomes, there was no statistically significant improvement in outcomes at 1, 2, or 3 years after enrollment in ACS NSQIP [28]. They concluded that feedback of outcomes data alone is not sufficient for improving surgical outcomes. Failure to implement quality improvement initiatives following review of ACS NSQIP report may play a role in lack of progress. Because the ACS NSQIP data is not publicly reported, institutions may not have a large enough incentive to drive quality improvement. Financial incentives are currently being implemented with the BPCI initiative, pay-for-performance, and nonpayment for adverse events. While change begins with the individual, physicians may not have resources to launch effective programs. Changing physician practice to adhere to quality improvement initiatives requires complex, multifaceted interventions that need to be championed and sustained by the system. To develop systematic approaches, the understanding of the interplay between human factors and adverse events in a system is crucial.

Human Factors in Surgery

Human error is inevitable in any discipline. While human error oftentimes go unnoticed and rarely cause significant harm, the occasions where they do translate into an adverse event cause much distress in the system. It is known that although the individual commits human errors, the system is usually at fault for inadequate organizational structures in not noticing the error occurred. Much work has been done in the arena of human factors of error, especially in the medical and surgical communities to detect vulnerable systems with the aim of reducing error and optimizing patient safety. Three principles exist to aid systems in their approach to understanding surgical errors; (1) human error is unavoidable, (2) defective systems allow human error to cause harm to the patient, and (3) systems can be designed to prevent or detect human error before the patient is harmed [29].

One of the most well-known human factors theories is the "Swiss cheese" model of accident causation, which provides a framework for how errors or accidents occur in a system designed to deflect error. In this theory, systematic defenses exist to prevent error; however, occasionally each specific event (e.g. organizational factors, unsafe supervision, preconditions for unsafe acts, or the unsafe act itself) at a given time and place lines up such that the event bypasses the system's defenses and translates into an error (Fig. 9.2) [30]. Therefore, preventable adverse events, despite committed by individuals, are rather a result of a defective system.

The Systems Engineering Initiative for Patient Safety Model (SEIP) effectively describes a system that is relevant to the surgical process (Fig. 9.3) [31]. The framework aids in understanding the structures, processes, and outcomes in a health care system. The model places the patient in the center while all the elements of the system not only affect the patient, but also affects the other elements within the system. The model implies that overall quality, patient safety, and outcomes are affected by the interplay between factors such as teamwork and communication, physical work environment, technology, workload factors, and other organizational variables. Specifically, in the operating room, environmental factors such as clutter, noise, lighting, and temperature can negatively impact the outcome of an operation [32–34]. Poor communication has also been shown to be the cause of a large number of sentinel events within the healthcare system with studies revealing that 40% of errors in surgery resulted from communication errors [35, 36]. From a technology standpoint, the advancements in minimally invasive and robotic surgery require new skill sets to be learned which, when combined with the other systematic elements, may be a source for stress-inducing conditions. Thus, operating rooms designed to effectively link these elements to prevent or detect human error before a patient is harmed will succeed in providing coordinated, effective, efficient, and safe surgery.

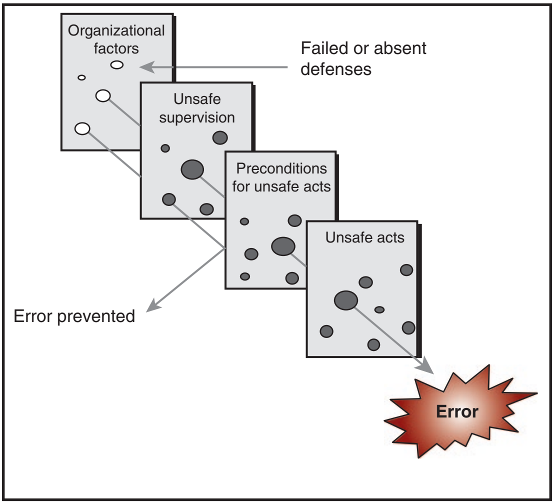

FIG. 9.2 Swiss cheese model of accident error causation

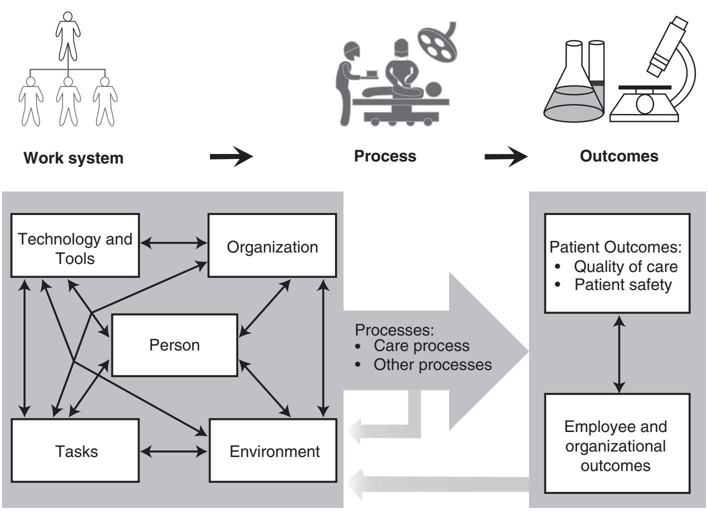

FIG. 9.3 The systems engineering initiative for patient safety model

Crew Resource Management

Communication plays a significant role in a success of a team, especially in the operating room. The well-known strategy, Crew Resource Management (CRM), developed in the aviation industry has been successfully adapted in some hospital systems to improve quality and safety. At one institution, The Ohio State University Wexner Medical Center, CRM was translated to the healthcare industry as a systematic approach to training leadership, staff, and physicians on the elements of communication, conflict management, safety tools, and internal monitoring. Safety tools include checklists, standardized protocols, and communication scripts. Within 3 years following CRM implementation, the health system reduced their total number of adverse events by 27.5% [37]. In another study, Funai et al. incrementally introduced multiple patient safety interventions at a university-based obstetrics service. The initiative included outside expert review, protocol standardization, creation of a patient safety nurse position and patient safety committee, and training in team skills and fetal heart monitoring interpretation. They reported significantly reduced adverse outcomes following intervention with significant improvement in the safety climate [38]. This demonstrates the measurable outcomes, effectiveness, and feasibility of a communication-based training program in improving patient safety.

Surgical Checklists

The implementation of checklists and standardized processes around the care of patients has been pivotal to the development of the patient safety culture [39]. Dr. Pronovost and his team at John's Hopkins were the first to pioneer a rounding checklist in the Intensive Care Unit (ICU) aimed at decreasing catheter-related bloodstream infections. In his cohort study of 103 ICU's, 1981 ICU days, and 373,757 catheter-days, he found that the use of the ICU checklist resulted in a sustained reduction of 66% in rates of catheter-related bloodstream infections [40].

In 2009, the World Health Organization issued a worldwide recommendation for the use of its surgical safety checklist for briefings in the operating room, which included a "sign in" immediately before induction of anesthesia, a "time out" immediately before the skin incision, and a "sign-out" following skin closure. The WHO checklist was evaluated in a study of eight hospitals in different parts of the world and was shown to result in a significant reduction of mortality in major surgery by 47% and a significant relative reduction of major morbidity by 36% [39]. Results from a meta-analysis including 20 studies concerning the effect of the WHO checklist on safety-related events in the OR support the WHO's recommendation to use the Surgical Safety Checklist in all operative procedures [41]. Institutions can create individual adaptations of content, form, and model of the checklist as long as the purpose remains the structured communication among team members regarding important information related to the procedure. Since then, checklists have been implemented during bedside procedures, obstetric processes, trauma cases in the Emergency Department, as well as patient handoffs between residents and nurses. Ultimately, the use of checklists and its success is entirely dependent on the implementation and monitoring from the institution as well as the collaboration of all health care providers.

Duty Hours and Physician Burnout

The introduction of the mandated work hour restrictions, introduced in July 2003 by the Accreditation Council for Graduate Medical Education (ACGME), was designed to improve patient safety by reducing resident fatigue. Since then, much interest has been placed in evaluating the effects of duty hour restrictions on patient safety. A 2012 survey indicated that most categorical surgery residents did not perceive that reduced duty hours noticeably improved quality of care, and their perceptions of causes of medical errors suggested that system changes were more likely to enhance patient safety than further hour limits [46]. Most recently, a national cluster-randomized trial comparing standard ACGME duty hours to more flexible policies (waived rules on maximum shift lengths and time off between shifts) was completed to assess differences in patient outcomes, resident education, and well-being. Results including 117 general surgery programs in the US between 2014 and 2015 demonstrated no significant difference in residents' satisfaction with overall well-being and education quality between the two duty hour policies [47]. These results question whether current ACGME duty hour restrictions provide residents with the optimal surgical training while balancing resident well-being with patient safety and outcomes.

In addition to balancing work hours, Hospital Systems are now faced with alarming rates of burnout among physician providers. National studies suggest that at least 50% of US physicians are experiencing professional burnout [48–50]. Burnout is characterized by exhaustion, depersonalization, cynicism, low sense of personal accomplishment, and reduced effectiveness. Physician burnout has been shown to impair job performance and influence quality of care, patient safety, and patient satisfaction [51–53]. Consequently, there has been a rising interest in interventional strategies focused on improving physician wellness. Individual stress reduction strategies have proved to be effective in healthcare professionals [54, 55]. However, mitigating professional burnout is not solely the responsibility of the individual physician but that of the entire hospital organization. In addition to providing resources to promote self-care and resilience, much work remains in developing sustained systematic strategies to harness physician wellness that will in turn impact safety and quality for patients.

Conclusions

The goal of any institution healthcare institution is to eliminate errors and improve patient safety. Over the last decade, much effort has been placed in this endeavor with significant success as indicated by results from CRM training and checklist implementation. Governmental quality improvement initiatives and systematic strategies have been developed to provide safe, timely, efficient, effective, equitable, and patient-centered care. These proposals now hold health care institutions and providers accountable for achieving the quadruple aim in healthcare: to enhance the patient's experience by improving costs, quality, and outcomes, while maintaining physician well-being. With increasing awareness and accountability, compliance has become less of an issue. What remains now is sustainability and growth of a culture around patient-safety.

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