A Comprehensive Unit-Based Safety Program (CUSP) in Surgery: Improving Quality Through Transparency

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THE SCIENCE FOR COMPREHENSIVE UNIT-BASED SAFETY PROGRAM (CUSP) IN SURGERY

Medical care is expanding in a way that is becoming more fragmented, making opportunities for medical errors more common. Patients are increasingly falling through the cracks or being harmed by confusion among providers. Sometimes a process of care is too complex to be safe. Other times mistakes happen because of a simple lack of communication. These problems require common-sense solutions, many times necessitating changes to the way care is delivered on a local level. Specifically, unit-based meetings to discuss how local systems are potentially dangerous for patients are needed to streamline care and eliminate safety hazards. These comprehensive safety programs unite physicians, nurses, technicians, and other staff in a regular meeting to take on individual safety hazards identified by each group. After all, who knows what’s best for a patient more than the doctors, nurses, and other team members that care directly for them? The implementation of a safety program typically includes the measurement of the unit’s safety culture and inclusion of hospital management. Representation from management allows for resources to be allocated more efficiently, and also serves to bridge the growing

Financial disclosures: The authors have nothing to disclose.

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KEYWORDS
- Wrong site
- Wrong patient
- Universal protocols
- Transparency

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divide between hospital administration and front-line providers. Surgery unit safety programs draw on many lessons learned in the literature and explored in this article, and they also serve to customize safety interventions (eg, the surgical checklist) using local wisdom.

In recent years, there has been an increased focus on the causes and prevention of medical errors, particularly in surgery. Medical errors can cause catastrophic injuries to patients and can have significant consequences for the surgeon and institution. Although mistakes are inherent in human nature, many mistakes can be attributed to large and vulnerable health care systems.

In 1999, the Institute of Medicine (IOM) published one of the first and most important documents raising awareness of injuries due to medical errors, To Err is Human: Building a Safer Health System.1 This report concluded that in American hospitals between 44,000 and 98,000 deaths and 1 million injuries occur each year due to medical error, amounting to more deaths in hospitals from medical errors than from motor vehicle accidents, breast cancer, and AIDS combined.1 The report shocked the medical community, and after its publication talking about mistakes became more acceptable. Over time, professional associations and medical centers began having honest conversations about how systems can be more safely engineered so that mistakes can be prevented. To this end, over the last decade hospitals have embarked on many quality improvement campaigns. However, despite this a retrospective study of 10 hospitals in North Carolina followed for patient harm from 2002 to 2007 showed that 25.1% of all inpatients had sustained a form of preventable harm due to a medical mistake.2 This finding shows that despite much attention in the medical community to improving patient safety and despite implementation of broad-sweeping quality measures, the field is still in its infancy. However, studies using sound scientific methods are beginning to populate the surgical literature.

NEVER EVENTS

In the nomenclature for quality and safety in health care, never events have become the most universally recognized quality indicator in surgery. Although the surgical community may disagree about quality metrics in general, there is universal agreement that never events represent preventable harm. Never events include wrong-site/wrong-patient surgery, an unintentional retained foreign body, and unexpected intraoperative death in a patient of American Society of Anesthesiologists (ASA) class I.3 Never events have become a quality measure that is now closely monitored, although hospitals are not currently transparent with the public about how many of these events occur each year. Increasingly there is a trend to request that hospitals publicly report their rates of never events yearly.

WRONG-SITE/WRONG-PATIENT SURGERY

One of the most devastating medical errors to both patient and physician is wrong-site or wrong-patient surgery. Wrong-site surgery is defined as any surgical procedure performed on the wrong patient, wrong side of the body, wrong body part, or the wrong level of a correctly identified anatomic site. Wrong-patient surgery may include patients who were never scheduled for a procedure, procedures that were performed but were never scheduled, and procedures that were scheduled correctly but were never performed.4 In the past these errors were believed to be extremely rare.5 However, the incidence of these events ranges from 1 in 112,994 to up to 1 in 15,500 cases, and they can have disastrous health and financial consequences to both the patient and the physician.6,7 Older patients, young children, and disabled
patients are at the highest risk for wrong-patient surgery, as they may lack the cognitive capacity to understand what they are undergoing.

The overall incidence is difficult to determine because it is often underreported by health care providers, and voluntary incident reporting may greatly underestimate the true incidence by a factor of at least 20.8,9 Because of this, a few states now have confidential reporting requirements for all wrong-site surgery events or sentinel events. This mandate allows an inquiry (internal and sometimes external) of the circumstances that lead to the event and ways to prevent it.

A review of reports submitted from 2004 to 2006 for wrong-site surgery events and near misses found that more than 40% of these errors reached the patient and nearly 20% resulted in completion of a wrong-side procedure.6 Most wrong-side surgery involved symmetric anatomic structures, with a 1 in 4 chance that surgeons who work on symmetric structures will be involved in a wrong-site error at some point in their career.6 Also, anonymous data from the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) indicated that wrong-site surgery can occur in any setting with 58% occurring in the ambulatory setting, 29% occurring in inpatient operating rooms (ORs), and 13% occurring in emergency departments and intensive care units (ICUs).10

Contributing factors to wrong-site surgery include the surgeon specifying the wrong site, not completing a proper time-out, not verifying consent or site markings, inaccurate consents/diagnostic reports/images, or inappropriate patient positioning.6 The risk of committing these errors is increased in:

Emergent cases when there may not be time to adequately prepare6
Cases with unusual physical characteristics, such as in morbidly obese patients or those with physical deformities, which require changes from the norm in patient positioning or equipment6
Cases that involve multiple procedures or multiple surgeons, especially if the procedures are on multiple parts of the body6
Surgeon characteristics, such as a left-handed surgeon, as most setups are for right-handed surgeons6
Communication breakdowns, such as on large surgical teams where team members do not have defined roles or in patients with language barriers.6,11,12

In addition, in hospitals with a poor safety culture, mistakes are less likely to be caught before they cause patient harm, as people often do not feel comfortable questioning the primary surgeon.

To reduce the likelihood of these errors, the Joint Commission put together a protocol to standardize the approach to verification of the patient and site. This protocol is organized into 3 phases: the preoperative verification process, marking of the operative site, and a preprocedural briefing time-out before the incision is made (Fig. 1).11–14

However, despite implementation of these measures, the Pennsylvania Patient Safety Authority saw a trend toward improvement but no significant decrease in the incidence of wrong-side/wrong-site surgery from June 2007 to July 2010. Based on their experiences, they recommended that injection of local or regional anesthetic should be treated as a separate procedure, and that marking of operative sites should always be performed before entering the OR.15

Despite the relative rarity of its occurrence, wrong-site/wrong-patient surgery can have catastrophic consequences, and every effort should be made to reduce its incidence. In addition to the safety protocols that are being implemented and improved, the creation of a safety culture and promotion of teamwork is critical to prevent these events from occurring.
Among various hospitals, there is up to a sixfold difference in the complication rate, not because the employees working in these hospitals are inherently less skilled or less competent, but because of a poor safety culture. In hospitals with poor safety cultures there are breakdowns in many areas, including a lack of acknowledgment of the high-risk nature of the medical care being performed, a fear of punishment or retaliation if someone reports an error or close call, a lack of communication in large medical teams, and a lack of willingness as an organization to address safety concerns. In one study by the JCAHO, communication was found to be the most important root cause of sentinel events including wrong-site surgeries, contributing to almost 70% of these events. In another study that examined safety cultures in 60 different hospitals, those with poorer safety cultures had increased incidences of wound infection, postoperative sepsis, and postoperative deep vein thrombosis (DVT). It is interesting that postoperative bleeding, which is secondary to a technical error, not a process, did not have an increased incidence across the different hospitals. In light of this, it is clear that creation and perpetuation of a safety culture is a fundamental part of a systems approach to improving patient care.

However, despite attempts at changing culture, some OR environments can be very intimidating for trainees, nurses, and technicians. Such a steep hierarchy combined with a history of disruptive behavior may not promote a culture of speaking up when employees have a safety concern. Studies have suggested that surgeons, in comparison with pilots and other health care professionals, may be less likely to admit that they have made a mistake, that they are at a higher risk for making mistakes than are other specialists, or that stress can have an impact on their decision making. Also, despite a movement in medicine to encourage teamwork and to encourage all members of the surgical team to discuss safety concerns, the steep hierarchy in surgery is still very strong at some medical centers. Although a clear-cut hierarchy is important for patient care in that there must ultimately be one captain of the ship, an atmosphere...
too intimidating to promote teamwork can result in preventable patient harm. A tense work environment and poor teamwork is often underappreciated by any captain, as demonstrated in a 2006 study on perceptions of teamwork in the OR. This study demonstrated a major disconnect in perceptions among various members of the team. Whereas surgeons rated everyone very highly, nurses rated surgeons very low (Table 1). In another study, ICU nurses reported that when compared with doctors, more decisions were made with inadequate input from the nurses, that they were not encouraged to discuss their concerns, and that conflicts were not properly resolved.21

Efforts to improve culture are best accomplished through the use of physician-champions who serve as local role models and champions of change.22 The culture is slowly changing as safety initiatives are being more and more widely implemented, and studies are showing the importance of teamwork and a good safety culture regarding patient care.

Assessment of Safety Culture

To encourage widespread change in safety cultures, it is important to measure a local safety and teamwork culture before and after an intervention to show its impact. The Safety Attitudes Questionnaire (SAQ), which was adapted from the Flight Management Attitudes Questionnaire, is a validated survey instrument used to assess safety culture in different hospitals.16 The SAQ focuses on 6 different domains including teamwork climate, safety climate, job satisfaction, perceptions of management, stress recognition, and working conditions. In this survey questions focused on the organizational commitment to safety, which has been shown to decrease patients’ length of stay and error rates in the ICU.23

Within a given hospital, the survey is submitted to all members of the OR team, including surgeons, anesthesiologists, certified registered nurse anesthetists, nurses, and surgical technicians. The safety climate portion of the questionnaire comprises the following:

I am encouraged by my colleagues to report any patient safety concerns I may have
The culture in this clinical area makes it easy to learn from the mistakes of others
Medical errors are handled appropriately in this clinical area
I know the proper channels to direct questions regarding patient safety in this clinical area
I receive appropriate feedback about my performance
I would feel safe being treated here as a patient
In this clinical area, it is difficult to discuss mistakes.

Table 1
Caregivers’ ratings of one another’s teamwork

<table>
<thead>
<tr>
<th>Caregiver position</th>
<th>Surgeon</th>
<th>Anesthesiologist</th>
<th>Nurse</th>
<th>CRNA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surgeon</td>
<td>85</td>
<td>84</td>
<td>88</td>
<td>87</td>
</tr>
<tr>
<td>Anesthesiologist</td>
<td>70</td>
<td>96</td>
<td>89</td>
<td>92</td>
</tr>
<tr>
<td>Nurse</td>
<td>48</td>
<td>63</td>
<td>81</td>
<td>68</td>
</tr>
<tr>
<td>CRNA</td>
<td>58</td>
<td>75</td>
<td>76</td>
<td>93</td>
</tr>
</tbody>
</table>

Surgeons rate everyone highly, each caregiver group rates themselves highly, but nurses rate surgeons very low.

Based on this survey, it has been found that safety climate varies dramatically by hospital, but that among various team members in a hospital, perception of safety climate is not significantly different (Figs. 2 and 3). Using this survey, hospitals can compare themselves to other hospitals with improved safety climates to determine how to improve. Also, with the push for increasing transparency of outcomes in hospitals, public reporting of SAQ results could further incentivize hospitals to improve their culture, as informed patients would be much less likely to go to the hospital with 16% satisfaction with the safety culture than with 100% satisfaction (see Fig. 3).

**Improving Teamwork, Communication, and Safety Culture**

One of the most effective ways to improve safety culture is to improve communication. In one study there was a 30% rate of communication failure in the OR, with 36% of those failures resulting in an impact on patient safety.\(^{24}\) In addition to people feeling that they cannot speak up in this environment, the standard workflow in the OR, especially with patient care hand-offs, is particularly prone to loss of important patient information.\(^{25}\) The introduction of team briefings and debriefings as well as protocols for commonly used procedures has been shown to improve patient safety in the OR and ICU.\(^{26,27}\)

Preoperative briefings are a discussion of important aspects of the procedure. The briefing can include the names and roles of team members, confirmation of the correct patient/procedure, necessity of antibiotics and if they have been given, the critical steps of the procedure, and potential problems.\(^{27}\) Such briefings can be tailored to any specialty and are associated with improved safety culture, reduction in incidence of wrong-site/wrong-side surgery, early reporting of equipment problems, fewer OR delays, and reduction in OR costs.\(^{28}\) Postoperative debriefings are also becoming important by allowing reflection after the case on causes for errors that have occurred and how the procedure could have been run more smoothly. These debriefings can also include a verification of needle and instrument counts and a confirmation of correct labeling of the OR specimen. In addition to reducing the incidence of a retained foreign object, ensuring the correct labeling of the OR specimen can greatly reduce patient harm. In one study 4.3 of 1000 surgical specimens were mislabeled, leading to delays in care, the need for additional biopsy or therapy, and failure to administer appropriate therapy.\(^{29}\)

![Fig. 2. Safety climate by position. It can be seen that the perception of safety climate is uniform among different surgical team members. CRNA, certified registered nurse anesthetist; OR, operating room. (From Makary MA, Sexton JB, Freischlag JA, et al. Patient safety in surgery. Ann Surg 2006;243:628–32; with permission.)](image_url)
MEASURING QUALITY IN SURGERY

Standardization of Patient Safety Terminology

In addition to bringing patient safety to the forefront of medical innovation, the IOM report standardized the terminology used in patient safety (Fig. 4).\(^1,30\) This standardization allowed various agencies to study health care systems using the same language.

Agency for Healthcare Researchers and Quality

The Agency for Healthcare Researchers and Quality (AHRQ) was created in 1989, and is an agency in the Department of Health and Human Services that specializes in research in quality improvement and patient safety, outcomes and effectiveness of care, clinical practice and technology assessment, and health care organization and delivery systems.\(^8\) The research conducted in conjunction with the AHRQ provides evidence-based information on health care outcomes, cost, use, and access, which can be used by health care reformers to make large system-based changes.\(^8\)

![Fig. 3. Safety climate by hospital; each bar represents one hospital. (From Makary MA, Sexton JB, Freischlag JA, et al. Patient safety in surgery. Ann Surg 2006;243:628–32; with permission.)](image)

![Fig. 4. Characterization of different types of medical errors.](image)
One of the major contributions of the AHRQ was the development of a set of Patient Safety Indicators (PSIs) using hospital inpatient data, initially released in 2003 and revised in 2010. These indicators were developed after a comprehensive literature review, analysis of ICD-9-CM codes, review by a clinician panel, implementation of risk adjustment, and empirical analysis. The 27 indicators provide information from hospital complications and adverse events that can be studied for further systems improvements (Box 1). The PSIs are divided into two groups: provider-level indicators and area-level indicators. The provider-level indicators are those whereby a potentially preventable complication occurred in the same hospitalization period during which a patient received initial care. Area-level indicators are specific

<table>
<thead>
<tr>
<th>Box 1</th>
<th>Patient safety indicators (PSIs)</th>
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<tbody>
<tr>
<td><strong>Provider PSIs</strong></td>
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<tr>
<td>Complications of anesthesia</td>
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<td>Death in low-mortality diagnosis-related groups</td>
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<td>Decubitus ulcer</td>
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<tr>
<td>Failure to rescue</td>
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<td>Foreign body left during procedure</td>
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<tr>
<td>Iatrogenic pneumothorax</td>
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<tr>
<td>Selected infections due to medical care</td>
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<tr>
<td>Postoperative hip fracture</td>
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<tr>
<td>Postoperative hemorrhage or hematoma</td>
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<tr>
<td>Postoperative physiologic and metabolic derangements</td>
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<tr>
<td>Postoperative respiratory failure</td>
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<td>Postoperative pulmonary embolism or DVT</td>
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<td>Postoperative sepsis</td>
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<tr>
<td>Postoperative wound dehiscence</td>
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<tr>
<td>Accidental puncture or laceration</td>
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<tr>
<td>Transfusion reaction</td>
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<tr>
<td>Birth trauma: injury to neonate</td>
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<tr>
<td>Obstetric trauma: vaginal with instrument</td>
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<tr>
<td>Obstetric trauma: vaginal without instrument</td>
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<tr>
<td>Obstetric trauma: cesarean delivery</td>
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<tr>
<td><strong>Area-Level PSIs</strong></td>
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<tr>
<td>Foreign body left during procedure</td>
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<td>Postoperative hemorrhage or hematoma</td>
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PSIs that are also used to assess the total incidence of certain adverse events within geographic areas, during either the initial hospitalization or a related subsequent hospitalization.

These indicators are currently being widely used in hospitals to identify potential safety problems that merit further investigations. As electronic medical records become more standardized, these indicators can be followed to track progress in patient safety at a hospital-specific and nationwide level.

**Surgical Care Improvement Project**

The Surgical Care Improvement Project (SCIP) is a national partnership of organizations focused on improving surgical care by significantly reducing surgical complications. The organizations involved include the Centers for Medicare and Medicaid Services, the Institute for Healthcare Improvement, JCAHO, the American College of Surgeons, Centers for Disease Control and Prevention, and others.

SCIP has 3 major improvement projects including reduction in infection, prevention of venous thromboembolism (VTE), and cardiac event prevention. Patients who experience these complications have significantly increased length of hospital stay (3–11 day increase), increased hospital cost (up to $18,000 for a thromboembolic event), and increased mortality (median survival decreases by 69%). The evidence-based measures to improve these complications have been shown to reduce infections, VTE, and cardiac events, and are summarized in [Table 2].

Surgical-site infections account for up to 15% of all hospital-acquired infections. In addition to significantly improved patient satisfaction, eradication of these infections could save hospitals up to $5000 per patient and reduce extended length of stay by 7 days. Surgical-site infections account for up to 15% of all hospital-acquired infections. In addition to significantly improved patient satisfaction, eradication of these infections could save hospitals up to $5000 per patient and reduce extended length of stay by 7 days.34–36

Cardiac events are common postoperatively, occurring in up to 5% of patients undergoing noncardiac surgery and up to 34% of those undergoing vascular procedures. Cardiac events can have significant consequences, with myocardial infarctions having a mortality rate of up to 70%. Multiple studies have shown that perioperative β-blockers likely reduce the risk of perioperative ischemia and prevent up to half of fatal cardiac events.36–38

Thromboembolic events occur after approximately 25% of all major surgical procedures if prophylaxis is not used, and in orthopedic surgery this number increases to 50%. Studies have shown that using low-dose unfractionated heparin can decrease the risk of fatal pulmonary embolism by up to 50%. Despite multiple studies showing the safety and efficacy of DVT prophylaxis, it continues to be underused or misused.36,39,40

Another new SCIP core measure is to publish practitioner performance. With improved transparency in medicine, practitioners can know their own performance and compare it with that of others to improve on individual measures. Also, and more importantly, with improved transparency hospitals can take a systems-based approach to improve patient safety. In addition, patients will be better informed about which hospital to use for their care, thus further incentivizing hospitals to improve.

The SCIP measures are easily implementable, with clear outcome measures to measure their success. With implementation of these measures the potential number of lives saved in the Medicare population alone is greater than 13,000 patients per year. As these are measures are applied to ever widening populations, and as hospital transparency becomes more standard, we will continue to see improvements in the delivery of care to surgical patients.

Although the overall impact of SCIP compliance on improved patient outcomes has been controversial, SCIP will continue to expand and be refined to better capture...
meaningful metrics of quality. Never events are more widely accepted as metrics of quality and preventable patient harm. At present, SCIP metrics are transparent but rates of never events are not.

**National Surgical Quality Improvement Program**

The National Surgical Quality Improvement Program (NSQIP) is a risk-adjusted data-collection mechanism that was created by the Veterans Health Administration (VA) to collect and analyze clinical outcomes data. It allows participating hospitals to collect data and use these data to develop surgical initiatives that improve surgical care.41 The program is used to compare the performance of participating hospitals, focusing primarily on 30-day morbidity and mortality. Within the first 10 years of its implementation of the program at the VA, the 30-day mortality rate after major surgery decreased by 30% and the 30-day postoperative morbidity decreased by 45%.16 Testing of the program at 18 non-VA sites from 2001 to 2004 showed feasibility for application of the program in the private sector, and in 2004 it was expanded to more than 200 hospitals to measure outcomes on a large scale.42

<table>
<thead>
<tr>
<th>Table 2</th>
<th>SCIP measures to reduce rates of infection, venous thromboembolism, and cardiac events</th>
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<tbody>
<tr>
<td><strong>Performance Measures</strong></td>
<td><strong>Outcome Measures</strong></td>
</tr>
<tr>
<td>Infection</td>
<td>Prophylactic antibiotic received within 1 h before surgical incision</td>
</tr>
<tr>
<td></td>
<td>Prophylactic antibiotic selection for surgical patients</td>
</tr>
<tr>
<td></td>
<td>Prophylactic antibiotics discontinued within 24 h after surgery end time</td>
</tr>
<tr>
<td></td>
<td>Cardiac surgery patients with controlled postoperative 6 AM blood glucose</td>
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<tr>
<td></td>
<td>Urinary catheter removed on postoperative day 1 or 2</td>
</tr>
<tr>
<td></td>
<td>Surgery patients with appropriate hair removal</td>
</tr>
<tr>
<td></td>
<td>Surgery patients with perioperative temperature management</td>
</tr>
<tr>
<td></td>
<td>Venous thromboembolism (VTE) prophylaxis</td>
</tr>
<tr>
<td></td>
<td>Surgery patients with recommended VTE prophylaxis ordered</td>
</tr>
<tr>
<td></td>
<td>Surgery patients who received appropriate VTE prophylaxis within 24 h before surgery to 24 h after surgery</td>
</tr>
<tr>
<td></td>
<td>Cardiac events</td>
</tr>
</tbody>
</table>
This program allows hospitals to implement changes and quickly see improvement or lack of improvement against placebo groups at either their own location or other hospitals. As NSQIP use is refined further, we will be able to better understand and fix systems problems and improve patient safety. Some hospitals have expressed eagerness to make their NSQIP outcomes public in the spirit of transparency.

SUMMARY

In the past 15 years, there has been a growing focus on the causes and prevention of medical errors, particularly in surgery. Medical errors are associated with serious patient harm and high health care costs. Although mistakes are inherent in human nature, many errors can be attributed to large and complex health care systems in which care is increasingly fragmented. One of the most important ways to improve health care safety is through improved communication and an improved safety culture. Hospitals with good safety cultures have lower complication rates, and improved patient and staff satisfaction. Transparency in health care is an increasingly recognized means to improve outcomes by allowing the free market to reward hospitals with a strong safety culture, good outcomes, and compliance with evidence-based medicine (ie, checklist compliance). As more data become available regarding strategies that work to improve patient safety and such strategies are more widely implemented, significant improvements in the quality of care that is delivered nationwide should become apparent.

REFERENCES