CHAPTER 11

Surgical Patient Safety

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HISTORY

Adverse events and errors have accompanied surgical care since antiquity. The ancient Mesopotamian Code of Hammurabi (1795-1750 BC) recognized adverse surgical outcomes and surgical errors.[1] Over centuries, the public and medical profession have accepted the risks associated with disease and its surgical treatment. During the 20th century, health care became increasingly effective but increasingly more complex, more dangerous, and error prone. Because of contemporary knowledge and technology, modern society expects error-free health care. Although no human endeavor will ever become error free, today's health care, including surgical care, has abundant opportunities for improving its safety.

Brennan and colleagues focused attention on adverse events and medical negligence in hospitalized patients and defined an adverse event as an injury caused by medical management that prolonged hospitalization, produced a disability at the time of discharge, or both.[2] Negligence is care falling below the standard expected of physicians in their community.

Their study of 30,121 randomly selected patient records in 51 acute care hospitals in the state of New York revealed adverse events in 3.7% of cases, with negligence causing 27.6% of these adverse outcomes. Of all adverse events, 70% caused disability for up to 6 months, 2.6% caused permanent disability, and 13% resulted in death.[2] A companion publication by Leape and associates revealed that 19% of the adverse events involved drug complications, 14% involved wound complications, and technical complications caused 13%. Forty-eight percent of adverse events in that study accompanied surgical operations. Most negligence was related to diagnostic mishaps, noninvasive therapeutic mishaps, and events in the emergency department.[3]

Another study by Gawande and colleagues focused on surgical adverse events in a 1992 review of 15,000 non–psychiatric hospital discharges in Colorado and Utah. Surgical care produced 66% of all adverse events in this cohort. Adverse events accompanied 3% of operations and deliveries. The investigators judged 54% of surgical adverse events to be preventable. Eight types of operations had high risk for preventable adverse events. Surgical adverse events were associated with 5.6% mortality and accounted for 12.2% of hospital deaths. Technique-related complications, wound infections, and postoperative bleeding produced nearly half of all surgical adverse events.[4]

Reducing surgical errors requires awareness of their various types of venues. Regarding venues, the operating room is the highest risk site for surgical errors, followed by the surgical intensive care unit (ICU), the ward, ambulatory care sites, and finally, consulting sites. The emergency department provides a very high-risk environment for errors. Because a large portion of surgical errors, particularly serious errors, arise from care in the operating room, safety improvement efforts should concentrate on operating room care. High-risk areas have the following characteristics: multiple individuals involved in the care of individual patients, high acuity, multiple distractions and interruptions, need for rapid decisions, narrow margins for safety, high volume and unpredictable patient flow, communication obstacles, and an instructional setting.[5]

Common operations have different levels of adverse events ranging from 4.4% for hysterectomy to 18.9% for repair of an abdominal aortic aneurysm. Eight operations have a high risk for preventable adverse events: lower extremity bypass graft (11.0%), abdominal aortic

Box 11-1 Types of Errors

Diagnostic

Error or delay in diagnosis
Failure to use 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 result
Inappropriate (not indicated) care

Preventive

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

Other

Failure of communication
Equipment failure
Other system failure

Adapted from Leape L, Lawthers AG, Brennan TA, et al: Preventing medical injury. Qual Rev Bull 19(5):144-149, 1993.

aneurysm repair (8.1%), colon resection (5.9%), coronary artery bypass graft/valve surgery (4.7%), transurethral resection (3.9%), cholecystectomy (3.0%), hysterectomy (2.8%), and appendectomy (1.5%). Serious errors tend to occur in operating rooms, ICUs, and emergency departments.[4] Box 11-1 presents the types of errors described by Leape and colleagues.[6] Surgeons sometimes summarize these as errors in diagnosis, errors in technique, and errors in judgment.

THE PATIENT SAFETY PROBLEM

The Institute of Medicine (IOM) conducted a comprehensive study of medical errors and safety in health care. In its report To Err Is Human, Building a Safer Health System,[7] the IOM defined safety as freedom from accidental injury. It defines error as failure of a planned action to be completed as intended or the use of a wrong plan to achieve an objective. Reason states that errors depend on two kinds of failure: either the correct action does not proceed as intended (an error of execution), or the original intended action is not correct (an error of planning). Not all errors produce harm. Large systems fail because recognized or unrecognized multiple faults occur together to cause an accident. An accident damages the system and disrupts the system's output.[8]

All human endeavors have a constant risk for error. Complex systems may experience active errors or latent errors. Active errors occur at the point of care, and the involved personnel recognize active errors almost immediately. Reason calls this the sharp end. At the blunt end, latent errors occur remote from the point of care and include poor design, incorrect installation, faulty maintenance, bad management decisions, and poorly structured organizations.[8] Practitioners at the sharp end—surgeons, anesthesiologists, nurses, and technicians—directly engage the hazardous process close to the patient. The blunt end affects system safety, with its constraints and resources allocated to practitioners at the sharp end. The blunt end includes government regulators, hospital administrators, nursing managers, and insurance companies.[9]

Extrapolation from the New York and Utah/Colorado studies suggest that 44,000 to 98,000 hospital patients die each year as a result of medical errors, which makes medical errors the eighth leading cause of death in the United States, with a total national cost of $17 to $29 billion. We have the opportunity not only to prevent deaths and suffering but also to reduce substantially the national cost burden of health care.[4,7,10] These studies addressed inpatient surgical care, whereas ambulatory surgery centers and office surgery went unexamined.

According to the latest data from the National Center for Health Statistics, 40.3 million inpatient surgical procedures were performed in the United States in 1996, followed closely by 31.5 million outpatient procedures.[11,12] A large proportion of operations are performed in ambulatory surgery centers or in surgeons' offices. This deserves special attention because procedures performed in unregulated doctors' offices have a 10-fold increased risk for adverse events and mortality than do procedures performed in accredited facilities.[13]

These studies document adverse events and negligence in hospital care and, in particular, surgical care in both inpatient and outpatient settings. More importantly, we have good reason to believe that behavior modifications throughout the health care industry can prevent more than half of surgical adverse events. *To Err Is Human* received wide recognition among politicians, business, the public, and the medical profession. It prompted substantial government funding for health care safety improvement, organization of committees, educational programs, and publications—an extraordinary effort. Yet in the 15 years since Brennan's landmark publication and in the 7 years since publication of *To Err Is Human,* no credible evidence has appeared to suggest that health care in general and surgical care in particular has become safer.

What explains this observation? Perhaps our profession has not assumed its responsibility to protect the interests of the sick. This happens in part because our profession fails to understand errors and how and why they occur. To correct this matter will require incorporating an understanding of safety into the mind of every surgeon. These questions and assertions reveal a remarkable paradox. Because of the high risks associated with surgical care, surgeons devote a majority of their professional energy to avoiding errors, adverse events, and complications. This effort begins on the first day of surgical residency.

The sociologist Charles Bosk provided a detailed and scholarly analysis of this topic in his carefully researched book *Forgive and Remember: Managing Medical Failure.* This study, published in 1979, exerted no impact on surgical errors. Why not? It clearly documented the admirable professional, technical, moral, ethical, and personal attributes and dedication of surgeons and surgical trainees of an elite academic department of surgery. It also documented a rigid hierarchy of autonomous superordinates who promoted disdain for outcome data, clinical trials, and scientific thought.[14]

> In general, surgeons believed that the only protection for patients, the only guarantee of high-quality care, was the individual surgeon's personal standards of attention to detail, honesty, and adequate training. They took every opportunity to instill residents with the proper professional values and to model proper professional conduct. At the same time they did virtually nothing to inculcate a sense of corporate or collective responsibility for outcomes. The patterns of assessment and surveillance suggested a hypertrophy of individual responsibility for outcomes and an atrophy of collective responsibility. This pattern reinforced and reflected the values of personal autonomy and the superiority of clinical over scientific judgment.[15(p168)]

Certainly, safe surgery requires well-informed, skilled, dedicated, conscientious, honest, trustworthy surgeons and much more (Box 11-2). Safe surgery requires teamwork among all health care professionals interacting effectively with other stakeholders in the health care industry and with available physical resources to form accountable, high-reliability organizations. High-reliability organizations develop a so-called systems approach to understand errors or accidents and to support decisions in complex health care. Such organizations create an open flow of information, learn to eliminate the culture of blame, and in addition, build partnerships among health care stakeholders to resolve differences and agree on common goals. According to Woods,

> High reliability organizations created safety by anticipating and planning for unexpected events and future surprises. These organizations did not take past successes as a reason for confidence. Instead, they continued to invest in anticipating the changing potential for failure because of the deeply held understanding that their knowledge base was fragile in the face of the hazards inherent in their work and the changes omnipresent in their environment. Safety for these organizations was not a commodity but a value that required continuing reinforcement and investment. The learning activities at the heart of this process depend on the open flow of information about the changing potential for failure.[16(p490)]

Health care in the United States does not possess the characteristics of a high-performance organization. The medical profession remains a cottage industry operating under the direction of powerful corporations and a powerful government. A safe health care system will require realignment of all health care professionals into a high-performance organization with a defined infrastructure.

Box 11-2 Characteristics of Safety

- Systems, not individuals, make safety.
- Designs for safety require a detailed understanding of the technical work.
- Safety is dynamic, not static; it is constantly renegotiated.
- Trade-offs compromise the core of safety.
- Adding complexity (e.g., technology) can compromise safety.
- People constantly create safety.

Adapted from Cook RI, O'Connor M, Reader M, et al: Operating at the sharp end: The human factors of complex technical work and its implications for patient safety. In Manuel BM, Nora P (eds): Surgical Patient Safety. Chicago, American College of Surgeons, 2004, pp 19-30.

W. Edwards Deming, a respected scholar in the field of quality control, stated, "We have learned to live in a world of mistakes and defective products as if they were necessary to life. It is time to develop a new philosophy in America."[17]

Deming established 14 points for management in industry or business. Those points and the Deming program contributed to improvement of goods and services in industry worldwide.[18] Although Deming's points addressed quality, we believe that they can apply to improving safety in surgical care. Six of the points modified to apply to surgical care can serve as a foundation or guiding principle for the discussions to follow in this chapter:

1. Appoint leaders who make as their top priorities helping people whom they supervise and improving the services that those individuals provide.
2. Break down the barriers between departments and specialties so that each professional who cares for a patient is part of a team and is able to foresee problems that may be encountered during the course of treatment.
3. Drive out fear so that everyone may work effectively in partnership.
4. Institute on-the-job safety training by using a practice-based approach to lifelong learning.
5. Institute a vigorous program of education and self-improvement.
6. Put everybody in the institution or office to work to accomplish the transformation. The transformation is everybody's job.[19]

THE SCIENCE OF SAFETY AND JOINT COGNITIVE SYSTEMS

During the past 3 decades, cognitive psychologists and systems engineers working in industry have examined the problem of errors in detail and revealed that most errors occur as a result of flaws in systems. We can apply their knowledge and the principles they defined to improving surgical safety. A system is an arrangement of components, people, and functions organized and managed to accomplish tasks or goals (Box 11-3). Hollnagel and Woods define a cognitive system as a system that can modify its behavior on the basis of experience

Box 11-3 Systems

A system has two or more parts and the following features:

- It has a function or purpose.
- Each part can affect the other parts.
- Subsets of the system's parts can function alone but cannot perform total system tasks.
- The function of any part depends on at least one other part.
- In large complex systems, certain events cannot be attributed to any single part.

Adapted from Hollnagel E, Woods DD: Joint Cognitive Systems: Foundations of Cognitive Systems Engineering. Boca Raton, FL, Taylor & Francis, 2005.

to achieve specific antientropic ends. Entropy is the amount of energy in a system unavailable for work or, viewed in another way, the amount of disorder in a system. Some systems, called *cognitive systems,* can maintain order in the presence of disruptions. Accordingly, a joint cognitive system (JCS) can control what it does and is defined by what it does. A cognitive system has two or more parts, each part can affect the other parts, and the way that any part behaves depends largely on at least one other part.[20]

Some system disruptions permit errors. Scholars challenge the notion of *human error.* Human error may be a post hoc rationalization starting from the assumption that all effects must have causes.[20,21] Although there are no medical errors, many errors occur in medical settings. We can predict the probability of errors, but we cannot predict when errors occur. Undetected or uninterrupted errors lead to accidents and perhaps injury. Cognitive systems engineering (CSE) states that one cannot understand why something fails without first understanding why it usually goes right. Efforts to make work safe should start from an understanding of the normal variability of human and system performance rather than from putative error mechanisms.

According to conventional thought, complex systems fail when multiple small failures, called *latent errors,* align to allow an accident. This so-called Swiss cheese accident model is being increasingly criticized because it is too linear, defects are more often transient, and the whole process is more dynamic than the model suggests. Sequential accident models inevitably lead to a root cause, which is the basis of the root cause analysis. The search for a root cause, often a human, tends to perpetuate the blame-the-person outcome. It may also suggest, incorrectly, that eliminating a root cause will solve the problem. Postaccident reviews frequently identify human error as the so-called cause of failure because of hindsight bias. That is, outcome knowledge made the failure seem foreseeable when it was not foreseen and not foreseeable. The work of Hollnagel reveals that comprehensive detailed inquiries often find multiple parallel factors leading to the event first considered a root cause (Fig. 11-1). This model focuses on examination of the system and provides a higher probability of improving safety than the other models do. Blaming a person has a poor track record of safety improvement because it leaves the faulty system uncorrected.[22]

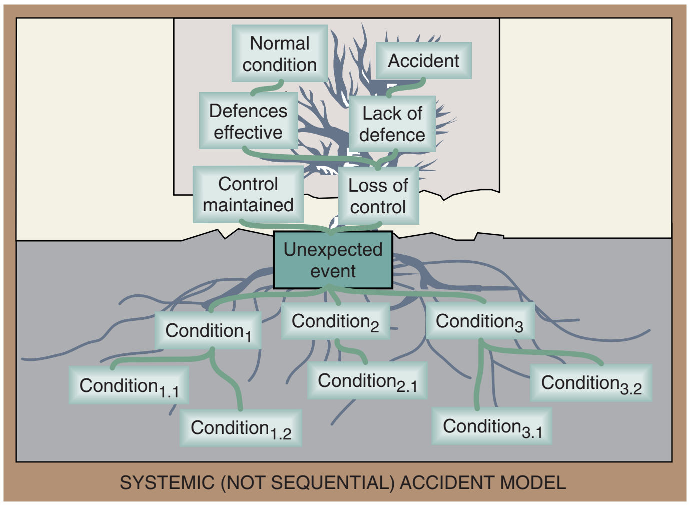

Figure 11-1 This Hollnagel accident model, which focuses on examination of the system, provides a higher probability of improving safety than sequential accident models do. (From Hollnagel E: Barriers and Accident Prevention. Aldershot, UK, Ashgate, 2004.)

CSE addresses the following themes:

1. How people cope with the complexity produced by technologic and sociotechnical developments
2. How people use artifacts in their work
3. How humans and artifacts form a JCS to focus on how humans and technology work together effectively

Hence, a JCS consists of purposeful human and technologic interactions. A JCS can recognize issues and understand events within the context of their occurrence. Proper system performance requires control of processes and events, and loss of control or loss of the ability to solve performance aberrations produces system instability. A JCS can deal with unexpected events best when they occur infrequently. The ability of a JCS to deal with and control complexity depends on a degree of orderliness or predictability, the time available, knowledge, competence, and resources.

A JCS can modify its behavior on the basis of experience to achieve its goals effectively. It can control what it does. CSE concerns a JCS with the following features:

1. Functioning is complex
2. The artifact (i.e., machinery, equipment, patient) functions unpredictably
3. The artifact has a dynamic process (i.e., it changes with time)

CSE recognizes other important features of a JCS:

1. Cognition is distributed among all system participants so that cooperation and coordination can become ubiquitous
2. Rapidly growing technologic development leads to more data, options, modes, displays, and the like, as well as ultimately to more complexity

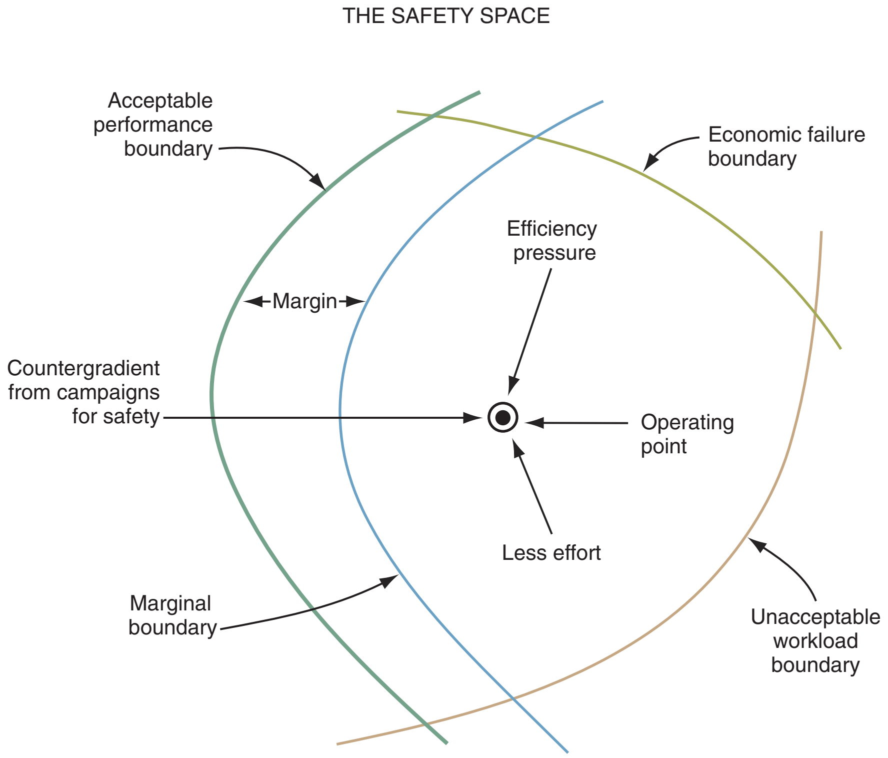

Figure 11-2 **Rasmussen's dynamic safety model as depicted by Cook and Rasmussen describes a relationship among workload, economic boundaries, and accident risk boundaries. The model suggests that increasing workload or economic pressure increases the potential for accidents. In addition, pressure to avoid accidents pushes back on the workload and economic boundaries.** From Cook R, Rasmussen J: "Going solid": A model of system dynamics and consequences for patient safety. Qual Saf Health Care 14:130-134, 2005.)

3. Growth of system complexity produces failures, currently called *human error*

Only cooperation and congruence of the participants allow control and smooth functioning of a JCS. The effectiveness of the system affects throughput capacity, efficiency, quality, safety, and organization culture.[20]

Surgical teams in busy hospitals must often manage around impediments in the smooth flow of patients into and through their system. Any single system component, such as the ICU, filled to capacity will require additional unit management. Frequently, another hospital unit can allow work flow to continue, for example, holding a patient in the recovery room until an ICU bed becomes available. When additional units reach capacity, management of the system becomes increasingly difficult. Cognitive systems engineers coined the phrase *tight coupling* to describe a deficiency of redundancy among the components of a system.

Tight coupling connects parts of the system so rigidly that actions at one place are immediately transmitted throughout. Prediction and control become harder, and accidents increase. Tight coupling promotes errors. Everyday examples of tight coupling include no hospital beds, no ICU beds, inadequate nurse staffing, overbooked operating room schedule, shortage of surgical instruments, delay in procedures, inadequate resources to staff operating room procedures, lengthy queues for operations, elective surgery in off-hours, and long queues for routine outpatient appointments. Tight coupling results from failure to recognize production limits that match production capacity. With all units filled to capacity, or maximal tight coupling, events in one hospital unit have an impact on the operation of all other units in the system. Cook and Rasmussen called this situation *going solid*. Going solid produces situations both hazardous and difficult to control. Though not directly producing accidents, it makes accidents more likely and more difficult to deflect and makes recovery more complicated. Conversely, although going solid may be difficult to manage, it can improve the hospital's financial performance considerably. The fact that more accidents do not occur when health systems become tightly coupled or go solid is a tribute to the health care professionals providing knowledge, technical skill, judgment, dedication, and commitment at the sharp end.[23]

A surgical system's operating space resides within three boundaries: the risk-of-economic-failure boundary, the risk-of-unacceptable-workload boundary, and the acceptable-performance (accident-free) boundary. Consequently, increasing economic pressure and increasing workload pressure can perturb the acceptable-performance boundary in ways to increase the risk for accidents (Fig. 11-2). High-reliability organizations develop accurate, precise, and shared understanding of the balance among economic, workload, and performance boundaries. Low-reliability organizations have inaccurate, imprecise, and divergent understanding of these boundaries. High-reliability organizations frequently anticipate accidents, whereas low-reliability organizations are often surprised by accidents. The increased complexity of tightly coupled systems makes system behavior unpredictable and increases the risk for accidents. However, tight coupling gains efficiency and economy. Tightly coupled system failures have produced large-scale power outages, for example.[23]

SAFER SURGICAL SYSTEMS

Surgical services represent JCSs amenable to improved effectiveness, improved efficiency, and improved safety with focused management practices and professional leadership. Improving surgical safety, particularly operating room safety, will require surgeons to assume their responsibility to lead the surgical JCS. Many surgeons currently lead efforts to improve surgical safety. The following paragraphs describe some of these efforts and delineate additional opportunities to prevent adverse events, errors, and accidents.

Team Development

Systems include people working with artifacts to accomplish goals: teams. Consequently, addressing systems of care begins with an examination of the people in the system forming the team. In surgical care the team includes surgeons, anesthesiologists, anesthetists, nurses, allied health personnel, and administrators. To work effectively in surgical teams the people require competency, proficiency, continued learning, and skill development. Competency refers to the cognitive skills and knowledge required to practice a profession. Proficiency is the ability to execute a task at a consistently optimum level and outcome. Learning is the acquisition of new knowledge. Maintaining surgical competency and proficiency requires a long-term, perhaps endless process that begins with the selection of trainees. Because some individuals learn and acquire skill faster than others do, the training process should possess continual, objective, standardized assessments of cognition and technical skills. These processes should then continue beyond the training period into continuing professional practice to provide continuing assessment of established surgeons for revalidation and recertification. Practicing surgical professionals of all disciplines require opportunities for continuing acquisition of new knowledge and new technical skills. Because of the rapidly increasing volume of new knowledge and new technology, learning and development of new skills assume increasing importance for maintaining patient safety.[24]

Surgical professionals need reliable performance assessment in the form of regularly provided outcome data such as morbidity rates, mortality rates, cure rates, and patient postoperative quality-of-life assessments. In addition, some system for analyzing and evaluating anonymous incident, error, and accident reports could promote safety in surgical practice. The U.S. Congress enacted laws permitting collection of such data without risk of legal discovery. The Agency for Healthcare Research and Quality is developing federal regulations to permit health care organizations to form patient safety organizations for the purpose of examining data on medical errors and accidents.

Surgeons have a special responsibility to promote safety by providing leadership to surgical teams. Surgeon leaders must have sufficient experience and surgical volume to sustain a high level of proficiency. A surgeon leader who understands the system will implement good team management and promote optimal performance of all involved professionals by focusing on the interests of the patient. Leadership requires the physical presence of the surgeon in the operating room.

A safety-oriented surgical system would include measures to identify impaired members of the team, including surgeons, anesthesiologists, anesthetists, nurses, allied health professionals, and administrators. These problems occur infrequently but can pose threats to patient safety when they occur. Our profession has not addressed this matter as well in the past as it must in the future. Team leaders should develop processes for recognizing impaired members. Impairments include substance abuse, mental illness, and physical illness. In addition, recognition and correction of declining competency and proficiency should promote safety. Teams should also recognize and correct behavioral problems causing disruption in the workplace. Professionals who cannot work effectively with others or who are abusive to others, including personnel and patients, must undergo rehabilitation. Institutional or team leaders should identify problem staff members early and take corrective action in a timely manner. A system of professional accountability must be objective, based on data; it must be fair and apply to everyone in the system; and it must respond with prompt and effective treatment with the goal of enabling all to continue professional practice.[25]

Surgeons, anesthesiologists, nurses, and allied health professionals recognize the importance of teamwork in the operating room. For many operations, pathologists play a crucial role in safe, effective surgery and smooth conduct of surgical procedures. A high-performance operating room requires good communication among all surgical team members because breakdowns in communication can lead to errors, adverse events, and accidents compromising patient safety. Medical team training can improve communication in the operating room. Operating room teams can use crew resource management (CRM) principles to enhance communication and patient safety. CRM principles include didactic instruction, interactive participation, role-playing, training films, and clinical vignettes. Awad and coworkers investigated CRM quantitatively and concluded, "Medical team training using CRM principles can improve communication in the operating room, ensuring a safer environment that leads to decreased adverse events."[26(p773)]

Preoperative Checklist–General Surgery
(To be Filled in by Chief Resident the Day Before the Operation)

Patient: ____________________ Date of Operation:

Operation: ____________________ Attending: ____________________

1. Outpatient H&P available ☐	11. Regimen for venous thrombosis prophylaxis implemented ☐
2. Office records available ☐	12. Prophylactic antibiotics decided & ordered ☐
3. Signed consent form here ☐	13. Resident assignments made ☐
4. Signed blood consent form here ☐	Special protocols:
5. Pertinent x-rays here ☐	13. Glucose control in insulin-dependent diabetics ☐
6. Pre-op chest x-ray, EKG and lab tests reviewed ☐	14. Patients on chronic anticoagulation ☐
7. Outside path slides read at UCSF; no discrepancy ☐	15. Splenectomy immunization ☐
8. Results of preop consults checked; recommendations implemented ☐	Initial the box or write n/a if a step is not applicable.
9. SFP Admit Form checked for other details ☐	
10. Beta-blocker protocol implemented ☐	____________________ Signed and checked by Date

Figure 11-3 **Checklists such as this one can maximize effective communication at gaps and during handoffs along the continuum of surgical care.** (Courtesy of the Department of Surgery, University of California, San Francisco.)

Gap Protection

Cook and colleagues introduced the useful concept of gaps and recognized that gaps provide opportunities for errors and accidents.[27] Gaps, or discontinuities, may produce loss of information, loss of momentum, or interruptions in delivery of care. Fortunately, gaps rarely lead to failure or produce errors because nurses, technicians, clerks, or physicians anticipate, identify, and bridge most gaps.

Organizational boundaries, changes in authority or responsibility, different roles of professionals, and divisions of labor produce gaps. For example, shift changes, patient transfer to different units within a hospital, patient transfer between hospitals, discharge to a rehabilitation facility, and discharge home produce gaps in care. Gaps can occur within the activities of a single practitioner, for example, when a nurse divides attention between two or more patients. Organizational change or the introduction of new technology can cause new gaps or disrupt bridges spanning established gaps. System complexity creates gaps in care, and information can be lost. Every transition in care constitutes a gap. The increasing fragmentation of medical care produces more gaps. Structured handoff routines and checklists can decrease information loss at gaps. A dozen or more gaps or handoffs can occur between evaluation in the clinic, surgical admission unit, operating room, recovery room, ICU, and surgical ward and discharge from the hospital. Each gap requires a handoff.

Handoff routines can include reading back orders and instructions, face-to-face review of clinical information, or handoff information technology resources. Checklists and standardized orders can also minimize loss of information at handoffs. Checklists can simplify preoperative planning, operating room scheduling, admission scheduling, night-before instructions, preoperative details (briefing), and postoperative care (Fig. 11-3). A system can apply standardization to admission and preoperative orders, postoperative orders, transition orders, discharge orders, and discharge instructions. Guidelines, clinical pathways, protocols, and algorithms can also facilitate bridging of gaps. All these gap transition artifacts prompt routine, necessary action at system gaps, can be

Box 11-4 JCAHO *Time-Out* Immediately Before Starting a Procedure

Must be conducted in the location where the procedure will be performed, just before starting the procedure. It must involve the entire operative team, use active communication, be briefly documented, such as in a checklist (the organization should determine the type and amount of documentation), and must, at the least, include the following:

- Correct patient identity
- Correct site and side
- Agreement on the procedure to be performed
- Correct patient position
- Availability of correct implants and any special equipment or special requirements

The organization should have processes and systems in place for reconciling differences in staff responses during the time-out

Adapted from the Joint Commission on Accreditation of Healthcare Organizations. Universal Protocol, 2006. Available at http://jointcommission.org?PatientSafety/UniversalProtocol. Retrieved October 27, 2006.

Box 11-5 Goals of the National Health Information Infrastructure

- National platform for standards
- Confidentiality
- Electronic medical records
- Computerized physician order entry
- Electronic prescriptions
- Quality improvement databases
- Repositories of best evidence
- Computer-assisted decision support
- Prompts and reminder systems

From U.S. Department of Health and Human Services. National Health Information Infrastructure (NIIH 2002-2004), 2006. Available at http://aspe.hhs.gov/sp/NHII/index.html. Retrieved October 27, 2006.

customized for individual patients, and are effective, inexpensive, low-tech, and efficient.[27]

The Joint Commission for Accreditation of Healthcare Organizations (JCAHO), the American College of Surgeons (ACS), and the Veterans Administration Health System (VAHS) recommend processes for preoperative review to promote safety and eliminate errors in patient and surgical site identification, as well as other important considerations.[28-30] The ACS, JCAHO, and VAHS endorse a preoperative briefing or *time-out* before every surgical procedure. Box 11-4 shows the JCAHO recommendations for its time-out procedure. This guide stipulates essential topics for preoperative discussion by all members of the surgical team and a checklist to verify that all personnel, all necessary equipment, and all necessary processes have been accomplished or are in place before making the incision or beginning the procedure. Development of a preoperative briefing guide and the related checklists can begin with the patient's first encounter with the surgical team. This first encounter can initiate an iterative process that produces a checklist for review by members of the surgical team on the preoperative evening in elective cases. The preoperative time-out in the operating room will then verify all items on the list. After the operation, members of the surgical team will bridge the gap between the operating room and the recovery room or the ICU.

Improvements in Information Technology

Federal and state governments and all health industry stakeholders assign high priority to the application of information technology for increasing the safety and quality of health care. With the leadership of the Department of Health and Human Services, 13 government agencies, professional organizations, private foundations, providers, and vendors formed an organization, the National Health Information Infrastructure (NHII), to promote the development and implementation of information technology systems and programs to support the development of a national health care system. Box 11-5 lists the goals and objectives of a national health information technology system. This task will require unprecedented leadership from government, industry, and the health professions. In addition, the project faces substantial financial challenges. As it develops over time, a national health information infrastructure will undoubtedly improve the quality and safety of health care.[31] However, the health care industry should introduce new information technology with care and deliberation because such new technology could create tighter coupling in the system and produce unforeseen challenges in system control and unanticipated opportunities for error.[23]

Nonetheless, computerized physician order entry and computerized prescription writing already show promise for reducing medical errors. Information technology provides multiple opportunities for improving patient safety; for example, computerized rounding and sign-out systems have the potential to improve the continuity of care and facilitate the bridging of gaps. Van Eaton and associates, working in an academic medical center, developed a centralized, Web-based computerized rounding and sign-out system that securely stores information, automatically downloads patient data, and prints the data to rounding, sign-out, and progress note templates. Authorized users could access the system from any hospital workstation or from their own computers. The centralized computer allowed residents to organize patient lists, enter detailed sign-out information, and compile "to do" lists. Residents could add patient data to other team's lists when cross-covering or consulting. The system produced sign-out reports and rounding lists that included clinical data and laboratory values downloaded from the hospital clinical information systems. This team evaluated the system in a prospective randomized trial involving six general surgery services and eight internal medicine services. Helping residents cope with the limitations of the 80-hour work week motivated this project, which succeeded in this objective by decreasing rounding time. However, the system also enhanced patient care by decreasing the number of patients missed on resident rounds and improved the continuity of care. Although a teaching hospital developed this system, the method and the principles developed should work in any hospital.[32]

Observational Studies of Perioperative Systems

Most efforts to improve surgical safety have relied on retrospective reviews of health records, administrative data, or malpractice claims. Recent prospective observational studies conducted in the perioperative period with particular focus on intraoperative events have provided new insight into safety in the operating room and have revealed opportunities for improving surgical safety. Because accidents, adverse events, and errors of consequence occur during or after operations, observations in the operating room can provide abundant opportunities for improving patient safety.[33] Christian and colleagues organized a multidisciplinary research team of surgeons and human factors experts experienced in investigating high-risk work environments. They developed a hierarchic coding scheme for system factors and human factors for each observation. They annotated, classified, and entered their field notes into a relational database with a custom software application. The investigators met the patient and the surgical team in the preoperative holding area and recorded detailed observations during the care from that time until completion of the operation. Of 10 cases, 9 were completed with preoperative, intraoperative, and postoperative observations. The surgeon cancelled one case in the preoperative phase.

Sixty-three hours of observation provided 4500 observations for analysis. Table 11-1 shows the quantitative analysis of communications/information flow and its influence on performance and safety. The 10 study cases had an average of nine instances of information loss or information degradation per case. These lapses caused delays in case progression, increased team workload, uncertainty in patient management, waste of resources, increased exposure of patients to injury, and cancellation of a case. Handoffs occurred during each case an average of 4.8 times, or once every hour during each case. The surgical team spent an average of 43 minutes, or 17.3% of the operating time, waiting for communication from pathology.

Table 11-2 presents a quantitative analysis of workload and auxiliary tasks and their influence on performance and safety in cases that progressed to the intraoperative phase. Note that the circulating nurse left the operating room an average of 33 times per case, or 7.5 times per hour of incision time. Instruments or other materials were added to the operative field 14.6 times per case. The routine of counting sponges and instruments attracted the attention of the investigators. During each procedure the team spent 35 minutes on counting activities, or 14.5% of the incision time. If the results of these counting activities were inconsistent or incorrect, it increased workload for non-nursing personnel, required radiographic confirmation in two cases, and exposed patients to injury. This study revealed that communication breakdown and information loss, as well as high workload and multiple competing tasks, can compromise patient safety. Direct field observations such as this have the potential to provide better understanding of the processes and systems of operative care and thereby improve patient safety and reduce errors.[34]

Table 11-1 Quantitative Analysis of Communication/Information Flow and Its Influence on Performance and Safety (*N*=10)

Instances of Information Loss or Degradation	
Aggregate number of instances across all cases	88
Per-case mean	9
Influence of Information Loss on Performance or Safety (Total Instances Across All Cases)	
Delay in case progression	19
Increased workload	15
Increased uncertainty in patient management for others	29
Overuse of material resources	6
Increased exposure to injury (patient)	6
Cancellation of case	1
No influence detected	12
Handoff of Patient Care Across Provider Groups	
Mean number per case	
All provider groups	4.8
Nursing staff	2.8
Anesthesia staff	1.8
Surgeons	0.4
Frequency of handoffs	1 per 60 minutes of operation
Communication With Pathology	
Mean time waiting for a pathologist's response	43 minutes
Mean percentage of incision time waiting for a response	17.3%

Adapted from Christian CR, Gustafson M, Roth EM, et al: A prospective study of patient safety in the operating room. Surgery 139:159-172, 2006.

The airline industry implemented a program called *Line Operations Safety Audits* (LOSA) that used methods similar to those described earlier to evaluate aviation safety. On April 4, 2006, the Federal Aviation Agency issued an Advisory Circular on LOSA. The program has a trained pilot observer on board the aircraft to complete a targeted observation form. LOSA is totally voluntary and the observations remain unidentified and confidential. LOSA is designed to permit crews to recognize opportunities for improving safety and decreasing the risk for error. It is possible that a similar, voluntary nonthreatening program could promote patient safety, improve processes of operative care, and reduce errors in operating rooms.[35]

Systems Engineers

Previous work has revealed that collaboration between surgeons and systems engineers can provide useful

Table 11-2 Quantitative Analysis of Workload and Auxiliary Tasks and Their Influence on Performance and Safety in Cases That Progressed to the Intraoperative Phase (N=9)

Circulating Nurse Exits for Procurement of Resources	
Aggregate number of exits across all cases	299
Per-case average number of exits	33
Mean frequency of exits	7.5 per hour of incision time
Addition of Instruments or Materials to the Operative Field After Start of the Procedure	
Aggregate number of objects added across all cases	131
Per-case average number of objects added	14.6
Mean frequency of addition to the field	1 per 27 minutes of incision time
Counting Activities	
Mean time spent on counting	35 minutes
Mean percentage of incision time spent on counting	14.5%
Influence of Counting Activities on Performance or Safety	
Aggregate number of performance issues during counting	28
Errors or inconsistencies in the count	17
Increased workload for non-nursing providers	11
Interruption of the procedure to take a radiograph after failure to resolve inconsistencies	2
Increased exposure to injury (patient)	2

Adapted from Christian CR, Gustafson M, Roth EM, et al: A prospective study of patient safety in the operating room. Surgery 139:159-172, 2006.

insight into understanding surgical system improvement. Systems engineers have the competency and proficiency that surgeons, anesthesiologists, and nurses lack in analyzing and quantifying system performance, human factors, communication, equipment design, and situation awareness. These skills will help health care professionals analyze, monitor, and manage their care systems to promote safety, minimize errors, improve the quality of care, and maintain a healthy satisfying workplace.

Operating Room Safety Committee

Most hospitals maintain an operating room committee to advise operating managers on asset allocation, equipment, scheduling, purchasing, and budgeting. Is there evidence that operating room committees effectively address surgical safety, perioperative systems, tight coupling, going solid, queuing, and elective cases after hours? Because traditional work flow consumes the operating room committee and because patient safety in the operating room deserves high priority, hospitals should consider forming operating room safety committees. Perhaps complex organizations bog down with too many committees and other forms of bureaucracy. However, *To Err Is Human* tells us that we can reduce errors by 50% by applying attention to our health system and to our operating rooms in particular. Focusing on operating room systems and safety remains a fruitful opportunity to save lives.

Fellowships in Surgical Safety

Careful examination reveals critical underfunding of research in surgical disciplines. Surgeons compete ineffectively with nonsurgeons and basic scientists in seeking research funding from the National Institutes of Health and other funding agencies. Improving surgical safety without high-quality research and scientific rigor will remain as ineffective in the future as it has in the past.[36] Improving surgical safety will require funding for surgeons, anesthesiologists, and nurses to develop research skills and will require funding for their research. Young surgeons, anesthesiologists, and nurses will require opportunities to work and study with systems engineers, human factors experts, and other scholars relevant to system safety. Health professional investigators should receive encouragement and academic recognition for revealing new knowledge and new insights about human factors, communication, equipment design, and the principles of CSE and management of JSCs. Editors of surgical journals can promote surgical safety by publishing the work of surgical safety researchers. Changing the culture of safety in surgery will require a cadre of devoted researchers and scholar experts in the field.

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