New technology

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Surgical Endoscopy and Other Interventional Techniques

A systems approach to surgical safety

J. F. Calland,[1] S. Guerlain,[2] R. B. Adams,[1] C. G. Tribble,[1] E. Foley,[1] E. G. Chekan[1]

[1] Surgical Technology and Safety Laboratory, University of Virginia, Post Office Box 800709, Charlottesville, VA 22908-0709, USA
[2] Department of Systems and Information Engineering, University of Virginia, School of Engineering and Applied Sciences, Post Office Box 400747, Thornton Hall, Charlottesville, VA 22904-4747, USA

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Morbidity and mortality conference case report: A 58-year-old woman with a recent history of hypertension and flushing, but otherwise without significant medical history, arrived in the preoperative surgical suite for a laparoscopic right adrenalectomy for a 1-cm pheochromocytoma. Standard preoperative workup and pharmacologic therapy were initiated and completed on an outpatient basis. On the day of surgery, in the preoperative area, she stated that there had been no change in her condition in the week since the completion of her history and physical in the office. Later that morning, she was taken to the operating room. There she underwent a difficult adrenal resection that required conversion to a laparotomy secondary to difficulty in exposing the gland. Next, ≃500 cc of blood was lost during isolation and ligation of the right adrenal vein. Despite resuscitation with 2 L of crystalloid, she remained tachycardic and hypotensive. Within a short time, she became bradycardic and suffered an intraoperative cardiac arrest. She was quickly resuscitated and moved to the intensive care unit with mildly elevated cardiac enzymes. Later that night, she arrested again and died. In a conversation with her husband, he reported that she had been having low-grade fevers and night sweats for 2 days prior to surgery, but she had dismissed these facts as insignificant and did not mention them to her surgeon on the morning of the procedure.

Cases similar to this fictitious one are often presented in institutional morbidity and mortality conferences, with the ensuing discussion frequently raising more questions than are answered. For instance, the most obvious question—Why did this patient die? Was it a surgeon's technical error, either surgical or anesthetic? Why was it difficult to expose the gland? Did her history of fever and night sweats contribute to her death? Why was this history unsolicited? Consideration of these questions then naturally begs a larger question—Was it an error that led to this patient's death, and if so, was it preventable? How? In this paper, we will outline the current state of error prevention in the practice of surgery, give examples of methods employed by other high-risk industries to successfully address similar issues, and suggest the implementation of a systems approach plan for increasing the safety of surgical procedures.

Background

Errors in general, including surgical errors, are classified as either latent or active. Active, or operator, errors are those committed by individual practitioners at the point of care, i.e., by the pilot in the cockpit, by the factory worker on the production line, or by the surgeon in the operating room. Typically, such events are clearly identifiable as errors at the moment they occur. In the airline industry, failure to extend the landing gear prior to touchdown would be an example of an active error. Latent errors, on the other hand, are circumstances established by policies and practices of an institution, culture, or society that predispose practitioners to errors. Examples of such latent errors include sleep deprivation, inadequate job training, poorly designed tools, or unclear procedure policies. Such errors have been clearly identified as risk factors for suboptimal outcomes in aviation and manufacturing. [18, 26, 48].

Adverse events are a separate issue. In the field of medicine, for instance, several authors have defined adverse events as events that unexpectedly result in death, extended hospital stay, or extended disability after discharge [5, 9, 10, 28, 35, 39, 47, 51]. Clearly, not all adverse events are preventable. When a patient dies from an extremely rare and fatal drug reaction, or their primary disease, it is unfortunate but often not preventable. On the other hand, when a patient suffers from a medication error and dies of anaphylaxis due to a clearly documented allergy, this is a preventable adverse event. Human errors do not necessarily result in adverse events, and not all adverse events are the result of errors. In theory, however, many adverse events are preventable

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Correspondence to: E. G. Chekan

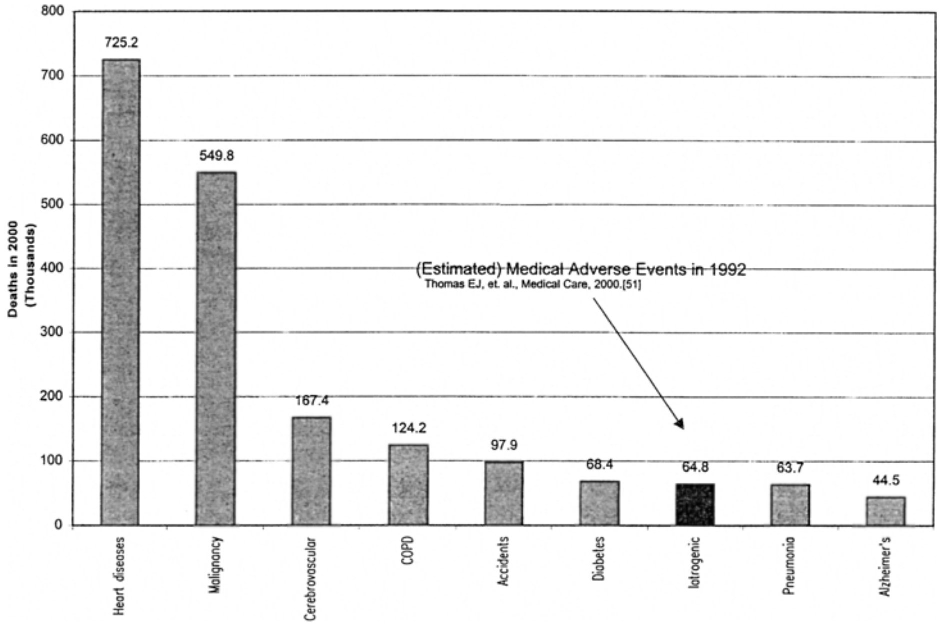

Fig. 1. Causes of mortality in the United States. Death from medical adverse events could be as much the fourth leading cause of death in the United States. In this figure, data from Thomas et al. were inserted into a graph of data on leading causes of death in the US for 1998 [43, 57]. COPD, chronic obstructive pulmonary disease.

if adequately understood. Certainly all errors are (in theory) preventable, especially when devices and processes are designed with an understanding of ergonomics (human factors) [8].

Incidence of surgical adverse events and errors

With an estimated 45,000–98,000 deaths per year, preventable adverse events remain a leading cause of death in the United States (Fig. 1) [10, 34, 39, 51]. Brennan et al. found that nearly 4% of more than 30,000 hospitalizations in New York in 1984 were affected by adverse events and that an estimated 70% of these events were preventable [10, 37]. Estimates of the incidence of adverse events during surgical patient admissions are higher, ranging from 7% to 40% [5, 37, 53]. Furthermore, the majority of large-scale epidemiological data on surgical adverse events and errors, including data presented in the Institute of Medicine report, have been collected retrospectively, likely leading to underestimation of the true incidence [34].

The operating room is the most common site for adverse events in the hospital (Fig. 2) [37]. This is due in part to the large number of groups that must coordinate their individual efforts in order to administer effective patient care (Fig. 3). Currently, during both hepatobiliary surgical procedures and thoracic-cardiovascular operations, patients face at least a 1% chance of death or a major avoidable complication [7, 30]. Studies addressing the issue of adverse events during laparoscopic procedures have reported similar results. During laparoscopic cholecystectomy, the risk of a common bile duct or bowel injury or other serious technical complications in some series is actually greater than 1% [1, 54]. Similarly, patients undergoing laparoscopic inguinal hernia repair experience chronic pain or numbness in at least 4% of cases [49].

Without question, medical adverse events and errors are difficult to measure and estimate, and the validity of current estimates has been called into question [41]. In either case, there is a consensus that errors occur in medicine and surgery and therefore should be preventable [38].

Systems theory

High error rates are not unique to surgery. A variety of other fields, including aviation and anesthesiology, have experienced similar error rates but have been able to reduce them using well-designed error reduction systems based on systems theory [14, 17]. Systems theory contends that events, objects, locations, and methods do not exist independently, but rather are intertwined as interdependent components of complex systems. Furthermore, complex systems also incorporate multiple layers of seemingly unrelated issues, including social, legal, cultural, and economic factors, which ultimately shape the system's final form. If an alteration occurs in any one of the components making up a complex system, its effect ripples throughout the entire system. Such perturbations may have far-reaching effects and may only be noticeable at distant points from the original alteration. Similarly, other interdependent systems interacting with the first system can also be influenced to varying degrees. The design of a system must consider all aspects of the task at hand, from specific instrumentation and work environment to more abstract human factors such as team dynamics (Fig. 4).

If workers must use tools that are difficult to grip, manipulate, handle, see, or access in the context of use,

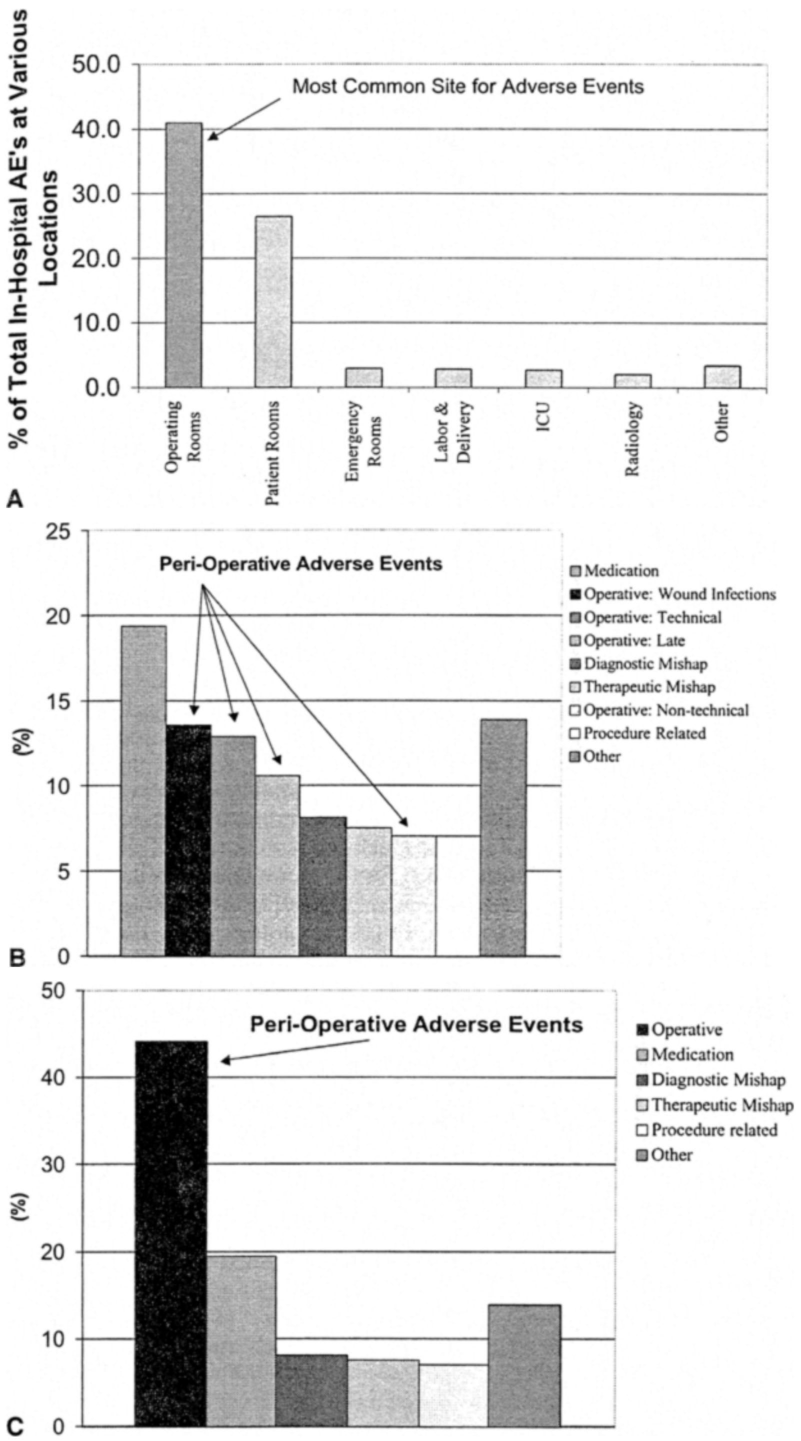

Fig. 2. Hospital adverse events. **A** Where adverse events occur in the hospital. Adverse events are more likely to occur in the operating room than any other place in the hospital. **B** Types and frequencies of adverse events. Medication error seems to be the most common type of adverse event (AE) until all perioperative AEs are grouped together. Technical complications are collateral, unintended injuries to organs such as to the spleen during operations on the stomach, or to the ureters during pelvic procedures. Late complications are technical complications or injuries that do not manifest themselves at the time of surgery, e.g., retained gallstones or incisional hernias. Nontechnical complications are conditions that are indirectly related to the procedure such as pneumonia or postoperative myocardial infarction (heart attack). Late failures are treatment failures such as recurrent radiculopathy (slipped disc) or hernia after a procedure to repair the same condition at the same site. **C** When all the operative adverse events are grouped together, it is clear that these events are two times more common than medication errors and six times more common than diagnostic or therapeutic mishaps. (*Data from Leape* [37].)

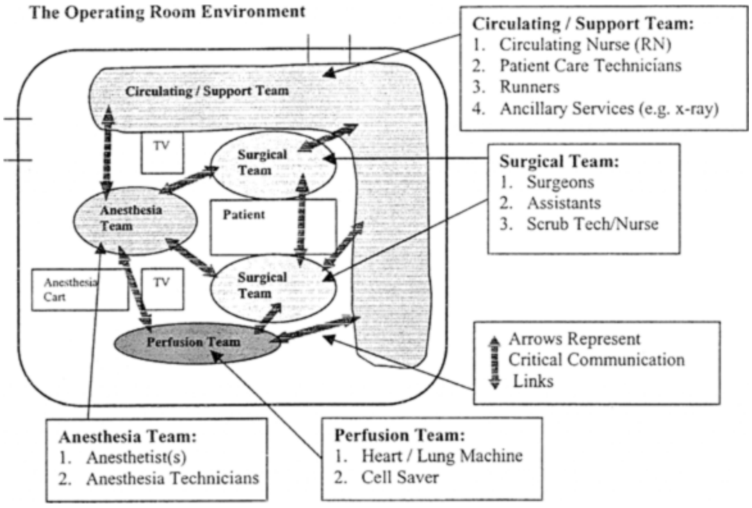

Fig. 3. Team composition of the operating room. The operating room is staffed by members of at least four distinct teams: anesthesia, surgical, circulating/support, and perfusion. Communication among the teams is critical to procedure safety and success.

there is a potential for unintended actions and outcomes. Similarly, if the instruments require users to remember complex information, mentally rotate images, or keep track of multiple and diverse data displays, then additional burdens are imposed on successful task performance. Equally important concerns are questions of instrument availability, room layout, and arrangement of data displays. Data critical to safety are of little use if operators cannot readily see, hear, or otherwise access them.

Human factors can also affect performance. For any high-risk task, supervisors must be capable of ensuring that each of the people involved is well prepared both mentally and physically, especially if the task is difficult. In military aviation, for example, one of the flight surgeon's tasks is to consider if the pilot/operator has had a recent bad experience that could affect performance on the present mission. Similarly, if performers of high-risk tasks are subjected to sleep deprivation or the disruption of normal sleep cycles, their performance will likely differ from periods when they are well rested. In addition, if there are multiple environmental distractions and pending tasks that are interrupting and affecting the current task, operator performance may suffer. Overreliance on human factors as the explanation for adverse events, however, leads to the phenomenon of hindsight bias. In nearly all high-risk tasks, adverse events are only identifiable retrospectively. "Hindsight bias" is a term used when retrospective analysis of an adverse event leads to the conclusion that the failure was solely due to operator error or that a simple solution capable of preventing the adverse event should have been intuitively obvious to those involved (Fig. 5). Hindsight bias must be avoided in a systems approach to error prevention.

Team dynamics is another important consideration. Participants must be aware at all times who is in charge of the task underway and how their individual role fits into the group effort. Communication of information critical to role fulfillment should be reliably transmitted and displayed where and when it is required. Likewise, each member must understand the other team members' level of competency, style of working, and knowledge of the current task. In any high-profile, high-risk field, the social, financial, or administrative disincentives or trade-offs involved in requesting assistance should be considered, and communication methods for facilitating such requests should be appropriately designed.

Once a system has been designed, engineers continuously analyze and reevaluate the components and their relationships to make the system function more safely and efficiently. Systems analysis entails observation of the individuals working within these complex environments and subsequent documentation of their current practices and tasks. Systems engineers evaluate the system's current practice of providing for adequate training, work scheduling, and information tools. Finally, task analysis involves identifying what information is intrinsically necessary for an individual to complete the task, followed by an evaluation to determine whether the system has provided this information.

Aviation

The aviation industry provides an interesting example of the utilization of systems theory. On the surface, the "systems" of commercial aviation seem to guide merely the everyday function of the industry, but closer examination shows that they are clearly geared to addressing error recognition, prevention, and reporting. For example, pilots are trained to avoid errors by using checklists. Such devices help to assure aviators that critical steps during take-offs and landings are not omitted or performed out of proper sequence [18]. Communication protocols, such as the mandatory repetition of commands between the control tower and crew members, have helped to improve team "situation awareness" and thus minimize the potential for miscommunication, inappropriate assumptions, and misunderstandings regarding the flight status of the aircraft [54].

Furthermore, airliner cockpits are equipped with black boxes. These devices record plane parameters and cockpit conversations in the cockpit, so that when a crash occurs, experts from multiple fields such as bal-

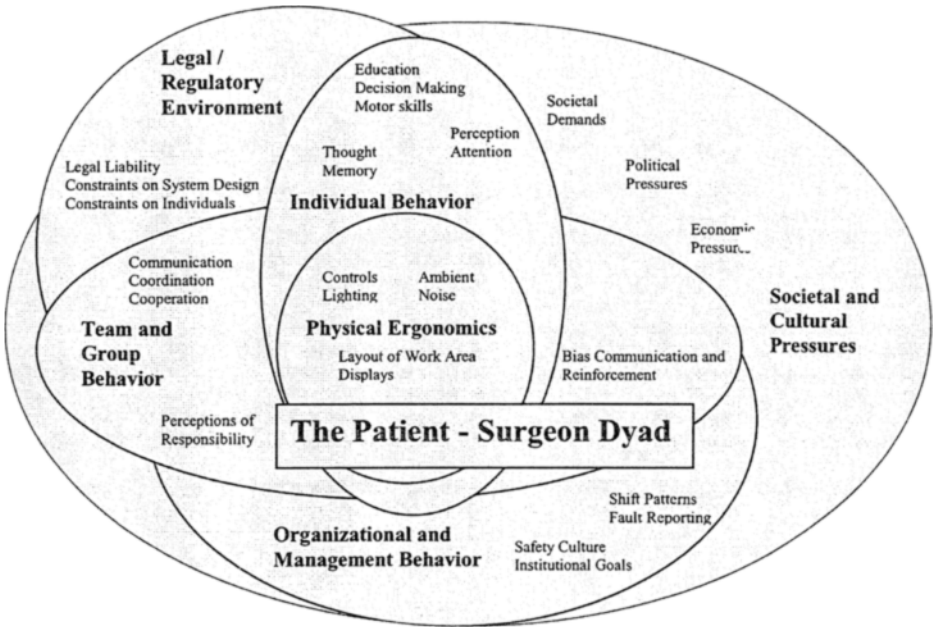

Fig. 4. The patient–physician relationship in a systems context. Patients and their physicians are inextricably linked as they navigate complex realms of social factors, equipment design, system policy, and the regulatory environment. (Adapted by Moray N [1994]. A general hierarchical systems oriented approach to design and analysis. Hillsdale, NH: Lawrence Erlbaum Associates)

listics, explosives, metallurgy, meteorology, and systems theory can access them and review the relevant parameters surrounding the event. Black boxes are currently used to produce individual reports on how events involving a specific system component might have affected the outcome of the accident. In the interest of optimizing passenger safety, aviation safety experts rigorously evaluate processes, policies, and devices related to airline travel both prospectively and retrospectively after crashes and near misses. In dozens of studies, pilot fatigue has clearly emerged as a latent error (i.e., a predisposing condition that exists prior to an adverse event) [19, 20, 52, 55].

The aviation industry has also created a culture that recognizes human factors as important elements in error prevention and has used information technology (IT) to address this issue. Flight simulators are used to prepare flight crews for adverse events. Pilots must go through mandatory training yearly in high-fidelity simulators and are required to demonstrate proficiency at handling multiple diverse adverse events.

Finally, and in many ways most importantly, in order to minimize personal liability and promote error reporting, the aviation industry has devised a system whereby aviation employees involved in a critical incident must report a deficiency in safety procedures within 24 h of the event. In doing so, the employees are subsequently immune from disciplinary actions, thus encouraging full disclosure. Such a system of error reporting helps to identify those events attributable to human factors and allows for prompt identification and implementation of systems solutions. Thanks to this policy of allowing immunity from repercussion and thus optimizing error reporting, the aviation industry has developed a powerful resource for identifying patterns of behavior, mishaps, or operational practices that can lead to error. Specifically, aviation safety experts and administrators can examine the incident reporting database to find previously unidentified trends.

Such efforts have proven their utility in preparing pilots for adverse events and have contributed to what has become an outstanding safety record for the airline industry. The major airlines now expect fatalities (from any cause, including human factors) less frequently than once in every 100,000 departures [44].

Anesthesiology

Anesthesia is another discipline worthy of evaluation because of its successful use of systems theory to deal with error and adverse events. In anesthesia, the work of several authors has improved practice through studies of operations and critical incidents [12–17, 26, 27]. In the late 1970s, the risk of death during general anesthesia was approximately one in 10,000 [46]. A variety of factors, including esophageal intubation, drug errors, and airway obstruction, were subsequently identified as being responsible for this significant risk. Today, anesthetic mortality risk has been reduced to the point where death from anesthesia is now expected only once in every 200,000 inductions [24, 40].

Similar to the advances in the aviation industry, this reduction in anesthetic mortality was achieved by collaborating with biomedical engineers to create and maintain detailed records of anesthetic deaths, complications, and near misses. Cooper et al. were the first to study perioperative and anesthetic mishaps using the critical incident technique described by Flanagan in 1954 [17, 25]. Cooper's work has had a far-reaching effect on the practice of anesthesia, largely due to his study of the "knobology" of anesthesia machines and other ergonomic topics [16]. Before 1970, to increase the concentration of anesthetic gases on some machines, the knobs turned clockwise; whereas on others (often in the

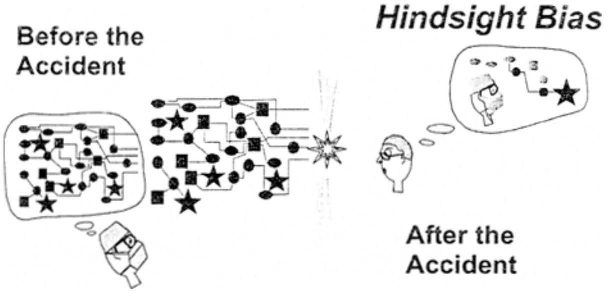

Fig. 5. Hindsight bias. Postaccident reviews identify human error as the cause of failure because of hindsight bias. Outcome failure makes the path to failure seem to have been foreseeable—although it was not foreseen. (Reprinted, with permission, from Richard Cook [1991] A brief look at the "new look" in complex system failure, error, and safety. University of Chicago Cognitive Technologies Laboratory, Chicago, IL, USA [2001]).

same institution), performance of the same functions required a counterclockwise motion. Similarly, older models of anesthesia machines allowed for combinations of volatile anesthetic gases to be delivered simultaneously, increasing the probability of error.

Since the 1970s, anesthesia machines have been completely redesigned from an ergonomic point of view. They have been standardized to include safety devices with integrated IT such as capnographs and mass spectrophotometers, and these devices have been incorporated into the daily practice of anesthesiology. Other systems-oriented changes were also made, including limits placed on the number of consecutive hours that anesthetists can work, provision for rest periods, and ongoing vigilance for system failures. In addition, anesthesia safety experts developed impressive simulators for research and the training of resident anesthesiologists and investigation of the operating room environment [29, 31, 45]. Their work has led to a 10-fold reduction in anesthesia-related mortality and innumerable improvements in operating room (OR) communication, device ergonomics, and general safety practice [24].

Current status of surgical error reduction

As in the fields of aviation and anesthesiology, the adoption of a systems approach to the study of surgical safety could improve patient care by error prevention. Currently, surgeons address adverse outcomes in morbidity and mortality conferences and quality assurance committees. While these traditional analyses stress perhaps the most important factor in error reduction, individual responsibility, because of hindsight bias, they often minimize other potentially critical factors that may be responsible for errors or adverse outcomes [33]. These factors range from training and staffing policies, to procurement or various patient factors. Finally, few prospectively collected data are currently presented in morbidity and mortality conferences. Such data would facilitate the examination of a variety of factors, such as those mentioned here, and allow for a more fruitful discussion of ways that adverse events or system failures might be prevented in the future.

Table 1. Practical errors in use of instruments during laparoscopic cholecystectomy (n = 20)

Procedural errors	Average occurrence/ case
Inadequate force used to hold GB	2.0
Clips placed out of sequence	1.5
Misorientation of hook toward GB/liver	0.9
Inadequate force used to tent tissue or retract gallbladder during dissection	0.5
Heel of hook used to cut	0.5
GB torn by excess traction during dissection or removal	0.4
Omission of cystic artery clip(s)	0.4
GB held in wrong position during dissection from liver bed	0.3
Wrong instrument used to grasp GB for removal	0.2
Clips closed with inadequate depth	0.1
Hook activated between steps	0.1
Failure to visualize tips of clip applier before application	0.1

GB, gallbladder.
The most common errors observed by Joice et al. [34] are listed according to how frequently they were observed (on average) per case (n = 20). (Adapted, with permission, from Joice et al. [32].)

At the national level, several organizations have used various methods for addressing the topic of systematic error reduction. The American College of Surgeons has been active in error reduction through testimony of its members in governmental forums and the development of outcome databases for trauma and oncologic care [2–4]. The Society of American Gastrointestinal Endoscopic Surgeons (SAGES) organized a laparoscopic outcome database that allows surgeons to anonymously enter patient outcomes for several variables. Similar to Basic Life Support (BLS) and Advanced Trauma Life Support (ATLS), the Fundamentals in Laparoscopic Surgery (FLS) program is being developed as a vehicle to ensure operator competency in basic laparoscopic skills. Finally, several groups have created simulated environments for the acquisition of safety-oriented technical skills [23, 50].

The field of laparoscopy has also recognized that optimizing ergonomics during laparoscopic surgery minimizes errors. Subsequently, various ergonomic designs describing the surgeon's position in relation to the patient and equipment have been studied with the aim of enhancing performance, minimizing fatigue, and reducing procedural errors. In 1998, Joice et al. prospectively evaluated the frequency of procedural errors during laparoscopic procedures and found an average of nine procedural errors per case in the hands of experienced operators (Table 1) [32]. Similarly, Dominguez et al. have studied various ways of using the video image produced during laparoscopic surgery to make laparoscopic procedures safer. These authors invited several surgeons to analyze the videotape from a difficult laparoscopic cholecystectomy to determine when and if it was appropriate to switch from the laparoscopic procedure to a more traditional open-incision procedure [21, 22]. They found that the decisions by operating surgeons to convert depended on a variety of factors, including their different surgical styles, their capability

Table 2. Implementation of systems approach plans

	Aviation	Anesthesia	Surgery
Acknowledge human factors			
Barriers to reporting	Addressed	Partially addressed	Lacking
Avoidance of operator errors	Written procedural protocols for emergencies	(a) ALS (b) PALS (c) Mentorship, supervision (d) Little standardization	(a) ATLS (b) FLS (c) Mentorship, supervision (d) Procedural standardization rare
Operator fatigue	Mandatory breaks/work limitations	Breaks/works limitations	Lacking
Sensory overload	"Sterile cockpit"	Lacking	Lacking
Academic investigation	Extensive, government-sponsored	Extensive, mainly with private funding	Lacking
Safety devices	Cockpit alarms	(a) Capnographs (b) Monitor alarms (c) Enhanced "inobology"	Lacking
Data collection presentation			
Record critical steps	Checklists	Checklists for equipment setup	Lacking
Incident data	Flight data recorder/voice recorder	Automated anesthesia record	Posthoc procedure notes
Incident investigation	NTSB crash investigation	Committees	M&M conferences
Safety reporting systems	NASA anonymous reporting system	Lacking	Lacking
Enhanced training			
Simulators	Complex and realistic	Simple	Not widely available
Communication	Crew resource management	Crisis resource management	Lacking
Standardization	Mandatory centralized training for new aircraft	RRC requirements	(a) RRC requirements (b) Lacking for surgical procedures

ATLS, advanced trauma life support; ALS, advanced life support; PALS, pediatric life support; FLS, fundamentals of laparoscopic surgery; NTSB, national transportation safety board; RRC, residency review committee; M&M, morbidity and mortality.

to assess the current situation, their ability to accurately predict future states, and their baseline knowledge of patient parameters (i.e., age and clinical history) [22]. By analyzing the verbal comments of surgeons examining the case, these authors were then able to identify the strategies that the operating surgeons used for avoiding errors, as well as deficiencies in recognizing key cues or warning signs of impending adverse events or errors [21]. They concluded that pattern recognition (i.e., recognizing anatomical structures) and situation assessment skills (i.e., clinical history) are crucial to effective surgical practice and error reduction.

Preventing surgical errors

Although there have been some sporadic movements toward fully understanding and addressing surgical errors, these important initial efforts must be further expanded to develop a more comprehensive system for the prevention of surgical error. Most important, the design of any robust, broad-based system must carefully consider the overlapping cornerstones of human factors, data management, and training. The importance of these issues to systems design is exemplified by the impressive record of error reduction achieved by other industries (Table 2).

Acknowledge human factors

Human factors are responsible for many operator errors that are committed within any given system. Such errors (whether latent or active) can be minimized by creating devices (procedural protocols) that help operators to avoid them. For instance, a specific intraoperative checklist of events for a given operative procedure, similar to the anesthesia record and instrument count currently practiced, could be helpful in promoting adherence to procedural protocols. The development of such a checklist would lead to the standardization of surgical procedures at the point of care. This would increase patient safety for two reasons: First, a checklist would serve as a memory aid that would help to avoid the omission of critical steps or activities, such as the administration of antibiotic prophylaxis or the surveillance of trocar sites for bleeding. Procedures such as laparoscopic cholecystectomy are ideal candidates for the development of such checklist protocols. Most successful surgeons already operate according to strict procedural protocols, but these protocols are rarely known to anyone except the surgeon. Second, by following the checklist, surgical teams will communicate with each other more frequently, thus enhancing the situation awareness of all members of the operating team. Such protocols would standardize certain basic "rules of engagement" so as to enhance and streamline the interactions among the members of a unified laparoscopic surgery team, both within the room or elsewhere via the Internet. Of course, not all procedures lend themselves to standardization, especially when an unusual disorder or anatomic distortion occurs. In these cases, checklists would simply ensure that the basics of good operative technique for the particular operation in question are maintained, such as reminders pertaining to irrigation volume, "no touch" rules, and appropriate resection margins.

When developing a system for surgical error prevention, the overall nature of surgeons as well as the surgical culture must be addressed. Historically, the surgical culture has placed a higher value on self-evaluation, arguably moreso than most other specialties, creating constituents who are often ruggedly individualistic, responsible, confident, and action oriented. However, these admirable and largely necessary attributes can be significant barriers to their ability to function within a system of conformity and systematic protocols [33]. The first step in resolving this imbalance lies in recognizing the existence of this conflict. Next, methods and practices that acknowledge the traditional surgical culture should be developed so that each participant in the system is encouraged to take the initiative and contribute both to the safety of their individual surgical practice and to overall institutional safety. This concept has been applied successfully in the areas of petrochemical refining, nuclear power, and manufacturing, where a culture of safety has been instituted to foster the workers' awareness of their individual responsibility for maintaining a safe environment. In addition, they are supported by safety devices and procedures. Workers' police themselves for error, and the system has a built-in "error safety net" (S. Guerlain, personal communication). In a similar vein, sports psychologists have recently recognized that a professional athlete's mindset and frustration level vis a vis task performance are important factors that can affect outcomes (D. Newburgh, personal communication). Thus, a confident athlete who has been well prepared in a structured training program will outperform an ambivalent, unfocused individual with similar physical attributes.

Finally, the evolving climate of medical malpractice has preyed on the well-recognized dogma-centered surgical culture and has tended to exacerbate the surgeon's fear of operative data collection, digital operative records, and video capture. In the past, the materials presented during morbidity and mortality conferences and their ensuing discussions enjoyed protection from legal discovery [6]. This situation helped to promote a free exchange of information among colleagues for quality-improvement purposes. Surgeons could be forthright and honest when presenting a surgical misadventure or suboptimal outcome, with the hope of learning from the experience without fear of legal retribution; however, this freedom from legal disclosure is disappearing. In fact, judges in many states have ruled that nearly all clinical data, including items such as incident reports and other records, are admissible in court. A recent legal decision reported that "records kept with respect to any patient in the ordinary course of business of operating a hospital" should be made available for medical malpractice cases. See, e.g., *Benedict v. Community Hospital*, 10 Va. 430 (1988). To many surgical practitioners, despite contrary evidence, detailed records seems to be a medicolegal liability, making error reporting and the critical analysis of adverse outcomes increasingly difficult. Freedom from legal discovery is of the utmost importance to the development of a systems approach plan for surgical error reporting.

Improve data collection and presentation

Data acquisition needs to be systematic, mandatory, and automated to allow for subsequent detailed prospective analysis of environmental, situational, and cultural factors. In the current practice of surgery, the only data that are routinely collected for the record of an operative intervention are the dictated, transcribed, subjective, post hoc report and the pathology specimen. For the most part, the report lacks objective data such as images, video sequences, time sequences, or real-time annotations. In the operating room, data can be collected through digital image capture from the laparoscope, in addition to cameras mounted on the surgeon's head, the operating room wall, and the ceiling. Such an arrangement can capture intracorporeal images as well as those external to the abdominal cavity, such as trocar placement, local anesthetic administration, maneuvering of the OR team, and positioning of operative equipment, in addition to voice annotations.

As technology for simple yet enhanced data capture and memory for storage of captured media becomes more accessible and affordable, detailed operative records will provide operators with the capacity for detailed review and "mining." Multiple variables will emerge as predictors of, or actual sources of, procedural error. In the future, for example, if a common bile duct injury is identified, the extra- and intracorporeal events occurring around the time of the dissection will be available for review. Intraoperative time sequences relating to the origin of intraoperative delay could also be reviewed to discern the effects of such delays on clinical outcomes. Similar video analysis has provided a rich data set from which to study anesthesia practices and identify improvements [41].

The utility of routinely collected intraoperative data to the clinician is directly related to the speed at which it can be collected, analyzed, interpreted, and then presented. Four years ago, Kurz et al. discovered that intraoperative hypothermia predisposes patients undergoing bowel resection to wound infections [36]. However, without intraoperative attention to such a factor, the data are lost or not addressed at a critical time. Soon it will be possible to present the data nearly immediately after they are collected.

Enhanced training

Even the most intricately designed system is worthless if its users are ignorant of its uses and pitfalls. Fortunately, a formal system for surgical education—namely, the 5–7 year surgical residency—already exists. National residency accreditation committees, such as the Residency Review Committee, have increasingly standardized such aspects of surgical resident education as case volume requirements and time allocation for pre-/postoperative patient visits. However, little progress has been made in standardizing the surgical approach to even the most common of procedures (i.e., cholecystectomy). Standardization of procedures will allow for more effective education of operators for a variety of common anatomical variations. If the same steps, in the same order, were followed during a laparoscopic cholecystectomy, the resident could more easily identify an aberrancy in anatomy vs an error in dissection. The standardization of such protocols could then lead to the development of effective surgical simulators. Prototypical simulators have now been developed, and there are plans for their pervasive implementation in the forseeable future. Potentially, the combination of standardized procedural protocols and robust yet accurate surgical simulators will have an effect on surgical education exceeded only by the formation of residency programs nearly 100 years ago.

Institute a systems approach plan

It is a daunting task for any individual to attempt to address each of these important factors (protocols, training, data use, and communication practices) when setting out to develop a surgical system than can ensure patient safety. Therefore, the initial step in this process is to assemble an appropriate team of dedicated individuals with varying backgrounds—i.e., surgeons, systems engineers, statisticians, risk managers, and psychologists. Once assembled, the team can work together to increase overall institutional understanding of the factors that create a safe environment for patients and, conversely, the factors that can lead to adverse patient outcomes. This overall understanding can then be used as a foothold toward the development of process improvements that minimize the chances of adverse events occurring. Needless to say, it should be focused on the aforementioned cornerstones of system design—human factors, data management, and training.

Both the design and the implementation of a systems approach plan involve identifying, quantitating, and altering an enormous volume of data. Therefore, the team must agree at the outset on the appropriate technology to be used. Clearly, IT must be the core of any systems approach. Information technology allows for much of the necessary data collection, processing, communication, and training necessary to create such a complex system. To date, surgeons have been reluctant to integrate IT into surgical education and practice; consequently, surgical practice still lags behind other high-risk industries in benefiting from all that IT allows [11]. There are enormous bodies of data that are not being harnessed. Moreover, there are glaring everyday issues, processes, and deficiencies that IT, guided by systems theory, could readily address. With the incorporation of IT, a surgical system would most likely involve the use of computer-aided support and a robust, safety-oriented record of medical procedures and discussions.

Conclusion

The documented and "accepted" incident rates in surgery are unacceptably high. Incident rates of 1–5% are generally accepted as a normal part of practice. Current morbidity and mortality reporting, while important, does not sufficiently examine or expose the active and latent errors that lead to adverse outcomes. Further, there is no process in place for systematically learning from surgical incident data so that appropriate changes can be incorporated in practice. Other high-risk industries have shown that process improvements, as well as the promotion of a culture of safety, can have a significant impact on an industry's safety record. The establishment of surgical protocols and checklists has the potential to improve the standards of training and practice, as well as enhancing operating room communications. Data collection and analysis can identify latent errors that could be addressed through better training, device design, or surgical methods. Computer-based training could be instituted to allow surgeons to practice the perceptual, decision-making, and problem-solving skills that are a major part of surgery. These kinds of activities have been incorporated successfully into other industries and should also be applied to the practice of surgery.

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