5 PATIENT SAFETY IN SURGICAL CARE: A SYSTEMS APPROACH

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High-profile catastrophes such as the explosion of the nuclear power plant at Chernobyl, the near meltdown of the nuclear power plant at Three Mile Island, the explosion of a chemical plant in Bhopal, numerous aviation disasters, and the loss of the space shuttles *Challenger* and *Columbia* share important characteristics. First, the casualties are notable for their number, their celebrity, or both. Second (and more germane to this chapter), each of them occurred as a result of multiple failures within complex systems. Human errors played a role in all these failures, but the errors were not single acts of negligence so much as they were magnifications of multiple seemingly small interactions, the significance of which was initially unrecognized or underestimated.

Until relatively recently, medical injuries, unlike these other events, rarely received much publicity, partly because they affected only one patient at a time and because their aggregate number was neither recognized nor well publicized. The Institute of Medicine (IOM) did much to change this situation with the publication of its 1999 report estimating that as many as 98,000 medical error–related deaths occur each year in the United States.[1] This estimate far exceeds the number of casualties from more publicized nonmedical disasters; if it is accurate, medical errors are one of the leading causes of death in the United States (http://www.cdc.gov/scientific.htm). In addition to the cost in lives, medical injuries carry a substantial cost in dollars.[2]

The IOM report also challenged the notions that medical injury is primarily the result of "bad apples" and that safety can be improved largely by ridding the system of these persons. Undoubtedly, bad apples exist, but it is increasingly clear that health care–related injuries represent system failures and are not simply the result of a few individual errors. The bad-apple perspective tends to persist because, at least until recently, our culture has placed more emphasis on individual human error as a cause of medical injury than on flaws in the health care system.[3] Currently, however, this perspective seems to be changing as a result of the growing recognition that modern health care is as complex as—if not more complex than—the systems associated with nuclear power, aviation, and space flight.[4] The cognitive and technical complexity of the tasks performed in the OR, the ICU, and the ED certainly rivals that of these other endeavors. Furthermore, optimal patient care increasingly requires coordination among an expanding number of participants. It has been estimated that in the early 20th century, health care involved the interaction of three persons, on average; by the beginning of the 21st century, that number had risen to 16.

In this chapter, I address (1) the characteristics of systems in general and (2) surgical care as a particular example of a system. I describe the growing knowledge of factors that affect human performance and how these factors contribute to adverse surgical outcomes. My primary focus is on patient safety, but I also touch on overall quality of care; in surgical settings, the two often cannot be entirely separated.[5] In addition, I outline current obstacles to improving safety, system approaches to making improvements, and ways in which surgeons can take the lead in overcoming these obstacles. Specific issues related to the cost-effectiveness of surgical care are discussed in greater detail elsewhere [*see ECP:7 Elements of Cost-Effective Nonemergency Surgical Care*].[6]

Nature and Magnitude of Adverse Events in Surgical Care

For most of the important concepts bearing on patient safety in the surgical setting, generally accepted definitions exist [*see Sidebar* Definitions of Terms Related to Patient Safety]; the ensuing discussion is based on these definitions.[6] A solid understanding of the key concepts—such as the distinctions between an adverse event (or adverse outcome), an error, and negligence—is critical for managing errors as system failures rather than as isolated incidents.[7] In particular, such an understanding can help in navigating the often-turbulent emotional milieu that can surround adverse patient events. Given their motivation to help patients, physicians tend to be highly sensitive to issues of causation, and this sensitivity can then interfere with the recognition and management of safety issues.

The two most widely cited estimates of adverse medical events derive from the Harvard Medical Practice Study (HMPS)[8] and from a study in Colorado and Utah.[9] The HMPS, a population-based study of patients hospitalized in New York State during 1984, found that nearly 4% of patients experienced an adverse event and that about half of such events occurred in surgical patients. The Colorado/Utah study, which randomly sampled 15,000 nonpsychiatric discharges during 1992, found that the annual incidence of adverse surgical events was 3.0% and that

Definitions of Terms Related to Patient Safety[6]

- An *adverse event* is an injury that was caused by medical management and that results in measurable disability.
- An *error* is the failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim. Errors can include problems in practice, products, procedures, and systems.
- A *preventable adverse event* is an adverse event that is attributable to error.
- An *unpreventable adverse event* is an adverse event resulting from a complication that cannot be prevented given the current state of knowledge.
- A *near miss* is an event or situation that could have resulted in accident, injury, or illness but did not, either by chance or through timely intervention.
- A *medical error* is an adverse event or near miss that is preventable with the current state of medical knowledge.
- A *system* is a regularly interacting or interdependent group of items forming a unified whole.
- A *systems error* is an error that is not the result of an individual's actions but the predictable outcome of a series of actions and factors that make up a diagnostic or treatment process.

54% of these events were preventable. Nearly half of all adverse surgical events were accounted for by technique-related complications, wound infections, and postoperative bleeding. This study also identified common operations that were associated with a significantly higher risk of an adverse event and a significantly higher risk of a preventable event.

Other studies yielded comparable or higher estimates,[10] and still others evaluated the rates at which specific events occurred, as follows:

- Retained sponges or surgical instruments were estimated to occur at a rate between 1/8,801 and 1/18,760 inpatient procedures at nonspecialty acute care hospitals.[11]
- Wrong-site surgery is more than just an isolated event.[12] The increased frequency at which such events are currently being reported probably reflects previous underreporting (www.jointcommission.org/NR/rdonlyres/6F94288C-EC8E-4B95-91F6-0A1C96C09708/0/se_trends_wss_reported.gif).
- Medication errors (e.g., wrong drug, wrong dose, wrong patient, wrong time, or wrong administration route) are alarmingly frequent.[13-15] The United States Pharmacopeia monitors these events through its reporting programs (www.usp.org/patientsafety). In 2001, these programs received reports of 105,603 errors, 2,539 (2.4%) of which resulted in patient injury. Of these, 353 necessitated hospitalization or prolonged its duration, 70 necessitated interventions to sustain life, and 14 resulted in a patient's death. The main contributing factors were distractions (47%), workload increases (24%), and staffing issues (36%). Miscalculating patient weight conversions (e.g., from pounds to kilograms) and subsequent improper dosing are all too common among pediatric patients. Errors in the administration of radiopharmaceuticals are also frequent and may involve the wrong isotope (68.9%), the wrong patient (24%), the wrong dose (6.5%), or the wrong route (0.6%).[16]
- Blood transfusions continue to be plagued by patient misidentification.
- Device-related deaths and serious injuries also occur at an alarming rate, even after premarket safety testing.[17] The Food and Drug Administration (FDA) maintains a registry of the thousands of such injuries that occur each year.
- A survey noted that 35% of physicians and 42% of the public said that they had experienced a medical mistake in their own care or in the care of a family member.[3]

As might be expected, the IOM report prompted a great deal of debate. Some medical professionals questioned the accuracy of the estimates, whereas others disagreed with the definitions of medical error and adverse event, with the extent to which either was considered preventable, or both. Still others argued that adverse events that are caused by conceptual errors (e.g., a contraindicated, unsound, or inappropriate approach) should be differentiated from the side effects of an intended action that is correct in the circumstances (e.g., an indicated diagnostic or therapeutic procedure).[18] The aim of this argument was to sharpen the distinction between accidents (i.e., unplanned, unexpected, and undesired events) and true side effects (which result from correct management and which are often accepted as reasonable therapeutic tradeoffs). The HMPS attempted to address these issues by characterizing adverse events as either preventable or unpreventable in the light of the prevailing state of knowledge. Preventable errors were further subclassified as either diagnostic errors or treatment errors; treatment errors included preventive errors such as failure of prophylaxis and failure to monitor and follow treatment.[8,19] The HMPS found that preventability varied according to the type of event: 74% of early surgical adverse events were judged preventable, compared with 65% of nonsurgical adverse events, and more than 90% of late surgical failures, diagnostic mishaps, and nonprocedural therapeutic mishaps were judged preventable.

Some medical professionals questioned the need to consider errors during terminal care. For example, one study reported much lower estimates of preventable deaths than the HMPS did, noting that many patients who experienced supposedly preventable deaths would have died of natural causes within a few months even with optimal care.[20]

A further consideration is the relative safety of health care in the United States compared with that in some other countries. For instance, in Australia, the estimated error/injury rates are between 10.6% and 16.6%; in the United Kingdom, between 10% and 11.7%; and in Denmark, about 9%. Still, several reports indicate that the U.S. rate would have to be reduced by one third to match the benchmark rates in Germany and the United Kingdom with regard to medical mistakes, medication errors, or laboratory test errors.[21]

The accuracy of these estimates should not be a major issue, however, given that even with the lower estimates of error frequency, the aggregate number of fatal medical errors is far greater than the number of fatalities associated with more widely publicized nonmedical disasters. A system that yields such high numbers of fatal errors would not be tolerated in nonmedical settings and should not be tolerated in patient care. The "no harm, no foul" approach that is often adopted in this setting discourages efforts to identify flaws in the system.[7]

The debate over estimates of patient injury rates has also raised speculations about trends in the frequency of adverse events. To some, the observation that the rate of such events was lower in the Colorado/Utah study than in the HMPS suggests that patient safety improved even before the IOM report. Others, however, argue that the number of patient safety incidents may actually be increasing (www.healthgrades.com/media/dms/pdf/PatientSafetyInAmericanHospitalsStudy2006.pdf). These disagreements aside, there is a general consensus that progress since the IOM report has been slow, that the results have been modest at best, and that the gap between the best possible care and the care actually being delivered remains large.[22-26] Although the lack of more evident improvement has been somewhat disappointing, clear progress has nevertheless been made with respect to (1) understanding the complexities of medical care systems, (2) identifying the challenges to improving these systems, and (3) developing new perspectives on the assessment of errors. Rising estimates of the incidence of adverse events may simply reflect improved reporting rather than actual increases in the occurrence of such events.

Nature and Characteristics of Systems

A system may be broadly defined as a regularly interacting or interdependent group of items that form a unified whole. System functions or tasks usually involve sequential steps that have human, technological, and logistical components. The overall probability of a system failure (i.e., an undesired outcome) is a function of the probability of error within each step, the total number of steps, and the degree to which the steps are coupled. The degree of coupling is the extent to which an error at one step can propagate through subsequent steps and adversely affect the final outcome. Compared with loosely coupled systems, tightly coupled systems have relatively little redundancy and relatively few fail-safe mechanisms. As a result, the success of a tightly coupled system is highly dependent on the success of each step in almost a factorial fashion. For instance, the probability of success in a tightly coupled linear 20-step process with a 1% likelihood of error at each step is equivalent to 0.99 factored 20 times, or 0.818. With tight coupling, a large number of steps can lead to a substantially reduced success rate, even if the probability of error for each step is quite low.

The importance of a system's latent failures as contributing factors in adverse outcomes may be illustrated by considering a general schema of an injury [*see Figure 1*].[27] Whereas overt system problems are relatively easy to identify and correct, latent failures are insidious and often do not become evident until a seemingly improbable series of events produces errors in otherwise routine processes. Latent failures tend to be introduced by persons who work at the "blunt end" of the system (e.g., management or housekeeping) but do not actively participate in the main processes of care. A typical injury pathway is one in which organizational processes introduce latent failures, which in turn produce system defects, which in turn interact with external events so that persons who work at the "sharp end" of the system (e.g., anesthesiologists, nurses, or surgeons) commit unsafe acts. These unsafe acts precipitate an active failure that then penetrates the final safety barrier or barriers.[28] Indeed, the greatest risk of an adverse event in a complex system may come not from a breakdown of one or more major subsystems or from isolated operator errors but from the presence or accumulation of latent failures.[27,29,30]

In loosely coupled systems, satisfactory outcomes are far less dependent on successful completion of each step; the reason is that an error occurring at a particular step in such a system may be "trapped" by one or another of the safety barriers associated with the system's built-in redundancy. Because these safety barriers are generally more numerous than in tightly coupled systems, it is relatively unusual for an isolated error to produce an injury or system failure in a loosely coupled system; instead, a failure typically involves malfunctions at multiple steps. The tradeoff with this level of redundancy is that it makes the system more complex, and the added complexity can introduce its own errors. A further impact of latent failures is to make systems appear more loosely coupled than they actually are.

The role of all these factors in accounting for a system's results may be summed up as follows: "Whether your output is good or bad, it is, nonetheless, the only output of which your systems, processes, and methods are currently capable."[31] In other words, every system is perfectly designed to get the results it gets.

Surgical Care as System

The characteristics of systems already discussed (see above) have many attributes that are directly applicable to medicine in general and to surgery and anesthesiology in particular. In addition to the parallels between the habitats associated with surgery (e.g., the OR, the ICU, and the ED) and those associated with many high-tech, high-risk nonmedical endeavors, strong parallels also exist between observed behavior in the OR and behavioral issues in an airplane cockpit.[32,33]

The nature of the OR as a system and the complexity of the interactions that occur there have been studied extensively. Patient factors, handoffs, inexperienced staff members, high workloads, and hierarchy issues among team members frequently contribute to safety-compromising events.[34] The potential for adverse outcomes as a result of such events was confirmed by a 2003 study of surgeon-reported errors.[35] In this study, system factors contributed to error in 86% of 146 incidents. Two or more clinicians substantially contributed to error in 70% of the incidents, and three or more were involved in 18% of the incidents. There was a median of two system factors per incident overall (range, 0 to 8), and a median of four system factors per incident involving emergency care. Inexperience or lack of competence was a factor in 53% of the incidents, and 55% of these involved a trainee. A relatively high level of trainee involvement has also been noted by other investigators.[36] The root of the failures here may be that inadequate supervision of trainees reduces both communication and redundancy, thereby also eliminating potential safety barriers and increasing the degree of coupling within the system.

Remarkably similar findings were noted in a 2006 study of 258 closed malpractice claims related to surgical error.[37] In this study, system factors were involved in 82% of the cases; more than one clinician was involved in 62%; and there was a median of three system factors per case. As in the previously cited study from 2003, trainees were frequently involved: they contributed to error in 46% of the cases and had substantial roles in 53% of the cases they were involved in. Attending surgeon error also played a role in virtually all of the cases. Neither report included details on the exact nature of the trainees' errors, but analysis of trainee performance during skills training noted that omission of important steps, execution of steps in the wrong sequence, and use of excessive force accounted for 92% of the errors.[38]

The factors that these two studies found to contribute to adverse surgical events are much the same as those known to contribute to

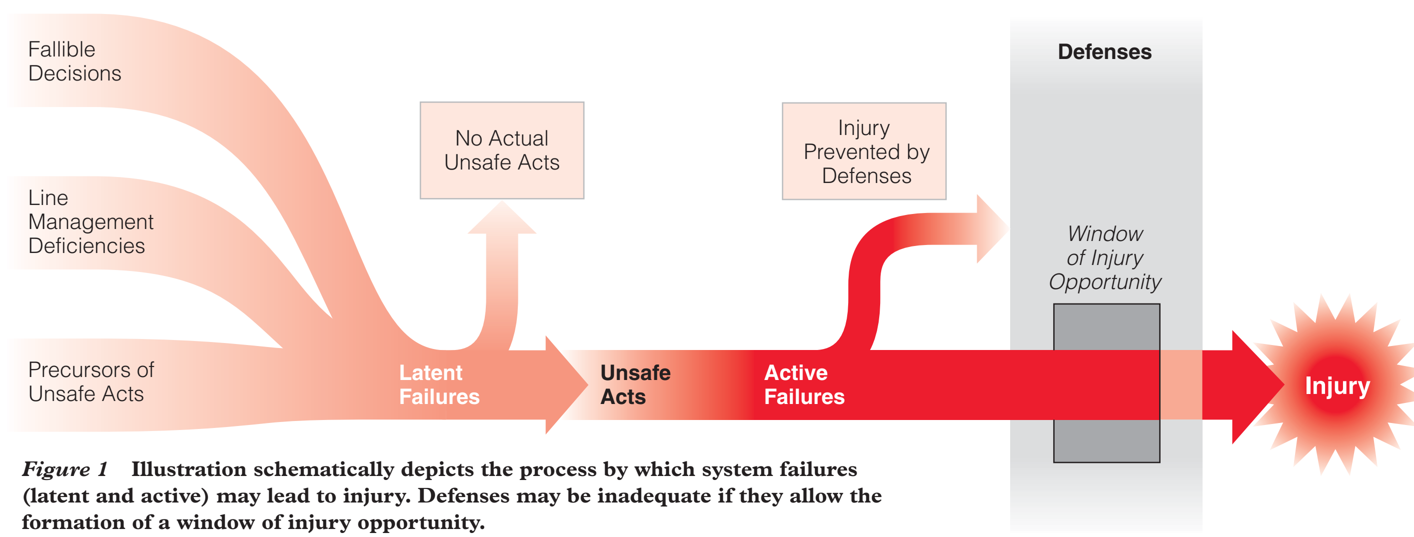

Figure 1 **Illustration schematically depicts the process by which system failures (latent and active) may lead to injury. Defenses may be inadequate if they allow the formation of a window of injury opportunity.**

nonmedical system failures. The most common of these contributing factors are operator inexperience, breakdowns in communication (e.g., handoffs and personnel conflicts), lack of supervision, and fatigue or excessive workload. In addition to exerting their individual effects, these factors often interact. Problems related to communication and information flow, workload, and competing tasks can have a measurable negative impact on team performance and patient safety. The likelihood of miscommunication being cited as a factor doubles when surgeons also report excessive workloads. Similarly, the likelihood of fatigue being cited as a factor doubles when surgeons report excessive workloads. The tradeoff between factors seems clear: measures aimed at reducing fatigue will increase problems with handoffs, and the converse is also true. The role of discontinuity among residents in increasing the risk of preventable adverse events has been noted by other investigators as well.[39] Fatigue related to extended-duration work shifts is associated with an elevated risk of significant medical errors, adverse events, and attention failures.[40,41] Fatigue contributes to unsafe acts that can harm both patients and health care personnel.

Like the OR, the ICU is a system and is a common site of medical errors.[42-44] Fatigue also plays a role in the errors that occur in this setting.[45] It may be fortunate that much of medical care is loosely coupled and that as a result, relatively few medical errors result in adverse events or injury. However, ever-increasing workloads may introduce more latent failures, tighten system coupling, and increase the number of adverse events. The importance of systems is underscored by the relation between variations in the frequency of risk-adjusted outcomes among institutions and differences in the systems of care in place within those institutions.[46]

The substantial similarities between medical and nonmedical systems notwithstanding, the complex content and organizational structure of health care make it distinctive. Many system concepts that derive primarily from analyses of human-engineered, highly technical nonbiologic systems may not be fully applicable to the more complex issues of patient safety and quality of care.[31] Linearly engineered systems are likely to be far more predictable than biologic systems, in which appropriate processes do not always result in good outcomes. Patients frequently differ greatly from each other in terms of their ability to communicate relevant issues, their severity of illness, their comorbidities, and their responses to diagnosis and treatment. When a system is not expected to work perfectly at all times—as health care is not—it becomes more difficult to distinguish problems related to individual error from problems related to flaws in the system. This distinction between nonmedical mechanical systems and medical systems may be akin to the distinction between complicated and complex endeavors.[47]

Differences in organizational structure between medical and nonmedical systems may be particularly relevant. A nonmedical system is typically a single structure that is managed vertically through hierarchical control. Patient care, in contrast, tends to consist of numerous diverse subsystems that may be only loosely aggregated.[48] These subsystems (including quality improvement components) tend to function in isolation, and intrasystem changes tend to be managed laterally across individual subsystems. The resulting loose structure often leads to the creation of ineffective or even contradictory policies, all of which increase the chances of error.

The potential role of a systems approach in improving safety and quality is further suggested by data that correlate improved outcomes with higher hospital or surgeon volume.[49,50] Whether these findings are explained by "practice makes perfect" or by "perfect makes practice" is yet to be resolved, but in either case, it seems likely that the improved outcomes reflect better care systems. That some high-volume hospitals and surgeons have below-average outcomes and many low-volume hospitals and surgeons have excellent ones is consistent with the role of systems.[51]

Basic Principles of Human Performance

Because human factors play a major role in system failure, any attempt to improve patient safety must be based on an understanding of the factors that affect human performance and their relation to human error.[52] Major advances in the field of cognitive psychology over the past several decades have greatly enhanced the understanding of human performance. A widely accepted schema classifies such performance into the following three types,[53] in descending order of familiarity with the specific task:

1. Skill-based performance. This type of performance is governed by stored patterns of preprogrammed instructions. It occurs without conscious control and uses long-term memory.
2. Rule-based performance. This type involves solving problems by means of stored rules of the if-then variety. Like skill-based performance, it uses long-term memory; however, unlike skill-based performance, it is associated with a consciousness that a problem exists.[29] The rules are usually based on experience garnered from previous similar situations and are structured hierarchically, with the main rules on top; their strength appears to be a function of how recently and how frequently they are used.[52] Rule-based performance varies according to expertise: novices tend to rely on a few main rules, whereas experts have many side rules and exceptions.
3. Knowledge-based performance. This type involves conscious analytic processes and stored knowledge. It relies on working memory, which is comparatively slow and of relatively limited

Table 1 Common Modes of Failure Associated with Specific Types of Performance[27]

Failures of Skill-Based Performance	
Inattention	*Overattention*
Double-capture slips Omissions following interruptions Reduced intentionality Perceptual confusions Interference errors	Omissions Repetitions Reversals
Failures of Rule-Based Performance	
Misapplication of Good Rules	*Application of Bad Rules*
First exceptions Countersigns and nonsigns Informational overload Rule strength General rules Redundancy Rigidity	Encoding deficiencies Action deficiencies Wrong rules Inelegant rules Inadvisable rules
Failures of Knowledge-Based Performance	
Selectivity Workspace limitations Out of sight, out of mind Confirmation bias Overconfidence	Biased reviewing Illusory correlation Halo effects Problems with causality Problems with complexity

capacity. Typically, people resort to knowledge-based performance when their existing skills are not applicable or their repertoire of rules has been exhausted.

Successful performance or problem-solving has three main phases: planning, storage, and execution. Errors resulting from failures in performance may be classified as slips, lapses, or mistakes,[27] depending on which phase of the problem-solving sequence is involved. Slips are failures of the execution phase, the storage phase, or both, and they may occur regardless of whether the plan from which they arose was adequate. Lapses are failures of the storage phase. Generally, slips are overt, whereas lapses are covert. Mistakes are failures of planning, reflecting basic deficiencies or failures in selecting an objective or specifying the means to achieve it, regardless of how well the plan was executed.

A key concept is that specific types of error tend to be associated with specific modes of failure [*see Table 1*].[27] Slips and lapses are failures of skill-based performance and generally precede recognition of a problem. Mistakes may be either failures of knowledge-based performance (i.e., attributable to lack of expertise) or failures of rule-based performance (i.e., attributable to failure of expertise). They typically arise during attempts to solve a problem. Mistakes tend to be more subtle, more complex, and less well understood than slips or lapses and thus more dangerous. It has been suggested that experienced surgeons are more prone to slips and lapses and that junior surgeons and trainees are more prone to mistakes.[54]

Underspecification of the problem is common in clinical practice and clearly affects performance. A problem may seem underspecified when limited attention is paid, when the wrong cues are picked up, when the problem is truly ill-defined, or when the problem falls outside the known rules. Underspecification is more likely to occur in situations where cues change dynamically or are ambiguous and is associated with two types of error forms: similarity matching and frequency bias (or frequency gambling). In similarity matching, a present situation is thought to resemble a previous one and consequently is addressed in the same way (which is not necessarily appropriate). In frequency gambling, a course of action is chosen that has worked before; the more often that course of action has been successfully used, the more likely it is to be chosen. These behavior patterns have been confirmed among anesthesiologists, who, like many dynamic decision makers, use approximation strategies (or heuristics) to handle ambiguous situations.[4]

Confirmation bias is another characteristic problem of performance. It may be defined as the propensity to stick with a chosen diagnosis or course of action and either to interpret new information so as to favor the original choice or else to disregard such information entirely. It is also referred to as cognitive fixation, cognitive lockup, or fixation error, and it is often associated with knowledge-based performance.[55] Confirmation bias is particularly likely when the situation is unusual or evolving and when there is concomitant pressure to maintain coherence[14]—again, situations frequently encountered in surgical practice. A well-known adage is relevant here: good surgeons believe what they see; bad ones see what they believe.[56] The issue of how cognitive psychology affects diagnostic and clinical reasoning has been addressed in detail elsewhere.[57-59]

Confirmation bias may be considered an error of perception; other errors may be classified as errors of cognition or execution. Thus, classification schemes may be modified to meet specific needs.[60] For instance, some experts categorize errors according to whether they can be addressed by engineering, design, societal, or procedural changes; others prefer to emphasize psychological intervention and modification; and still others classify errors by their mode of appearance—for example, as errors of omission, errors of insertion, errors of repetition, or errors of substitution (e.g., misadministration of lidocaine, heparin, or potassium chloride as a result of poor package labeling).

To date, error in medicine has almost always been regarded as a special case of medicine, rather than as a special case of error.[4] The unfortunate result of this view has been the isolation of medical errors from much of the body of theory, analysis, and application that has been developed to deal with error in fields such as aviation and nuclear power. The observation that the basic principles of human error are highly applicable to clinical practice should go a long way toward refuting this erroneous notion of medical error. A truer view of medical error will allow health care professionals to make use of the lessons learned from study of nonmedical systems.

Performance versus Error

To many, the concepts of performance and error, as they relate to patient care, seem straightforward—obvious, even. To others, however, it is crucial to make a distinction between human error and human performance, both because the assignment of error is often retrospective and thus subject to hindsight bias and because the term error is inherently prejudicial.

The difficulty of making this distinction may be illustrated by an analysis of surgeon-reported errors[35] and a review of closed malpractice claims.[37] In the former, system factors were deemed responsible for 86% of incidents, and inexperience or lack of competence for 53%. Yet cognitive factors (primarily involving errors in judgment or vigilance) were also involved in 86% of the incidents. The latter study reported similar findings: errors in judgment, failure of vigilance or memory, and lack of technical competence or knowledge were factors in 66%, 63%, and 41% of the cases, respectively.

In one sense, surgeons' performance is a system factor, but in another sense, their cognitive and technical abilities make up a large part of the system's safety barriers. Legal concerns aside, it is vital that surgeons not overemphasize the first sense and interpret it as an excuse for avoiding responsibility for complications.[61] Nevertheless, placing too much emphasis on surgeons' individual role retards rather than advances understanding of system failure and tends to evoke defensiveness rather than constructive action.[28,29,62] Regardless of whether these adverse events are performance failures or errors, eliminating them entirely is an impossible goal; a more realistic goal is to gain a better understanding of their causes and then to minimize—or possibly even eliminate—their consequences. The overall implication here is that to achieve meaningful improvements in safety and quality, it is necessary to shift the focus from fallible individuals to the situational and organizational circumstances through which human performance leads to medical errors.[28]

There is little question that performance is affected by the context of the problem. An individual's physical and psychological well-being is a key consideration here, as are the effects of sleep deprivation and fatigue on performance and learning.[40,41,45,63,64] Fatigue, by impairing vigilance, can accentuate confirmation bias. In addition, errors increase as time on task increases; no other hazardous industry permits—let alone requires—employees to work the regular long hours common in hospitals.[55] Stress may increase the likelihood of error, but it is clearly neither necessary nor sufficient for cognitive failure.[27] Unfortunately, physicians tend to have unrealistic beliefs about their ability to deal with stress and fatigue and so may not seek help even when they clearly need it.[65] They also appear to have only a limited ability to assess their own learning needs, with those who are least skilled and those who are most confident being the worst at this task.[66] As a corollary, surgical skill is positively related to the ability to detect errors.[54]

The mental overload that can occur in situations involving a plethora of tasks may compromise the ability to respond to secondary tasks. Errors related to loss of vigilance include not observing a data stream at all, not observing a data stream sufficiently frequently, and not observing the particular data stream that is optimal for the existing situation. In watching for rare occurrences (a not uncommon situation in medicine), it is difficult to remain alert for longer than 10 to 20 minutes. Knowing when and how to verify data is an important metacognitive skill.

In addressing these types of errors, a great deal of emphasis has been placed on reducing work hours, but there seems to have been relatively little consideration of the impact of workload and workflow on medical errors.[35] Yet data on resident work activities indicate that residents experience extremely fragmented workflows that result in frequent interruptions and changes in focus.[67] Moreover, the current limit on resident work hours does not appear to have improved patient safety[68] or reduced the incidence of technical complications.[69] Thus, demands for greater productivity within a health care system that is increasingly constrained by cost considerations may also contribute to an increase in medical errors.

Psychological framing effects also play a role in judgment. Examples of such effects are the irrational preference for established treatments when outcomes are framed in terms of gain (e.g., survival) and the similarly irrational preference for risky treatments when outcomes are framed in terms of loss (e.g., mortality). The impetus to "do the right thing" can adversely affect medical judgment.[70]

Teamwork and communication among team members also play essential roles in determining performance, particularly when there is a lack of cohesion and mutual support among team members.[4,55] On one hand, a team structure that is too informal tends to undermine patterns of authority and responsibility and to hinder effective decision-making. On the other hand, a hierarchy that is too strong may make it excessively difficult for juniors to question decisions made by those at higher levels of authority. Rigid behavior may impair the ability to cope with unforeseen events and discourage initiative.

Teamwork can be an especially complex matter in the OR. The crews from nursing, surgery, and anesthesia often have fundamentally different perceptions of their respective roles, and these perceptual differences can adversely affect situational awareness. For example, anesthesiologists and nurse anesthetists are much more likely to feel that a preoperative briefing is important for team effectiveness than surgeons and surgical nurses are; surgeons and surgical nurses are more likely to feel that junior team members should not question the decisions of senior staff members.[71] Such varying perceptions can not only compromise patient safety but also hinder teaching and learning. Unfortunately, there is no broad consensus on how to achieve optimal team coordination in this setting.

The importance of teamwork issues in the OR is illustrated by a study that analyzed the time needed to learn minimally invasive cardiac surgery.[72] On the fast-learning teams, the members had worked well together in the past, they went through the early learning phase together before adding new members, they scheduled several of the new procedures close together, they discussed each case in detail beforehand and afterward, and they carefully tracked results. Of particular interest was that surgeons on the fast-learning teams were less experienced than those on the slow-learning teams but more willing to accept input from others on the team.

The role of teamwork and communication in the ED is evident from a study that reported an average of 8.8 teamwork failures per malpractice incident, with more than half of the deaths and permanent disabilities judged to be avoidable.[73]

Table 2 Nonmedical System Techniques Also Applicable to Medical Systems

Simplify or reduce handoffs	Adjust work schedules
Reduce reliance on memory	Adjust the environment
Standardize procedures	Improve communication and teamwork
Improve information access	Decrease reliance on vigilance
Use constraining or forcing functions	Provide adequate safety training
Design for errors	Choose the right staff for the job

Approaches to Improving Patient Safety

Given the similarities between medical and nonmedical systems, it should not be surprising that many safety-improvement techniques derived from nonmedical settings have been successfully applied in medical contexts [*see Table 2*].[74,75] Other useful strategies include prioritization of tasks, distribution of the workload over time or resources, changing the nature of the task, monitoring and checking all available data, effective leadership, open communication, mobilization and use of all available resources, and team building.[4] The general idea behind many of these approaches is to redesign the problem space to reduce the cognitive workload.[53,76]

A vital early step in improving patient safety is to establish a safety culture throughout the workplace. An important development in this area is the ability to make valid measurements of an organization's safety climate.[77] An appropriate organizational culture views errors as signals for needed changes and focuses on learning rather than on accountability. If the team or organization is designed to learn from and benefit from experience, its collective wisdom should be greater than the sum of the wisdom of its individual members. Needed changes often involve difficult choices among strategic factors and sometimes introduce new latent flaws.[35,78] Accordingly, once a change in procedure or policy has been implemented, its impact must be monitored closely.[79] New latent fail-

Table 3 Agency for Healthcare Quality and Research Patient Safety Indicators

Complications of anesthesia	Postoperative hemorrhage or hematoma
Death in low-mortality diagnosis-related group	Postoperative pulmonary embolism or deep vein thrombosis
Decubitus ulcer	Postoperative sepsis
Failure to rescue	Postoperative wound dehiscence
Foreign body left during procedure	Accidental puncture or laceration
Iatrogenic pneumothorax	Transfusion reaction
Selected infections	Obstetric trauma
Postoperative hip fracture	

ures may result from either oversimplification[14] or redundancy. As noted (see above), the latter enhances reliability, but its benefits are often offset by greater complexity and a consequent increase in the risk of human failure.[55] In addition, the more complex the system, the greater the chance that a change will have more than local effects. How to control some errors without relaxing control over others is a general problem in error management.[55,80]

Good teamwork requires that team members share a clear understanding of what is happening and what should happen (i.e., situational awareness).[55] Unfortunately, there is a common tendency to believe that the prevailing level of situational awareness is greater than it actually is. For example, the aviation industry further improved its safety record when it identified and removed barriers that impeded junior officers from communicating with the captain. This achievement is noteworthy because these improvements took place after good communication was already thought to exist.[81]

Information technology (IT) can be valuable in improving safety and quality.[55,82] The main classes of strategies for using IT in this way correspond to the most frequent causes of errors. These strategies include tools to improve communication, to make information more readily accessible, to require key pieces of information for subsequent steps in a process, to assist with calculations, to perform checks in real time, to assist with monitoring information, and to provide decision support.[83] Studies of computerized clinical decision support systems indicate that practitioners perform better with systems that provide automatic prompts than with systems that first require system activation. Such studies also find that there is a greater likelihood of better performance in systems that were developed by the authors than in those that were not.[84] Computerized physician order entry (CPOE) has been shown to reduce medication errors[85] and facilitate ventilator weaning,[86] but it is not foolproof and can introduce other types of errors.[87]

Even though physicians appear to have increasing access to information technology in practice (www.hschange.org), their acceptance of computerization has been neither easy nor universal, and medicine is far behind other industries in terms of the extent to which it has adopted such technology. Studies from the past few years suggest that only about one third of physicians receive any data (process data, outcome data, or patient surveys) about the quality of care they provide.[88] This finding may be partly explained by the cost of introducing IT (which can become outmoded relatively quickly). Another part of the explanation is concern that caregivers might become too dependent on computerized advice-giving systems and thus might start making a habit of perfunctorily acceding to the computer's advice rather than trusting their own judgment. Issues of legal liability then arise: how much computer advice is too much, and is relying on such advice tantamount to abandoning responsibility for critical independent thought? A related concern is that many patient care tasks may be too complex for computerization and thus may be better suited to human performance. The tradeoff for retaining the human ability to deal with such complexity is the human susceptibility to error: systems that rely on error-free human performance are destined to experience failures. Because the kinds of transitory mental states that cause errors are both unintended and largely unpredictable, they are the last and least manageable links in the error chain.

Another approach to improving patient safety has been the development of specific tools and indicators for identifying common safety problems. Examples of these are the Patient Safety Indicators (PSIs) from the Agency for Healthcare Research and Quality (AHRQ) (www.ahrq.gov) [*see Table 3*] and the serious reportable event list from the National Quality Forum (NQF) (www.qualityforum.org) [*see Table 4*]. The lists are similar in some respects but not identical: the NQF further subcategorizes events into surgical events, product or device events, patient protection events, care management events, environmental events, and criminal events. Both lists specify clearly identifiable and readily measurable events, both include a variety of causes in addition to a medical error that leads to the adverse event, and both were developed by panels of experts.

Table 4 National Quality Forum List of Health Care Facility–Related Serious Reportable Events

Category	Event
Surgical	A. Surgery performed on the wrong body part B. Surgery performed on the wrong patient C. Wrong surgical procedure on a patient D. Unintended retention of a foreign object in a patient after surgery or other procedure E. Intraoperative or postoperative death in an ASA class I patient
Product or device	A. Patient death or serious disability associated with use of contaminated drugs, devices, or biologics B. Patient death or serious disability associated with use or function of a device in patient care, in which the device is used or functions otherwise than intended C. Patient death or serious disability associated with intravascular air embolism
Patient protection	A. Infant discharged to the wrong person B. Patient death or serious disability associated with patient elopement (disappearance) C. Patient suicide or attempted suicide resulting in serious disability
Care management	A. Patient death or serious disability associated with a medication error B. Patient death or serious disability associated with a transfusion reaction C. Maternal death or serious disability associated with labor and delivery in a low-risk pregnancy D. Patient death or serious disability associated with hypoglycemia E. Death or serious disability associated with failure to identify or treat neonatal hyperbilirubinemia F. Stage 3 or 4 pressure ulcer acquired after admission G. Patient death or serious disability associated with spinal manipulative therapy H. Artificial insemination with wrong donor sperm or wrong egg
Environmental	A. Patient death or serious disability associated with electrical shock B. Any incident in which a line designated for oxygen or other gas to be delivered to a patient contains the wrong gas or is contaminated by toxic substances C. Patient death or serious disability associated with a burn incurred from any source D. Patient death or serious disability associated with a fall E. Patient death or serious disability associated with the use of restraints or bedrails
Criminal	A. Any care ordered by someone impersonating a physician or other licensed health care provider B. Abduction of a patient of any age C. Sexual assault of a patient D. Death or significant injury of a patient or staff member from a physical assault

ASA—American Society of Anesthesiologists

Identifying System Flaws

Intensive examination of system flaws is usually triggered by a catastrophic failure or a near miss. The appropriate investigation of such events is known as root cause analysis (RCA). The Joint Commission (formerly known as the JCAHO) (www.jointcommission.org) has developed a matrix for RCA, and experience with RCA in health care institutions has been reported.[89,90]

Once an area for analysis has been identified, the next steps are to identify all the relevant subsystems and to assemble a team whose members represent all the components. Determining all of the components within a complex system can be challenging, and it may prove necessary to add members to the team as more subsystems are identified. In this regard, it is better to err on the side of inclusivity rather than exclusivity so as to minimize the chances of missing latent flaws and maximize the number of possible solutions. Studies that relate nurse staffing to quality of care illustrate the important roles that other members of the health care team play in ensuring patient safety.[91-93]

The next steps in RCA are to decide on the measures for analysis and to identify an appropriate data source. Medical record audits yield far greater detail than claims data, but they are expensive, labor intensive, and time consuming. Moreover, information on the environment or behavior in medical records may be irrelevant or even contradictory; this problem can sometimes be mitigated by employing appropriate screening criteria.[94] Some of the shortcomings of medical record audits can be avoided by using administrative data, but such data often lack the requisite accuracy or depth. Electronic health records have the potential to simplify this process and possess a number of other advantages.[95,96]

Regardless of the data source, the process is likely to be evolutionary: rarely is a perfect set of measures available from the start. In some situations, it may be difficult to generate interest in RCA because the circumstances are so unusual that they are unlikely ever to combine in the same way again. Although the findings from such an analysis might seem to offer little benefit to the institution in which they occurred, such incidents may occur frequently enough at a regional or national level to make the analysis worthwhile. RCA can be automated,[97] but the potential advantages of doing so may be offset by a dependence on the developer's interpretation of the risk reduction process or by the factors identified as the principal event.

Systems analysis in the absence of a specific event may help avoid errors. Areas where such analyses might be fruitful include those identified by the AHRQ [*see Table 3*], the NQF [*see Table 4*], and the Joint Commission. Another source for specific topics is *AHRQ WebM&M* (www.webmm.ahrq.gov), an AHRQ-developed Web site that provides expert analysis of medical errors in five specialty areas (including surgery), as well as interactive learning modules. The AHRQ has also created extensive lists of other quality measures (www.qualitymeasures.ahrq.gov) and quality tools (www.qualitytools.ahrq.gov) for use in improving patient safety.

Additional analyses associated with successful quality-improvement efforts include patient notification systems,[98] patient safety systems,[99] analyses of system failures in laparoscopic surgery,[100] and analyses of medical microsystems.[78] Critical analyses of evidence-based practices also identified 11 surgically relevant quality-improvement practices for which the data were strong enough to support more widespread implementation [*see Table 5*].[101,102] A note of caution that should be sounded here is that exclusive emphasis on evidence-based data could skew safety priorities and might actually prevent relatively few adverse events.[103] Another potential area for review involves changes in policy or equipment that might introduce unanticipated problems or unexplained variations in a relevant outcome measure. Every change of this type necessitates a new learning cycle, and the new environment is often conducive to error.[104]

Table 5 Surgically Relevant Quality Improvement Practices Appropriate for Widespread Implementation[101]

Appropriate use of prophylaxis to prevent venous thromboembolism in patients at risk
Use of perioperative beta blockers in appropriate patients to prevent perioperative morbidity and mortality
Use of maximum sterile barriers while placing central venous catheters to prevent infection
Appropriate use of antibiotic prophylaxis to prevent postoperative infections
Requesting that patients recall and state what they have been told during the informed consent process
Continuous aspiration of subglottic secretions to prevent ventilator-associated pneumonia
Use of pressure-relieving bedding materials to prevent pressure ulcers
Use of real-time ultrasound guidance during central line placement to prevent complications
Patient self-management for warfarin to achieve appropriate outpatient anticoagulation and prevent complications
Appropriate provision of nutrition, with particular emphasis on early enteral nutrition in critically ill and surgical patients
Use of antibiotic-impregnated central venous catheters to prevent catheter-related infections

Successes and Obstacles to Success

In view of the complexities of health care, taking a systems approach to safety improvement may seem a daunting endeavor. Nevertheless, there are a number of cases in which this task has been successfully accomplished. For the purposes of illustration, it is worthwhile to review these examples briefly.

Anesthesiologists were among the first physicians to take a systems approach to patient safety, and their success is irrefutable: anesthesia-related mortality fell from approximately 2/10,000 to the current 1/200,000 to 1/300,000[105-107]—a degree of safety approaching that advocated for nonmedical industries (i.e., < 3.4 defects or errors/10^6 products or events).[108] This improvement primarily resulted from a broad effort involving teamwork, practice guidelines, automation, simplification of procedures, and standardization of equipment and many functions. For instance, before the anesthesiologists' safety initiatives, design standards for anesthesia machines did not exist. As a result, it was not unusual to have one machine in which turning a valve in a given direction would increase gas flow and other machines in which turning it in the same direction would decrease flow; in fact, both types might be present in the same hospital. Equipment manufacturers subsequently worked together to standardize anesthesia equipment, and these kinds of arbitrary design variations are no longer seen.

The experience with safety efforts in anesthesiology underscores the importance of understanding the human-technology interface and the ergonomics of equipment design.[109] To improve patient safety, it is necessary to understand the devices and techniques employed, the ways in which individual persons use the technology, and the means by which these users interact with other aspects of the system.[110,111] Similar considerations should be applied to innovative practices.[112]

Examples of successful safety improvement efforts within surgery include the Northern New England Cardiovascular

Disease Study Group,[113] Intermountain Health Systems in Utah, the Maine Medical Assessment Foundation,[114] and Quality Surgical Solutions in Kentucky.[115] These organizations share four important characteristics: (1) providers responded to practice variations by participating in outcomes research; (2) voluntary, physician-initiated interventions were as effective as, if not more effective than, external regulatory mechanisms in reducing morbidity and mortality; (3) a systems approach to quality improvement produced better results than a bad-apple approach; and (4) quality-improvement programs successfully included groups that otherwise might have been competitors. None of these efforts increased liability exposure; often, they reduced it. Because the practice profiles were physician-initiated, there was little risk that the findings would be used to make decisions about credentialing, reimbursement, or contracting.[114] In addition, the funding parties (including insurers) usually agreed to confidentiality in return for the benefit associated with voluntary physician involvement. Other notable safety improvement efforts include the Society for Thoracic Surgery national database, which is now widely accepted as a benchmark for quality in cardiac surgery (www.sts.org/sections/stsnationaldatabase); the Washington State Surgical Clinical Outcomes Program[116]; the New England Colorectal Cancer Quality Project[117]; and the National Surgical Infection Collaborative.[118]

The Veterans Affairs National Surgical Quality Improvement Program (NSQIP) is another example of a successful safety initiative, achieving a 27% decrease in 30-day mortality after major procedures and a 45% decrease in morbidity.[5] NSQIP found the two most important risk factors for prolonged hospital stay after major elective surgery to be (1) intraoperative processes of care and (2) postoperative adverse events.[119] Other notable findings were that for many common procedures, there was no significant association between procedure or specialty volume and 30-day mortality and that the savings from improved surgical care far exceeded the investment in the project.[120] NSQIP has now expanded into the broader community under the auspices of the American College of Surgeons (ACS). It has also been used to validate the AHRQ Patient Safety Indicators (www.academyhealth.org/2005/ppt/tsilimingras.ppt).

Trauma care also improved after efforts were made to understand and enhance systems of care.[121] Moreover, the perception of preventability increased in parallel with the appreciation of the importance of the system.

The conspicuous success of these large-scale examples should not be allowed to obscure the many successes achieved by smaller-scale initiatives within single institutions.[98,122] In addition to top-level efforts, individual efforts at safety improvement can and must occur in accordance with the resources available to each practice or hospital.

These examples of success are encouraging, but considerable obstacles to improving patient safety still exist. Specific obstacles include (1) a residual lack of awareness that a problem exists, (2) a traditional medical culture based on individual responsibility and blame (and shame), (3) a perceived vulnerability to legal discovery and liability, (4) primitive medical information systems, (5) the time and expense involved in defining and implementing evidence-based practice, (6) inadequate resources for quality improvement and error prevention, (7) the local nature of health care, and (8) the perception of a poor return on investment (i.e., the lack of a business case).[123] Although the need to redefine health care on the basis of value seems obvious, the current environment still appears to focus primarily on cost; value (i.e., quality per unit cost) is not part of the equation.[124]

One hindrance to improving patient safety is the idea that the quality improvement methods already available are adequate to address the problem. The persistence of patient safety problems in the face of the ongoing use of these methods should be a sufficient argument for the inadequacy of existing approaches (see below).

Morbidity and mortality (M & M) conferences are perhaps the most traditional venue for discussion of adverse events, but they frequently do not consider all complications, they are not consistently well attended, they do not categorize complications systematically, and they often do not involve extensive debriefing.[35,125-127] For instance, a study that compared NSQIP with traditional M & M conferences noted that the latter failed to consider about 50% of the deaths and about 75% of the complications.[128] Furthermore, M & M conferences tend to be intradepartmental and thus provide little opportunity for discussion of system problems that involve other departments (e.g., anesthesiology or nursing). M & M conferences also typically do not consider near misses (i.e., close calls), even though such events can identify important actual and potential system flaws. Finally, M & M conferences have a tradition of focusing on the actions of individuals rather than on the circumstances within which the individuals acted. This tradition serves to perpetuate a defensive attitude among trainees that is counterproductive. It is possible, however, that a more systematized review process could improve the value of the M & M conference.[129,130]

The Joint Commission accreditation of hospitals is based on analyses of safety and quality information (www.jointcommissionreport.org). However, it has been observed that the Joint Commission's accreditation program lacks the ability to identify many patient safety problems.[131]

Continuing medical education (CME) attempts to focus on the link between knowledge and quality of patient care. Yet the structural incentives associated with health care in the United States lead to highly variable patterns of care and a widespread failure to implement evidence-based practice.[132] There is a clear relation between CME activity and performance on board recertification examinations,[133] but the actual relation between CME and better patient care is far more complex. There is evidence to suggest that performance on cognitive examinations is related to performance in practice[134,135] and that board certification is linked with improved outcomes,[136] but the studies from which this evidence derives usually have methodologic shortcomings. Systematic reviews of differences in the impact various CME strategies have on actual practice change have raised serious concerns about the value of some current CME.[137] The strategies shown to be most effective for practice change (e.g., reminders, patient-mediated interventions, outreach visits, opinion leader input, and multifaceted activities) place substantial emphasis on performance change rather than simply on learning.[138,139]

The purpose of clinical pathways and guidelines is to improve safety and quality—especially in high-risk procedures—by standardizing medical processes.[140] The presumed benefits of standardization notwithstanding, critics of these tools argue that guidelines often do not apply to particular patients and can be difficult to use in patients with other, more urgent medical problems. Finally, guidelines may become quickly outdated.[141]

Peer review organizations were originally intended as a mechanism for professional self-evaluation but subsequently became subject to anticompetitive abuse and other undesired consequences.[142] The potential for inequity was a particular concern, in that physicians who relinquished privileges on their own initiative might be treated more leniently than those against whom action was initiated by a peer review committee. Moreover, the data reviewed by peer review organizations were often legally discoverable, and this lack of anonymity and confidentiality tended to deter voluntary participation. Even when peer review organizations identified problems, they were often unable to implement solutions. Peer review organizations have now been largely supplanted by quality improvement organizations, though it is not yet clear whether the latter are substantially more effective.[143,144]

Hospital incident reports have much the same shortcomings as the peer review process. They place limited emphasis on close calls and tend to lack systematic follow-up. Individuals also may be reluctant to file reports out of fear that their employment might be jeopardized or that the reported party might seek retribution.

The present professional liability system is particularly controversial with respect to whether it facilitates or hinders improvements in patient safety. This system has its basis in the traditional paradigm of surgical care (see below), which holds the individual surgeon accountable as the "captain of the ship." This paradigm has enabled many great achievements in surgical care, but it has also probably fostered a dangerous sense of infallibility. As a consequence, errors tend to be equated with negligence, and questions of professional liability tend to involve blaming individuals. Indeed, the very willingness of professionals to accept responsibility for their actions makes it convenient to focus more on individual errors than on collective ones[28]; an individual surgeon is a more satisfactory target for the anger and grief of a patient or family than a faceless organization would be. This is certainly not to say that surgeons should avoid responsibility; rather, the point is that focusing on the errors of individual surgeon without addressing flaws in the underlying system does little to improve health care.

Another notable flaw in the liability process is that judgments of causality or fault are vulnerable to hindsight bias, which can skew experts' assessments of quality of care. This tendency was illustrated by a study of anesthetic care in which differences in outcome significantly influenced the perception of negligence, even when the care provided was equivalent.[145] Hindsight bias focuses too narrowly on adverse outcomes and pays insufficient attention to the processes of care. Yet another defect of the liability process is that it can be emotionally devastating for physicians (and their families),[146-148] often adversely affecting their problem-solving abilities. To the extent that experience with or fear of a liability action deters efforts at quality improvement, it is counterproductive. Defensive medicine, with its attendant costs, adds very little value to health care.[149]

Many believe that major reform of the professional liability system is a prerequisite for achieving any significant improvements in quality. Undoubtedly, tort reform is highly desirable; however, the real prerequisite for improving identification and correction of system failures is the provision of increased protection for privileged discussion of such failures. The federal Patient Safety and Quality Improvement Act of 2005 (Public Law 109-41) was enacted for the purpose of improving patient safety by encouraging voluntary and confidential reporting of events that adversely affect patients. This act creates patient safety organizations whose goal is to collect, aggregate, and analyze confidential information reported by health care providers. It also calls for establishing a network of patient safety databases as an interactive, evidence-based management resource. The act limits the use of this information in criminal, civil, and administrative proceedings and includes provisions imposing monetary penalties for violations of confidentiality or privilege protections. The notion that a reduction in liability concerns may facilitate disclosure and discussion of mistakes is suggested by international comparisons of health care systems. In one study, patients in New Zealand, which has no-fault medical malpractice, were the most likely to report error discussions with their physicians.[21]

It is to be hoped that the tort reform movement and the patient safety movement can seek and find common ground.[150] The improvements in patient safety achieved by anesthesiologists speak for the benefits of such an approach. Instead of pushing for laws to protect them against patients' lawsuits, anesthesiologists focused on improving patient safety. As a result, they pay less for malpractice insurance today, in constant dollars, than they did more than 20 years ago.[151]

Table 6 Contrasting Characteristics of Medical Practice in the 20th and 21st Centuries[157]

20th Century Characteristics	21st Century Characteristics
Autonomy	Teamwork/systems
Solo practice	Group practice
Continuous learning	Continuous improvement
Infallibility	Multidisciplinary problem solving
Knowledge	Change

Even before the enactment of the Patient Safety Act, the view that open discussion of medical errors was appropriate appeared to be gaining adherents.[27] Today, there is even more evidence that such open communication may reduce the likelihood of legal action and enhance public confidence in health care providers.[152,153] Unfortunately, some hospitals persist in separating risk management from quality-assurance issues, to the detriment of both.[154]

The obvious need for liability reform notwithstanding, there are issues involved in enhancing safety and quality that are too complex to be addressed solely by changes in the liability system. Major safety and quality problems exist in nations where professional liability is not an issue; however, the higher rates of adverse events in these countries should not be taken as evidence of the benefits of the current U.S. liability system. Physicians tend to act defensively even in a no-fault liability system. To minimize such defensiveness, greater emphasis must be placed on measurement for improvement than on measurement for judgment.[155,156]

Challenges to Traditional Surgical Paradigm

Contemporary surgical practice requires that surgeons rethink the traditional paradigm of surgical practice (see above). The burgeoning growth of knowledge, the accompanying increase in specialization, the expanding role of technology, and the rising complexity of practice are making surgeons more and more dependent on persons or factors beyond their immediate control. As a result, surgeons are finding it more and more difficult even to appreciate, let alone manage, the larger context within which they provide care. The traditional surgical paradigm, despite its past successes, is no longer entirely adequate to the task now at hand [*see Table 6*].[157] Paradoxically, surgeons seeking to improve patient safety must acquire a deeper understanding of patient care systems at the very time when those systems are becoming increasingly difficult to understand.

To achieve the requisite understanding, it is necessary to have a reporting system that collects, tabulates, and analyzes data on the frequency and nature of both adverse events and near misses.[158] The primary function of a patient safety reporting system should be to identify both real and potential adverse consequences of latent flaws and make them visible to others. Once these real and potential adverse events are identified and made visible, the system can be redesigned so as to eliminate or minimize them. A good example of the type of reporting system needed in health care is the highly successful Aviation Safety Reporting System (ASRS).[28,99]

A successful reporting system such as the ASRS is typically nonpunitive, confidential (and preferably anonymous), independent, timely, systems oriented, and responsive.[159] In addition, it includes expert analysis, meaning that reports are evaluated by persons who understand the relevant circumstances and are trained to recognize underlying system-based causes. A successful reporting system usually also tabulates seemingly rare incidents (including near misses) even if there seems to be little direct or immediate benefit to doing so; in addition to their potential value in larger contexts, such analyses may help institutions predict and thereby avoid errors and system failures. The absence of a punitive focus reduces health care workers' concerns that reports might be used against them and thus minimizes underreporting.[60,160,161] The concerns about the possible adverse consequences of a reporting system are quite strong—so much so that many believe that a health care reporting system can succeed only if legal immunity is available.[162] The fear of being sued is widespread among physicians; however, the perceived risk of being sued is three times greater than the actual risk, and there is no good correlation between hospitals' claims ratings and their injury rates.[78]

Whether such reporting should be voluntary or mandatory is still a matter of debate. On one hand, voluntary reporting has a high inaccuracy rate even when mandated by state or federal regulations. On the other hand, many surgeons believe that mandatory reporting may increase the pressure to conceal errors rather than analyze them; that it is unworkable in the current legal system; and that it may result not in constructive error-reducing solutions but merely in more punishment or censure.[163]

Some argue that patient safety efforts should focus (at least initially) on medical injury rather than on medical errors.[164,165] A focus on medical injury recognizes the difficulties of identifying medical errors and is based on a public health improvement model that has been useful in addressing other types of injuries; it also recognizes that most medical injuries are not caused by negligence. Such an approach may be more compatible with the current liability system and may help restore physicians' stature as patient advocates. Moreover, placing the initial focus on medical errors rather than injuries might divert attention from other system flaws, with the result that such flaws go uncorrected. Although ultimately, a successful reporting system must focus both on errors and on injuries; an initial focus on injury may achieve greater initial buy-in from surgeons and may therefore be a more pragmatic first step. The issues associated with reporting errors or injuries must also be distinguished from those associated with reporting outcomes to the public. The latter type of reports are currently being seen with increasing frequency, but they may have unintended consequences.[166]

The complexities involved in understanding and improving health care systems make it likely that patients' expectations of improved safety may grow faster than they can be met.[167,168] This potential disparity between expectations and performance may be further exacerbated by the likelihood that errors have been substantially underreported.[169] A reporting system that is punitive or not anonymous may discourage appropriate reporting of medical errors. Underreporting of adverse events is also more likely if side effects are delayed or unpredictable, if there is a longer survival or latency interval, or if a patient has been transferred from one facility to another. In addition, inadequate doses of drugs or anesthetics may not be reported if they cause no immediately evident injury.

Another challenge facing surgeons is how to incorporate current concepts of performance and error into undergraduate and residency education.[170] The optimal basis for such education might be an objective-based curriculum that provides defined skills, rules, and knowledge.[36,171] The blame-and-shame approach must be eliminated from both the educational setting and the practice atmosphere. If, instead, educators focus on making residents aware of their tendencies in the presence of uncertainty, residents (like pilots) may be able to develop better responses to underspecified situations. In addition, it is vital to monitor the residents to ensure that they learn to assess and address knowledge deficits, as well as acquire healthy and effective techniques for dealing with errors. Such monitoring will make the learning curve less painful for all concerned.[172]

There is some question as to whether safety improvements are more likely to result from compliance with standards (i.e., individual performance) or from improvements in the system. Better training of individual physicians will certainly improve performance, but only so far. For substantial improvements in safety, it is probably necessary to make use of both approaches.[173] If every system indeed is perfectly designed to achieve the results it gets, the obvious conclusion is that to obtain the desired results, it is necessary to change the system. Determining what form the new system should take is a critical step.[124,174]

Conclusion

Reducing adverse events during the course of medical care is a dauntingly complex topic, and the progress made in reducing such errors has, in many cases, been disappointingly slow. Roughly a century ago, surgeons were called on to report their results, but over the intervening years, this call largely went unheeded.[175] It must be said, however, that at the beginning of the 20th century, the basic principles of human performance and error were not as well understood as they currently are, and the tools necessary for systems analysis did not exist. A further difference between then and now is the increase in public awareness of safety issues, as well as the potential consequences of this awareness.[3,176] For instance, the growing concern about safety is changing the way in which patients select providers: there has been a substantial increase in the percentage of patients who would choose a highly rated surgeon whom they had not seen before over a less highly rated surgeon whom they had seen before (www.ahrq.gov/qual/kffhigh00.htm). Improving patient safety thus becomes a matter of self-interest for the provider. It also may have a direct bearing on the maintenance of physicians' social contract with their patients.

The systems approach to improving patient safety is based on three principles: (1) human error, as an inherent aspect of human work, is unavoidable; (2) faulty systems allow human error to injure patients; and (3) systems can be designed that prevent or detect human error before such injuries occur.[177,178] Support for a systems approach to patient safety will come from patients, purchasers from both the public and the private sector, professional societies, and specialty boards.[179] It is crucial for all these parties to acknowledge that most medical errors are attributable to system flaws rather than incompetence or neglect. It is also essential to recognize that the current systems of surgical care are shaped by the larger system within which all these parties interact. This means that any worthwhile effort to improve such systems is likely to require substantial collaboration among the parties involved,[180] as well as significant change in the larger system. Physicians, with their history of patient advocacy and scientific innovation, are in the best position to provide the leadership necessary for such changes.[98,155] To restore the public's trust in the health care system, safety and quality must be made high priorities,[181] and transparency must be ensured.[182] If physicians do not take the opportunity to lead the movement to improve the safety and quality of care, they may anticipate further erosion of public trust and further loss of professional autonomy.

References

1. To Err Is Human: Building A Safer Health System. Institute of Medicine, Kohn LT, Corrigan JM, Donaldson MS, Eds. National Academy Press, Washington, DC, 2000
2. Zhan C, Miller MR. Excess length of stay, charges, and mortality attributable to medical injuries during hospitalization. JAMA 290:1868, 2003
3. Blendon RJ, DesRoches CM, Brodie M, et al: Views of practicing physicians and the public on medical errors. N Engl J Med 347:1933, 2002
4. Gaba DM: Human error in dynamic medical domains. Human Error in Medicine. Bogner MS, Ed. Lawrence Erlbaum Associates, Inc, Hillsdale, New Jersey, 1994, p 197
5. Khuri S: Safety, quality, and the National Surgical Quality Improvement Program. Am Surg 72:994, 2006
6. Doing What Counts for Patient Safety: Federal Actions to Reduce Medical Errors and Their Impact. Report of the Quality Interagency Task Force (QuIC) to the President, February 2000 http://www.quic.gov/report/errors6.pdf
7. Espin S, Levinson W, Regehr G, et al: Error or "act of God"? A study of patients and operating room team members' perceptions of error definition, reporting, and disclosure. Surgery 139:6, 2006
8. Brennan TA, Leape LL, Laird NM, et al: Incidence of adverse events and negligence in hospitalized patients, results of the Harvard Medical Practice Study I. N Engl J Med 324:370, 1991
9. Gawande AA, Thomas EJ, Zinner MJ, et al: The incidence and nature of surgical adverse events in Colorado and Utah in 1992. Surgery 126:66, 1999
10. Report of the California Medical Insurance Feasibility Study. Mills DH, Ed. California Medical Association, San Francisco, 1977
11. Gawande A, Studdert DM, Orav EJ, et al: Risk factors for retained instruments and sponges after surgery. N Engl J Med 348:229, 2003
12. Seiden SC, Barach P. Wrong-side/wrong-site, wrong procedure and wrong-patient adverse events: are they preventable? Arch Surg 141:931, 2006
13. Hanlon JT, Schmader KE, Koronkowski MJ, et al: Adverse drug events in high risk older outpatients. J Am Geriatr Soc 45:945, 1997
14. Leape LL: Error in medicine. JAMA 272:1851, 1994
15. Bates DW, Cullen DJ, Laird N, et al: Incidence of adverse drug events and potential adverse drug events. Implications for prevention. ADE Prevention Study Group. JAMA 274:29, 1995
16. Serig DI: Radiopharmaceutical misadministrations: what's wrong? Human Error in Medicine. Bogner MS, Ed. Lawrence Erlbaum Associates, Inc, Hillsdale, New Jersey, 1994, p 179
17. Feigal DW, Gardner SN, McLellan M: Ensuring safe and effective medical devices. N Engl J Med 348:191, 2003
18. Perper JA. Life-threatening and fatal therapeutic misadventures. Human Error in Medicine. Bogner MS, Ed. Lawrence Erlbaum Associates, Inc, Hillsdale, New Jersey, 1994, p 27
19. Leape L: The preventability of medical injury. Human Error in Medicine. Bogner MS, Ed. Lawrence Erlbaum Associates, Inc, Hillsdale, New Jersey, 1994, p 13
20. Hayward RA, Hofer TP: Estimating hospital deaths due to medical reviewers: preventability is in the eye of the reviewer. JAMA 286:415, 2001
21. Schoen C, Davis K, How SKH, Schoenbaum SC: US health system performance: a national scorecard. Health Aff (Millwood) 25(suppl):w457, 2006
22. Altman DE, Clancy C, Blendon RJ: Improving patient safety—five years after the IOM report. N Engl J Med 351:2041, 2004
23. Wachter R. The end of the beginning: patient safety five years after 'To Err is Human'. Health Affairs 23(suppl):w4, 2004
24. Longo DR, Hewett JE, Ge B, et al: The long road to patient safety—a status report. JAMA 294:2858, 2005
25. Leape LL, Berwick DM: Five years after To Err is Human—what have we learned? JAMA 293:2384, 2005
26. Pronovost PJ, Miller MR, Wachter RM: Tracking progress in patient safety—an elusive target. JAMA 296:696, 2006
27. Reason JT: Human Error. Cambridge University Press, Cambridge, England, 1990
28. Reason JT: Foreword. Human Error in Medicine. Bogner MS, Ed. Lawrence Erlbaum Associates, Inc, Hillsdale, New Jersey, 1994, p vii
29. Cook RI, Woods DD: Operating at the sharp end. Human Error in Medicine. Bogner MS, Ed. Lawrence Erlbaum Associates, Inc, Hillsdale, New Jersey, 1994, p 255
30. Rasmussen J: Afterword. Human Error in Medicine. Bogner MS, Ed. Lawrence Erlbaum Associates, Inc, Hillsdale, New Jersey, 1994, p 385
31. Scholtes PR: The Leader's Handbook: Making Things Happen, Getting Things Done. McGraw-Hill, New York, 1998, p 73
32. Ewell MG, Adams RJ: Aviation psychology, group dynamics, and human performance issues in anesthesiology. Proceedings of the Seventh International Symposium on Aviation Psychology, Columbus, Ohio, 1993
33. Howard SK, Gaba DN, Fish KJ, et al: Anesthesia crisis resource management: teaching anesthesiologists to handle critical incidents. Aviat Space Environ Med 63:763, 1992
34. Christian CK, Gustafson ML, Roth EM, et al: A prospective study of patient safety in the operating room. Surgery 139:159, 2006
35. Gawande A, Zinner MJ, Studdert DM, et al: Analysis of errors reported by surgeons at three teaching hospitals. Surgery 133:614, 2003
36. Battles JB, Shea CE: A system of analyzing medical errors to improve GME curricula and programs. Acad Med 76:125, 2001
37. Rogers SO, Gawande AA, Kwaan M, et al: Analysis of surgical errors in closed malpractice claims at 4 liability insurers. Surgery 140:25, 2006
38. Tang B, Hanna GB, Cuschieri A: Analysis of errors enacted by surgical trainees during skills training courses. Surgery 138:14, 2005
39. Petersen LA, Brennan TA, O'Neil, et al: Does housestaff discontinuity of care increase the risk for preventable adverse events? Ann Intern Med 121:866, 1994
40. Barger LK, Ayas NT, Cade BE, et al: Impact of extended-duration shifts on medical errors, adverse events, and attentional failures. PLoS Med 3:2440, 2006
41. Landrigan CP, Rothschild JM, Cronin JW, et al: Effect of reducing interns' work hours on serious medical errors in intensive care units. N Engl J Med 351:1838, 2004
42. Hart GK, Baldwin I, Gutteridge G, et al: Adverse incident reporting in intensive care. Anaesth Intensive Care 22:556, 1994
43. Becher EC, Chassin MR: Improving quality, minimizing error: making it happen. Health Aff (Millwood) 20:68, 2001
44. Donchin Y, Gopher D, Olin M, et al: A look into the nature and causes of human errors in the intensive care unit. Crit Care Med 23:294, 1995
45. Lockley SW, Cronin JW, Evans EE, et al: Effect of reducing interns' weekly work hours on sleep and attentional failures. N Engl J Med 351:1829, 2004
46. Daley J, Forbes MG, Young GJ, et al: Validating risk-adjusted surgical outcomes: Site visit assessment of process and structure. National VA Surgical Risk Study. J Am Coll Surg 185:341, 1997
47. Westley F, Zimmerman B, Patton QP. Getting to Maybe: How the World Is Changed. Random House Canada, 2006, p 9
48. Van Cott H: Human errors: their causes and reductions. Human Error in Medicine. Bogner MS, Ed. Lawrence Erlbaum Associates, Inc, Hillsdale, New Jersey, 1994, p 53
49. Interpreting the Volume-Outcome Relationship in the Context of Health Care Quality. Institute of Medicine Workshop Summary. National Academy of Sciences, Washington, DC, 2000
50. Interpreting the Volume-Outcome Relationship in the Context of Cancer Care. Institute of Medicine Workshop Summary. National Academy of Sciences, Washington, DC, 2001
51. Dudley RA, Johansen KL: Physician responses to purchaser quality initiatives for surgical procedures (invited commentary). Surgery 130:425, 2001
52. Ternov S: The human side of medical mistakes. Error Reduction in Health Care: A Systems Approach to Improving Patient Safety. Spath PL, Ed. Jossey-Bass, San Francisco, 2000, p 97
53. Rasmussen J: Skills, rules, knowledge: signals, signs and symbols and other distinctions in human performance models. IEEE Transactions: Systems, Man & Cybernetics, SMC-13, 1983, p 257
54. Bann S, Mansoor K, Datta V, Darzi A. Surgical skill is predicted by the ability to detect errors. Am J Surg 19:412, 2005
55. Moray N: Error reduction as a systems problem. Human Error in Medicine. Bogner MS, Ed. Lawrence Erlbaum Associates, Inc, Hillsdale, New Jersey, 1994, p 67
56. Cook RI: Seeing is believing. Ann Surg 237:472, 2003
57. LeBlanc VR, Brooks LR, Norman GR: Believing is seeing: the influence of a diagnostic hypothesis on the interpretation of clinical features. Acad Med 10(suppl):S67, 2002
58. Croskerry P: The importance of cognitive errors in diagnosis and strategies to minimize them. Acad Med 78:775, 2003
59. Redelmeir DA: The cognitive psychology of missed diagnoses. Ann Intern Med 142:115, 2005
60. Senders JW: Medical devices, medical errors, and medical accidents. Human Error in Medicine. Bogner MS, Ed. Lawrence Erlbaum Associates, Inc, Hillsdale, New Jersey, 1994, p 159
61. Lillemoe KD: To err is human, but should we expect more from a surgeon? Ann Surg 237:470, 2003
62. Gaba DM: Human error in dynamic medical domains. Human Error in Medicine. Bogner MS, Ed. Lawrence Erlbaum Associates, Inc, Hillsdale, New Jersey, 1994, p 197
63. Gaba DM, Howard SK: Fatigue among clinicians and the safety of patients. N Engl J Med 347:1249, 2002

64. Gravenstein JS, Cooper JB, Orkin FK: Work and rest cycles in anesthesia practice. Anesthesiology 72:737, 1990
65. Helmreich RL, Schaefer H-G: Team performance in the operating room. Human Error in Medicine. Bogner MS, Ed. Lawrence Erlbaum Associates, Inc, Hillsdale, New Jersey, 1994, p 225
66. Davis DA, Mazmanian PE, Fordis M, et al: Accuracy of physician self-assessment compared with observed measures of competence: a systematic review. JAMA 296: 1094. 2006
67. Gabow PA, Karkhanis A, Knight A, et al: Observations of residents' work activities for 24 consecutive hours: Implications for workflow resign. Acad Med 81:766, 2006
68. Poulose BK, Ray WA, Arbogast PG, et al: Resident work hour limits and patient safety. Ann Surg 241:847, 2005
69. Naylor RA, Rege RV, Valentine RJ. Do resident duty hour restrictions reduce technical complications of emergency laparoscopic cholecystectomy? J Am Coll Surg 201:724, 2005
70. Vaughan D: The Challenger Launch Decision: Risky Technology, Culture, and Deviance at NASA. University of Chicago Press, Chicago, 1996
71. Heimreich RL: Cockpit management attitudes. Human Factors 26:583, 1984
72. Pisano GP, Bohmer RMJ, Edmondson AC: Organizational differences in rates of learning: evidence from the adoption of minimally invasive cardiac surgery. Management Science 47:752, 2001
73. Risser DT, Rice MM, Salisbury ML, et al: The potential for improved teamwork to reduce medical errors in the emergency department. The MedTeams Research Consortium. Ann Emerg Med 34:373, 1999
74. Spath PL: Reducing errors through work system improvements. Error Reduction in Health Care: A Systems Approach to Improving Patient Safety. Spath PL, Ed. Jossey-Bass, San Francisco, 2000, p 199
75. Risser DT, Simon R, Rice MM, et al: A structured teamwork to reduce clinical errors. Error Reduction in Health Care: A Systems Approach to Improving Patient Safety. Spath PL, Ed. Jossey-Bass, San Francisco, 2000, p 235
76. DaRosa D, Bell RH Jr, Dunnington GL: Residency program models, implications, and evaluation: results of a think tank consortium on resident work hours. Surgery 133:13, 2003
77. Makary M, Sexton JB, Freischlag JA, et al: Patient safety in surgery. Ann Surg 243:628, 2006
78. Exploring Innovation and Quality Improvement in Health Care Micro-Systems: A Cross-Case Analysis. National Academy of Sciences, Washington, DC, 2000
79. Larson EB: Measuring, monitoring, and reducing medical harm from a systems perspective: a medical director's personal reflections. Acad Med 77:993, 2002
80. Dörner D: The Logic of Failure: Recognizing and Avoiding Error in Complex Situations. Perseus Books, Cambridge, Massachusetts, 1996
81. Nance J: Establishing a safety culture. Read before the Conference on the Role and Responsibility of Physicians to Improve Patient Safety. Arlington, Virginia, September 2001
82. Sheridan TB, Thompson JM: People versus computers in medicine. Human Error in Medicine. Bogner MS, Ed. Lawrence Erlbaum Associates, Inc, Hillsdale, New Jersey 1994, p 141
83. Bates DW, Gawande AA. Improving safety with information technology. N Engl J Med 348:2526, 2003
84. Garg AX, Adhikari NKJ, McDonald H, et al: Effects of computerized clinical decision support systems on practitioner performance and patient outcomes: a systematic review. JAMA 293:1223, 2005
85. Kuperman GJ, Teich JM, Gandhi TK, et al: Patient safety and computerized medication ordering at Brigham and Women's Hospital. Jt Comm J Qual Improv 27:589, 2001
86. Horst HM, Mouro D, Hall-Jenssens RA, et al: Decrease in ventilation time with a standardized weaning process. Arch Surg 133:483, 1998
87. Koppel R, Metlay JP, Cohen A, et al: Role of computerized order entry systems in facilitating medication errors. JAMA 293:1197, 2005
88. Audet AJ, Doty M, Shamasdin J, et al: Measure, learn, and improve: Physicians' involvement in quality improvement. Health Aff (Millwood) 24:843, 2005
89. Spencer FC: Human error in hospitals and industrial accidents: current concepts. J Am Coll Surg 191:410, 2000
90. Bagian JP, Gosbee J, Lee CZ, et al: The Veterans Affairs root cause analysis system in action. Jt Comm J Qual Improv 28:531, 2002
91. Needleman J, Buerhaus P, Mattke S, et al: Nurse staffing levels and the quality of care in hospitals. N Engl J Med 346:1715, 2002
92. Aiken LH, Clarke SP, Sloane DM, et al: Hospital nurse staffing and patient mortality, nurse burnout, and job dissatisfaction. JAMA 288:1987, 2002
93. Vincent C. Understanding and responding to adverse events. N Engl J Med 348:1051, 2003
94. Karson AS, Bates DW: Screening for adverse events. J Eval Clin Pract 5:23, 1999
95. Liang L. The gap between evidence and practice. Health Aff (Millwood) 26:w119, 2007
96. Platt R. Speed bumps, potholes, and tollbooths on the road to panacea: Making best use of data. Health Aff (Millwood) 26:w153, 2007
97. Latino RJ: Automating root cause analysis. Error Reduction in Health Care: A Systems Approach to Improving Patient Safety. Spath PL, Ed. Jossey-Bass, San Francisco, 2000, p 155
98. Becher EC, Chassin MR: Taking back health care: the physician's role in quality improvement. Acad Med 77:953, 2002
99. Patient Safety Manual, 3rd ed. Manuel BM, Ed. American College of Surgeons, Chicago, 2001
100. Calland JF, Guerlain S, Adams RB, et al: A systems approach to surgical safety. Surg Endosc 16:1005, 2002
101. Making Health Care Safer: A Critical Analysis of Patient Safety Practices. Evidence Report/Technology Assessment No. 43. Pub. No. 01-E058. Agency for Healthcare Research and Quality, Rockville, Maryland, 2001
102. Shojania KG, Duncan BW, McDonald KM, et al: Safe but sound: patient safety meets evidence-based medicine. JAMA 288:508, 2002
103. Leape LL, Berwick DM, Bates DW: What practices will most improve safety? Evidence-based medicine meets patient safety. JAMA 288:501, 2002
104. Feldman SE, Roblin DW: Accident investigation and anticipatory failure analysis in hospitals. Error Reduction in Health Care: A Systems Approach to Improving Patient Safety. Spath PL, Ed. Jossey-Bass, San Francisco, 2000, p 139
105. Eichhorn JH: Prevention of intraoperative anesthesia accidents and related severe injury through safety monitoring. Anesthesiology 70:572, 1989
106. Sentinel events: approaches to error reduction and prevention. Jt Comm J Qual Improv 24:175, 1998
107. Orkin FW: Patient monitoring in anesthesia as an exercise in technology assessment. Monitoring in Anesthesia, 3rd ed. Saidman LJ, Smith NT, Eds. Butterworth-Heinemann, London, 1993
108. Chassin M: Is health care ready for Six Sigma quality? Milbank Q 76:565, 1998
109. Hyman WA: Errors in the use of medical equipment. Human Error in Medicine. Bogner MS, Ed. Lawrence Erlbaum Associates, Inc, Hillsdale, New Jersey, 1994, p 327
110. Samore MH, Evans RS, Lassen A, et al: Surveillance of medical device-related hazards and adverse events in hospitalized patients. JAMA 291:325, 2004
111. Small SD: Medical device-associated safety and risk. Surveillance and stratagems. JAMA 291:367, 2004
112. Strasberg SM, Ludbrook PA: Who sees innovative practice? Is there a structure that meets the monitoring needs of new techniques? J Am Coll Surg 196:938, 2003
113. O'Connor GT, Plume SK, Olmstead EM, et al: A regional intervention to improve the hospital mortality associated with cardiopulmonary bypass surgery. JAMA 275:841, 1996
114. Keller RB, Griffin E, Schneiter EJ, et al: Searching for quality in medical care: the Maine Medical Assessment Foundation model. Pub. No. 00-N002. Agency for Healthcare Research and Quality, Rockville, Maryland, 2000
115. Shively EH, Heine MJ, Schell RH, et al: Practicing surgeons lead n quality care, safety, and cost control. Ann Surg 239:752, 2004
116. Flum DR, Fisher N, Thompson J, et al: Washington State's approach to variability in surgical processes/outcomes: Surgical Clinical Outcomes Assessment Program (SCOAP). Surgery 138:821, 2005
117. Hyman NH, Ko CY, Cataldo PA, et al: The New England colorectal cancer quality project: a prospective multi-institutional feasibility study. J Am Coll Surg 202:36, 2006
118. Dellinger EP, Hausmann SM, Bratzler DW, et al: Hospitals collaborate to decrease surgical site infection. Am J Surg 190:9, 2005
119. Collins TC, Daley J, Henderson WH, et al: Risk factors for prolonged length of stay after major elective surgery. Ann Surg 230:251, 1999
120. Khuri SF, Daley J, Henderson W, et al: Relation of surgical volume to outcome in eight common operations: results from the VA National Surgical Quality Improvement Program. Ann Surg 230:414, 1999
121. Davis JW, Hoyt DB, McArdle MS, et al: An analysis of errors causing morbidity and mortality in a trauma system: a guide for quality improvement. J Trauma 32:660, 1992
122. Cohn LH, Rosborough D, Fernandez J: Reducing costs and lengths of stay and improving efficiency and quality of care in cardiac surgery. Ann Thorac Surg 64:S58, 1997
123. Galvin RS: The business case for quality. Health Aff (Millwood) 20:57, 2001
124. Porter ME, Teisberg EO. Redefining Health Care. Creating Value-Based Competition on Results. Harvard Business School Press, Boston, 2006
125. Orlander JD, Barber TW, Fincke BG: The morbidity and mortality conference: the delicate nature of learning from error. Acad Med 77:1001, 2002
126. Thompson JS, Prior MA: Quality assurance and morbidity and mortality conference. J Surg Res 52:97, 1992
127. McGreevy J, Otten T, Poggi M, et al: The challenge of changing roles and improving surgical care now: Crew resource management approach. Am Surg 72:1082, 2006
128. Hutter MM, Rowell KS, Devaney LA, et al: Identification of complications and deaths: An

assessment of the traditional surgical morbidity and mortality conference compared with the American College of Surgeons-National Surgical Quality Improvement Program. J Am Coll Surg 203:618, 2006
129. Goldfarb MA, Baker T. An eight-year analysis of surgical morbidity and mortality: data and solutions. Am Surg 72:1070, 2006
130. Pine M, Fry DE. Linking processes and outcomes to improve surgical performance. A new approach to morbidity and mortality peer review. Am Surg 72:1115, 2006
131. Miller MR, Pronovost P, Donlithan M, et al: Relationship between performance and accreditation: Implications for quality of care and patient safety. Am J Med Qual 20:239, 2005
132. Coye MJ: No Toyotas in health care: why medical care has not evolved to meet patient's needs. Health Aff (Millwood) 20:44, 2001
133. Rhodes RS, Biester TW, Ritchie WP, et al: Continuing medical education activity and American Board of Surgery examination performance. J Am Coll Surg 196:604, 2003
134. Norcini JJ, Lipner RS: The relationship between the nature of practice and performance on a cognitive examination. Acad Med 75:S68, 2000
135. Tamblyn R, Abrahamowicz M, Dauphinee WD, et al: Association between licensure examination scores and practice in primary care. JAMA 288:3019, 2002
136. Sharp LK, Bashook PG, Lipsky MS, et al: Specialty Board certification and clinical outcomes: the missing link. Acad Med 77:534, 2002
137. Davis DA, Thomson MA, Oxman AD, et al: Changing physician performance: a systematic review of the effect of continuing medical education strategies. JAMA 274:700, 1995
138. Davis, DA, O'Brien MJT, Freemantle N, et al: Impact of formal continuing medical education: do conferences, workshops, rounds, and other traditional activities change physician behavior or health care outcomes? JAMA 282:867, 1999
139. Mazmanian PE, Davis DA: Continuing Medical Education and the physician as learner: guide to the evidence. JAMA 288:1057, 2002
140. Ferraco K, Spath PL. Measuring performance of high risk processes. in Error Reduction in Health Care: A Systems Approach to Improving Patient Safety. Spath PL, Ed. Jossey-Bass, San Francisco, 2000, p 17
141. Shekelle PG, Ortiz E, Rhodes S, et al: Validity of the Agency for Healthcare Research and Quality clinical practice guidelines: how quickly do guidelines become outdated? JAMA 286:1461, 2001
142. Livingston EH, Harwell JD: Peer review. Am J Surg 182:103, 2001
143. Rollow W, Lied TR, McGann P, et al: Assessment of the Medicare quality improvement organization program. Ann Intern Med 145:342, 2006
144. Snyder C, Anderson G. Do Quality Improvement Organizations improve the quality of care for Medicare beneficiaries? JAMA 293:2900, 2005
145. Caplan RA, Posner KL, Cheney FW: Effect of outcome on physician judgments of appropriateness of care. JAMA 265:1957, 1991
146. Andrews LB, Stocking C, Krizek T, et al: An alternative strategy for studying adverse events in medical care. Lancet 349:309, 1997
147. Lang NP: Professional liability, patient safety, and first do no harm. Am J Surg 182:537, 2002
148. Manuel BM: Double-digit premium hikes: the latest crisis in professional liability. Bull Am Coll Surg 86:19, 2001
149. Studdert DM, Mello MM, Sage WM, et al: Defensive medicine among high-risk specialist physicians in a volatile malpractice environment. JAMA 293:2609, 2005
150. Budetti PP. Tort reform and the patient safety movement: seeking common ground. JAMA 293:2660, 2005
151. Once seen as risky, one group of doctors changes its ways. Wall Street Journal, June 21, 2005
152. Stewart RM, Corneille MG, Johnston J, et al: Transparent and open discussion of errors does not increase malpractice risk in trauma patients. Ann Surg 243:645, 2006
153. Kesselheim AS, Ferris TG, Studdert DM: Will physician-level measures of clinical performance be used in medical malpractice litigation? JAMA 295:1831, 2006
154. Brennan TA: Physicians' responsibility to improve the quality of care. Acad Med 77:973, 2002
155. Berwick DM: Quality of health care. Part 5: payment by capitation and the quality of care. N Engl J Med 335:1227, 1996
156. Measuring the Quality of Health Care: A Statement by the National Roundtable on Health Care Quality. Donaldson MS, Ed. National Academy Press, Washington, DC, 1999
157. Shine KI: Health care quality and how to achieve it. Acad Med 77:91, 2002
158. Clarke JR: Making surgery safer. J Am Coll Surg 200:229, 2005
159. Leape LL: Reporting of adverse events. N Engl J Med 347:1633, 2002
160. Leape LL, Bates DW, Cullen DJ, et al: Systems analysis of adverse drug events. ADE Prevention Study Group. JAMA 274:35, 1995
161. Pennachio D: Error reporting does a turn around. Hosp Peer Rev 23:121, 1998
162. Andrus CH, Villasenor EG, Kettelle JB, et al: "To Err is Human": Uniformly reporting medical errors and near misses, a naïve, costly, and misdirected goal. J Am Coll Surg 196:911, 2003
163. Roscoe LA, Krizek TJ: Reporting medical errors: variables in the system shape attitudes toward reporting. Bull Am Coll Surg 87:12, 2002
164. Layde PM, Cortes LM, Teret SP, et al: Patient safety efforts should focus on medical injuries. JAMA 287:1993, 2002
165. McNutt RA, Abrams R, Aron DC: Patient safety efforts should focus on medical errors. JAMA 287:1997, 2002
166. Werner RM, Asch DA: The unintended consequences of publicly reporting quality information. JAMA 293:1239, 2005
167. Galvin R: Pay-for-performance: too much of a good thing? A conversation with Martin Roland. Health Aff (Millwood) 25:w412, 2006
168. Grissom TL: Comments during panel discussion at invitational conference on Contemporary Surgical Quality, Safety, and Transparency. Am Surg 72:1024, 2006
169. Heget JR, Bagian JP, Lee CZ, et al: John M. Eisenberg Patient Safety Awards. System innovation: Veterans Health Administration National Center for Patient Safety. Jt Comm J Qual Improv 28:66, 2002
170. Volpp KGM, Grande D: Residents' suggestions for reducing errors in teaching hospitals. N Engl J Med 348:851, 2003
171. Hugh TB: New strategies to prevent laparoscopic bile duct injury—surgeons can learn from pilots. Surgery 132:826, 2002
172. Gawande A: The learning curve. New Yorker, January 28, 2002, p 52
173. Clarke JR: How a system for reporting medical errors can and cannot improve patient safety. Am Surg 72:1088, 2006
174. Enthoven AC, Tollen LA: Competition in health care: it takes systems to pursue quality and efficiency. Health Aff (Millwood) 24(suppl 3):w5, 2005
175. Codman EA: A Study in Hospital Efficiency. Joint Commission on Accreditation of Healthcare Organizations, Oakbrook Terrace, Illinois, 1996
176. Robinson AR, Hohmann KB, Rifkin JI, et al: Physician and public opinions of quality of health care and the problem of medical errors. Arch Intern Med 162:2186, 2002
177. Etchells E, O'Neill C, Bernstein M: Patient safety in surgery. World J Surg 27:936, 2003
178. Cuschieri A: Nature of human error: implications for surgical practice. Ann Surg 244:642, 2006
179. Gallagher TH, Waterman AD, Ebers AG, et al: Patients' and physicians' attitudes regarding the disclosure of medical errors. JAMA 289:1001, 2003
180. Birkmeyer NJ, Share D, Campbell DA Jr, et al: Partnering with payers to improve surgical quality: the Michigan plan. Surgery 138:815, 2005
181. Russell T: Safety and quality in surgical practice. Ann Surg 244:653, 2006
182. Polk HC: Presidential address: quality, safety, transparency. Ann Surg 242:293, 2005

Selected Reading

Human Error in Medicine. Bogner MS, Ed. Lawrence Erlbaum Associates, Inc, Hillsdale, New Jersey, 1994
Perrow C: Normal Accidents. Living with High-Risk Technologies. Princeton University Press, Princeton, New Jersey, 1999.
Error Reduction in Health Care: A Systems Approach to Improving Patient Safety. Spath PL, Ed. Jossey-Bass, San Francisco, 2000

Acknowledgment

Figure 1 Seward Hung.