# 6 Improving Patient Safety

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This chapter includes an accompanying lecture presentation that has been prepared by the authors: Video 6.1.

## KEY CONCEPTS

- Medical errors have a large impact on the field of neurosurgery, affecting quality and cost tremendously.
- Errors in neurosurgery can lead to preventable and nonpreventable adverse events.
- A systems approach is critical to improving patient safety in neurosurgery in order to identify deficits in the system, rather than the individual neurosurgeon.
- Incident reports, morbidity and mortality conferences, claims data, registries, and electronic medical record reports are all sources of data for error analysis.
- Mechanisms for improving patient safety include root cause analyses that investigate systemic causes of adverse events, preoperative checklists, and postoperative debriefing to ensure adequate communication during transitions in care.
- Surgical site infections are a common neurosurgical complication, and often can be prevented with antibiotic prophylaxis.
- There is a well-known relationship between operative volume and positive surgical outcomes.

Physicians routinely dedicate their time, skills, and expertise to their patients, helping to prevent illness and restore health. Despite the best efforts of health care workers, however, many patients are unintentionally injured by the very medical system from which they seek help. Understanding why these injuries happen, how they happen, and how we can prevent them from happening forms the core of the patient safety movement in contemporary medicine.

## EPIDEMIOLOGY OF PATIENT SAFETY

The modern patient safety movement arguably coalesced in the wake of the 2000 publication of *To Err Is Human* (taken from Seneca's Latin phrase *errare humanum est*) by the National Academy of Medicine (formerly the Institute of Medicine).[1,2] This decidedly influential report drew on the 1991 Harvard Medical Practice Study[3] and estimated that between 44,000 and 98,000 Americans were killed yearly by medical errors. This shockingly high figure spawned the evocative "jumbo jet" analogy—deaths caused by medical errors were numerically equivalent to one passenger jet crashing daily. More recent studies, following the Harvard Medical Practice Study, have adjusted the estimate of those killed by errors even higher, at 210,000 to 440,000.[4]

The early report by the National Academy of Medicine stoked renewed national interest in patient safety, and a large contingent of researchers, physicians, nurses, and administrators have invested heavily in identifying and preventing such errors.[2] Medication errors have been reduced through computerized provider order entry,[5] an increase in clinical pharmacists,[6-9] medication reconciliation,[10-12] and bar-code scanning.[13-15] Hospital-acquired infections have been reduced through standardized protocols for central line placement,[16-18] daily "sedation vacations" to reduce ventilator-associated pneumonia,[19,20] and timely use of perioperative antibiotics to prevent surgical site infections (SSIs).[21,22] Surgical errors are reduced by time-out procedures,[23,24] instrument counts,[25,26] site marking,[27] and other standardized procedures.[28-32]

Yet the size and impact of medical errors remain vast. Medication errors are perhaps the best documented. By some estimates, 5% of all hospital admissions are due to adverse events related to medications,[2] and at least 5% of all hospitalized patients experience at least one adverse drug event.[33] Cost estimates place ambulatory medication errors at \$5 billion yearly[34] and inpatient errors at \$16.4 billion yearly.[2,35]

Surgical adverse events are also unfortunately common. An estimated 3% of all surgical patients experience an adverse event in the perioperative period, half of which are preventable.[36] In neurosurgical patients specifically, 14.3% have at least one complication.[37] Roughly 1 in every 100,000 operations involves the wrong site or wrong patient, and the wrong side is operated on in 2.2 of every 10,000 craniotomies.[38] A recent poll of neurosurgeons revealed that 25% reported making an incision on the wrong side of the head, and 35% reported wrong-level lumbar surgery during their career.[39] Retained instruments and sponges occur in about 1 in every 5500 to 10,000 operations.[2] The economic cost of these errors is high. Analysis of the National Practitioner Data Bank shows \$1.3 billion in settlements alone between 1990 and 2010.[40] This does not include the 90% of patients who do not receive payments and are not included in the database. A single wrong-site surgery has an average payout of \$127,159, and that for a retained foreign body is \$86,247.[41] More troubling, the number of these events appears to be increasing over time.[42]

Infections are another source of preventable harm. As many as 1 in 10 patients will develop an iatrogenic infection, according to the Centers for Disease Control and Prevention.[2,43] Some estimates place the number of resulting deaths from iatrogenic infections at 100,000 annually, with costs of around \$40 billion.[2,43]

## ADVERSE EVENTS AND ERRORS

There are many ways in which the medical field can inadvertently harm patients. The following taxonomy was developed to categorize these types of events[2] (Figure 6.1).

*Adverse events* are inadvertent injuries resulting from medical care, or the failure to deliver appropriate care. The Institute for Healthcare Improvement (IHI) further defines adverse events as "unintended physical injury resulting from or contributed to by medical care (including the absence of indicated medical treatment) that requires additional monitoring, treatment, or hospitalization, or that results in death."[2]

Adverse events can further be split into *preventable adverse events* and *nonpreventable adverse events. Nonpreventable* adverse events include accepted surgical complications, such as the risk of

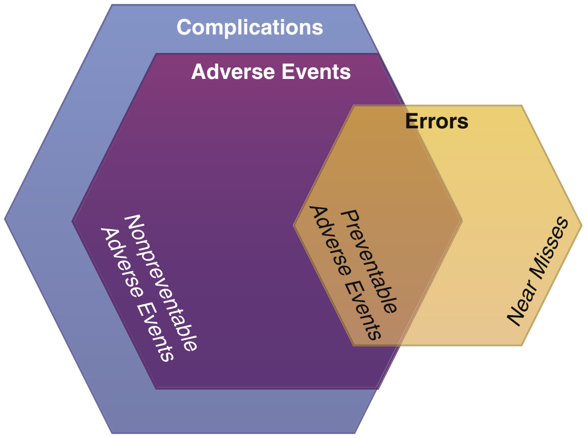


**Figure 6.1.** Diagram depicting patient safety terminology.

hemorrhage with external ventricular drain placement, and some medication side effects, such as the increased risk of hyperglycemia with high-dose dexamethasone. *Preventable* adverse events, on the other hand, include harm caused by clear errors, such as wrong-side and wrong-level surgery, or failure to offer standard treatment, such as neglected deep venous thromboembolism prophylaxis in surgical patients.

*Complications*, a common term in surgical specialties, are less well defined but are probably best understood as including all adverse events, both preventable and nonpreventable, but also including harm directly related to the disease rather than from medical care associated with the disease. An example of a complication would include an intracranial hemorrhage associated with a brain tumor, even if it happened outside the hospital and without medical care contributing at all to its occurrence (i.e., an inevitable "complication" of the disease).

*Errors* are acts or omissions that lead to undesirable outcomes or have a high potential for such an outcome. Thus errors overlap with preventable adverse events but crucially include events that cause no harm (so-called near misses or close calls). That is, some errors by health care workers are detected by the health care system and prevented from injuring the patient, such as incorrectly ordered medication doses or medication cross-reactions caught by computerized provider order entry systems or clinical pharmacists.

Errors can be further broken down into *active errors* (or "sharp end" errors) and *latent errors* (or "blunt end" errors) (Table 6.1). Active errors are errors that occur when the patient is in contact with health care personnel, are usually readily apparent, and almost always involve a health care worker on the front line. Latent errors refer to less apparent failures of the organization or design that allow harm to come to patients. An example is chemotherapy being infused at the wrong rate. The active error would be a nurse programming the wrong rate into the intravenous (IV) pump. A latent error would be the health care system or organization using multiple types of IV pumps, thus leading to increased nursing confusion and the increased probability of an adverse event occurring.

Active errors have been extensively studied in psychology, and many subdivisions have been proposed to further delineate errors and identify common mechanisms. Examples are James Reason's classification of active errors into *slips* and *mistakes*.[44] Slips occur when an intended action is carried out imperfectly—as in literally slipping with a scalpel while operating, and damaging uninvolved tissue. Thus slips occur as a result of lapses of concentration or failures of schematic behaviors, and can happen in the face of competing distractions, fatigue, and stress. Mistakes occur when the wrong action is selected, even if carried out perfectly. Mistakes are failures of active problem solving resulting from incorrect judgment, lack of knowledge or skills, or intentional failure to adhere to common standards. A classic example is wrong-side or wrong-level surgery.

**TABLE 6.1** Systems View for Sources of Errors

| Level | Examples |
|---|---|
| Governmental | • Federal laws and regulations (e.g., EMTALA, Affordable Care Act)<br>• US Food and Drug Administration requirements and reporting<br>• Centers for Disease Control and Prevention reporting<br>• The Joint Commission regulations<br>• Occupational Safety and Health Administration regulations |
| Institutional | • Medication formulary decisions<br>• Hiring and staff sizes<br>• Shift length and timing policies |
| Infrastructure | • Electronic medical record system<br>• Building and facility layout<br>• Equipment and facility maintenance |
| Team | • Ease of physical communication (pager, phone, e-mail, etc.)<br>• Frequency of interactions<br>• Formalized procedures for information exchange (e.g., SBAR)<br>• Hierarchy and ability to question plans |
| Individual health care worker | • Medical knowledge base<br>• Physical and mental health<br>• Institutional knowledge base (i.e., ability to navigate the current system) |
| Individual patient | • Complexity of case<br>• Language and communication barriers<br>• Social or personality barriers<br>• Health literacy |

Errors can be latent or active (see text). Latent errors occur at a variety of levels, from governmental regulations to hospital policies that increase the risk of a patient experiencing an adverse event. Active errors occur at the system's "sharp end," where a health care worker makes a slip or mistake. However, most active errors occur in a background of latent errors. Latent errors are a major contributor to adverse events, and arguably have more impact in protecting patients than individual practitioners.

*EMTALA,* Emergency Medical Treatment and Labor Act; *SBAR,* situation, background, assessment, and recommendation.

More complex divisions of errors include the classification by the National Coordinating Council (NCC) for Medication Error Reporting and Prevention, which divides errors into nine classes (A through I) determined by how much harm, if any, was caused.[2] The NCC classification is notable, however, for dividing errors by their effects, as compared with Reason's classification, which focuses on mechanisms.

## SYSTEMS THINKING

Adverse events and medical errors are costly and common. What is the source of these errors? When prospectively analyzing errors in neurosurgical procedures, in one study only 23.7% to 27.8% were related to the technical skills of the surgeon.[45] The remainder, roughly 75%, involved various other participants in the patient's care—for example, nurses, anesthetists, and equipment technicians.[45]

It is crucial for the surgeon to acknowledge that many errors arise from factors outside his or her direct control. Such

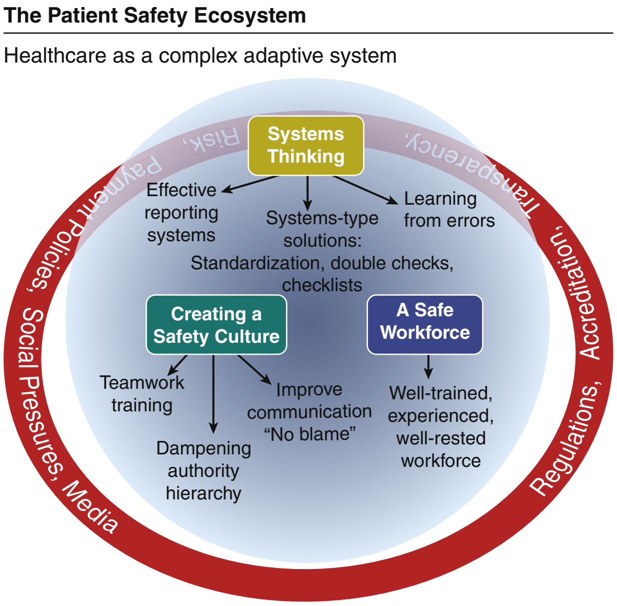


**Figure 6.2.** The "Patient Safety Ecosystem" consists of systems-based approaches to avoid errors, a culture in which open communication is valued, and a well-trained and well-rested workforce. These are created and influenced by a variety of external forces.

observations, which abound across medical specialties, make it clear that improving patient safety requires an analysis of the entire health care system to which a patient is exposed. Thus *systems thinking* is critical.[2,46] Even if a surgeon performs his or her procedure perfectly, only a quarter of errors might be prevented.

Systems thinking has been advocated for patient safety since the publication of *To Err Is Human*. Essentially, a complex system such as medicine produces errors not only through technical mistakes and slips, but also through cultural, social, and organizational problems.[47] All of these domains feed into one another and are interrelated (Figure 6.2). Systems thinking acknowledges that all humans will make mistakes, and these mistakes will occur throughout the health care system. To prevent these inevitable errors from harming patients, the system should be robustly designed to catch these errors and mitigate their harm, which has long been the case in other industries concerned with safety, such as nuclear power and air transportation.[2]

In order to rationally develop processes to address patient safety, two main steps are involved. First, errors and adverse events must be reliably identified and documented. Only when the problem scope is known can limited resources be directed to the most pressing areas. Second, solutions can be proposed to prevent or mitigate adverse events across the extent of the health care system (see Table 6.1). In line with systems thinking, these solutions are not restricted to the "sharp end" of the system—that is, surgeons and other providers directly interacting with the patient—but also can be applied at the "blunt end"—the management, regulations, facilities, and other entities that influence patient care in sometimes dangerous ways.[2]

## TOOLS FOR IMPROVING PATIENT SAFETY

A large variety of tools have arisen to improve patient safety, often targeted to a single previously identified problem (e.g., surgical checklists, site marking). Yet even identifying threats to patient safety in the first place remains challenging. Many strategies exist, such as the Global Trigger Tool, chart reviews, incident reports, and claims data, and all offer tradeoffs between expense, sensitivity, and specificity.

### Finding Errors and Complications

The IHI *Global Trigger Tool* relies on a variety of events that are likely associated with adverse events and errors, such as return to the operating room, intraoperative death, transfer to a higher level of care, readmission to the emergency department after discharge, or naloxone use. Each case that produced one of these events (and set off the "trigger") is then manually analyzed for errors and adverse events. This process is laborious and currently impractical with large patient volumes. However, the sensitivity and specificity are superb, estimated at 94.9% and 100%, respectively.[48]

*Incident reports* are generally unstructured event reports by nurses, physicians, and other health care workers through a paper-based or, increasingly, a computerized hospital-based system. Such reports are not standardized—for example, different workers harbor different thresholds for reporting events. Furthermore, the unrewarded effort in generating reports and frequent failure to "close the loop" and visibly act on reports by the hospital lower the incentive for reporting. Hospital-wide culture also plays a role, with few physicians generally taking part in these systems[49] and large variances existing between floors and even units within floors.

*Morbidity and mortality conferences* are a well-established method of identifying errors and complications in the neurosurgical field.[35,50,51] Benefits include a relatively low-cost method of surveillance that has educational relevance and importance and that allows for self and group reflection on performance. A major limitation to morbidity and mortality conferences is that they traditionally involve physicians focused on individual (and sometimes team) performance. As discussed earlier, there needs to be less of a focus on individual blame and more of a discussion on systems issues and the latent errors that result from these systems-based problems. That being said, individual accountability should also remain important because patient safety is also compromised if there is a lack of individual accountability.

*Automated reports in electronic medical records* may also be used to find errors and complications. This is an active form of surveillance because the user can specify what types of events to look for over what time period. Another advantage is that once these automated reports have been built, little manpower is needed to run them. Drawbacks to this method of surveillance include a heavy reliance on what is documented in the electronic medical record, thus leading to high rates of false-positives that may require manual chart review to validate each event or error. This leads to large amounts of data that must be manually sorted in order to improve the specificity of these reports.

*Claims data* are perhaps the most widely used form of complication detection and reporting in the neurosurgical literature. Many databases exist, such as the Nationwide Inpatient Sample, that are easily obtainable and codify patient complications with International Classification of Diseases, 9th and 10th Revisions (ICD-9, ICD-10) or Current Procedural Terminology (CPT) codes. However, this information is rarely complete (especially with regard to demographic data), and there are serious concerns about the accuracy of this coding, which is rarely done by physicians or health care workers who have physically seen the patient or taken part in the patient's care. Use of structured Agency for Healthcare Research and Quality indicators, which include events such as retained foreign bodies, postoperative wound dehiscence, and postoperative sepsis, was shown to have a high specificity of 98.5% but an abysmal sensitivity of 5.8%, showing that many adverse events are going underreported in such systems.[48]

*Prospective databases and registries* are increasingly used as methods for tracking adverse events associated with medical care. In surgery, the American College of Surgeons National Surgical Quality Improvement Program (NSQIP) database began tracking patients in 2005, and includes data from over 300 participating hospitals.[52,53] Cases are followed for a set of defined complications such as urinary tract infections, strokes, and thromboembolic events. The specially trained personnel responsible for entering data are frequently audited to ensure uniformity and accuracy. In neurosurgical patients, the NSQIP records complications in 14.3% of cases, with cranial patients 2.6 times more likely than spine patients to experience a complication.[37] However, because the NSQIP addresses all surgical specialties, it fails to account for some complications specific to neurosurgery (e.g., spinal fluid leaks). Therefore, several databases dedicated solely to neurosurgery have been created, such as the National Neurosurgery Quality and Outcomes Database[54] and the International Spine Study Group,[55,56] which focuses on spinal deformity research. Although these databases are successful in tracking complications and adverse events, they do not track errors, which is a major limitation.

## Preventing Specific Errors and Complications

One standard method of not only identifying but also preventing subsequent specific errors and complications is through a root cause analysis (RCA). RCAs are typically performed by an interdisciplinary team, and are deliberate and comprehensive dissections of an error in a protected environment to discover all relevant facts to determine the underlying "root causes" of an error. RCA teams also design and implement risk reduction strategies to prevent subsequent similar errors from happening in the future. Lastly, effective RCA teams evaluate their changes over time and communicate the results of such changes to the affected providers.

In addition, many other processes have been developed to address frequent and dangerous medical errors, such as adverse medication events and central line–associated infections. For neurosurgery in particular, three main areas of improvement are notable: preventing wrong-site, wrong-side, and wrong–spinal level surgeries; preventing postoperative infections; and examining volume-outcome relationships.

### Wrong-Site Surgery and Checklists

Neurosurgery is the third most likely specialty to perform a wrong-site or wrong-level surgery, after orthopedic and general surgery.[38,39] Wrong-side and wrong-level surgeries are classified as "sentinel events" by The Joint Commission (formerly "never events") and are reportable to the state in which they occur. When such events occur, they garner serious public scrutiny, cause severe patient harm, and often lead to costly litigation or settlements. The etiology of these adverse events in neurosurgery appears to stem largely from communication breakdown,[38] helping to bolster the argument for formalized time-out procedures and surgical checklists. In addition, improved intraoperative localization using navigational tools and fluoroscopy can help confirm surgical site location intraoperatively.[57]

In response to similar worries across multiple surgical disciplines, the World Health Organization (WHO) developed a Surgical Safety Checklist in 2008 to improve team communication and ensure that critical preoperative steps were carried out.[30,31] The hypothesis was that the WHO formalized protocol would not only prevent wrong-site surgeries but also contribute to the reduction of other surgical complications, such as SSIs, ventilator-associated pneumonia, and unplanned returns to the operating room. A multisite pilot study using the WHO checklist found a 4% reduction in complications and 0.7% reduction in mortality.[31] Subsequently, many neurosurgical programs have adopted similar checklists and time-out procedures[57,58] and have reported a consequent reduction in wrong-site surgeries.[59] The ability to prevent complications other than wrong-site surgery by using checklists has not been directly investigated in neurosurgical procedures, but strong evidence exists across multiple studies involving diverse surgical disciplines.[60] An important lesson of these processes is that the most successful method to prevent wrong-site surgeries is not solely under the control of the surgeon. An entire surgical team must be involved and leveraged to prevent these mistakes, an example of systems thinking. That is, although the surgeon is ultimately responsible for carrying out the wrong-site operation, the best way to prevent these errors in the future is by stepping back to understand the whole system in which the surgeon operates, rather than simply placing all the focus on the system's "sharp end"—the surgeon.

In addition to preoperative checklists, systematic postoperative debriefing has become increasingly common.[61] Studies have demonstrated that postoperative debriefing can reduce morbidity and mortality of procedures and improve operating room efficiency. The goals of postoperative debriefs are to ensure that standardized communication occurs between team members postoperatively and to provide a mechanism for tracking systems issues around operating room inefficiency. These debriefs have been shown to improve surgical team safety awareness and willingness to communicate problems to other members of the team.

### Surgical Site Infections

SSIs are another costly adverse event in neurosurgical patients, occurring in around 1% of cases and more frequently in spine than cranial cases.[37] Many techniques have been proposed to help prevent such infections. Preoperative antibiotics have long been shown to lower the risk of subsequent infection, as long as they are administered in a timely fashion.[62] This likely explains why preoperative checklists (see earlier) lead to reduced SSIs—because they act as reminders for this critical step. Other researchers have looked at techniques such as instilling vancomycin powder into wounds, particularly in spine cases. One study suggested that vancomycin powder can reduce the odds of postoperative infection in spine surgery to 0.19 compared with surgeries without the use of vancomycin powder, but this effect has not been replicated in subsequent studies.[63,64] Other techniques include substitution of cyanoacrylate glue for staples,[65] negative pressure wound therapy,[66] irrigation with saline[67] or antibiotics,[68] and careful control of medical comorbidities such as diabetes.[62,67] In addition, systems approaches, such as limiting the number of providers and visitors in the operating room and shortening the duration of surgery, have been shown to decrease SSI rates.[61] Again, SSIs, like wrong-site surgeries, are best controlled through a systems approach. Checklists, operative techniques, and management of outpatient diseases such as diabetes all contribute to the prevention of disease.

### Volume-Outcome Relationships

Volume-outcome relationships refer to the often-noted effect of reduced morbidity and mortality at centers with high procedural volumes, at least when compared with low-volume centers. This effect has been observed in epilepsy surgery,[69] transsphenoidal surgery,[70] aneurysm surgery,[71] endovascular therapy,[72] carotid endarterectomy,[73] and spine surgery[74,75] (Figure 6.3). The cause is frequently attributed to surgical provider practice, and evidence exists for such learning curves. For example, surgeons performing laparoscopic cholecystectomies have a 1.7% chance of causing an injury on their first surgery, compared with a 0.17% chance on their 50th.[76] Evidence for such learning curve effects exists in recent studies of neurosurgical procedures, such as vestibular schwannoma surgery,[77] transsphenoidal surgery,[78] and transforaminal lumbar interbody fusions.[79] However, another aspect of improving outcomes with higher volumes is dependent on the

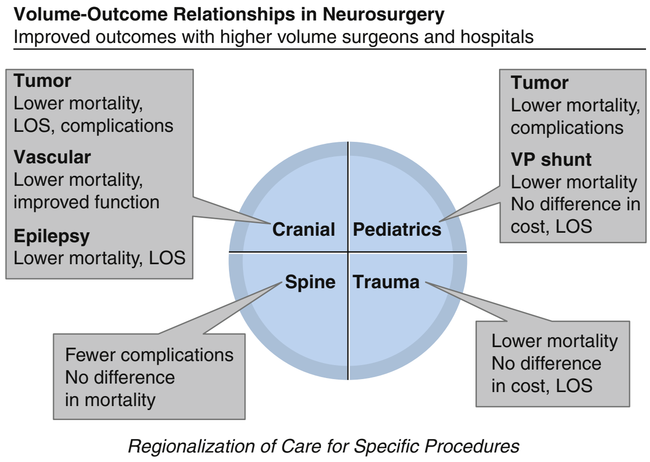


**Figure 6.3. The volume-outcome relationship in neurosurgery.** High-volume surgeons and hospitals have better outcomes with certain procedures, which argues for regionalization of care for several types of neurosurgical operative procedures. *LOS,* Length of stay; *VP,* ventriculoperitoneal.

surrounding system—specialized anesthesia, nursing, hospital policies, scrub technicians, and the like. Again, it is the system as a whole that cares for the patient. To improve the patient's outcome, the entire system must be improved.

## ERAS Pathways

Other mechanisms of standardizing care, such as adoption of Enhanced Recovery After Surgery (ERAS) pathways, have been shown to improve quality by standardizing evidence-based care. ERAS pathways have been implemented in surgical subspecialties such as colorectal surgery, otolaryngology, gynecologic oncology, and spine surgery. There are studies in the neurosurgical spine literature that show that ERAS pathways can decrease costs and increase quality.[80]

## Artificial Intelligence in Neurosurgery

In recent years there has been increased access to large complex data sets, increased computational power, and an advent of sophisticated machine learning algorithms. This has led to the rise of artificial intelligence that uses advanced neural networks to "learn" to perform predictive modeling with neurosurgical applications. These advanced neural networks can be used to elucidate diagnoses, predict outcomes, and prognosticate with promising early results. A study in November 2018 showed that advanced neural networks were able to more successfully predict outcomes of pediatric patients with traumatic brain injury after 6 months than conventional models.[42] Another study in the spine literature showed that future low back pain could be predicted in asymptomatic patients by using artificial neural networks and kinematic measurements.[42] A study showed that preoperative risk stratification could be enhanced by using machine learning algorithms in place of conventional risk stratification approaches, and a study that examined the use of large clinical radiology data sets showed accelerated times to diagnosis of cranial pathology as compared with conventional approaches.[15] These studies show early promise for novel approaches using artificial intelligence to improve diagnostic accuracy and prognostication in neurosurgery.

## CONCLUSION

Medical errors contribute to an alarming number of deaths each year, and neurosurgery is not exempt from this. However, it is not enough for the surgeon to improve his or her technical skills, striving for perfection; nearly three-quarters of neurosurgical errors are due to factors involving the health care system at large. Systems thinking is essential to enhancing patient safety. To improve patient safety, we must first document where errors and adverse events arise, through registries, incident reports, and global trigger tools, and then develop systems-level solutions to help prevent errors and mitigate them as they inevitably occur. As has been acknowledged in numerous other safety-conscious industries, humans will make mistakes. Blaming and shaming such practitioners does little to prevent these errors from recurring. Solutions must come from the system itself, targeting the entire organizational span of surgical practice, to truly improve patient safety. In addition, the clinical culture of health care organizations needs to shift to truly acknowledge the importance of patient safety in order for safer care to be provided to all neurosurgical patients.

### SUGGESTED READINGS

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