Patient harm and preventable error in orthopedic surgery

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ABSTRACT

In 1999, the Institute of Medicine released a report estimating that between 44,000 to 98,000 Americans die each year as a result of medical errors. The frequency of these errors has continued to rise, in addition to the significant patient morbidity and mortality, which give rise to a substantial economic burden. This study used the PubMed database to review the terminology associated with medical errors, the current prevalence of medical errors within orthopaedics, and strategies for prevention. Patient safety is of the utmost importance. Medical errors still occur and efforts should be focused to standardize care processes, improve error reporting, and promote a team based care process to reduce harm and promote patient safety.

Keywords: Preventable harm, Medical error, Orthopaedic Surgery, Surgical risks, Patient Safety

INTRODUCTION

“First, do no harm” is a central tenet of medicine that physicians strive to abide by when treating their patients. However, all too often patients encounter adverse events while navigating the healthcare system. Specifically, these adverse events are defined as an injury to a patient caused by medical management rather than the underlying condition which prolonged the hospitalization, produced disability at the time of discharge, or both.1 The healthcare environment is not without risk, and some adverse events are unavoidable. However, despite the diligence of healthcare professionals to uphold the code of “do no harm”, adverse events were found to occur in 9.2% of all admissions, with an estimated 27.6-43.5% of those events deemed preventable and occurring as a result of medical error.1,2

In 1999, the Institute of Medicine (IOM) released a report estimating that between 44,000 to 98,000 Americans die each year as a result of medical errors.3 Unfortunately, this approximation relied on outdated data and is likely an inaccurate measure of the current prevalence.4 A more recent analysis suggested that between 210,000 and 400,000 deaths per year are attributable to medical errors.4 Furthermore, the prevalence of non-lethal medical errors is estimated to be 10 to 20 times more common than lethal medical errors and could occur 2-4 million times per year.4 The frequency of these errors, in addition to the significant patient morbidity and mortality, give rise to a substantial economic burden with an estimated annual cost exceeding 17 billion dollars.3

Although the IOM report increased awareness of medical errors in the public and government, orthopaedic surgeons had recognized the importance of reducing...
medical errors prior to its release. As early as 1994, initiatives were being implemented to address medical errors in orthopaedics. While these error prevention programs and protocols have shown to be effective at reducing the occurrence of medical errors, the complex nature of the healthcare system creates an environment where complete eradication of errors is difficult. Despite many efforts, including “Sign Your Site” programs and surgical checklists, more than 50% of orthopaedic surgeons reported observing a medical error within the past 6 months, suggesting that medical errors are still highly prevalent within the field. This article reviews terminology associated with medical errors, the current prevalence within orthopaedics, and strategies for prevention.

**Terminology**

Though medical errors are a widely discussed topic, its precise definition remains considerably variable. In their pivotal report, the IOM adopted James Reason’s view of medical error, defining it “as the failure of a planned action to be completed as intended (i.e., error of execution) or the use of a wrong plan to achieve an aim (i.e., error of planning)”.

However, this interpretation neglects errors of omission and therefore may be inadequate to comprehensively describe medical errors. Medical error can also be described as any deviation in a process of care that may or may not cause harm to patients. While this definition is more encompassing, it may be too general. Exemplifying the current variability in definitions, the World Health Organization’s Glossary of Patient Safety Concepts and References lists seven different definitions for medical error.

Discussion of medical errors is often linked with the aforementioned term “adverse event”. Notably, adverse events may occur independently of any error, but when the events are preventable, they are referred to as medical errors. Not all medical errors result in patient injury. In fact, some errors may go unnoticed, while others are recognized but have little risk of patient injury. Medical errors that could have resulted in patient injury, but did not, as a result of chance or intervention, are referred to as “near misses”.

As medical errors can go unnoticed or have no discernable effect on patient outcome, the true rate of occurrence is difficult to ascertain. Consequently, research into medical errors has focused on the rate of adverse events, quantified through analysis of bad outcomes and thus is a much easier metric to quantify. However, this approach drastically underestimates the true prevalence of medical errors as many do not have a measureable effect on outcome. Research utilizing self-reporting or participant observation of errors have found higher error rates than methods looking only at chart reviews of identifiable adverse events. Though self-reporting and observation may yield a more accurate insight into the actual rates, these assessments have relatively low reliability, and better methods are needed to accurately measure the true incidence of medical errors.

**Current errors in surgery**

The majority of adverse events are associated with surgical providers. A systematic review found potentially preventable adverse events occurring in 5.2% of surgical patients, arising from non-operative management as well as surgical technique. However, the type and frequency of surgical errors are not homogenous throughout all surgical fields. Each specialty and subspecialty is predisposed towards particular errors. For instance, errors in testing and surgical planning were found to occur much more frequently in ENT, whereas communication and equipment related errors occurred more often in orthopaedics. Furthermore, within orthopaedics, surgeries involving the knees and hands were found to have the highest frequency of errors, both at 35% each, followed by foot/ankle procedures at 15%.

A medical error of particular significance is wrong-site surgery. This devastating error can result in significant patient morbidity and is often indefensible for the surgical team. Unsurprisingly, 84% of wrong site surgeries result in indemnity payments. Though wrong site surgery is an issue across all surgical disciplines, it is especially prevalent within orthopaedic surgery. Orthopaedic surgeons have been shown to perform higher numbers of wrong site surgery than all other specialties.

The frequency of wrong-site errors can be broken down by anatomical location. Among hand surgeons, 21% reported to have performed wrong site surgery at least once within their career. The area associated with the highest occurrence of wrong-site surgery among hand surgeons was the finger (63%), followed by the wrist (9%), and hand (8%). Notably, the incidence of wrong-site surgery was also found to occur more often with increasing age of the surgeon and higher volume of surgeries. Within these occurrences, 38% resulted in legal action or settlement. Among foot/ankle surgeons, 13% claimed to have performed wrong-site surgery at least once in their career. Of all the foot/ankle surgeons polled, 75% indicated that they personally mark the correct surgical site prior to surgery, leaving the other 25% between usually and never mark. Within these foot/ankle wrong-site surgery reports, 51% resulted in legal action and/or monetary settlement.

Within spine surgery, wrong site surgery often manifests itself as “wrong level surgery”. Wrong level/part surgery is defined as a surgical procedure performed at the correct site but at the wrong level or part of the operative field. Wrong level surgeries not only fail to resolve the clinical symptoms and pathology but may also necessitate revision operations, contributing to both additional healthcare costs and further patient harm.
Unsurprisingly, these errors often result in litigation. In fact, a study of 69 wrong level surgeries, 99% resulted in litigation, of which 54% were settled out of court resulting in indemnity payments from $62,000-$1,500,000. Unfortunately, these errors are not uncommon. Whereas 1 in 5 hand surgeons have reported performing wrong site surgery, 50% of spine surgeons have reported at least 1 wrong level surgery throughout their career. The actual incidence is difficult to ascertain based on the current literature. Nevertheless, it has been estimated that wrong level spine surgeries occur 1 in every 3,110 procedures, 9 times more prevalent than wrong site hand surgery (1 in 27,686). However, differences in protocol, non-adherence to those protocols, as well as underreporting of adverse events make the actual frequency of surgical errors, including wrong-site surgery, hard to accurately quantify.

Near misses in wrong-site surgery are also not infrequent. Among hand surgeons, 16% reported to have prepared to operate on the wrong site but corrected the error before the initial incision was made. 23% of foot/ankle surgeons reported the same near-miss occurring at least once within their career. Despite the surgeon correcting themselves prior to incision, the fact that the patient’s incorrect anatomical area was prepared and ready for surgery is sufficient cause for alarm. It is due to the continued recurrence of these errors performed within all surgical specialties worldwide that has brought wrong-site surgery to the forefront of new implementation measures for increased surgical patient safety.

Root cause of medical errors

Surgical outcomes are often seen to be dependent on the patient’s condition and comorbidities going into the surgery, as well as the skill and performance of an individual surgeon. While these are undoubtedly important factors to consider when examining surgical outcomes, they provide an incomplete list. Using this approach, it is logical to blame the physician when errors do occur. However, it is becoming quite apparent that errors occurring within complex systems are rarely a result of individual failure but rather multifactorial system failures. James Reason proposes that errors often occur as a result of latent conditions and active failures. Latent conditions are flaws within the system that lead to downstream errors. Understaffing, time pressure, fatigue, and inexperience, while not errors by themselves, create an environment that is prone to error and can be seen as “accidents waiting to happen.” These latent conditions often lead to active failures, which are unsafe acts committed by those in direct contact with the patient or system. Humans, by their nature, are fallible, and therefore prone to error. However, system failures can facilitate error occurrence, making it crucial to look past the active failure when examining medical errors and identify the system flaws that contribute to its occurrence.

Systemic factors, often outside of the surgeon’s control, can be major contributing factors to medical errors. The operating room is a high activity environment full of distractions, which contribute to a variety of errors. External factors such as OR scheduling errors, often committed well in advance of surgery, can also be significant contributing factors to error. One study found booking errors occurred 0.86% of the time, with 36% of those errors being wrong side, 25% incomplete, and 9% wrong procedure bookings. In orthopaedics, equipment and OR set up is often tailored to the procedure being performed. Any errors in scheduling may result in the wrong equipment or incorrect theater arrangement, necessitating changes and delays. Other surgical disciplines have similar problems, and a study of surgical errors in the Veterans Health Administration found 8% of errors to be due to OR scheduling problems.

Looking past the system versus individual classification of medical errors, there has been much investigation into the identifiable causes of medical errors. The team-based approach to healthcare, which involves multiple players working together to ensure the best patient outcome, is prone to communication failures which also occur more frequently than previously recognized. One study examining communication in the operating room found communication failure occurred in 30% of team exchanges. 36.4% of these failures altered system processes, which could have placed the patient at risk of an adverse event. Looking at all surgical specialties, communication breakdowns were associated with 21-43% of all errors. In orthopaedics specifically, 24.7% of all errors were classified as communication failures, one third of which resulted in a negative patient outcome. When investigating wrong site surgery, an all too common error within orthopaedics, communication was found to be the root cause in 48.6% of wrong site errors. The same study found 100% of wrong patient surgeries to be a result of communication errors.

Surgical technique is also commonly cited as a source of error. A survey of surgeons across multiple disciplines found that surgical technique was associated with 63.5% of errors. In orthopaedic surgery, 13% of all errors were classified as errors in technique. While multiple factors may contribute to a technical error, perhaps most important are surgical skill and experience. It is well established that high volume surgeons tend to have better outcomes with reduced complication rates. Unsurprisingly, inexperience is often cited as a contributing factor to error. Lack of competence in a surgical task is another common source of error and while it is evident that surgical skill or competence is undoubtedly an important component in the prevention of technical errors, it has been historically difficult to measure and quantify its impact on outcomes and error.

Surgeon fatigue may also play a role. One study found sleep deprived surgeons made 20% more errors in a
laparoscopic simulator than those who were well rested. Studies of orthopaedic residents found those who were fatigued or sleep deprived had an increased risk of error compared with those who were well rested. However, several other studies have found no significant differences in outcomes of sleep-deprived surgeons and their well-rested counterparts. While the effect of fatigue on surgical technique needs further elucidation, the effect of fatigue on cognitive performance is well established.

**Current initiatives**

In 1997, the American Academy of Orthopaedic Surgeons Task Force on Wrong Site Surgery published a report that brought attention to the frequency and likelihood of surgeries (of all disciplines) performing wrong site surgery. In the report, orthopaedic surgeons in particular were estimated to have a 25% chance of performing a wrong site surgery at least once in a 35-year career. The results prompted the AAOS to respond the following year with the formation of the ‘Sign Your Site’ campaign, a voluntary program with the aim of eliminating these errors from occurring. The campaign was a relative success with 70% of orthopaedic hand surgeons having reported awareness of ‘Sign Your Site,’ and 45% having changed their practice habits as a result. However, fewer numbers of hand surgeons from other surgical disciplines (plastics and general) reported awareness of the “Sign Your Site” program indicating that the campaign of ‘sign your site’ needed to be more widely disseminated to other surgical disciplines.

In 2004, surgical site marking became part of a broader initiative by The Joint Commission (TJC) called the Universal Protocol (UP). The UP was able to both reach a broader audience and also ensure adherence from surgeons and staff by mandating UP adoption to maintain or receive TJC accreditation status. This provided a continuity standard for all surgical centers involved and leads to widespread implementation of the UP.

The Universal Protocol comprises three parts: a pre-procedure verification process, site marking, and a time out. All parts must be completed prior to the procedure, with the time out occurring in the operating room before the incision is made. The UP ensures all members involved in the surgery are in accordance of what the procedure is, who it is on, and where it is taking place anatomically. While all members of the surgical team are involved in the process, it is the surgeon who ultimately must ensure all precautions outlined in the UP have been correctly performed before proceeding with the initial incision. However, a surgical safety survey conducted by the AAOS in 2011 revealed a considerable number of orthopaedic surgeons had insufficient knowledge of the UP and safety processes, despite their common use in the OR.

As with all systems, each step of the UP is prone to some form of error. Various factors, including mislabeling of diagnostic tests, mix-up of patients with similar or identical names, or wrong side dictations from an earlier clinic note may impair the pre-procedure verification process. In addition, the ritualistic and repetitious manner in which the UP is enacted can potentially cause surgical staff members to become disengaged and unfocused while aspects of the UP are being carried out. Some steps may be rushed, while others are ignored completely. It has been shown that, despite being a mandatory step in the UP, pre-surgical “time outs” only occur in 89.7% of cases. In 18.4% of cases, at least one member of the surgical team is inattentive during the timeout. Perhaps most surprising, despite UP implementation, the surgical site remains unmarked in 8.2% of cases.

The data supporting the overall effectiveness of the UP in preventing surgical errors of ‘wrong site, wrong-patient, wrong-procedure’ is mixed. In a retrospective analysis of non-spine wrong-site operations performed, 63% were found to potentially avoidable if the UP had been implemented. Among neurosurgeons, UP implementation has been shown to decrease the rate of wrong-site surgery. However, another study reported that wrong-site surgery among orthopaedic surgeons was not found to be significantly different when comparing the rates before and after implementing the UP. Despite these varying results in the literature, it is clear that wrong-site surgery has continued to occur in spite of UP implementation in accredited hospitals for over a decade.

Although it is challenging to quantify the effect of any single initiative on the rate of medical errors, the increased awareness and commitment within the healthcare community towards improving quality of care and promoting patient safety have resulted in overall favorable progress over the years. The Department of Health and Human Services reported an estimated 1.3 million hospital acquired patient conditions and 50,000 hospital patient deaths were avoided/reduced within the years 2011 to 2013, due to concerted efforts from hospitals around the country to reduce adverse events and increase quality of care provided. This equated to approximately $12 billion in saved health care costs.

**Future directions**

It has been over a decade since the Institute of Medicine released To Err Is Human, which highlighted the high prevalence of medical errors within the healthcare system. Since then, both healthcare professionals and government officials have worked to establish programs to promote patient safety. Despite growing progress, patient harm continues to occur due to errors, necessitating continuous patient pathway improvements in healthcare.
A key aspect of patient safety is process standardization. Pre, intra, and postoperative protocols must be designed with safeguards to prevent errors. Once these protocols are established, they must be executed with minimal deviation to maximize patient safety. Currently, there are widespread efforts to standardize the patient care process. In surgery, many of these efforts, including the Universal Protocol, involve the preoperative process. However, there is still a need to increase standardization in the intraoperative and postoperative period. Though standardization of the intraoperative process is difficult as each patient and operation is unique, creation of standard technical competencies for each surgeon during their training may lead to a reduction in intraoperative technical errors that lead to patient harm. Additionally, the post-operative period has numerous opportunities for standardization. Many institutions have been utilizing the Electronic Health Record to implementing postoperative order sets, which allow for a streamlined but consistent approach to the postoperative patient. In addition, other postoperative care protocols, such as DVT prophylaxis, have been established in an attempt to further reduce patient harm. Standardization of the postoperative care process is essential to maximizing patient safety and operative outcomes.

In order to develop “evidence based” patient safety initiatives, accurate data on medical errors must be collected and analyzed. However current reporting systems may underestimate the true prevalence of errors. To improve the collection of data on error, there needs to be standardization and dissemination of the definition of medical error. “Near misses” and errors occurring far removed from the patient must still be reported to ensure complete understanding of the situations that lead to error. In addition, there needs to be a removal of the embarrassment and fear of repercussion that goes alongside reporting errors. Accomplishing this will require a paradigm shift from focusing on the individual failure that resulted in error, to understanding that it was a system failure that resulted in error. In order to embrace this change, the medical malpractice system must also be transformed from a system of blame to one of no fault compensation when errors do occur. Adoption of this “system” view of error will lead to more effective “system” solutions.

Finally, and most importantly, in order to prevent patient harm and promote patient safety, orthopaedic surgeons must transform the operating culture from surgeon-centric to team focused. It is essential that orthopaedic surgeons foster an operative environment that is open to input from all team members. In order to accomplish this, it is crucial to abandon the well-ingrained vertical hierarchy in favor of a more horizontal hierarchy. Establishment of a horizontal hierarchy within the operating room will create an environment where all team members feel comfortable expressing their ideas and concerns throughout the patient care process. This will not only encourage communication and collaboration among members of the healthcare team, but also increase the sense of “ownership” all team members have in the patient’s safety.

CONCLUSION

Patient safety is of the utmost importance. Orthopaedic surgeons, along with the rest of the medical profession, have been working to reduce the occurrence of medical errors and implement systems that promote patient safety. Although it is evident that errors are still occurring at an unacceptable rate, current efforts to standardize care processes, improve error reporting, and promote a team based care process will likely lead to a reduction in errors resulting in harm and promote patient safety.

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