

Surgery Risks: Through the Lens of Malpractice Claims

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What you'll learn from this report

- Specific areas of greatest vulnerability during the surgical episode of care — preoperative, intraoperative, and postoperative — and how you can reduce risk at each stage.
- Risk trends in the top surgical specialties to trigger claims: general surgery, orthopedic surgery, and neurosurgery.
- Recurrent themes in surgical risk.
- How medications and the practice of anesthesiology factor into the overall risk of surgery.
- The complex nature of surgical claims and issues unique to caring for patients before, during, and after surgery.
- General principles for managing risk and improving safety for patients undergoing surgery.

“Quality, which will be increasingly data- and outcomes-driven, is the benchmark by which future surgeons will be judged. Surgeons must own quality.”

– J. David Richardson, MD, FACS
Professor and Vice Chairman of Surgery, University of Louisville School of Medicine;
Former President of the American College of Surgery¹

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Surgery is the second most common cause for medical malpractice claims overall.

Introduction

Each year in the United States, more than 48 million surgical inpatient procedures are performed² and more than 35.8 million outpatient surgical procedures occur.³ The average American, in his or her lifetime, will undergo an estimated nine surgical procedures of varying severity.⁴ Coverys data shows that surgery — and the care and decision-making leading up to and following surgery — is the second most common cause for medical malpractice claims overall.

The surgical episode of care is also where:

- Multiple providers and influencers must collaborate, coordinate, and communicate fully and effectively.
- Resources can be stretched thin during periods of emergency, such as when operating room schedules and surgical teams are changed with short notice.
- Even common procedures are not foolproof and can cause injury.
- Advances in and reliance upon technology can pose complications and risk.
- Patient consent, understanding, and compliance is vital.
- Provider skill and judgment — sometimes under the most trying of circumstances — is paramount for optimal outcomes.

This report provides insight into the root causes of claims involving surgery based on an analysis of 2,579 surgery-related closed malpractice claims at Coverys across a five-year period (2014-2018).^{*} Our goal is to provide surgeons and other healthcare professionals with fresh perspectives, data-driven insights, and more effective strategies to meet the needs of their surgical patients.

^{}Unless otherwise indicated, statistics and other information in this publication were derived from this proprietary data.*

This report is intended to provide general guidelines for risk management. It is not intended and should not be construed as legal or medical advice.

A Fresh Approach to Claims Data

At Coverys, we refer to claims data as “signal intelligence.” Our conclusions from analysis of the data are not absolute findings. Rather, they are hypotheses — signals from the past about where vulnerabilities existed and may still be at play.

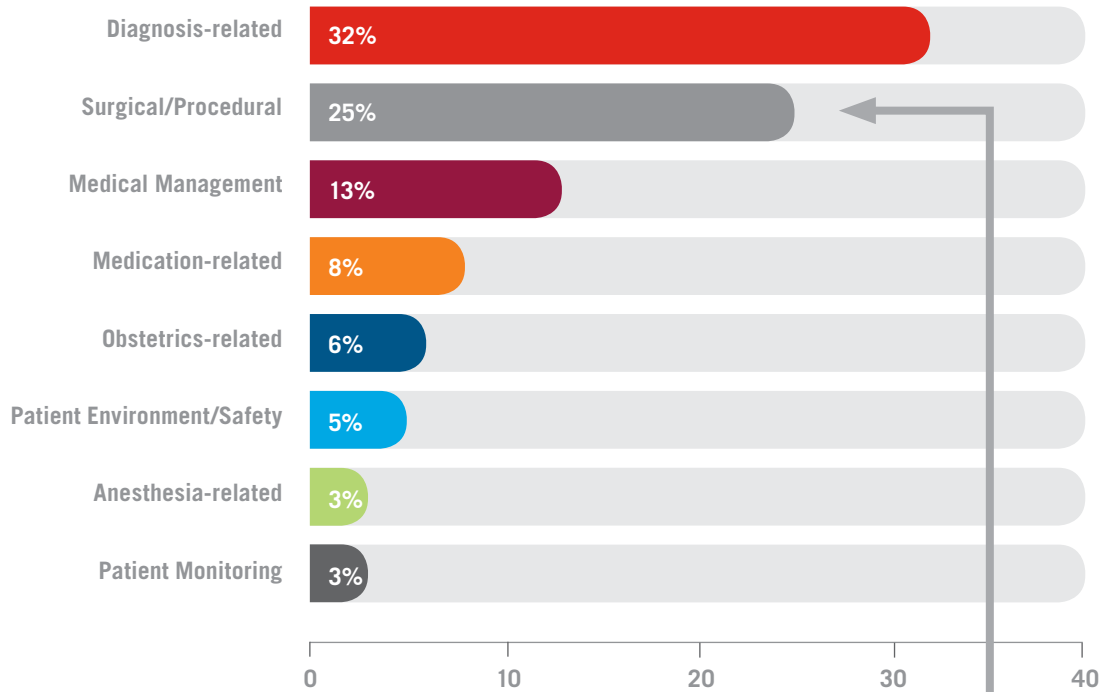
Typically, a fully investigated malpractice claim will include:

- Allegations.
- Patient health and demographic information.
- Injury severity.
- Physician specialty.
- Risk management issues.
- Location of the alleged error (e.g., office/clinic, operating room, surgical recovery).
- Financial costs.
- Expert reviews and opinions.

Coverys uses this information to create evidence-based recommendations to help mitigate future risks in the delivery of care.

LEADING CAUSES OF CLAIMS

Surgery is the second most common cause for claims overall, with 25% of claims involving surgical care and/or procedure.

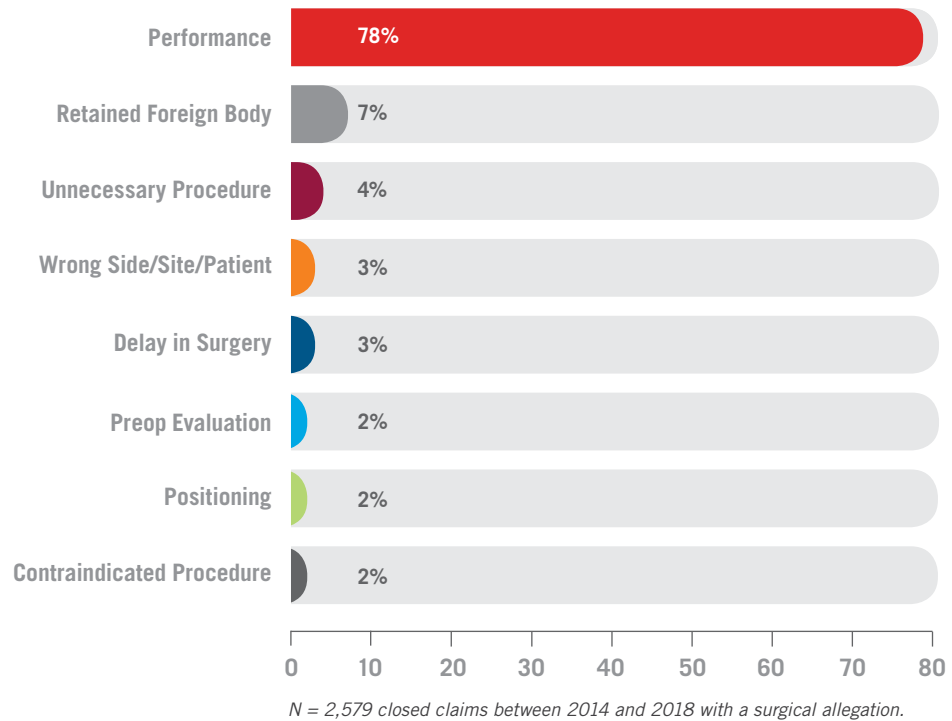


N = 10,307 closed claims between 2014 and 2018.

Surgery is the second most common cause for claims overall.

TOP SURGICAL ALLEGATIONS

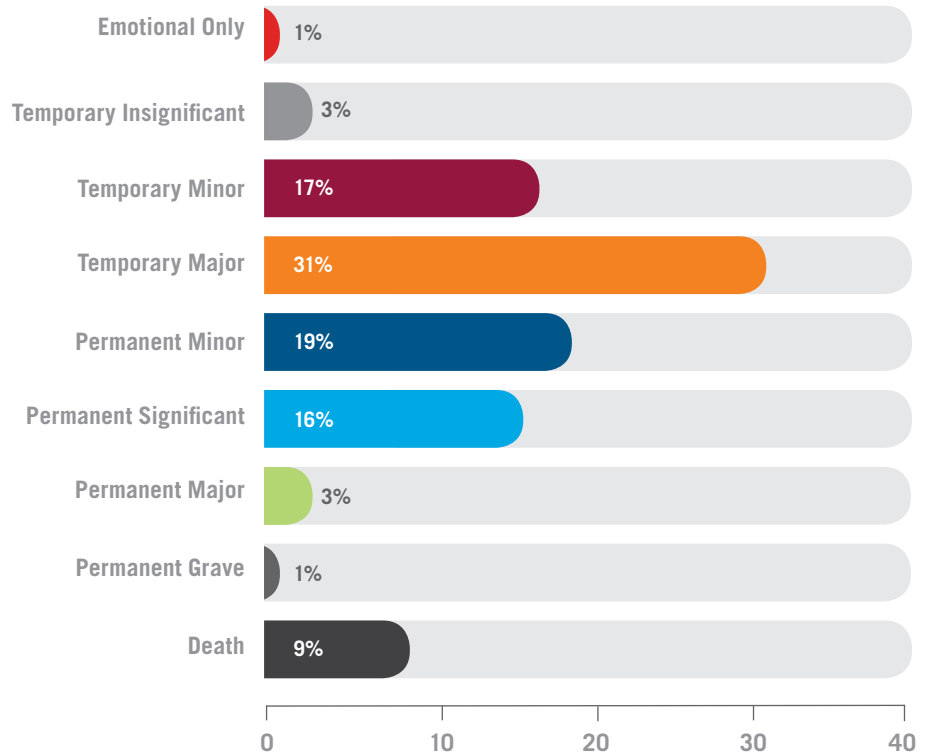
The vast majority of surgical allegations come down to practitioner performance during the procedure itself.



INJURY SEVERITY*

29%

of surgery injuries are permanent significant or worse, with 9% resulting in death.



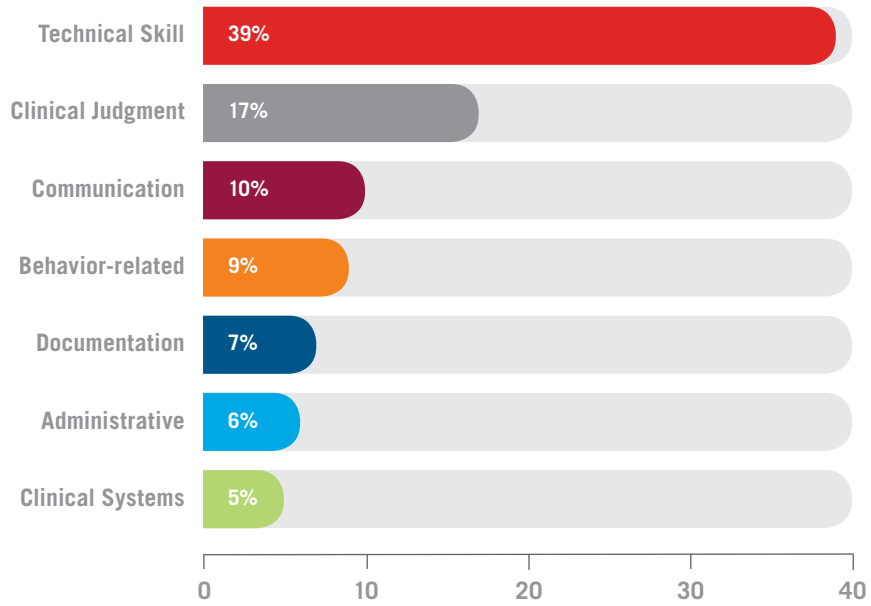
N = 2,579 closed claims between 2014 and 2018 with a surgical allegation.

**Injury severity based on National Association of Insurance Commissioners (NAIC) codes.*

TOP RISK MANAGEMENT ISSUES

27%

of surgical claims allege a failure in clinical judgment and/or communication.



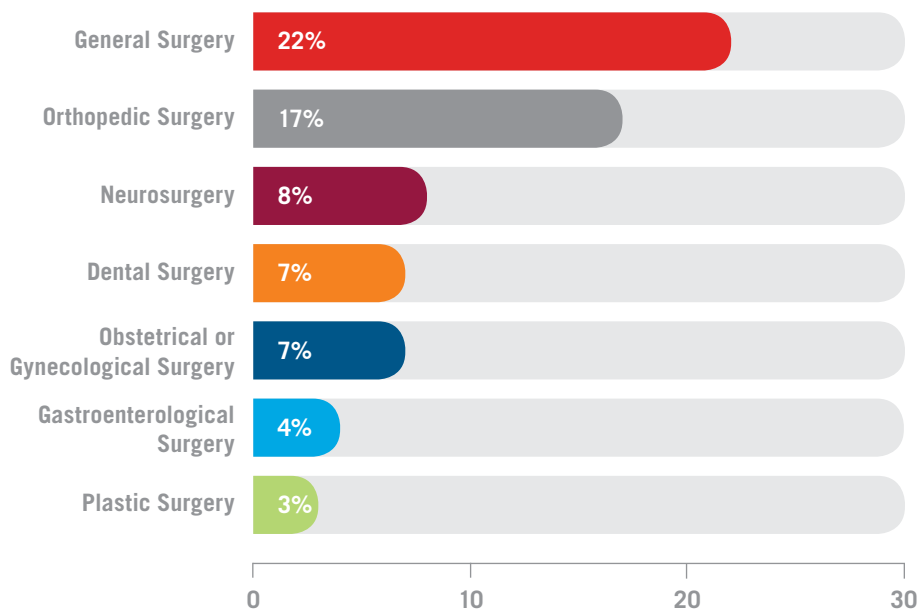
N = 2,521 risk management issues in closed claims between 2014 and 2018 with a surgical allegation.

TOP SURGICAL SPECIALTIES THAT TRIGGER CLAIMS

47%

of claims from among more than 50 surgical categories involve just three specialties:

- General Surgery (22%)
- Orthopedic Surgery (17%)
- Neurosurgery (8%)



N = 1,881 closed claims between 2014 and 2018 with a surgical allegation and a named provider.

Recurrent Themes in Surgical Risk

Surgical allegations account for 25% of the more than 10,000 closed claims we've analyzed at Coverys in the past five years.

**More than 10%
of surgical claims
allege a failure in
communication.**

In an era of productivity and profitability, surgeons and their support teams are challenged to do more with less time. More procedures, more patients, more billing codes. And those pressures can have patient safety consequences.

Throughout this report, we provide risk management recommendations, case studies, and statistics that likely either reflect your own experiences or are relevant to your future (or both) and an analysis of the state of risk in the practice of surgery overall. Among this information, you will see clear themes, like:

The patient is a valuable “player” on the surgical team. If they are not truly informed, properly assessed, ready physically and emotionally for their surgical procedure, fully heard, or willing and able to comply with preoperative and postoperative instructions, the final outcome can fall short of the patient's expectations. Practices and practitioners involved in the discipline and art of surgery must be devoted to patient-centered care because no amount of surgical skill or good judgment can replace comprehensive understanding and active participation on the part of the patient or their family.

Technology is both friend and foe. Technological innovations — like radio-frequency identification (RFID) gauze and tape, or a well-managed electronic patient perioperative status management board — can greatly improve safety and reduce risk. But overreliance upon technology can put patients at risk.

Good communication matters at every step. More than 10% of surgical claims allege a failure in communication. From the staff who are afraid to speak up to a surgeon, to the ad hoc surgical teams that are sometimes assembled at a moment's notice, to the many players who sometimes fail to fully document patient history, care, or surgical notes — communication failures during surgery and at any point during the episode of care can negatively impact a patient's outcome.

Patient handoffs present an opportunity for improvement or risk. From preoperative to operating room, to postoperative, hospital floor, home, or rehabilitation center, as well as follow-up with other providers, successful handoffs must be well-organized with thorough instructions, clear communication, and adequate documentation.

A diverse population introduces complexity to the surgical experience. No two patients are alike. Some speak the same language as you do, and many do not. Some present with excess weight that requires bariatric equipment (like beds that can accommodate larger patients) or with other co-morbidities that require changes to the surgical plan. Some patients feel judged or embarrassed because of their lack of health literacy, so they don't ask vital questions that impact their medical care. And some are transgender or have physical and emotional differences that require your close professional attention and personal sensitivity.

Outsourcing surgical processes can have unintended consequences. Outsourcing work during the surgical episode of care can impact quality or patient safety. Consider, for example, claims where surgical instruments provided by third-party vendors were not properly sterilized and organized, and the mistake was not discovered until after the surgery was in process. Additionally, specimens may be sent to outside laboratories for analysis and become misplaced and/or lost.

Standardization and practice contribute to successful outcomes. When preparing a patient, readying the surgical procedure space, or communicating with a patient before or after surgery, doing it “the same way every day” can improve safety and outcomes. Because surgery is highly complex and full of variability, routine and rigor are vitally important.

TRENDS TO WATCH

Patient selection. Coverys data shows that patients continue to undergo surgeries that are arguably unnecessary (triggering 4% of surgical claims) or contraindicated (1% of claims). While these percentages are low, they can be reduced through practices related to taking a thorough history and physical (H&P), as well as improved communication and documentation to ensure that the only patients having surgery are the ones who need and/or want it.

Patient consent. We continue to see cases in which detailed patient consent forms are not provided in the patient's preferred language and those in which procedures (and their risks) are not fully explained to patients and their families. Great strides can still be made to develop and execute processes and scripts for explaining the nature of a surgery — and the risks, benefits, or alternative(s) to it — and subsequently ensuring patient understanding.

It's important to identify patients who are most vulnerable to risk.

The rise of advanced practice providers in surgery. With the increase in advanced practice providers outpacing the increase in new physicians, we will continue to see these practitioners involved in surgery and perioperative care.⁵ It remains to be seen what appreciable impact on safety, if any, this trend might trigger. Of the 2,579 surgery cases analyzed for this report, just 39 had allegations pertaining to advanced practice providers and, notably, physicians were more likely to have an alleged failing of technical skill (39%) than their advanced practice provider counterparts (26%).

Caring for At-Risk Patients

Providing safe care for patients is the top priority of all surgical teams. To do so, it's important to identify patients who are most vulnerable to risk, such as:

- Those whose communications skills or cognition may be compromised as a result of a hearing impairment, a language barrier between provider and patient whose native languages are not the same, or a memory or cognitive special need.
- Those with common but significant comorbidities (like obesity, diabetes, clotting or bleeding disorders, or cardiovascular conditions).
- The elderly or the disabled, particularly if they do not have a capable daily advocate or caregiver to assist with pre-surgical and post-surgical instructions.

SURGERY AND READMISSIONS

Problems or complications before, during, or after surgery can impact patients, families, practices, and facilities beyond the anticipated recovery, rehabilitation, and follow-up periods. A recent study by the American College of Surgeons National Surgical Quality Improvement Program⁶ (ACS NSQIP) revealed that hospital readmissions within 30-days after surgery are not easy to explain away, nor should they be ignored. In an ACS study that included readmission information from nearly 350 hospitals, it was found that “readmissions the first 30 days after surgery were associated with new post-discharge complications related to the surgical procedure and not a worsening of any medical conditions the patient already had while hospitalized for surgery.”

The unplanned readmission rate in the case of the nearly 500,000 surgical procedures included in the ACS study was 5.7%. The most common cause for unplanned readmission was surgical site infection, which was cited in 19.5% of surgical readmissions. Ileus (or obstruction) and bleeding were the second- and third-most common reasons for unplanned readmission of surgical patients.

The authors of the ACS study offer this advice to hospitals, which mirrors our own: “Efforts should focus on reducing complication rates overall [rather] than simply those that occur after discharge, and this will subsequently reduce readmission rates as well.”

Medication & Surgical Risk

The administration and management of medication before, during, and after surgery introduces distinct risk. Among all surgical claims analyzed for this report, 5% involved an allegation related to medication. The most common medications cited are: antibiotics, local and general anesthesia drugs, adrenal corticosteroids, opioids, anticoagulants, topical preparations, and cardiovascular agents. Three of these medication types — opioids, anticoagulants, and antibiotics — are discussed at length in the Coverys report *A Dose of Insight: A Data-driven Review of the State of Medication-related Errors and Liability in American Healthcare*, available at <https://www.coverys.com/Knowledge-Center/A-Dose-of-Insight-Medication-Related-Errors>.

DISTRACTIONS

As we review surgical malpractice cases, we are frequently seeing suits alleging technical performance issues brought against experienced surgeons — ones who have proper credentialing in place and a proficient skill level. Potentially, the surgical procedure was one that the surgeon had performed multiple times. Yet, on a particular day, in a particular setting, something went wrong. These are perplexing cases, largely because they seem to have no logical explanation.

The clinical record doesn't give us much, but sometimes depositions do. Occasionally, we will hear a doctor say, “I've done that surgery many times, and I never made that mistake before,” or “The OR was a zoo that day.” References to specific environmental factors come to the surface, such as: “There was loud music playing,” or “People kept getting and taking calls on their cellphones,” or “The number of people coming in and going out of the OR all through the procedure was extreme.”

**Is it time for
operating rooms to
adopt the “sterile
cockpit” concept?**

The frenetic environments that often define healthcare pose high levels of distractions to providers. Clinical alarms, multitasking, the widespread use of personal electronic devices, and unnecessary noise are among the more serious distractors present. This is particularly problematic when surgeons are attempting to perform complex procedures that require higher levels of cognitive processing and technical skill.

Is it time for operating rooms to adopt the “sterile cockpit” concept⁸ from aviation and create a model environment for surgeons to optimize their surgical performance? The “sterile cockpit rule” is an informal name for the Federal Aviation Administration regulation that specifically prohibits crew members from performing non-essential duties or activities while the aircraft is involved in taxi, takeoff, landing, and all other flight operations conducted below 10,000 feet, except cruise flight.⁷

In the perioperative environment, the “sterile cockpit rule” likens “taxiing” to the preparation of the surgical area as well as the patient for the procedure and moving the patient into the room. “Takeoff” correlates to the surgical procedure and the “landing” in surgery would be the closing, instrument count, and transition of the patient through the postoperative period. It is well known that the “takeoff” and “landing” are the most risky maneuvers in flight. Likewise, the preoperative and postoperative periods are identified as the most at risk for error. Reduction and elimination of activities and distractions, such as excess traffic in the OR and cellphones, permits the OR team to focus on the patient and the task at hand.

STERILE COCKPIT CONCEPT

No non-essential duties performed during these stages.

AVIATION

OPERATING ROOM



TAXI

= Preparation of surgical area and patient



TAKEOFF

= Surgery



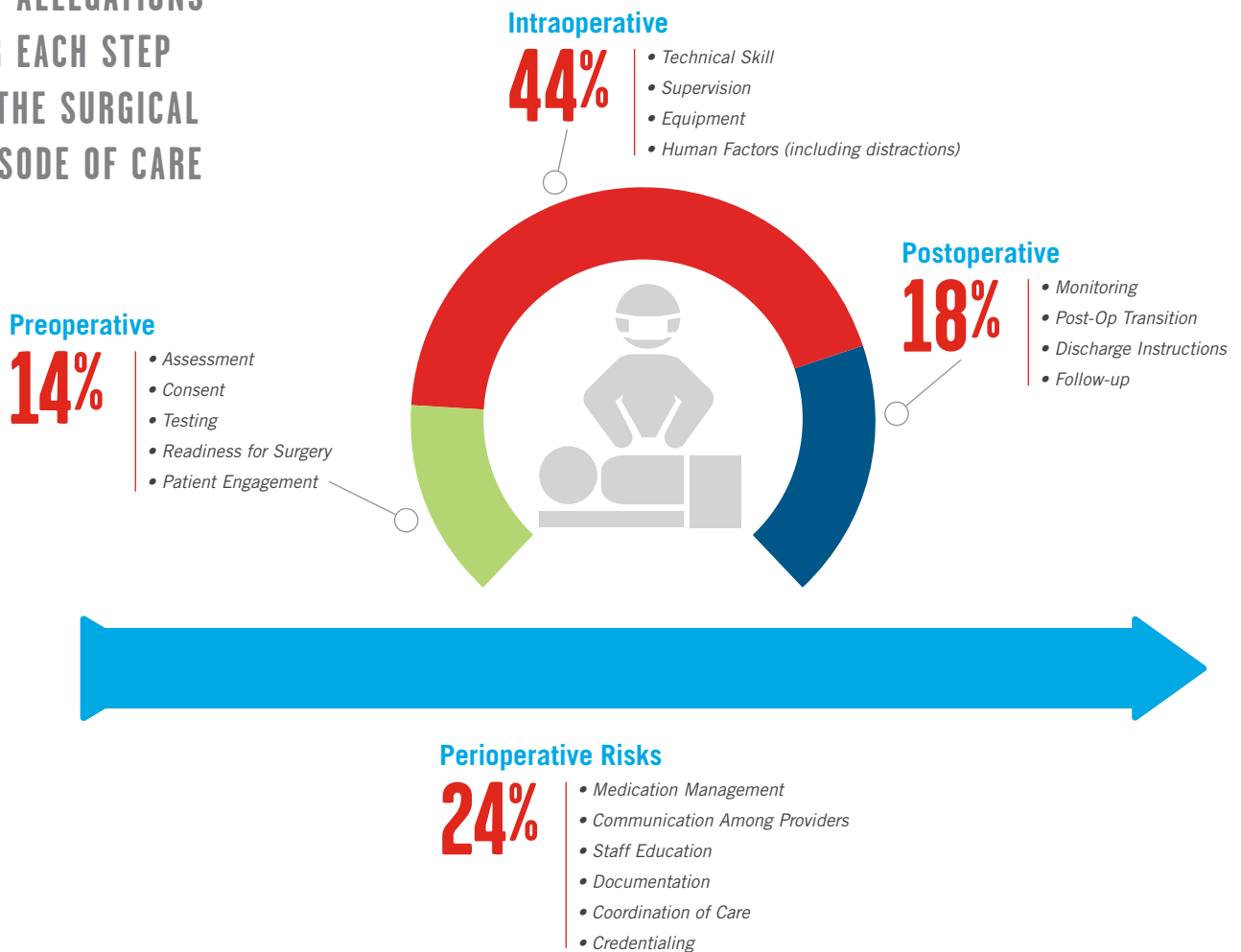
LANDING

= Closing, instrument count, transition of patient to postoperative care

Process Vulnerabilities During the Surgical Episode of Care

Every surgical case is unique to the specific patient involved; however, there is predictability in the preoperative, intraoperative, and postoperative steps taken for all patients. These range from diagnosis and surgical recommendations, to patient and surgical space preparation, to procedural performance, to patient monitoring in recovery, and ultimately during patient follow-up. This section of our report provides insight into the process vulnerabilities we have identified at each major step — preoperative, intraoperative, and postoperative care.

TOP ALLEGATIONS FOR EACH STEP IN THE SURGICAL EPISODE OF CARE



14%

of surgery claims involved allegations pertaining to the preoperative phase.

PREOPERATIVE RISKS

The preoperative phase can include everything from a series of conversations and a battery of tests, to pre-surgical medication changes, consent dialogues, and a host of preparatory steps to ensure the patient, the operating space, the provider, and the staff are ready. Key to the preoperative phase is determining whether there should be surgery at all, or whether there are better alternatives. Overall, 10% of the surgery claims we reviewed involved allegations pertaining to the preoperative phase, such as unnecessary and contraindicated surgeries, problems with the preoperative evaluation, or a delay in performing surgery.

PREOPERATIVE CASE STUDY #1 – LACK OF CONSENT



A man in his early 60s, himself a practicing surgeon, consulted a neurosurgeon for shoulder blade pain and numbness in his dominant arm. A cervical spine MRI showed multi-level degenerative changes, including abnormalities at C4-C6. The neurosurgeon documented that this area might require operative management at some point. The patient underwent a conservative course of treatment that included oral steroids, physical therapy, and traction.

Several months later, the patient suffered a fall, resulting in neck pain. A second MRI showed a questionable area of focal edema and myelomalacia at the C2-3 level. Urgent surgery was scheduled for the following day.

On the day of the surgery, the patient signed a consent form for posterior cervical decompression of C2-3. The consent form was altered at some point, with a line struck through the “3,” changing it to a “6.” This change was initialed by the neurosurgeon but not by the patient. The actual procedure performed consisted of C2-C6 decompressive laminectomies with C4-C5 foraminotomies and was completed with no intraoperative complications noted.

The patient was left with persistent right-sided C5 and C6 radiculopathies, muscular weakness in his biceps, a prominent deltoid, and a less significant brachioradialis. He made significant improvement over time, but is no longer able to perform surgery. He insists he did not consent to surgery on C2-C6 and thought the surgery was confined to the C2-C3 discectomy. The pre-admission worksheet, admission data, and pre-admission insurance approval forms supported the patient’s claim that the procedure should have been confined to the C2-C3 area.

PREOPERATIVE CASE STUDY #2 – COMMUNICATION FAILURE



A man in his late 60s suffered a deep vein thrombosis (DVT) following a total knee replacement. Shortly after, the patient developed a pulmonary embolism (PE) and atrial fibrillation. His primary care physician recommended Greenfield filter and a hematology consult. The hematologist diagnosed hypercoagulability and prescribed Coumadin.

The PCP retired, and a new internal medicine physician assumed responsibility for the patient’s primary care, including his anticoagulation therapy. The patient was also cared for by a cardiologist who prescribed digoxin and amiodarone. A routine office visit revealed the patient’s PSA was elevated, and a follow-up with a urologist resulted in a diagnosis of prostate cancer. The patient was scheduled for robotic prostatectomy.

The internist advised the patient to consult with his cardiologist and hematologist regarding the need to bridge his anticoagulation therapy prior to prostate surgery and suggested the use of Lovenox. The patient refused to see the hematologist. The internist consulted with the cardiologist, who suggested withholding Coumadin for 4-5 days prior to surgery and then resuming anticoagulation afterward, with no plan for bridging. The patient underwent prostate surgery and awoke with bilateral vision loss. Ultimately, he was diagnosed with an occluded left internal carotid artery and acute bilateral occipital infarct.

Significant communications failures occurred in this case, including: the cardiologist was unaware of the patient’s previous hypercoagulability diagnosis made by the hematologist, the patient deferred to advice from the cardiologist without consulting a hematologist, and the patient was unaware of or confused about his hypercoagulability and had wanted to discontinue Coumadin even before the prostate cancer diagnosis. Further, the patient denied having ever seen a hematologist and didn’t comply with the internist’s recommendation for pre-surgical bridge anticoagulation or a pre-surgical hematology consult.

Ensure patient's participation and understanding using shared decision-making techniques.

Preoperative Risk Management Recommendations⁸

The surgeon has many responsibilities during the evaluation and preparation phase including:

- Use standardized selection criteria to determine the patient's "appropriateness for surgery." Criteria should include not just indications, but contraindications, higher-than-acceptable risks, possible complications, potential alternatives to surgery, and the timing of when the procedure should take place.
- Address major medical conditions that may impact the ability to safely perform the surgical procedure.
- Counsel the patient on modifying or reducing problematic risk factors (e.g., smoking, alcohol intake, weight, nutrition, etc.).
- Manage medications that have heightened relevance to the operative phase (e.g., anticoagulants, beta blockers, insulin, etc.).
- Perform an overall evaluation of the patient's risk factors and predicted outcomes. The ACS has developed the ACS National Surgical Quality Improvement (ACS NSQIP) Risk Calculator for this very purpose: <https://riskcalculator.facs.org/RiskCalculator/>.

The surgeon and the facility where the surgery is performed both have responsibilities in the immediate preoperative phase.

SURGEON RESPONSIBILITIES⁹

- Ensure patient's participation and understanding using shared decision-making techniques. The surgeon should encourage the patient (or patient's family) to ask questions, and the surgeon should provide instructions on how to contact the surgical team should concerns arise. It's helpful to provide several contact methods, such as phone, email, and text.
- Document comprehensive informed consent discussion(s) — including the patient's response — in the patient's medical record.
- Adhere to standard work processes throughout the continuum of surgical care to ensure information, equipment, staff, and other resources are available and ready for patient arrival.

**Review relevant
tests in a timely
and consistent way.**

- Review relevant tests in a timely and consistent way, ensuring that all preoperative results are well understood and incorporated into the decision to proceed.
- Facilitate that various clinicians involved in the patient's overall care are aware and ready to co-manage the patient once the surgical procedure has been completed. This is particularly important with patients who have complex clinical profiles, are taking numerous medications, and have been treated by other specialists.

FACILITY RESPONSIBILITIES

- Develop patient criteria to ensure patient selection is appropriate for provider and staff capability and training, as well as being well suited to facility resources.
- Assess the patient's care and recovery needs during preoperative office visit and no later than admission assessment to identify special recovery and rehabilitation needs (i.e., home care, environmental safety, and family and/or support system).
- Ensure that a comprehensive and detailed initial credentialing and privileging process is in place, including board oversight.
- Develop, implement, and maintain focused professional performance evaluation (FPPE) of new and problematic procedures before granting privileges.
- Develop, implement, and maintain an ongoing professional performance evaluation (OPPE) of high-risk, high-volume, and highly sensitive procedures with medical staff oversight and board support.

77%

of intraoperative allegations were related to provider performance.

INTRAOPERATIVE RISKS

The vast majority of surgical claims alleged issues during the surgery itself. These allegations are overwhelmingly related to the provider’s performance, with 77% of intraoperative cases being deemed “performance issues.” Other intraoperative claims involve retained foreign bodies (RFBs), wrong side/site/patient errors, and problems with positioning.

INTRAOPERATIVE CASE STUDY #1 – PROVIDER PERFORMANCE



A man in his 40s had a lump in his upper arm that was causing pressure and aching. He consulted a surgeon, who noted a 2-centimeter subcutaneous mass with no overlying redness. She diagnosed the lesion as a lipoma and recommended excision. During the procedure, the surgeon noted a band of fibrous tissue. She requested an intraoperative consultation with an orthopedic surgeon who came to the operating room but did not scrub in. He observed the mass, the surrounding tissues, and the local anatomy, indicating that while he was not sure what the mass was, it was safe to remove the mass. The surgeon then clamped and transected the fibrous band and it was immediately apparent to her that the ulnar nerve had been transected, as nerve fibers were visible within the mass. She requested an immediate consult with a hand specialist, who repaired the nerve. A pathologist confirmed the mass was not a lipoma but a benign schwannoma, and the orthopedic surgeon denied having said it was safe to remove the mass.

As a result of the injury, the patient developed a claw deformity of his hand, fixed contractures of the fingers, and decreased strength and numbness in two fingers and the back of his hand. He had significant loss of use of his entire arm and can no longer work in his prior occupation as a construction heavy equipment operator.



INTRAOPERATIVE CASE STUDY #2 — PROVIDER PERFORMANCE

A man in his 50s, suffering from diverticulitis and morbid obesity, underwent an emergency sigmoid colectomy and colostomy for treatment of a bowel obstruction. Two months later, the same surgeon performed a surgical reversal of the patient’s colostomy. The procedure was started laparoscopically. Extensive adhesions and scar tissue were encountered, and the surgeon converted to a “partial open” procedure so he could move the instrument used for the anastomosis closer to the rectal stump. Methylene blue dye was administered into the patient’s Foley catheter and then via IV; no leaks were evident.

On the day following surgery, the patient was unable to pass urine and had elevated BUN and creatinine levels. A CT scan showed a large fluid collection in the pelvis, consistent with urinoma. Possible disruption of both ureters was noted on a retrograde ureterogram. The patient was transferred to a tertiary care hospital with discharge diagnoses of bilateral intraoperative ureteral disruption and renal failure secondary to ureteral disruption. The patient required bilateral nephrostomy tubes. Additionally, the colonic anastomosis broke down, necessitating the creation of a permanent colostomy.

Intraoperative Risk Management Recommendations

The surgeon and the facility where the surgery is performed both have responsibilities in the intraoperative phase.

SURGEON RESPONSIBILITIES¹⁰

Some of the surgeon’s responsibilities can be delegated, but all must stay within his or her line of vision.

- Ensure that all steps in the OR safety checklist are performed, including a surgical team briefing and a time-out to review that critical factors are in order (e.g., confirmation of patient identity, correct procedure, fully executed consent, accurate site marking, anesthesia readiness, and verification of any patient allergies, blood management issues, etc.).
- During the briefing and time-out, ensure that close attention is being paid by all team members. Additionally, there should be active encouragement by the surgeon for any members of the team to “speak up” if they see anything that causes worry or concern at any point during the procedure.

Establish a distraction-free environment.

- Establish a distraction-free environment. It is the surgeon who needs this the most, and he or she should appropriately dictate what is needed so that the risk for distraction is lowered as much as possible. This could include limiting conversations in the OR, turning off cellphone ringers and requesting that calls not be taken, having no music playing, banning visitors or observers while the procedure is taking place, etc.
- Active oversight of — and alert attention to — all elements related to the patient's clinical status, including patient positioning, hypothermia prevention, glucose control, DVT/PE prophylaxis, and medication management (particularly critical ones such as beta blockers, insulin, anticoagulants, anti-platelets, etc.).
- Proactively focus on not losing track of sponges, sharps, and instruments that have the potential of becoming a retained foreign body. While maintaining attention to counts is a surgical team responsibility, the surgeon can appropriately set the stage for closer attention being paid — particularly in surgical procedures where the potential for retained foreign bodies are higher.
- Maintain high degrees of situational awareness — unexpected complications or findings may arise during a surgical procedure. The surgeon must stay alert to those possibilities and be ready to respond (even if it requires consulting with other surgeons or specialists).
- Use verified communication techniques, such as TeamSTEPPS® and Just Culture to support Stop the Line and ensure patient safety.
- Implement double-checks of medications, including antibiotic and anticoagulation selection, and audit for compliance.
- Most importantly, ensure that one's individual skills are current and refreshed as needed through training and, if available, skills lab simulation.

FACILITY RESPONSIBILITIES

- Implement a safe surgery checklist, such as the WHO Surgical Safety Checklist (2008) or the AORN Comprehensive Surgical Checklist (2019) for all operative procedures.
- Train providers and staff on procedures and equipment prior to implementation for patient use. Developing an in-house skills lab is recommended. But, if resources are limited, develop relationships with external simulation labs to allow for routine active skills training.

- Ensure ongoing competency of staff, especially as it pertains to low-use, high-risk equipment and procedures.
- Establish appropriate turnover times to reduce staff pressure as well as over-utilization of equipment and operative rooms.
- Consider patient selection and assess the potential to convert selected laparoscopic procedures to open procedures, including elevated risk related to patient habitus.
- Assign specific OR team members to vigorously control and monitor room traffic, cellphone access, and other distractions during patient presence in the operative room.
- Ensure consistent and timely documentation of supplies, instruments, and equipment entry into the operative room using count boards and verbal response of the team.
- Consider comprehensive visual and medical-surgical record audits to ensure ongoing compliance and to identify opportunities for improvement.
- Provide annual education and review of critical processes and protocols including use of RFID supplies, surgical site checklist, traffic control, and accurate count protocols. Include role-playing scenarios to maintain provider and staff competency and compliance.

POSTOPERATIVE RISKS

The complex nature of the surgical patient, especially during recovery, requires seamless care coordination and communication throughout the continuum of care.

A patient's response to anesthesia, both during the procedure and the recovery period, may be complicated and unexpected. The anesthesia provider must communicate anesthesia-related concerns which may influence the patient's immediate postoperative recovery.

The surgeon continues to manage the patient's care throughout the acute recovery period until satisfactorily completing follow-up care. This includes, but is not limited to, inpatient care, return to surgery and office visit, and telephone follow-up.

Early identification and intervention of complications may be accomplished through seamless communication with the patient and support system as well as handoff information between care providers.



POSTOPERATIVE CASE STUDY #1 – DELAYED RESPONSE TO COMPLICATIONS

A man in his 70s, who had a history of diabetes, obesity, tobacco use, and alcohol abuse, was diagnosed with a minimally displaced left distal fibula fracture. He was evaluated by an orthopedic surgeon who recommended open reduction and internal fixation (ORIF). Three days later, the procedure was performed, a short leg cast was applied, and the patient was discharged with outpatient physical therapy and visiting nurse services to his home. The cast was removed 12 days after surgery, at which time the orthopedist noted large areas of possible necrosis of the skin of the medial and lateral ankle. An air cast was provided. The plan was to allow increasing activity and observe.

Several weeks later, the patient's visiting nurse left a message for the orthopedist, requesting a vascular referral and expressing concern that the wounds were getting larger and were draining. The orthopedist declined this request. The nurse subsequently arranged for a referral to a wound-care center by way of the patient's primary-care provider, and the wound-care specialist referred the patient to a vascular surgeon.

An angiogram of the leg revealed its vasculature was non-reconstructable. Given the patient's gangrenous foot, diabetic neuropathy, and inoperable arterial disease, the vascular surgeon and the orthopedist agreed that a below-knee amputation was the most reasonable treatment. The amputation was subsequently performed.

POSTOPERATIVE CASE STUDY #2 – INADEQUATE MONITORING



A woman in her 50s, with a history of interstitial cystitis (IC), presented to her OB/GYN with complaints of bladder pain and painful urination. Her physician noted her history of IC, continued urinary frequency, and vaginal dryness, and recommended urethra dilatation and cystoscopy with hydrodistention. The patient consented to the procedure, which was performed in a surgical outpatient center. No complications were noted during the procedure, and the patient asked to be discharged after one hour in the recovery area. A nurse advised the patient that she couldn't be discharged until she emptied her bladder. After using the bathroom, the patient told the nurse that she had voided a small amount. The nurse had not measured or visualized the patient's output. Based on the patient's word that she had voided, the nurse discharged the patient.

After arriving home, the patient slept. Upon waking, she was unable to void. As instructed, she called the outpatient surgery center but got no answer and left a message. Forty-five minutes later, she called again and asked to speak with a family member who happened to work at the facility. The patient was advised to go to the hospital emergency department, where she was ultimately seen by her own OB/GYN and underwent an exploratory laparotomy and subsequent repair of a ruptured bladder.

Postoperative Risk Management Recommendations

The surgeon and the facility where the surgery is conducted have shared responsibility in the postoperative phase.

SURGEON AND FACILITY RESPONSIBILITIES¹¹

- Develop consistent handoff communication criteria and processes to be used during patient transfer points throughout the continuum of care.
- Provide written and verbal postoperative expectations and care in the patient's preferred language, including appropriate communications for patients who are vision and/or hearing impaired.
- Ensure patients entering postoperative care receive a comprehensive assessment, including ongoing monitoring of airway and pain management.
- Establish criteria for discharge of patients from postoperative care based on evaluation of consciousness, activity, respiratory status, circulation, and oxygen saturation.
- Clearly define communication channels, both between providers (multidisciplinary) and between surgeon and patient (post-discharge). Particularly for the latter, these should not be vague messages such as "Let me or my office know if you are having problems." Rather, they should be laid out in clear detail, e.g., "If you are having any symptoms such as..., I want you to call me. Here is my card with my cellphone number. If you don't get an answer, here is an alternate way to get a message to me."

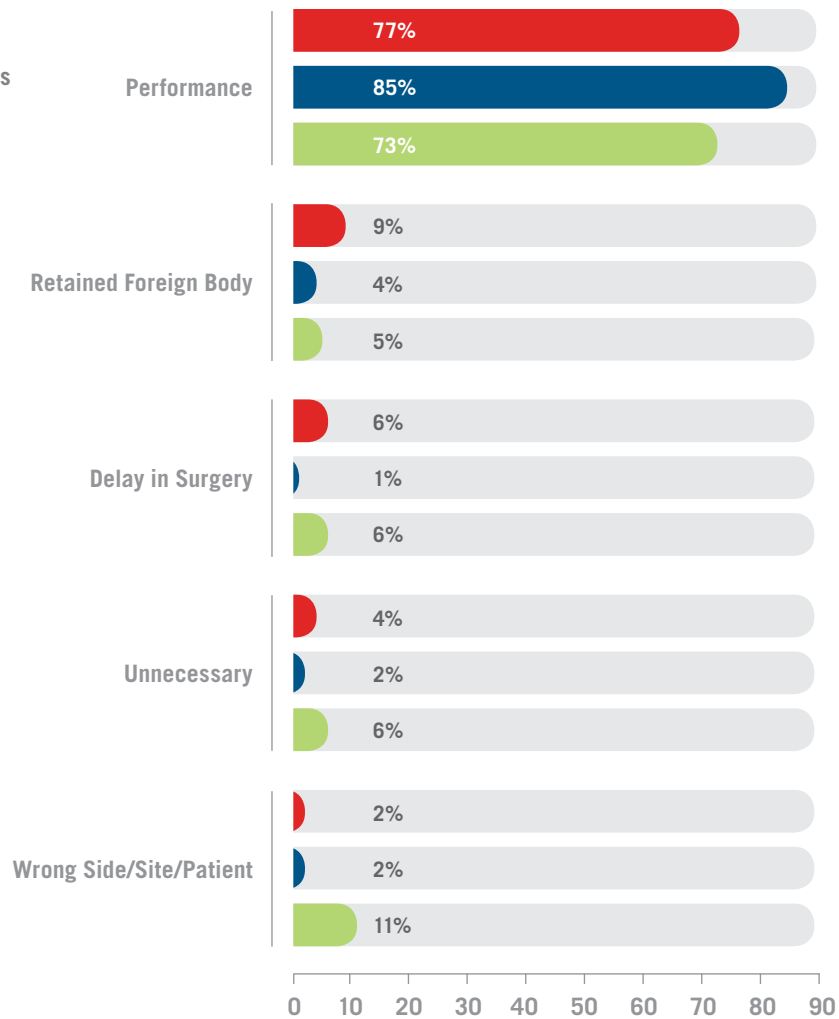
Top Surgical Specialties to Trigger Claims

The granularity of our claims data allows us to examine surgical allegations across surgical subspecialties. However, just three specialties — general surgery, orthopedic surgery, and neurosurgery — account for 47% of all surgery-related claims involving a surgeon. For these three specialties, surgical performance is the most frequent allegation. The other allegations vary by specialty. We've investigated these top three specialties to identify trends that practitioners and risk management professionals should consider closely.

TOP ALLEGATIONS

The vast majority of allegations are related to performance during surgery.

- General Surgery*
- Orthopedic Surgery**
- Neurosurgery***



*N = 410 closed claims between 2014 and 2018 with a surgery allegation and a general surgeon named.

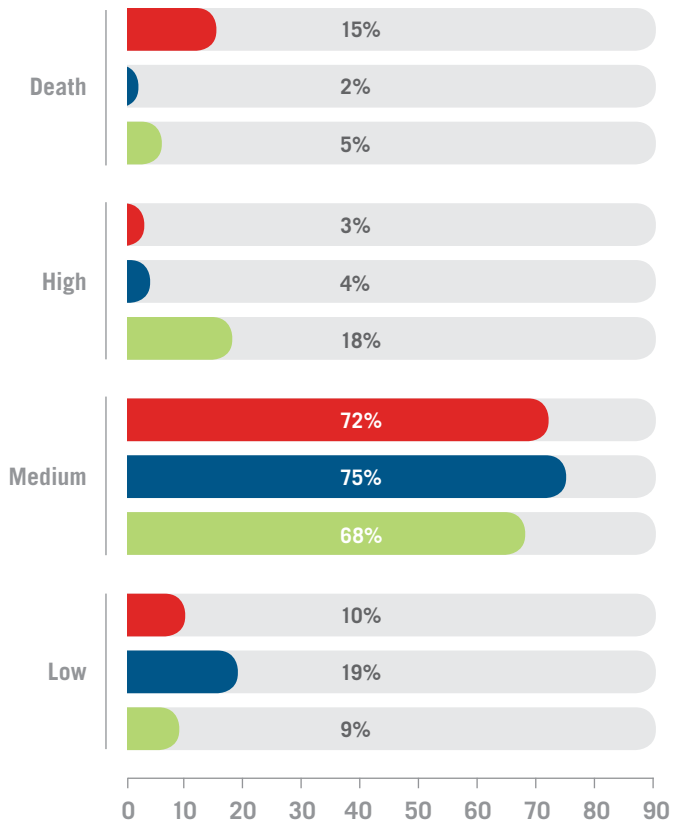
**N = 311 closed claims between 2014 and 2018 with a surgery allegation and an orthopedic surgeon named.

***N = 142 closed claims between 2014 and 2018 with a surgery allegation and a neurosurgeon named.

INJURY SEVERITY*

General surgery has a higher-than-expected death rate of 15%.

- General Surgery*
- Orthopedic Surgery**
- Neurosurgery***



*N = 410 closed claims between 2014 and 2018 with a surgery allegation and a general surgeon named.

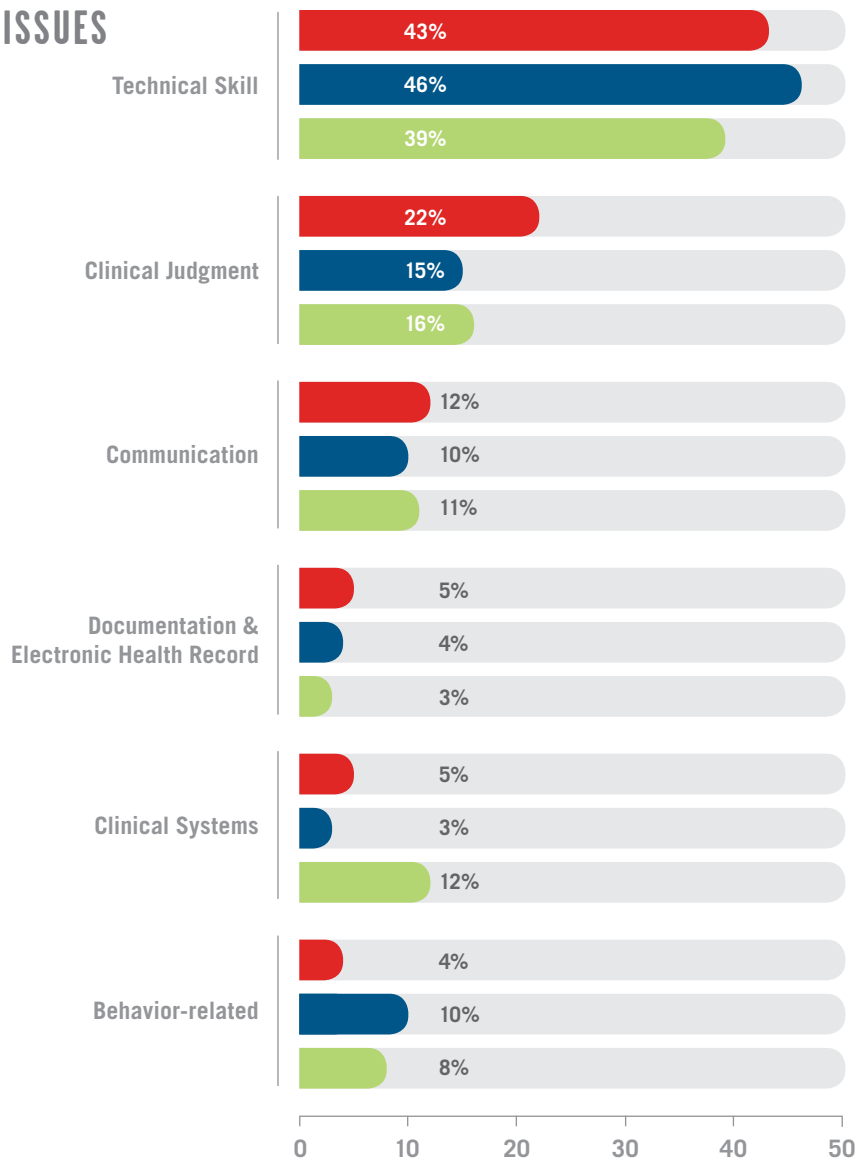
**N = 311 closed claims between 2014 and 2018 with a surgery allegation and an orthopedic surgeon named.

***N = 142 closed claims between 2014 and 2018 with a surgery allegation and a neurosurgeon named.

*Injury severity based on National Association of Insurance Commissioners (NAIC) codes.

RISK MANAGEMENT ISSUES

- General Surgery*
- Orthopedic Surgery**
- Neurosurgery***



*N = 448 risk issues in closed claims between 2014 and 2018 with a surgery allegation and a general surgeon named.

**N = 310 risk issues in closed claims between 2014 and 2018 with a surgery allegation and an orthopedic surgeon named.

***N = 158 risk issues in closed claims between 2014 and 2018 with a surgery allegation and a neurosurgeon named.

General surgery claims had the highest percentage of cases that resulted in death, at

15%

GENERAL SURGERY

CHALLENGES

General surgical teams face issues surrounding appropriate patient selection by colleagues in primary care and a broad range of medical specialties. They must make proactive and sometimes on-the-spot decisions about open vs. robotic procedures, are called upon in cases of trauma, and many don't have ongoing relationships with their patients, making it difficult to develop trust. They also lead procedures at high risk of subsequent surgical site infection because of the frequency of involving the GI tract (including bariatric surgeries).

KEY DATA

- Of the three surgery specialties most likely to trigger a claim, general surgery claims had the highest percentage of cases that resulted in death, at 15%.
- A retained foreign body rate of 9% was higher than the rates for orthopedic surgery and neurosurgery, with about twice the relative incidence.
- General surgery claims had higher-than-average allegations related to patient monitoring — 34% of clinical judgment allegations involved patient monitoring, versus an average of 25% among all surgical specialties combined.

Risk Management Recommendations

- Implement use of assistive technology for soft products such as sponges, packing, and towels.
- Create highly reliable equipment and material management processes including count boards, bar code scanning, and “shout out” rechecks throughout the procedure.
- Monitor surgical quality data for proactive identification of potential opportunities for infection.
- Implement team huddles pre- and post-procedure to promote open communication.

85%

of orthopedic surgery claims allege issues related to surgeon performance.

ORTHOPEDIC SURGERY

CHALLENGES

Orthopedic surgery challenges include: the complexities of joint replacement (and the reliance upon proper post-surgical physical and/or occupational therapy), the sometimes serious risks of spinal surgery (whether open or minimally invasive), the often aging population in need of such surgeries, the extensive use of medical implants and surgical hardware, and the behavior-related and emotional nuances of patients who may be suffering from chronic pain that cannot be completely ameliorated by surgical intervention.

KEY DATA

- Allegations related to surgeon performance appear in 85% of orthopedic surgery claims, as compared to an average of 78% across all surgical specialties.
- A relatively high rate (10%) of claims have a risk management issue considered to be behavior-related. This is driven by two key issues: patient compliance and patients unhappy with their surgical outcome. Compliance issues include patients who didn't return for timely follow-up or who didn't follow discharge instructions.
- Technical skill issues were cited more frequently for orthopedic surgeons (46% of claims) relative to other top specialties (43% for general surgery and 39% for neurosurgery). Improper technique is most commonly identified in this risk category.

Risk Management Recommendations

- Provide effective patient education including informed consent discussions and implement "teach-back" to verify patient's understanding of information provided.
- Ensure comprehensive credentialing and privileging process is in place.
- Conduct vigorous focused professional peer review and ongoing professional peer review of all newly requested procedures and high-risk, high-volume procedures.

11%

of neurosurgery claims allege wrong site/side surgery.

NEUROSURGERY

CHALLENGES

Neurosurgery poses unique challenges because of the sometimes unforgiving nature of cutting in or near the brain or spinal cord, the post-surgical needs of patients who are often admitted to the hospital (including those in the intensive care unit), the myriad physical and occupational therapy requirements after some neurosurgical procedures, the sometimes emergent or trauma-related nature of procedures in neurosurgery, and the possibility that patients presenting for neurosurgery may be relatively frail and at high risk for poor outcomes.

KEY DATA

- Neurosurgery is inherently a high-risk specialty, so it is perhaps not surprising that 23% of alleged injuries were categorized as high severity or death.
- Wrong site/side surgeries were alleged in 11% of neurosurgery claims versus just 2% each for general and orthopedic surgeries. In the case of neurosurgery, these claims most often involve an incorrect identification of the level of the spine.
- Among the top three surgery specialties to trigger claims, neurosurgery is the only specialty in which clinical systems issues were in the top three risk management categories. A deeper dive into these clinical systems issues reveals a lack of (or failure in) systems used to identify the correct body part for surgery, or a failure or delay in scheduling or performing a recommended test.

Risk Management Recommendations

- Use the same counting technique during the preoperative MRI and intraoperative imaging technique. Reach out to colleagues and staff during difficult cases, such as bariatric patients or those with anatomical variances, to verify imaging guidance.
- Adhere to time-out recommendations including open communication and use of checklists.
- Consider implementation of a “second time-out” to radiologically verify level and correlate with pre-procedure planning and consent.

26%

of anesthesia-related claims cite an issue with patient monitoring.

Additional Considerations

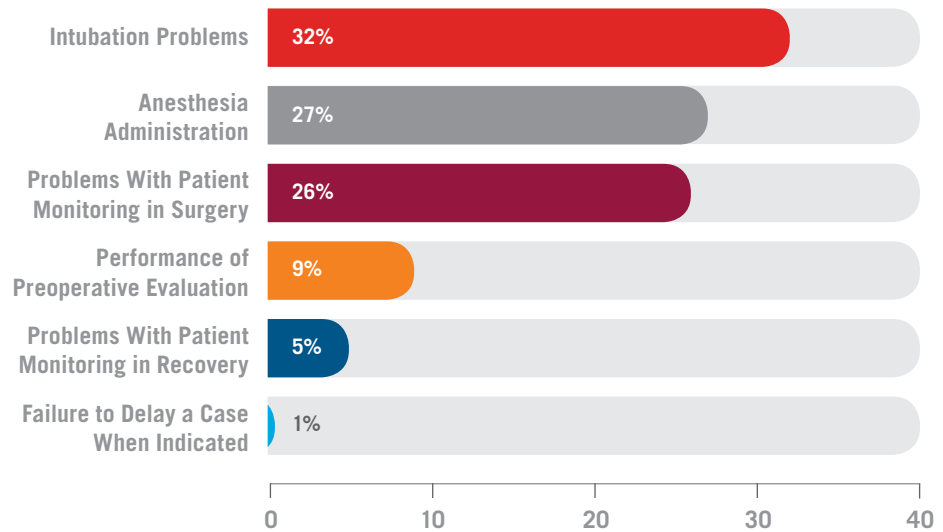
THE ROLE OF ANESTHESIA IN SURGICAL RISK

Nearly all surgical procedures performed in the U.S. involve the use of some form of anesthesia. And the professionals who administer anesthesia do so with a diverse range of training and experience — ranging from RNs (for some local anesthetic administration) to nurse anesthetists and anesthesiologists (for procedures that involve general anesthesia and conscious sedation). Among the Coverys claims analyzed were 329 that involved alleged issues with anesthesia. The impact of these claims is significant — 31% resulted in death and an additional 11% in injuries considered high-severity.

Our data reveals six primary categories of allegation with regard to anesthesia. Given the inherent demands of administering anesthesia — which may involve a mix of boredom and inactivity that can quickly change to crisis response and critical thinking — the fact that 26% of anesthesia-related claims cite an issue with patient monitoring may be an important signal about an area of worrisome vulnerability.

ALLEGATION CATEGORIES AMONG ANESTHESIA-RELATED SURGICAL CLAIMS

N = 329 closed claims between 2014 and 2018 with an anesthesia-related allegation.



OUTPATIENT SURGERY AND AMBULATORY SURGICAL CENTERS

Nearly half of surgeries performed in the United States are done on an outpatient basis.¹² Despite near equality in surgical volume between inpatient and outpatient procedures, Coverys data shows an approximate 70/30 split between inpatient and outpatient surgical claims. This is primarily because the riskiest surgeries and patients are typically managed in hospital inpatient settings. But relative safety now doesn't prevent future risk, and providers of outpatient surgery should closely watch the trends outlined in this report to address areas of vulnerability. Postoperative infections, communication breakdowns, performance issues, operating room distractions, and more — they happen in any environment.

SURGICAL RISK IN REMOTE COMMUNITIES

In big cities and large hospitals, a physician's colleagues are always within arm's reach. But in critical access hospitals in remote or rural areas, help usually comes by telephone. As such, our risk recommendations for surgery in remote communities are unique.

Risk Management Recommendations

- Establish reliable relationships with transport and higher-level-of-care facilities to ensure timely and appropriate care.
- Conduct annual drills with partners to evaluate performance, identify risks, and implement opportunities for improvement.
- Develop telemedicine pathways to support providers in on-the-spot consults and enhanced patient care.
- Complete drills to assess response time and ongoing readiness of surgical team and resources, especially for low-volume cases.

General Principles for Managing Risk and Improving Safety

Throughout this publication, we have provided data-driven recommendations for reducing risk and improving outcomes related to the surgical episode of care, from preoperative considerations through full postoperative recovery and treatment. Following is a final list of recommendations that apply broadly to the phenomena of surgical risk in U.S. healthcare — regardless of where your hospital or facility is located, and who it serves. As you and your colleagues approach each new day with an eye toward improving patient care and reducing risk, we strongly encourage you to consider these general principles:

Right patient, right surgery, right time. Surgical performance begins long before anyone scrubs in. Significant strides in surgical safety will be made by practitioners who focus their efforts on optimal patient selection, consideration of alternatives and variable surgical approaches, and striking the right balance between not rushing to an unnecessary procedure and not causing undue delay in performing surgery.

Functional teams, safer patients. With few exceptions, surgery is a team endeavor. Practices and facilities that invest in the ongoing improvement of team dynamics (in and out of the operating room and during handoffs) and those that empower every member of the team to speak up on behalf of the patient will remain less prone to surgical risk and subsequent claims. Communication and teamwork are, in and of themselves, risk management strategies.

Begin with the end in mind. It's easy to think of surgery as the period in which the procedure is active — when patients are sedated or numbed, and when providers have instruments in hand. But surgeons and surgical teams who are vigilant about every step in the surgical episode of care — from initial planning and preoperative decisions through postoperative monitoring and aftercare — increase the likelihood of good outcomes. Technical skill and surgical performance, by themselves, are not enough to keep patients safe.

Words before scalpels. Communication is crucial, not just among team members, but particularly between provider and patient. As you seek to improve outcomes, increase surgical volume, or offer new procedures, you would be wise to build your strategy with initial emphasis on world-class practices in shared decision-making, comprehensive patient consent, and proactive and ongoing communication that seeks to create clarity, trust, and meaningful relationships.

Ongoing education, in all areas, is key. Surgery is not a perfect art, nor is it an unchanging science practiced by providers whose skills and judgment will never wane. As you plan to improve surgical safety (or maintain an already strong record), high standards for credentialing, education, and training will serve you well — not once, but over and over again, especially as new procedures, technology, equipment, or processes are introduced.

Discipline counts: processes, rigor, and unwavering consistency. Whether it's your rules about counting sponges, your adherence to proven checklists, or your gut feeling about the safest way to set up an operating room, remember that successful surgical teams are disciplined surgical teams who understand that variability opens up vulnerability and that policies and procedures developed with patient safety in mind should rarely, if ever, be considered optional or adjustable.

Conclusion

Every day in the United States, tens of thousands of surgical procedures are performed, most without major incident but all with inherent risk for poor outcomes. At Coverys, we believe that the stories within the data from claims that arise out of surgery are signals — beacons of hope, signs of vulnerability, and clues for continuous improvement. As we think about the imperative for surgeons, we suspect it could not be better articulated than it is in the mantra of the American College of Surgeons: “Inspiring Quality: Highest Standards, Better Outcomes.”¹³

When determining what creates quality or puts it at risk, data is a good place to start. It is our sincere hope that the insights offered in this report will inspire improvement in your hospitals, practices, and facilities; that they might give rise to your own analysis of what’s working and what’s not; and that, in the future, all surgeries — major or minor, emergent or elective, inpatient or outpatient — might be safer because of your commitment to your patients, to your work, and to your colleagues.

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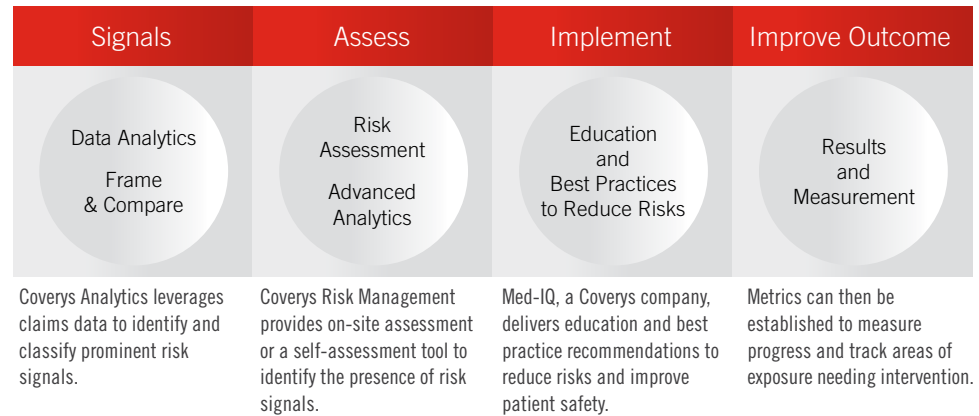
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The Coverys Value-Based Model to Improve Outcomes

As organizations transition from a volume-based to a value-based reimbursement model, healthcare providers must shift from reactive risk mitigation to proactive and preemptive solutions. To help make this shift, Coverys recommends a value-based model that uses data analytics and risk assessment to identify and assess risks that overlap with quality metrics.



For more information about the root causes of claims, access the Coverys Interactive Risk Analytics Dashboard at Dashboard.Coverys.com.

Case studies and other patient examples shared in this publication are derived from actual liability claims with identifying details removed or altered to protect the anonymity of patients, families, practitioners, and healthcare organizations.

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