Mapping the Perioperative Claims Experience of General Surgeons

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Introduction

Many of the common surgical procedures in the country, including cholecystectomies, appendectomies, inguinal hernia repairs, mastectomies, and colectomies, are performed by general surgeons. General surgeons are also among the surgical specialists with the highest rates of medical malpractice claims, at rates of 3.5 to 4 times that of other physicians. About 63 percent of general surgeons have been involved in a medical malpractice suit.

One way to investigate the potential risks involved in a general surgeon's surgical care is to review past medical malpractice claims related to certain procedures. The primary purpose of this study was to explore the perioperative continuum to visualize at what points along that continuum general surgeons' patients experienced adverse events.

> The research question was: *Among medical malpractice claims in the loss years of 2015 to 2020, what were the most common contributing factors in the different phases along the surgical continuum for general surgeons?*

The Doctors Company is the nation's largest physician-owned medical malpractice insurer, with over 84,000 members. Its mission is to advance, protect, and reward the practice of good medicine. To achieve this, The Doctors Company studies malpractice claims to better appreciate the factors that motivate patients and their families to pursue claims and to gain a broader overview of system failures and processes that result in patient harm. From these studies, The Doctors Company designs risk mitigation strategies to improve patient safety and reduce malpractice risk.

Methodology

This analysis was guided using the five perioperative phases defined by the American College of Surgeons (ACS). Clinical summaries from The Doctors Company's medical malpractice claims involving general surgeon surgical claims that occurred between the loss years of 2015 to 2020 were retrieved. The interest for this study was in the management of the surgical patient over the various phases of the surgical continuum, which is captured in the case type of improper management of the surgical patient. Therefore, those claims related to the improper management of a surgical patient were sorted by perioperative phase: (1) preoperative, (2) perioperative, (3) intraoperative, (4) postoperative, and (5) postdischarge. Members of the research team independently reviewed each clinical summary, then

flagged the contributing factors according to phase of care. (A contributing factor could be included in more than one phase if applicable.) Thereafter, team members met and reviewed their findings. After all summaries were reviewed, the results were tabulated.

Findings

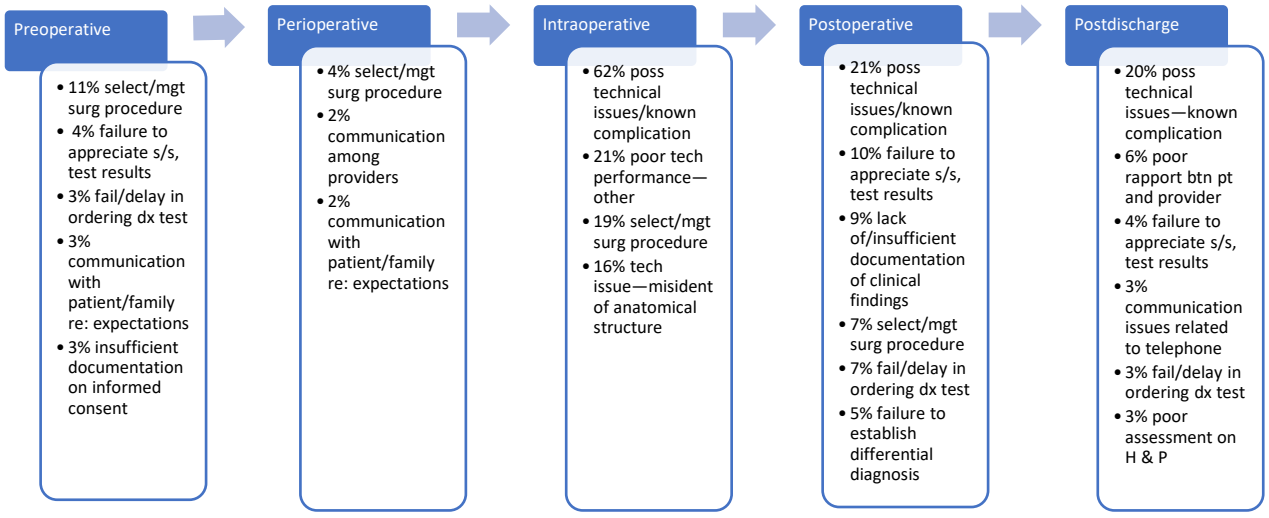
A total of 203 general surgery claims involving improper management of the surgical patient were included in the study. The average patient age was 51 years old, with a range of 2 years old to 95 years old (median age 52 years old). These claims included 115 female patients and 88 male patients.

The claims occurred more frequently in the inpatient setting (n=139) than in the ambulatory setting (n=63). One claim occurred in the emergency department (ED). Using the National Association of Insurance Commissioners (NAIC) Severity Scale, the overall injury severity was 64 percent medium (n=129) (nondisabling), 32 percent high (n=64) (disabling, including death), and 4 percent low (n=9). However, the injury severity differed widely between inpatient and ambulatory settings. In the ambulatory setting, the injury severity was 79 percent medium (n=50), 11 percent high (n=7), and 10 percent low (n=6), while in the inpatient setting, the injury severity was 57 percent medium (n=79), 41 percent high (n=57), and 2 percent low (n=3).

Obesity was the most common comorbidity in the sample at 22.7 percent (n=46), including 22 claimants who were morbidly obese (Body Mass Index [BMI] >40). Seventeen percent had hypertension (n=35), 11 percent had diabetes (n=23), and 10 percent smoked (n=20).

Laparoscopic cholecystectomies were the most common surgeries (28 percent; n=57) involved in the claims, followed by hernia repairs (17 percent; n=34).

Contributing Factors Along the Phases of Surgical Care



Phase 1: The Preoperative Phase

The surgical preoperative evaluation and preparation phase of care begins when the patient and provider start the decision-making process / informed consent process in the doctor's office or in the hospital.

The contributing factors in this phase centered around clinical judgment and communication. Eleven percent (n=22) of the claims involved issues surrounding the selection of the type of surgery. Issues involving communication between the general surgeon and the patient were seen in this phase. Choosing the right tests to optimize the patient for surgery, as well as setting expectations with the patient via communication about the procedure, are essential to minimize surgical risks.

Case example:

A male patient, in his late sixties with multiple comorbidities, including chronic obstructive pulmonary disease (COPD) and diabetes, who had undergone several previous abdominal surgeries, was admitted to the hospital with left upper quadrant pain and known gallstones. An abdominal CT showed a large hiatal hernia, with wall thickening around the duodenum suggestive of duodenitis, but with no choledocholithiasis and no air. The diagnosis was duodenitis. A perforation of the duodenum was suspected, prompting a surgical consult. The patient's condition improved over the day. He denied any nausea or vomiting, was tolerating

clear liquids well, and was hungry. His pain had resolved when the surgeon saw the patient later that evening. The surgeon thought the patient had chronic cholecystitis with a possible cholecystoduodenal fistula. He discussed laparoscopic surgery with the patient, including the possibility of conversion to an open procedure. No documentation showed that any alternate treatment options were discussed, such as a medical approach or watchful waiting to see if symptoms returned. The patient consented to proceed with surgery the next day.

Upon entering the abdomen, the surgeon found many adhesions and a distortion of the anatomy. The procedure was converted to open. A puncture was noted in the colon, and promptly repaired. Postoperatively, the patient developed pneumonia and an infection, requiring at-home wound care. He had an extended stay in the hospital.

The patient had been improving medically prior to surgery, and experts agreed that less invasive treatment should have been considered prior to surgery.

Recommendations

Development of a surgical plan and the goals of that plan should be discussed with the patient and their family. The consideration, discussion, and documentation of the patient's comorbidities are also part of the preoperative process. This process includes review of the patient's medical records, including past records.

Communication with the patient and family is essential and includes active listening on the part of the healthcare provider. Include information about how the surgery may affect the patient's activities of daily living and what to expect during the postoperative recovery period. Most importantly, encourage the patient and family to ask questions.

Inform the patient and the family about surgical risks in general and the specific risks based on the patient's specific condition and unique personal risks. Set patient expectations about the use of multiple checks for their safety during the surgical experience, so they are comfortable with the process and ask questions if they see those checks do not occur.

Surgeons should consider incorporating these two tools:

1. The ACS National Surgical Quality Improvement Program (NSQIP) Surgical Risk Calculator is one tool a surgeon may use to aid in estimating the risk of postoperative complications based on an individual patient's physical condition and comorbidities. Further discussion with the patient about the goals of treatment helps to align expectations, and to create more effective communication and shared decision making. Once the patient understands the treatment options and how each may impact their personal health, as well as the risks, benefits, and goals for treatment, they are better prepared to choose the best treatment to meet their goals.
2. Strong for Surgery, developed by the ACS, is another tool that can assist physicians in optimizing patient health for surgery. It uses pre-surgery checklists to focus on four areas (blood sugar, nutrition, smoking, and medication). The checklists support a standardized presurgical evaluation and then recommend opportunities for intervention.

Phase 2: The Perioperative Phase

The perioperative phase of care begins when the patient enters the status of nothing by mouth / *nil per os* (NPO), starts prep for the procedure, holds or begins pre-op medications, has the placement of invasive lines for surgery, arrives in the preoperative holding area, or when the patient comes to the ambulatory surgery setting. The phase ends when the patient enters the operating room.

In this phase, contributing factors related to the choice of procedure are important, but so are the communication between healthcare providers and addressing administrative issues like staffing and policy/procedure issues. Although the healthcare provider should have already reviewed the patient's medical records, another careful review of the patient's medical records, including the surgical consent, should occur during this phase. Team communication about any conditions or special equipment that may be needed for the patient and their specific risks are discussed. Checklists are an important part of assuring everything is available and ready. During this phase, confirmation of the exact location of the surgical site and assurance that all documents concur with each other occur in collaboration with the surgical team and, more importantly, with the patient. Communications confirming the administration of preoperative antibiotics and/or completion of preps are verified. Discussing expectations for the surgery and offering the patient and family a final opportunity to ask questions are also important steps that occur during this phase.

Case example:

An obese male patient (BMI 43) with multiple comorbidities presented to an ambulatory surgery setting for the removal of a lesion at the base of the thumb, radial side of the arm. The surgeon marked just the radial aspect of the wrist, not the particular site. In the operating room the nurse used Hibaclens, which did not remove the ink used to mark the site. However, the surgeon could not locate the markings he had put on in the preoperative holding area.

The surgeon's options were to stop the surgery in order to wake the patient and reidentify the correct site or to proceed. The surgeon decided to continue with the surgery and made an incision the pinkie side of the wrist (ulnar side) instead of thumb (radial) side. The surgeon excised a 1.5 to 2.0 cm fatty mass from near the ulnar styloid. Pathology identified the mass as a lipoma. Nothing else abnormal was noted in the area. A few days later, during the postoperative follow-up, the surgeon realized the wrong site was operated on and apologized to the patient. A follow-up operation was scheduled, but the patient did not return.

The nurse's deposition indicated that only the wrist was marked to indicate the radial side, with no indication of a precise surgical site. The surgery center has since made a policy that surgeons must circle the location of anything that is be removed in the operating room.

Recommendations

The use of preoperative checklists provides a layer of safety, redundancy, and standardization. Checklists may proactively identify and prevent potential surgical errors related to misidentification of patients, procedure, surgical site, and medications. Completing the checklist and using that information provides an opportunity to brief the surgical team about allergies, comorbidities, and patient status indicators such as vital signs and oxygen saturation readings.

Documentation of informed consent and what was discussed with the patient, including the risks and the patient's understanding, is important information to review in this phase to make sure expectations are aligned. Marking the surgical sites should be performed with the patient actively involved. Ideally, the marking should be done by the surgeon who will be responsible for the surgery and will be present in the operating room. The marking ink needs to be visible after prepping is completed and not covered by drapes or other coverings.

A time-out conducted in the pre-op holding area is needed to assure that all the required documentation, including radiological reports and lab results, is present and that the correct orientation of the films are identified. The time-out needs to involve the patient and includes verification of the patient's identity, surgical procedure, anatomical site, and laterality (if appropriate). The surgical team should be empowered to stop surgery during the time-put process if there are any discordant findings. Surgery should not resume until there is resolution of any conflicting information.

Phase 3: The Intraoperative Phase

The intraoperative phase of care begins when the patient enters the operating room in a hospital or ambulatory surgery center and ends when the patient leaves the operating room.

This phase had the largest number of contributing factors. Technical skill issues in this phase were prevalent, with known complications occurring most often (62 percent; n=125). Some examples of known complications in the intraoperative phase included nerve damage, an incidental tear of internal structures, or a nick from an instrument. Issues related to poor technique and misidentification of an anatomical structure were notable as well (16 percent; n=32), with the majority of cases involving misidentified anatomical structures during laparoscopic cholecystectomies.

Additionally, in 19 percent (n=38) of the claims, clinical decisions about the selection and management of invasive procedures occurred in the intraoperative phase. These decisions often involved the decision, or lack of it, to convert to an open procedure.

Issues involving monitoring patients for risks related to positioning or fire were also seen.

Case example:

An elderly patient was admitted to ambulatory surgery for a biopsy on the chest. In the operating room, the general surgeon requested a skin preparation of ChloraPrep (an alcohol-based skin prep), which was applied by the surgical nurse and allowed to dry. The general surgeon inspected the prep area and did not see any pooling. The surgical tech placed a drape, and a time-out was done, but did not include discussion of fire precautions. The anesthesiologist administered IV anesthesia and 6 L pure pressurized oxygen (O2) through a mask (not a closed system). The general surgeon then made an incision and used an electrocautery unit for bleeding. There was no communication between the surgeon and anesthesia that the cautery was about to be applied. A flash fire ignited and traveled under the oxygen mask, spreading quickly to the drapes. Staff immediately removed the drapes, and wet towels were applied to the patient's face. Surgery was completed, and the surgeon informed the family of the fire and patient burns. The patient was admitted to the burn unit, having sustained second- and third-degree burns to the face, and required a skin graft.

Recommendations

Time-outs have evolved as a critical action for patient safety in a procedural setting. Prior to the incision in the surgical suite, the team conducts a time-out to confirm the patient's identity, surgical procedure, anatomical site, and laterality (if appropriate) before starting the procedure. The team can discuss the plan for the procedure and any unusual concerns for the safety of the patient. The time-out sets the tone for the case and should empower every member of the team to speak up for patient safety. An additional time-out occurs to count the instruments, sponges, and other surgical objects at the end of the procedure. This critical safety step assures that there are no foreign bodies left in the patient. Finally, the surgical team conducts a debriefing at the end of the procedure.

The Academic Medical Center Patient Safety Organization's (AMC PSO's) *Patient Safety Guidance for Perioperative Fire Safety* recently recommended that, in addition to the OR time-out, teams conduct a preoperative huddle to discuss the risk of a fire. Separate from these in-theater discussions, AMC PSO recommends standardized fire education with both interactive (simulation opportunities) and didactic instruction for the entire team.

ECRI reports that about 90 to 100 surgical fires occur each year, further emphasizing that the use of time-outs, briefs, huddles, and surgical debriefs are important patient safety tools. Training opportunities for the prevention of and response to surgical fires and teamwork skills that focus on communication, psychological safety, situational monitoring, and vigilance are important to create and sustain a culture of safety. This means that all members of the surgical team should encourage and embrace a safety culture in the operating room. The entire surgical team, from the technician to the surgeon, should feel secure speaking up about any safety concerns. Communication, or the lack of it, has contributed to surgical fires, in addition to wrong site surgeries and unintended retained foreign body claims.

Distractions such as socializing, multiple calls into the operating room, and loud music all may contribute to errors. Creating an atmosphere that appreciates critical parts of surgery and issuing a call to focus during those times are effective ways to decrease risks. Situational awareness and cross-monitoring are skills that should be cultivated and regularly practiced. Unintended retained foreign bodies, fires, and wrong surgeries are a team failure. High-functioning teams are an imperative, but particularly in this intraoperative surgical phase. Another critical time in any surgery is at closing the surgical wound and the tasks that occur related to counts. Calling for focus and keeping distractions at a minimum, with communication open, are strategies that can prevent errors.

Phase 4: The Postoperative Phase

The postoperative phase of care begins when the patient enters the postanesthesia care unit (PACU) in a hospital or ambulatory surgery center and ends upon discharge.

The second-highest number of contributing factors occurs in this immediate post-op phase. Known complications, such as delayed perforations and infections, were often detectable during this phase. Surgeons should always maintain a high index of suspicion for the most serious complications and rule those out before moving to a less serious complication. They should also communicate with nursing regarding any concerns calling for a watchful eye—issues involving inadequate communication between healthcare providers were observed in 10 percent of the claims.

Patients posing the greatest risk of developing serious complications include those who had complicated surgeries, such as those with adhesions; those with a chronic illness, such as Crohn's disease; or those with anatomical anomalies that make identifying structures more challenging.

Issues related to incomplete or deferred patient assessments were observed as contributing to a delay in diagnosis of complications. In 10 percent (n=20) of the claims filed based on events occurring during the postoperative phase, there was a failure to appreciate the signs and symptoms the patient was experiencing. Failure to document clinical findings such as pertinent negatives were present in 9 percent (n=15) of the claims.

Case example:

A female patient in her thirties was admitted from the ED with severe abdominal pain, nausea, and vomiting. An abdominal CT showed cholelithiasis and possible cholecystitis. The patient was seen the next day by a general surgeon, who diagnosed acute cholecystitis. Later in the day, she was taken to the operating room for a laparoscopic cholecystectomy. The operative report documented that the general surgeon had achieved the "critical view of safety." There were no complications.

The next day, the patient had complaints of severe pain in the right scapula and nausea. The surgeon ordered Toradol and ambulation. Postoperative day two, the severe pain continued, and the patient was taking Dilaudid every two hours. She also had hematuria and was not passing flatus. The general surgeon noted the symptoms and attributed them to acute anxiety. He ordered lorazepam and increased her Dilaudid dose.

Postoperative day three, the patient was passing flatus, had a low-grade fever, and improved pain, but remained on pain medications. The plan was a trial of tramadol for pain, a review of morning labs, and to discharge if the pain was tolerable. Postoperative day four, the patient's bilirubin level was high, and her pain was difficult to control off the Dilaudid. Discharge was cancelled until the following day. The patient was discharged, despite pain and vomiting.

Two days later, the patient was admitted to a different hospital with abdominal pain, nausea, and vomiting. She was started on antibiotics. A CT showed a large amount of free fluid in the abdomen. The next day an endoscopic retrograde cholangiopancreatography (ERCP) confirmed a common bile duct injury (cut and clipped). A drain was placed, but the patient subsequently developed sepsis.

Once the patient was stabilized, she had a bile duct resection and biliary reconstruction. The experts were critical of the failure to timely diagnose the injury based on the symptoms.

Recommendations

Postoperative management involves the need for a complete assessment, including the consideration of the most serious possible complications from the procedure. Complications are not always avoidable, but to preclude litigation when they do occur, documentation of clinical reasoning may explain the approach taken, thus making the case defensible. In this case, there was no assessment documented to rule out more serious causes of pain or to reveal the thought process of working through various

differential diagnoses. Adding insult to injury was the attribution of the patient's symptoms to acute anxiety.

Effective communication between healthcare providers is crucial to ensure patient safety. The use of a structured communication tool, like the mnemonic SBAR (Situation, Background, Assessment, Recommendation), can aid in assuring that healthcare providers reach shared understanding.

Be alert for potential implicit bias. In this situation, the reference to "acute anxiety," with no evidence of working through and ruling out the most severe and most probable cause, worked to the plaintiff's advantage. Careful observation for signs of infection and consideration of common causes of infection should always be a primary concern with unresolved pain or variance from the normal course of recovery. Documentation should demonstrate that every symptom was evaluated, and the most serious cause ruled out with precision.

Phase 5: The Postdischarge Phase

The postdischarge phase of care begins when the patient is discharged from the hospital or ambulatory surgery center to their home, to rehab, and/or to a nursing home.

During this phase, known complications can present—with communication issues and clinical judgment contributing to diagnostic errors. Specifically, communication issues between the provider and the patient frequently develop. Six percent (n=12) of the claims revealed issues related to poor rapport between the general surgeon and the patient, while another 3 percent (n=7) showed factors related to telephone communication.

Case example:

A patient had a right hemicolectomy and appendectomy by a general surgeon. The patient developed a postoperative ileus, which resolved prior to discharge. The patient had watery bowel movements prior to discharge and remained on a liquid diet at discharge. The patient's wife called to make a follow-up appointment and related to staff the patient had no appetite and was experiencing watery stools. There was no documentation about any complaints or questions.

The wife called the office to report the patient was not tolerating his diet and had not had a bowel movement in two days. Again, the documentation by the nurse did not address pain, how long the patient had not been tolerating the diet, or other details about the patient's condition. The wife was offered an appointment for that day, but she said they did not have a ride and were coming in few days for the scheduled appointment.

The patient died later that day. An autopsy showed an infection and necrosis at the bowel anastomosis site right lower quadrant (consistent with a partial or total obstruction). There was 1500 cc blood in abdomen along with stool in the colon below the anastomosis site.

The wife said she had told the nurse that the patient had been having pain since discharge, had been unable to eat, and had vomited repeatedly. The nurse denied these details were shared with her.

Recommendations

Patient education should begin early and should be repeated at discharge regarding what to expect in the postoperative period. Communication with the patient and family should include a description of any signs or symptoms that would indicate they should seek immediate attention. All communication with the patient and family needs to be clearly documented in detail reflecting the questions asked (e.g., denies pain, no nausea or vomiting, etc.). Validate that the patient and the family understand the expected outcome of the surgery by asking them to repeat instructions back. Encourage questions and reinforce what they should expect during the upcoming recovery period. To gauge their understanding, have the patient say, in their own words, what they understand about the information that was shared. Educate office staff via written protocols regarding when to work patients into the schedule or send them to the ED. Unlicensed staff should not be allowed to assess the symptoms and make decisions without involving the responsible clinician.

Health literacy needs to be considered when providing discharge instructions. Healthcare providers should be careful to note language barriers, age, and socioeconomic barriers that may possibly impede the understanding of the information. Written instructions need to be in an easy-to-understand format. Whenever possible, make a follow-up appointment at the time of discharge to prevent missing important postoperative follow-up intervals.

Written policies that address the documentation of calls from patients are advisable. These policies should include which calls require referral to a physician. Written protocols for when to bring postoperative patients in should be clear to all staff. Recent post-op patients with any unusual recovery patterns such as prolonged pain, inability to tolerate diet, or issues with urinary output should be referred to the physician. Policies should also include how to have on-call physicians document their calls. Some EHRs offer an integrated EHR/messaging system, which provides an efficient means of recording documentation and creating alerts for physicians.

Discussion

This analysis illustrated that malpractice claims involving general surgeons can have contributing factors beyond just the technical aspects. Patients often present with multiple and/or severe comorbidities, and issues can arise during various phases of their surgical care. Surgeons need to synthesize and communicate information about risks, so that patients can make informed decisions about surgery and the outcomes they can expect based on their individual risks.

This analysis highlights the importance of the selection of the specific surgical procedure. The choice of a traditional approach vs. a minimally invasive or even robotic approach to the surgical procedure entails several considerations. The ACS NSQIP Surgical Risk Calculator may help surgeons and their patients identify potential risks from surgical procedures based on the patient's comorbidities. The surgical risk calculator is a tool, and as such, it should be understood that no tool is perfect.

A recent study notes the challenges with communication during the informed consent process. The study findings propose a visual-based consent tool, which the authors note could improve shared decision making between the patient and the surgeon.

The March 2022 issue of Candello's *Illuminating Risks* examined 38,000 medical malpractice claims (including The Doctors Company's claims) and found that 16 percent of the general surgery claims had issues related to known complications. These are complications that are known risks of surgery and that

are discussed with the patient preoperatively. When a complication arises, one factor affecting the likelihood of a malpractice claim is the degree to which potential complications were discussed preoperatively. The report explained that 27 percent of claims involving a known complication settled with payment, and that comorbidities add to the chance of complications. Documentation of clear, concise communication with the patient prior to the surgery and after surgery about potential complications helps to set patient expectations about the surgical outcome. Should a claim arise, strong communication and documentation increase the likelihood of prevailing with a defense verdict.

Many claims and injuries were associated with laparoscopic cholecystectomies in this analysis. However, laparoscopic cholecystectomies are the most common procedure performed by general surgeons in the U.S., with over 600,000 completed annually. Recurring issues with cholecystectomy procedures involve the lack of an intra-operative cholangiogram with a surgical procedure complicated by adhesions, so the consideration of an intra-operative cholangiogram may be warranted. Failure to document that there was visualization of the "critical view," followed by failure to manage complications during the postoperative or postdischarge phases, are other issues commonly seen in laparoscopic cholecystectomy claims.

Limitations

This data was extracted from a retrospective review of closed malpractice claims from a single large national malpractice carrier. Data was limited to what was available at the time of the review. Clinical summary information was altered to assure no personal information was disclosed.

This study does not represent complications that arose in situations where the patients did not file a claim. It also excludes situations where patients did not experience complications from their procedures. This study was limited to claims that demonstrate improper management of a surgical patient.

Conclusion

Complications can occur in all phases of the perioperative episode. Understanding the most common types of complications and the factors that contribute to errors may provide insights for general surgeons about their practice. Surgeons and their support staff can use those insights to identify vulnerabilities in their processes and proactively create defenses to prevent similar errors from occurring. Designing processes with intentional communication and collaboration between the surgeon's office and the surgical setting is paramount to creating a culture of safety. Delays and errors may occur when documentation from the office is not available for the surgical team to proactively review risks, verify the surgical site, or verify the procedure. It is essential in preparing for surgery to have patient information, including all images and necessary equipment, available and ready. High-functioning teams that routinely simulate emergencies respond more effectively in a true emergency. Learning from past errors can improve patient safety.

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