



Common Factors[™]

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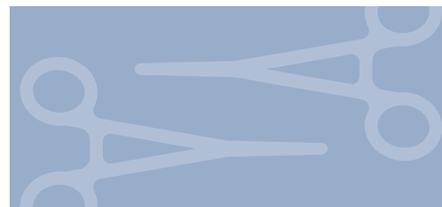
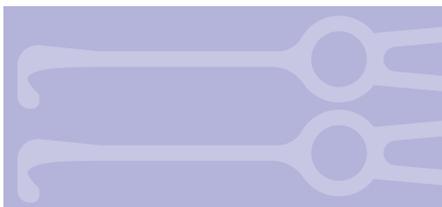
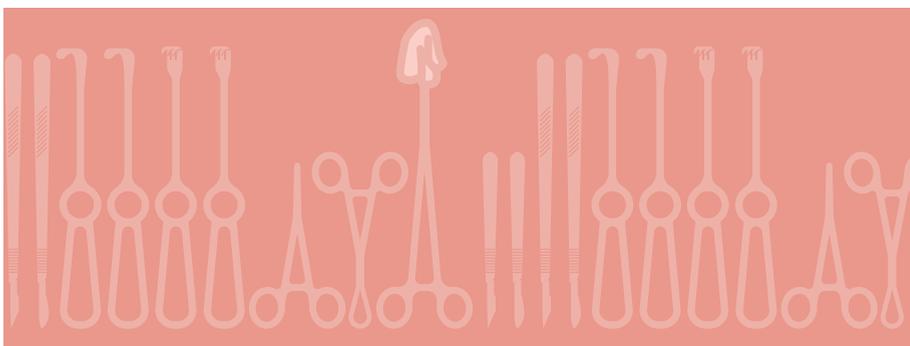
THE SURGERY ISSUE

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by LORI ATKINSON,
RN, BSN, CPHRM, CPPS
and LIZ LACEY-GOTZ



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Common Factors™ is published four times annually by Constellation, a growing portfolio of medical professional liability insurance companies formed in response to the ever-changing realities of health care and dedicated to reducing risk and supporting physicians and care teams, thereby improving business results. Formed in 2012 as a response to an increasingly challenging market, Constellation is guided by its own board of directors comprised of physicians, medical liability professionals and health care leaders. MMIC is a founding member company; UMIA joined Constellation in 2013 and Arkansas Mutual joined in 2015.

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Deep Cuts

A dive into the data on surgery claims

By Lori Atkinson, RN, BSN, CPHRM, CPPS and Liz Lacey-Gotz

Surgeries continue to increase in number in the United States each year, with a significant increase in procedures being performed in outpatient surgery centers. Estimates from a 2015–2017 National Quality Forum report show that more than 100 million procedures are performed each year in surgery centers, including both inpatient and outpatient facilities.

Errors can occur and lead to surgical patient harm, as well as malpractice claims, not only in the performance of surgery but also in the preoperative and postoperative phases, and they can involve both technical skill issues and patient management issues.

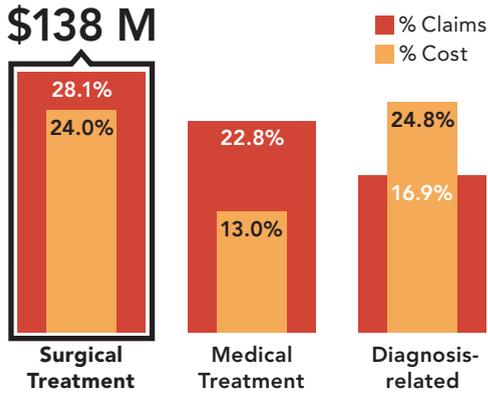
Our analysis of Constellation medical professional liability (MPL) claims* shows that **surgical allegations top the list in occurrence and are second in cost incurred.**

Surgical allegations

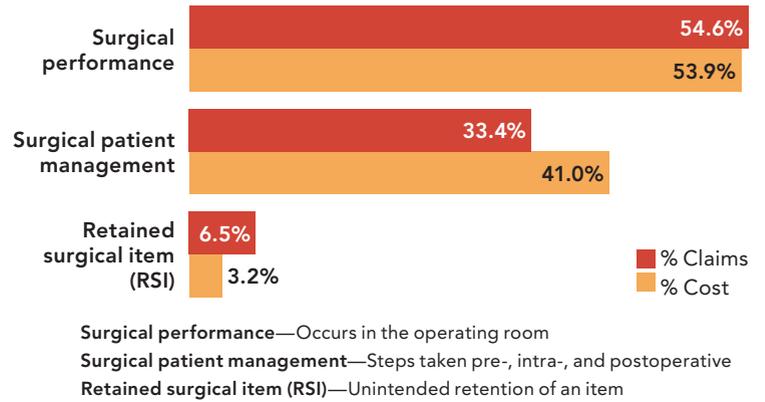
#1 in occurrence **#2** in cost **\$138 M** total incurred cost

*Constellation MPL claims asserted from 2010–2017

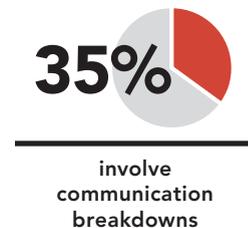
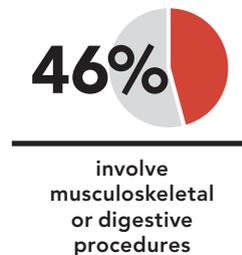
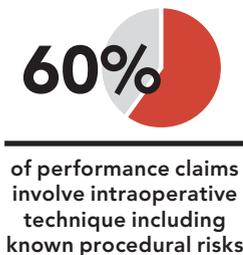
Allegations triggering all claims



Allegations triggering surgical claims



What is driving surgery claims?



Surgical claim costs

When surgeries go wrong, costs can occur in the form of payment to the injured patient or family, and also in the investigation and defense of a claim. Beyond these monetary costs are stress and lost productivity for clinicians and care teams, reputation damage to the organization and breakdown of patient–surgeon relationships.

Our analysis shows that 28% of surgical claims are closed with indemnity paid, meaning that a payment was made to the injured patient or their family after investigation into the claim determined the standard of care was not met. This percentage is significant, but similar to the 28.9% of all claims that are closed with an indemnity payment. The average indemnity paid on a surgical claim was \$297,000.

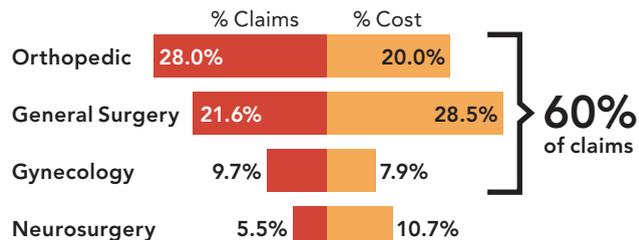
Although the majority of claims closed without an indemnity payment, there were expenses involved in investigating a claim—the average expense of a surgical claim was \$47,000. The majority of these surgical claims involved technical skill factors, including known procedural risks that should have been discussed prior to surgery while obtaining informed consent from the patient. Yet patients still file malpractice claims.

Key Questions for Leaders

1. Why aren't surgeons recognizing these known risks and complications intraoperatively or early postoperatively and intervening before serious patient harm occurs?
2. Was the communication about the procedure's alternatives, benefits and risks clear and understandable when obtaining informed consent from the patient?
3. Did the informed consent process include a discussion of postoperative expectations and goal setting?

What specialties are driving claims?

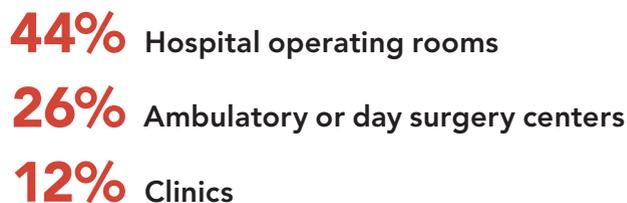
Sixty percent of claims involve clinicians in three clinical specialties: orthopedics, general surgery and gynecology. Neurosurgery claims are notable as well, as they account for a disproportionately large amount of costs.



Where is loss occurring?

Patient harm events that lead to malpractice claims are happening in three key settings: hospital operating rooms, ambulatory or day surgery centers, and clinics.

Top 3 locations of loss



Which procedures are involved?

Some common surgical procedures are more likely to lead to claims, including musculoskeletal surgeries involving hips, knees or shoulders; digestive procedures such as laparoscopic gall bladder surgery, sigmoidectomy or laparoscopic appendectomy; spinal surgeries involving intervertebral discs or spinal fusions; and gynecologic procedures including hysterectomies.

Top 4 surgery types involved



What injuries are most cited?

- Puncture/perforation
- Laceration/tear
- Nerve damage
- Infection

24%

are high-severity events including death

Surgery claims are serious

When surgical patient harm occurs, roughly one-fourth (24%) involve high-severity injuries, including death. Common instances of claims include things like sepsis and death following abdominal surgery, or wrong-site spinal surgery resulting in total disability. Nearly three-fourths of claims (72%) involve medium-severity injuries—things like postoperative infection or non-debilitating nerve damage.

What can be done to improve outcomes and limit patient harm?

Clinicians seek to do no harm, but it is inevitable that errors can and will occur. When these events happen despite clear intentions to improve the lives of our patients, there are ways to better manage going forward. Some factors are within our control and can make a significant difference. The following section summarizes the key areas of focus that can help you improve care and limit claims, benefitting your care teams and your organization in myriad ways.

Top 3 Areas of Focus to Improve Your Care and Help Prevent Claims

Clinical analysis of Constellation claims reveals that they are often driven by factors that can be mitigated with patient safety strategies. These three areas of focus can help you improve your systems and processes, better support your care teams and help limit risk to your clinicians and organization.

1. Improve your preoperative decision-making and communication

- Use clinical decision support tools to assess surgical appropriateness/readiness/risk
- Improve your informed consent process, including expectation and goal setting

2. Be aware of potential gaps in intraoperative technical skill and recognize potential complications up front

- Are there experience issues, including outdated technique or inexperience with new procedures?
- Are there equipment issues, including inexperience with new equipment, operator error or equipment malfunction?

- Is there failure to recognize complications/known procedural risks during surgery?
- Is there failure to have or follow procedural checklists?

3. Watch for failures in postoperative judgment and communication

- Patient assessment and monitoring failures
- Hierarchical and handoff communication challenges
- Lack of strong patient safety culture
- Poor critical thinking skills
- Postoperative discharge instruction and communication failures



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HEALSM  A better way forward
after patient harm events

Honor • Empower • Act • Learn

Constellation's HEALSM Program Offers a Better Way Forward After Patient Harm Events

Our new HEALSM program is designed to equip health care teams to act promptly and effectively after unanticipated outcomes, in order to achieve meaningful resolution.

When a patient is harmed in health care, the way the health care team responds can cause additional harm—for the patient, the team and the organization. Constellation's HEAL program

replaces silence, doubt, fear and frustration with an honest, human-centered acknowledgement of what happened, its impact and what to expect next.

HEAL is based on Constellation's more than 40 years of helping health care teams and their organizations enhance the way they interact with patients and families following adverse events.

HEAL includes four core services:

Clinician Peer Support

Clinicians involved in a harm event frequently struggle with reduced confidence, feelings of shame, distracted thoughts, and emotions that can interfere with their productivity and ability to continue providing safe, high-quality care to their patients. Our Clinician Peer Support Program links them to skilled peers who can help navigate these minefields, maintain their perspective and stay connected with their passion for health care.

Risk Consultation

Figuring out what contributed to a harm event and helping your organization—and future patients—benefit from that hard-won knowledge is important to helping everyone move forward. Our senior risk consultants have decades of experience as hands-on nurses, malpractice defense lawyers and health system risk managers. They'll move quickly to help you focus attention in the right places and leverage your organization's strengths to problem-solve.

Communication Assistance

Research shows that communicating openly and compassionately when a harm event occurs can reduce the likelihood of lawsuits and has many additional benefits, for both patients and clinicians. We'll guide your team through communication challenges in ways that help move everyone toward healing and resolution.

Expert Case Review

Constellation partners with external medical experts to determine whether the standard of care was met as soon as we receive report of a harm event. If it is determined that the standard of care was not met, and that this caused the harm, we let you know right away. Options at this early stage could include an offer of compensation, well before the situation progresses to a claim or a suit, both of which lead to rapidly escalating costs (emotional, financial, and otherwise) and uncertain outcomes.

Learn how our new HEAL program can help your organization
by contacting HEAL@ConstellationMutual.com



When Skill and Technique Fall Short

Surgical performance allegations are the top driver of surgical claims and costs.

By Lori Atkinson, RN, BSN, CPHRM, CPPS and Liz Lacey-Gotz

More than half of surgery claims (55%) involve allegations of surgical performance related to issues with the technical skill or knowledge of technique of the surgeon. More than half of performance claims (56%) originate from patient harm event in hospital operating rooms (ORs), with about one-third (35%) occurring in outpatient surgery center ORs.

Largely, these claims center on intraoperative technical skill/technique and clinical judgement issues, including patient assessment and selection of the surgical procedure.

Surgical performance allegations

Included in

55%

of surgery claims

Account for

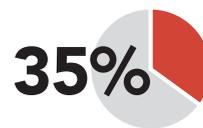
54%

of costs

Where claims are happening



Hospital OR



Outpatient
surgery center OR



Physician's office



Three C's at work: Culture, critical thinking and communication

Culture can play a significant role in surgical claims. You might not think of culture as connected to performance, but when hierarchical or other negative behaviors are present in a care team, it can easily impact the patient. If team members don't feel they can ask for help or call out a concern, performance can be negatively impacted.

In a healthy culture without hierarchical issues, for example, nurses can double check that the surgeon has privileges and is credentialed for the procedure and equipment involved. They can make sure to say something if they see something that needs addressing. They should feel comfortable—and respected—for speaking up. Leadership also plays a key role in culture by upholding proper credentialing, and holding physicians accountable for ensuring they have the proper training, equipment and staff to proceed.

Critical thinking also plays an important role in preventing surgical patient harm and resultant malpractice claims, especially as the surgeon diagnoses the condition and assesses which procedure is best for the patient. Sometimes an outlier diagnosis or a less invasive procedure is missed as an option. Why? Because it is easy to have an automatic response, especially when you think this is something you've seen before and have the answer. But with critical thinking we stay open and alert so that we can see something we can improve, overcoming the biases that narrow our focus and prevent us from seeing the bigger picture.

Communication issues can also be involved in surgery claims related to technical performance. Most specifically, obtaining informed consent, setting realistic expectations and discussing known procedural risks are critical to getting a patient on board with both the benefits and the risks of their surgery. This can include making sure a patient is aware that their medical history—including existing conditions such as obesity or diabetes—might have an impact on recovery or complications. It's also important to make sure you are communicating in a way, and at an appropriate health literacy level, that the patient clearly understands. Having tools like videos or professional interpreters can help.

Constellation uses claim data to help customers identify key areas of risk in their organization. A hospital may only have one claim of a certain type, but the data can help them see larger trends that might indicate areas of potential risk that need to be addressed. With analysis, it's possible to develop solutions to help mitigate risk in the future—benefiting the organization, their care team and also their patients. Because every patient harm event, and every single resulting claim or lawsuit, is significant.

Diving Deeper into the Data

The top five factors* contributing to surgical performance claims include:

1. **Technical skill issues (93%)**, including known procedural risks not recognized during surgery
 - ✓ **Experience issues**, including first time doing a procedure, a twist on procedure, not staying current with practice, out-of-date technique or poor learning environment
 - ✓ **Equipment issues**, such as settings not maintained or not observed, inexperience with new equipment, user error or other type of equipment malfunction
2. **Clinical judgment issues (45%)** include:
 - ✓ **Patient assessment issues**, including failure to use clinical decision support tools to assess surgical appropriateness, readiness and risk
 - ✓ **Poor assessment**, poor monitoring, poor decision making, not considering alternatives to surgery, diagnostic focus too narrow
 - ✓ **Failure to recognize known risks/complications** intra-operatively or soon postoperatively, lack of situational awareness, not being vulnerable to having made an error during surgery
 - ✓ **Failure to have or follow procedural checklists**
 - ✓ **Poor critical thinking skills**
3. **Patient behavior factors (25%)**, including a patient seeking care from another physician due to dissatisfaction with the surgeon's care. Patient behavior could be related to an adverse outcome or complication combined with poor rapport with the surgeon or other communication breakdown.
4. **Communication issues (25%)**
 - ✓ **Patient communication**
 - Includes ineffective informed consent process, including expectation and goal setting, especially involving claims with known procedural risks
 - ✓ **Team communication**
 - Surgical team not knowing the privileges or credentials of the surgeon
 - Hierarchical structure
 - Poor patient safety culture in team members not speaking up due to unprofessional surgeon behavior, or fear of retaliation.
5. **Documentation (10%)**
 - ✓ Surgeon not documenting thought process regarding the selection of procedure, especially consideration of non-surgical alternatives
 - ✓ Late operative reports (dictated months after procedure)

*Note that a claim can and often does have more than one contributing factor.

Surgical Performance Claims Examined

Limited technical experience compounded by late documentation

A 55-year-old woman with a history of a pelvic fracture due to a fall was referred to an orthopedic surgeon after failed cement injections. The orthopedist recommended surgery and placed a four-hole plate into the sacrum with three screws (the three-hole plate he requested was not available at the facility where surgery was performed).

Following surgery, she was noted to have a peripheral nerve injury and the surgeon took her back to surgery. The plate was removed. She continued to have numbness, weakness in dorsiflexion, and she required assistance with activities of daily living.

The experts who reviewed the claim were critical of the orthopedist as he had only done a limited number of these procedures. The operative report was also dictated as being “uncomplicated” and was done three months after the procedure.

Contributing factors:

- ✓ Surgical skill/performance
 - Inexperienced in procedure
 - Equipment availability issues
- ✓ Communication issues: no disclosure to patient about the plate discrepancy
- ✓ Documentation issues
 - Dictated as uncomplicated with no mention of four-hole vs. three-hole plate being used
 - Late dictation of operative report

Poor treatment plan and technique lead to serious postoperative complications

A general surgeon performed a colonoscopy on a patient but stopped the procedure before visualizing the entire colon because he was worried about perforating the colon. He then recommended a total colectomy procedure without discussing other conservative treatments with the patient. The general surgeon encountered a stapler failure during the colectomy procedure and noted “operator error” in his operative note. He then hand-stitched the residual stump area.

Two months after surgery, a CT of the abdomen showed anastomosis clips with dehiscence and abscess. The general surgeon performed fluid drainage on the area. Two months later, a pelvic CT still showed residual abscess and the general surgeon referred the patient to a colorectal surgeon for further surgical treatment.

The experts who reviewed the claim were critical of the colectomy technique used by the general surgeon.

Contributing factors:

- ✓ Surgical skill/performance
 - Practicing outside of specialty training
- ✓ Communication issues: poor informed consent process in not disclosing alternatives including conservative treatment vs. surgery

Potentially unnecessary surgery causes long hospital stay and long-term disability

A 54-year-old man with complaints of diverticulitis was referred to a colorectal surgeon. The surgeon performed laparoscopic surgery to remove the diseased portion of the bowel but had to convert to an open procedure due to the amount of diseased bowel he encountered. Three days after surgery the patient began running a fever and a CT identified an anastomotic leak. The surgeon took the patient back to the OR and placed multiple drains. The man remained hospitalized for 31 days.

Two months later the patient began vomiting what he thought was stool. He was taken by ambulance to a tertiary center where a surgeon removed more sections of diseased bowel and created a colostomy. One year later, he had surgery to reconnect his bowel. He was out of work and then disabled as a result of this complication.

The patient and his spouse said if they had known about this potential disabling complication, they would not have consented to the procedure. They would have opted for more conservative antibiotic treatment first.

Contributing factors:

- ✓ Surgical skill/performance
 - Known procedural risks not disclosed
- ✓ Clinical judgment failures
 - Patient assessment
 - Selection of surgery
- ✓ Communication with patient
 - Poor informed consent

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Is it Technique or Management? Or Both?

Surgical claims primarily involve allegations concerning technical performance issues or management-related issues. The chart below highlights the key differences. Sometimes a claim may involve both a technical performance issue and a management issue, often due to a delay in responding to complications resulting from poor performance.

Technical Performance Issues	Management-related Issues
Involves intraoperative performance	Includes steps taken to manage the patient pre-, intra- and postoperatively
More about skill, technique and performance of the procedure	More about clinical judgment in selecting the procedure and assessing the patient's surgical risk, as well as assessing the patient postoperatively to diagnose or rule out a surgical complication in a timely manner
Communication breakdowns with the patient in obtaining informed consent	Communication breakdowns among the care team about the patient, or between the care team and the patient/family
Examples include pulmonary artery laceration during biopsy for mediastinal mass, or uterine puncture during myomectomy	Examples include delayed diagnosis of anastomotic leak after colorectal resection, or mismanagement of anticoagulation resulting in a pulmonary embolism

Beyond the OR

One-third of surgical malpractice claims involve management issues.

By Lori Atkinson, RN, BSN, CPHRM, CPPS and Liz Lacey-Gotz

Unlike surgical claims due to technical performance issues, claims from improper management of a patient are more about clinical judgment in selecting the procedure and assessing the patient's surgical risk, as well as assessing the patient postoperatively to diagnose or rule out a surgical complication in a timely matter.

Surgical management allegations account for about one-third, or 33%, of cases, and 41% of costs. These allegations of patient harm involve steps taken when managing patients

preoperatively, intraoperatively and postoperatively.

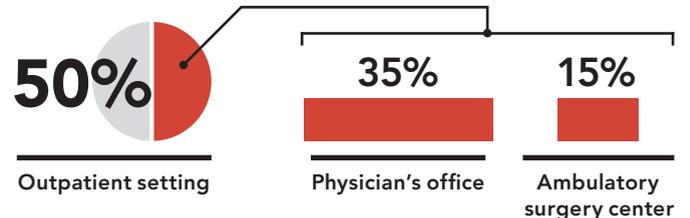
Cases involving claims of improper surgical management tend to cost more to investigate and defend, due largely to the length of time involved when postoperative diagnosis is delayed, when additional specialists and/or procedures are required, or when patient complaints go unnoticed or unresolved. These claims also involve more high-severity injuries (34%) than performance-related claims (20%), which increases costs.

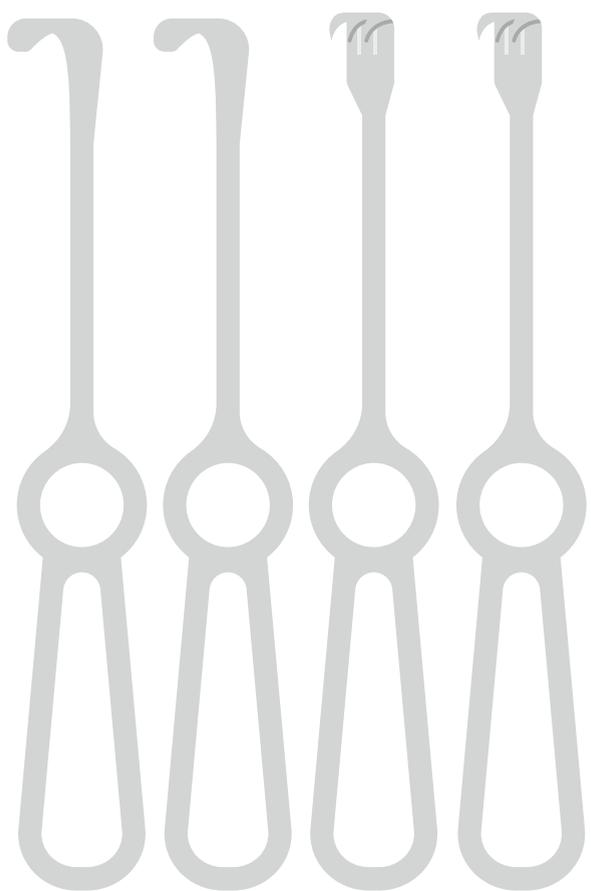
Surgical management allegations

Included in
33%
of surgery claims

Account for
41%
of costs

Where claims are happening





Communication breakdowns are more of an issue in surgical claims involving management issues vs. technical performance

Claim data show that when you have a technical performance issue in surgery, you will also likely find postoperative management issues compounding the problem. As in most claims, there can be many factors that contribute.

When looking at surgical management issues, one is likely to find a lack of communication between the surgeon and the next level of care. Things often don't get resolved soon enough, or they escalate quickly and patient harm increases.

These communication breakdowns are a key driver of surgical management-related claims. This can be patient–surgeon communication, or it can be care team communication. When it comes to communicating with other physicians, other health care team members and/or the patient and family members, our data shows that a lack of communications impacts more than half of surgical management claims.

Poor clinical judgment with patient assessment and selection of the procedure is a contributing factor in 84% of surgical management claims. Early recognition of postoperative issues and prompt action can make a significant difference, yet this doesn't always happen. It can be related to a lack of attention to medical history or failure to use available assessment tools. In the second claim example below, the pre-existing abrasion may have indicated that the patient needed preoperative antibiotics, or perhaps the procedure should have been delayed until the abrasion healed.

Patient factors may also be involved in surgical management claims. Patients may have unrealistic expectations for outcomes or recovery. They may be unhappy with the results, or they may have understood the surgery but not what was involved in rehabilitation.

Diving Deeper into the Data

The top five factors* contributing to surgical management claims include:

- 1. Clinical judgment problems (84%)**
 - ✓ Poor selection/management of procedure
 - Patient assessment issues, including failure to use clinical decision support tools to assess surgical appropriateness, readiness and risk
 - Inadequate history and physical exams
 - ✓ Patient assessment issues
 - Failure to appreciate and reconcile relevant symptoms
 - Failure to respond to repeated patient postoperative complaints
 - Narrow diagnosis focus to rule out surgical complication
 - Failure/delay in ordering diagnostic tests to rule out surgical complication
 - ✓ Poor critical thinking skills
- 2. Technical skill and performance (61%)**—These factors may lead to adverse outcomes that have not been recognized and managed in a timely manner
- 3. Communication breakdowns (54%)**—Communication is a bigger issue with claims involving patient management vs. technical performance
 - ✓ Between patient/family and providers
 - Postoperative discharge instruction and communication failures
 - ✓ Among team
 - About the patient's condition
 - Hierarchical and handoff communication challenges
 - Lack of strong patient safety culture, including an inability to speak up
- 4. Patient factors (21%),** including a patient seeking care from another physician due to dissatisfaction with the surgeon's care. Patient behavior could be related to an adverse outcome or complication combined with poor rapport with the surgeon or other communication breakdown.
- 5. Documentation (21%)**
 - ✓ Insufficient, lack of or late documentation

*Note that a claim can and often does have more than one contributing factor.

Surgical Management Claims Examined

Team communication breakdown and late documentation lead to permanent disability

A surgeon removed a 51-year-old patient's existing spinal hardware and performed a lumbar spinal fusion. The evening following surgery, the man developed bilateral weakness and his nurse contacted the on-call resident who ordered her to continue monitoring the patient. Overnight the man developed complete bilateral weakness and the nurse again called the on-call resident. The resident elected not to come in and examine the patient.

The next morning the on-call resident notified the surgeon who then examined the patient and noted no motor function in the man's legs. He took the patient back to the OR for evacuation of a hematoma. The man suffered permanent disability with bowel and bladder dysfunction.

The defense of the claim was harmed because the surgeon dictated both operative reports four months following the surgeries.

Contributing factors:

- ✓ Clinical judgment
 - Failure to assess and respond to escalating patient symptoms
- ✓ Team communication failure
 - Culture issues: nurse did not speak up and use the chain of command when the resident would not examine the patient
- ✓ Late documentation
 - Operative reports dictated four months following the procedures

Lost call record leads to Staph infection and additional procedures

An orthopedic surgeon performed an arthroscopic meniscus repair on a 41-year-old woman who developed a postoperative knee infection. There were two preoperative notes from OR nursing team members concerning a preexisting abrasion on the patient's operative knee.

Two days following surgery, the patient called the orthopedic surgeon's office to report she had new swelling of that knee. There was no documentation of the call in the patient medical record. However, cell phone records confirm the patient called the orthopedist's office.

The patient went on to develop an infection in the knee and eventually had irrigation and debridement of the knee. Cultures revealed a Staph infection. She was referred to an infectious disease specialist for a persistent knee infection.

Contributing factors:

- ✓ Clinical judgment
 - Poor selection of procedure based on patient condition and risk factors
- ✓ Team communication issues
 - Failure to directly inform surgeon of abrasion
 - Failure of office team to inform surgeon of new postoperative symptoms needing attention
- ✓ Documentation deficiency
 - Failure to document patient symptom telephone call in the medical record

Poor assessment leads to potentially unnecessary surgery and complications

A general surgeon examined a 60-year-old man for right upper quadrant post-prandial pain. An ultrasound showed no gallstones. The surgeon recommended gall bladder surgery and performed a laparoscopic cholecystectomy. The day after surgery, the man called the surgeon's office with complaints of abdominal pain. He was informed that abdominal pain following surgery was normal; no exam was done.

One week later he was examined by the general surgeon for continued complaints of abdominal pain. An ultrasound showed a golf-ball-sized fluid collection in the abdomen and the surgeon recommended further evaluation if the pain continued. Two weeks later, the patient was still complaining of pain and a scan showed a probable biliary leak. An ECRP was ordered and a stent inserted for a bile leak which then caused pancreatitis. His abdominal pain persisted and he was examined at a tertiary center.

The man had an extended recovery with chronic pancreatitis and a pancreatic abscess. Experts were critical of proceeding with surgery without a HIDA scan and opined that the man did not need gall bladder surgery.

Contributing factors:

- ✓ Clinical judgment
 - Poor selection of procedure based on patient assessment
 - Improper patient assessment: no HIDA scan when ultrasound showed no gall stones
 - Failure to appreciate and reconcile relevant symptoms postoperatively
 - Failure to respond to repeated patient postoperative complaints
- ✓ Technical skill/performance
 - Known procedural risk (biliary leak) not recognized and treated in a timely manner

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What We Leave Behind

Retained surgical items are common, yet largely preventable.

By Lori Atkinson, RN, BSN, CPHRM, CPPS and Liz Lacey-Gotz

“Surgical teams are often pushed to make sure everything happens on time. The pressure to perform can create a culture that takes shortcuts and inadvertently overlooks errors.”

Heather Meyer,
MBA, RN, C-LNC, CHSP, CPHRM
Senior Risk Consultant
Constellation



Retained surgical items (RSIs) are known as “never events” per the National Quality Forum, because they are errors that are “serious, largely preventable, and harmful clinical events that should never happen.” Despite this, Constellation data show that RSIs are the third most likely cause of a surgical malpractice claim. Items are most commonly left in the abdominal, vaginal and chest cavities, and while these events are rare, their occurrence can cause significant harm to a patient’s postoperative outcome, as well as significant damage to the health care organization’s reputation and bottom line. RSIs are considered a clear violation of the standard of care and are difficult to defend.

Half of the claims involve leaving a surgical item in an abdominal cavity, and surgical sponges account for the majority of RSIs.



So, if RSIs are considered preventable, why do they still occur? “A lot of organizations may have procedures in place regarding surgical counts, but they may not be followed for a number of reasons,” says Heather Meyer, senior risk consultant for Constellation. “Surgical care teams may get overly confident and relax safety behaviors, or may be too quick to assume a miscount has occurred rather than a medical error. There may be lack of trust within a team so no one ‘speaks up,’ or a simple case of distraction, or a gap in communication during operating room (OR) team changes.”

Time pressures also play a role. “Surgical teams are often pushed to make sure everything happens on time,” Meyer says. “The pressure to perform can create a culture that takes shortcuts and inadvertently overlooks errors.”

Key ways to help prevent RSIs, according to Meyer, happen while the patient is in the OR. Before the patient is closed up and any team member leaves the room, counting procedures must be followed and repeated if necessary. X-rays can help determine if an object remains present in the body cavity. Ideally, every team member takes accountability to prevent RSIs.

At the end of the day, it’s a team effort, Meyers says. “The surgeon may be considered the captain of the ship, but everyone in the room needs to be accountable, and a culture of safety should allow anyone on the team to speak up and be heard if they see an issue.”

Technology is also readily available to help assist the counting of surgical items—before, during and after surgery. “Technology may appear expensive at first, but considering the impact of a single RSI claim—which can be nine times the cost of the technology—it could easily pay for itself in the long run,” Meyer says.

It is key to document discrepancies such as any missing sponges, broken items such as device tips or broken wires, because postoperative patient symptoms could be connected and can be serious. Transparent communication with the patient and their family is also important: If patients are made aware of potential issues, they are more likely to be a partner in their care moving forward, helping to watch for symptoms and playing a role in deciding next steps.

Diving Deeper into the Data

RSI claims account for 6.5% of all surgical claims and 3.2% of costs. Most of these claims involve care provided in the OR, with 77% in a hospital OR and 17% in an ambulatory surgery center OR. Half of the claims involve leaving a surgical item in an abdominal cavity, and surgical sponges account for the majority of RSIs.

Risk factors for RSIs include patients with a high body mass index, emergent/urgent procedures, unexpected changes in the procedure or technique, multiple procedures or multiple OR team changes.

The top five contributing factors* to these claims include:

1. Technical skill and performance (97%)
 - ✓ Inadvertently leaving a sponge, wire or device tip in the patient
 - ✓ Incorrect surgical item counts
 - ✓ Lack of technology to locate all surgical items
 - ✓ Poor standardization of practice among surgeons and surgical teams
 - ✓ Human factors, including distractions in the OR
2. Clinical judgment and patient assessment issues (43%)
 - ✓ Failure to respond to repeated patient complaints
 - ✓ Failure to order diagnostic tests
 - ✓ Narrow diagnostic focus
3. Administrative (32%)
 - ✓ Failure to follow policy
 - ✓ Team training issues
4. Communication breakdowns (19%)
 - ✓ Among the team/handoffs
 - ✓ With patients and families
5. Documentation (16%)
 - ✓ Inaccurate documentation

*Note that a claim can and often does have more than one contributing factor.

Retained Surgical Items Claims Examined

Human error found three years late

An orthopedic surgeon performed lumbar spine surgery on a 49-year-old man with a history of back pain.

Three years later the man returned with complaints of lumbar back pain. An MRI revealed an encapsulated soft tissue lesion with necrosis on the right side of L4-5. The orthopedic surgeon performed a removal and biopsy of the mass and it was identified as a retained surgical sponge.

The man continued to have back pain and was diagnosed with arachnoiditis. He was left with permanent back pain and partially disabled. The surgical counts in the procedure were documented as correct.

Contributing factors:

- ✓ Administrative issue
 - Policy or protocol not followed
- ✓ Human factors error: count inaccurate
- ✓ Documentation error: count recorded as accurate

Postoperative RSI unreported, leads to sepsis

A 72-year-old woman with a history of gastric bypass surgery 20 years earlier was evaluated by a general surgeon for complaints of a chronic cough due to diaphragmatic irritation. He recommended surgery and removed the gastric band, lysed adhesions, repaired a hernia and performed a Nissen fundoplication.

The woman developed a wound infection postoperatively and underwent multiple debridements. The infection resulted in an incisional hernia which was repaired surgically with mesh placement and she was discharged to home.

Several days later, she was readmitted through the emergency room in acute respiratory failure due to perforation of her colon. She underwent emergency laparotomy, removal of mesh and a transverse colon resection. A retained sponge was found. She developed sepsis requiring a prolonged hospitalization.

Contributing factors:

- ✓ Administrative issue
 - Policy or protocol not followed
- ✓ Human factors error: count inaccurate
- ✓ Documentation error: sponge count documented as correct

Undocumented RSI leads to prolonged recovery and ongoing pain

A 49-year-old woman was examined by a gynecologist for recurrent ovarian cyst problems and he recommended surgery. He performed a laparoscopic vaginal hysterectomy and bilateral salpingo-oophorectomy and documented that surgery went well and all sponge and instrument counts were accurate. Her postoperative recovery went well.

Months later when she had pain and bleeding after intercourse, she presented to the emergency room where an exam revealed a defect in the vaginal cuff with small bowel herniating through the vagina. She was taken to surgery where a surgical sponge was found in her pelvis.

She had a prolonged recovery and continued to complain of pain with intercourse.

Contributing factors:

- ✓ Administrative issue
 - Policy or protocol not followed
- ✓ Human factors error: count inaccurate
- ✓ Documentation error: sponge count documented as correct

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Claim Review

Patient Complaints Addressed Too Late

A 60-year-old man develops pain, swelling and weakness in his right lower leg following knee replacement surgery. His orthopedic surgeon does not diagnose a popliteal pseudoaneurysm until six weeks after surgery, leaving him with a permanent nerve injury and mobility problems.

SPECIALTY	ALLEGATION	PATIENT SAFETY & RISK MANAGEMENT FOCUS
✓ Orthopedic surgery	✓ Improper performance of total knee arthroplasty ✓ Improper management of surgical patient	✓ Repeat patient complaints postoperatively ✓ Informed consent

28%

of surgical claims cite **orthopedic surgeons** as the clinician most responsible for care at time of alleged injury

Facts of the claim

An orthopedic surgeon performed a right total knee arthroplasty (TKA) on a 60-year-old man with a history of right knee pain and osteoarthritis. Six days later on a Friday afternoon, the man called the orthopedist's office complaining of pain and swelling in his right knee and calf. The office team member told the man to keep his orthopedic appointment the following week and to follow the postoperative instructions to use ice and elevation for swelling. The next week, the orthopedist examined the man who was still complaining of right lower leg pain, swelling and weakness. The orthopedist ordered a duplex exam, which showed no evidence of a deep vein thrombosis.

Over the next several weeks, the man

continued to complain of pain, swelling and weakness in his right lower leg for which he called the orthopedist's office several times. Six weeks after surgery, the man went to his local hospital emergency department (ED) with complaints of right lower leg pain, swelling and weakness. The ED physician ordered a Doppler ultrasound of the right knee, which showed a pseudoaneurysm of the popliteal artery. A vascular surgeon was consulted, and he performed a repair of the pseudoaneurysm.

The man suffered a permanent nerve injury and foot drop. He was unable to return to work and later filed a malpractice claim against the orthopedist alleging improper performance of surgery, failure to obtain informed consent and improper postoperative management.

Experts who reviewed the care were critical of the delay in diagnosing the pseudoaneurysm, considering the man made repeated complaints of pain, swelling and lower leg weakness.

Disposition of the claim

The malpractice claim was settled against the orthopedist.

Risk and patient safety perspective

The experts who reviewed the care felt that the popliteal artery was injured during surgery, causing the man to develop the pseudoaneurysm, which put pressure on the peroneal nerve, leading to the nerve injury and foot drop. The experts were critical of the delay in diagnosing the pseudoaneurysm, considering the man made repeated complaints of pain, swelling and lower leg weakness.

The experts were also critical of the orthopedist's office team in the handling of the man's repeated telephone calls complaining of continued symptoms. The involved orthopedic office team members testified that they did not have formal telephone triage protocols to manage postoperative patients.

The man testified that he complained of severe pain and swelling postoperatively but that the surgeon did not listen to him. He also testified that the orthopedist did not tell him that a nerve injury was a possible risk and complication of surgery.

Top malpractice allegations against orthopedics

In our analysis of Constellation surgical malpractice claims, the most frequently cited clinician responsible for care at the time of the alleged surgical injury is the orthopedic surgeon, accounting for 28% of claims and 20% of costs.

Risk and patient safety strategies

Understanding the factors driving orthopedic patient injuries and resulting malpractice claims is a first step in protecting patients, orthopedists and their organizations. Orthopedists and their office teams should review their risk and patient safety program and consider the following recommended strategies.

For orthopedic surgeons:

- Use a preoperative risk assessment and stratification system including a full review of surgical risk factors and previous surgical histories and comorbidities, including visits with specialists for each comorbidity, to ensure readiness for surgery
- Ensure full consideration of all available clinical information, including medical-surgical history, previous complications and input from specialists when determining surgical procedure/approach
- Employ evidence-based guidelines to manage risks, including surgical site infections, venous thromboembolism prophylaxis and acute pain management (including prescription opioids)
- Improve and maintain technical skills and practice with awareness of nerve and adjacent structure injury
- Facilitate regular case review conferences to maintain perspective on surgical treatment decisions
- Implement a patient-centered shared decision-making model for educating and obtaining informed consent that includes a discussion of realistic expectations and goals
- Use web-based patient education and informed consent tools to supplement the informed consent discussion and reinforce expectations

- Educate patients and families on key signs and symptoms of postoperative complications, and encourage them to speak up with any concerns

For orthopedic care teams:

- Implement a notification trigger tool to communicate among the care team during transitions of care
- Provide education for surgical office team members responsible for telephone or electronic communications with patients regarding symptoms or questions
- Utilize evidence-based written protocols for triaging patient symptoms postoperatively
- Document all communication with patients in the medical record concerning informed consent discussions, postoperative instructions and postoperative communication regarding symptoms
- Train care team in empathic communication with patients and families

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Claim Review

Unprofessional Behavior Contributes to Poor Postoperative Outcomes

A general surgeon performs a robotic-assisted colon resection on a 54-year-old man. Delays in diagnosis and treatment of an anastomotic leak lead to sepsis and permanent kidney damage.

SPECIALTY	ALLEGATION	PATIENT SAFETY & RISK MANAGEMENT FOCUS
✓ General surgery	✓ Improper performance of surgery ✓ Improper management of surgical patient ✓ Delay in diagnosis and treatment of surgical complications	✓ Communication ✓ Unprofessional clinician behavior

Issues with surgical skill and performance account for

59%

of allegations made against general surgeons

Facts of the claim

A 54-year-old man with a history of recurrent diverticulitis was referred to a general surgeon. The surgeon recommended and performed a robotic-assisted low anterior colon resection that was described in the surgeon's operative note as "without complication." On day one after surgery, the patient reported a greater degree of pain than expected. His nurse called the general surgeon twice to discuss pain management. On the second call, the surgeon yelled at the nurse for calling a second time.

On the third day after surgery, the patient developed hypotension, confusion, agitation and decreased urinary output. His nurse called a rapid response team to evaluate the man and he was transferred to ICU. The ICU intensivist ordered antibiotics and dialysis. The man's condition improved and he was transferred back to the surgical unit. The general surgeon approached the nursing care team and was

angry they had called a rapid response team to evaluate the patient and accused them of mismanaging the patient's IV fluids.

On the sixth day after surgery, the man developed a fever and increased white blood cell count. He was transferred back to ICU and abdominal imaging showed an anastomotic leak. The general surgeon took the man back to surgery the next morning for a laparotomy, lavage drain placement and loop ileostomy. The nursing team reported persistent confusion and agitation in the patient. One week later, the man continued to have significant wound drainage. The patient's wife complained loudly to the general surgeon and the general surgeon responded by transferring care to the assistant surgeon. He told the patient's wife he no longer wanted to care for her husband due to her complaints.

One month later the patient requested a transfer to a tertiary center where he

underwent an upper GI and feeding tube placement. Two weeks later he was transferred to a skilled nursing facility for rehab. Over the next seven months the man underwent multiple surgeries and procedures. He had permanent kidney damage and was disabled, unable to work. He filed a malpractice claim against the general surgeon and the hospital alleging improper performance of surgery, improper management post-operatively, and delay in diagnosis and treatment of surgical complications.

Disposition of the claim

The malpractice claim was settled against the general surgeon.

Risk and patient safety perspective

The experts who reviewed the care felt an imaging study should have been ordered sooner, the complication identified sooner and the patient taken back to surgery for re-exploration to drain and repair the anastomotic leak. The experts stated that as a result of the delay in diagnosis of the anastomotic leak, the patient rapidly progressed from sepsis to severe sepsis, which then required multiple additional surgeries. This resulted in permanent kidney damage, cognitive impairment and disability.

This case was difficult to defend due to the strained relationship that developed postoperatively between the general surgeon, the patient and the patient's wife. They felt the general surgeon was not listening and dismissed their concerns. The general surgeon ultimately resigned from the patient's care in an angry outburst in the patient's room.

The general surgeon and the surgical nursing care team also had a strained relationship. The surgical nurses caring for this man kept private journals of their patient care concerns and contentious interactions with this general surgeon. The defense team felt these private notes would be discoverable and damaging to the defense of the claim.

Also compounding the difficulty in defending the case was the hospital's review of the general surgeon's

privileges due to his unprofessional behavior and patient care concerns.

Top malpractice allegations against general surgeons

In our analysis of Constellation surgical malpractice claims, general surgeons are the second most frequently cited clinician responsible for patient care at the time of alleged injuries, with 21.6% of claims, and number one in costs (28.5%). Issues with surgical skill and performance are the top allegations made against general surgeons (59%), followed by poor surgical patient management claims (30%). Communication breakdowns were identified as contributing factors in 35% of surgical claims.

Risk and patient safety strategies

Disruptive and unprofessional behaviors are common in health care and often indicate a toxic culture that undermines patient safety. A recent study done by the Center for Patient and Professional Advocacy at Vanderbilt University School of Medicine reveals that surgeons with higher numbers of complaints of unprofessional behavior typically have patients who experience more complications following surgery.¹ The study showed that patients whose surgeons had one to three reports of unprofessional behavior had an 18% higher risk of experiencing complications. This could indicate that postoperative complications can be attributed not only to surgical skill and technique, but also to disruptions in teamwork and care processes. In an article reviewing the study's findings, the author identified that these behaviors can be manifested as bullying, intimidation or disregard for internal procedures such as surgical checklists.²

In a 2017 study also done at Vanderbilt University, researchers found that analyzing patient and family reports about rude and disrespectful behavior could predict surgeons with higher rates of surgical site infections and other adverse outcomes.³

Addressing unprofessional behavior

□ Assess your patient safety culture with a tool such ARHQ's Surveys on Patient

Safety Culture. These tools can help identify areas of strength to build on and areas of weakness to address.

- Establish and enforce a strong policy regarding professional behavior standards for employees and clinicians with medical privileges. The policy should include definitions of unprofessional behavior, professional code of conduct standards, reporting process, investigative process and consequences for breaching the standards. Professional code of conduct standards should be included as part of the Medical Staff Bylaws.
- Implement a program to educate and encourage a culture of mutual respect and collaboration among clinicians and nursing care team members.

Resources

AHRQ Surveys on Patient Safety Culture <https://www.ahrq.gov/sops/index.html>

TeamSTEPS <https://www.ahrq.gov/teamsteps/index.html>

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Meditations on Medicine



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The Universal (and Inescapable) Journey of Loss and Grief

But when anyone in health care is witness to, a part of, or the cause of an adverse outcome, it impacts us all: the patient, the patient's family and the entire health care team.

I've recently been meditating on the journey one takes when coping with loss and grief, whether it be living through a disaster such as the current pandemic, being a part of a patient harm event and perhaps getting sued, or living with a terminal illness or significant chronic health condition. Interestingly, each of these life-altering challenges typically follows well-understood phases of emotional responses, and understanding that these phases are normal and almost predictable can help those who support people dealing with loss and grief. The fact is that all of us deal with difficult circumstances at some point in our lives, so being educated and aware of these phases can help everyone.

All physicians intend to help, heal and serve those who seek them out for care. But when anyone in health care is witness to, a part of, or the cause of an adverse outcome, it impacts us all: the patient, the patient's family and the entire health care team. Though the specific emotions we experience will vary, most of us will at some point go through the phases noted in the Kübler-Ross change curve: shock, denial, frustration, depression, experiment (and engagement), decision and ultimately integration.

Since my days of training in emergency medicine, I have taken a particular interest in the study of grief and loss. Knowing how to tell people difficult news is a skill that must be learned in order to practice medicine with emotional competence, not just technical competence. During my 25 years in the emergency department, I learned many techniques for communicating bad news that were helpful, and others that weren't.

Later, I studied the work of Rachel Naomi Remen—a very wise woman who is also a physician, educator and author—who developed a Healer's Art course about 30 years ago for first-year medical students at University of California-San Francisco. This course offers a well-developed curriculum on grief and loss, which includes learning from one's own experiences and the experiences of others, and contemplating and sharing what was helpful in the past and what was not when coping with grief and loss. This course is now taught in over 90 medical schools around the world (rishiiprograms.org), including the University of Minnesota Medical School, where I help teach it.

I recently came across an article about emotional wellbeing and the phases of disaster (www.samhsa.gov/dtac/recovering-disasters/phases-disaster). This is

obviously pertinent as we all struggle with the pandemic caused by COVID-19. What stood out to me in this article was that, as a society, we are currently in the "disillusionment" phase, the length of which is unknown and our control over which is limited, at least currently. And it is during this phase when we all need to provide even more support to one another. I believe there is an interesting parallel between the disillusionment phase and the frustration and depression phases of the [Kübler-Ross change curve](#).

In both of these curves—whether suffering an adverse outcome as a clinician or a patient, or as anyone living in this pandemic—the downward sloping section of the curve is when people need the most support. This is the moment when we need to lock arms, walk together and help one another.

Raising awareness of our common human needs when we are living with some sort of loss—whether it be from the pandemic, involvement in a patient harm event, or being informed of a life-altering diagnosis—will help all physicians in tending to those we serve. And when we walk with those who are enduring those phases of disillusionment or depression, our dedication to provide care is more important than ever. We at Constellation are here for you, wherever you are in your journey.

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