

Risks in the Ambulatory Setting

Data Focused Mitigation
ISHRM Conference

August 25, 2023

Objectives



Ambulatory Surgery

Data Insight

2023



Introduction

INTRODUCTION | KEY POINTS | GENERAL DATA ANALYSIS | CONTRIBUTING FACTORS | FOCUSED DATA ANALYSIS | CASE EXAMPLES | RISK MITIGATION

This publication contains an analysis of aggregated data from clinically coded cases opened between 2012-2021 and arising in an ambulatory surgery center location.

Keep in mind...

Our data system, and analysis, rolls all claims/suits related to an individual patient event into one case for coding purposes. Therefore, a case may be made up of one or more individual claims/suits and multiple defendant types such as hospital, physician, and other healthcare professionals.

Cases that involve attorney representations at depositions, State Board actions, and general liability cases are not included.

This analysis is designed to provide insured doctors, healthcare professionals, hospitals, health systems, and associated risk management staff with detailed case data to assist them in purposefully focusing their risk management and patient safety efforts.

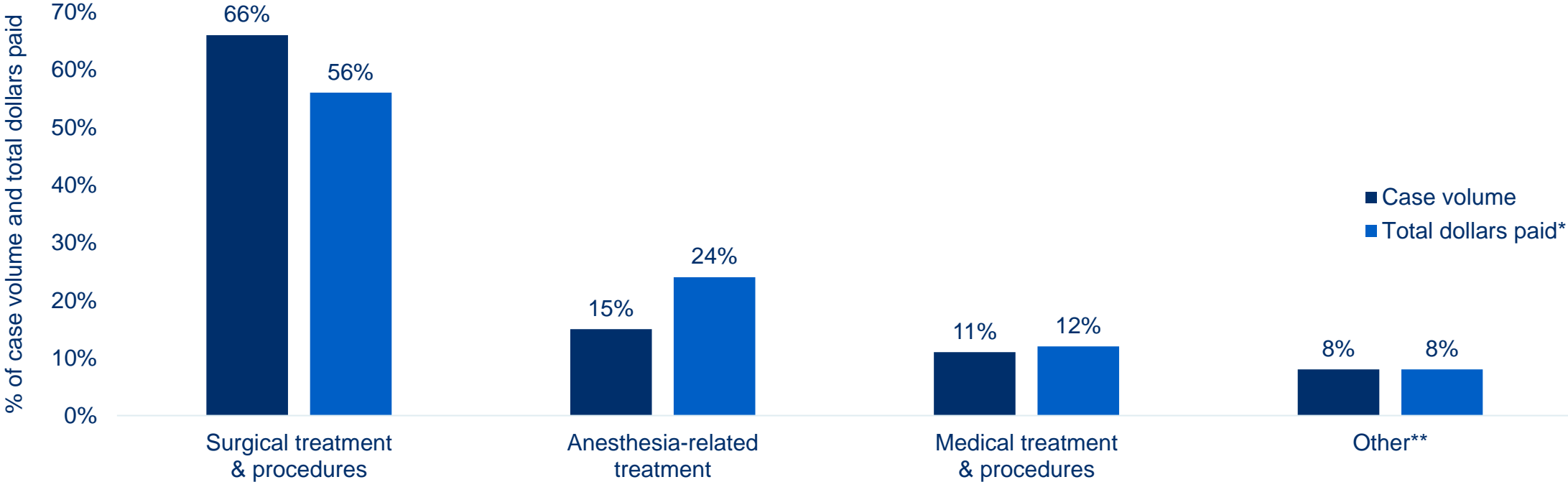
Key Points - Clinically Coded Data

INTRODUCTION | **KEY POINTS** | GENERAL DATA ANALYSIS | CONTRIBUTING FACTORS | FOCUSED DATA ANALYSIS | CASE EXAMPLES | RISK MITIGATION

- **As would be expected, surgical allegations account for two-thirds of ambulatory surgery center case volume (and more than half of total dollars paid*).** Performance-related allegations account for half of those, with the majority involving ophthalmology, orthopedic and cosmetic-related procedures.
 - Management-related cases are noted also; these cases, involving the management of pre-, intra-, and post-operative surgical patients, are often related to the surgeon's response to developing complications. While complications of procedures may have been the result of procedural error, the failure to timely recognize and/or monitor/manage the issue prevents the opportunity for early mitigation of the risk of serious adverse outcome.
- **Anesthesia-related cases account for another 15% of ambulatory surgery center case volume.** Performance-related and management cases account for the majority of these.
 - Performance cases encompass procedural technique issues, including injections, intubation and extubation. Extubation cases (excluding those involving tooth damage) often reflect immediate post-extubation complications, bringing into question whether extubation was appropriate/timely. Management-related cases encompass recognition of and reaction to vital signs, awareness while under anesthesia, monitoring while receiving blood products and during the post-operative recovery process.
- **Contributing factors, which are multi-layered issues or failures in the process of care that appear to have contributed to the patient's outcome, and/or to the initiation of the case, provide valuable insight into risk mitigation opportunities.**
 - **Several factors**, including failures to follow policies/procedures, inadequate staff training, poor procedural technique, insufficient documentation and inadequate patient assessments, **are key drivers of both clinical and financial ambulatory surgery center case severity.**

Major Allegations & Financial Severity

Each case reflects one major allegation category. Categories are designed to enable the grouping and analysis of similar cases and to drive focused risk mitigation efforts. The coding taxonomy includes detailed allegation sub-categories; insight into these is noted later in this report.



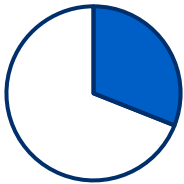
MedPro Group + MLMIC cases opened 2012-2021, ambulatory surgery location (N=2395); *Total dollars paid = expense + indemnity; **Other includes allegations for which no significant case volume exists

Clinical Severity*

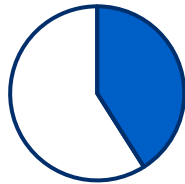
Clinical Severity Categories	Sub-categories	% of case volume
LOW	Emotional Injury Only	5%
	Temporary Insignificant Injury	
MEDIUM	Temporary Minor Injury	34%
	Temporary Major Injury	
	Permanent Minor Injury	
HIGH	Significant Permanent Injury	61%
	Major Permanent Injury	
	Grave Injury	
	Death	

Typically, the higher the clinical severity, the higher the indemnity payments are, and the more frequently payment occurs.

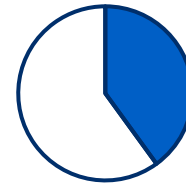
Focus on high severity cases for the top three allegations
(percentage of each allegation category's high severity cases)



Surgical cases
31%



Anesthesia cases
41%

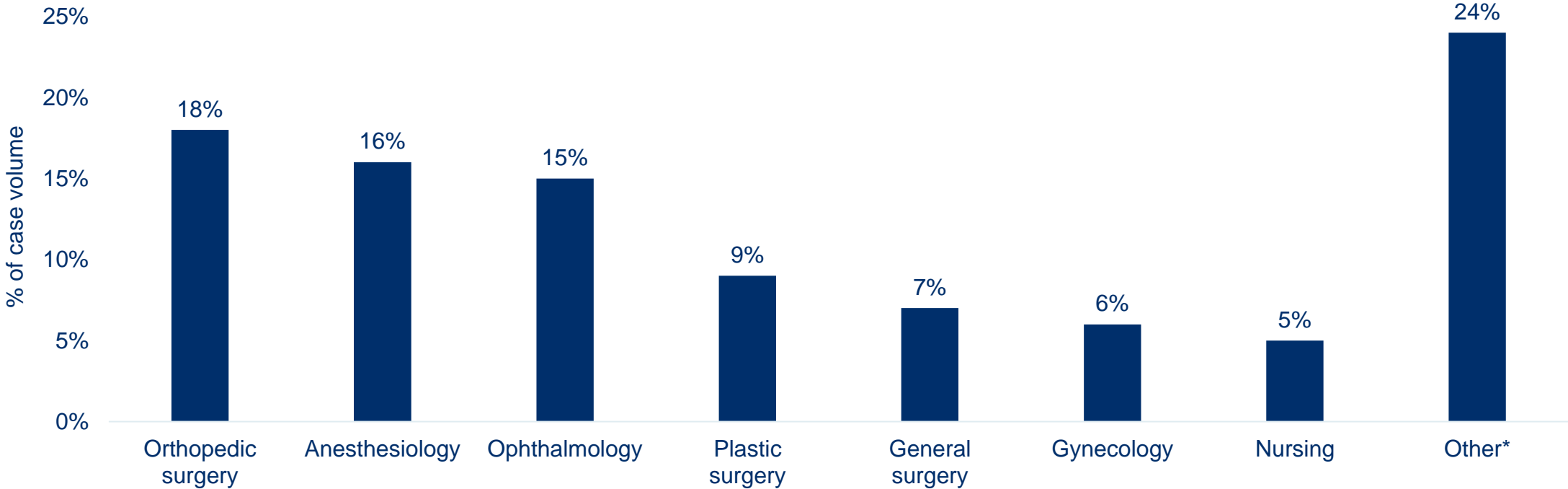


Medical cases
40%

MedPro Group + MLMIC cases opened 2012-2021, ambulatory surgery location (N=2395); *Severity codes reflect National Association of Insurance Commissioners (NAIC) injury severity scale

Primary Responsible Services

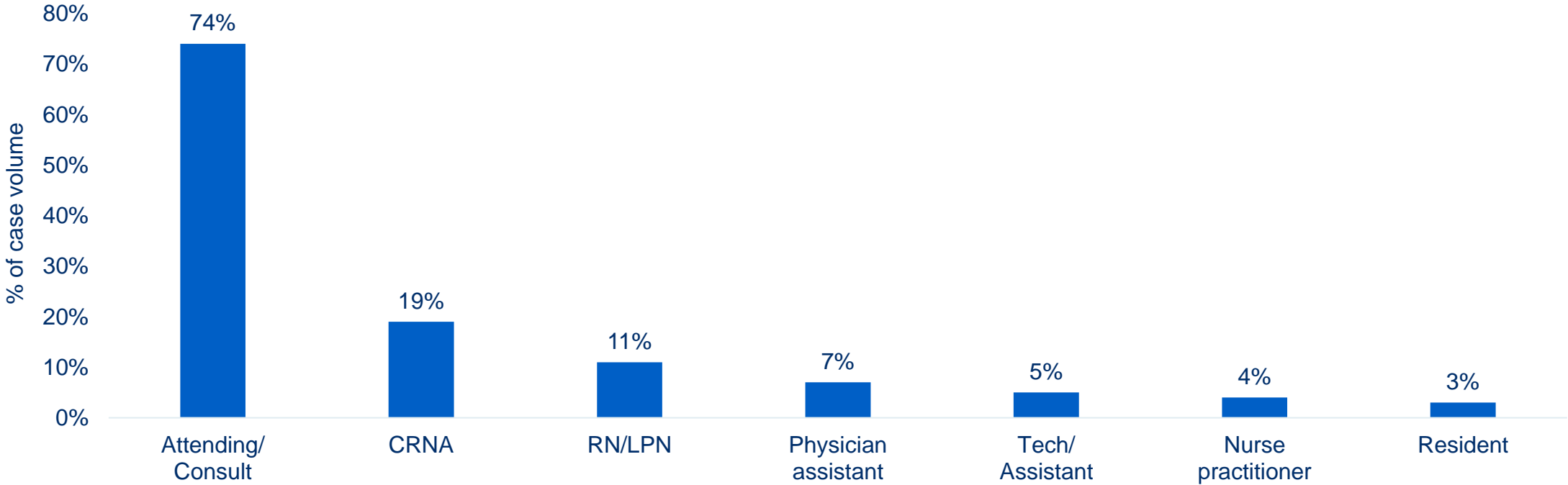
Each case reflects one primary responsible service. This is the specialty that is deemed to be most responsible for the resulting patient outcome. Cases can also reflect one or more 'secondary' responsible services. In the ambulatory surgery setting, nursing staff and anesthesiology are the two most common services noted as secondarily responsible.



MedPro Group + MLMIC cases opened 2012-2021, ambulatory surgery location (N=2395); *Other includes services accounting for $\leq 4\%$ of case volume

Primary Responsible Services: Focus on Primary Roles*

“Roles” reflect the **specific position within the specialty service team that was involved at the time of the event**. There may be multiple primary roles within the same service team (i.e., an attending/consult and a CRNA – both practicing under the anesthesiology responsible service).



MedPro Group + MLMIC cases opened 2012-2021, ambulatory surgery location with an identified role (N=687); *Role codes have been evolving for several years. The role code portion of the taxonomy was enhanced and made mandatory in July 2021, therefore not all cases coded prior to that date have a role indicated.

Contributing Factors

“Contributing factors reflect both provider and patient issues. They denote breakdowns in technical skill, clinical judgment, communication, behavior, systems, environment, equipment/tools, and teamwork. The majority are relevant across clinical specialties, settings, and disciplines; thus, they identify opportunities for broad remediation.”

Despite best intentions, processes designed for safe patient outcomes can, and do, fail.

Contributing factors are multi-layered issues or failures in the process of care that appear to have contributed to the patient's outcome, and/or to the initiation of the case, or had a significant impact on case resolution.

Multiple factors are identified in each case because generally, there is not just one issue that leads to these cases, but rather a combination of issues.



Administrative



Behavior-related



Clinical environment



Clinical judgment



Clinical systems



Communication



Documentation



Supervision



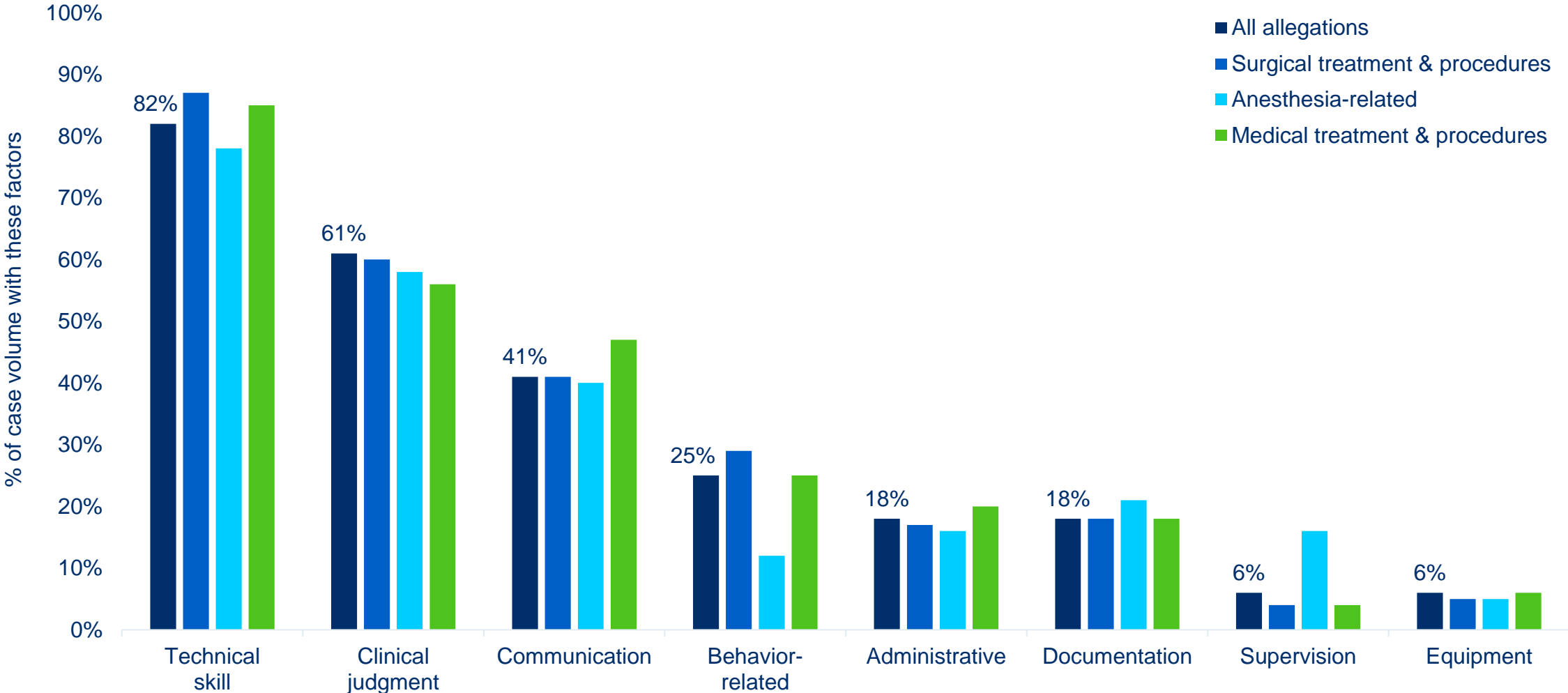
Technical skill

Contributing Factor Category Definitions

INTRODUCTION | KEY POINTS | GENERAL DATA ANALYSIS | **CONTRIBUTING FACTORS** | FOCUSED DATA ANALYSIS | CASE EXAMPLES | RISK MITIGATION

Administrative	Factors related to medical records (other than documentation), reporting, staff education/training, ethics, policy/protocols, regulatory issues
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Clinical systems	Factors related to coordination of care, failure/delay in ordering test, reporting findings, follow-up systems, patient identification, specimen handling, nosocomial infections
Communication	Factors related to communication among providers, between patient/family and providers, via electronic communication (texting, email, etc), and telehealth/tele-radiology
Documentation	Factors related to mechanics, insufficiency, content
Equipment	Factors related to malfunction and failures to maintain/inspect equipment/materials
Supervision	Factors related to supervision of nursing, house staff, advanced practice clinicians
Technical skill	Factors related to improper use of equipment, medication errors, retained foreign bodies, technical performance of procedures

Most Common Contributing Factor Categories by Allegation



MedPro Group + MLMIC cases opened 2012-2021, ambulatory surgery location (N=2395); More than one factor per case, therefore totals >100%

Contributing Factors: Focus on Drivers of Clinical & Financial Severity

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These factors are commonly noted in cases with clinically severe patient outcomes and indemnity payments.

Administrative

Failure to follow policy/procedure

Inadequate staff training/education

Clinical judgment

Selection of most appropriate surgical/invasive procedure

Failure to appreciate/reconcile relevant signs/symptoms/test results

Inadequate patient monitoring

Choice of practice setting (ambulatory vs inpatient)

Inadequate history/physical

Delay in ordering diagnostic testing

Failure/delay in obtaining consult/referral

Inadequate assessment resulting in premature discharge from care

Narrow diagnostic focus – failure to establish differential diagnosis

Communication

Suboptimal communication among providers about patient condition

Inadequate informed consent for procedures

Documentation

Insufficient or lack of documentation regarding clinical findings (impacts team communication and makes subsequent defense of malpractice cases more difficult)

Technical skill

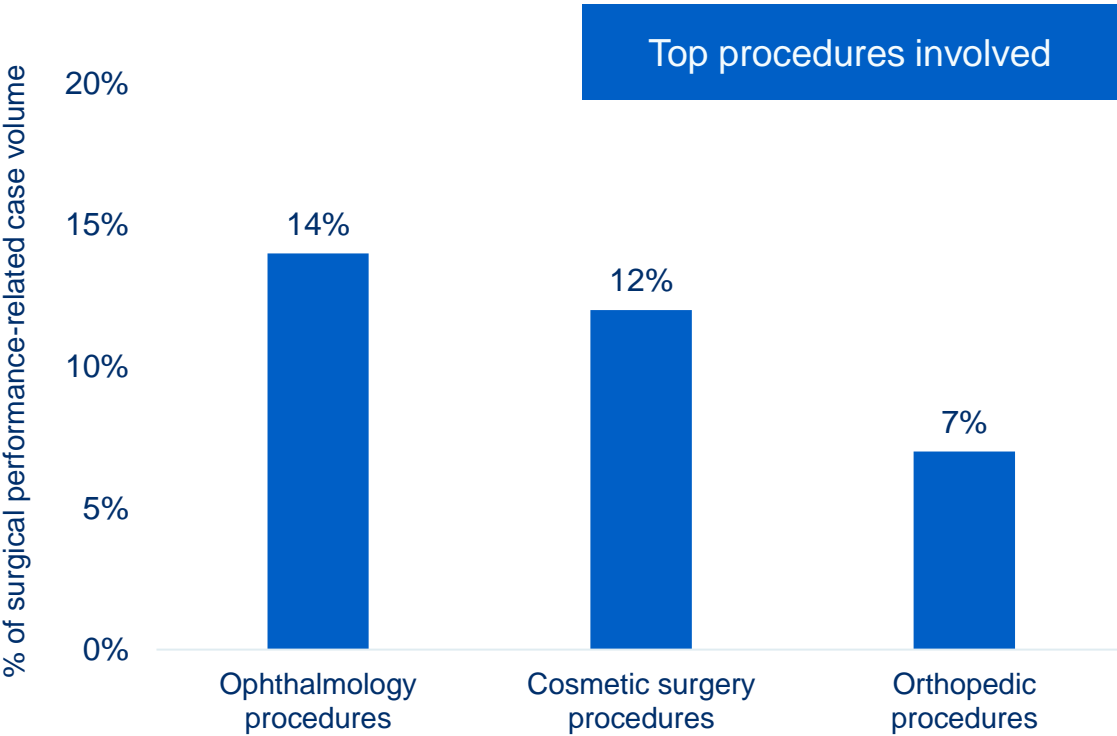
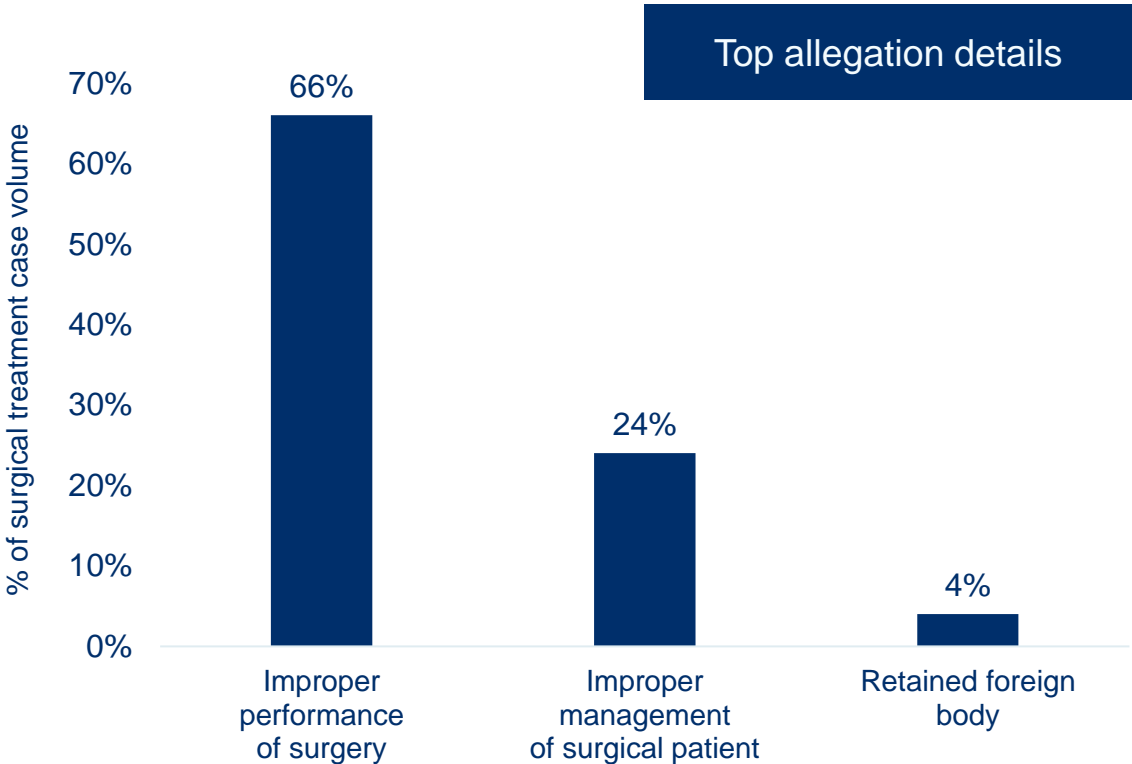
Poor technique

Recognition and management of known complications

Misidentification of anatomical structures

Improperly utilized equipment

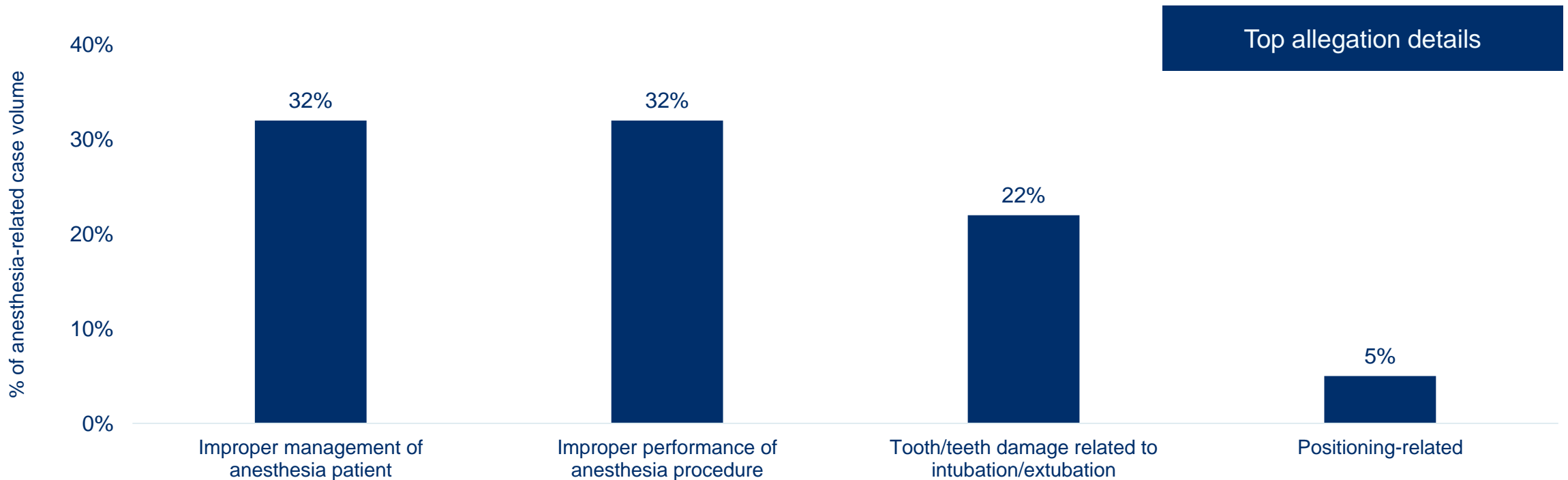
Focus on Surgical Treatment Allegations



Cases involving the **management of surgical patients**, including pre-, intra-, and post-operatively, are often related to the **surgeon’s response to developing complications**. While complications of procedures may have been the result of procedural error, the **failure to timely recognize and/or monitor/manage the issue prevents the opportunity for early mitigation of the risk of serious adverse outcome**.

Focus on Anesthesia-Related Allegations

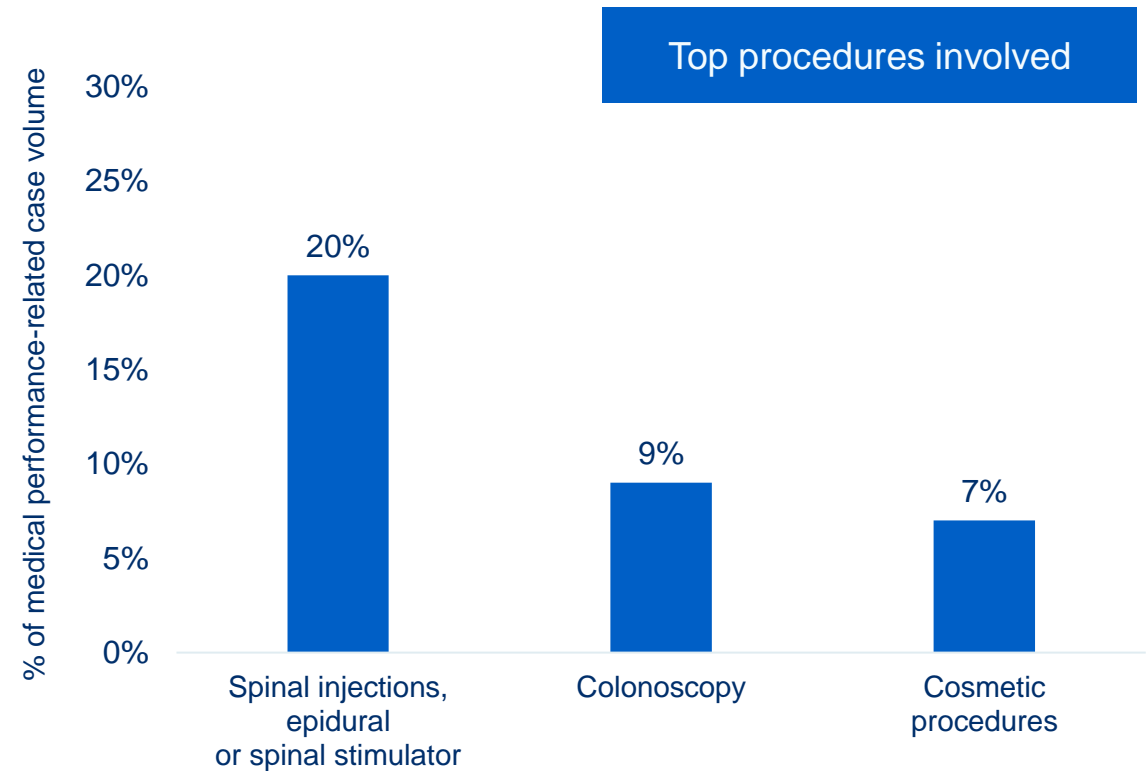
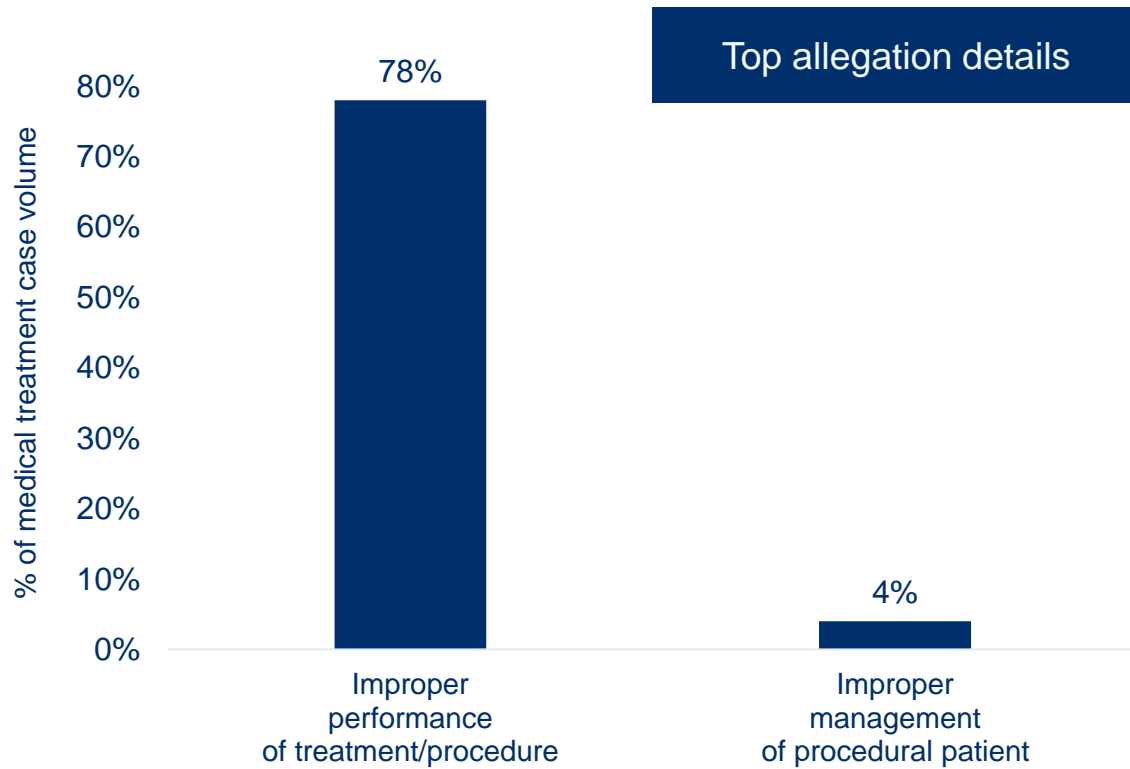
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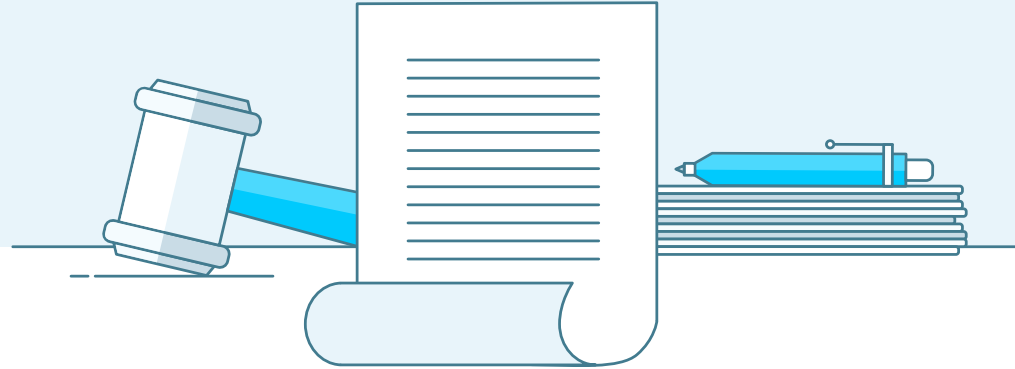
Performance-related cases encompass procedural technique issues, including injections, intubation and extubation. Extubation cases (excluding those involving tooth damage) often reflect immediate post-extubation complications, bringing into question whether extubation was appropriate/timely. **Management-related cases encompass recognition of and reaction to vital signs**, awareness while under anesthesia, monitoring while receiving blood products and during the post-operative recovery process. The failure to timely recognize and/or monitor/manage procedural complications prevents the opportunity for early mitigation of the risk of serious adverse outcome. **Positioning-related cases reflect when positioning of the patient is the key issue**, and includes situations where the patient was positioned correctly, but for an extended period of time resulting in injury.

Focus on Medical Treatment Allegations

INTRODUCTION | KEY POINTS | GENERAL DATA ANALYSIS | CONTRIBUTING FACTORS | **FOCUSED DATA ANALYSIS** | CASE EXAMPLES | RISK MITIGATION



Procedural performance cases can be impacted by delayed recognition of complications, while management cases most often reflect issues with selection of the most appropriate course of treatment for the patient, and appreciating and reconciling symptoms and test results.



The following stories are reflective of the allegations and contributing risk factors which drive cases arising in an ambulatory surgery location.

We're relaying these true stories as lessons to build understanding of the challenges that you face in day-to-day practice. Learning from these events, we trust that you will take the necessary steps to either reinforce or implement best practices, as outlined in the section focused on risk mitigation strategies.

Case Examples

INTRODUCTION | KEY POINTS | GENERAL DATA ANALYSIS | CONTRIBUTING FACTORS | FOCUSED DATA ANALYSIS | **CASE EXAMPLES** | RISK MITIGATION

SETTLED

\$300K

CONTRIBUTING FACTORS

Clinical judgment

Inadequate assessment resulting in premature discharge from surgery center (patient was unable to void on her own)

Technical skill

Poor recognition/management of known complication (two day delay in returning patient to surgery)

Poor technique

IMPROPER PERFORMANCE OF BREAST RECONSTRUCTION SURGERY RESULTING IN UNRECOGNIZED SMALL BOWEL TEARS AND SEPSIS

A patient in her late 60's, with a history of mastectomy, initial breast reconstruction, chemotherapy and radiation treatment, presented to the ambulatory surgery center for the second phase of breast reconstruction. The initial stage of reconstruction had been complicated by asymmetry and a post-operative infection, resulting in removal of the implant and placement of a tissue expander.

The patient consented to the second phase of reconstruction, to be performed by a plastic surgeon, involving removal of the tissue expander, placement of a silicone implant, and fat grafting from abdominal liposuction. Surgery appeared to have gone well, and the patient was discharged to home (albeit without having been able to void on her own, requiring catheterization prior to discharge). Several hours later, **she presented to the Emergency Department, complaining of increased abdominal pain and nausea.** She was admitted for IV hydration and pain control. **A CT of the abdomen showed free air.**

Two days later, the plastic surgeon took the patient back to surgery for an exploratory laparotomy. This revealed **two small bowel tears which were repaired. The patient's post-operative course was complicated by sepsis, an enteric fistula, and atrial fibrillation with congestive heart failure. She developed necrotic breast and abdominal wall tissue and required 20 additional surgeries for treatment of a fistula, and a wound vac replacement.**

Expert review noted that the patient's bowel injury, was likely caused by the aspiration suction cannula used by the surgeon during the liposuction phase.

Case Examples

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SETTLED

\$3.5M

CONTRIBUTING FACTORS

Clinical judgment

Inadequate patient assessment
– history & physical

Failure to appreciate/reconcile
relevant signs/symptoms/test
results

Selection of most appropriate
procedure (moderate sedation
in a prone patient with history of
OSA vs spinal sedation)

Communication

Inadequate informed consent

Documentation

No documentation of informed
consent discussion

Technical skill

Improper intubation (criticized
for using LMA instead of ETT)

IMPROPER MANAGEMENT OF ANESTHESIA PATIENT WITH HISTORY OF OBSTRUCTIVE SLEEP APNEA RESULTING IN DEATH

A male patient in his mid-40's presented to the ambulatory surgery center for **bone marrow harvesting** (voluntary bone marrow donor). The anesthesiologist met with the patient pre-operatively, and discussed the plan for anesthesia involving regional epidural (spinal) sedation.

The patient stated he didn't want spinal anesthesia due to concerns for spinal headache and a fear of needles. The **anesthesiologist agreed to a local anesthesia with moderate IV sedation instead**. he later stated that he **discussed with the patient the risks for cardiac and respiratory depression, but did not document this discussion in the record.**

At 7:30am, the patient was given IV midazolam and fentanyl, and rolled to the prone position. **At 7:47, propofol 50mcg was given, with another 20mcg given at 7:50 and again at 7:55 as well as via IV.** Oxygen was provided via nasal cannula. **Pre-procedure vital signs were within normal limits, with oxygen saturation (O2) at 95%.** The procedure began at 8:03; O2 was at 91%. At 8:08, O2 dropped to 89%. **The anesthesiologist attempted multiple maneuvers to raise the oxygen level without success. At 8:09, O2 was at 71%.**

A laryngeal mask airway (LMA) was placed while the patient was still prone; O2 improved briefly but then decreased to 71% by 8:12. The patient was then placed supine and intubated. **O2 decreased to 31% by 8:15. Propofol was turned off.** The patient then went into cardiac arrest, was resuscitated, and sent to the ICU at 9:39. A CT showed no acute bleed or evidence of infarct, however, the patient had no response to pain and his pupils were non reactive to light. Supportive treatment was provided, but he ultimately did not regain meaningful neurological response, and died two months later.

The patient's family claimed that the anesthesiologist failed to properly assess his history of obstructive sleep apnea (OSA), should have used spinal anesthesia instead, and improperly managed the provision of anesthesia. Experts were not supportive of the anesthesiologist's decision to use a LMA when O2 was at 71%, opined that endotracheal intubation (ETT) was not timely, and that the dosages of propofol were too high for a patient with OSA.

SETTLED

\$600K

CONTRIBUTING FACTORS

Administrative

Need for policy/protocol (none required pre-operative imaging)

Clinical judgment

Failure to order diagnostic test (pre-operative imaging)

Selection of most appropriate medication (particulate steroid vs non-particulate)

Technical skill

Poor procedural technique

IMPROPER PERFORMANCE OF SPINAL INJECTION RESULTING IN RIGHT-SIDED PARALYSIS

A active male patient in his mid-80's presented to an orthopedic surgeon for onset of right-sided neck pain. A conservative course of treatment, including high-dose nonsteroidal anti-inflammatory medication and physical therapy, was initiated. The plan was to refer the patient for cervical epidural steroid injections if conservative therapy failed.

Nine months later, the patient returned, **complaining of no relief and in fact, a marked increase in symptoms.** Rather than a referral to a pain medicine specialist, the patient **consented for the spinal injection to be performed by the orthopedic surgeon at an ambulatory surgery center;** the consent process did include coverage of procedural risks, including paralysis. **No pre-operative imaging was obtained.** Following the procedure, the patient was able to transfer himself to a wheelchair to be transported to recovery room. Shortly afterwards however, **while still in the recovery room, the patient developed weakness in his right arm and leg.** He was given a 10mg dose of a corticosteroid and sent to the emergency department via EMS, accompanied by the orthopedic surgeon.

MRIs of the cervical spine and brain showed no acute findings. The patient was admitted, and **ultimately underwent a discectomy. Repeat MRIs post-operatively revealed new findings concerning for an infarction in branches of the anterior spinal artery.** The patient was discharged to inpatient rehab, but did not regain right-sided function, and could not walk without assistive devices.

Although the patient's outcome was a known risk of the procedure, it was a rare risk. **Expert reviews were critical of the surgeon's failure to order imaging prior to injection** (even though post-procedure imaging revealed nothing specific which would have precluded the injection), **the technique used to perform the injection, and use of a "particulate" steroid which likely caused the infarct.**

Key Ambulatory Surgery Center Recommendations

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Policy & procedure includes a statement that guidelines do not replace judgment.

A culture of safety assessment is conducted.

A risk management/quality plan is in place.

Preoperative assessments include screening for obstructive sleep apnea.

Processes are in place to manage clinical emergencies in the OR.



Additional Risk Mitigation Strategies: Ambulatory Surgery

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- **Ongoing evaluation of procedural skills and competency with equipment is critically important.**
- **Conduct a thorough assessment of the patient pre-operatively.**
 - Ensure that all testing and specialty evaluations are available for review prior to induction; in an ambulatory setting, these details might not always be as readily available as in the inpatient setting.
 - Maintain a consistent post-procedure assessment process.
 - Update and review medical and family history at every visit to ensure the best decision-making.
- **Communicate with each other.**
 - Actively collaborate with other members of the patient's surgical care team – including all operating and recovery room staff. Coordinate the steps of the patient's care, including post-operatively.
 - Talk also to the patient/family, elicit a comprehensive patient history and conduct a thorough informed anesthesia consent with the patient – separate from the surgical consent
- **Engage patients as active participants in their care.**
 - Consider the patient's health literacy and other comprehension barriers.
 - Recognize that patient satisfaction with treatment outcomes can be influenced by a thorough informed consent and education process.
- **Document.**
 - The operative and anesthesia records are critically important for detailing the pre-operative patient assessment, intra-operative steps, and post-operative sequence of events. Discrepancies or gaps in the details/timing make it much more difficult to build a supportive framework for defense against potential malpractice cases.

Medical Office & Clinic-Based Cases

Data Insight

2023



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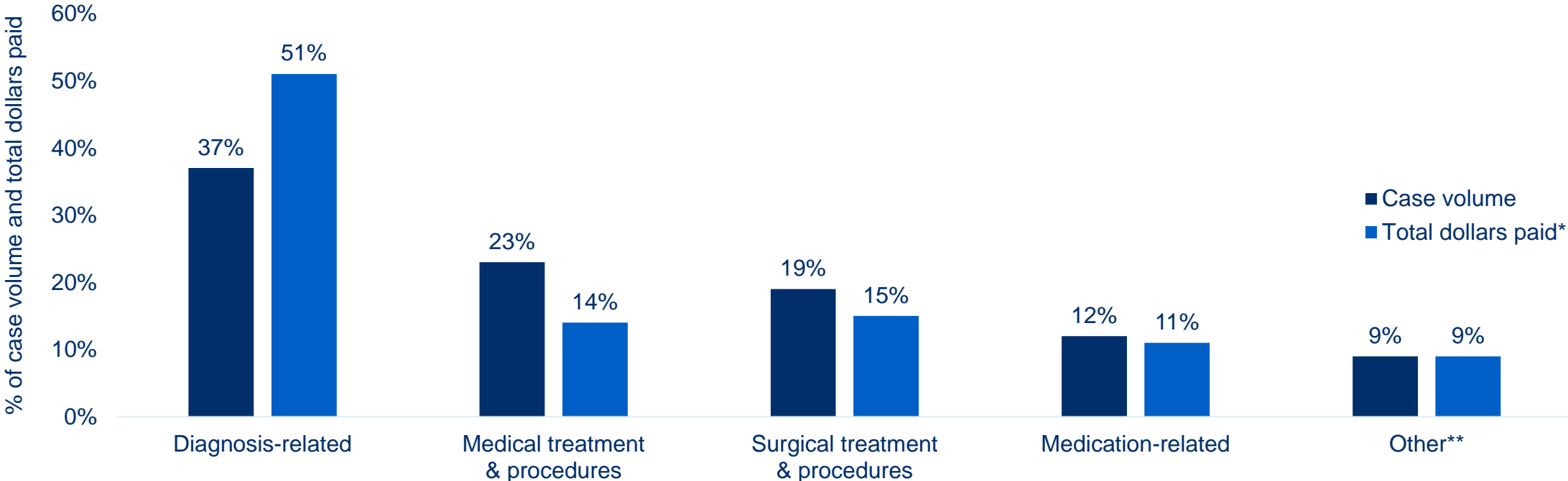
Key Points - Clinically Coded Data

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- **As would be expected, diagnosis-related allegations account for more than one-third of medical office/clinic case volume** (and more than half of total dollars paid*). Cancers account for 44% of the diagnoses.
 - These allegations encompass wrong diagnoses, failures/delays, and misdiagnoses. **Key opportunities to reduce diagnostic errors along the diagnostic process of care exist**, specifically during the initial diagnostic and follow-up/care coordination phases.
- **Medical, surgical and medication-related cases are also noted.**
 - **Medical cases are distributed evenly between performance and management-related.** Procedural performance cases (i.e. injections and skin excisions/biopsies) can be impacted by delayed recognition of complications, while management cases most often reflect issues with selection of the most appropriate course of treatment for the patient, and appreciating and reconciling symptoms and test results.
 - **Cases involving the management and follow-up of surgical patients within an office setting** are often related to the provider's recognition of and response to developing complications.
 - **Medication cases most often involve management of narcotic, anticoagulant, and antibiotic regimens**; ordering errors are also noted.
- **Contributing factors, which are multi-layered issues or failures in the process of care that appear to have contributed to the patient's outcome, and/or to the initiation of the case, provide valuable insight into risk mitigation opportunities.**
 - **Several factors**, including inadequate staff training and supervision, insufficient documentation, and inadequate patient assessments and diagnostic decision-making, **are key drivers of both clinical and financial medical office/clinic case severity.**

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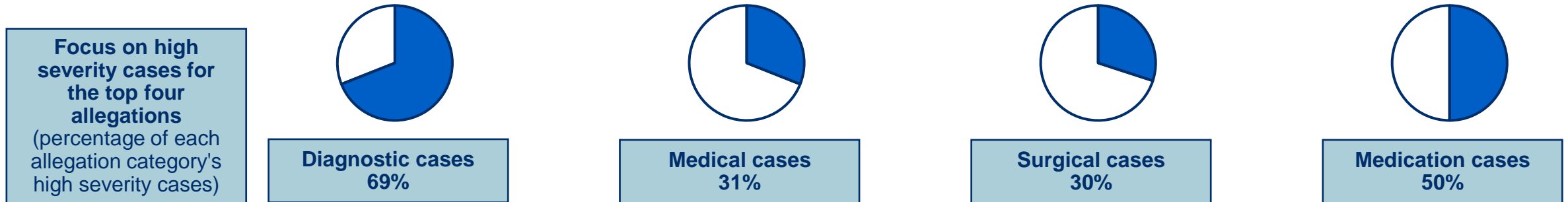


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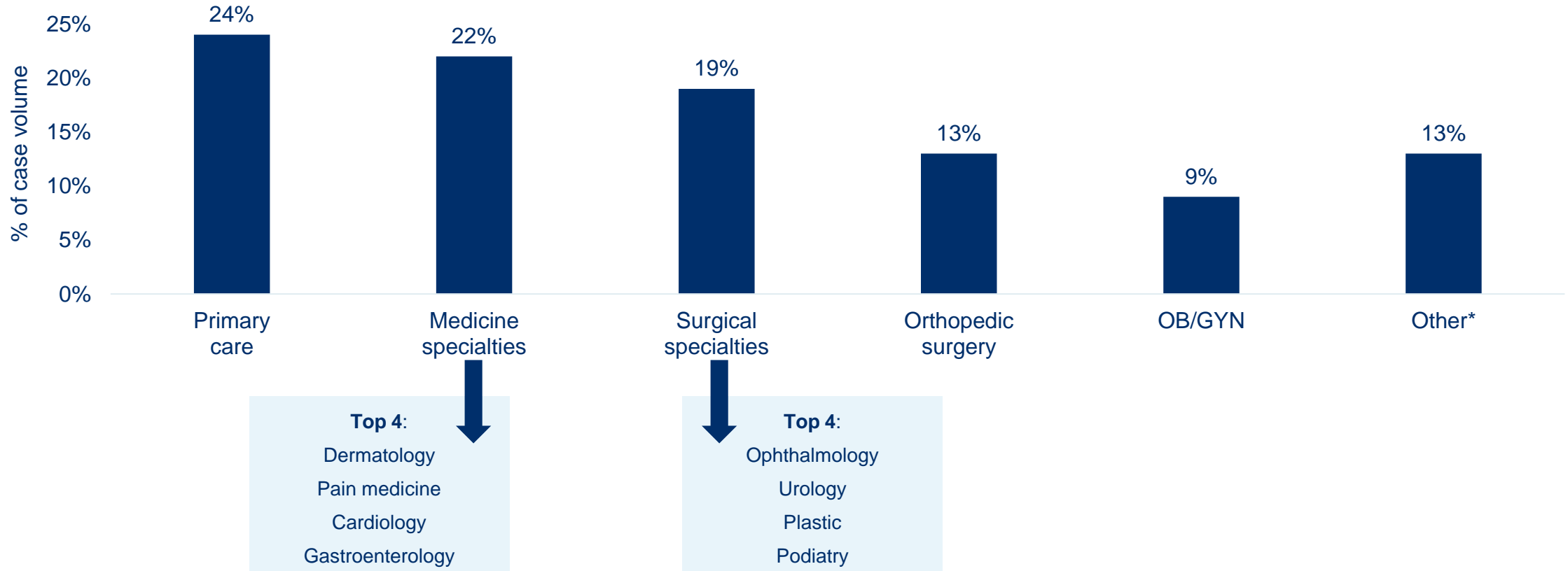
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Most Common Primary Responsible Services

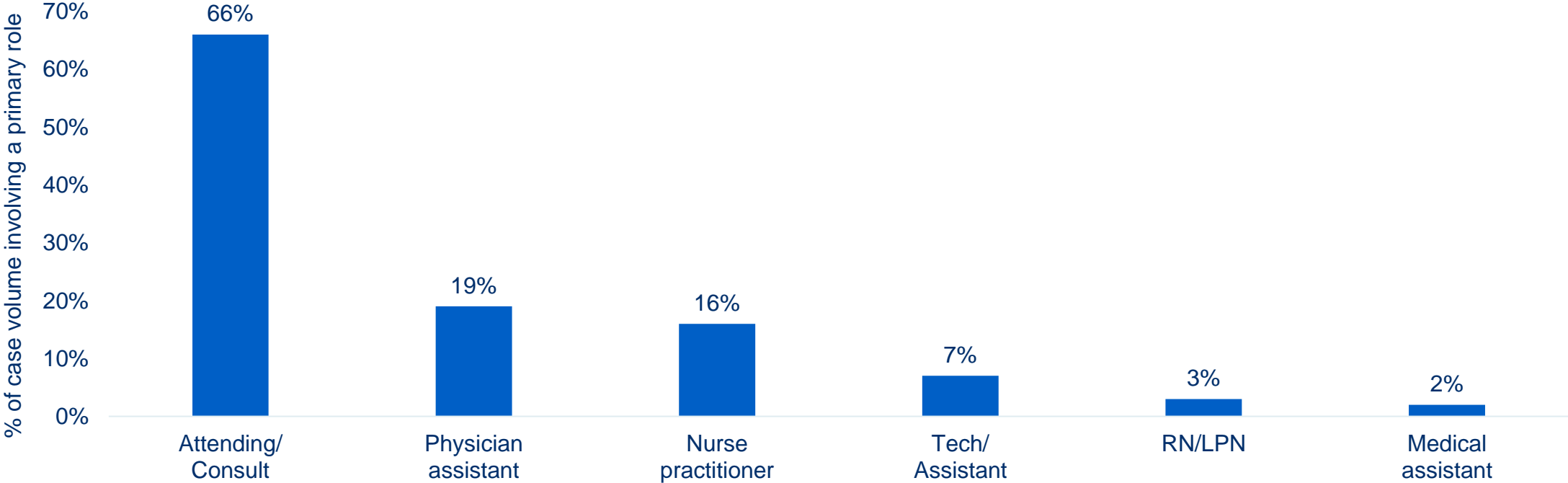
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MedPro Group + MLMIC cases opened 2012-2021, medical office/clinic with an identified role (N=2256); *Role codes have been evolving for several years. The role code portion of the taxonomy was enhanced and made mandatory in July 2021, therefore not all cases coded prior to that date have a role indicated.

Contributing Factors

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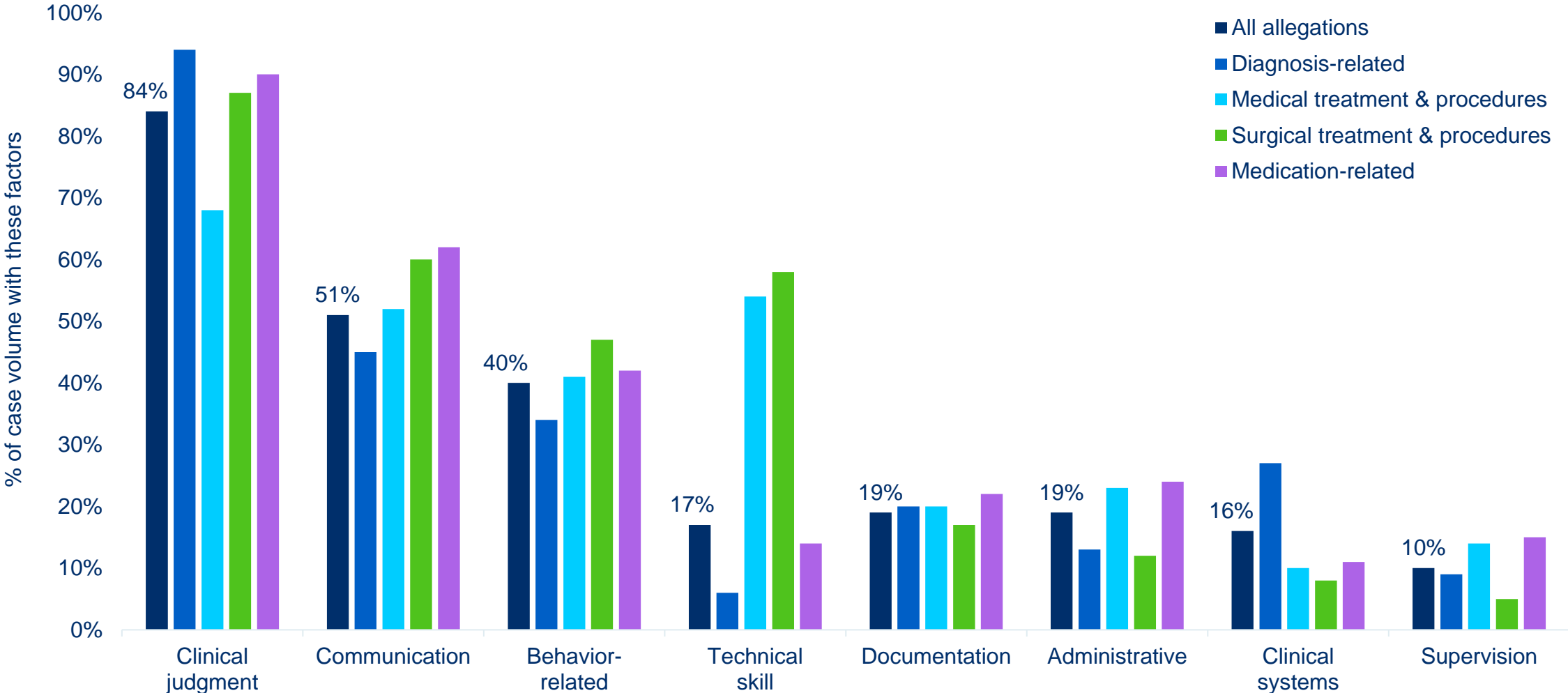
Technical skill

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Most Common Contributing Factor Categories by Allegation



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Contributing Factors: Focus on Drivers of Clinical & Financial Severity

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These factors are commonly noted in cases with clinically severe patient outcomes and indemnity payments.

Administrative Inadequate staff training/education

Behavior-related Patient non-adherence with treatment regimen and/or follow-up call/appointment

Clinical judgment

Selection of most appropriate treatment/procedure

Failure to appreciate/reconcile relevant signs/symptoms/test results

Failure to establish differential diagnosis

Misinterpretation of diagnostic results

Inadequate history/physical

Delay in ordering diagnostic testing

Failure/delay in obtaining consult/referral

Inadequate assessment resulting in premature discharge from care

Narrow diagnostic focus – failure to establish differential diagnosis

Communication Suboptimal communication among providers about patient condition

Failure to read medical record

Documentation Insufficient or lack of documentation regarding clinical findings (impacts team communication and makes subsequent defense of malpractice cases more difficult)

Focus on Diagnosis-Related Allegations

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Diagnosis-related allegations encompass wrong diagnoses, failures/delays, and misdiagnoses. See below for the top diagnoses* noted in these cases.

**Cancers
(44%)**

Primarily lung, prostate, breast, colorectal, urinary tract and colorectal

**Circulatory system
(13%)**

Primarily cardiac and cerebrovascular diseases

**Injuries
(10%)**

Primarily fractures, wounds, sprain/strains, and management of procedural complications

Focus on Diagnosis-Related Allegations

Diagnosis-related allegations encompass wrong diagnoses, failures/delays, and misdiagnoses. Note the key opportunities to reduce diagnostic errors along the diagnostic process of care* below.

Phase 1

Initial diagnostic assessment 88% of cases	Patient notes problem & seeks care
	History & physical
	Patient assessed, symptoms evaluated
	Differential diagnosis established
	Diagnostic testing ordered

Phase 2

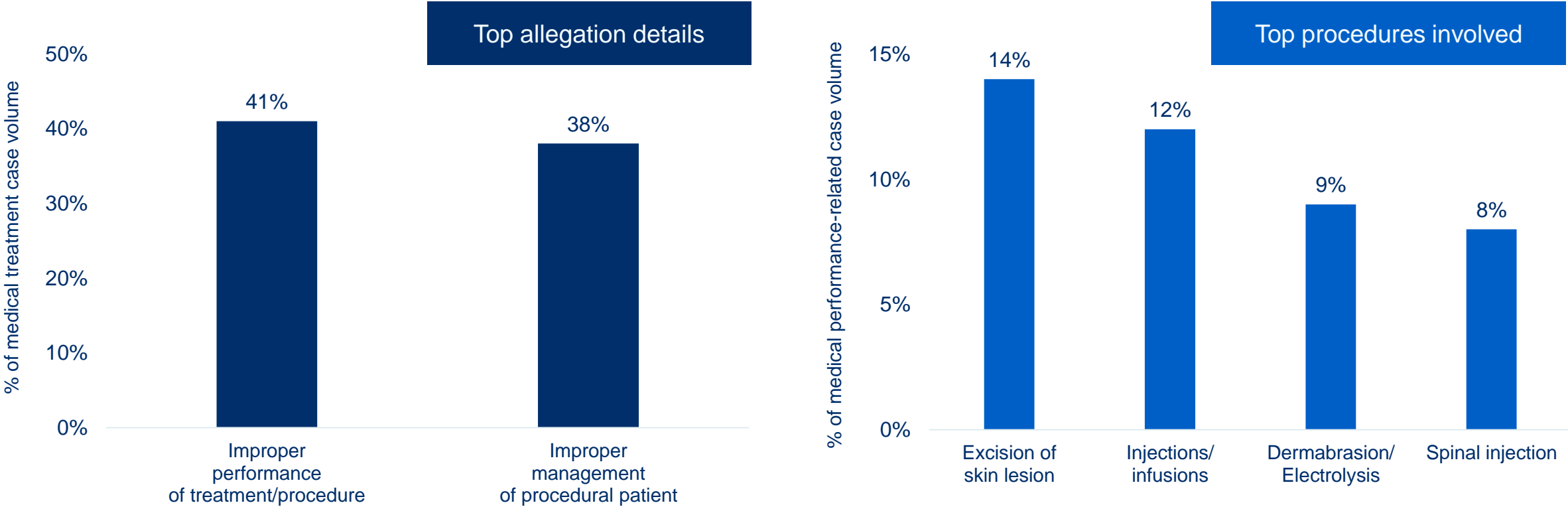
Testing and results processing 24% of cases	Performance of diagnostic tests
	Interpretation of diagnostic test results
	Test results transmitted to/received by ordering provider

Phase 3

Follow-up and coordination 68% of cases	Physician follows-up with patient
	Referrals/Consults
	Patient information communicated among care team
	Patient compliance with follow-up plan

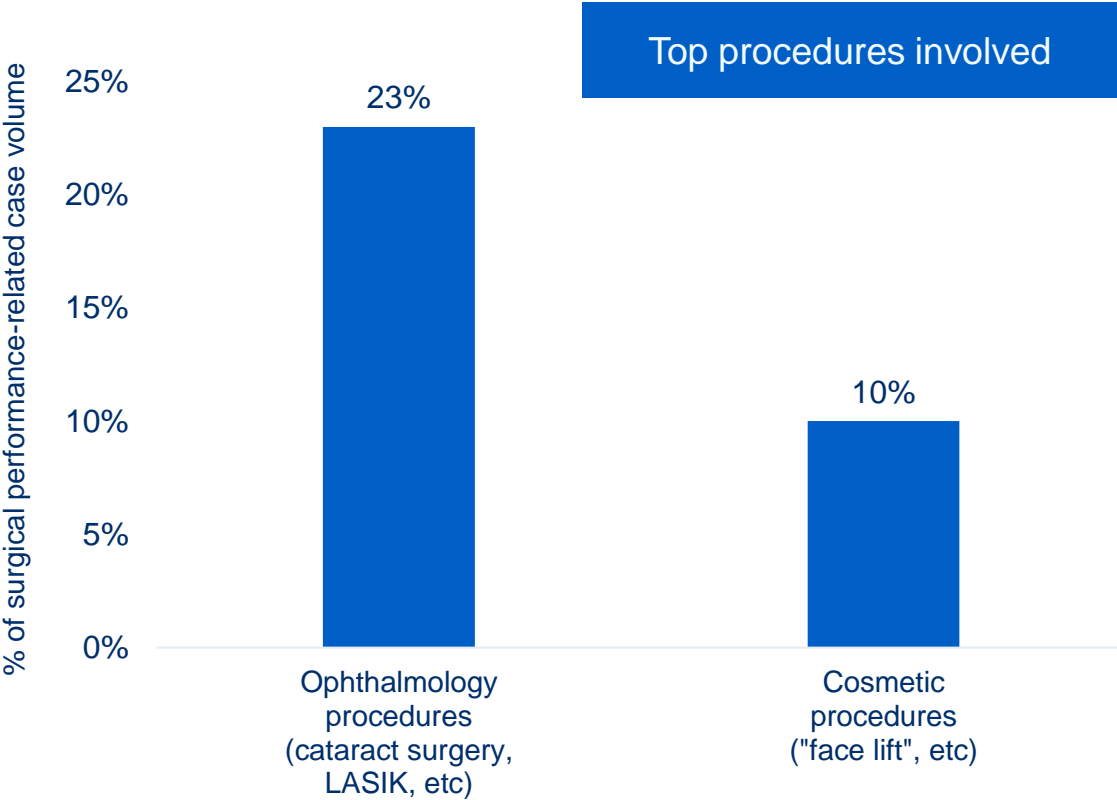
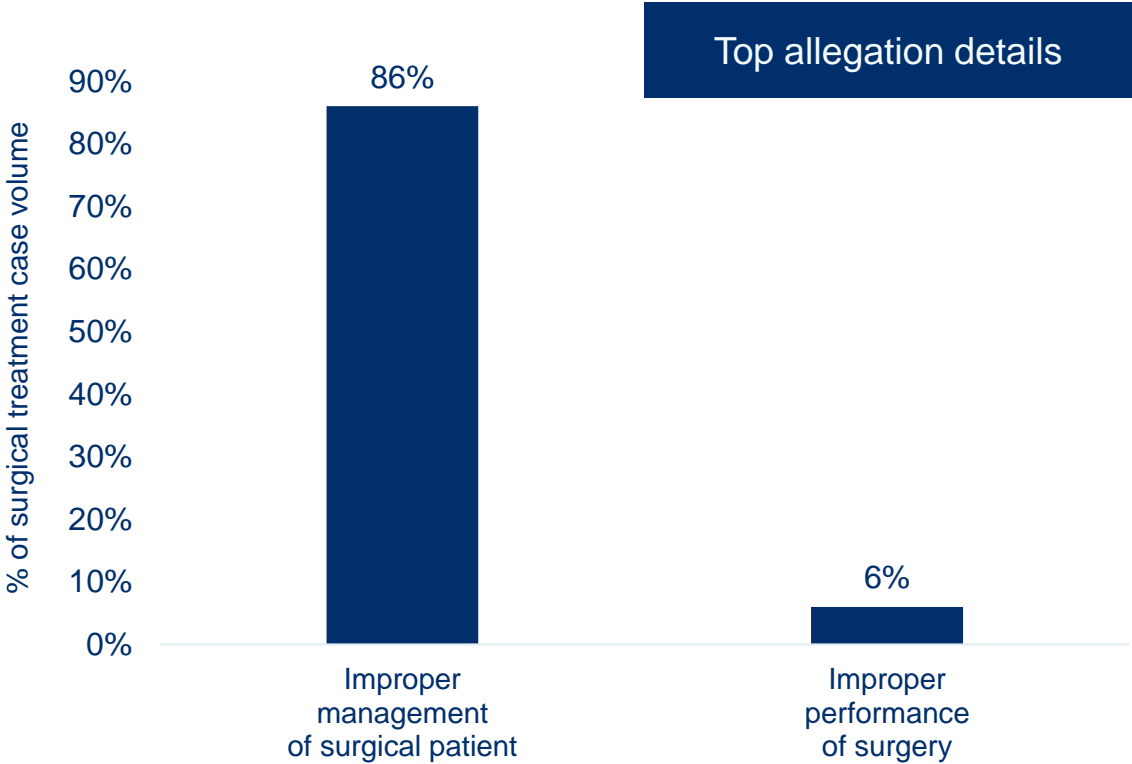
MedPro Group + MLMIC cases opened 2012-2021, medical office/clinic, diagnosis-related allegations(N=2240); *each step reflects a combination of contributing factors; diagnostic process of care algorithm courtesy of Candello, a division of CRICO Strategies

Focus on Medical Treatment Allegations



Procedural performance cases can be impacted by delayed recognition of complications, while management cases most often reflect issues with selection of the most appropriate course of treatment for the patient, and appreciating and reconciling symptoms and test results.

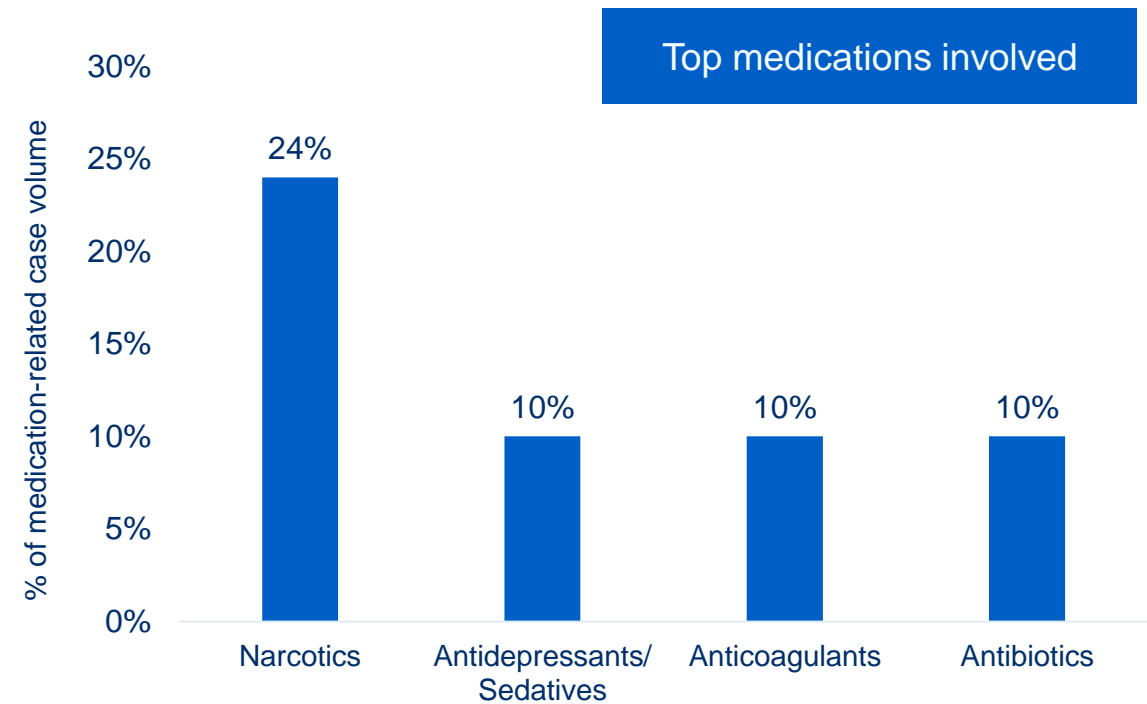
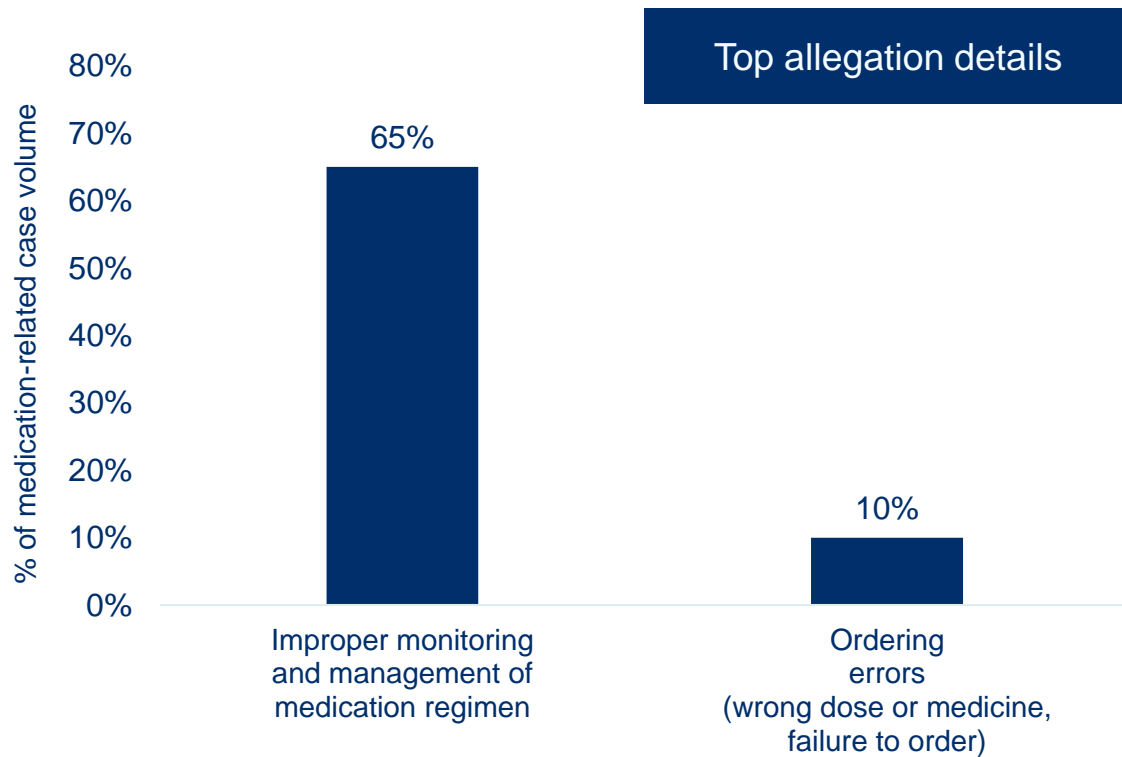
Focus on Surgical Treatment Allegations



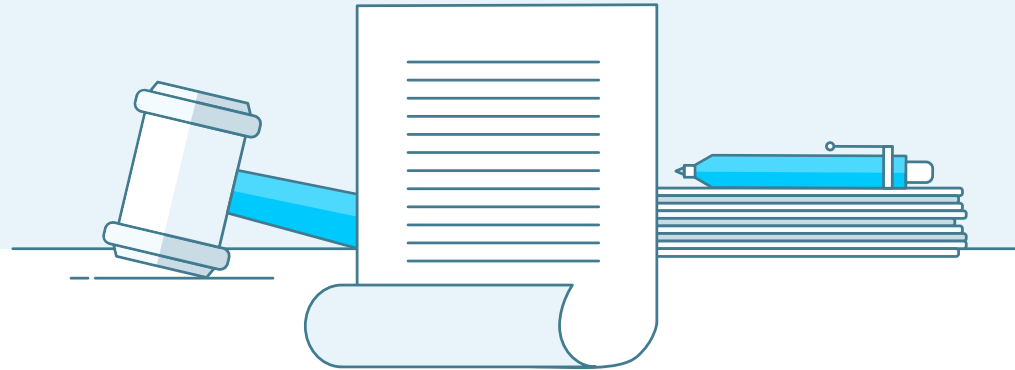
Cases involving the **management and follow-up of patients within an office setting** are often related to the provider's **recognition of and response to developing complications**. While complications of procedures occurring in a clinic may have been the result of procedural error, the **failure to timely recognize and/or monitor/manage the issue prevents the opportunity for early mitigation of the risk of serious adverse outcome**.

Focus on Medication-Related Allegations

INTRODUCTION | KEY POINTS | GENERAL DATA ANALYSIS | CONTRIBUTING FACTORS | **FOCUSED DATA ANALYSIS** | CASE EXAMPLES | RISK MITIGATION



Selection of the most appropriate medication for the patient's condition is a noted risk issue in narcotic cases, along with patient non-adherence to prescriptions. Issues with **inadequate patient/family education about medication regimens is an often-noted factor across all medication types**. **Anticoagulant cases reflect a few instances of failures to restart/reorder** and failures to identify which provider is coordinating anticoagulant regimens following a period of holding the medication (i.e. for surgery).



The following stories are reflective of the allegations and contributing risk factors which drive cases arising in a medical office or clinic.

We're relaying these true stories as lessons to build understanding of the challenges that you face in day-to-day practice. Learning from these events, we trust that you will take the necessary steps to either reinforce or implement best practices, as outlined in the section focused on risk mitigation strategies.

Case Examples

INTRODUCTION | KEY POINTS | GENERAL DATA ANALYSIS | CONTRIBUTING FACTORS | FOCUSED DATA ANALYSIS | CASE EXAMPLES | RISK MITIGATION

SETTLED

\$900K

CONTRIBUTING FACTORS

Administrative

Office record unavailable at the appointment due to electronic health record conversion

Clinical judgment

Narrow diagnostic focus with an atypical presentation (young female)

Failure to appreciate/reconcile relevant signs/symptoms

Failure/delay in ordering diagnostic test (colonoscopy)

FAILURE TO DIAGNOSE COLON CANCER IN YOUNG WOMAN RESULTING IN METASTASIS AND DEATH

A female patient in her mid-20's presented to a colorectal surgery office with **complaints of rectal bleeding and a strong family history of colon cancer** (grandfather with cancer, and father with colon polyps). She was examined, found to have hemorrhoids, and was encouraged to have a colonoscopy, which she refused. **She did not return to the office for another six years.**

At that time, she presented to the same office with complaints of hemorrhoids and rectal bleeding. She reported no family history of colon cancer or inflammatory bowel disease. In the intervening years, the patient's last name had changed, and her **prior office records were unavailable to review.** An in-office scope revealed **internal hemorrhoids with mild prolapse. No additional examination was done, and due to her age, no colonoscopy was recommended.**

Two years later, the patient presented again, this time with rectal bleeding, urgency with bowel movements, and abdominal cramping. A colonoscopy identified a mass loss in the colon; biopsy revealed a malignancy. The surgeon met with the patient and her father, who related the family history of colon cancer and polyps. **Post-operative testing revealed metastases to the liver.** The patient succumbed to her disease three years later.

Pathology review experts opined that the cancer would have been at Stage II-III if found in when the patient presented to the office for the second time (six years after the first time). **Experts were not supportive that of the colorectal surgeon's failure to seek out and read the patient's prior office record or offer a colonoscopy at that second visit.**

Case Examples

INTRODUCTION | KEY POINTS | GENERAL DATA ANALYSIS | CONTRIBUTING FACTORS | FOCUSED DATA ANALYSIS | CASE EXAMPLES | RISK MITIGATION

SETTLED

\$200K

CONTRIBUTING FACTORS

Clinical judgment

Intended selection of non-prescribed treatment (soothing oil)

Selection of inappropriate medication (antibiotic ointment)

Clinical environment

Failure to ensure a safe environment (chemicals kept in unlocked cabinet in patient care room)

Supervision

Supervision of advanced practice providers

Technical skill

Administration of incorrect "treatment" (chemical vs oil)

IMPROPER PERFORMANCE OF CERUMEN REMOVAL RESULTING IN BURNS TO EAR CANAL, FACE AND HANDS AND HEARING LOSS

A female patient in her mid-80's was an established patient at an ear, nose and throat clinic (ENT), **presenting routinely for removal of cerumen (earwax)**. At this visit, she complained of additional hearing loss in her right ear (she wore bilateral hearing aids). Rather than the impaction being removed by the ENT physician, **the procedure was performed by a physician assistant (PA), with no supervising physician on site.**

After cleaning out her ears, the **PA wanted to apply soothing oil from her "private stash."** However, rather than selecting the oil, the **PA inadvertently picked up a caustic solution intended for chemical peels. The PA placed an entire dropper of the caustic solution into the patient's ear, causing a burn in the ear canal.** It also spilled on the patient's hand as she reacted. The PA then compounded the situation by administering an antibiotic ointment to the burns despite the patient being allergic to that particular ointment.

The patient was diagnosed with second-degree burns, a perforated tympanic membrane and right-sided tinnitus. She also required two new hearing aids, because while hearing aids can be adjusted for slight changes, when one ear suffers such a drastic change, both hearing aids must be replaced to readjust the communication between them.

Experts were critical of the PA for not reading the label on the bottle of solution before administering it. In addition, personal products should not have been kept in the same room/cabinet with caustic chemicals, and those should have been stored in a locked cabinet (was unlocked within the room where patients are seen). The patient's burns were likely made worse by the administration of an antibiotic ointment to which the patient was allergic.

Case Examples

INTRODUCTION | KEY POINTS | GENERAL DATA ANALYSIS | CONTRIBUTING FACTORS | FOCUSED DATA ANALYSIS | CASE EXAMPLES | RISK MITIGATION

SETTLED

\$175K

CONTRIBUTING FACTORS

Behavior-related

Patient dissatisfaction/sought different provider

Clinical environment

Saturday ED visit/phone call potentially impacting diagnostic testing decision

Clinical judgment

Failure to order diagnostic test
Failure to appreciate/recognize relevant signs/symptoms

Documentation

Lack of clinic documentation of patient's first two visits

IMPROPER MANAGEMENT OF KNEE REPLACEMENT PATIENT RESULTING IN INFECTION AND ADDITIONAL SURGERIES

A male patient in his early 60's presented for a **total right knee replacement surgery** following failed conservative treatment for degenerative joint disease and osteoarthritis. **Two months later, on a Saturday, the patient presented to the Emergency Department (ED) complaining of a red, hot, and swollen right knee.** Labs revealed an elevated white blood cell count. The ED physician contacted the patient's orthopedic surgeon and sent pictures of the patient's knee. **The orthopedic surgeon opined that the patient had a superficial wound infection. He was given IV antibiotics while in the ED and discharged with oral antibiotics. No aspiration/cultures of the infection were obtained while in the ED.**

On Monday, the patient saw the surgeon in the outpatient clinic for a knee aspiration, and again on Tuesday to discuss ongoing care (no documentation in the patient's chart was found for either visit). The patient was seen four more times in the clinic, did not complain of significant symptoms, and was participating in physical therapy.

One week prior to the last clinic visit with the orthopedic surgeon who had performed the surgery and who had been seeing the patient in clinic visits, **the patient presented to a second orthopedic surgeon with complaints of knee pain** (and did not tell the first surgeon of this visit). **The second surgeon ordered labs which revealed active inflammation. A knee aspiration showed bacterial growth. Two weeks later, the second surgeon performed a revisional knee surgery with removal of hardware.** An antibiotic 'spacer' was placed, and a **large defect/infection of the patient's quad tendon was noted.** New knee hardware was placed four weeks later, with removal of a hematoma. The hematoma recurred, requiring a second evacuation.

The patient never regained full movement of his knee and required subsequent surgeries for loosening hardware and repeat infections. Experts opined the first surgeon should have ordered aspiration of the knee prior to administration of antibiotics in the ED, followed by incision and drainage with removal and replacement of the hardware. **The untreated infection caused the quad tendon defect to persist and progress, ultimately inhibiting rehabilitation.**

Case Examples

INTRODUCTION | KEY POINTS | GENERAL DATA ANALYSIS | CONTRIBUTING FACTORS | FOCUSED DATA ANALYSIS | CASE EXAMPLES | RISK MITIGATION

SETTLED

\$195K

CONTRIBUTING FACTORS

Clinical judgment

Failure to order medication

Management of pregnancy

Communication

Language barrier

FAILURE TO ORDER MEDICATION DURING PREGNANCY RESULTING IN INFANT WITH HEMOLYTIC DISEASE AND NEUROLOGICAL DELAYS

An Arabic-speaking female in her early 30's presented began care with her obstetrician when she was nine weeks pregnant. Her husband served as her translator during all visits. Previous history revealed that she was Rh-negative (a protein found on the surface of red blood cells) with two prior pregnancies, and had been given RhoGAM during each of those pregnancies to prevent complications with maternal/fetal Rh incompatibility.

Antibody screening was performed at this **initial visit, which revealed a low Rh-antibody titer (Rh-negative). The obstetrician did not document any discussion of prescribing RhoGAM. The patient continued to be seen by the obstetrician for four additional visits through the 29th week of pregnancy, but there was still no documentation discussing RhoGAM prescription with the patient.** At 31 weeks, the patient saw a second obstetrician who noted that she had not yet received the medication, and referred her to a maternal-fetal medicine specialist. Testing showed she was already Rh sensitized and therefore could not now receive the RhoGAM injection, however, the fetus' biophysical profile testing was normal. The fetus was at risk for hemolytic disease if antibodies attempt to destroy the fetus' red blood cells, including fetal anemia, jaundice, heart failure or brain damage.

At 35 weeks, the fetus' biophysical profile was concerning for anemia and a decision was made to perform a caesarean section due to non-reassuring fetal heart tracings. A 5 pound 11 ounce boy was delivered; he was severely anemic and was transferred to NICU. The placenta had two intra-parenchymal hemorrhages. The baby was transfused and suffered a small brain bleed with the potential risk of developmental delays.

By age two and a half, the boy required speech, behavioral and occupational therapy, and the mom was now at high risk of complicated future pregnancies. Experts were critical of the first obstetrician for failing to prescribe/administer RhoGAM between 26-28 weeks of pregnancy. Chart was silent as to any discussions with the mom regarding the necessity of RhoGAM (standard of care). **It is unknown, but possible, that the language barrier made a difference in the patient's care and whether she (and her husband) understood the significance of missing the medication.**

Key Medical Office & Clinic-Based Recommendations

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A culture of safety assessment is conducted.

Health record documentation is monitored for completeness and accuracy.

HIPAA compliance program is in place.

Policy & procedure includes a statement that guidelines do not replace judgment.

Informed consent process is defined.



Additional Risk Mitigation Strategies: Medical Office & Clinic-Based Cases

INTRODUCTION | KEY POINTS | GENERAL DATA ANALYSIS | CONTRIBUTING FACTORS | FOCUSED DATA ANALYSIS | CASE EXAMPLES | RISK MITIGATION

- **Conduct an appropriate and thorough assessment of the patient.**
 - Understand patient complaints and concerns.
 - Update and review medical and family history at every visit to ensure the best decision-making.
 - Be alert to high-risk diagnoses, such as cancer, cardiac disease, stroke and infections.
 - Maintain problem lists.
- **Communicate with each other.**
 - Focus on care coordination if other specialties are involved, including next steps and determining who is responsible for the patient.
 - Give thorough and clear patient instructions.
- **Engage patients as active participants in their care.**
 - Consider the patient's health literacy and other comprehension barriers.
 - Recognize that patient satisfaction with treatment outcomes can be influenced by a thorough informed consent and education process.
- **Document.**
 - Timely document thorough, objective information about the results of patient assessments, education of the patient/family about treatment plans - including medication regimens, and any instances of patient non-adherence.
 - Thorough, consistent documentation in the chart enhances communication between providers and provides a supportive framework for defense of any subsequent malpractice case.
- **Review office processes for test tracking, consults/referrals, appointment setting, and managing patient non-adherence.**
- **Know (and adhere to) your supervision responsibility for advanced practice providers.**

MedPro Group & MLMIC Data

MedPro and MLMIC are partnered with Candello, a national medical malpractice data collaborative and division of CRICO, the medical malpractice insurer for the Harvard-affiliated medical institutions.

Derived from the essence of the word candela, a unit of luminous intensity that emits a clear direction, Candello's best-in-class taxonomy, data, and tools provide unique insights into the clinical and financial risks that lead to harm and loss.

Using Candello's sophisticated coding taxonomy to code claims data, MedPro and MLMIC are better able to highlight the critical intersection between quality and patient safety and provide insights into minimizing losses and improving outcomes.

Leveraging our extensive claims data, we help our insureds stay aware of risk trends by specialty and across a variety of practice settings. Data analyses examine allegations and contributing factors, including human factors and healthcare system flaws that result in patient harm. Insight gained from claims data analyses also allows us to develop targeted programs and tools to help our insureds minimize risk.



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