ANESTHESIA & the LAW
A Risk Management Newsletter
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PPM

Adverse Anesthesia Events: Did COVID-19 Change Anything?

In this Issue

In March 2020, COVID-19 was declared a pandemic and the world completely changed almost overnight. Despite the high risk to their individual and families' safety along with enormous physical and psychological strain caused by the pandemic, PPM's insureds continue to care for patients on the frontlines every day. In this issue, we review the top 5 adverse anesthesia events[1] reported to PPM in 2020 and offer risk management analysis and patient safety strategies to prevent them. At the conclusion of this article, we specifically examine whether COVID-19 affected the types of injuries or unanticipated outcomes collected in PPM's loss database.[2]

5. Emotional Injury

Examples of emotional injuries include fear, anxiety, depression, anger, patient dissatisfaction, and billing disputes. In rare cases, patients may assert that the event they experienced caused post-traumatic stress disorder symptoms. Many emotional injuries arise from incidents of awareness or perceived awareness. For example, a patient receives a labor epidural and reports awareness postoperatively due to a lack of understanding of the epidural's expected effects. Most emotional injury claims are managed by PPM's in-house claims attorneys and claims specialists. They are typically either closed with no payment or resolved through nominal settlements before trial, as highlighted by the following case study.

Case Study

A 70-year-old female underwent a laparoscopic gastric sleeve procedure. Two CRNAs provided general anesthesia whom an anesthesiologist supervised. The patient was taken to the OR and induced. The CRNA turned off the vaporizer to refill it, and the surgeon started the procedure. The second CRNA came into the OR to relieve the first CRNA and noticed the vaporizer had not been turned back on. The second CRNA turned the vaporizer on and notified the anesthesiologist of what had occurred. The procedure was completed without any complications.

The anesthesiologist saw the patient in recovery and unsolicited she said, "I felt everything." She described the beginning of the procedure with her abdomen's incisions, trocar placement, and insufflation. He apologized for this adverse event and explained what had occurred. He also offered the patient counseling. The patient had three visits with her primary care physician where she reported complaints of depression and anxiety due to the awareness and five visits with a counselor.

The patient retained an attorney who made a $220,000 settlement demand for his client's emotional damages. Shelley Strome, PPM's Senior Claims Specialist, who managed this claim file, educated the patient's attorney regarding PPM's loss data involving awareness cases. After several rounds of negotiations, PPM settled this case for $35,000 before the patient filed litigation.

Risk Management Analysis and Considerations

Effective preoperative and postoperative communication is key to preventing and responding to emotional injury claims. PPM's investigation of emotional injury claims often reveals ineffective communication with patients or family members regarding the anesthetic technique, expected results, known risks and complications, lack of availability or follow-up after an adverse event, or a perceived lack of compassion. PPM recommends considering the following practices to prevent and respond to adverse events resulting in emotional injury claims:

- Conduct a thorough informed consent discussion asking the patient or surrogate open-ended questions to ensure the patient understands the planned anesthetic technique, expected results, and known risks, and document that discussion
- Be available (or make sure an appropriate person is available) to the patient or family for questions immediately following an adverse event
- Be candid and honest; avoid speculation and finger-pointing
- Listen and empathize without being defensive; convey compassion for the patient's situation and focus on the patient's needs
- Participate in discussions with the patient or family with other health care providers or risk management
- Address the patient's current health care needs; obtain necessary consults, tests, or referrals
- Maintain contact with the patient or family when practical and accepted
- Apologize if appropriate (39 states and the District of Columbia have laws allowing medical professionals to make apologies or sympathetic gestures and prevent those statements from being used against them in court)[3]
- Contact PPM to discuss effective communication strategies such as resolving billing disputes, disclosures, and meetings with patients and families

4. Tissue Injury

Tissue injury is a broad category PPM uses to capture multiple types of injuries. More common examples of tissue injuries include injury to the mouth, tongue, oropharynx, tonsils, vocal cords, and arytenoid cartilage. These types of injuries are often associated with laryngoscopy, endotracheal intubation, or placement of a laryngeal mask airway (LMA), which are known risks and complications. Other tissue injuries include IV infiltration, corneal, eyelid and facial abrasions, and pressure injuries related to positioning. Most of these tissue injuries do not result in significant or permanent injuries when promptly identified and treated.

However, PPM's loss data reflects a trend involving increased significant and permanent tissue injuries, including compartment syndrome resulting in amputation, complex regional pain syndrome, and esophageal and stomach perforation. While PPM can successfully defend these types of injuries, PPM has had to resolve multiple preventable significant tissue injury cases, as highlighted by the following case study.

Case Study

A 42-year-old female presented for a laparoscopic gastric band procedure. A CRNA provided general anesthesia who was supervised by an anesthesiologist. The surgeon utilized a dual lumen lap-band system calibration tube. One lumen is used for drainage, suction, and irrigation, while the second lumen inflates and deflates the balloon. The surgeon requested the CRNA to place the calibration tube. The CRNA connected the oxygen tubing to the port for the balloon. The balloon quickly inflated and ruptured, tearing a large section of the lower esophagus. A thoracotomy and an extensive esophageal repair were performed. The patient was transferred to the ICU after the procedure.

The patient sued the anesthesiologist, CRNA, anesthesia practice group, surgeon, and hospital. Total medical bills exceeded $275,000. The patient also claimed approximately $25,000 in lost wages in addition to non-economic damages, including pain and suffering.

The CRNA testified during her deposition that she had never seen or used the calibration tube device requested by the surgeon. She also testified that she did not question the surgeon about the two ports' functioning to ensure she was applying air to the correct port.

The plaintiff's surgical expert criticized the surgeon for using a calibration tube device that was not approved for this procedure. He testified that since the surgeon was using the device "off-label," he had a duty to instruct and demonstrate to the anesthesia staff how the ports worked and explain the risks of utilizing the wrong port.

The parties agreed to participate in mediation before trial. The plaintiff's opening settlement demand was $975,000. With our insureds' consent, PPM settled this case on behalf of all PPM insureds for $500,000 based primarily on the CRNA's failure to speak up and ask the surgeon for direction. The remaining co-defendants reached confidential settlements.

Risk Management Strategies for Preventing Injury from Unfamiliar Procedures or Devices

- Proactively engage hospitals and facilities regarding involvement in these surgical procedures and obtain appropriate credentialing
- Ensure proper training and familiarity with the device and its use before the procedure or require the surgeon to instruct on the use of the device or technique specifically
- Discuss with the surgeon or independently determine any contraindications during preoperative assessment
- Document surgeon's request and direction to use the device and note any "off-label" use

3. Nerve Injury

One of the most common nerve injuries is ulnar nerve damage. While anesthesia providers are frequently primary targets in ulnar nerve injury claims, surgeons and nurses may also be included based on shared responsibility for positioning.

Despite epidemiologic and anatomic studies suggesting that a significant number of patients will experience ulnar nerve damage regardless of proper padding and positioning, plaintiff attorneys have no difficulty recruiting anesthesia experts willing to testify that the mere existence of the injury demonstrates negligent care. However, PPM has a long and successful history of aggressively defending upper extremity nerve damage cases related to positioning.

To date, PPM continues an impressive trial record defending these cases: 44 defense verdicts, 0 plaintiff verdicts. In addition to courtroom victories, plaintiffs have voluntarily dismissed litigation in several other upper extremity nerve damage cases upon learning PPM's successful trial record.

Nerve injuries typically associated with regional anesthesia blocks include femoral, popliteal, sciatic, peroneal, brachial plexus, and axillary nerve damage. Other rare, significant nerve injuries include spinal cord injuries due to infarction or epidural hematoma resulting in cauda equina syndrome and paraplegia.

Common allegations in regional anesthesia block claims include:

- Failure to identify appropriate anatomic structures
- Inappropriate testing or technique – e.g., failure to aspirate, failure to document test dose or concentration, improper block technique, and wrong needle size or length

- Failure to timely diagnose and treat complications – e.g., lack of appropriate discharge instructions and follow-up, and failure to obtain or provide timely diagnostic testing, consultations, or referrals
- Wrong-site blocks
- Lack of informed consent

Despite the frequency of nerve injuries associated with regional anesthesia blocks, PPM has successfully defended most of these claims. As illustrated by the following case study, educating juries regarding other potential causes of nerve injury, and that nerve injury is a known risk and complication are some of PPM's most effective defense strategies.

Case Study

A 31-year-old male, 170 cm, 91 kg, with a medical history of a work-related injury presented for a left elbow conjoined tendon repair with total intravenous anesthesia. The anesthesiologist performed a supraclavicular nerve block for postoperative pain relief at the surgeon's request. The anesthesiologist administered 6 mg Versed and 100 mcg fentanyl for sedation for the block. Ultrasound guidance and neurostimulation were utilized, and there were no noted complications during the block. The patient did not complain of pain, burning, or other abnormal sensations prior to discharge.

Approximately six months post-op, the anesthesiologist learned that the patient had reported numbness, pain, and swelling in his left hand. The anesthesiologist called the patient, who reported the same symptoms and decreased use of his left hand. He also indicated he had been referred to a neurologist. The anesthesiologist told the patient he was sorry he had these symptoms, and he would follow up with his treating neurologist. The patient's treating neurologist informed the anesthesiologist he believed the patient had sustained a brachial plexus injury but that he had been noncompliant with recommendations for medical treatment, including physical therapy.

The patient filed a lawsuit against the anesthesiologist and his anesthesia practice group. The patient alleged the anesthesiologist negligently administered a left brachial plexus block resulting in an injury to the medial cord and claw deformity.

The plaintiff's anesthesiology expert testified that the anesthesiologist improperly placed the needle, causing trauma in the brachial plexus's left medial cord. He testified further that the patient was over-sedated during the administration of the nerve block.

The defense anesthesiology expert testified that the 6 mg Versed and 100 mcg fentanyl administered for sedation was within the standard of care based on the patient's size. He testified further that EMG and MRI showed an isolated ulnar nerve injury suggesting medial cord injury was unlikely. He also testified that the cause of the patient's injury was just as likely related to his workplace accident. Finally, he confirmed that nerve injury is a known risk and complication of regional anesthesia blocks and can occur absent negligence.

The plaintiff's attorney made a $975,000 settlement demand before trial. In his closing argument, he asked the jury to return a verdict in favor of the patient for $6,000,000. Following an eight-day trial, the jury returned a unanimous defense verdict in favor of the anesthesiologist and his anesthesia practice group.

Risk Management Analysis and Considerations

Thorough preanesthesia assessment, informed consent, and documentation are the most critical elements for reducing the likelihood of nerve injury claims or litigation. Preanesthesia assessment should include a discussion of factors that may place the patient at increased risk of injury. Patients who are made aware in advance that such injuries are known risks and complications are less likely to conclude that the injury resulted from negligence.

Communication among health care providers is also extremely important in recognizing and treating injuries and managing the patient's expectations after an injury. PPM recommends considering the following practices to minimize the possibility of nerve injury claims and litigation:

- Document if surgeon or patient requested the block
- Ask patients if they have any preexisting nerve damage or problems; document any described
- Explain the planned anesthetic technique and document that risks, benefits, and alternatives were discussed
- Highlight specific risks more thoroughly – e.g., nerve damage, failed block, infection, vascular injury, and intravascular injection
- Monitor patients continuously throughout the procedure and avoid placing regional anesthesia blocks in deeply sedated or anesthetized patients; exceptions include pediatric patients, TAP blocks, and other blocks away from major neural structures, or if medically indicated

2. Death

This injury category includes reports of deaths from many potential causes involving very diverse patient populations, including infants to elderly patients. PPM policyholders often report deaths as a precaution even when there is no evidence or indication that the cause of death was related to anesthesia care.

Many death reports involve patients designated as III or IV under the ASA Physical Status Classification System.

Consequently, most of these reported deaths do not result in claims or litigation against PPM's policyholders.

However, PPM's loss data reflects a trend involving an increasing number of death claims and litigation for procedures that the public commonly perceives as routine or safe, such as orthopedic, cosmetic, cardiac catheterization, and endoscopy.

Endoscopic anesthesia claims and litigation often involve allegations of inappropriate patient assessment and selection. As highlighted by the following case study, another common allegation is over-sedation, causing bradycardia and adverse respiratory events resulting in death.

Case Study

A 64-year-old male, ASA III, with a medical history of morbid obesity (BMI 44), obstructive sleep apnea (OSA), diabetes, hypertension, and diverticulitis, presented for an elective colonoscopy. The anesthesiologist administered monitored anesthesia care (MAC) with deep sedation. Medications were propofol (total of 400 mg) and lidocaine (not documented). Oxygen (O2) was delivered via nasal cannula at 4 l/m.

During the procedure, the endoscopist noted intermittent ventricular ectopy with bigeminy and hypotension followed by bradycardia. When the lights were turned back on, the patient was noted to be ruddy with a darkened complexion. O2 sat was 75%, with heart rate (HR) of 49. O2 was increased to 8 l/m, and mask valve ventilation was initiated. O2 sat dropped to 43%, and bradycardia turned to asystole. A code blue was called, the patient was intubated, and CPR continued. The patient's blood pressure and HR were restored approximately 13 minutes after the code was called.

Postoperative EEG and CT scan showed brain edema with loss of gray-white differentiation. The family stopped supportive care, and the patient expired four days post-op. The cause of death was determined to be from hypercarbia, cardiac arrest, and anoxic brain damage.

The patient's wife sued the anesthesiologist, his anesthesia practice group, and the hospital. She alleged that the anesthesiologist was negligent in failing to recognize evolving respiratory depression and failing to secure the airway promptly.

The plaintiff's anesthesiology expert testified that the anesthesiologist was negligent in failing to assess the patient's airway. The expert testified further the patient was at "extremely high risk" given his morbid obesity and OSA. He also testified that the patient was initially a candidate for MAC with sedation. However, the anesthesiologist should have recognized respiratory obstruction early in the case and placed an LMA or ETT to secure the airway. He further testified there was no evidence that capnography was used or that end-tidal carbon dioxide (ETCO2) was monitored. Finally, he testified that the anesthesiologist breached the standard of care by ignoring alarms and failing to remain vigilant in monitoring the patient's BP, HR, and ETCO2.

The parties agreed to mediation before trial. Plaintiff's opening demand was $1,800,000. With our insured's consent, PPM ultimately settled the case on behalf of the PPM insureds for $970,000. The hospital was dismissed from the case as the claims against the facility were premised mainly on the anesthesiologist's care.

Risk Management Analysis and Considerations

When high-risk patients, such as those with morbid obesity, untreated or suspected OSA, pulmonary disease, or heart failure, are identified during the preanesthesia evaluation, PPM policyholders should consider:

- Whether the patient is an appropriate candidate for the planned procedure and facility; discuss and document any concerns with the endoscopist
- Delaying or canceling the procedure for further evaluation and treatment, if medically indicated
- Avoiding IV general anesthesia with an unprotected airway and instead administer minimal or moderate sedation or general anesthesia with a secured airway
- Oxygen delivery via non-rebreathing mask with sampling device used for qualitative ETCO2 measurement
- Prophylactic vagolytic therapy – e.g., atropine or glycopyrrolate to reduce the incidence of bradycardia, if medically indicated
- Aggressive treatment of bradycardia

1. Dental Injury

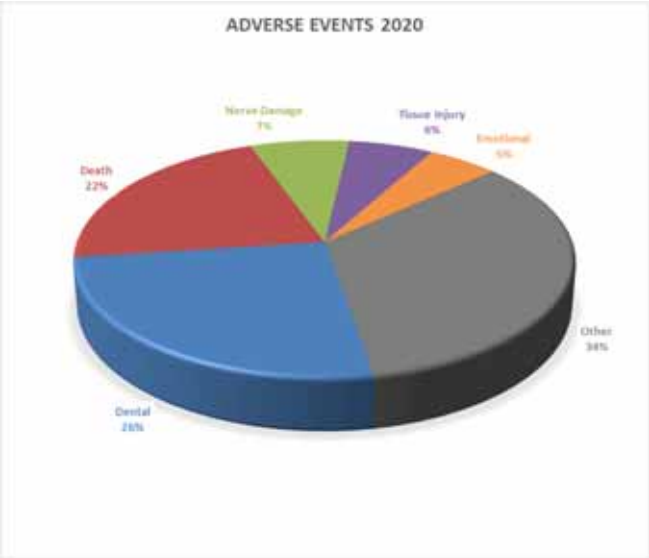
Adverse events involving dental injury remain at the top of all types of injuries reported by PPM policyholders. Perioperative dental injuries are a known risk and complication and infrequently caused by clinical negligence. However, many patients who experience dental injury assume the anesthesia provider was negligent and should pay for their dental consultation and repair. To respond to a significant number of questions and concerns from PPM policyholders regarding dental injuries and claims, PPM developed updated guidelines to minimize the number of dental claims and help policyholders avoid the inconvenience of processing, investigating, and resolving dental claims. PPM's in-house attorneys and claims specialists are available to assist groups develop best practices for addressing dental injuries. For additional information contained in our updated dental claim guidelines, please visit www.ppmrrg.com/issue-47.

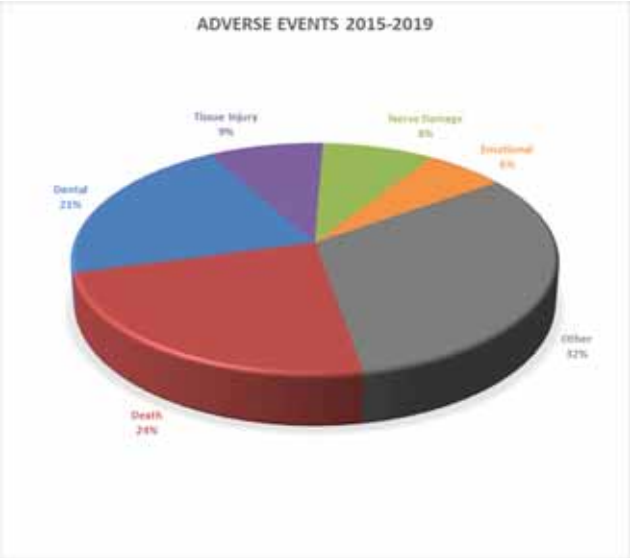
Did COVID-19 Change Anything?

Notably, to date, PPM has not received any reports of adverse events directly related to COVID-19. However, PPM's in-house attorneys and claims specialists assisted many policyholders with risk management questions and concerns including, but not limited to, personal protective equipment (PPE), non-urgent and elective cases, informed consent related to COVID-19 risks, staffing, turnaround times following intubation and extubation, and anesthesia professional wellness.

In response to the pandemic, PPM also created our COVID-19 Resources and Coverage Information webpage on PPM's website[4] to respond to policyholder's questions related to their insurance coverage for practicing in the ICU, CCU, and other parts of the hospital (to care for COVID-19 patients), licensure requirements, and telehealth. PPM's COVID-19 Resource and Coverage Information webpage also provides links to articles, guidelines, joint statements, and other critical information related to COVID-19 for anesthesia professionals published by the Anesthesia Patient Safety Foundation, the American Society of Anesthesiologists, and the American Association of Nurse Anesthetists, as well the Centers for Disease Control and Prevention and the Centers for Medicare and Medicaid Services.

Despite all the incredible challenges PPM's policyholders and insureds have faced during the pandemic, PPM's loss data does not reflect or forecast a trend in COVID-19 claims and litigation against anesthesia providers. While COVID-19 drastically impacted nearly every aspect of our lives, as illustrated by the charts below, the adverse events reported to PPM in 2020 were consistent with the adverse events reported in the preceding five years.





References:

1. Adverse anesthesia events or unanticipated outcomes are typically a negative or unexpected result stemming from medical judgment or treatment, or failing to perform a test or intervention. An adverse anesthesia event may or may not be the result of negligence. Note: Adverse anesthesia events are distinguishable from claims and litigation. Most states' statutes of limitations allow patients or their legal representatives to file a claim or lawsuit typically between 2-3 years from the date of injury. Several exceptions can extend the amount of time to file a claim including, but not limited to minor patients, incapacitated adult patients, and retained instruments.
2. PPM assigns an injury severity code and description to every reported adverse anesthesia event based on the National Association of Insurance Commissioners (NAIC) scale ranging from (01) - Emotional injury only to (09) - Death. PPM uses injury severity codes and descriptions to collect and aggregate adverse anesthesia events in our loss database by injury type (e.g., death, brain injury, nerve injury, and dental).
3. Medical Professional Apologies Statutes. National Conference of State Legislatures, www.ncsl.org/research/financial-services-and-commerce/medical-professional-apologies-statutes.aspx. Accessed March 23, 2021.
4. PPM Coronavirus (COVID-19) Resources & Coverage Information, www.ppmrrg.com/news-events/covid-19-update. Accessed March 23, 2021.

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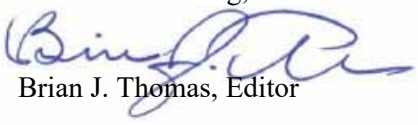
Thanks for reading,



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