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Be Conscious of Those Who Shouldn't Be: Revisiting Intraoperative Awareness During Anesthesia

Introduction

Intraoperative awareness occurs when a patient experiences consciousness during general anesthesia or has recall of intraoperative events.[1] Depending on the procedure, anesthesia technique, and patient-specific risk factors, the estimated rate of adult patients who experience intraoperative awareness under general anesthesia ranges from 0.005% to 0.1%.[2] However, Preferred Physicians Medical's (PPM) claims experience suggests the incidence of awareness may be even lower.[3]

In *Anesthesia & the Law* Issue 20, PPM explored the frequency of intraoperative awareness claims reported to PPM from 1989-2007.[4] During that 19-year period, 43 awareness claims were investigated by PPM, an average of 2.26 per year. Intraoperative awareness remains a relatively rare basis for claims. Between 2008 and 2025, PPM investigated an additional 32 awareness claims, an average of 1.78 per year (Figure 1).

However, for purposes of capturing claims data, PPM uses the injury description "awareness" more broadly than the anesthesia community. PPM includes this injury description when awareness under general anesthesia results from a human error, such as a medication mix-up or neglecting to turn on the vaporizer. Moreover, the awareness injury description is used anytime a reported event involves a patient who experienced intraoperative pain from surgical stimuli, regardless of the anesthesia plan. For example, a sizeable number of PPM's "awareness" claims involve obstetric patients who experience pain during emergency cesarean sections (C-section) due to inadequate neuraxial anesthesia.

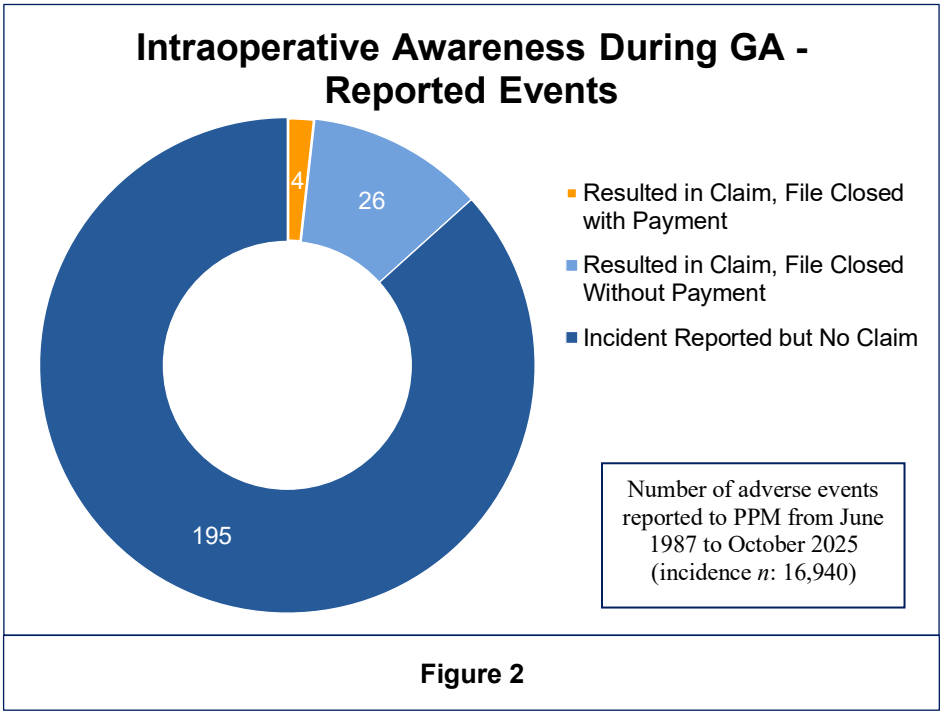

Figure 2

If we exclude claims involving neuraxial anesthesia and human errors and examine only events involving the phenomenon "accidental awareness during general anesthesia" (AAGA), awareness claims are exceedingly rare. PPM insureds have reported 225 AAGA events over the course of the company's 38-year history, but only 30 reported events resulted in a claim or lawsuit. In addition to being infrequent, AAGA claims are largely defensible. Since 1987, only 4 AAGA claims were closed with an indemnity payment (Figure 2).

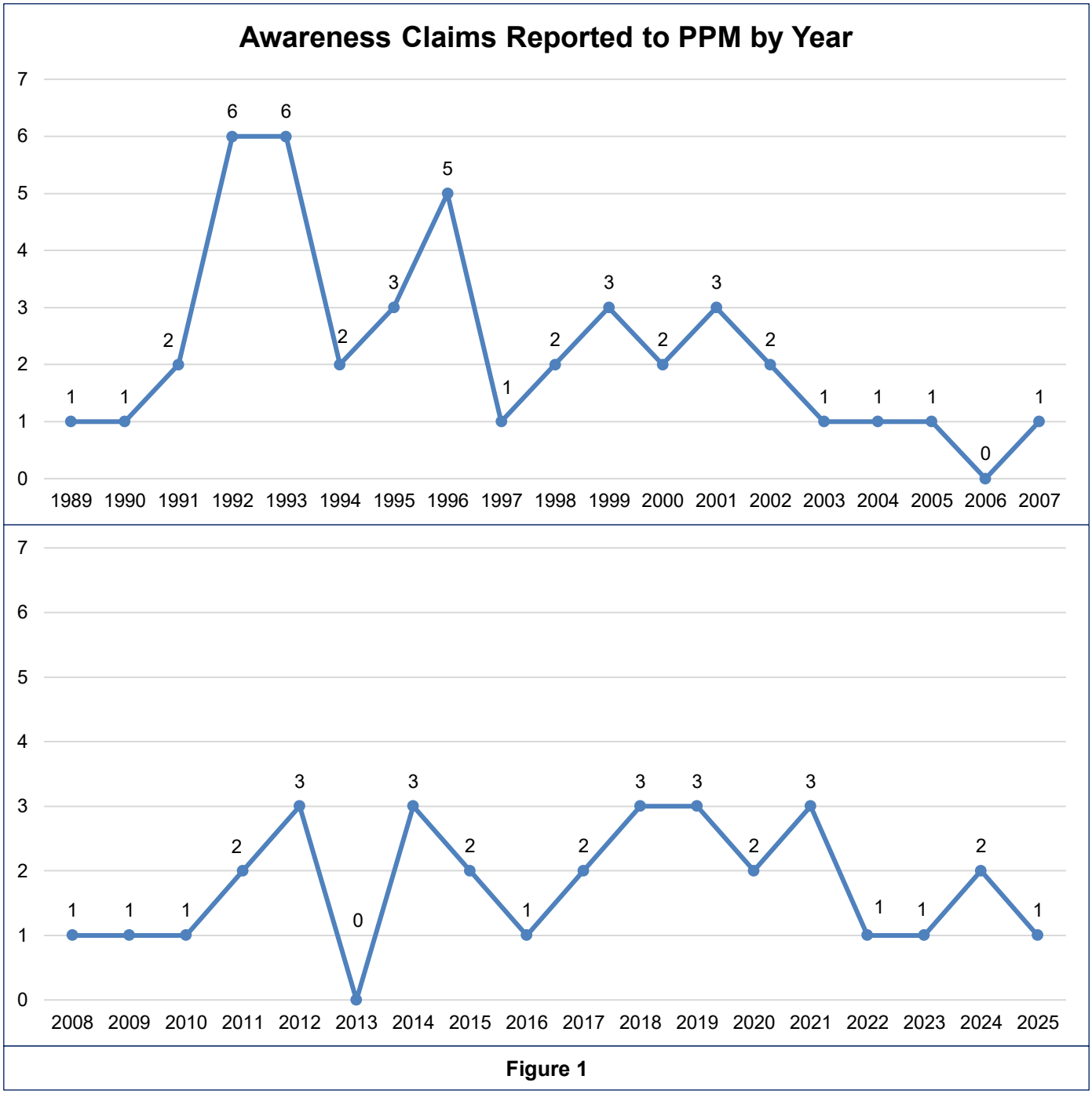

Figure 1

The largest number of AAGA events reported to PPM involved patients who underwent general surgery or orthopedic procedures (Figure 3). This is likely attributable to the high volume of orthopedic and general surgery procedures performed annually in the United States.[5] Consistent with the medical literature, a sizeable number of reported AAGA events occurred during obstetrical and gynecological procedures and cardiothoracic surgery, the latter of which carries a heightened risk for AAGA due to the pharmacokinetics associated with cardiopulmonary bypass.[2]

"PPM INSUREDS HAVE REPORTED 225 AAGA EVENTS OVER THE COURSE OF THE COMPANY'S 38-YEAR HISTORY, BUT ONLY 30 REPORTED EVENTS RESULTED IN A CLAIM OR LAWSUIT"

Anesthesia professionals are tasked with balancing a variety of risks and benefits based on the individual patient's presentation and the type of procedure performed. AAGA events reported by PPM insureds often

result from the anesthesia professional tailoring the anesthesia plan to avoid a different complication. For example, when providing anesthesia for a very fragile patient, an anesthesia professional must administer enough anesthesia to provide amnesia and analgesia, immobilize patients and suppress sympathetic nervous system response to surgical stimuli, while carefully avoiding an anesthesia depth that could induce hemodynamic compromise.[2] If the anesthetic depth is too light, the patient might experience AAGA.[2] Or, as we examine in the case study below, an anesthesia plan tailored to address a patient's reported history of postoperative nausea and vomiting (PONV) can leave the patient more susceptible to experiencing AAGA.

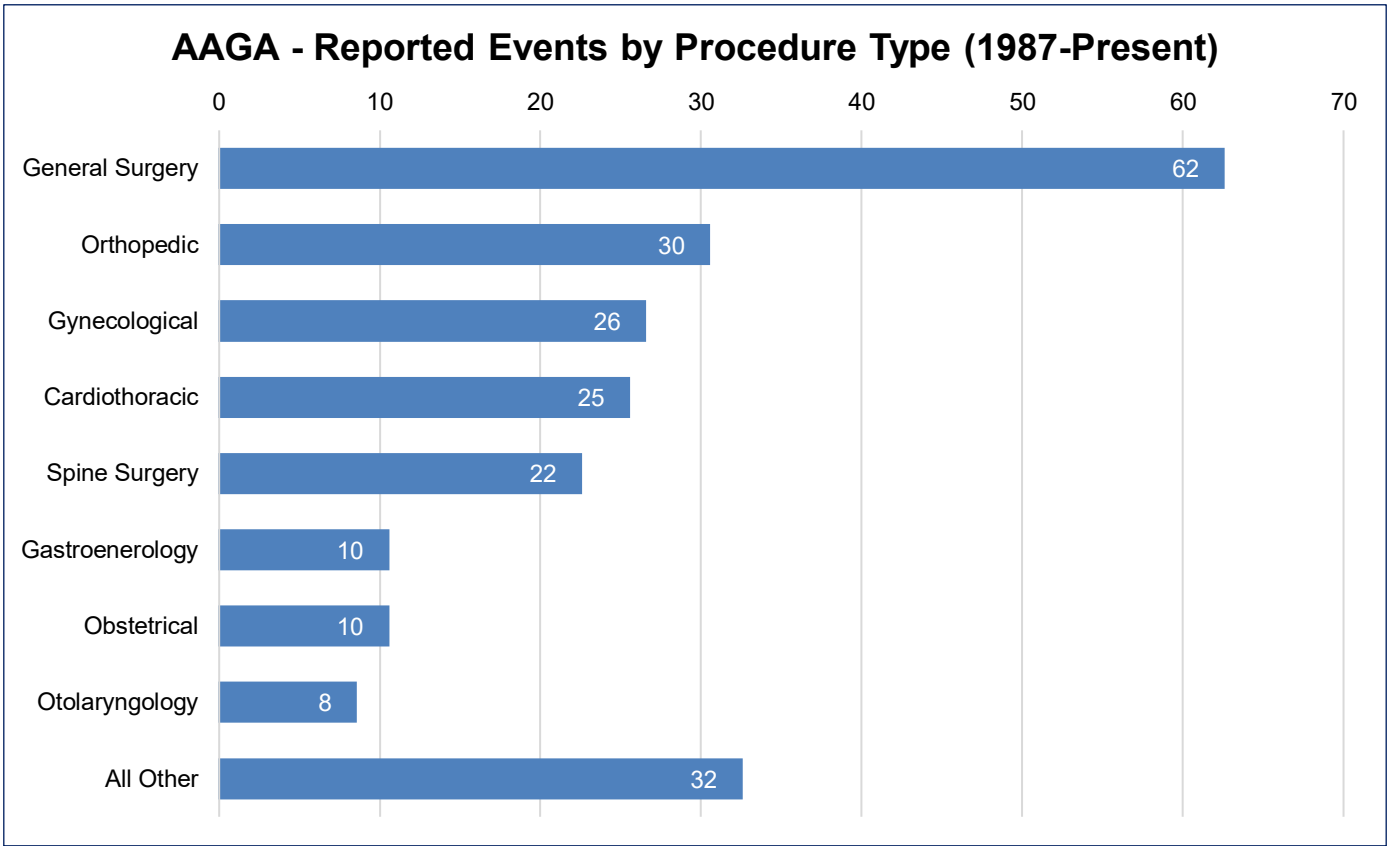

Figure 3

Case Study

A 30-year-old female presented to an outpatient surgery center for left hip arthroscopy. Anesthesia services were provided by a PPM-insured anesthesiologist and an independent-contractor CRNA, who was insured by a different company. During the preanesthesia evaluation, the patient reported a history of experiencing PONV. Accordingly, to avoid PONV associated with inhalation agents and narcotics, the anesthesiologist and CRNA determined the appropriate anesthesia plan for the patient was total intravenous anesthesia. Prior to surgery, the patient received ondansetron and a scopolamine transdermal patch to mitigate PONV.

The anesthesia team administered 200 mg propofol and 10 mg cisatracurium at induction, and the CRNA secured the patient's airway without incident. The CRNA started a 130 ug/kg/min propofol infusion to maintain anesthesia, and the anesthesiologist left the OR to check on the other rooms and preop the next patient. Around surgery start time, the CRNA increased the propofol infusion to 150 ug/kg/min because the patient's heart rate was elevated (120 BPM from 92 BPM preoperatively). Approximately 20 minutes later, the CRNA gave a second dose of cisatracurium to facilitate muscle relaxation around the hip joint. The CRNA noted the patient's HR remained elevated, but he attributed the tachycardia

to nociception or a side effect of the muscle relaxant. The anesthesiologist returned to the OR at the conclusion of the 90-minute procedure, and the CRNA administered a reversal agent for the neuromuscular blockade and extubated the patient. Upon emerging in the OR, the patient informed the anesthesiologist and the CRNA that she was awake during the procedure.

The anesthesiologist spoke with the patient in the PACU and apologized for her experience. She recalled hearing the surgical team discuss vacations and described the music that was played in the OR. The patient acknowledged her memory was a little fuzzy, but she recounted feeling her leg pulled by traction and the anchors being placed in her hip. She reported experiencing an intraoperative pain level of 6/10. The anesthesiologist expressed empathy and informed the patient that he felt responsible because he developed the anesthesia plan. On postoperative day #4, the anesthesiologist contacted the patient to make sure she was doing okay, and he offered to assist with a referral for counseling.

Approximately two years later, the patient filed a lawsuit against the anesthesiologist, the CRNA, and the facility. The patient alleged that she developed post-traumatic stress disorder, anxiety, and depression following her hip procedure as a result of the AAGA event. In addition to claiming general damages for pain and suffering, the patient sought compensation for medical expenses and lost wages. She introduced evidence to support her claim that she regularly attended therapy sessions following the event, and she contended that she quit her job due to health problems, including anxiety stemming from the AAGA event.

"[PLAINTIFF'S ANESTHESIOLOGY EXPERT] STATED THAT IN THIS INSTANCE, THE ANESTHESIOLOGIST DEPARTED FROM THE STANDARD OF CARE BY DEVELOPING AN ANESTHESIA PLAN ENTIRELY CENTERED AROUND PREVENTING PONV, AND THAT HE FAILED TO APPRECIATE THE PATIENT WAS AT A HEIGHTENED RISK OF EXPERIENCING INTRAOPERATIVE AWARENESS"

During her deposition, the plaintiff's anesthesiology expert testified that intraoperative awareness events are typically caused by inadequate medication dosing, a problem with the delivery of anesthetic agents, or an improper anesthesia plan. She stated that in this instance, the anesthesiologist departed from the standard of care by developing an anesthesia plan entirely centered around preventing PONV, and that he failed to appreciate the patient was at a heightened risk of experiencing intraoperative awareness. Plaintiff's anesthesiology expert further testified that the anesthesiologist and CRNA failed to properly recognize the patient's elevated HR was a sign of intraoperative awareness. Had the anesthesia professionals considered awareness, they could have increased the maintenance dose of propofol, administered an additional sedative or dose of fentanyl, or augmented the IV medication with a small amount of an inhalation agent. In her opinion, the benefits of these interventions outweighed the risk of the patient experiencing PONV.

The defense anesthesiology experts opined that the anesthesia plan was appropriate and tailored to the patient based on her reported history of PONV. However, they shared plaintiff's expert's criticisms relating to the anesthesia team's failure to consider intraoperative awareness as a potential cause of the patient's elevated HR. Since a prolonged period of tachycardia occurred during the maintenance phase of anesthesia, the PPM-insured anesthesiologist's liability exposure hinged upon whether he had knowledge of the patient's vital signs. During his deposition, the anesthesiologist testified that he did not recall being informed about the patient's tachycardia. Unfortunately, the CRNA subsequently testified that he believed he brought the issue to the anesthesiologist's attention.

The facility was dismissed from the case at the conclusion of discovery, and the remaining parties agreed to participate in mediation. There, the case was resolved for a low six-figure amount. Both the anesthesiologist and the CRNA contributed to the settlement.

Guidance from the Anesthesia Patient Safety Foundation

In 2022, the Anesthesia Patient Safety Foundation's (APSF) Committee on Technology released a consensus statement in support of the utilization of monitoring systems beyond those currently included in the basic monitoring standards.[6] Notably, under certain circumstances, the committee recommends anesthesia professionals use EEG-based monitoring systems to prevent AAGA if the technology is available at the facility.[6] For example, the committee encourages the use of EEG monitoring when neuromuscular blockades and inhalation agents are administered to patients who are unable to tolerate inhaled anesthetic concentrations necessary to achieve a 0.7 MAC due to their vulnerability to hemodynamic compromise.[6] Similarly, when the plan is total intravenous anesthesia with a neuromuscular blocking agent, the committee stated that it is a good practice to use EEG monitoring to assess the depth of anesthesia in the interest of preventing awareness.[6]

While not standard of care, PPM supports the use of EEG monitoring if it is readily available and can be used effectively for the planned procedure. Though AAGA is not a major source of claims in PPM's experience, augmenting the ASA Standards for Basic Anesthetic Monitoring with EEG monitoring can advance patient safety and help anesthesia professionals avoid claims such as the case study discussed above.

Risk Management Strategies and Considerations

Preoperative

Informed Consent

PPM encourages anesthesia professionals to utilize an anesthesia-specific informed consent form containing the risk of intraoperative awareness.

Identify High-Risk Patients

When developing an anesthesia plan, anesthesia professionals should contemplate whether the patient's clinical presentation, the underlying procedure, or reported history of awareness are associated with an enhanced risk of intraoperative awareness.

Intraoperative

Depth of Anesthesia Monitoring

Though not a monitoring standard, EEG-based monitoring systems, such as the Bispectral Index (BIS) monitoring system, can act as an adjunct to guide anesthesia professionals' medication dosing to reduce AAGA events. EEG monitoring is a particularly useful tool to utilize when patients receive total intravenous anesthesia (TIVA), as anesthesia professionals cannot reference end-tidal anesthetic agent concentrations to assess the patient's depth of anesthesia.

Watch for Vital Sign Changes

If a patient's heart rate and/or blood pressure remain elevated after induction, anesthesia professionals should consider whether the patient might be experiencing awareness, especially if the patient's medical history, the procedure, or the anesthesia plan carry a heightened risk for intraoperative awareness.

Postoperative

Disclose Event

If a patient experiences intraoperative awareness due to medication error or mechanical issue, the anesthesia professional should disclose the cause of the event.

Assist Patient with Support

To ensure there is proper continuity of care following an awareness event, anesthesia professionals should offer to assist the patient with a referral for counseling or other psychological support.

Contact PPM

Our in-house claims & risk management professionals are available 24/7 to provide guidance to our insureds if a patient reports awareness following a procedure.

In the News

FDA Provides Update to Health Care Professionals About Risk of Inadvertent Intrathecal (Spinal) Administration of Tranexamic Acid Injection

On October 21, 2025, the U.S. Food & Drug Administration (FDA) announced a strengthened safety warning for tranexamic acid injection, adding a Boxed Warning to highlight the risk of serious and fatal medication errors from accidental neuraxial (spinal or epidural) injection of tranexamic acid instead of a local anesthetic. As PPM has previously cautioned its insureds, inadvertent administration of tranexamic acid via this route has resulted in seizures, cardiac arrest, and death. The FDA's decision to issue a stronger warning was prompted by reports from several stakeholders, including PPM, the APSF, and the Institute for Safe Medication Practices (ISMP).

According to PPM Policyholder Anthony Frasca, M.D., "I had been working with the FDA since early 2020 on the look-alike vials of tranexamic acid and bupivacaine. My initial efforts led to an FDA alert in 2022. When I saw the cover of *Anesthesia & the Law* from October 2024, I knew something more definitive needed to be done. On that cover was the exact picture of the look-alike vials I had sent to the FDA in 2020. My thought was to put the FDA and PPM together to find a more permanent solution to what was clearly a serious patient safety issue. The FDA, in collaboration with PPM, were able to come up with what will hopefully be a permanent solution to this serious problem."

The new requirements and recommendations for tranexamic acid injection include:

- **Boxed Warning:** A black box warning has been added to the prescribing information, stating that the injection is for intravenous (IV) use only and must not be a neuraxial administration.
- **Clarified route of administration:** The "Dosage and Administration" section of the prescribing information has been updated to clarify that the injection is for IV use only and provides instructions for preparation and administration.
- **Labeling changes:** Manufacturers are now required to update container labels to prominently display the product name and the IV route of administration.
- **Separate storage:** Store tranexamic acid injection vials and ampules away from local anesthetics or kits intended for spinal or epidural anesthesia.
- **Increased visibility of labels:** Arrange medication vials so labels are clearly visible to avoid reliance on vial cap colors, which can sometimes be mistaken for other drugs.
- **Barcode scanning:** Use barcode scanning when stocking medication cabinets and when preparing and administering tranexamic acid.
- **Auxiliary labels:** Consider adding auxiliary warning labels to vials and ampules to clearly note that the product is tranexamic acid and for intravenous use only.
- **Use of premixed bags:** To minimize potential mix-ups, use commercially available or pharmacy prepared IV infusion bags of tranexamic acid when possible.

The update posted on the FDA website is available at:
https://www.fda.gov/drugs/drug-safety-and-availability/fda-provides-update-health-care-professionals-about-risk-inadvertent-intrathecal-spinal [fda.gov]

The updated Prescribing Information is available at:
https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/019281s048lbl.pdf [accessdata.fda.gov]

Upcoming Events

ASA ADVANCE 2026: The Anesthesiology Business Event – January 23-25 – Las Vegas, NV

Guest Panel Speaker: Brian J. Thomas, JD Vice President Claims & Risk Management

"Professional Liability: Things Every Anesthesiologist Should Know"

https://www.asahq.org/advance/education/event-schedule

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In This Issue

- We review PPM's closed claims data to evaluate the frequency of intraoperative awareness events and provide risk management strategies and considerations to identify patients with enhanced risks for intraoperative awareness, intraoperative monitoring, and guidance in the event patients experience this rare adverse event
- In the News – PPM collaborated with the APSF, other stakeholders, and the FDA resulting in the FDA providing updated and strengthened warnings to prevent wrong drug – wrong route medication errors involving the intrathecal injection of tranexamic acid
- Upcoming Events – Follow PPM's guest speakers at anesthesia conferences in 2026

Thanks for reading,

Brian J. Thomas, Editor