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Medication Errors: Intrathecal Injection of Tranexamic Acid and Other Mix-Ups

Defending Medication Errors Litigation

Medication errors continue to cause serious patient harm, including catastrophic brain damage and death. Medication errors may also create significant liability exposure for anesthesia providers. As highlighted in the following case studies, claims and litigation involving allegations of medication errors are both challenging to defend and frequently result in significant settlements.

Case #1

- A 59 year-old female was scheduled for a total right hip replacement performed under spinal anesthesia. Two certified registered nurse anesthetists (CRNAs) participated in the anesthesia tray set up. One CRNA was drawing up the various medications into syringes and preparing the anesthesia tray while the other CRNA was responsible for initialing and dating each syringe. The medication syringes in question were reportedly marked with a white label for the bupivacaine and grey label for the tranexamic acid (an antifibrinolytic).

  In preparing the patient for surgery, the CRNA assigned to the case administered the spinal injection. Shortly thereafter, the patient complained of some lower back or buttock itching. As the patient was being prepared for surgery, the nurses attempted to place a urinary catheter but had trouble due to the patient's leg movements and resistance. The anesthesia team then decided to convert to a general anesthetic. The patient also experienced some bouts of hypertension that were treated with increased levels of anesthetic. The patient exhibited continued leg twitching despite the administered paralytics.

  At the end of the procedure, the patient did not arouse as expected. Following transfer to PACU, the patient, who was still not awake, began to exhibit seizure like activity. The supervising anesthesiologist called for a neurological consult and a CT was performed, which was normal. The patient was given Dilantin, Versed and propofol to alleviate her tonic/clonic activity. She was subsequently placed in a barbiturate coma to stop the activity and was on continuous EEG monitoring.

  Shortly after this incident, one of the CRNAs involved in preparing the syringes performed a Google search for "bupivacaine/spinal seizure-like activity" that returned an abstract of a research article identifying "Inadvertent Administration of Tranexamic Acid into Spine," which matched the patient's symptoms. The CRNA immediately printed the abstract and provided it to the supervising anesthesiologist. Based on the review of the abstract of the article and the patient's symptoms, the supervising anesthesiologist believed the patient likely received an intrathecal injection of tranexamic acid instead of bupivacaine.

  The hospital conducted a prompt investigation of the incident, but was unable to determine which CRNA was responsible for causing the suspected medication mix-up. Following multiple consults and tests over several days, the anesthesia practice group and hospital jointly informed the patient's husband a medication mix-up likely had occurred. The patient sustained significant neurologic injuries and was transferred to a rehabilitation facility. The patient ultimately was able to return home, but was anticipated to require home healthcare for the remainder of her life.

  The patient's husband sued the two CRNAs, the supervising anesthesiologist, the anesthesia practice group and the hospital. After considerable litigation discovery and with the consent of the PPM insureds, the lawsuit

was eventually settled on behalf of all the anesthesia defendants within the available $2,000,000 insurance policy limits. Settlement discussions with the hospital remain ongoing at the time of publication.

Risk Management Analysis

The anesthesia group implemented a new policy immediately after this devastating incident requiring all spinal tray medications to be checked by a second healthcare provider prior to administration. The policy also mandates that bupivacaine and other spinal medications should not be opened or prepared until the time of actual administration.

Additionally, as illustrated below, PPM recommends anesthesia providers should consider working with the facility pharmacy to minimize medication errors – e.g., tranexamic acid to be mixed by the pharmacy in an IV bag and not accessible as a vial to anesthesia care givers.

Case #2

- A 41 year-old male presented for pain management for exacerbation of low back pain and failed back syndrome. The patient's history included two previous back surgeries. The patient was to undergo a caudal epidural steroid injection followed by epidurography. The anesthesiologist personally retrieved the contrast dye to be utilized for the procedure. There were no apparent complications with the injection or the procedure and the patient was discharged.

Approximately 3 hours post-discharge, the patient's caregiver called the anesthesiologist and reported the patient was in severe pain. The anesthesiologist instructed the caregiver to take the patient to the emergency room (ER) immediately. Approximately 30 minutes later, the anesthesiologist received a call from the ER physician inquiring about the procedure the patient had undergone. Shortly after this phone call the patient coded and could not be resuscitated.

Following this incident, the anesthesiologist discovered the radiopaque diagnostic agent used for this procedure was Hypaque dye, which is contraindicated for use in the epidural space. Serious adverse effects from an epidural injection of Hypaque dye include convulsions and death. Despite the dangers associated with the inadvertent use of the drug, the hospital's practice for handling this radiological medication was to remove the medication from its packaging, discard the medication insert and place the medication in a bin in a common area.

The patient's wife and minor daughter sued the anesthesiologist, the anesthesia practice group and the hospital. The allegations against the anesthesiologist included not reviewing the dye's package insert, improperly administering Hypaque dye in the caudal epidural injection, failing to recognize and diagnose the patient's condition when contacted by the ER physician, and failing to communicate to the ER physician the recommended treatment for an epidural injection.

The allegations against the hospital included removing the package insert, storing the Hypaque dye in a common area where it was readily available, and failing to have appropriate policies and protocols requiring the pharmacy to check off on the proposed procedure and use before the dye was administered.

No experts reviewing this case could support the administration of Hypaque dye in the epidural space. The experts were also critical of the hospital for failing to have appropriate policies and protocols in place to prevent the inadvertent administration of a contraindicated contrast dye in the epidural space.

Defense counsel estimated a potential verdict range from $5 million to $7 million. The estimated settlement range was $1.5 million to $2 million for the anesthesiologist and the anesthesia practice group. Based on a lack of expert support and defense counsel's evaluation, including the potential for a jury verdict in excess of the insurance policy limits, this case was settled on behalf of the anesthesiologist and the anesthesia practice group for $1,850,000. The hospital also entered into a settlement with plaintiffs for a confidential amount.

Risk Management Analysis

The hospital's practice of removing the medication from the packaging, discarding the medication insert and placing the medication in a bin in a common area set the stage for this catastrophic medication error. Anesthesiologists and anesthesia departments should work closely with their practice facilities to develop departmental protocols for the prescription, storage, preparing, administration and documentation of medications, especially those that pose a significant patient risk.

Case #3

- A 28 year-old female received a spinal anesthetic for a cesarean-section delivery. The spinal was uneventful and the supervising anesthesiologist asked the CRNA to administer Reglan. Shortly after the administration, the patient said she was not feeling right and her blood pressure increased significantly. The anesthesiologist treated her symptoms and the baby was delivered with no complications.

  The patient was transferred to ICU and was kept there for 1 day with mild hypoxia and pulmonary edema. The symptoms resolved and she was discharged home. The anesthesiologist believed the patient was

administered phenylephrine instead of Reglan. It was determined the patient likely received a dose of phenylephrine 100 times the usual dose. According to the anesthesiologist, both phenylephrine and Reglan used at the hospital had similar packaging thereby increasing the likelihood of a medication mix-up. The patient and her husband were informed of the suspected medication error.

The patient and her husband sued the anesthesiologist, CRNA, the anesthesia practice group and the hospital. The patient alleged the medication error caused cardiac damage and hypoxia resulting in brain damage measurable on neuropsychological testing. The patient's treating neuropsychologist opined the patient was impaired in executive functioning, learning, memory and motor functioning.

The patient's economist expert valued lost earnings, home services, future lost earnings and medical expenses at $2,213,900. Based on defense counsel's evaluation of the facts, counsel indicated the case would likely be submitted to a jury as a case of admitted liability by all defendants with evidence of damages in excess of $2 million. Based on those facts and evidence, defense counsel recommended settlement. The parties participated in mediation and the case settled on behalf of the CRNA for $450,000.

Scope of the Problem

Historically, medical literature and retrospective studies addressing medication errors in the anesthesia workplace have been limited and typically consisted of self-reported incidents. However, according to one recent study, medication errors in the perioperative setting occurred in nearly half of all operations, and one in 20 perioperative medication administrations included some type of medication error. More than one third of these errors led to patient harm, and the remaining two thirds had the potential for patient harm.[1] Other studies have cited medication errors as the most common cause of patient injuries in hospitals occurring in an estimated 1.5 million patients in the United States annually.[2]

Causes of Medication Errors

Unlike other patient care areas such as inpatient units and outpatient clinics, the perioperative setting typically has fewer systems and safeguards to avoid medication errors. Anesthesia providers frequently select, prepare, label and administer medications without pharmacy review of medication orders, electronic clinical decision support and other secondary checks by other providers.[3] The absence of adequate systemic medication safety practices in the perioperative setting continues to cause patient injuries.

Syringe and ampule swaps with look-alike and sound-alike drug names are a leading cause of medication errors resulting in patient injury and death. Other common errors include incorrect labeling, wrong doses, omitted medications, and workarounds created to overcome perceived design flaws in bar code-assisted and electronic anesthesia information management systems. Lack of information and understanding of a patient's history of reactions to drugs and antibiotics, failure to carefully read all labels, and overreliance on the expected location of medications and syringes also contribute to human error that cause patient injury.

Other system-related causes of medication errors may include the high-stress, time-sensitive nature of operating rooms (ORs), distractions from various sources, different locations for medication storage, use of distal instead of proximal port to inject medications, and repetitive task designs that encourage automatic behavior and lack of attention.

Patient Safety Strategies to Prevent Medication Errors

In 2010, the Anesthesia Patient Safety Foundation (APSF) convened a consensus conference of 100 stakeholders, including PPM, to develop a new paradigm to reduce medication errors in the OR with the following recommendations:

APSF Medication Safety Strategies[4]

Standardization

- High alert medications (such as phenylephrine and epinephrine) should be available in standardized concentrations/diluents prepared by pharmacy in a ready-to-use form (bolus or infusion) that is appropriate for both adult and pediatric patients. Infusions should be delivered by an electronically controlled smart device containing a medication library.
- Ready-to-use syringes and infusions should have standardized, fully compliant machine-readable labels.

Technology

- Every anesthetizing location should have a mechanism to identify medications before drawing up or administering them (e.g. bar code reader) and a mechanism to provide feedback, decision support, and documentation (e.g. automated information system).

Pharmacy/Prefilled/Premixed

- Routine provider-prepared medications should be discontinued whenever possible.
- Clinical pharmacists should be a part of the perioperative/OR team.
- Standardized pre-prepared medication kits by case type should be used whenever possible.

Culture

- Establish a "just culture" for reporting errors (including near misses) and discussion of lessons learned.
- Establish a culture of education, understanding, and accountability via a required curriculum, CME/CE, and dissemination of dramatic stories in the APSF Newsletter and educational videos.
- Establish a culture of cooperation and recognition of the benefits of APSF paradigm within and between institutions, professional organizations, and accreditation agencies.

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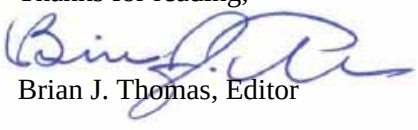
In This Issue

Despite recent developments in technology including color coding labels, electronic dispensing carts and cabinets and bar code scanning systems, medication errors in the anesthesia workplace continue due to a number of factors. These medication errors can cause serious, life-threatening injuries to patients. In this issue, we highlight some cases involving these errors, examine the ongoing problem of medication errors in the anesthesia workplace, and offer some risk management analysis and strategies to avoid these errors and improve patient safety.

Thanks for reading,



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