ANESTHESIA & the LAW
A Risk Management Newsletter
OCTOBER 2013 – ISSUE 37
PPM

Securing Narcotics: Standard of Care Evolves in Wake of Hepatitis C Outbreaks

In Colorado, a surgical technician stole fentanyl syringes from anesthesia carts, injected herself with the drug and then substituted used syringes filled with saline solution contaminated with her blood. The contaminated syringes were returned to the anesthesia cart and ultimately administered to patients. Subsequent testing of nearly 6,000 patients confirmed 36 patients had been infected with hepatitis C and at least 18 were infected with the same genotype of hepatitis C as the surgical technician.[1]

In New Hampshire, a cardiac catheterization lab worker was arrested and accused of stealing fentanyl, injecting himself and substituting tainted syringes filled with saline that were later used on patients. After testing more than 1,100 patients, the state has determined that at least 32 patients had been infected with same genotype of hepatitis C as the accused lab worker.[2]

Although the specific mechanism of contamination may have varied from case to case, in the majority of reported cases the diverted narcotics were typically withdrawn from dispensing machines and then left unattended while the anesthesia provider and/or nursing staff left the operating or procedure room to perform other duties, such as transferring patients from the pre-operative holding area. In some cases, the diverted narcotics were left in the presence of other health care providers, concealed under a towel or other objects, or placed in an unlocked drawer. In other cases, the diverted narcotics were simply left unattended on top of anesthesia carts.

The Fallout

Following the arrest of the drug-seeking hospital workers, the facilities in both cases initiated processes to identify and notify patients who may have been infected with hepatitis C. Involved health care facilities are typically subjected to intense investigations by both state and federal authorities and exposed to a significant level of negative media coverage and public relations challenges. Implicated facilities must also navigate a lengthy testing regimen and provide both information and treatment to infected patients. Ultimately, facilities should anticipate several years of costly litigation. In both cases cited above, former patients filed dozens of lawsuits against the involved facilities. Additionally, nursing staff, anesthesiologists, and proceduralists who may have had some responsibility for handling and safeguarding the diverted medications were implicated both in the investigations and the litigation. In Colorado, at least 18 patients who were infected with the same genotype of hepatitis C as the former infected surgical technician filed lawsuits. A class-action lawsuit was filed against the hospital in New Hampshire on behalf of 169 patients, including some of the 32 patients whose genotype of hepatitis C matched the former lab worker.

Other consequences of these hepatitis C outbreaks included medical licensing board investigations of the physicians named in these lawsuits. For several physicians, the nature of these outbreaks and the pattern of diversion created the possibility of multiple lawsuits against the same physician. In these situations, the plaintiff attorneys surmised that the drug-seeking worker may have actually targeted certain physicians whose handling of narcotics made diversion easier. While PPM has ultimately been able to successfully resolve this type of claim when asserted against our policyholders within the available

[1] The former surgical technician is serving a 30-year sentence after pleading guilty in federal court to allegations she stole and tampered with syringes of narcotics that were unknowingly used on patients.
[2] The former cardiac catheterization lab worker pleaded guilty to 16 federal drug theft and tampering charges in exchange for a lighter sentence of 30 to 40 years in prison. Forty-six patients in 4 states have been diagnosed with the same genotype of hepatitis C the former lab worker carries. Thirty-two patients were infected in New Hampshire, 7 in Maryland, 6 in Kansas and 1 in Pennsylvania. The former lab worker also worked at hospitals in Michigan, New York, Arizona and Georgia.

insurance limits, these mass infection outbreaks pose a risk of exhausting a physician's or facility's aggregate professional liability insurance limits.

The following case summary provides one example of how the intentional criminal acts of a drug-seeking hospital worker exposed a PPM insured anesthesiologist to a hepatitis C lawsuit.

- In December 2008, a 20 year-old male presented for excision of a thyroglossal duct cyst with general anesthesia administered by a PPM insured anesthesiologist. At 1459, while administering anesthesia in another case, the PPM insured anesthesiologist obtained medications, including fentanyl, from an Acudose cabinet in preparation for the thyroglossal duct cyst surgery. The physician drew up the medications into syringes and then placed the syringes in the anesthesia cart. According to the physician, it was her customary practice to rotate the drawers of the anesthesia cart she used to secure the medications and to cover the syringes so they would not be visible.

  When the first surgery ended, the physician accompanied the first patient to post-anesthesia care unit (PACU) and then went to pre-operative holding to evaluate the next patient. The Anesthesia Consent for this patient's thyroglossal cyst procedure was signed at 1520. The pre-anesthesia evaluation was timed at 1530. The patient arrived in the operating room (OR) at 1538. The infected hospital worker was the surgical technician assigned to this case and, according to her testimony, there was a "window of opportunity" to divert the fentanyl from approximately 1520 to 1538.

  The patient's surgery proceeded uneventfully. The PPM insured anesthesiologist administered 150 mcg of fentanyl, along with versed, propofol, lidocaine, succinylcholine, and rocuronium. There were no physiological findings to suggest the fentanyl was ineffective. The PPM insured anesthesiologist administered an additional 100 mcg of fentanyl after approximately 15 minutes. The surgery ended at 1657. The patient's cyst was benign and he ultimately recovered from his surgery.

  Following the hospital worker's arrest in July 2009, the hospital notified the patient that he may have been exposed to hepatitis C and should be tested. Lab work performed by the patient's primary care physician showed elevated bilirubin, AST and ALT (liver function tests). His viral load was 427,900 and genotype was 1b - the same genotype as the infected hospital worker.

  In August 2009, the patient was evaluated by a hepatologist. Results from the Department of Public Health testing that showed a 99.4% degree of relatedness to the infected hospital worker's virus. Subsequently, the patient decided to receive treatment with interferon and ribavirin. After 13 weeks of treatment, his virus load had dropped significantly, but was still detectable. The patient reported he continued to experience fatigue, decreased appetite and weight loss. By February 2010, the patient had no detectable virus load, which remained undetectable until stopping his treatment in August 2010. When seen for follow up in March 2011, the patient still had no detectable virus load and the treating hepatologist noted that there was a "low likelihood" of a relapse.

  The patient sued the hospital, the infected hospital worker and the PPM insured anesthesiologist. The patient claimed the PPM insured anesthesiologist failed to comply with the hospital's policy by leaving narcotic medication unattended prior to the plaintiff's surgery. The hospital's policy in effect at the time of these incidents stated, in part, "All drugs and biologicals are kept in secure areas, and locked when appropriate." Several anesthesiologists involved in these cases indicated it was their understanding that the operating rooms were "secured areas;" therefore, locking or securing narcotics was not required. According to the Medical Director of the Anesthesiology Department, prior to these incidents anesthesiologists frequently filled syringes for multiple

patients to be better prepared before procedures. The Medical Director stated, "You were looked at poorly if you waited until the patient came in the room."

The injured patient alleged the PPM insured anesthesiologist's failure to comply with the hospital's policy allowed the infected hospital worker to divert the fentanyl intended for the patient's surgery. As a result, the patient claimed he did not receive the pain medication required for his surgery and ultimately contracted hepatitis C. In his lawsuit, the patient claimed he was unable to work due to the nausea, vomiting and fatigue from his hepatitis C treatment and was eventually diagnosed with post-traumatic stress disorder (PTSD) with increased depression and anxiety. The patient also asserted a claim for future medical expenses, including subsequent treatment for liver cancer and liver failure with possible transplantation.

The patient's anesthesiology expert, Laurence J. Krenis, MD, from Boston, Massachusetts, testified the standard of care requires that controlled substances must be locked when not attended, kept physically on the person of the anesthesiologist or the anesthesiologist must remain aware of the controlled substances at all times. Dr. Krenis admitted that controlled substances cannot always be under lock and key and he is not critical of an anesthesiologist drawing up the medications in advance. He also admitted that there are times during a surgery when the anesthesiologist's attention must be directed to the patient, such as when starting an arterial line or an internal jugular line. On those occasions, the anesthesiologist can leave the drugs on top of the anesthesia cart. However, the anesthesiologist must not allow anyone to approach the anesthesia cart without being monitored.

The defense anesthesiology expert retained by PPM was prepared to testify the PPM insured anesthesiologist met the applicable standard of care despite the fact the narcotic syringe was left in an unlocked drawer of the anesthesia cart while the anesthesiologist accompanied the previous patient to the PACU. This defense expert was also prepared to testify the rules regarding securing controlled substances in the hospital were geared to areas where patients, visitors and nurses have access. The OR, on the other hand, is a secure environment and unauthorized personnel are not allowed access. The defense expert stated, in his opinion, the PPM insured anesthesiologist could not reasonably foresee the infected hospital worker would engage in criminal activity that would result in the patient being infected with her hepatitis C virus. This expert indicated that in 2008 there was no nationwide standard of care regarding the handling, dispensing, storage, security and administration of controlled substances; anesthesiologists were not required to keep controlled substances locked at all times in the OR, and when in the OR anesthesiologists were not responsible for continuously monitoring the drug or anesthesia cart. Finally, the defense expert was prepared to testify that the infected hospital worker caused the plaintiff to become infected with hepatitis C, not the PPM insured anesthesiologist.

Prior to trial, the hospital settled for a confidential amount. The claims against the hospital focused not only on its responsibility for safeguarding medications, but also for its alleged negligence in hiring and retaining the hospital worker implicated in the diversion of drugs. A default judgment was entered against the infected hospital worker who did not file an Answer to the lawsuit naming her as a defendant.

Based on discussions with PPM and defense counsel, the PPM insured anesthesiologist consented to settlement and PPM engaged in settlement negotiations with the plaintiff attorney representing the patient. After several rounds of negotiations, however, the PPM insured anesthesiologist decided to revoke her consent and to proceed to trial.

With the trial date less than one month away, the Court allowed the patient to amend his lawsuit to add a claim for punitive damages. Punitive damages may only be awarded when it is proven that a defendant acted willfully, maliciously, or fraudulently. Punitive damage claims in medical

negligence litigation are virtually unheard of and frequently excluded from coverage by the professional liability insurance policy or state law.

Based on a concern of a plaintiff's verdict that could theoretically exceed the PPM insured anesthesiologist's insurance coverage, the threat of punitive damages and defense counsel's recommendation to settle the case, the PPM insured again consented to settlement and a confidential settlement was obtained. ❖

Expert Testimony Suggests a Heightened Standard of Care for Securing Controlled Substances and Medications Likely to be Diverted

Two well qualified anesthesiology experts who reviewed cases on behalf of PPM insured anesthesiologists testified, in their opinion, the standard of care in 2008 and 2009 did not require anesthesiologists in a secured operating room to keep medications, even those subject to possible diversion, in a lock box or on the anesthesiologist's physical person. These experts opined the anesthesiologist could rely on the fact that the operating room was a secure location and that access to the area was restricted to authorized personnel. Additionally, PPM's defense theory focused, in part, on the foreseeability of a hospital employee diverting medications in a manner that would expose patients to infection.

Multiple anesthesiology experts, especially in light of these two high profile cases, have been unwilling to support the practice of dispensing such medications in any manner that leaves such medications unattended or unsecured. Additionally, the defense that such diversions are not foreseeable has also been undermined by these highly publicized cases in Colorado and New Hampshire.

Based on formal and informal discussions with a number of expert witnesses, PPM anticipates the majority of anesthesiology expert witnesses will in the future testify that today's standard of care requires physicians to keep medications likely to be diverted under lock or on the person of the anesthesiologist until the medications are ready to be administered. Dispensing such medications well in advance of administration should generally be avoided and facilities should implement protocols requiring such medications to remain secured until administered to the patient.

According to Wade Willard, PPM's Vice President of Claims, "the emerging consensus among anesthesiology experts is medications likely to be diverted must be secured under lock or controlled by the anesthesiologist from the time the medication is obtained until it is administered."❖

Risk Management Tips

- PPM encourages anesthesia practice groups to develop and implement workplace drug testing policies.
- **NEVER** leave controlled substances or medications likely to be diverted unsecured and unsupervised – for example, on top of anesthesia cart, unlocked in a drawer, wrapped in a towel, etc.
- Carefully review and adhere to all hospital/facility drug storage and security policies. PPM's Claims Attorneys and Specialists can assist you in reviewing existing drug storage and security policies. Policies that do not meet today's standard of care should be supplemented by additional safety measures until these policies are improved.
- Carefully consider whether to keep controlled substances or medications likely to be diverted on your person once dispensed. (PPM has learned of at least 2 reports in which anesthesiologists unwittingly left facilities with narcotics on their person and/or misplaced narcotics, which triggered suspension of hospital privileges and medical licensing board investigations).
- Report any suspicious behavior or activity if you suspect drug diversion.

PREFERRED PHYSICIANS MEDICAL RISK RETENTION GROUP, INC.
9000 West 67th Street
Shawnee Mission, KS 66202-3656

T 913.262.2585 • 800.562.5589
F 913.262.3633

NEWSLETTER EDITOR
Brian J. Thomas, JD
Senior Claims Attorney
Director of Risk Management

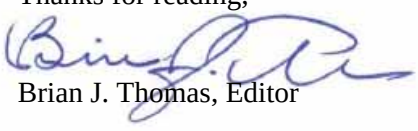
ANESTHESIA & the LAW
A Risk Management Newsletter
OCTOBER 2013 – ISSUE 37
PPM

In This Issue

We examine how two recent incidents involving the diversion and tampering of narcotics by hospital employees have driven an evolving standard of care for securing narcotics and other medications. These intentional criminal acts resulted in dozens of patients being infected with hepatitis C and subjected those facilities and anesthesiologists who were involved to significant liability exposure. We also offer some risk management advice for preventing diversion and tampering of narcotics and other medications.

- Securing Narcotics: Standard of Care Evolves in Wake of Hepatitis C Outbreaks
- Expert Testimony Suggests a Heightened Standard of Care for Securing Controlled Substances and Medications Likely to be Diverted
- Risk Management Tips

Thanks for reading,



Brian J. Thomas, Editor