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How Not to End Up on the Nightly News: Safe Injection Practices

Velma Angella Joseph, M.D.
Albert Einstein College of Medicine/Montefiore Medical Center, Bronx, NY

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Stem Case and Key Questions Content

A 44 year old anesthesiologist is working in a busy endoscopy suite. The gastroenterologist prefers that propofol is used. There has been a recent drug shortage of propofol. He decides to divide up the remaining vials of propofol by himself before the start of the first case.

1. Is there anything wrong with this practice?
2. Are there other options to anesthetizing these patients?
3. Describe the risks and benefits of this practice.
4. What is the difference between a single use and a multi-use vial?
5. Why have there been so many drug shortages recently?
6. What steps can be taken to minimize the effects of drug shortages?
7. Are there any entities who could be used to help the anesthesiology department during this drug shortage?
8. Has the federal government become involved with this problem?

He decides to re-use syringes between patients because he is running short due to a delay in the last shipment. He makes sure that he does not aspirate prior to injecting medication. The gastroenterologist would fire him if he cancelled a case.

1. Is there any real risk of re-using syringes?
2. Why is it difficult to follow the CDC's Guidelines on Safe Injection Practices?
3. Aside from medication injection, what else is covered in these Guidelines?
4. What is the potential risk financially if a patient gets an infection?

A few months later he gets informed that there has been an outbreak of HIV and hepatitis C infections in the endoscopy suite. The Centers for Disease Control and Prevention have notified hundreds of patients. Several staff members of the endoscopy suite have been interviewed. There is a quality management meeting held by the endoscopy suite. In addition, the State Board of Medicine is investigating the role various members of the endoscopy suite had in this outbreak.

1. What should he do?
2. Have these outbreaks ever happened before to other endoscopy suites?
3. What could be some potential causes of this outbreak?
4. What impact will this have on his practice?
5. If he attends this quality management meeting, does he have any rights?

His medical license is suspended by the State Medical Board. He is devastated. He decides to move to a different part of the country in order to start afresh.

1. Is this a wise career move?
2. Will he be affected by the Healthcare Quality Improvement Act?
3. Is there other federal legislation which would impact his move?

One year after the outbreak, he gets served with a malpractice lawsuit.

1. What are the steps to a malpractice lawsuit?
2. Are there any actions he should do to protect himself?
3. What are some helpful things he can do to assist his defense attorney?
4. Should he be concerned about a criminal lawsuit?
5. What are some characteristics that make healthcare providers high risk for lawsuits?
6. Is there any benefit to apologizing to the patients and families?
7. Is there any legal protection given to healthcare providers who *apologize*?
8. What is an effective way of apologizing to a patient/family member?

Model Discussion Content

Iatrogenic infections due to improper injection practices have increasingly been identified in the spread of various bacteria and viruses to patients. Unsafe injection practices in non-hospital settings such as hemodialysis units, endoscopy suites and long term facilities have been noted to cause outbreaks of infections. In addition, hospital acquired infections (HAIs) are a known complication in medicine and approximately 2 million occur annually in the United States of America. There are an estimated 90,000 deaths due to HAI which account for $37.5 billion to $45 billion in annual healthcare costs when using the Consumer Price Index for all U.S. inpatient hospital services. There have been outbreaks of hepatitis, human immunodeficiency virus and meningitis resulting in a statistically significant increase in mortality amongst surgical patients. The Centers of Disease Control issued a Guideline (CDC) for Isolation Precaution in 2007 to help educate patients and healthcare providers about recommended safe injection practices. It frequently takes many years before guidelines become routinely used in practice and sometimes they may never be adopted.

Anesthesiologists frequently utilize syringes and needles during their daily practice and little research has been performed on their injection practices. Unsafe injection practices have occurred in endoscopy suites, pain clinics where anesthesiologists may play a role. There have been reports of the reuse of syringes, use of single-use vials on multiple patients, and re-use of needles resulting in patient injury.

The CDC's guideline on safety practices was created to protect patients from life-threatening infections that occur when medications get contaminated from improper use by healthcare providers. Interestingly, an unacceptable number of practitioners utilize unsafe injection practices. Some health care providers even with adequate knowledge of the CDC Guideline still fail to follow the safety injection practice guidelines. Studies elicited the factors that cause this behavior, such as bad habits, time constraints, conservation of resources, avoidance of waste and cost consideration. All these have contributed to high levels of resistance to change the culture.

Usually, there are no safety injection practices education and awareness sessions held in most residency training programs. Some residents lack the knowledge of the difference between

single-dose vials vs. multiple single-use vials. Single-dose/single-use is a vague concept to these residents. Residents play a significant role in helping to decrease surgical site injections with the timely administration of antibiotics and maintaining normothermia intraoperatively. Enhanced education on safe injection practices is necessary for all residents and should be recommended by the ACGME.

Continuing medical education is vital to maintaining an anesthesia provider's knowledge of various issues. The importance of iatrogenic infections has been highlighted by several different media venues. For instance, the lay press has reported on high-profile trials from New York to Nevada on improper use of medication vials and other injection practices. Professional societies have spent substantial resources in making sure this issue is conveyed to anesthesia providers. Certain states mandate education on safe injection practices be part of their requirements for medical licensure.

Some health providers blame the problem of drug shortages and efforts to reduce waste as the biggest obstacles to using a new vial of medication for each patient. The CDC urges the healthcare provider to deal with drug shortages and drug waste concerns appropriately to prevent unsafe medical practices that impose increased infection risk on patients. Meanwhile, some of these problems can be solved by compounding where a previously unopened single-dose/single-use vial is repackaged into multiple single-use vehicles by a qualified healthcare person. Legislatively, there is more protection of the practice of compounding when there is a drug shortage by passage of the Pharmaceutical Quality, Security, and Accountability Act of 2013 (http://beta.congress.gov/bill/113th-congress/senate-bill/959).

In 1986 the federal government established the Health Care Quality Improvement Act (HCQIA) to limit the practice of incompetent physicians by fostering effective professional peer review and credentialing procedures for physicians. It allowed the individual review committee and hospital to perform these duties without the threat of litigation. In addition it established certain ground rules for peer review meetings. For instance, there must be a belief that the peer review action was in the furtherance of quality health care only after a reasonable effort was made to obtain the facts of the case, after adequate notice and hearing procedures are afforded to the physician involved and in the belief that the action was warranted. The physician being investigated also has rights such as: notice stating that a professional review action has been proposed to be taken against the physician, reasons for the proposed action, that the physician has the right to request a hearing on the proposed action, any time limit (of not less than 30 days) within which to request such a hearing, and a summary of the rights. There are three components to peer review protection at the state level: privilege, confidentiality, and immunity. Privilege means that information is not discoverable and may be suspended in some states if there is a lawsuit or if a state medical board needs access to case details. Confidentiality means that information may not be repeated and may be in the form of preventing those not involved in a judicial hearing access to the case. Immunity means that physicians participating in peer review may not be open to civil, criminal or antitrust actions. Immunity may be limited or far reaching (hospital or peer review panel). As of now these peer review protections vary by state. The results of peer review meetings are of interest to groups outside of an anesthesiology department. A hospital's risk management department investigates all events associated with adverse outcomes that may result in litigation thereby allowing for a cost-effective resolution of an adverse outcome. Risk management is the process in which reasonable steps are taken to reduce the probability of liability. Risk management strategies include risk identification, risk

analysis, risk treatment and an evaluation of the risk treatment strategies. Risk identification means that a risk manager will look for activities and situations that may expose a hospital to the potential loss through liability, loss of property, or loss of public image. They may obtain this information through incident reporting, Joint Commission surveys, patient complaints, or generic departmental quality assurance. During the risk analysis, the hospital will concentrate on the areas where the risk may yield the greatest financial loss. Various risk treatments exist such as risk acceptance; risk avoidance, risk transfer, and risk avoidance may be used. Usually a multidisciplinary evaluation is performed with the help of the medical staff, lawyers, insurers, hospital administrators, and governing board. There is increasing awareness that open dialogue may act to heal rather than harm the physician-patient relationship when there is an adverse outcome. The Joint Commission of Healthcare Organizations endorses this tactic as discussed in a product of the Joint Commission's Public Policy Initiative entitled Health Care at the CrossroadsStrategies for Improving the Medical Liability System and Preventing Patient Injury. Certain states are allowing peer review meeting notes be made public. Other states are endorsing an I'm sorry letter, which has may express sympathy but not necessarily admit fault or cause. Thus far, apologizing to a patient or family been not shown to result in an increase in medical malpractice liability.

Finally, malpractice litigation may arise from an adverse outcome. The basis of malpractice is that the patient, was owed some duty by the physician, claims injury, and that the duty was breached resulting in injury. Stages of a lawsuit include receiving a summons, answering the summons, going through a discovery phase, having a deposition, expert witness review, and potentially going to trial. Due to *Res ipsa loquitur,* the burden of proof shifts from the plaintiff to the defendant. One study found that there are sixteen times as many injuries as there are patients who receive compensation for medical negligence. Another study found that when malpractice cases were peer reviewed they were found to be due to system error as opposed to human error.The National Practitioners Databank (NPDB) was established in 1990 as a result of the HCQIA. It prevented incompetent physicians from moving from state to state without disclosure or discovery of the physician's previous damaging or incompetent performance. If a settlement or judgment is made in a physician's name (or licensed healthcare provider), it is reported to the NPDB. In addition, the description of the acts or omissions, injuries occurred, the hospital name, and the payment amount is also given to the NPDB. Other information was also reported to the NPDB such as reporting sanctions taken by the Board of Medical Examiners. This includes those actions which revokes or suspends (or otherwise restricts) a physician's license or censures, reprimands, or places on probation a physician, for reasons relating to the physician's professional competence or professional conduct. In addition, if a health care entity restricts a physician's practice, accepts the surrender of clinical privileges, or membership in a professional society is adversely affected it must be reported.

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