

Current Reviews in Clinical Anesthesia®

The Opioid Epidemic and Anesthesia Practice

LESSON 22
Volume 37
5/25/2017*

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Send address changes to Current Reviews® 1828 SE 1st Avenue, Ft. Lauderdale, FL 33316 or email info@currentreviews.com.

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The Opioid Epidemic and Anesthesia Practice

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LESSON OBJECTIVES

Upon completion of this lesson, the reader should be able to:

1. List the contributing factors to the United States opioid epidemic.
2. Discuss how the Joint Commission's pain initiative impacted opioid prescribing.
3. Quantify prescription painkiller overdose deaths in the United States.
4. List the pros and cons of random urine drug testing.
5. Define "drug diversion".
6. Provide examples of how a healthcare worker could transmit a bloodborne pathogen to a patient while diverting drugs.
7. List work areas in a hospital that are considered high risk for drug diversion.
8. Discuss elements of the 2016 CDC guideline for opioid prescribing.
9. Explain how tracking of opioid use in anesthesia departments can identify possible diversion.
10. List the behavioral signs of drug diversion in healthcare workers.

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Introduction

For thousands of years the human family has used opiates derived from opium. Laudanum is a preparation of opium in a solution of alcohol and was used as an analgesic from the 16th century forward. Morphine was derived from opium in the early 1800s and was used as a painkiller during the United States Civil War. In 1914, morphine was designated as the first controlled substance in the United States under the Harrison Narcotics Tax Act. Despite the clear medical benefits of opioids, their addictive potential is well known and addiction and overdose continue to plague users of these drugs.

Simultaneously, a significant portion of the population of the United States suffers from chronic pain. Pain of a severity to limit activity is seen in approximately 25 million Americans and the annual cost of chronic pain is estimated to be over 600 billion

dollars. These costs come in the form of medical expenses, lost work and lost productivity. In fact, the cost of chronic pain in the United States is greater than the cost of diabetes, heart disease and cancer combined. The greatest number of opioid prescriptions are written by primary care providers in the United States, but all medical specialties have contributed to the prescription opioid epidemic.

The purpose of this lesson is to review the history of the ongoing opioid epidemic in the United States, to quantify the magnitude of the epidemic, and to explore how that epidemic affects the workplace for anesthesia providers in terms of drug diversion risk by addicted healthcare workers. Questions that will be addressed include:

- What is the history of the current opioid epidemic in the United States?
- How severe is the epidemic in terms of overdose deaths?

- What is drug diversion and what are the signs of a healthcare worker who is diverting controlled substances?
- How are regulatory agencies and medical societies responding to the opioid epidemic?
- What systems and procedures should be in place within an anesthesia department to minimize the risk of drug diversion?
- How frequent is drug diversion among anesthesia providers?
- Is random urine drug testing in the workplace a “cure all” to prevent drug diversion?

The Prescription Drug Epidemic

In recent years, the illicit opioid and prescription drug epidemic has grown in severity in the United States. Several factors that have contributed to the development of the prescription drug/opioid epidemic are discussed below (Table 1).

Availability. Prescribing of prescription pain killers has increased dramatically in the United States over the last several decades. In 2011, approximately 220 million prescriptions were written in the United States for the drugs hydrocodone and oxycodone alone. In contrast, there were 76 million prescriptions for these same drugs in 1991. These prescription pain killers are found in many homes across the country, and are frequently used by individuals other than the patient. **It is striking that the United States has only 5% of the world's population but consumes 80% of the world's opioids.**

Simultaneously, other drugs are making their way to the United States in the form of heroin and illegally manufactured fentanyl. Heroin overdose deaths have increased dramatically in recent years, with 2,000 heroin overdose deaths in 2007 and > 10,000 deaths in 2014.

Table 1
Factors Contributing to the Prescription Drug Epidemic

- Liberal prescribing of prescription pain killers
- Regulatory emphasis on recognizing and treating pain
- Aggressive marketing by pharmaceutical companies
- Physician efforts to destigmatize opioid use for chronic pain
- Perception of safety relative to street drugs
- Long-acting preparations of opioids (e.g., oxycodone)

Perception of safety. Street drugs are inherently dangerous because of variable quantity and quality of the drug, including potency. And street drugs may be contaminated with impurities or spiked with stronger opioids like fentanyl. In contrast, prescription drugs have at least the illusion of safety because they were produced by a pharmaceutical company in a regulated environment.

The development of long-acting oxycodone. In 1996 a long-acting form of oxycodone was produced. Oxycodone has physical properties very similar to heroin and has significant addictive potential.

During the late 1990s, some pharmaceutical companies and physicians strongly advocated for more aggressive use of opioids to treat severe pain. These advocates stated that the addiction risk was low for patients with chronic pain and that prescribers should be more liberal in treating pain with opioids. They typically quoted a < 1% risk of addiction for chronic pain patients. In 2014, over 25,000 deaths in the United States were attributed to overdoses of prescription drugs.

The Joint Commission's Pain Initiative. Around 2001, the Joint Commission emphasized pain management and elevated the pain score to a vital sign. Emphasis was placed upon assessing a patient's pain and treating it appropriately. Many healthcare organizations and providers felt obligated to more aggressively use opioids to treat pain.

The factors noted above combined to produce an environment in the United States where pain treatment was emphasized and opioids were more readily prescribed; therefore, the consumption of opioids increased dramatically compared to historic levels. Subsequently, addiction to prescription painkillers became more common as evidenced by the opioid epidemic seen in the United States today. It has only been in recent years that the magnitude and severity of the epidemic has been recognized and steps have been taken by regulatory bodies to “bend the curve” of opioid prescribing. Tamper-proof formulations of drugs like long-acting oxycodone have come to market; unfortunately, this has led some users to seek cheaper and easier-to-obtain forms of opioids, such as heroin and fentanyl purchased illegally.

The Magnitude of the Epidemic

As noted above, over 200 million prescriptions are written each year in the United States for hydrocodone and oxycodone alone. Data from the National Survey on Drug Use shows that while marijuana is the most commonly used illicit drug in the United States, prescription pain relievers are now second (ahead of cocaine and other stimulants or sedatives). **In 2014, over 25,000 people in the United States died from a prescription drug overdose.** As

Table 2
The Magnitude of the Opioid Epidemic
2014 Data, National Center for Health Statistics

- **> 25,000 US deaths from prescription drug overdose**
- **> 18,000 died from prescription opioids**
- **~ 8,000 died from benzodiazepine overdose**
- **> 10,000 heroin overdose deaths**

per the National Center for Health Statistics, this included more than 18,000 people who died from prescription opioid pain relievers. Benzodiazepines accounted for approximately 8,000 overdose deaths in 2014. And as noted above, the number of deaths from heroin overdoses has increased dramatically in recent years, with more than 10,000 deaths in 2014 (Table 2).

To put these overdose deaths in perspective, in 2008 the number of motor vehicle accident deaths were exceeded for the first time in the United States by overdose deaths from prescription painkillers and heroin. In 2013, 46,500 people died from prescription painkillers and heroin overdoses versus 35,300 people who died in motor vehicle accidents while 33,600 died from firearms (data from the Drug Enforcement Agency).

It is noteworthy that today, when an individual first begins illicit drug use, prescription painkillers are only exceeded by marijuana as the drug of choice. Interestingly, these prescription drugs are most frequently obtained from a friend or relative or purchased from a friend or relative. Therefore, the notion of these drugs being obtained from a back-alley drug dealer is more the exception than the rule; rather, most of the time the drugs come from a friend or relative.

When Drug Addiction Comes to the Workplace

When a healthcare worker takes a controlled substance from a lawful use and moves it to an unlawful use, "drug diversion" has occurred. Unfortunately, addicted healthcare workers may steal from their employer and patients to support their habit. In some instances, the worker self-injects diverted drugs and cross-contaminates syringes of opioids like fentanyl, subsequently infecting patients with blood-borne pathogens.

A 2014 study from Mayo Clinic Proceedings documented the outbreaks of disease that resulted from healthcare workers diverting controlled substances. In two cases, more than 30 patients became infected with gram-negative bacteremias. This was

due to registered nurses drawing opioids out of patient-controlled analgesia devices (PCAs) and replacing the diverted opioid with saline. In the process, they contaminated the PCA with bacteria and infected multiple patients. In four other outbreaks documented in the manuscript, more than 80 patients were infected with the hepatitis C virus by healthcare workers who were diverting and cross-contaminating syringes with their own blood. Most of these healthcare workers were identified and prosecuted. They included a radiology technician, surgical technicians and a nurse anesthetist. In the hospitals where these events occurred, some 30,000 patients had to be screened for bloodborne pathogens. The expense and legal risk for these hospitals was considerable.

While it is not known how frequent drug diversion occurs, each healthcare organization must be suspicious and vigilant regarding controlled substances. High risk areas for diversion include procedural areas such as the operating room, endoscopy suite, the cardiac catheterization lab and interventional radiology suite as well as other areas where controlled substances may be stored, such as the pharmacy and research areas (Table 3).

It should be noted that healthcare workers who seek to steal controlled substances will often attempt to exploit the "waste stream".

This means that they will try to obtain opioids that are being wasted after a procedure rather than stealing the drugs before their intended use. Technicians, housekeepers and other employees who do not have direct access to opioids may still attempt to obtain them at work. **Anesthesia providers must be particularly vigilant with the controlled substances in their possession and not leave these drugs unattended at any time.** There are risks for the healthcare facility as a result of drug diversion, but also individual providers can be held accountable if they were not responsible with their controlled substances and the drugs are stolen.

Table 3
Clinical Areas at Risk
for Drug Diversion

- **Procedural areas**
 - **Operating room**
 - **Endoscopy suite**
 - **Interventional radiology suite**
- **Pharmacy**
- **Research laboratories**
- **Any area that stores controlled substances**

Table 4
The “5 A’s” Used to Determine Effectiveness of Opioids

- Analgesia
- Activity
- Adverse events
- Aberrant behaviors
- Affect

Responding to the Opioid Epidemic

In recent years, many government agencies and medical societies have attempted to address the opioid epidemic in the United States. One example is the Federation of State Medical Boards, which published its *“Model Policy of the use of Opioid Analgesics in the Control of Pain”* (www.fsmb.org). While the details of this policy are beyond the scope of this lesson, any provider prescribing opioids should review the Federation’s guidelines, which include concepts like regular evaluation of opioid patients, and use of the “5 A’s” (Analgesia, Activity, Adverse events, Aberrant behaviors, and Affect) to judge their patients’ status and progress (Table 4).

In 2016, the Centers for Disease Control (CDC) produced a guideline for prescribing opioids for chronic pain. This document, which can be found on the CDC’s website, outlines twelve principles for prescribing opioids (Table 5). These principles are briefly reviewed below:

- Non-opioids should be first-line therapy for any type of pain.
- The provider should set expectations and goals with the patient when initiating opioid therapy. Opioid therapy should only be continued if there is meaningful improvement in the patient’s function and pain, and a plan should be in place to taper the opioids off if they are not effective.
- A discussion of the risks and benefits of opioids should be held with the patient before prescribing begins. The patient should be aware of the risk of addiction and the provider should consider the patient’s personal and family history for risk of opioid abuse.
- When opioids are initiated, immediate-release preparations should be used rather than long-acting preparations. The CDC advises that when assessing the patient with chronic pain, the provider consider the “PEG score” which includes Pain, Enjoyment of life and General activity. Each of these are rated on a 0-10 scale and provide a baseline of the patients functioning which can be reassessed later after the initiation of opioids.

- When a long-acting opioid is felt to be indicated, the lowest effective dose should be used. **The CDC cautions clinicians regarding increasing the dosage of opioid to more than 50 morphine milligram equivalents (MME) per day and further advises against treatment with more than 90 MME per day without careful justification for the decision to titrate above 90 MME.** These higher doses increase the risk of overdose and death, although critics of the guideline point out that there is no clear opioid dosage threshold below which adverse events—including catastrophic respiratory depression—can be guaranteed not to occur.
- The CDC recommends the use of opioids for acute pain for only a short period of time. The CDC suggests that 3 days of opioids or less will usually be sufficient for acute pain and more than 7 days is rarely needed. They point out that long-term opioid use frequently begins with acute pain therapy and many patients who become addicted trace their addiction to the treatment of acute pain.
- Patients initiated on opioids should be evaluated in 1-4 weeks and then at least every 3 months.
- During therapy, clinicians should evaluate patients for harm and should use strategies to mitigate risk. This can include co-prescribing of naloxone, particularly in patients using more than > 50 MME/day. The patient and family members must be educated on the signs/symptoms of overdose and how to use naloxone.
- Prescribers are advised to use a Prescription Drug Monitoring Program (PDMP), which are State-run programs to track prescriptions of opioids. The provider is able to determine if their patients are receiving prescriptions from more than one provider and filling them at more than one pharmacy. A PDMP is now available in every state except Missouri. Unfortunately, a national prescription-monitoring program is currently not available, allowing patients to cross state lines without the knowledge of the prescriber.
- The CDC recommends the use of urine drug testing before initiating opioid therapy and at least once annually afterwards.
- Prescribers are advised to avoid concurrently prescribing benzodiazepines with opioids.
- Patients who have opioid-use disorder should be offered evidence-based treatment programs.

While the CDC’s efforts to educate and reduce opioid prescribing seems to be having a positive effect, some physicians in the pain management community feel that patients most in need of opioids are less likely to find a prescriber because of the chilling effect of these guidelines. To complicate matters, the Drug Enforcement Agency (DEA) has required a 25% or more reduction in the manufacturing of opioids in 2017.

Unfortunately, many patients who overdose on prescription opioids continue to receive prescriptions after the event. A 2016 study of patients treated for non-fatal overdose in an emergency department showed that 91% of them subsequently received opioid prescriptions, and 7% of the patients overdosed again within a year. The greatest risk for repeat overdose was among patients treated with high-dose opioids (> 100 MME/day)

Preventing Drug Diversion in the Workplace

As noted above, any healthcare facility which houses controlled substances is at risk for diversion and any employee is capable of diverting drugs. Experience has shown that traditional paper charting and audits of opioid wastage are not adequate and are too easily defeated by those who would divert drugs. At the author's institution, a system of tracking controlled substances throughout the process of care has been developed. This includes the ability to reconcile drug pulls from the Pyxis machine with recorded opioid usage on the anesthesia record, combined with waste documentation. In addition, a system of waste drug assays has been implemented to confirm that the controlled substances being discarded do in fact contain the drug in question in the appropriate concentration. We believe this system of tracking drug use and waste acts as both a deterrent to drug diversion and an early warning sign of drug diversion by anesthesia providers.

Table 5
Elements of the CDC
Opioid Prescribing Guideline

- Non-opioids are first line therapy for pain
- Set expectations and goals
- Use immediate release before long-acting opioid preparations
- Use the lowest effective dose of opioid
- Use opioids for acute pain for only a short period of time
- Consider co-prescribing of naloxone, especially for high dose opioid patients
- Use a Prescription Drug Monitoring Program (PDMP)
- Urine drug test before initiating opioids and at least once yearly thereafter
- Avoid concurrently prescribing benzodiazepines
- Refer patients with opioid-use disorder to treatment

To illustrate this point, a 2011 study from *Anesthesia and Analgesia* demonstrated that a similar tracking system was able to detect atypical transactions of opioids by anesthesia providers. Examples of atypical transactions included removal of opioids for patients after they had exited the OR, or the removal of drugs for patients at a location other than where the procedure was performed. **In other words, a robust tracking system for opioid use allows the institution to not only track use and wastage of controlled substances, but also to identify aberrant patterns of use by healthcare providers.** While the majority of these atypical transactions are innocent, some of them will be early warning signs in a provider who is diverting drugs.

Every healthcare organization that houses controlled substances should have a drug diversion prevention program.

To manage and guide the process of tracking controlled substances, a "drug diversion response team" can be designated at the hospital. This type of team should have multi-disciplinary representation from pharmacy, administration, legal and anesthesiology. When a concern is raised about drug diversion, the drug diversion response team gathers to review information and decide what if any response is indicated: an intervention, an employee interview, further observation or no action. The presence of the drug diversion response team provides for a consistent response to concerns regarding drug diversion and a standardized approach.

Along with these measures, each institution should educate their staff about the risks of drug diversion and the appropriateness of confidentially speaking up when they observe unusual behavior around controlled substances. Sharing a concern will trigger a thorough, fair and confidential review of the evidence.

Some institutions use random urine drug testing to identify and deter drug diversion. While this may provide some deterrence, the author's institution has placed its resources in the system as described above rather than random urine drug testing. Testing of urine requires significant resources and the need for a system to address false positives, which are probably more common than true positives because of the overall low incidence of drug diversion.

Substance Use Disorder and Anesthesia Providers

A 2013 study of anesthesiology residents concluded that the incidence of substance use disorder (SUD) among residents was 3 per 1000 resident years, meaning that of 1000 residents in training for one year, 3 of them would be identified as having a SUD. The most common drugs used were IV opioids,

Table 6
Signs of Drug Diversion
by Healthcare Workers

- Under-performance
- Behavioral changes at work
- Aberrant patterns of medication use relative to peers
- Frequent unexplained absences
- Patients who are under medicated
- Overdose and death

ethanol and then marijuana/cocaine. Unfortunately, over 7% of these individuals died during training.

Among these trainees with a SUD, there was an estimated relapse rate of 43% over a 30-year career. This risk calls into question the wisdom of an anesthesia provider returning to anesthesia practice after treatment for opioid addiction. Unfortunately, individuals with addictions are experts at hiding their behavior. Some possible signs of drug diversion by anesthesia providers include under-performance, behavioral changes at work, aberrant patterns of medication use relative to their peers, frequent unexplained absences, patients who are under medicated, and overdose and death at work (Table 6).

The frequency of substance use disorders among anesthesia providers is unknown.

Summary

An opioid abuse epidemic is ongoing in the United States. It is driven by many factors including the liberal prescribing of painkillers, emphasis by the Joint Commission on the treatment of pain, and aggressive marketing by pharmaceutical companies. Simultaneously, addiction has come to the healthcare workplace and the theft of controlled substances occurs. Employees who divert drugs may be individuals with no legitimate access to the drugs. Nationally, the CDC and other organizations have provided guidelines for opioid prescribing and the DEA has mandated a reduction in opioid manufac-

turing in the United States. Tamper-proof formulations of various drugs like long-acting oxycodone are available, but in some cases addicted individuals have turned to street drugs like heroin. Finally, each anesthesia department should participate in drug diversion prevention including the ability to carefully track controlled substances throughout the episode of care.

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Tips for your Clinical Practice: Key Points

- The number of **motor vehicle accident deaths** has now been exceeded by the number of **deaths attributed to overdoses** of prescription analgesics and heroin.
- **Factors that have contributed to this drug epidemic** include aggressive marketing by drug companies, liberal prescribing of pain killers, an emphasis on recognizing and treating pain, the perception that prescription drugs are safe, and the use of long-acting opioid preparations.
- **While diverting drugs**, healthcare workers can **transmit bloodborne pathogens** to patients when they self-inject and thereby cross contaminate syringes containing opioids.
- **Signs of drug diversion** include under performance, behavior changes, unexplained absences, under-medicated patients, aberrant patterns of medication use, and overdose and death.
- **The CDC has produced a guideline** for prescribing opioids for chronic pain; it contains twelve basic principles with which pain practitioners should be familiar.
- **The recidivism rate** among anesthesia trainees with a substance abuse disorder is about 43%; this calls into question the wisdom of an anesthesia provider returning to practice after being treated for addiction.

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POST-STUDY QUESTIONS

1. **Which of the following is a contributing factor to the United States opioid epidemic:**
 - ☐ A. The Joint Commission's prohibition against opioid prescribing.
 - ☐ B. Rare use of opioids in the United States relative to other countries.
 - ☐ C. Increased prescribing resulting in widespread availability.
 - ☐ D. The CDC opioid prescribing guideline.
2. **The Joint Commission's pain initiative impacted United States opioid prescribing by:**
 - ☐ A. Encouraging pain assessment and treatment.
 - ☐ B. Legalizing opioid prescriptions for > 90 MME/day.
 - ☐ C. Making methadone the drug of choice for chronic pain.
 - ☐ D. Penalizing providers if their patient overdosed on opioids.
3. **To quantify prescription drug overdose deaths in the United States:**
 - ☐ A. Cocaine overdose is the most common cause of death.
 - ☐ B. In 2014, over 25,000 people died from a prescription drug overdose.
 - ☐ C. Heroin overdose deaths have decreased in recent years.
 - ☐ D. Motor vehicle related deaths are more common than drug overdose deaths.
4. **Drug diversion is:**
 - ☐ A. Mislabeling of a medication in the operating room.
 - ☐ B. Prescribing > 90 MME/day.
 - ☐ C. Respiratory depression caused by a combination of morphine and lorazepam.
 - ☐ D. Transfer of a controlled substance from a lawful to unlawful purpose.
5. **Healthcare workers may transmit bloodborne pathogens to patients while diverting drugs by:**
 - ☐ A. Cross-contaminating syringes used to self-inject opioids.
 - ☐ B. Prescribing oral morphine instead of tamper-proof oxycodone.
 - ☐ C. Over-prescribing opioids to many chronic pain patients.
 - ☐ D. Failing to stop opioid prescribing to patients who overdose.
6. **Which of the following areas in the hospital are at high risk for drug diversion:**
 - ☐ A. The operating rooms.
 - ☐ B. Interventional radiology suite.
 - ☐ C. The endoscopy suite.
 - ☐ D. All of the above.
7. **The 2016 CDC guideline on opioid prescribing states:**
 - ☐ A. It is illegal to prescribe > 90 MME/day.
 - ☐ B. When opioids are initiated, immediate-release preparations should be used initially rather than long-acting preparations.
 - ☐ C. Law enforcement should be called whenever a patient loses their opioid prescription.
 - ☐ D. Methadone should never be used for chronic benign pain.
8. **Opioid tracking in anesthesia departments can identify possible diversion by:**
 - ☐ A. Ensuring all waste is placed in sharps containers.
 - ☐ B. Providing video tape surveillance of all opioid administrations.
 - ☐ C. Identifying atypical transactions.
 - ☐ D. Screening anesthesia providers for a history of substance use disorder (SUD).
9. **Random urine drug testing:**
 - ☐ A. May result in more "false positives" than "true positives".
 - ☐ B. Is the only effective deterrent against drug diversion available today.
 - ☐ C. Can be carried out without expending significant resources.
 - ☐ D. Generates no inconvenience for employees who are tested.
10. **Behavioral signs of drug diversion in anesthesia providers include:**
 - ☐ A. Unexplained absences.
 - ☐ B. Under-medicated patients.
 - ☐ C. Overdose and death.
 - ☐ D. All of the above.

CORRECT ANSWERS TO LESSON 21, VOLUME 37 (ARGALIOUS)

1. A 2. C 3. D 4. D 5. B 6. A 7. C 8. A 9. D 10. D