Auditing for Drug Diversion

Why and How

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Presentation Overview

- About MUSC and Internal Audit
- What are controlled substances
- Scope of the problem
- Impact of diversion
- Conducting an audit
**MUSC is Large and Complex Controlled Substances**

<table>
<thead>
<tr>
<th>Registration Type</th>
<th>Locations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Research</td>
<td>71</td>
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<tr>
<td>Hospital Nursing Units with 1 to 12 ADMs</td>
<td>78</td>
</tr>
<tr>
<td>Pharmacy</td>
<td>16</td>
</tr>
<tr>
<td>Clinic</td>
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</tr>
<tr>
<td>Off site Clinic</td>
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</tr>
<tr>
<td><strong>Total</strong></td>
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The term **narcotic** (/nɑrˈkɒtɪk/, from ancient Greek ναρκῶ narkō, "to make numb") originally referred medically to any psychoactive compound with any sleep-inducing properties. In the U.S. it has since become associated with opiates and opioids, commonly morphine and heroin and their derivatives, such as hydrocodone.

• The term is, today, imprecisely defined and typically has negative connotations.

• When used in a legal context in the U.S., a *narcotic* drug is simply one that is totally prohibited, or one that is used in violation of governmental regulation, such as codeine or morphine.

• From a pharmacological standpoint it is not a useful term, as is evidenced by the historically varied usage of the word.
Definition of Controlled Substance Schedules

The Controlled Substances Act (CSA) divides controlled substances into five schedules. A complete list of the schedules is published in 21 CFR §§ 1308.11 through 1308.15.

Substances are placed in their respective schedules based on:

– Whether they have a currently accepted medical use in treatment in the United States
– Their relative abuse potential, and
– The likelihood of causing dependence when abused
Schedule I Controlled Substances

- No currently accepted medical use in the U.S.
- Lack of accepted safety for use under medical supervision
- High potential for abuse
  - Heroin
  - Lysergic acid diethylamide (LSD)
  - Marijuana (cannabis)
  - Peyote
  - Methaqualone
  - 3,4-methylenedioxymethamphetamine ("Ecstasy")
Schedule II/IIN Controlled Substances (2/2N)

High potential for abuse which may lead to severe psychological or physical dependence.

Examples of Schedule II narcotics
Hydromorphone (Dilaudid®)
Methadone (Dolophine®)
Meperidine (Demerol®)
Oxycodone (OxyContin® Percocet®)
Fentanyl (Sublimaze®, Duragesic®)
Morphine
Opium
Codeine
Hydrocodone

Examples of Schedule IIN stimulants
Amphetamine (Dexedrine®, Adderall®)
Methamphetamine (Desoxyn®)
Methylphenidate (Ritalin®)

Other Schedule II substances:
Amobarbital
Glutethimide
Pentobarbital.

Changing What’s Possible
Schedule III/IIIN Controlled Substances (3/3N)
Potential for abuse less than substances in Schedules I or II and abuse may lead to moderate or low physical dependence or high psychological dependence.

Examples of Schedule III narcotics

- Products containing not more than 90 milligrams of codeine per dosage unit
- Tylenol with Codeine®
- Buprenorphine (Suboxone®)
- Hydrocodone/Acetaminophen (Lortab®, Vicodin®)

Examples of Schedule IIIN non-narcotics

- Benzphetamine (Didrex®)
- Phendimetrazine (Bontril®)
- Ketamine
- Anabolic steroids such as Depo®-Testosterone
Schedule IV Controlled Substances

Low potential for abuse relative to substances in Schedule III

- Alprazolam (Xanax®)
- Carisoprodol (Soma®)
- Clonazepam (Klonopin®)
- Clorazepate (Tranxene®)
- Diazepam (Valium®)
- Lorazepam (Ativan®)
- Midazolam (Versed®)
- Temazepam (Restoril®)
- Triazolam (Halcion®)

Dangers of Ativan Abuse
After several months or years of use, the cumulative effects of Ativan misuse can pose serious health risks.

- Blush skin
- Headaches
- Kidney problems
- Learning difficulties
- Insomnia
- Physical and mental fatigue
- Seizures
- Memory loss
- Disorientation
- Increased anxiety
- Confusion
- Tremors
- Increased drowsiness or sedation

Recreational use of Ativan greatly increases the risk of becoming dependent and eventually addicted to the drug.
Schedule V Controlled Substances

Low potential for abuse relative to substances listed in Schedule IV and consist primarily of preparations containing limited quantities of certain narcotics

- Cough preparations containing not more than 200 milligrams of codeine per 100 milliliters or per 100 grams (Robitussin AC®, Phenergan with Codeine®)
- Ezogabine
Scope of the Problem

Economic Impact of the Opioid Epidemic:

$55 billion in health and social costs related prescription opioid abuse each year\(^1\)

$20 billion in emergency department and inpatient care for opioid poisonings\(^2\)

2013;14(10):1534-47.\(^2\)

1. CDC, MMWR, 2015; 64;1-5.
2. CDC Vital Signs, 60(43);1487-1492
## Scope of the Problem

On an average day in the U.S.:

- More than **650,000 opioid prescriptions** dispensed\(^1\)
- **3,900 people** initiate nonmedical use of prescription opioids\(^2\)
- **580 people** initiate heroin use\(^2\)
- **78 people** die from an opioid-related overdose\(^3\)

*Opioid-related overdoses include those involving prescription opioids and illicit opioids such as heroin*

**Source:** IMS Health National Prescription Audit\(^1\) / SAMHSA National Survey on Drug Use and Health\(^2\) / CDC National Vital Statistics System\(^3\)
Scope of the Problem

- The American Nurses Association estimates that 10 percent of nurses are dependent on some type of drug.
- The AMA used the analogy that if one works with 10 nurses, one of the ten is probably struggling with some type of addiction.
- With almost 3 million nurses working in their field, approximately 300,000 may be substance abusers.
Impact of Healthcare-associated Drug Diversion

- **Drug Diversion** - When prescription medicines are obtained or used illegally.

- Addiction to prescription narcotics called opioids has reached **epidemic proportions** and is a major driver of drug diversion.

- According to the CDC, “there are no reliable statistics about diversion by healthcare providers...because diversion is done covertly, and methods in place in many institutions leave cases undetected or unreported. At a facility with a strong diversion program ... identified 1-2 new cases of staff members diverting each month. Well over 50% of those caught were diverting and using injectable opioids.”


- Drug diversions can result in several types of patient harm including:
  - Substandard care delivered by an impaired healthcare provider,
  - Denial of essential pain medication or therapy, or
  - Risks of infection (e.g., with hepatitis C virus or bacterial pathogens) if a provider tampers with injectable drugs.
U.S. Outbreaks Associated with Drug Diversion by Healthcare Providers 1983-2013

1985: 3 cases of Pseudomonas pickettii bacteremia associated with a pharmacy technician at a Wisconsin hospital

1989: 26 cases of Serratia marcescens bacteremia associated with a respiratory therapist at a Pennsylvania hospital

1992: 45 cases of HCV infection associated with a surgical technician at a Texas ambulatory surgical center

1999: 26 cases of Achromobacter xylosoxidans bacteremia associated with a nurse at an Illinois hospital

2004: 16 cases of HCV infection associated with a certified-registered nurse anesthetist at a Texas hospital

2006: 9 cases of Achromobacter xylosoxidans bacteremia associated with a nurse at an Illinois hospital

2008: 5 cases of HCV infection associated with a radiology technician at a Florida hospital

2009: 18 cases of HCV infection associated with a surgical technician at a Colorado hospital

2011: 25 cases of gram-negative bacteremia associated with a nurse at a Minnesota hospital

2012: 45 cases of HCV infection associated with a radiology technician at hospitals in New Hampshire, Kansas, and Maryland

Prescription Opioid Overdose Data

Opioid overdoses driving increase in drug overdoses overall

Drug overdose deaths involving opioids, by type of opioid, United States, 2000-2014

SOURCE:
Prescription Opioid Overdose Data

Nearly 15,000 people die every year of overdoses involving prescription painkillers.

In 2010, 1 in 20 people in the US (age 12 or older) reported using prescription painkillers for nonmedical reasons in the past year.

Enough prescription painkillers were prescribed in 2010 to medicate every American adult around-the-clock for a month.

http://www.cdc.gov/vitalsigns/painkilleroverdoses/
Scope of the Problem

Heroin use is part of a larger substance abuse problem.

Nearly all people who used heroin also used at least 1 other drug.

Most used at least 3 other drugs.

Heroin is a highly addictive opioid drug with a high risk of overdose and death for users.

People who are addicted to...

- Alcohol are 2x more likely to be addicted to heroin.
- Marijuana are 3x more likely to be addicted to heroin.
- Cocaine are 15x more likely to be addicted to heroin.
- Rx Opioid Painkillers are 40x more likely to be addicted to heroin.


http://www.cdc.gov/vitalsigns/heroin/infographic.html

Changing What’s Possible
Did you know...

- SC Code of Laws Section 40-33-110 [Nurse Practice Act].
  Grounds for discipline of licensees.
  - Violated a federal, state, or local law involving alcohol or drugs
  - Obtained, possessed, administered, or furnished prescription drugs to a person...except as directed by lawful prescriber
  - Engaged in the practice of nursing when judgment or physical ability is impaired by alcohol, drugs, or controlled substances or has declined or been unsuccessful in accomplishing rehabilitation
  - Failed to make or keep accurate, intelligible entries in records as required by law, policy, or standards for the practice of nursing
Possible Signs of Impairment

- Personality change
- Patient and staff complaints about quality of care, attitude, or behavior
- Interpersonal relations with colleagues, staff, and patients suffer
- Wearing long sleeves when inappropriate
- Deteriorating personal appearance
- Increasing personal and professional isolation

Nurses who are chemically dependent may be successful at disguising dependency issues because they are often stellar employees, popular, respected, and bright.

Source: Nurse Drug Diversion and Nursing Leader’s Responsibilities: Legal, Regulatory, Ethical, Humanistic, and Practical Considerations. JONA's Healthcare Law, Ethics, & Regulation. 13(1):13-16, January/March
Possible Signs of Diversion

• Patient complaints about poor pain control
• Inaccurate narcotics counts
• Offers to administer medications to patients the nurse is not assigned to
• Frequent delays between administration and wasting drugs
• Frequent or unexplained disappearance from the unit

*The ANA estimates approximately 6% to 8% of nurses are practicing while impaired.*

Recognition of Diversion

• Hospitals may have automated drug cabinets that produce data about controlled substance transactions, but many diversion schemes can’t be detected this way.

• Personal observation is vital!

• It may be the only clue.
Recognition of Diversion/Impairment

• Tardiness, unscheduled absences and an excessive number of sick days used
• Frequent disappearances from the work site and taking frequent or long trips to the bathroom or to the stockroom where drugs are kept
• Volunteers for overtime and is at work when not scheduled to be there
• Arrives at work early and stay late
• Pattern of removal of controlled substances near or at end of shift
Recognition of Diversion/Impairment

• Work performance alternates between periods of high and low productivity, may suffer from mistakes, poor judgment and bad decisions

• Interpersonal relations with colleagues, staff and patients suffer. Rarely admits errors or accepts blame for errors or oversights (denial)

• Insistence on personal administration of injected narcotics to patients

• Heavy or no "wastage" of drugs; and

• Pattern of holding waste until oncoming shift
Understanding the Technology Automated Dispensing Machines

• RN signs on with unique username and password (or biometric capability)
• RN selects the patient, drug desired and quantity
• Single bin is unlocked and nurse required to key in the quantity present before removal
• 2 users required for “waste” or return
Understanding the Technology
Automated Dispensing Machines
Surveillance Technology
Automated Dispensing Machines
Surveillance Technology
Automated Dispensing Machines

![Bar chart showing diversion scores for different medication families: Hydrocodone has a significantly higher score compared to Oxycodone and Oxymorphone.]

Changing What’s Possible
Surveillance Technology
Automated Dispensing Machines

- HYDROMORPHONE 2 MG/ML 2 MG INJ - Dispense Per Day Worked Variance - This user has a 611.54% variance over the average of dispenses for HYDROMORPHONE 2 MG/ML 2 MG INJ. They are dispensing at a rate of 3.70 quantity per day worked (111.00 over 30 days worked on the unit). The average on this unit is 0.52 quantity dispensed per day worked.

- HYDROMORPHONE 2 MG/ML 2 MG INJ - Total Dispense Qty Variance - This user has a total dispense quantity variance of 1025.76% for HYDROMORPHONE 2 MG/ML 2 MG INJ. The user dispensed 111.00 and the average total dispense quantity on this unit is 9.86.

- HYDROMORPHONE 2 MG/ML 2 MG INJ - Sole User Dispensing to Patients - This user was the sole dispenser of HYDROMORPHONE 2 MG/ML 2 MG INJ to 4 patients. On this unit, there are 0 other users out of 64 with a dispensing pattern similar to this.
Surveillance Technology
Automated Dispensing Machines

• HYDROMORPHONE 2 MG/ ML 2 MG INJ User to Patient Max Dispenses - This user dispensed the medication HYDROMORPHONE 2 MG/ ML 2 MG INJ more times than any other user to 14 patients. This excludes when the user dispensed the most but it was less than 25% over the average.

• HYDROMORPHONE Drug Family Variances - This user has variances for multiple medications that begin with HYDROMORPHONE
Diversion Investigation

Review all controlled substance activity for suspect for ninety day minimum.

1. Compare all controlled substance dispenses of suspect from the ADM to the patient’s MAR. Look for undocumented medications (waste/returns/administrations).

2. Compare suspect’s frequency of administrations to peers for each patient. Is the suspect maximizing PRN Meds?

3. Compare patient’s pain assessments of suspect to peers’ pain assessments. Are there deviations? Are scores recorded?

4. Interview manager about behaviors, personality changes, stresses in personal life, etc.
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