Identifying Controlled Substance Diversion Within the Health System

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Disclosure

I have no conflict of interests to disclose at this time.
Learning Objectives

• Define drug diversion
• Discuss why drug diversion is an ongoing issue within a health system
• Describe methods to identify possible diverters within an institution
• Explain the potential regulatory penalties and consequences for improper oversight
What is Drug Diversion?

Diversion:
• The use of prescription drugs for recreational purposes.
• Diverting a prescription drug for other than its intended purpose.

Addiction:
• Continued use despite harm
Drug Diversion Statistics

In 1992 7.8 million people and in 2003 15.1 million people, admitted using scheduled drugs. This increase of 94% was seven times faster than the increase in US population.

(15.1 million is approximately equal to 2 times the population of New York City)
Developed by The Controlled Substances Act of 1970

• Currently there are 5 Schedules
  • **Schedule I:** no accepted medical use, high potential for abuse.
    • Example: heroin, ecstasy
  • **Schedule II:** accepted medical use with severe restrictions with high potential for abuse.
    • Example: morphine, hydrocodone, fentanyl
  • **Schedule III:** accepted medical use with moderate to low potential for abuse.
    • Example: codeine, Tylenol 3
  • **Schedule IV:** accepted medical use with potential for abuse, but less than Schedule III.
    • Example: Valium, Ambien
  • **Schedule V:** accepted medical use with low potential for abuse.
    • Example: Robitussin AC

• State and local laws may be more restrictive
Most Frequently Abused Drugs

- To relieve pain: opioids like OxyContin® and Vicodin®
- To relieve anxiety: sedatives like Valium® and Xanax®
- To boost attention and energy: medicines that speed up physical and mental processes like Ritalin®, Adderall® and Dexedrine®
- To improve athletic performance: steroids like Anadrol® and Equipoise®
# Drug Diversion Methods

<table>
<thead>
<tr>
<th>Method</th>
<th>Example</th>
</tr>
</thead>
<tbody>
<tr>
<td>Improper wasting</td>
<td>Taking the waste for personal use</td>
</tr>
<tr>
<td>Stealing controlled substances from the patients</td>
<td>Not dosing the patients properly</td>
</tr>
<tr>
<td>Remove excessive amounts of controlled substances from the automated dispensing machine</td>
<td>Using the “PRN” (as needed for pain) medications</td>
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<tr>
<td>Tampering with the patients controlled substance medications</td>
<td>Done by replacing an injectable pain medication with another substance, usually saline. The replaced substance is then given to the patient.</td>
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Drug Diversion Methods

Removal of medication when not needed
• Often initial method of diversion
• Very difficult to detect
• Falsification of records

Removal for discharged patient

Removal of duplicate dose
• May not be caring for patient
• May be preceptor

Removal of/diversion from fentanyl patches
• Removal of gel with syringe and needle
• Keeping new patch for self and putting used patch on patient
Drug Diversion Methods

Failure to waste
• Unwasted medication kept for self (proper waste procedure is to waste upon removing whenever possible)

Frequent wasting of entire doses (should be returned)

Substitution in administration and wasting
• Substitution of look-alike pills
• Saline substituted for injectable medication
• Potential for tampering charges
Why is Drug Diversion in Health Systems Common

- Reliable statistics on the prevalence of *drug diversion* by nurses are not available
- By its nature, diversion is a clandestine activity, and the detection methods in place throughout many institutions leave cases undiscovered or unreported
- Drug diversion by health care providers is universal among institutions in the United States
- If your institution is not finding and reporting drug diversion, then consider revising your drug diversion detection methods
Common Areas of Weakness

• Lack of internal controls over controlled substances stored in emergency kits for trauma or urgent needs
• Pain response documentation not regularly reviewed for patterns
• Inadequate segregation of duties
• End user passwords not changed per hospital policy
  • Job changes/responsibilities
  • Termination
• Discharged patient list remaining available for hours after DC
• Drug testing
  • Not done at pre-employment screening
  • Not performed randomly for staff with access
• Staff with no or little training/competency on system (poor practices)
• Built in System controls “turned off”- too cumbersome
Why Drug Diversion Occurs

**Occupational factors**
- Suppression of feelings and emotions
- Vicarious trauma
- Physical demands of job
- Legitimate use and chronic pain
- **Ease of access to prescriptions and medication**
- Knowledge and sense of control

The major factors impacting the incidence of drug misuse by healthcare professionals are access and availability of controlled substances.
Approximately 1 healthcare professional per month is diverting controlled substances

**Diverters are also those you may not expect to be diverting, such as:**

- Award winners
- New Grads
- Team Leaders
- Pediatric and neonatal nurses
- Pregnant nurses
- Clusters of nurses
- Anesthesiologists
Recent Headlines

Boulder Community Hospital (Boulder, Colorado)

• Fall 2008
• Over 300 potential victims
• Used same needle to inject himself with Fentanyl, refilled the syringe with saline or water, and injected the patient.
• Sentenced to 54 months in federal prison followed by 3 years supervised release
Recent Headlines

Rose Medical Center (Denver, Colorado)
• February 2010
• 18 patients infected with Hepatitis C
• Used same needle to inject herself with Fentanyl, refilled the syringe with saline or water, and injected the patient.
• Plea bargain rejected, sentenced to 30 years

Kristin Parker
Recent Headlines

Exeter Hospital (Exeter, New Hampshire)

- December 2013
- Worked at 18 hospitals in 7 states
- Used same needle to inject himself with Fentanyl, refilled the syringe with saline or water, and injected the patient.
- 3,798 patients tested for Hep C from Exeter alone
- 45 cases of hepatitis C infections at hospitals in New Hampshire, Kansas, Maryland, and Pennsylvania.
- Sentenced to 39 years in prison.

David Kwiatkowski
Massachusetts General Hospital (MGH) (Boston, Massachusetts)

• September 2015
• 2 RN’s stole over 16,000 pills from ADS (Mainly oxycodone)
• Count discrepancies totaled over 20,000 missing or incomplete inventories
• Hundreds of missing drug records
• Fined $2.3 million by DEA
Health System Diversion

Healthcare professionals
• Lacking skills and failing to recognize diversion

Physicians as a source
• Using the wrong drug for diagnosis not having the ability to make good decisions
• Addicted to drugs affecting mental health engaged in illegal drug trafficking activities

Pharmacist as a source
• Not checking for the accuracy of physicians’ DEA number receiving phone orders and dispensing or giving out medications based on incomplete information on prescription
Other Health System Diversion

Purchasing department:
• Order more controlled substances than is needed by the facility
• Falsify purchase orders
• Theft of controlled substances after being delivered to receiving areas

Theft from: physicians, pharmacies, and residential properties
Losses: during transportation or from pharmacies
Recognizing Diversion Activity

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.
Essential Components of Diversion Prevention and Detection Program

• Policies to prevent, detect and properly report diversion
• Collaborative relationship between nursing and pharmacy
• Method of surveillance/auditing including concurrent review of medical records
• Prompt attention to surveillance data received
• Collaborative relationship with law enforcement and regulatory agencies
• Education, education and education
Most essential component of any diversion program!

- All-inclusive
- At hire and at least annually
- Emphasize recognition and reporting

Goal – Develop a culture in which employees recognize the risks and feel individual responsibility for reporting
Education

• Tailor to audience
• Clinical Staff and Managers:
  • Methods of Diversion (Managers)
  • Behavioral Clues
  • Physical Signs of Opioid Abuse
  • How to Use Automated Data
• Make it real - use actual cases and examples
Educate Staff to Identify Compromised Vials
Signs of Diversion or 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
Signs of Diversion or 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
- Pattern of holding waste until oncoming shift
Signs of Opioid Abuse

**Physical**
- Constricted pupils
- Itching/Scratching
- Sweating
- Chills
- Runny nose
- Vomiting/Diarrhea
- Anorexia
- Tracks

**Behavioral**
- Malaise/Fatigue
- Euphoria
- Anxiety
- Insomnia
- Depression
- Apathy
- Paranoia
Monitor Staff for Suspicious Activity

• A single suspicious transaction may be easily explained
• Watch for a pattern of activity
• Consider using a “watch list”
• An intensified review may be warranted before you are sure (i.e., review of all ADM transactions and documented administrations)
Audit Frequently

Who are you protecting?
• The organization’s reputation
• The patient
• Family and Friends
• The care givers

With all this technology, what is the risk?
• More sophisticated, more creative tactics
• More harm

Tools often under-utilized
• Lack of awareness
• Off the shelf instillation
• Lack of reporting
• Poor understanding of clinical processes
Auditing

What can we do?
- Learn more about the system used
- Understand the capabilities of reporting
- Use data to report regularly
- Share the information to monitor
- Require reporting and follow through
Auditing

Investigate the system

• What are the recommended settings for the system used?
  • Understand the programming
    • What functions are “on”?
    • What is available that is “off”?  
    • Why is it “off”? (This better be good!)
  • Understand the end user’s view
    • Who authorizes access?
    • What are the settings on access?
    • What are the different access levels?
    • How do these differ in different care areas?
    • Who can override?
    • Who can waste?
    • What authorization is needed?

Setting up your technology to help safely use meds and prevent diversion where possible. The settings then dictate what kind of auditing is possible or needs to be done.
Data to Audit

• Cancelled transactions report
• Discrepancies
• Overrides
• Medication waste

Include in reports:
  • End User name
  • Workstation/Patient care area
  • Medication
  • Date and time of transaction
Data to Audit

• Unusual or high patterns of:
  • Wastage
  • Overrides

• Patterns of “waste buddies”

• Time of transaction patterns

• Volumes of administration at unexpected levels based on patient care area

• Uneven administration to one patient or groups of patients in one area

• Floating nurses with higher than area administration averages, waste, discrepancies and/or override functions
Auditing Process

- **Survey Controlled Substance areas**
  - Pharmacy
  - Medication Rooms

- **Job shadowing**
  - Pharmacy
    - Pharmacists
    - Techs
  - Clinicians in Patient Care Areas
    - Nurses
    - Physicians
    - Mid-Level Staff (NP, PA who have access)

- **Operative Procedures**
  - Pre-op
  - OR
  - Post op
Auditing

Review

• Current Policies and Procedures
  • Are they current?
  • “Work-Arounds”?

• Previous DEA Form 106’s
  • Report of Theft or Loss of Controlled Substances

• Completed DEA form 41’s
  • Registrants Inventory of Drugs Surrendered
  • Used in the disposal or destruction of a controlled substance

• Past purchase orders DEA form 222’s
  • DEA Controlled Substance Order Form
  • Must be used when Schedule I and II are bought, sold or transferred between qualified parties

• Data Reports
  • Management Report Monitoring
  • Utilization Reports
When Diversion Suspected

• Diversion team put on alert
• Verification of data and analysis of situation
• Nurse immediately removed from patient contact or intercepted; drug cabinet access discontinued
• Initial interview of nurse including review of medical record and drug cabinet records
• Suspension pending conclusion of investigation

*Initial notification to the DEA within 24 hours*
Interview Suspected Staff Member

• **Interview**
  • What processes are used?
  • Have they been trained?
  • How often?
  • Proper segregation of duties?
  • Are there back up to staff who perform critical functions?

• **Challenge their knowledge**
  • Staff know where weaknesses are
  • Don’t fail to ask the obvious questions
Diversion Confirmed

- Determine employment disposition
- Report to law enforcement and all relevant state and federal agencies
  - DEA form 106
  - Board of Pharmacy
  - Board of Nursing (RN, LVN, NP)
  - Medical Board (MD, PA, MA)
- Consider billing implications and credit medication charges if necessary
- Assist and educate law enforcement and other agencies involved in investigating or prosecuting case
- Notify patients if applicable
Case Study
(St. Luke’s Hospital, PA)

The Facts

• Dr. A, a 42-year old anesthesiologist, suffered from depression and began using IV narcotics for the past 6 months, which he obtained illicitly from his job at the hospital.

• He sought the help of a psychiatrist after a drug overdose left him unconscious and sent him to the ER, where he was revived.

• After attending only 4 sessions, Dr. A was found dead in the anesthesia on-call room due to an overdose of Demerol, which he had stolen from the hospital, and Prozac, which was prescribed by the psychiatrist.

• The plaintiff’s lawyer filed a $12 million malpractice lawsuit on behalf of Dr. A’s family, his wife and 2 children, against the psychiatrist for failing to prevent his death and against the hospital for failing to prevent him from stealing narcotics.
Case Study

Discovery

• Investigations revealed Dr. A would sign out a quantity of medications at the beginning of each work day from the hospital pharmacy for use in anesthesia.

• However, the hospital failed to account for unused medication at the end of the day and this lapse in security allowed him to divert Demerol for his own use.

• The plaintiff’s lawyer argued that Dr. A’s psychiatrist failed to adequately manage his drug abuse problem, which should have been more actively investigated, documented, and treated.

• According to the defense, Dr. A had denied abusing drugs, claiming he had recently stopped after 6 months of sporadic IV narcotic abuse.
Who was responsible for Dr. A’s death?
The Verdict

• Jury delivered a $5.6 million verdict in favor of Dr. A’s family based upon an economist’s estimate of lost earnings.

• Percentages for comparative negligence – 48% of the fault was attributed to the hospital, 32% to the treating psychiatrist, and 20% to Dr. A
Ways to Prevent Diversion

• Documentation of each step in the chain of custody for all controlled substances
  • Establish electronic ordering methods for CIIs
  • Occasional rotation of personnel
  • Assign job responsibilities so that a single individual doesn’t order and receive controlled substances
  • Lock up all controlled-substances in a central location with 1 person in charge of the key

• Computerized record-keeping controls in nursing units
  • Dosage-unit counts at shift changes, record-of use sheets, duplicate entry of doses administered
  • Require all unused drugs to be sent back to the pharmacy for wasting so the pharmacy can monitor the destruction
  • Automated dispensing cabinets that feature reports that automatically reconcile transactions to rapidly identify discrepancies
Ways to Prevent Diversion

• Inventory-management systems
  • Periodically audit and reconcile records of controlled substances received against purchase records
  • Limit physician access
  • Use computerized physician order-entry
  • Lock up prescription pads in a safe location

• Pre-employment checks
  • Assign 1 or 2 pharmacy employees to assist with all phases of transfer of controlled substances to an expired returns company
  • Design a distribution system in the operating room that will limit the risk of diversion and detect the problem.
Ways to Prevent Diversion

- Have a reliable process for identifying discrepancies and handling discrepancies after they’ve been detected
  - Track doses reported to the pharmacy as administered but not charted
  - Maintain a log of photographs and signatures of staff

- Use a controlled-substance kit prepared by the pharmacy for the OR that contains a selection of controlled-substances agreed upon by the pharmacy and anesthesia staff
  - Randomly test controlled-substances returned to the pharmacy to validate identity and assess purity
  - Refractometer or ultraviolet light waves
Penalties for Drug Diversion (Employee)

Legal consequences
• Criminal record
• Termination of employment
• Loss of professional licensure

Financial consequences
• Individual (Fines imposed by court)
• Employer (Fines imposed by regulatory agency)
• Taxpayer (Cost to house inmate and court costs)
Penalties for Drug Diversion (Hospital)

Regulatory Consequences
- Loss of DEA Registration
- Loss of BOP License

Financial consequences
- Fines imposed by DEA
- Fines imposed by BOP
- Chargebacks by individual insurance carriers / CMS
Penalties for Drug Diversion

• The Office of Diversion Control’s Title 21 “Unites States Code (USC) Controlled Substances Act, Part D - Offenses and Penalties” lists the various unlawful acts and the penalties

• Penalties could be imprisonment, fines, or both

• For specific examples go to: http://www.deadiversion.usdoj.gov/21cfr/21usc/21idusct.htm
Federal Narcotic Trafficking Penalties

- Vary depending upon the drug, schedule of drug, quantity, number of prior offenses, harm caused, and number of individuals involved.

Penalties for trafficking Fentanyl (Schedule II)-400 gms or more mixture:
- First Offense: ≥ 10 yrs, and ≤ life. If death or serious injury: ≥ 20 yrs and ≤ life. Fine of ≤ $4 million if an individual, ≤ $10 million if not an individual.
- Second Offense: ≥ 10 yrs, and ≤ life. If death or serious injury life imprisonment. Fine of ≤ $8 million if an individual, ≤ $20 million if not an individual.
- Two or More Prior Offenses: Life imprisonment.

For more information go to http://www.usdoj.gov/dea/agency/penalties.htm
Drug diversion involves the use of legal drugs for illegal purposes and can occur through patients, physicians, pharmacists, pharmaceutical companies, thefts and losses.

Agencies and programs such as the FDA, DEA, BOP, BRN, and Medical Board help to prevent drug diversion by the use of various regulations and acts such as the CSA, chemical diversion act, and trafficking act.

Pharmacists have an ethical, professional, personal, and a legal responsibility to control prescription drug abuse and diversion.

The penalties for trafficking ranges from fines, to life imprisonment, and depend upon the schedule of drug, quantity, harm caused, number of prior offenses and individuals involved.

A strong diversion detection and management system must include a multi-disciplinary team of health care providers and adequate surveillance.
What may be considered drug diversion in your hospital?

A. Giving patients more medication to control pain
B. Taking home CS waste that was to be destroyed
C. Removing 2 tablets of Norco and only giving patient 1 without returning the other
D. Both B and C
Both B and C:

- Taking home CS waste that was to be destroyed
- Removing 2 tablets of Norco and only giving patient 1 without returning the other

The Answer IS…..
What two pain drugs are frequently abused?

A. OxyContin and Vicodin
B. Valium and Xanax
C. Marijuana and Cocaine
D. Ritalin and Adderall
E. Anadrol and Equipoise
F. Tobacco
The top 2 pain relievers frequently abused are:

- OxyContin and Vicodin
What agency oversees controlled drugs?

A. The Food and Drug Administration (FDA)
B. California State Board of Pharmacy (BOP)
C. The Drug Enforcement Agency (DEA)
D. All of the Above
What agency oversees controlled drugs?

✓ The Drug Enforcement Agency (DEA)
References


Session Code:

1. Write down the course code. Space has been provided in the daily program-at-a-glance sections of your program book.

2. To claim credit: Go to www.cshp.org/cpe before December 1, 2016.