Infectious Risks of Drug Diversion
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Outline

• Background
• CDC Recommendations
• Outbreaks
• Summary
• Resources

Transmission of Pathogens

Infectious Person → Contaminated Medication or Equipment → Susceptible Person

*National Institute of Diabetes and Digestive and Kidney Diseases, National Institutes of Health*
Infectious Risks of Unsafe Injections

- **Hepatitis B virus**
  - High viral load, can cause infection in the absence of visible blood
  - Stable in the environment for 1 week or longer

- **Hepatitis C virus**
  - Can cause infection in the absence of visible blood
  - Stable in the environment for up to 1 week dried and up to 3 weeks in suspension

- **HIV**
  - Does not generally survive well in the environment
  - Can survive in syringes for several days
  - Has been transmitted from patient to patient in the outpatient setting
    - In one case, mode of transmission was suspected to be contamination of multi-dose vials of saline
Infectious Risks of Unsafe Injections

• Bacterial
  ➢ Respiratory flora
  (e.g., spinal injections performed without a mask)
  ➢ Miscellaneous from contaminated medication
  (e.g., Serratia marcescens, Staphylococcus aureus, Klebsiella oxytoca, Enterobacter cloacae)

CDC Recommendations

Diversion: Patient Safety Threat

• Failure to receive prescribed medication
  ➢ Resulting in inadequate pain management
• Exposure to substandard care from an impaired healthcare provider
• Exposure to life-threatening injections
• Patient harm may be overlooked
Mechanisms of Diversion by Healthcare Personnel

• False documentation
  ➢ Medication dose not administered to the patient or “wasted” but instead saved for use by the provider

• Theft by tampering
  ➢ Removal of medication and replacement with saline or other similar-appearing solution

Mechanisms of Diversion by Healthcare Personnel

• Scavenging of wasted medication
  ➢ Removal of residual medication from used syringes

CDC Provider Diversion Web Page

http://www.oneandonlycampaign.org/content/risks-healthcare-associated-infections-drug-diversion
U.S. Outbreaks Associated with Diversion, 2003-2013

- At least 6 documented outbreaks
  - 4: HCV transmission by HCV-infected healthcare personnel
  - 2: Gram-negative bacteremia
- >100 cases
- >25,000 patients placed at risk of infection

Bacterial Outbreaks

Outbreak of Gram-Negative Bacteremia, Minnesota 2011

- Cluster of 4 patients on surgical unit with bacteremia (*Ochrobactrum anthropi*)
  - All had received hydromorphone administered by PCA
- Investigation focused on possible sources of bacteremia, including diversion
  - Review of narcotic access logs during outbreak period identified specific nurse
Outbreak of Gram-Negative Bacteremia, Minnesota 2011

- Nurse admitted to obtaining narcotic bags from locked boxes, withdrawing narcotic from the bag and replacing the displaced liquid with saline
  - Testing of saline bottle from nurse’s desk identified bacteria
- Surveillance identified additional 25 patients
- Nurse sentenced to 2 years in prison

Hepatitis C Outbreaks

Hepatitis C Outbreak, Colorado 2009

- Public health identified 2 patients with acute hepatitis C virus (HCV) who shared a common link with a hospital
  - Patients had undergone surgical procedures at same hospital
  - Both had HCV genotype 1b infection
- Investigation revealed HCV-infected surgical technician stole syringes filled with fentanyl that had been left unlocked in the OR
- Technician injected self with fentanyl, refilled syringes with saline, returned contaminated saline syringe to fentanyl supply in OR
Hepatitis C Outbreak, Colorado 2009

- At least 18 patients infected; >8,000 patients notified
  - Notification included ambulatory surgery center that employed tech after she was fired from hospital and NY hospital where tech worked prior to the CO hospital
- In 2010, tech sentenced to 30 years in prison

Radiology Technician Diverting in Several States

When Drug Addicts Work in Hospitals, No One is Safe

- Worked in temporary jobs at hospitals in seven states
- 2010: Fired after an employee found him passed out in bathroom with a syringe floating in the toilet
- 2012: Later found to be stealing fentanyl syringes from surgical patients in New Hampshire
- CDC recommended 12,000 patients be tested
- Infected at least 45 people with HCV; one died
- 2013: Sentenced to 39 years for causing a multistate outbreak
Diversion/Substitution in New York State

- 2016: Nurse sentenced to five years probation for diverting narcotics, substituting with saline, and returning to stock
- 2016: Nurse fired for diversion is arrested for sneaking back into facility, convincing a co-worker to sign out narcotics, diverting and substituting with tap water, and returning meds to coworker for returning to stock
- 2013: Nurse sentenced to 3 years probation for creating false entries in medical records to conceal diversion

October 6, 2015: Albany NY, VA Hospital Nurse Charged with Syringe Tampering

Available Now!
NYSDOH Provider Diversion Podcast

Featuring interview of provider diversion expert Kimberly New, JD, RN, BSN, by NYSDOH Commissioner Dr. Howard Zucker, MD, JD
Summary

• These outbreaks revealed gaps in prevention, detection and response to drug diversion
• Healthcare facilities need strong narcotics security measures and active monitoring systems
• Appropriate response by healthcare facilities includes
  ➢ Prompt reporting
  ➢ Assessment of harm
  ➢ Consultation with public health officials

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References

References
Warner et al. Outbreak of HCV infection associated with narcotics diversion by an HCV-infected surgical technician. AJIC 2015;43:53-8

Resources
http://www.cdc.gov/injectionsafety/

Safeguarding Controlled Substances
Rick Boettcher, Investigator
Bureau of Narcotic Enforcement
January 4, 2019
Bureau of Narcotic Enforcement Overview

BNE MISSION

• To combat illegal use of and trade in controlled substances

• To allow legitimate use of controlled substances in health care . . . and other uses authorized by this article or other law

Bureau of Narcotic Enforcement
LEGAL AUTHORITY—OVERSIGHT of CONTROLLED SUBSTANCE ACTIVITIES

• Public Health Law, Article 33
• Addresses:
  – General Provisions: e.g., definitions, prohibited acts, schedules of controlled substances
  – Manufacture and Distribution of Controlled Substances
  – Research, Instructional Activities and Chemical Analysis Relating to Controlled Substances

LEGAL AUTHORITY

• Public Health Law, Article 33 (Cont.)
  – Dispensing to Ultimate Users: prescription requirements, dispensing requirements, reports and records
  – Medical Marijuana Program
  – Records and Reports: inspection of records, confidentiality of records
  – Offenses, Violations and Enforcement

LEGAL AUTHORITY

• NY Code of Rules and Regulations (NYCRR)
  – Title 10
    • Part 80, Part 910 and Part 1004
KEY PROVISIONS OF PUBLIC HEALTH LAW

• NYS PHL Article 3304.1
  **Prohibited Acts**
  It shall be unlawful for any person to manufacture, sell, prescribe, distribute, dispense, administer, possess, have under their control, abandon or transport a controlled substance except as expressly allowed by this article.

• NYS PHL 3374—Notification by licensee
  • Persons licensed . . . pursuant to this article shall be under a continuing duty to promptly notify the department of each incident or alleged incident of theft, loss or possible diversion of controlled substances manufactured, ordered, distributed or possessed by such person.

Safeguarding Controlled Substances
SAFEGUARDING and RESPONSIBILITY

• Responsibility  NYCRR 80.6

- The administrative head of a licensed facility . . . is responsible for the safeguarding and handling of controlled substances within the . . . facility.

SAFEGUARDING and RESPONSIBILITY

• Required Reports and Activities

Controlled Substance Recordkeeping
NYS PHL  Article 3397

• Fraud and Deceit

No person shall obtain or attempt to obtain a controlled substance... by fraud, deceit, misrepresentation, or subterfuge or... willfully make a false statement in any prescription, application, report or record required by this article.

REQUIRED RECORDS

• NYS PHL 3342

An institutional dispenser shall maintain records of all controlled substances dispensed and administered in such manner as the commissioner shall, by regulation, require.

REQUIRED RECORDS

• NYCRR 80.48 A (2)

A separate record, at the main point of supply for controlled substances showing the type and strength of each drug in the form of a running inventory indicating the dates and amounts of such drugs – received from other persons and their distribution or use.
REQUIRED RECORDS

• **NYCRR 80.48 4(b)**
  – Records of Controlled Substances received shall include date of receipt, name and address of vender, and type / quantity of drugs received.
  – A duplicate invoice or separate itemized list furnished by the vender will satisfy this requirement provided it provides all necessary information and is maintained in a separate file.
  – Separate copies of Federal order forms for C-IIIs must be retained.

January 4, 2019

REQUIRED RECORDS

• **NYCRR 80.48 A (3)**
  – A record of authorized requisitions for such drugs for distribution to substations or wards.
  – Record must show signature of person authorized at such substation or ward to show receipt at such substation or ward.
  – Type of CS, dose and number of doses furnished to the substock.
  – With each substock of C-IIIs, an administration sheet shall be furnished.

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REQUIRED RECORDS

• **NYCRR 80.48 A (1)**
  – An order signed by prescriber specifying the Controlled Substance medication indicated for the patient.
REQUIRED RECORDS

• NYCRR 80.48 (4)
  – A record in the patient’s chart indicating administration of the controlled substance including name of the administering attendant and date and hour of administration.

REQUIRED RECORDS

• NYCRR 80.48 A (3) ii
  – Administration sheet must list:
    • Name of drug
    • Date and hour of administration
    • Name of patient
    • Name of prescriber
    • Quantity of administration
    • Balance on hand after each administration
    • Signature of administering nurse

REQUIRED ACTIVITIES

• NYCRR 80.46 f (7)
  Doses of controlled substances shall be withdrawn from the container immediately before administration is to be made to the patient.
REQUIRED ACTIVITIES

• NYCRR 80.51
  Single unit doses or partial doses remaining after the administration . . . of a portion of a liquid or solid unit dose of a controlled substance may be destroyed on the premises . . by a pharmacist or a nurse provided that . . .

• NYCRR 80.51 cont’d
  ...a notation is made on the administration record sheet
  and
  the destruction is witnessed by a second pharmacist or nurse or other responsible person designated by the administrator.

Chemical Dependency
Signs and Symptoms
CHEMICAL DEPENDENCY

• Job Performance and Attendance
  - Late to work
  - Disregards standards of care
  - Frequent breaks or time away from floor
  - Disorganized
  - Unreasonable excuses for poor performance
  - Inappropriate behavior
  - Increase use of sick time
  - Appears on unit on days off

CHEMICAL DEPENDENCY

• Physical Symptoms
  - Difficulty with speech
  - Shakiness
  - Inattentive
  - Alcohol on breath
  - Flushed face
  - Gastric upset
  - Constant complaint of “not feeling well”

CHEMICAL DEPENDENCY

• Behavioral Changes
  - Mood swings
  - Drowsiness at work
  - Paranoid behavior
  - Unduly sensitive to criticism
  - Inability to separate truth from fiction
  - Depression
  - Poor personal appearance
CHEMICAL DEPENDENCY

- On-duty Indicators
  - Unwitnessed or excessive wasting
  - Inconsistencies with patient PRN doses required from shift to shift
  - Discrepancies with the drug counts
  - Patients complaining of not receiving their medications
  - Medicating of patients assigned to other nurses

Consequences of Controlled Substance Diversion

CONSEQUENCES

- Violations of Public Health Law and its corresponding Rules and Regulations can result in civil charges with actions ranging from a warning to fines of several thousand dollars and a potential loss of license.
CONSEQUENCES

- Violations of NYS Penal Law can result in arrest and conviction on Felony and/or Misdemeanor charges resulting in penalties including fines, probation, in-patient rehabilitation, jail time or all of the above.

PENAL LAW VIOLATIONS

- Criminal Possession of a Controlled Substance – Class A Misdemeanor up to A-1 Felony
- Falsifying Business Records – Class E Felony 1st
- Reckless Endangerment – Class D Felony 1st
- Assault – Class B felony 1st
- Forgery
- Larceny

SUMMARY

- Nurses authority to access, temporarily possess, and administer controlled substances is granted by NYS PHL Article 3305.1c

- Types of tamper-proof packaging include:
  - flip tops on vials
  - snap offs on tubexes and carpujects
  - foil or plastic seals on unit dose solid oral doses
SUMMARY

• Always have waste witnessed and waste the remainder of the dose in a manner that makes it impossible to reclaim

• If you are the nurse administering the medication - you should be the nurse who signed out the medication

SUMMARY

• Document, document, document everything you do with a controlled substance from withdrawal - to administration - to waste

• Report any tampering or suspicious activity to your supervisor

Questions?