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*
Transmission of Pathogens

Infectious Person → Contaminated Medication or Equipment → Susceptible Person

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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
Infectious Risks of Unsafe Injections

• 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

Injection Safety

Injected medicines are commonly used in healthcare settings for the prevention, diagnosis, and treatment of various illnesses. Unsafe injection practices put patients and healthcare providers at risk of infectious and non-infectious adverse events and have been associated with a wide variety of procedures and settings. This harm is preventable. Safe injection practices are part of Standard Precautions and are aimed at maintaining basic levels of patient safety and provider protections. As defined by the World Health Organization, a safe injection does not harm the recipient, does not expose the provider to any avoidable risks and does not result in waste that is dangerous for the community. Visit the page on CDC’s role in safe injection practices.

Public Health Education Resources

Information for Providers
Slide presentations, FAQs...

Information for Patients
Resources for Patients and family, FAQs, Syringe Reuse...

Patient Notification Toolkit
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

Risks of Healthcare-associated Infections from Drug Diversion

When prescriptive medicines are obtained or used illegally, it is called drug diversion. Addiction to prescription narcotics called opioids has reached epidemic proportions and is a major driver of drug diversion. This webpage focuses on diversion involving healthcare providers who steal controlled substances such as opioids for their own use. This can result in several types of patient harm including:

- Substandard care delivered by an impaired healthcare provider;
- Denial of essential pain medication or therapy;
- Risk of infection (e.g., with hepatitis C virus or bacterial pathogens) if a provider tampers with injectable drugs.

Outbreaks

CDC and state and local health departments have assisted in the investigation of infection outbreaks stemming from drug diversion activities that involved healthcare providers who tampered with injectable drugs. A summary of recent outbreaks is illustrated in the following timeline.

U.S. Outbreaks Associated with Drug Diversion by Healthcare Providers, 1983-2013

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
When Drug Addicts Work in Hospitals, No One is Safe

Eichenwald, K. When drug addicts work in hospitals, no one is safe. Newsweek; 2015, June.
Radiology Technician Diverting in Several States

- 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
Acknowledgments

• Melissa Schaefer, MD
  Division of Healthcare Quality Promotion - CDC

• Mary Beth Wenger
  Health Communications Specialist
  Public Affairs Group - NYSDOH
References


References


Resources

http://www.cdc.gov/injectionsafety/
Safeguarding Controlled Substances

Rick Boettcher, Investigator

Bureau of Narcotic Enforcement
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
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.
KEY PROVISIONS OF PUBLIC HEALTH LAW

- **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
• 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 vendor, and type / quantity of drugs received.
  - A duplicate invoice or separate itemized list furnished by the vendor 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.
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,
  - and type of CS, dose and number of doses furnished to the substock,
  - With each substock of C–IIIs, an administration sheet shall be furnished.
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 . . . .
REQUIRED ACTIVITIES

• 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.
• 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?
BUREAU OF NARCOTIC ENFORCEMENT

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