Drug Diversion and Safe Injections: Risks, Recommendations, & Resources

Oregon Public Health Division
Healthcare-Associated Infections HAI Program
Drug diversion can lead to infection

Hepatitis C concerns prompt response from McKay-Dee Hospital

4,800 patients have been notified about possible exposure to the virus

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- Hepatitis C virus (HCV) positive (genotype 2b) healthcare worker (HCW) fired November 2014 for diverting medication
- Former emergency room patient subsequently diagnosed with genotype 2b HCV infection
- HCV strain match, plus lack of other risk factors, led authorities to link cases
- Utah Department of Health notifies 4,800 patients of potential exposure, offering testing and counseling

GRAYSON, Kentucky: “Prosecutors said a former Carter County paramedic […] stole fentanyl from the EMS storage center for her own personal use [and] would replace the empty vials of fentanyl with saline and glue the caps back on to conceal her theft.”
Hepatitis C outbreak, Colorado 2009

- Colorado Department of Public Health & Environment received reports of two acute HCV infections in patients who had undergone surgery at the same hospital
- HCV-infected surgical technician stole fentanyl syringes that had been pre-drawn by anesthesia staff and left unlocked in the operating room (OR)
- HCW refilled contaminated syringes with saline to swap with fentanyl syringes

At least 18 patients infected; over 8,000 patients notified
- Notification included an ambulatory surgery center (ASC) that employed the HCW after being fired from CO hospital, and NY hospital of previous employment
- HCW sentenced to 30-year prison term

Multistate HCV outbreak, 2012

- 45 cases of HCV in New Hampshire, Kansas & Maryland associated with radiology technician
- HCW also diverted opiates in Michigan, Arizona, New York, and Pennsylvania
- Investigation reveals holes in licensure, certification, placement, hospital detection programs, and peer/supervisor reporting
- HCW sentenced to 39 years in prison

Article discusses six outbreaks over the 10 year period beginning in 2004

Implicated HCW: three technicians and three nurses

Two outbreaks: tampering with opioids administered via patient-controlled pumps, associated with bacterial infections in 34 patients

Four outbreaks: tampering with fentanyl syringes or vials

- HCV infection was transmitted from infected HCW to 84 patients
- Nearly 30,000 patients were potentially exposed and contacted regarding bloodborne pathogen testing
U.S. Outbreaks Associated with Drug Diversion by Healthcare Providers, 1983-2013

- **Bacterial outbreak**
- **Hepatitis C virus (HCV) outbreak**

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

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

**1999:** 26 cases of *Serratia marcescens* bacteremia associated with a respiratory therapist at a Pennsylvania 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.

http://www.cdc.gov/injectionsafety/drugdiversion/
Why what we know is just the tip of the iceberg

- **Underestimated infections**
  - Infections (especially HCV) may go undetected for years
  - Difficult to identify infected patients and link them to HCWs diverting drugs

- **Underreported drug diversion**
  - Healthcare facilities are reticent to publicize these events, especially if risk to patients appears low
  - Misaligned incentives on the part of agencies who place HCWs
  - “Culture of silence” among HCWs who witness substance abuse among co-workers
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Figure 2. Rates of opioid overdose deaths, opioid sales, and opioid substance abuse treatment admissions, United States, 1999-2010

Context: Substance abuse in HCW tracks with population at large

- 10-12% of physicians will develop substance use disorder during careers\(^1,2\)

- 5 year British Medical Journal (BMJ) study found that physicians with substance use disorders are
  - 87% male
  - **36% abused opioids**
  - 50% abused alcohol
  - 14% history of IDU

- Less data on non-physician HCW substance abuse, but diversion documented in these HCWs

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1. Hughes, JAMA, 1992
Mechanisms of diversion

• False documentation (e.g., medication not administered to the patient or “wasted” and instead used by the HCW)

• Scavenging of wasted medication (e.g., removal of residual medication from trash or used syringes)

• Theft by tampering (e.g., removal of medication from a container or syringe and replaced with similarly appearing solution that may be administered to patients)
Risks to patients

• Patient safety is compromised whenever drug diversion by HCWs occur

• Harms can include
  – Failure to receive prescribed medication (including pain management)
  – Exposure to substandard care from an impaired HCW
  – Exposure to potentially life-threatening infections

Berge KH et al. Mayo Clin Proc. 2012;87(7);
Schaefer MK, Perz JF. Mayo Clinic Proc.2014; 89 (6)
Resource: CDC injection safety website

http://www.cdc.gov/injectionsafety/drugdiversion/
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https://www.cdc.gov/injectionsafety/drugdiversion/index.html
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Prevention Resources:
- National Association of Drug Diversion Investigators
- Minnesota Hospital Association Drug Diversion Prevention Toolkit
- Drug Diversion in Hospitals: A Guide to Preventing and Investigating Diversion Issues
- CDC Public Health Ethics Case Study, Unsafe Injections: Duty to Warn
- Premier Inc. Drug Diversion Website
- Substance Abuse and Mental Health Services Administration
- National Institute on Drug Abuse (NIDA)

Enforcement Agencies:
- Drug Enforcement Administration
- FDA Office of Criminal Investigations

State Health Department Reports:
- Minnesota Controlled Substance Diversion Prevention Coalition
- New Hampshire Hepatitis C Outbreak Report
- Public Health Vulnerability Review: Drug Diversion, Infection Risk

Videos, Blogs, News, and Podcasts:
- Podcast on Healthcare Provider Diversion/Substitution from NY One & Only Campaign
- Making Lemons: One CRNA's Story of Addiction and Recovery – American Association of Nurse Anesthetists Video Lecture
- Drug Diversion in Healthcare Settings - NEW Medscape Video Commentary
- CDC Shares Resources on the Risks of Healthcare-associated Infections from Drug Diversion
- Drug Diversion Define: Steps to Prevent, Detect, and Respond to Drug Diversion in Facilities (CDC's Safe Healthcare Blog, June 20, 2014)
- Drug Diversion Define: Consequences for Hospitals and Other Healthcare Facilities (CDC's Safe Healthcare Blog, June 11, 2014)
- Drug Diversion Define: A Patient Safety Threat (CDC's Safe Healthcare Blog, June 3, 2014)
- Outbreaks Highlight Infection Risks Associated with Drug Diversion (CDC's Safe Healthcare Blog, June 2, 2014)
- Drug Diversion in Healthcare Settings Can Put Patients At Risk for Viral Hepatitis
- Doctors, medical staff on drugs put patients at risk
- Why Aren't Doctor's Drug Tested?
- Hospitals Address Drug Problem

https://www.cdc.gov/injectionsafety/drugdiversion/index.html
Resource: DEA Page on drug diversion

Are You Illegally Purchasing Prescription Drugs Online?

Registration Support
- Call: 1-800-882-9539 (8:30 am–5:50 pm ET)
- Email: DEA.Registration.Help@usdoj.gov
- Locate Field Registration Specialists

- New Applications
- Renewal Applications
- Registration Changes (Address, Drug Code, Name, Schedule)
- CMEA (Combat Meth Epidemic Act)
- Registration for Disposal of Controlled Substances
- Duplicate Certificate Request
- Duplicate Receipt of Registration
- Order Forms (DEA 223)
- Registration Validation

http://www.deadiversion.usdoj.gov/pubs/brochures/drug_HC.htm
Recommendations resulting from multistate 2012 HCV outbreak

• Increase regulation and information sharing across healthcare facilities
  – Interstate staffing agencies need to be regulated
  – National Data Bank should include information on allied health professionals and be accessible to healthcare facilities
  – Licensing boards should not rely on self report

• Strengthen healthcare systems to promote early detection of drug diversion
Recommendations resulting from multistate 2012 HCV outbreak

- Recommendations to strengthen detection
  - Limit access to controlled substances
  - Improve processes for medication preparation and use
  - Ensure accountability
  - Enhanced oversight
  - Minimize mobile medication boxes
  - Comprehensive approach to drug diversion
  - Clear action plan for suspected drug diversion
Limit access to controlled substances

• Integrate automated access to controlled substances with HCW schedules
  – HCWs found to be diverting drugs often found coming in when not scheduled or offering to help when not scheduled

• Document presence of HCW at procedures in patient medical records

• If possible, use biometrics to allow access to controlled substances

Improve processes for medication preparation & use

• Whenever possible, controlled substances should not be prepared ahead of time

• If medications are prepared in advance, keep and maintain in a locked drawer or cabinet
  – Leaving a pre-filled syringe on top of a Pyxis machine may enhance procedure flow, but medications may be out of sight

• Controlled substances should not follow patients when transferred
  – Waste at end of procedure
  – New vial in recovery room

Ensure accountability

• “Time out” for controlled substances procedure end, similar to process for counting surgical instruments
  – Document amount dispensed (administered and unused)

• If discrepancy identified, lockdown to locate substance before HCWs leave room
  – If not found, mandatory drug test for all HCW present

• Process for wasting clearly communicated
  – Investigate any wasting of full vial; comprehensive review if repeated
  – Controlled substances in non-procedure setting: meaningful observer (HCW to observe dispensing, administration, and wasting)

Enhanced oversight

- Pyxis should be in visible location
  - If possible, visible from nursing station or control room

- Perform manual audits of Pyxis at random times

- To the extent possible, integrate information
  - Auto-checks to see if amount dispensed = amount given + wasted + returned
  - Programmed alert to detect patients getting significantly higher dose than usual/average

Minimize mobile medication boxes

• All mobile medication boxes should be locked
• Boxes should stay in pharmacy under second lock until signed out to HCW
• Clinician/pharmacist unseal box, check contents together and sign off, then lock
• Box only unlocked only when needed
• Wasting to occur in location where medication administered

Comprehensive approach to drug diversion

• Dedicated staff to address drug diversion
  – Could be task force or single person

• Review concept with each unit supervisor, assess gaps, return to review remediation

• Regular education on signs/symptoms of being under the influence

• Formal process of reporting concerns in place and accessible
  – Consider a system for anonymous reporting

Comprehensive approach to drug diversion

• All staff must sign policy prior to employment
  – Mandatory drug testing for suspected mishandling, including suspect behavior
  – All staff, regardless of suspicion or history, may be tested when materials (such as empty syringes) are found

Clear action plan for suspected drug diversion

• Place implicated HCW on leave
• Report to law enforcement
  – Relationships help!
  – Law enforcement should identify a specific contact to handle these calls
• Report as an adverse event; report to licensing board and to Data Bank
• Notify health department
  – Can help with investigation and notification, if needed
• Test implicated HCW for bloodborne pathogens

From New Hampshire Division of Public Health Services report, available:
Outbreaks of Infections Associated With Drug Diversion by US Health Care Personnel

Melissa K. Schaefer, MD, and Joseph F. Perz, DrPH

**TABLE 2. Steps for Health Care Facilities to Address Patient Safety When Drug Diversion Is Identified**

1. Prevent further risk to patients at the facility
   a. Remove the implicated health care professional from the clinical environment and revoke any previously authorized access to controlled substances (eg, suspend computerized access to automated medication dispensing machines) pending further investigation
   b. Evaluate security of controlled substances to address gaps in adherence to recommended and required practices

2. Prevent risk to patients at other health care facilities
   a. Engage law enforcement
      i. Local law enforcement
      ii. Drug Enforcement Administration (DEA)
         a. DEA registrants are required to notify the DEA of the theft or significant loss of any controlled substance within 1 business day of discovery of such loss or theft
      iii. Food and Drug Administration Office of Criminal Investigation, particularly if product tampering, including substitution, is suspected
   b. File report with applicable licensure agencies (eg, physician or nursing board, state board of pharmacy)

3. Assess retrospective risk to patients
   a. Attempt to ascertain the mechanism(s) of diversion used by the implicated health care professional
      i. Were injectable medications diverted?
      ii. Was any type of tampering with injectable medication performed? If yes, assess potential for patients to be exposed to the health care professional’s blood (eg, through swapping with syringes previously used by the health care professional)
   b. If tampering with injectable medication is suspected, pursue blood-borne pathogen testing of the implicated health care professional
   c. Use information from steps 3a-b to determine need for patient notification and testing. This should be performed in consultation with the local or state health department
Risks of Healthcare-associated Infections from Drug Diversion

When prescription 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, or
- Risks 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
Thank you for your collaboration to improve care for Oregonians!

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