Outbreaks of Infections Associate with Drug Diversion by US Health Care Personnel

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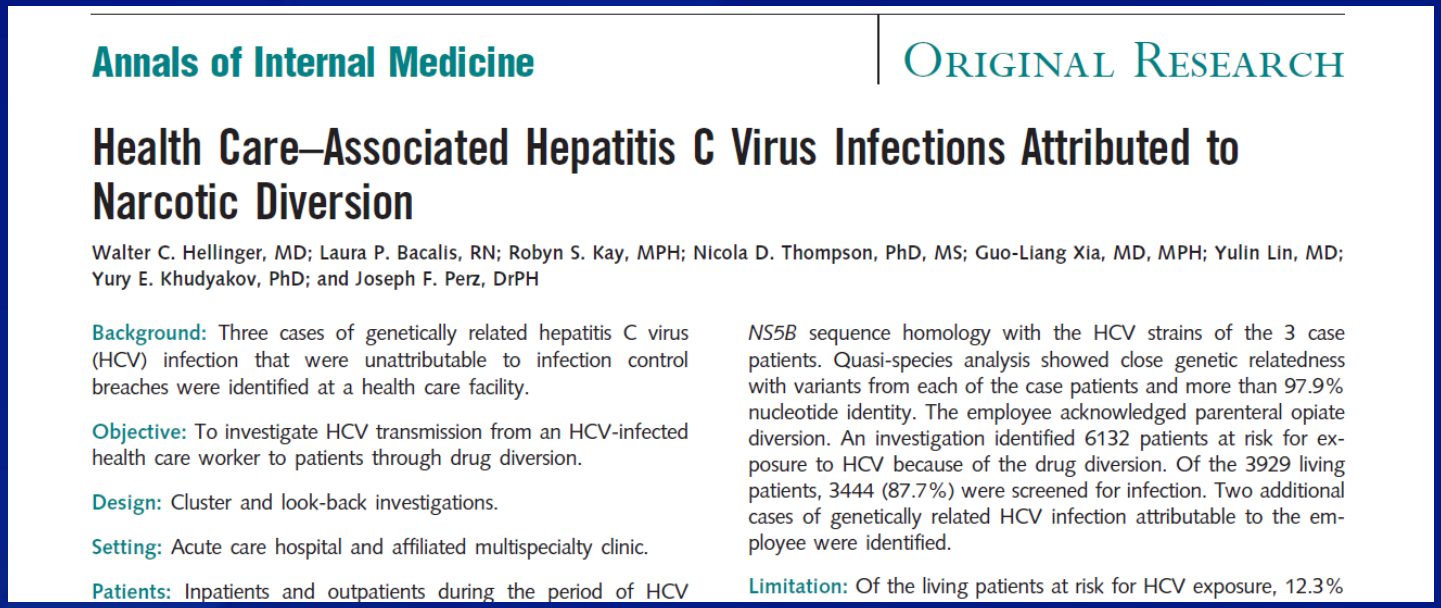
June 26, 2014

Speaker Disclosures

- Disclosures: None
- The findings and conclusions in this presentation are those of the author and do not necessarily represent the official position of the Centers for Disease Control and Prevention

Emerging Issue: Diversion & Tampering



Annals of Internal Medicine | ORIGINAL RESEARCH

Health Care–Associated Hepatitis C Virus Infections Attributed to Narcotic Diversion

Walter C. Hellinger, MD; Laura P. Bacalis, RN; Robyn S. Kay, MPH; Nicola D. Thompson, PhD, MS; Guo-Liang Xia, MD, MPH; Yulin Lin, MD; Yury E. Khudyakov, PhD; and Joseph F. Perz, DrPH

Background: Three cases of genetically related hepatitis C virus (HCV) infection that were unattributable to infection control breaches were identified at a health care facility.

Objective: To investigate HCV transmission from an HCV-infected health care worker to patients through drug diversion.

Design: Cluster and look-back investigations.

Setting: Acute care hospital and affiliated multispecialty clinic.

Patients: Inpatients and outpatients during the period of HCV

NS5B sequence homology with the HCV strains of the 3 case patients. Quasi-species analysis showed close genetic relatedness with variants from each of the case patients and more than 97.9% nucleotide identity. The employee acknowledged parenteral opiate diversion. An investigation identified 6132 patients at risk for exposure to HCV because of the drug diversion. Of the 3929 living patients, 3444 (87.7%) were screened for infection. Two additional cases of genetically related HCV infection attributable to the employee were identified.

Limitation: Of the living patients at risk for HCV exposure, 12.3%

The National Association of Drug Diversion Investigators defines drug diversion as “any criminal act or deviation that removes a prescription drug from its intended path from the manufacturer to the patient.”

Diversion: Patient Safety Threat

Patient safety is compromised whenever diversion by healthcare personnel occurs

Harms can include:

- Failure to receive prescribed medication
  - Resulting in failure to obtain adequate pain management
- Exposure to substandard care from an impaired provider
- Exposure to life-threatening infections

Mechanisms of Diversion by Healthcare Personnel

- False documentation (e.g., medication dose not actually administered to the patient or "wasted" but instead saved for use by the provider)
- Scavenging of wasted medication (e.g., removal of residual medication from used syringes)
- Theft by tampering (e.g., removal of medication from a medication container or syringe and replacement with saline or other similarly appearing solution that may be administered to patients)

MAYO CLINIC

ORIGINAL ARTICLE

Outbreaks of Infections Associated With Drug Diversion by US Health Care Personnel

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

Abstract

Objective: To summarize available information about outbreaks of infections stemming from drug diversion in US health care settings and describe recommended protocols and public health actions.

Patients and Methods: We reviewed records at the Centers for Disease Control and Prevention related to outbreaks of infections from drug diversion by health care personnel in US health care settings from January 1, 2000, through December 31, 2013. Searches of the medical literature published during the same period were also conducted using PubMed. Information compiled included health care setting(s), infection type(s), specialty of the implicated health care professional, implicated medication(s), mechanism(s) of diversion, number of infected patients, number of patients with potential exposure to bloodborne pathogens, and resolution of the investigation.

Results: We identified 6 outbreaks over a 10-year period beginning in 2004; all occurred in hospital settings. Implicated health care professionals included 3 technicians and 3 nurses, one of whom was a nurse anesthetist. The mechanism by which infections were spread was tampering with injectable controlled substances. Two outbreaks involved tampering with opioids administered via patient-controlled analgesia pumps and resulted in gram-negative bacteremia in 34 patients. The remaining 4 outbreaks involved tampering with syringes or vials containing fentanyl; hepatitis C virus infection was transmitted to 84 patients. In each of these outbreaks, the implicated health care professional was infected with hepatitis C virus and served as the source; nearly 30,000 patients were potentially exposed to bloodborne pathogens and targeted for notification advising testing.

Conclusion: These outbreaks revealed gaps in prevention, detection, and response to drug diversion in US health care facilities. Drug diversion is best prevented by health care facilities having strong narcotics security measures and active monitoring systems. Appropriate response includes assessment of harm to patients, consultation with public health officials when tampering with injectable medication is suspected, and prompt reporting to enforcement agencies.

http://www.mayoclinicproceedings.org/article/S0025-6196(14)00342-5/fulltext

Background and Methods

- CDC frequently assists health departments and institutions with investigations of outbreak involving healthcare exposures, including diversion
- We reviewed internal records and CDC- or state health department-authored reports pertaining to diversion-related outbreaks
- Performed searches of published medical literature
- Focused on period extending from 2000-2013
- Excluded outbreaks occurring outside the US

U.S. outbreaks associated with diversion by healthcare personnel, 2003-2013

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

http://www.mayoclinicproceedings.org/article/S0025-6196(14)00342-5/fulltext

Bacterial Outbreaks

Outbreak of *A. xylosoxidans* bacteremia, Illinois 2006

- Cluster of *Achromobacter xylosoxidans* bacteremia on a medical-surgical unit
- All 9 cases had received morphine via PCA pump prior to development of bacteremia
- 1 nurse had worked during period from hospital admission to before fever onset for all 9 patients
  - Nurse resigned from hospital upon being informed of her association with the cases
- Investigators hypothesized nurse may have substituted contaminated water for morphine or used contaminated needle/syringe to extract morphine from cartridges

Behrens-Muller et al. Investigation and Control of an Outbreak of *A. xylosoxidans* Bacteremia. ICHE 2012, 33:180-184

Outbreak of *A. xylosoxidans* bacteremia, Illinois 2006 cont.

- 9 cases
- No disciplinary action occurred

Behrens-Muller et al. Investigation and Control of an Outbreak of *A. xylosoxidans* Bacteremia. ICHE 2012, 33:180-184

Outbreak of gram-negative bacteremia, Minnesota 2011

- **Cluster of 4 patients on surgical unit with bacteremia (*Ochrobactrum anthropi*)**
  - All had received hydromorphone administered by patient controlled analgesia pumps (PCA)
- **Investigation focused on possible sources of bacteremia, including diversion**
  - Review of narcotic access logs during outbreak period identified specific nurse
- **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

http://www.health.state.mn.us/divs/idepc/dtopics/hai/drugdiversionreport.pdf

Outbreak of gram-negative bacteremia, Minnesota 2011 cont.

- 25 cases
- Nurse sentenced to 2 years in prison

http://www.health.state.mn.us/divs/idepc/dtopics/hai/drugdiversionreport.pdf

HCV Outbreaks

Outbreaks of Hepatitis C associated with diversion: U.S. Experience since 2000

Year	State	Setting	Cases	Healthcare Worker
2004	TX	Hospital	16	CRNA
2008	FL	Hospital	5	Radiology technician
2009	CO	Hospital	18	Surgical technician
2012	NH, KS, MD	Hospital	45	Traveling cardiac technician

TRANSMISSION OF BLOODBORNE PATHOGENS
Associated with Injection Drug Use

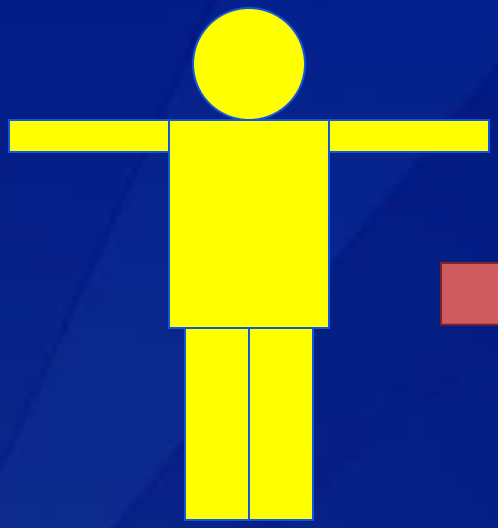
SOURCE
Infectious person,
e.g. chronic, acute

CONTAMINATED INJECTION EQUIPMENT OR PARENTERAL DRUG

CASE
Susceptible,
non-immune person

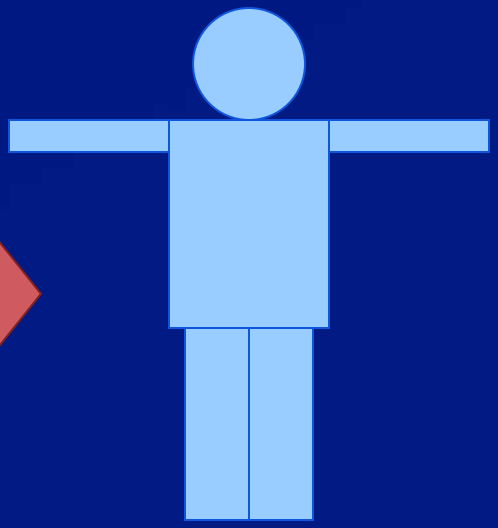
TRANSMISSION OF BLOODBORNE PATHOGENS
Associated with Healthcare

SOURCE
Infectious person,
e.g. chronic, acute

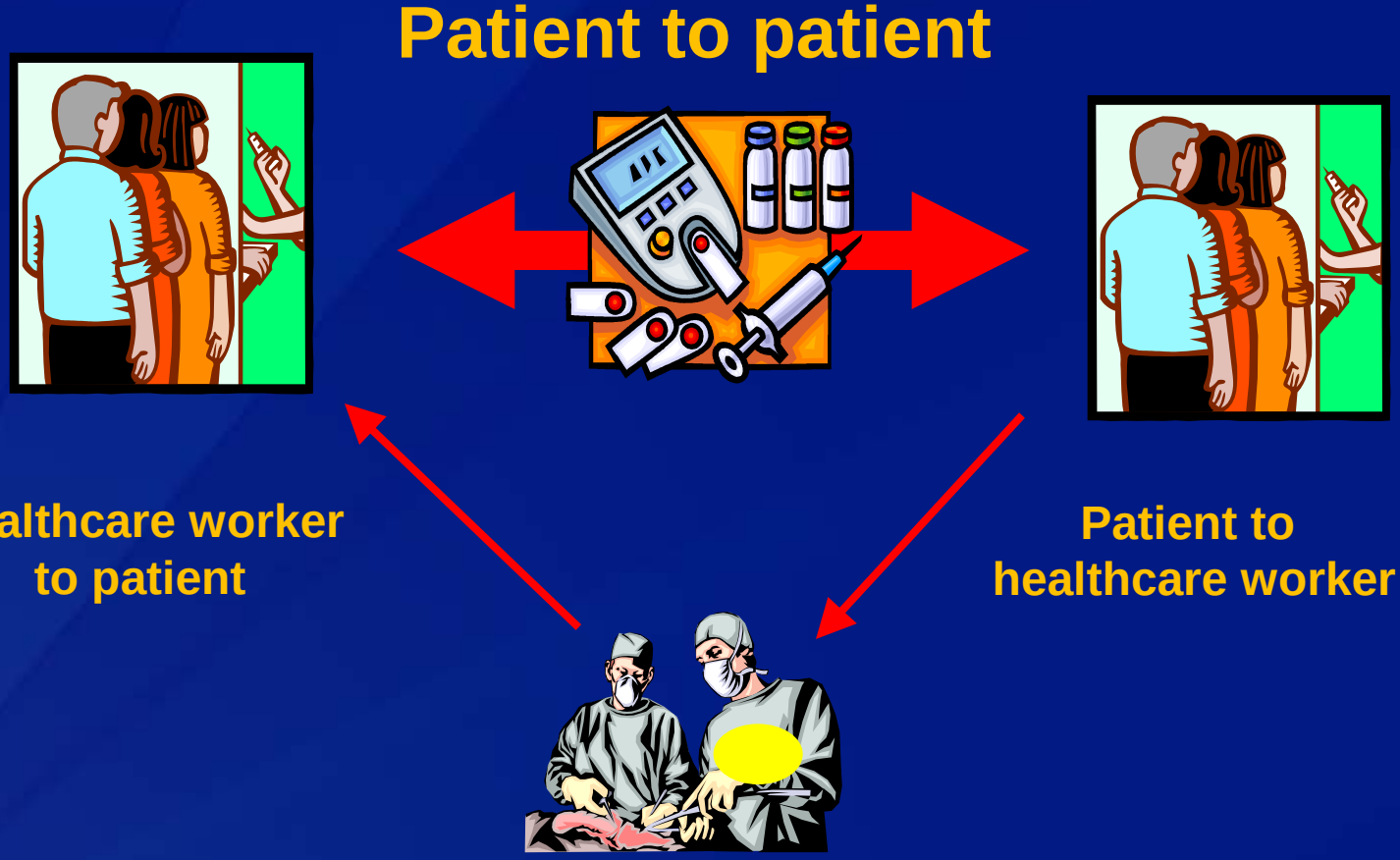


CONTAMINATED INJECTABLE EQUIPMENT OR PARENTERAL MEDICATION

CASE
Susceptible,
non-immune person



HBV and HCV Transmission in Healthcare Settings



See: Clinical Infectious Diseases 2004; 38:1592–8

HBV and HCV Transmission in Healthcare Settings

Pa

Narcotics tampering has emerged as the leading cause of provider-to-patient HCV transmission

Healthcare worker to patient

Patient to healthcare worker

See: Clinical Infectious Diseases 2004; 38:1592–8

Hepatitis C outbreak, Colorado 2009

- CO Department of Public Health and Environment received 2 reports of acute HCV infection
  - Patients had undergone surgical procedures at same hospital
- HCV-infected surgical technician stole fentanyl syringes that had been predrawn by anesthesia staff and left unlocked in the OR
- Tech refilled contaminated syringes with saline to swap with additional fentanyl syringes
- At least 18 patients infected; >8,000 patients notified
  - Notification included ASC that employed tech after she was fired from hospital and NY hospital where tech worked prior to the CO hospital
- Tech sentenced to 30-year prison term

http://www.mayoclinicproceedings.org/article/S0025-6196(14)00342-5/fulltext

"How do you go to a hospital and then walk out of the hospital with hepatitis C from a dirty needle?"

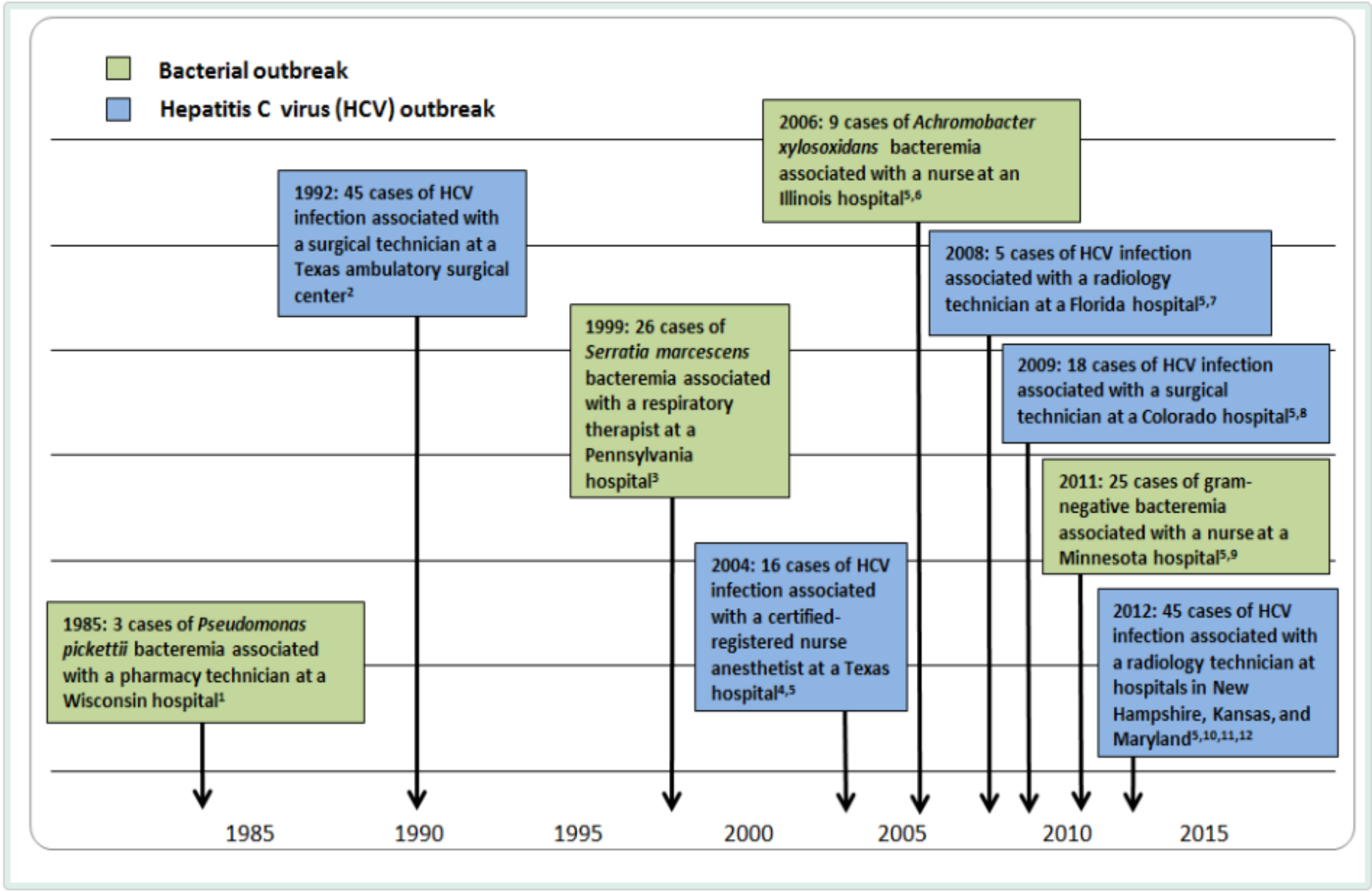
http://www.thespec.com/news-story/2225350-hepatitis-cases-spur-safety-measures/

Syringe Swaps

- **The 3 most recent hepatitis C outbreaks involved syringe swaps by HCV-infected technicians**
  - Lack primary access to controlled substances
  - One technician reported scavenging fentanyl syringes from red box waste containers
- **Standard Precautions:**
  - Once used the needle AND syringe are contaminated they should not be used on another patient or reused to enter a medication container
- **Contamination is not prevented by:**
  - Changing the needle; injecting through an intervening length of IV tubing; maintaining pressure on the plunger
- **This type of diversion = tampering (federal offense)***
  - Not detectable by typical monitoring activities (e.g. dispensing cabinet records

* http://www.fda.gov/RegulatoryInformation/Legislation/ucm148785.htm

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



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

Discussion

Prevalence of diversion by U.S. healthcare workers

- **Minnesota: April 2005-Nov 2011**
  - 345 events of theft or loss of controlled substances due to "employee pilferage" or "other" reported by healthcare facilities to DEA
  - 39% of these events involved IV or IM medications
- **A study examining substance use disorders in anesthesiology trainees, found an overall incidence of nearly one percent, with fentanyl and other intravenous opiods accounting for 57% of reports**
- **In Georgia, more than 3000 unresolved nurse discipline cases pending → Vast majority involve addiction**

Minnesota Controlled Substance Diversion Prevention Coalition
Warner et al JAMA 2013
Atlanta Journal Constition Nov 23 2013

Prevalence of diversion by U.S. healthcare workers

- No national estimates
- Likely underestimate the frequency of diversion in healthcare settings
- Reported outbreaks associated with diversion underestimate the harm to patients

*Minnesota Controlled Substance Diversion Prevention Coalition
http://www.leg.state.mn.us/docs/2012/other/120452.pdf

PROVIDENCE Journal

BREAKING NEWS

] Hospital surgeon suspended for drug abuse

By Felice Freyer

Health Director has suspended the license of Dr. , a surgeon whose privileges at Hospital were suspended after he admitted to drug abuse.

After another doctor caught removing syringes from an operating room, "admitted to resuming drug abuse" and to injecting himself with propofol, a sedative used in anesthesia, and fentanyl, a painkiller, according to :'s summary suspension order. A search of his sleeping room found syringes, needles, blood-soaked gauze and vial caps. placed on medical leave of absence on Nov. 15 and he has not seen patients since.

Key questions to consider when assessing patient safety threat

- **What medications were diverted?**
  - Injectable?
- **Mechanism of diversion?**
  - Did the theft involve substitution or other tampering?
  - What happened to the containers or injection equipment?
    - Were they shared with others?
- **What is the bloodborne pathogen status of the implicated healthcare worker?**

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 3 a-b to determine need for patient notification and testing. This should be performed in consultation with the local or state health department

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

Injection Safety

Related Links
CDC's HAI site
2007 Guideline for Isolation Precautions
HHS Action Plan to Prevent HAIs
HICPAC

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

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Join the conversation

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 [Word - 137 KB]
- CDC Public Health Ethics Case Study, Unsafe Injections: Duty to Warn? [PDF - 264 KB]
- Premier Inc. Drug Diversion Website
- Substance Abuse and Mental Health Services Administration
- National Institute on Drug Abuse (NIDA)

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Enforcement Agencies:

- Drug Enforcement Administration
- FDA Office of Criminal Investigations

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State Health Department Reports:

- Minnesota Controlled Substance Diversion Prevention Coalition [PDF - 391 KB]
- New Hampshire Hepatitis C Outbreak Report [PDF - 3.93 MB]
- Public Health Vulnerability Review: Drug Diversion, Infection Risk [PDF - 1.04 MB]

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Blogs, Commentaries, and News:

- Drug Diversion in Healthcare Settings - NEW Medscape Video Commentary
- Drug Diversion Defined: Consequences for Hospitals and Other Healthcare Facilities (CDC's Safe Healthcare Blog, June 11, 2014)
- Drug Diversion Defined: 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 Health Care Settings Can Put Patients At Risk for Viral Hepatitis (AIDS.gov Blog, May 2, 2014)
- Doctors, medical staff on drugs put patients at risk (USA Today, April 17, 2014)

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

Safe Healthcare

Hosted by CDC's Division of Healthcare Quality Promotion

Drug Diversion Defined: A Patient Safety Threat

Categories: Healthcare-associated infections, Injection Safety

June 3rd, 2014 8:24 am ET - CDC's Safe Healthcare Blog

Guest Author: **Kimberly New, JD BSN RN**
President, Tennessee Chapter of the National Association of Drug Diversion Investigators


Kimberly New, JD BSN RN

You may have seen some recent media reports about drug diversion. Today, I want to break down the issue of drug diversion and provide some details about this serious patient safety threat.

Drug diversion, or theft of drugs, by healthcare personnel poses a continuous threat to patient safety in any healthcare setting in which controlled substances are handled. Although personnel who divert originally went into healthcare to care for patients, they have made poor choices for which they are accountable, including the impact their actions have on others. The longer a healthcare worker is allowed to steal medication, the greater the consequences become. Impaired providers can harm patients by providing sub-standard care, denying medications to patients, or exposing patients to tainted substances.

Tampering is the worst type of diversion. Commonly, the diverter removes medication from a syringe, vial, or other container and injects him- or herself with the medication. The diverter then replaces the stolen medication with saline or sterile water, or another clear medication or liquid. The "replacement liquid" is later used on the patient by an unaware provider. When tampering, the diverter may rarely use sterile technique. Ultimately the patient doesn't receive

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

Summary / Conclusions

- These outbreaks revealed gaps in prevention, detection, or response to drug diversion in U.S. healthcare facilities
- Healthcare facilities should have strong narcotics security measures and active monitoring systems to prevent and detect diversion activities
- Appropriate response by healthcare facilities includes
  - Assessment of harm to patients
  - Consultation with public health officials when tampering with injectable medication is suspected
  - Prompt reporting to law and other enforcement agencies (e.g., state boards of pharmacy)

Thank you

For more information please contact Centers for Disease Control and Prevention

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E-mail: cdcinfo@cdc.gov Web: www.cdc.gov