



Preventing and Detecting Bloodborne Pathogen Infections Due to Drug Diversion

Pamela Talley MD, MPH
Deputy Director

Healthcare-Associated Infections and Antimicrobial Resistance

Disclosures

- **No financial disclosures**

Objectives

- **Review patient safety implications of drug diversion in healthcare settings**
- **Focus on tampering and substitution resulting in patient infection — both bacterial and viral bloodborne pathogen transmission**
- **Advocate for inclusion of viral bloodborne pathogen testing as a routine part of a diversion investigation**

Patient Safety Implications

- Impaired providers → patient harm

Patient Safety Implications

- Impaired providers → patient harm
- **Inadequately treated pain**
 - **2010 Minnesota patient with “intractable pain” → below the elbow amputation**

Patient Safety Implications

- Impaired providers → patient harm
- Inadequately treated pain
 - 2010 Minnesota patient with “intractable pain” → below the elbow amputation
- **Escalating narcotic doses followed by respiratory failure and death upon receipt of ordered dose**

Patient Safety Implications

- Impaired providers → patient harm
- Inadequately treated pain
 - 2010 Minnesota patient with “intractable pain” → below the elbow amputation
- Escalating narcotic doses followed by respiratory failure and death upon receipt of ordered dose
- **Tampering/Substitution → patient infections (bacterial and viral bloodborne)**
 - **Acute onset, life-threatening bacterial bloodstream infections**
 - or*
 - **Delayed onset viral bloodborne pathogen infections often not linked to the healthcare exposure**

DRUG DIVERSION* SPREADS INFECTION FROM HEALTHCARE PROVIDERS TO PATIENTS



HEALTHCARE PROVIDER
with Hepatitis C or other
bloodborne infection
tampers with injectable drug



**CONTAMINATED
INJECTION EQUIPMENT
AND SUPPLIES**
present in the
patient care environment



EXPOSURE OF PATIENT
results from use of contaminated
drug or equipment for patient
injection or infusion

*Drug diversion occurs when prescription medicines are obtained or used illegally by healthcare providers.

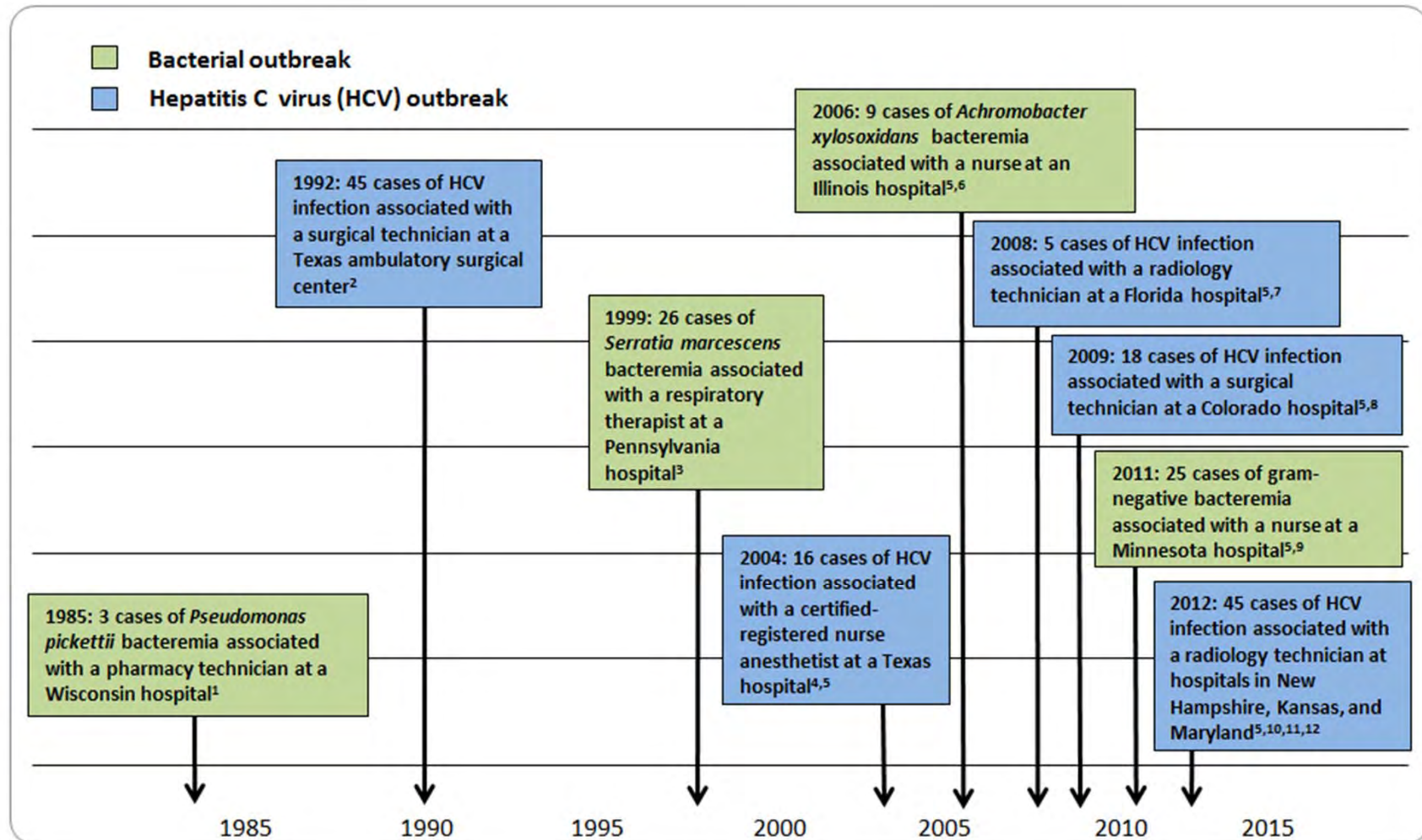
FOR MORE INFORMATION, VISIT CDC.GOV/INJECTIONSAFETY/DRUGDIVERSION





Outbreaks Associated with Drug Diversion

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



2015 Cover Story



2015 Newsweek Cover Story

TECH & SCIENCE

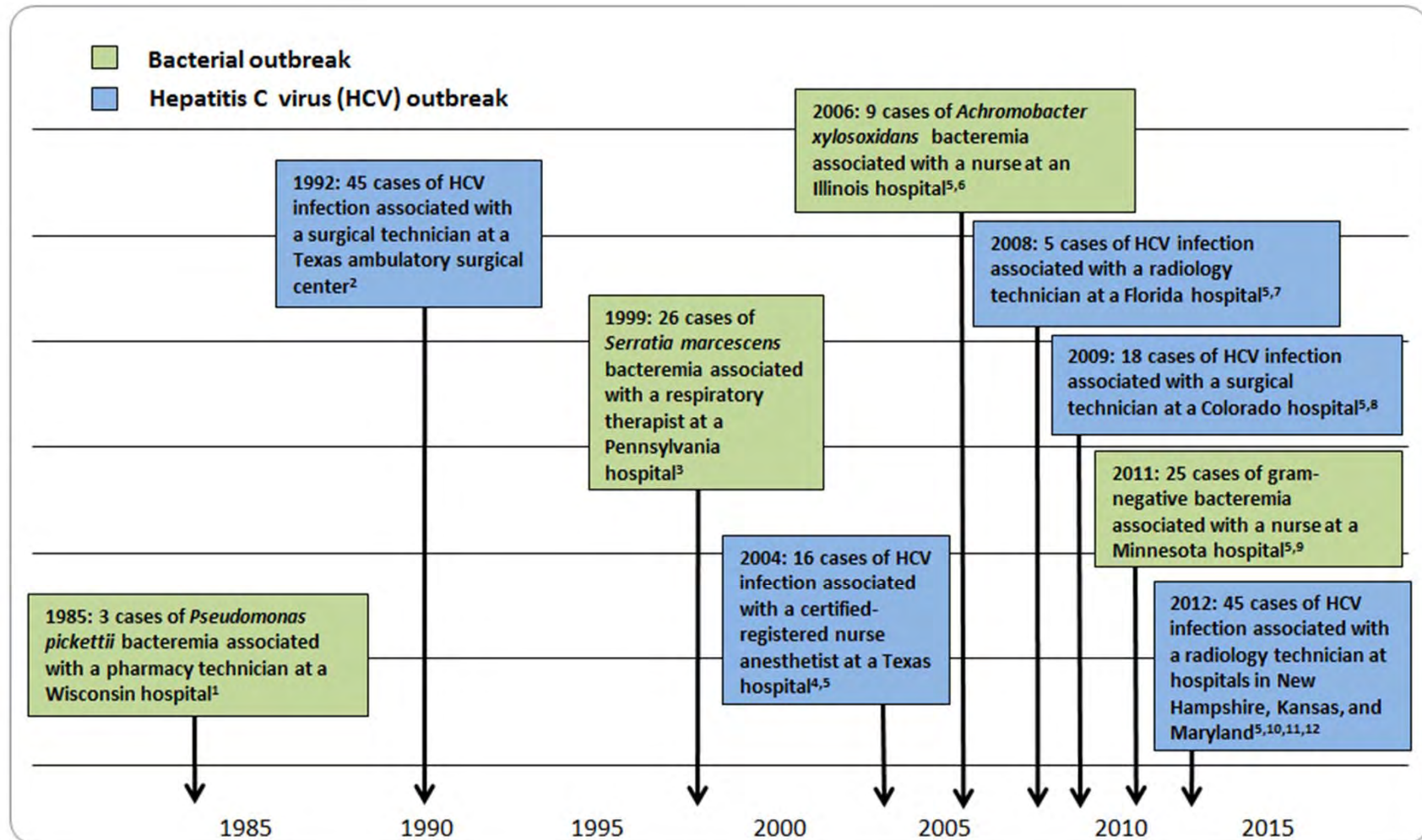
WHEN DRUG ADDICTS WORK IN HOSPITALS, NO ONE IS SAFE

BY **KURT EICHENWALD** ON 6/18/15 AT 6:07 AM

06/26/15
COVER STORY

“it's easy to score a high and much easier still to get away with it as hospitals rarely report the crime”

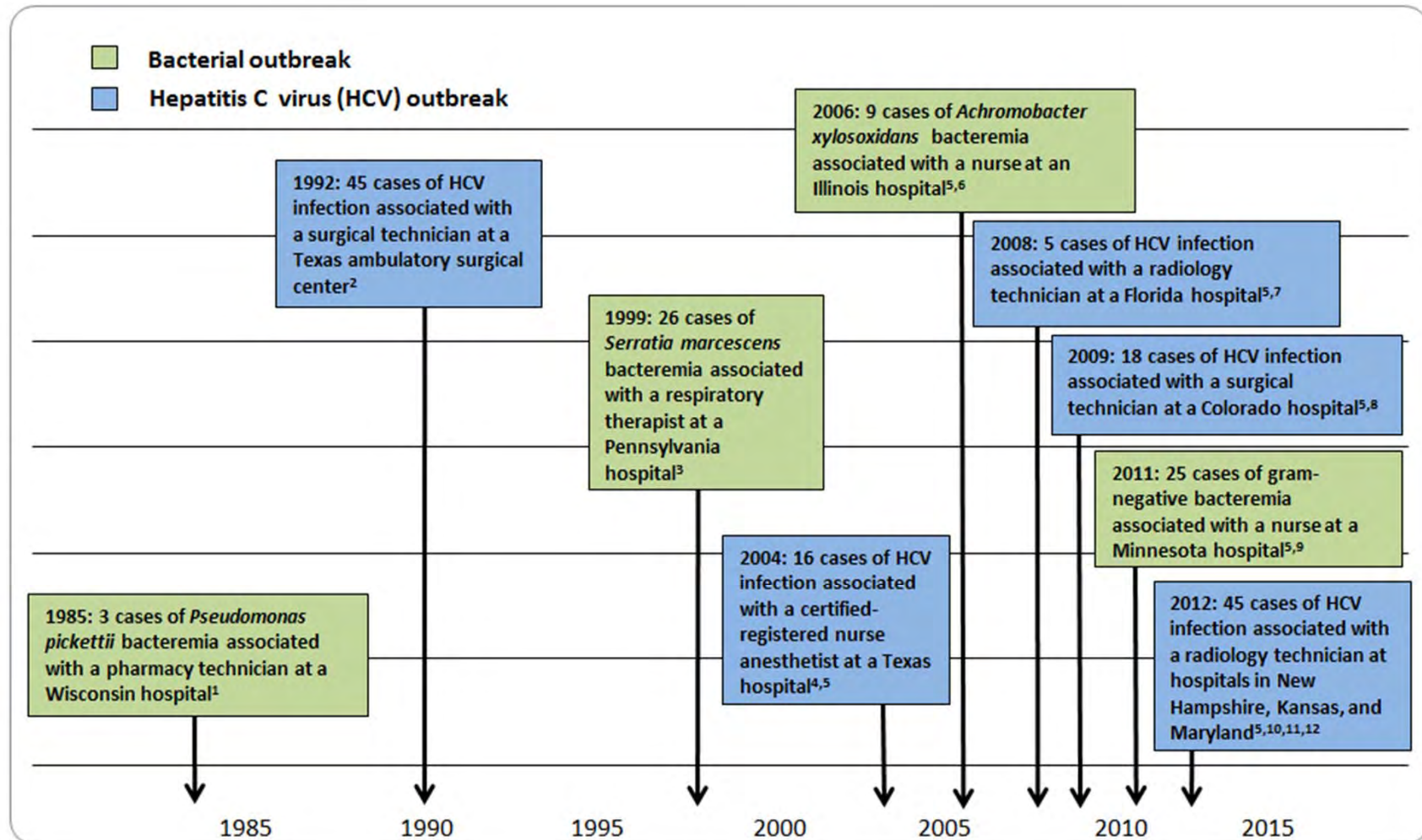
U.S. Outbreaks Associated with Drug Diversion by Healthcare Providers, 1983-2013



2009 Colorado: 18 cases

- Public health identified 2 patients with acute HCV with common link to one hospital
- Investigation implicated HCV-infected **surgical technician**
- Removed pre-drawn syringes of fentanyl from unattended anesthesia carts, replaced them with saline-filled syringes that the tech had previously taken from a cart left the area, self-injected and refilled again with saline in anticipation of a future syringe swap.
- 5970 Colorado patients notified of possible exposure
- 88% tested
- 18 patient's HCV highly linked to technician's
- Pleaded guilty to tampering and illegally obtaining a controlled substance. Sentenced to 30 years in prison.

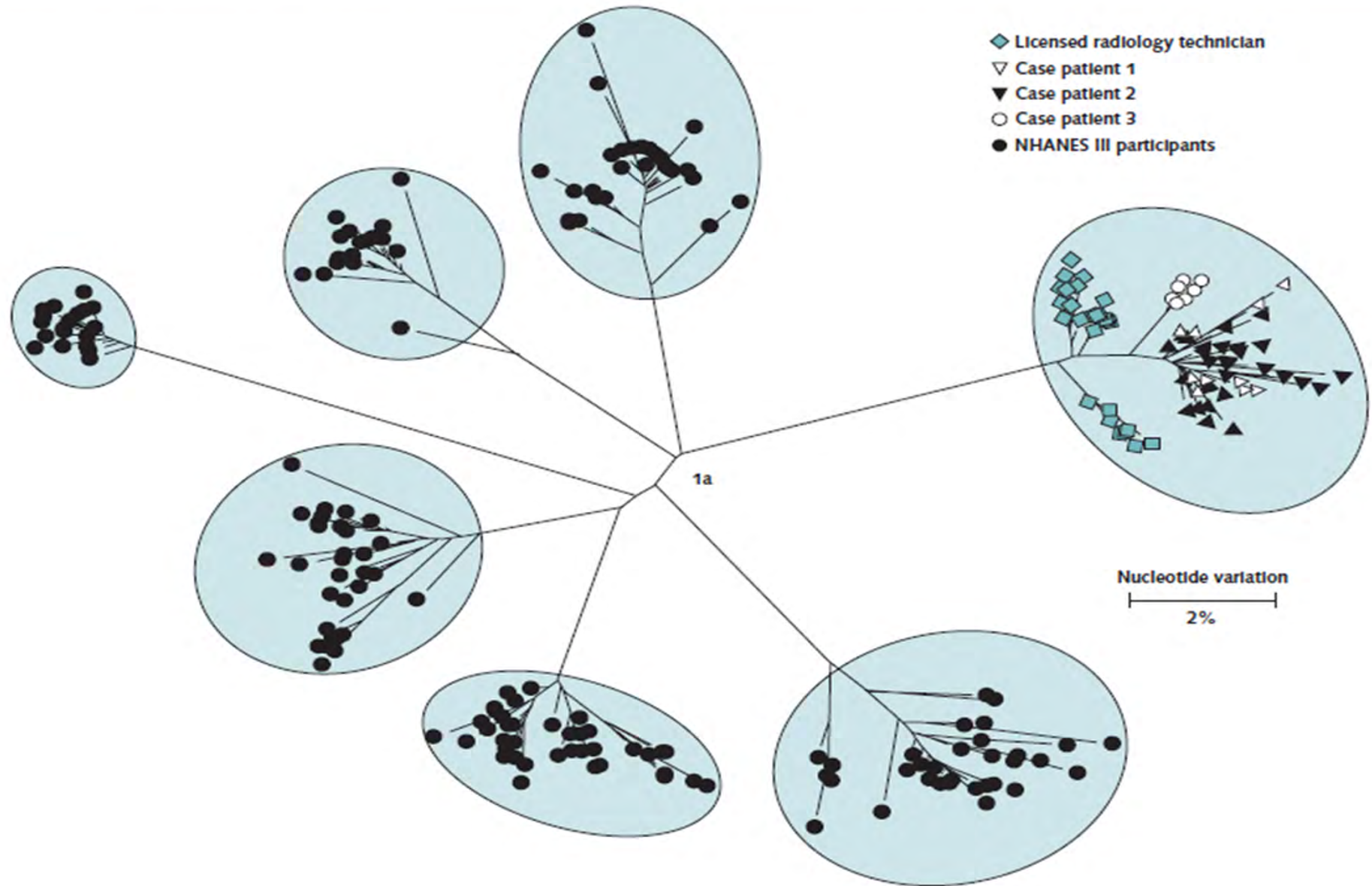
U.S. Outbreaks Associated with Drug Diversion by Healthcare Providers, 1983-2013



2008 Florida: 5 cases

- 3 patients with highly-related HCV identified at a single institution over **24 months**
- Exhaustive investigation ultimately led to hypothesis of drug diversion
- 21 employees working when narcotics administered to patients were tested
- 1 HCV-infected employee had >95% NS5B sequence homology
- Employee admitted to parenteral drug diversion
- 6132 patients identified as potentially exposed—only 64% were still living
- 87% screened
- Two additional cases genetically related HCV infections attributed to employee

Figure. Phylogenetic tree of 291 nucleotide sequences derived from the E1-HRV1 genomic region of hepatitis C virus intrahost variants obtained from 3 case patients, 1 licensed radiology technician, and 6 randomly selected NHANES III participants.



Detection Challenges

- **Radiology and surgical technicians do not have primary access to controlled substances (i.e., dispensing cabinets)**
- **Usual monitoring of dispensing cabinet records will not detect these losses**

2015 Utah: Single patient

- **Frequent blood donor identified with acute HCV**
- **Department of Health investigated dental clinic—no obvious infection control breaches or significant procedures**
- **Investigated emergency department where IV pain medication had been given**
 - **Nurse on duty was subsequently terminated for suspected drug diversion**
 - **Nurse tested + HCV genotype 2b with 100% viral sequencing match to patient**
- **7217 potentially exposed patients notified**
- **Results were pending at time of presentation**

Tip of the Iceberg...





Dangerous Injection Safety Misperceptions

Dangerous Misperception 1

**Myth:
Changing the needle
makes a syringe safe for
reuse**



Dangerous Misperception 1

Myth:
Changing the needle
makes a syringe safe for
reuse



Truth:
Once they are used, both the
needle and syringe are
contaminated and must be
discarded

Dangerous Misperception 2

Myth:
Syringes can be reused
as long as an injection
is administered through
IV tubing



Dangerous Misperception 2

Myth:
Changing the needle
makes a syringe safe for
reuse



Truth:
Syringes and needles should never be reused. The tubing, syringe and other parts are a single, interconnected unit. Distance from the patient, gravity, or infusion pressure do not ensure that small amounts of blood won't contaminate the syringe once connected to the unit.

Dangerous Misperception 3

Myth:
If you don't see blood
in the IV tubing or
syringe, it means that
those supplies are safe
for reuse



Dangerous Misperception 3

Myth:

If you don't see blood in the IV tubing or syringe, it means that those supplies are safe for reuse



Truth:

Hepatitis C virus or bacteria such as MRSA are invisible to the naked eye but can easily infect patients even when present in microscopic quantities



Diversion as an Infection Control Breach

Definition

- **Infection control breach — when there is a failure to follow established infection control procedures that prevent the transmission of infectious organisms**
- **Tampering and substitution violates safe injection practices**

Steps for Evaluating an Infection Control Breach

- **Identification**

Steps for Evaluating an Infection Control Breach

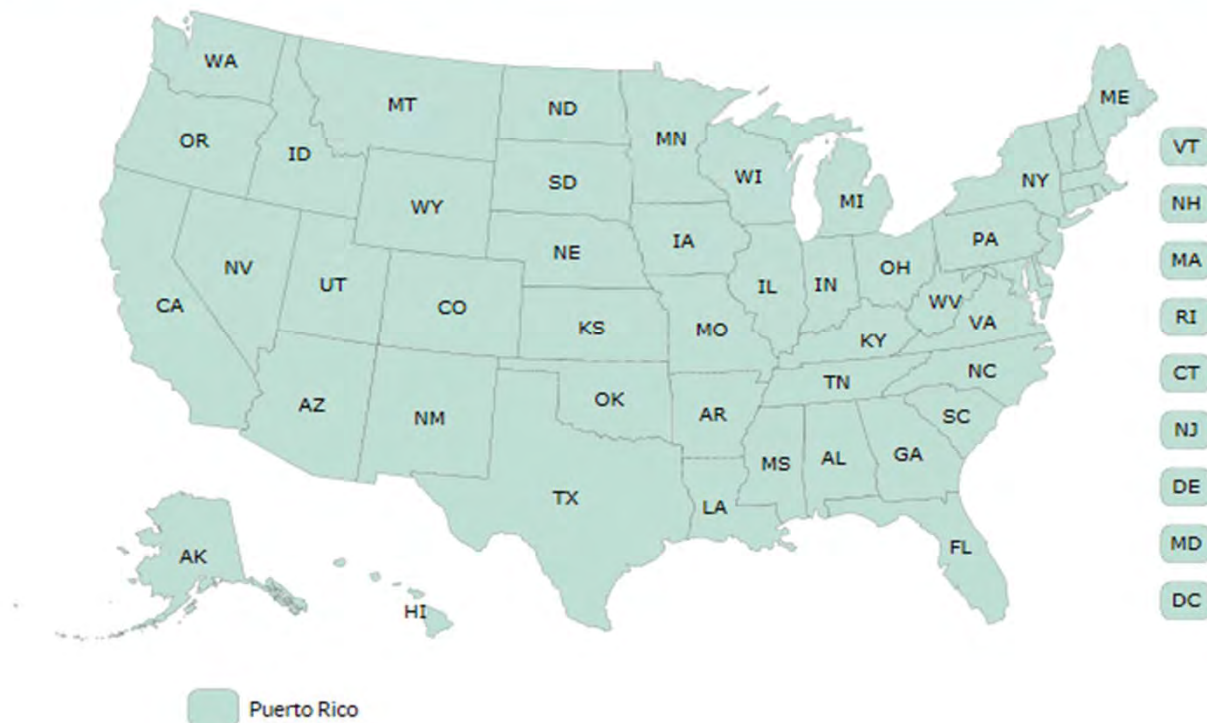
- Identification
- **Data gathering**

Steps for Evaluating an Infection Control Breach

- Identification
- Data gathering
- **Notify and involve key stakeholders**

State-based Public Health Contacts

State-based HAI Prevention Activities



Steps for Evaluating an Infection Control Breach

- Identification
- Data gathering
- Notify and involve key stakeholders
- **Qualitative assessment of breach**
 - **Category A errors: gross mistakes in infection control with identifiable risk including **TAMPERING AND SUBSTITUTION****
 - **Category B errors: less likelihood of blood exposure than category A (e.g., colonoscope reprocessed for shorter time than recommended)**

Steps for Evaluating an Infection Control Breach

- Identification
- Data gathering
- Notify and involve key stakeholders
- Qualitative assessment of breach
 - Category A errors: gross mistakes in infection control with identifiable risk including TAMPERING AND SUBSTITUTION
 - Category B errors: less likelihood of blood exposure than category A (e.g., colonoscope reprocessed for shorter time than recommended)
- **Decision regarding patient notification and testing**
 - ***Warranted in category A breaches!***

Sentinel Events — The Joint Commission

- **1996 formal policy regarding serious adverse patient events or “sentinel events”**
- **Sentinel event defined as:**
 - “**patient safety event (not primarily related to the natural course of the patient’s illness or underlying condition) that reaches the patient and results in any of the following: 1) death; 2) permanent harm; or 3) severe temporary harm”**
- **Plus other conditions that require immediate investigation and response by the hospital, and these investigations and responses are subject to review by TJC for appropriateness**



Patient Notification

CDC Patient Notification Toolkit

Toolkit Contents



Pages in this Report

1. **Developing Documents for a Patient Notification**
2. [Planning Media and Communication Strategies](#)
3. [Establishing Communication Resources](#)
4. [Best Practices in Conducting Patient Notifications](#)
5. [Scope/Acknowledgement](#)
6. [Additional Resources](#)

Dear Sir or Madam,

In DATE the HEALTH DEPARTMENT NAME began investigating reports of recent NAME OF INFECTION among several people who had undergone procedures at the MEDICAL CENTER NAME, located at ADDRESS. Through the investigation, we identified an unsafe practice, which may have exposed patients to the blood of other clinic patients.

This letter serves as notification that you have been identified in clinic records as a former patient of the clinic who was placed at risk for possible exposure to bloodborne pathogens. **As a precaution, and in order to take appropriate steps to protect your health, we recommend that you get blood tests for hepatitis C, hepatitis B, and HIV.** We are committed to providing you with support through every step of this process.

It is not possible to determine specifically which people were exposed, but **all patients who received injected medicine at the center** were placed at increased risk for exposure. As a result, we are notifying all people who received injected medications between DATE and DATE. Our investigation has identified that the infections were associated with the unsafe injection practices and **not** with the procedures themselves.

People infected with viruses such as hepatitis B, hepatitis C, or human immunodeficiency virus (HIV) may not have symptoms for many years, so you may have been infected and not know it. Even though

Developing Documents

- **What patients expect**
 - How/where
 - Possible symptoms
 - Corrective actions taken
 - 24 hour hotline number
 - Assurance that correct patients are being contacted
 - Next steps plan

Developing Documents (cont.)

- **Key patient concerns**
 - What to do next
 - Timeframe of disease/testing
 - Who's paying
 - Who's liable
 - What disease, how serious is it

- **Recommended tone**
 - Factual, clearly stated
 - Apologetic, empathetic
 - Personal, urgent
 - Assurance that things will be taken care of

Notification Best Practices

- **Timing**
 - Letters should arrive early in week
 - Be aware of holidays
- **Ensure call center employees are well trained and available in adequate numbers**
- **Testing contract pre-arranged**
- **Plan media notification after letters sent**
- **Do not delay!**



Bloodborne Pathogen Testing

History

- **National Institute for Occupational Safety and Health (NIOSH)**
 - **1999 “Preventing Needlestick Injuries in Health Care Settings”**
- **Focus on education and prevention of transmission of bloodborne pathogens**
- **Improved awareness**
- **Engineering advances**
- **Post-exposure prophylaxis advances**

Adapt Employee Health Needlestick Protocols

- **Pre-employment screening**
- **Develop policies and SOPs with notification upon hire**
- **Adapt needlestick protocols in advance to ensure appropriate testing is done**

Viral Hepatitis Testing Resources

	Initial baseline testing of potentially exposed person (s) ^{*, **}	Follow-up testing ^{†, **, ††}
HBV^{†1,2}	<p>HBsAg test</p> <p><i>Also consider antibody to hepatitis B core antigen (anti-HBc) antibody to hepatitis B surface antigen (anti-HBs) tests to determine past infection and immunity status.</i></p>	<p>HBsAg test at ≥ 12 weeks post exposure³⁻⁵</p> <p><i>Note: if immune at baseline or most recent exposure ≥ 12 weeks prior to baseline, <u>no</u> follow-up testing needed.</i></p>
HCV	<p>HCV antibody^{‡6} and if positive reflex to HCV RNA</p> <p><i>Note: may need to draw two blood specimens for reflex testing.</i></p> <p style="text-align: center;">-OR-</p> <p>HCV RNA test</p>	<p>HCV antibody test at ≥ 6 months post exposure⁷⁻⁸</p> <p><i>Note: If initial antibody test positive, test HCV RNA instead of HCV antibody.</i></p> <p style="text-align: center;">-OR-</p> <p>HCV RNA test at ≥ 3 weeks post exposure[†]</p> <p><i>Note: If most recent exposure ≥ 6 months prior to baseline anti-HCV test, or ≥ 3 weeks prior when HCV RNA tested at baseline, <u>no</u> follow-up testing is needed.</i></p>

HIV Testing Resources, 2014

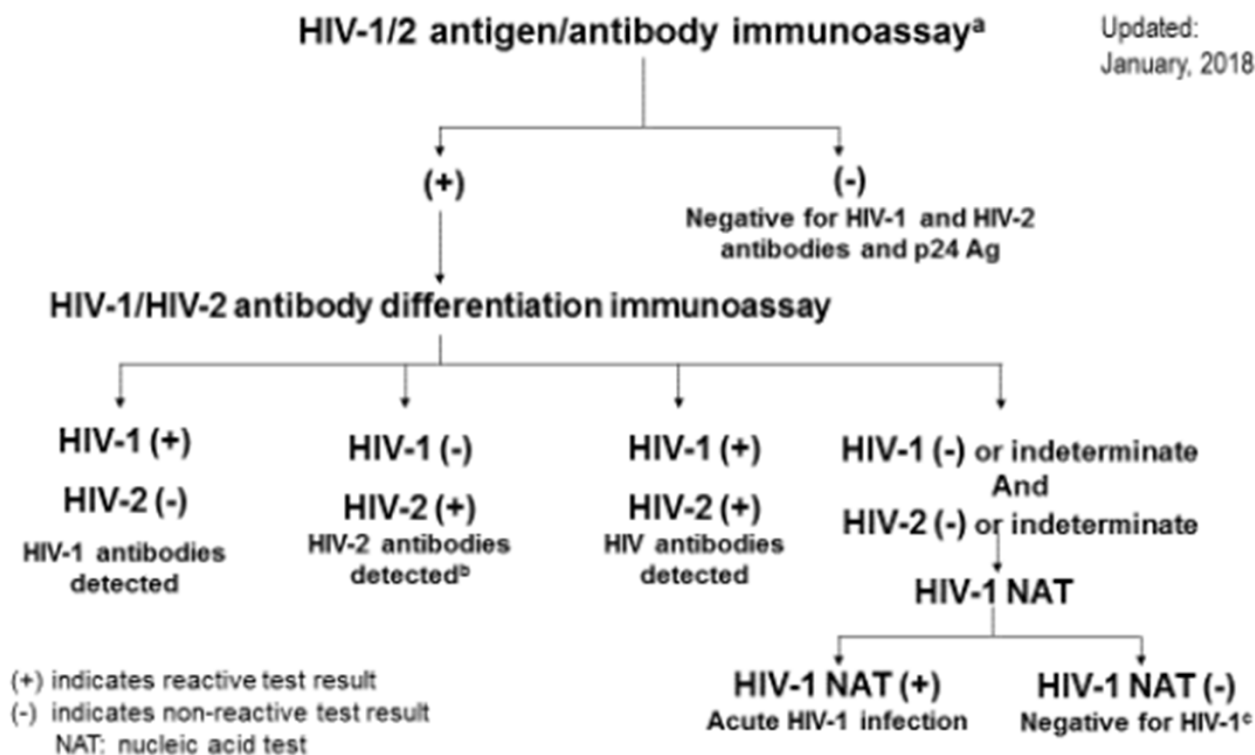
Laboratory Testing for the Diagnosis of HIV Infection

Updated Recommendations

Some aspects of this 2014 guidance have been updated, including the laboratory testing algorithm figure. For a summary of updates, see 2018 Quick Reference Guide: Recommended laboratory HIV testing algorithm for serum or plasma specimens (<https://stacks.cdc.gov/view/cdc/50872>).

HIV Testing Resources, 2018 Updates

Recommended Laboratory HIV Testing Algorithm for Serum or Plasma Specimens



Testing Tips

- **Prepare in advance**
- **Update annually to accommodate changing assays and recommendations**
- **Be the patient safety advocate!**



Wrap Up

Prevention & Response Summary

- **Prevent and treat addiction**

Assistance for Healthcare Providers

- **Provider/Peer Assistance Programs**

Offer consultation, referral, and monitoring

Assistance with re-entry and aftercare

Results vary by specialty but early intervention matters

Assistance for Healthcare Providers

- **Provider/Peer Assistance Programs**

Offer consultation, referral, and monitoring

Assistance with re-entry and aftercare

Results vary by specialty but early intervention matters

***Not a substitute for doing the right thing for
patient safety***

Prevention & Response Summary

- Prevent and treat addiction
- **Identify at-risk employees in hiring process**
 - Reference checks
 - **Know your contract services—you are responsible!**
 - **New employee baseline testing considerations & drug screens**
 - **Clarity in contracts that random and for cause drug screens and BBP testing may be required**

Prevention & Response Summary

- Prevent and treat addiction
- Identify at-risk employees in hiring process
 - Reference checks
 - Know your contract services—you are responsible!
 - New employee baseline testing considerations & drug screens
 - Clarity in contracts that random and for cause drug screens and BBP testing may be required
- **Safeguard others**
 - **Rapid response including terminating access to opioids**
 - **Inclusion of bloodborne pathogen testing when any parenteral diversion suspected**
 - **Patient notification and testing**
 - **Consistent “not eligible for re-hire” message when terminated**
 - **Appropriate reporting to health boards**

Headlines

Business

Abington Memorial pays \$510K in drug diversion settlement

Updated: JANUARY 9, 2017 — 1:37 PM EST

Health

April 06, 2016 8:03PM

Exeter Hospital settles with more than 200 patients in hepatitis C case

Intermountain Healthcare to pay \$1M to settle drug diversion case

by [Joanne Finnegan](#) | Dec 11, 2017 1:25pm

FOR IMMEDIATE RELEASE

Monday, September 28, 2015

MGH to Pay \$2.3 Million to Resolve Drug Diversion Allegations



Two nurses died of overdoses inside a Dallas hospital. What went wrong?

<https://www.dallasnews.com/news/investigations/2018/12/02/two-nurses-died-overdoses-inside-dallas-hospital-went-wrong>

Questions?



ptalley@ihfda.org
pamela.talley@tn.gov