

Investigation of Acute Hepatitis B and C Cases



March 14, 2013

Overview

- Healthcare-associated transmission of hepatitis B and C
- Infection risks in ambulatory care settings
- What to look for when acute hepatitis B and C case reports are submitted
- What to do if a report suspicious for healthcare-associated transmission of hepatitis B or C is identified



Healthcare-Associated Hepatitis B and C Infections

- A number of large healthcare-associated hepatitis B and C outbreaks have been identified over the past decade
- Most occurred in ambulatory care facilities and were caused by unsafe injection practices; hospital outbreaks less common and often associated with drug diversion
- More than 150,000 patients potentially exposed in U.S. healthcare facilities over the past decade
- Public health departments increasingly expected to play a role in identifying and responding to healthcare-associated transmission of hepatitis B and C

50,000 Patients Potentially Exposed to Hepatitis C

Las Vegas Sun

LAS VEGAS SUN

Nevada hepatitis C outbreak largest in U.S.

Health officials report 105 possible hepatitis C cases

By Mary Manning
Thursday, Oct. 23, 2008 | 10:25 a.m.

The Southern Nevada Health District has classified 105 cases of chronic hepatitis C infection as possibly associated with two endoscopy centers in Las Vegas, making it the largest outbreak of the blood-borne illness in the country.

Another nine hepatitis C cases have been directly linked to two

Special section
■ Topic: Hepatitis scare

- 105 patients possibly infected with HCV

Former patients sue NY hospital over insulin pens

Published: February 27, 2013 3:01 AM

By The Associated Press



BUFFALO, N.Y. - (AP) -- Three former patients of a western New York hospital say they contracted hepatitis because the hospital misused multidose insulin pens.

A lawsuit announced Tuesday against Olean General Hospital and several insulin pen manufacturers comes after authorities say at least 12 people tested positive for hepatitis C after being screened by the Cattaraugus County hospital.

The hospital last month notified 1,915 former patients that they may have been exposed to HIV or hepatitis B or C through the sharing of multidose insulin pens from November 2009 through January this year.

Infection Risks in Ambulatory Care Settings

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Learning Objectives

- Describe infection control concerns in ambulatory care settings including lack of regulatory oversight and common lapses in infection control

HEALTHCARE EPIDEMIOLOGY

INVITED ARTICLE

Robert A. Weinstein, Section Editor

Viral Hepatitis Transmission in Ambulatory Health Care Settings

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Why is this on Public Health's Radar?

- Healthcare-associated infections (HAIs) have been identified by CDC as a winnable battle
- Goals:
 - Improve adherence to infection prevention guidelines
 - Improve national surveillance
 - Improve capacity at state and local health departments to address HAIs

Attention to Basic Infection Control Must Extend Across the Entire Healthcare Continuum



Ambulatory Care – Growth and Concerns

- Approximately 1.2 billion outpatient visits / year
 - Between 1995 and 2007, the average person made four visits to physician offices each year
- Increasingly complex procedures, vulnerable patients
 - Each year more than one million cancer patients receive outpatient chemotherapy and/or radiation therapy
- Lack systematic surveillance to detect infections originating in ambulatory settings
- Expansion of services without parallel increases in attention to and oversight of infection control
 - Many lack written infection control policies and procedures
 - Often no infection control training for staff

Oversight of Ambulatory Care Settings

- Medicare has oversight of a subset of ambulatory care settings, e.g., ambulatory surgical centers (ASCs) and hemodialysis facilities
 - Subject to inspections by state survey agencies (or accrediting organizations) to determine compliance with CMS's minimum health and safety standards
- Majority of ambulatory care settings operate only under physician's medical license +/- business license
 - Not subject to routine surveys/inspections
 - In California, ASCs owned by physicians are not licensed by CDPH (Capen vs. Shewry 2007)
 - Therefore, local health departments often investigate infection control concerns in these settings

Infection Risks in Ambulatory Care Settings

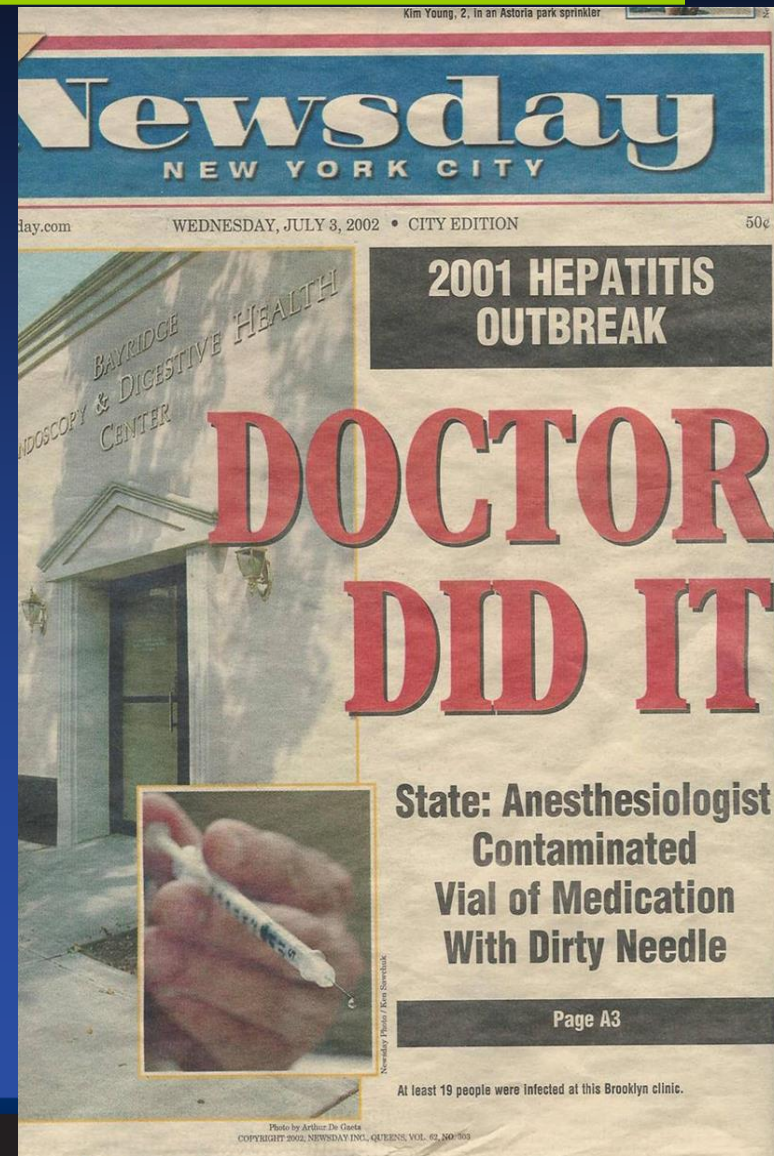
- Common theme of outbreaks and notification events
 - Breakdowns in standard procedures / breaches of standards of care
 - Preventable with basic infection control practices
 - Healthcare personnel not aware of their errors



www.cdc.gov/mmwr/preview/mmwrhtml/mm6109a3
www.cdc.gov/mmwr/pdf/wk/mm60e0301.pdf

Viral Hepatitis Outbreaks in Outpatient Settings Due to Unsafe Injection Practices, 2001-2010

<u>State</u>	<u>Setting</u>	<u>Year</u>	<u>Type</u>
NY	Private MD office	2001	HCV
NY	Private MD office	2001	HBV
NE	Oncology clinic	2002	HCV
OK	Pain remediation clinic	2002	HBV+HCV
NY	Endoscopy clinic	2002	HCV
CA	Pain remediation clinic	2003	HCV
MD	Nuclear imaging	2004	HCV
FL	Alternative medicine clinic	2005	HBV
CA	Alternative medicine clinic	2005	HCV
NY	Endoscopy/surgery clinics	2006	HBV+HCV
NY	Pain remediation clinic	2007	HCV
NV	Endoscopy clinic	2008	HCV
NC	Cardiology clinic	2008	HCV
NJ	Oncology clinic	2009	HBV
FL	Alternative medicine clinic	2009	HCV
CA	Pain remediation clinic	2010	HCV+HBV



Where Lapses Have Occurred That Resulted in Outbreaks and/or Patient Notifications

- **Injection safety**

- Reuse of syringes (with or without new needles) for multiple patients or to access multidose medication vials or solution containers (e.g., saline bag)
- Use of single-dose vials for multiple patients
- Use of a single needle/syringe to administer intravenous medication to multiple patients

- **Equipment reprocessing**

- Failing to follow the manufacturer's instructions
- Failure to pre-clean instruments prior to sterilization or high-level disinfection
- Failure to use the appropriate connectors between endoscope and AER

- **Point-of-care devices**

- Using same finger stick devices, insulin pens for >1 person
- Failure to clean and disinfect blood glucose meters after each use

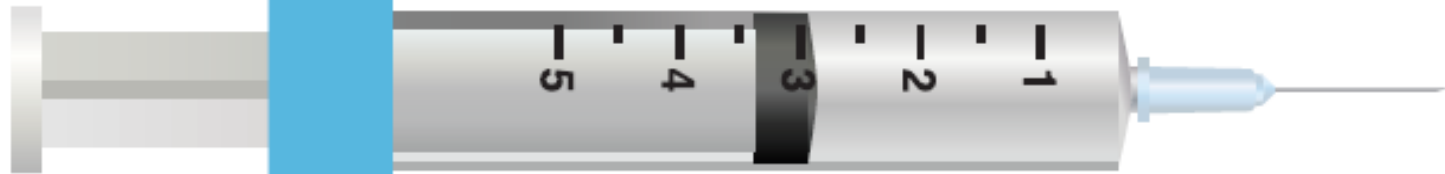
- **Environmental cleaning**

- No clearly assigned responsibility for who cleans what and when

To Prevent Transmission of Infections in Healthcare



**ONE NEEDLE,
ONE SYRINGE,
ONLY ONE TIME.**



Safe Injection Practices Coalition

www.**ONEandONLY**campaign.org

Injection Safety is Every Provider's Responsibility

Ambulatory Care Setting Investigations

- Infection control lapses occur in ambulatory care settings
- Given lack of regulatory oversight, local health departments often investigate
- CDPH can assist with these investigations

An Outbreak of Hepatitis C Virus Infections among Outpatients at a Hematology/Oncology Clinic

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Case Review to Identify Possible Healthcare-Associated Acute Hepatitis B and C

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Case Review

Goal:

Identify possible healthcare-associated hepatitis B and C transmission

Methods:

1. Confirm case - not all reported acute hepatitis B or C cases are actually hepatitis cases or acute cases
2. Obtain information on risk factors for infection
3. Assess need for further investigation

Confirm Acute HBV Cases

- **Acute illness:** Discrete symptom onset and at least one item in each column:

I	II	III
Jaundice ALT >100 IU/L	HBsAg positive	IgM anti-HBc positive (if done)

OR

- **Seroconversion:** Negative HBsAg result with a positive HBsAg result in the following 6 months; may be asymptomatic

Confirm Acute HCV Cases

- **Acute illness:** Discrete symptom onset and at least one item in each column:

I	II	III	IV
Jaundice ALT >400 U/L	Anti-HCV positive* HCV RIBA positive HCV RNA positive HCV genotype result	IgM anti-HAV negative (if done)	IgM anti-HBc negative (if done)

OR

- **Seroconversion:** Negative Anti-HCV result with a positive anti-HCV result in the following 6 months; may be asymptomatic

*With signal to cut off ratio specified by CDC: www.cdc.gov/hepatitis/HCV/LabTesting.htm#section1

Collect Information

- Once case is confirmed, contact patient and ask about traditional behavioral risk factors during the incubation period, as well as other possible risk factors
 - Healthcare exposures
 - Cosmetic procedures
 - Accidents or injuries that may have involved blood exposure
 - Employment/occupation
 - How case thinks infection occurred
- Contact provider
 - Ask about any previous negative test results
 - Ask about suspected source of infection
- Focus on what occurred during incubation period
 - Hepatitis B: 45 days – 6 months
 - Hepatitis C: 14 days – 6 months

Additional Information

- If patient denies traditional behavioral risk factors
 - For hepatitis B cases, determine hepatitis B status of sexual and household contacts
 - For hepatitis C cases, determine hepatitis C status of sexual contacts
 - Collect information about healthcare or cosmetic facility names, locations, procedures, and dates care received
- If no field in CalREDIE for data collected on paper form, enter data into comments section
- CDPH Immunization Branch will maintain database of facility names even if no investigation conducted

Behavioral

Exposure	Vehicle
Injected drugs, not prescribed	Drug equipment
Noninjected street drugs ²⁵	Drug equipment
Incarceration ²⁶	Tattoo equipment Drug equipment Sex
Male sex partners	Sex
Female sex partners	Sex
STD treatment	Sex

Contact of a Case

Exposure

Contact with blood from a suspected or confirmed case

Vehicle

Sex

Drug use equipment

Razor blades (hepatitis B)

Toothbrushes (hepatitis B)



Accidents and Injuries

Exposure

Accidental stick with an object contaminated with blood^{1,2}

Other exposure to the blood of another person³

Vehicle

Scalpel

Needle

Tagging gun

Car accident

Fist fight



- Ask about occupation and employment: healthcare worker or other work with sharps

Healthcare



Exposure	Vehicle
Transfusion*	Blood
Hemodialysis ⁴⁻⁷	Surfaces Machine?
Hospitalization ^{8,9}	Surfaces Medication Vials Glucose monitors
Outpatient procedure (i.e., colonoscopy, endoscopy) ¹⁰⁻¹⁴	Medication vials Instruments
Injections or infusions prescribed by doctor ^{15,16}	Medication vials

*Rarely, since new blood screening recommendations were implemented

Healthcare, continued



Exposure	Vehicle
Nonroutine dental work or oral surgery ¹⁷	Dentist/oral surgeon
Other surgery ^{8,9,18}	Medication vials Surgeon
Finger stick or blood draw ^{19,20}	Glucose monitors Lancets
Podiatric procedures ²¹	Equipment
Chemotherapy ²²	Medication vials
Acupuncture ²³	Needles

Cosmetic

Exposure

Body piercing²⁴

Tattoo²⁴

Manicure/Pedicure

Vehicle

Equipment

Equipment

Equipment



Handmade prison tattoo gun

Identify Red Flags

- Age >50 years
- No traditional behavioral risk factors
- High risk healthcare exposures
 - Glucose monitoring
 - Multidose vials
 - Pain medications
- Patient or physician suspicion
- Linked to facility named by other cases
- Recent seroconversion



HBV
CMR



What Next?

- If there is suspicion of healthcare-associated transmission, contact CDPH Immunization Branch
- Secure any available blood specimens from infected persons for possible molecular testing and comparison with specimens from other infected persons
- If contacts need hepatitis B or C testing and cost is a barrier, CDPH can provide funds for testing

Morbidity and Mortality Weekly Report

Weekly

September 26, 2003 / Vol. 52 / No. 38

**Transmission of Hepatitis B and C Viruses in Outpatient Settings —
New York, Oklahoma, and Nebraska, 2000–2002**

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Hepatitis C Case Investigation in an Outpatient Hemodialysis Center

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Learning Objective

- Describe CDPH assistance provided to a local health department investigating a cluster of hepatitis C cases among hemodialysis patients



Notification

- July 2012: CDPH HAI Program notified by a local health department of 4 confirmed hepatitis C seroconversions within 4 months at one hemodialysis center
- Survey site visit by Licensing & Certification (L&C) and root cause analysis by hemodialysis center in process at time of report to local health department
 - No deficient practices or transmission events identified

Next Steps

- Local health department requested assistance from HAI Program
 - HAI Program consulted with CDC Hepatitis Branch
 - CDC agreed to provide sequencing of hepatitis C virus in patient blood specimens to determine linkages
 - Initial local public health site visit
 - CDC hemodialysis assessment tool used
 - Limited due to CMS audit on same day
 - Hemodialysis center hepatitis C data from patients were reviewed
 - HAI Program assisted local health department with second site visit

Hemodialysis Center Site Visits

- Objectives:
 - Obtain information about surveillance processes, policies and practices
 - Observe infection control practices
 - Identify breaches
 - Provide recommendations to prevent future hepatitis cases

Site Visit Results

- August and September 2012
 - Reviewed infection control changes since June 2012; numerous changes to improve procedures and decrease cross-contamination
 - No deficient practices noted
 - No infection control breaches identified

Molecular Testing Results

- Identical molecular sequencing revealed in all 4 hemodialysis patients
 - Healthcare transmission implicated
- Results led to third site visit by local health department to review patient medical records and identify possible transmission date, time and causes
 - No transmission day or event identified
- Final report with recommendations provided to local health department

Lessons Learned

- CDPH and CDC can assist local health departments with hepatitis case investigations
- Site visits and medical record review may not identify the transmission event
- Investigations may help to correct deficient practices even if causal deficiency not identified

