

Practical Tips on Investigating Single Cases of Viral Hepatitis

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Disclosures

- None!
- The views we present are our own and do not necessarily represent the official views or policies of the Los Angeles County Department of Public Health



Three Parts of the Presentation

- 1) Initial investigation a single case of possible nosocomial or facility-based hepatitis
- 2) Full Investigation including site visit
- 3) Case study of an investigation



CDC Guidance on Investigating Single Cases of Hepatitis B and C

Healthcare Investigation Guide

Recommended Steps for Investigating Single Cases of Hepatitis B Virus (HBV) or Hepatitis C Virus (HCV) that are Suspected to be Related to Healthcare Delivery

PURPOSE

This toolkit provides a framework for use by state and local health departments to investigate possible healthcare-associated viral hepatitis transmission events, particularly those involving only a single patient. Investigation of these single cases is an important public health response as it can result in the identification of an outbreak or unsafe clinical practices that are putting additional patients at risk.

<http://www.cdc.gov/hepatitis/Outbreaks/index.htm>



Four Parts in an Investigation

- Epidemiological assessment
- Initial investigation
- Full investigation (including site visit)
- Monitor



Epi: In-Depth Questionnaire

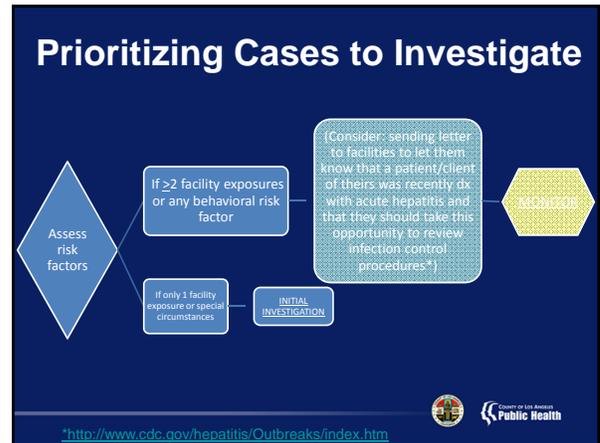
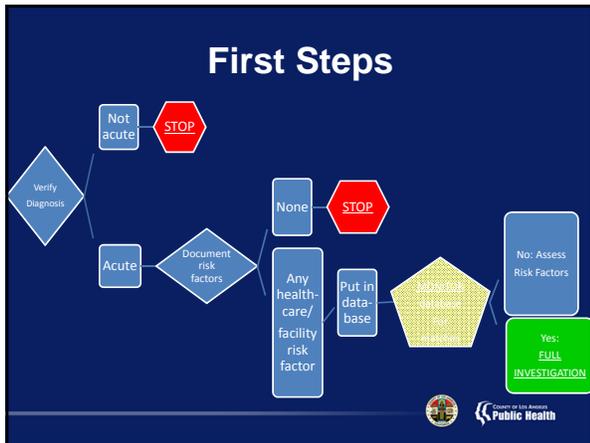
- Used for those <50 years with specific nosocomial risk factors elicited on initial interview
- Used for all >50 years regardless of answers to initial interview

Los Angeles County Department of Public Health Acute Communicable Disease Control Program
Healthcare-Related Hepatitis Investigation Supplement
Patient Exposure Assessment

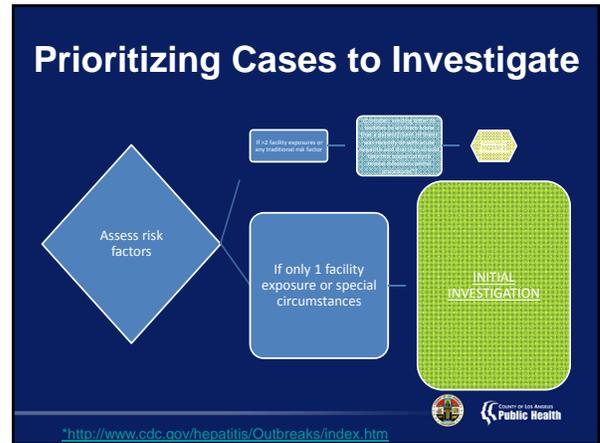
Exposure Period: ____/____/____ to ____/____/____

Procedures during Exposure Period: Check the box next to the appropriate procedure and complete table below for each checked procedure.

<input type="checkbox"/> Anesthesia	<input type="checkbox"/> Dental oral surgery	<input type="checkbox"/> Overnight hospitalizations
<input type="checkbox"/> Allergy injections	<input type="checkbox"/> Dialysis	<input type="checkbox"/> Organ or tissue donation
<input type="checkbox"/> Aspiration	<input type="checkbox"/> Electroly	<input type="checkbox"/> Pain management injections
<input type="checkbox"/> Apheresis	<input type="checkbox"/> Gastroenterology study	<input type="checkbox"/> Podiatry
<input type="checkbox"/> Arthroscopy	(e.g. endoscopy, colonoscopy, sigmoidoscopy, ERCP)	<input type="checkbox"/> Radiation treatments
<input type="checkbox"/> Blood Transfusion	<input type="checkbox"/> Gynecologic Procedures (e.g. D&C, abortion)	<input type="checkbox"/> Receive medical care outside US
<input type="checkbox"/> Blood tests	<input type="checkbox"/> Hospital ED visit	<input type="checkbox"/> Steroid/orthopedic injections
<input type="checkbox"/> Bronchoscopy	<input type="checkbox"/> Injected Imaging Dye	<input type="checkbox"/> Surgery (inpatient or outpatient)

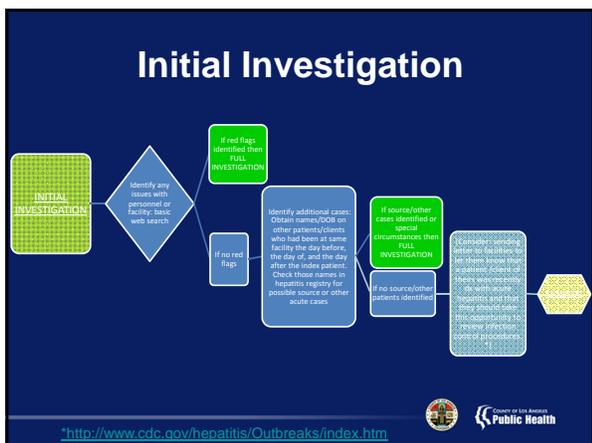


- ### Monitor
- Check facility/personnel database regularly
 - Monthly
 - Check by name of facility/personnel
 - Also check by address (some facilities change names)



- ### Special Circumstances: AKA “Spidey Sense”
- Patient in skilled nursing facility or assisted living facility who is diabetic
 - Patient who received fingersticks with equipment not their own
 - High Risk Facilities
 - Dialysis units
 - Pain, oncology, alternative medicine clinics
-

- ### Diabetes: A Special Case
- Hepatitis B commonly associated with outbreaks in diabetics
 - Due to re-use of pen-like devices between patients
 - Greater understanding that there might be microcontamination of other equipment that is used for multiple patients including glucometers
-
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- ## Goals of Full Investigation
- FULL INVESTIGATION
- Conduct case finding
 - Determine source of infection
 - Identify and recommend control measures
 - Identify and notify other patients at risk

- ## Aspects of Site Visit
- Interviews
 - Document review
 - Chart Review
 - Observation
- 

- ## Before the Site Visit
- Consider announced or unannounced visit
 - Pick a day when procedures are taking place
 - Anticipate that you might need to return to the clinic

- ## Site Visit- Be Prepared!
- List of questions and tool kit
 - Camera
 - Photo consent forms
 - Chart abstraction form
 - Legal authority
 - Title 17 of California Code of Regulations § 2501
 - Letter from County Counsel

- ## Site Visit: Tool Kits
- Tool kits help you focus what you should observe
 - Tool kits help you systematically document behaviors observed
 - Three main tool kits-
 - CMS Worksheet
 - CDC Infection Prevention Checklist for Outpatient Settings
 - One and Only Campaign Injection Safety Checklist

Exhibit 351
Ambulatory Surgical Center
INFECTION CONTROL SURVEYOR WORKSHEET
(Rev. 68 Issued: 11-24-10, Effective: 11-24-10, Implementation: 11-24-10)

I. Hand Hygiene
Observations are to focus on staff directly involved in patient care (e.g., physicians, nurses, CRNAs, etc.). Hand hygiene should be observed not only during the case being followed, but also while making other observations in the ASC throughout the survey. Interviews are used primarily to provide additional evidence for what the surveyor has observed, but may in some cases substitute for direct observation to support a citation of deficient practice.

Practices to be Assessed	Was Practice Performed?	Manner of Confirmation
A. All patient care areas have: Note: 42 CFR 416.51(a) should be cited only if the answer to both a and b is "No."	<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> Observation <input type="radio"/> Interview <input type="radio"/> Both
a. Soap and water available	<input type="radio"/> Yes <input type="radio"/> No	<input type="radio"/> Observation <input type="radio"/> Interview <input type="radio"/> Both

http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107_exhibit_351.pdf

GUIDE TO INFECTION PREVENTION FOR OUTPATIENT SETTINGS:
Minimum Expectations for Safe Care

<http://www.cdc.gov/HAI/settings/outpatient/outpatient-care-guidelines.html>

Section I: Administrative Policies and Facility Practices

Facility Policies	Practice Performed	If answer is No, document plan for remediation
A. Written infection prevention policies and procedures are available, current, and based on evidence-based guidelines (e.g., CDC/HICPAC), regulations, or standards <i>Note: Policies and procedures should be appropriate for the services provided by the facility and should extend beyond OSHA bloodborne pathogen training</i>	Yes No	
B. Infection prevention policies and procedures are re-assessed at least annually or according to state or federal requirements	Yes No	
C. At least one individual trained in infection prevention is employed by or regularly available to the facility	Yes No	

<http://www.cdc.gov/HAI/settings/outpatient/outpatient-care-guidelines.html>

Injection safety

A. Needles and syringes are used for only one patient (this includes manufactured prefilled syringes and cartridge devices such as insulin pens)	Yes No	
B. The rubber septum on a medication vial is disinfected with alcohol prior to piercing	Yes No	
C. Medication vials are entered with a new needle and a new syringe, even when obtaining additional doses for the same patient	Yes No	
D. Single dose (single-use) medication vials, ampules, and bags or bottles of intravenous solution are used for only one patient	Yes No	
E. Medication administration tubing and connectors are used for only one patient	Yes No	
F. Multi-dose vials are dated by HCP when they are first opened and discarded within 28 days unless the manufacturer specifies a different (shorter or longer) date for that opened vial. <i>Note: This is different from the expiration date printed on the vial.</i>	Yes No	

<http://www.cdc.gov/HAI/settings/outpatient/outpatient-care-guidelines.html>

1 ONE NEEDLE, ONE SYRINGE, ONLY ONE TIME.

Safe Injection for www.ONEar

The One and Only Campaign is a part of raising awareness among the providers about safe injection practices.

INJECTION SAFETY CHECKLIST

The following Injection Safety Checklist items are a subset of items that can be found in the CDC Injection Prevention Checklist for Outpatient Settings. Outpatient Settings are defined as ambulatory surgical centers, ambulatory care centers, and other ambulatory care settings. This checklist is a supplement to facility inspection and is not intended to replace the CDC Injection Prevention Checklist for Outpatient Settings. Assessment of adherence should be conducted by direct observation of healthcare personnel in each injection practice. Assessment of adherence should be conducted by direct observation of healthcare personnel during the performance of their duties.

Injection Safety Checklist Item	Practice Performed?	Is answer to this assessment plan for remediation?
Needles are changed using aseptic technique and change area free from contamination or contact with blood body fluids or contaminated equipment	Yes No	
Needles and syringes are used for only one patient (this includes manufactured prefilled syringes and cartridge devices such as insulin pens)	Yes No	
The rubber septum on a medication vial is disinfected with alcohol prior to piercing	Yes No	
Medication vials are entered with a new needle and a new syringe, even when obtaining additional doses for the same patient	Yes No	
Single dose (single-use) medication vials, ampules, and bags or bottles of intravenous solution are used for only one patient	Yes No	
Medication administration tubing and connectors are used for only one patient	Yes No	
Multi-dose vials are dated by HCP when they are first opened and discarded within 28 days unless the manufacturer specifies a different (shorter or longer) date for that opened vial	Yes No	

<http://www.oneandonlycampaign.org/>

**Site Visit:
Facility Background**

- Ownership
- Accreditation/Inspection
 - Previous inspection reports
- Primary procedures done
- Patients/month or year
- Procedures per month

Site Visit: Personnel

- Who/how many
- License(d)
- Procedures performed
- Employment other locations
- History of drug use
- Interview
 - Knowledge of policies
 - Infection control training



Site Visit: Document Review

- OSHA training
- HCW vaccination policies
- Infection control policies
 - Injection policies
 - Medication preparation and administration policies



Site Visit: Observation

- Conduct walk through
 - Identify where meds are prepared
 - Identify handwashing stations or hand gel
- Observe staff involved in medical procedures
 - Ideally on patients
 - Alternatively as “mock” procedures
- Take photos/video



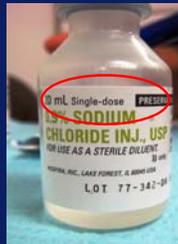
Site Visit: Injection Safety

- Medication Handling
 - Single dose/multi-dose vials
 - Re-use of needle or syringe
 - Re-entry of vials
 - Where meds are stored/prepared
- Equipment used on >1 patient



Injection Safety

- Multi-Dose Vial
- Single Dose Vial



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Multi-Dose Vial

- Dated when opened-discarded within 28 days
- Dedicated to individual patients when possible

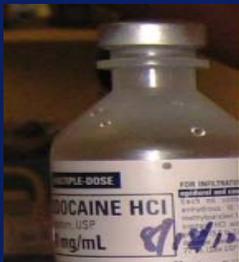


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Where Medications Prepared



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Point of Care Devices for Diabetes

- Single use auto-disabling devices for fingersticks
- If glucometer used for more than one patient, meter is cleaned and disinfected after every use



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Disposal of Sharps



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Chart Review

- Date and time of procedure performed
- Medications received
- Names of all staff involved with procedures
- Any mention of previous history of viral hepatitis



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Bloodwork

- Very helpful to definitively link patient(s) to source(s)
- Consult with CDPH before obtaining specimens
 - Hepatitis C often lasts longer in the body but specimens need special processing
 - Hepatitis B may be cleared quickly from the body but remnant specimens may be useable



Case Study



First Report of HCV

- In July 2010 –Orange County (OC) reports a case of acute HCV in OC resident
 - Stated patient medical procedures at an outpatient clinic in Los Angeles County during incubation period



Initial Epi

- Confirmed patient diagnosis and incubation period
- Detailed interview of index patient using healthcare-associated exposure questionnaire
 - Patient reported one major healthcare related exposure



Initial Investigation



- Requested a list of patients receiving treatment on/adjoining days as index case
- Reviewed names of patients in hepatitis registry for prior report of hepatitis B and/or C



Initial Investigation Results

- 208 Patient Names Reviewed
 - 3 additional Hepatitis C patients identified
 - 1 acute hepatitis B patient identified



Full Investigation



- Interviewed owner/staff
- Obtained infection control, OSHA, vaccination, and accreditation documents
- Chart review
- Observed medical procedures



Interviews

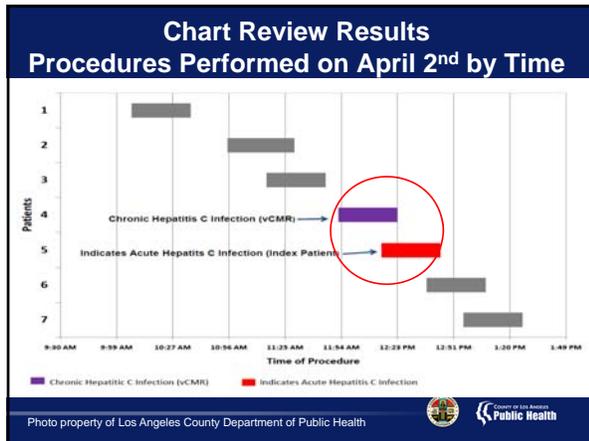
- Outpatient Pain Clinic
- 1 physician (MD) and 2 registered nurses (RN) who alternate days
- Majority of patients seen for back pain
- Most common treatments are epidural injections
- IV sedation offered during epidural procedures



Document Review

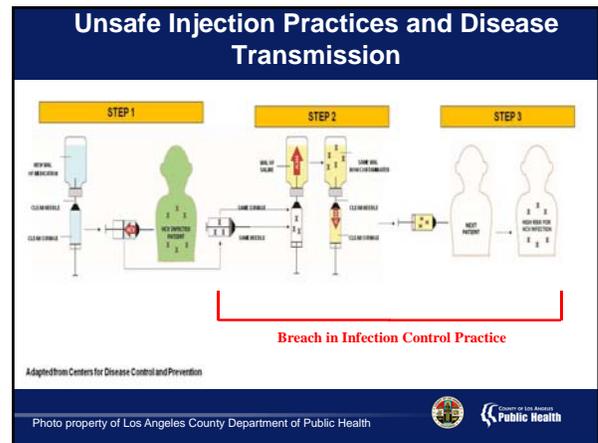
- Accreditation certificate
- Infection control training of staff was OSHA focused
- Standard Infection Control Policy was outdated
- No Injection Safety Policy



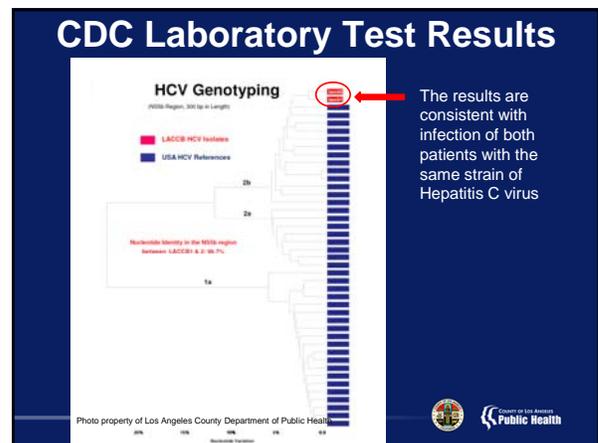


- ### Observation of Injection Practices
- We observed 2 RNs insert heparin locks and administer sedation medication
 - We observed epidural procedures by MD
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- ### Infection Control Observations
- Using single dose vials for multiple patients
 - No alcohol swab to access vials
 - Vials not dated when opened
 - The physician re-used thick gloves between patients with no cleaning of the gloves
-
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- ### Laboratory Methods
- Blood samples were obtained and sent to CDC for analysis
-
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Conclusions

- Documented patient to patient transmission
- Identified the likely cause of transmission



Immediate Interventions

- Infection control recommendations given during site visit
 - Immediately cease unsafe injection practices
 - Use single dose vials only one patient



Notifications

- Notified Medical Board and Board of Registered Nursing
- Patient Notification
 - Letters sent to 2,293 patients advising them to get tested for bloodborne pathogens



Challenges for Investigation and Control of Nosocomial Hepatitis

- Lack regulatory oversight for infection control and injection safety
- Lack of infection control programs in outpatient clinics
- Lack of education for healthcare workers in the community regarding infection control
- Limited expertise/experience of Public Health staff in investigating these situations



Solutions

- Consider regulations that require assessment of infection control as part of accreditation
- Consider requiring education for healthcare workers
- Train public health investigators
- Encourage greater use and acceptance of investigation guidelines and tool-kits



Questions!

- Don't be shy
- No question is stupid
- If you have a question, then at least one other person has the same question and wishes someone would ask it
- So ask away!

