



Linda S. Vail MPA, Health Officer

Kathy Kacynski MS, RN Disease Control
Nurse

**INVESTIGATING HEPATITIS C
INFECTIONS ASSOCIATED WITH
UNSAFE INJECTION PRACTICES
AT A PAIN MANAGEMENT
CLINIC**



Ingham County
Health Department

Background

- Patient with acute Hepatitis C infection notified Michigan Department of Health and Human Services (MDHHS) that infection may have been acquired at health facility located in Ingham County
- MDHHS and LHD (Ingham County) collaboration
- Legal jurisdiction and documents for health facility inspection



Additional Cases

- Licensing of facility fell solely on providing physician's license to practice
- No complaints against physician
- No other cases in MDSS appeared to be linked to clinic



Unannounced Clinic Site Visit

- Clinic voluntarily allowed site inspection
- Site visit team consisted of six members
 - Two from MDHHS and four from ICHD
 - Five of six team members were RNs
 - Four of team reviewed infection control protocols, policies and procedures, medication logs and staff training records
 - Two RN members performed direct observations of procedures being performed
 - Obtained medical records and lists of other patients seen during potential HCV acquisition window



Investigation

Utilized CDC Health Care Investigation Guide:

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

1. Verify acute HCV diagnosis
2. Assess client's overall exposure history
3. Enter data into healthcare investigation database
4. Assess health care encounters and look for additional cases
5. Respond to information identified during health care assessment



STEP ONE: *Verify* acute HCV



Index Patient

Acute HCV illness in early to mid-October 2014

- ALT=1164
- Positive HCV antibodies and RNA
- Discrete onset with abdominal pain, fatigue, fever, vomiting, loss of appetite and jaundice
- All other Hepatitis labs were negative
- Liver CT and biopsy did not show chronic disease



STEP TWO: Assess exposure window



Exposure window

- HCV incubation period is 2 weeks to 6 months prior to onset of symptoms
- Patient probable exposure was late April 2014 to September 2014
- Client interview revealed that only possible HCV exposure was at a Pain Management Clinic located in Ingham County



STEP THREE: Data entry



Data Entry

- Utilized Excel for data entry
- Data maintained by Ingham County Health Department
- Single individual coordinated data collection and entry



STEP FOUR: Assess healthcare encounter
(pain center) and look for additional cases



Clinic Site Visit Findings

- Performed the following procedures:
 - Infusion pump refill
 - Sacroiliac joint injection
 - Epidural injection
 - Facet joint injection
 - Peripheral nerve stimulation
 - Discography
 - Sympathetic nerve block
 - Spinal cord stimulation
 - Rhizotomy



Site Visit Findings continued

- Staff of one physician, five medical assistants (MAs), an office manager, a surgical technician (ST), a psychologist, and a registered nurse (RN)
- The five MAs rotated duties periodically with three assigned daily to patient care
- RN assisted physician during all procedures with intravenous sedation
- ST trained to refill pain medication infusion pumps



Medications Administered

- Dexamethasone
- Marcaine
- Lidocaine
- Propofol
- Fentanyl
- Versed
- Compounded meds for specific patients
(Hydromorphone, Dilaudid, Morphine)



Infection Control Exceptions

- No written infection control policies or procedures
- No staff training on infection control on hire or annually
- No autoclave logs
- Medication counts and wasting logs not recorded
- Single use medication vials were used on more than one patient



Exceptions continued

- Compounded medications arrived in prefilled syringes but not tamper proof
- Sharps disposal containers were not secured
- Needle recapping observed
- Filter needles were not used with glass ampules
- Medications, staff food and beverages in same refrigerator



Medical Record Review Results

On August 21, 2014:

- Patient #1 had bilateral epidural injections at 11:15 AM - - - known to have chronic HCV infection (GT1b)
- Patient #2 had bilateral hip injections at 11:30 AM - - - presented in October 2014 with acute HCV infection (GT1b)
- Index patient had facet joint injections at 11:45 AM - - - presented in October 2014 with acute HCV infection (GT1b)



STEP FIVE: Respond to information identified during health care assessment



Next steps

- Develop written report of findings and make recommendations for pain clinic
- Pursue additional case finding through targeted patient notification and testing



Recommendations

- Develop and enforce infection control policies and procedures
- Develop and maintain and instrument sterilization log
- Develop and maintain medication count logbook
- Use tamper proof sharp disposal containers
- Stop recapping sharps after use



Recommendations continued

- Single-use and single dose vials are not be used on more than one patient
- A new needle and syringe used for every injection and infusion
- Use filter needles with glass ampules
- Separate refrigerators for staff food and drinks and medications



One and Only Campaign

- Provided Pain Clinic with Provider Toolkit for One and Only Campaign

<http://www.oneandonlycampaign.org/content/one-only-campaign-toolkits>



Notification and Testing

- Selected three weeks of scheduled patients for notification and targeted testing (blood borne pathogens)
- Arrangements made with Sparrow Laboratory for “special” lab slip, so patients not billed
- Notification letter constructed using CDC patient notification toolkit
- Pain clinic printed letters on their letterhead and their physician signed letter



Notification and Testing

- 122 letters sent out on 04/27/2015 to patients in 11 counties and two states
- If patients did not test, follow-up phone calls were made on 05/13/2015 to ensure letter was received and to facilitate testing



Testing results

- 92 patients tested (75% of target)
- No positive HBV or HIV results
- 6 tested positive for HCV antibodies and 1 equivocal
 - 3 of 6 were HCV RNA positive
 - All positive HCV patients already knew they were positive and were reported in MDSS



Testing results

- Three with positive RNA sent to CDC for quasispecies analysis
 - Inconclusive quasispecies results
 - CDC recommend relying on epidemiological evidence to draw conclusions

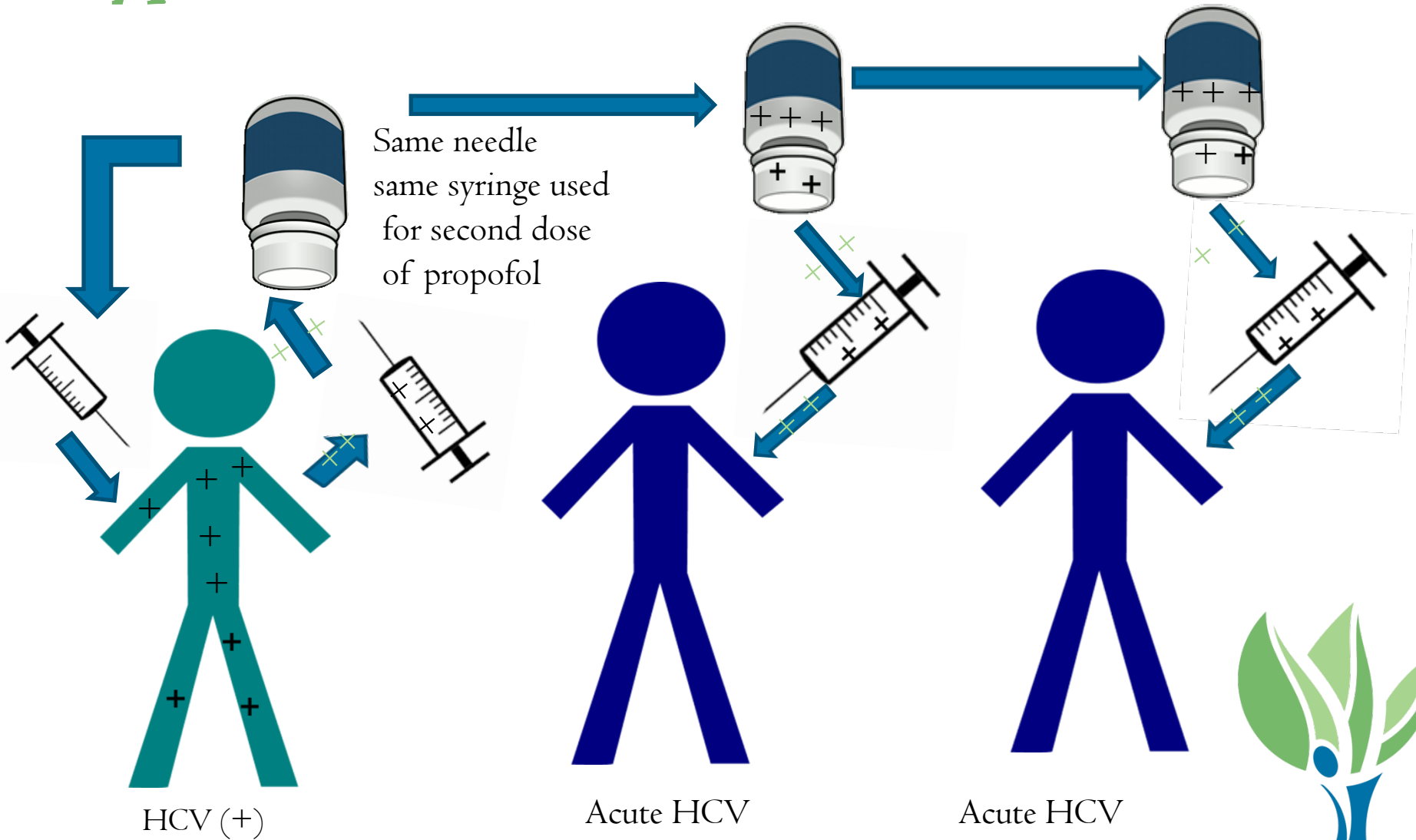


Conclusions

- Multi-dose propofol vial most likely inoculated with HCV during chronic HCV patient procedure (this patient received two doses of propofol)
- Transmission of HCV most likely occurred during the use of the inoculated propofol vial with downstream patients



Hypothesis



Conclusions

- Fortunately, this HCV cluster appeared to be an isolated incident, so no further patient notification was indicated



Follow-up Clinic Visit August 2015

- Clinic had implemented all recommendations
- Other changes implemented:
 - Hired part-time RN as Infection Control Nurse
 - Previous RN retired and a paramedic was administering IV sedation
 - Physician drawing up all medications into individual syringes at beginning of work day to comply with one syringe, one needle, one time protocol



Lessons learned

- Ongoing education of all health care personnel is essential to ensure the universal implementation of: “One Needle, One Syringe, Only One Time”



Lessons Learned

- Collaboration between MDHHS, ICHD, Sparrow, CDC and Pain Center was essential for success of investigation and ensuring patient safety
- CDC checklist very useful in organizing investigation
- One person coordinating information and data was crucial



Recognition of the following people:

- MDHHS: Joe Coyle, Emily Goerge, Dr. Janice Matthews-Geer
- ICHD: Linda Vail, Dr. Sugandha Lowhim, Ruby Rodgers, Patty Raines, Shelly Holtz and Kathy Kacynski
- Sparrow: Dr. Walid Khalife and Art VanDyke
- Pain Center: all the staff



QUESTIONS

