

Acute Hepatitis C outbreak, Southern Nevada, 2007-2008

Presenting group: Genetically Modified Brussels Sprouts, MARPHLI Year 17 Fellows

Functional Area: Policy Development

Case Setting:

Hepatitis C is the most serious of the group of Hepatitis viruses. More than 4.5 million people in the US are chronically infected with this illness that spreads primarily through infected blood and causes liver damage. Persons can most likely become infected through sharing needles, syringes, injecting drugs (i.e. needle stick injuries in healthcare settings) or through neonatal transmission from an infected mother. Currently, there is no vaccine for Hepatitis C Virus (HCV) nor is there a medication available to treat acute HCV infection. For Chronic HCV, combination drug regimens are available but not everyone benefits from treatment.

In January 2008, CDC's Division of Viral Hepatitis and Division of Healthcare Quality Promotion responded to a request from a local health department in Nevada to help investigate an abnormal cluster of acute hepatitis C virus (HCV) infection. Three identified cases of Acute Hepatitis C had undergone procedures at a local endoscopy clinic. The health department normally sees less than four cases in the entire year, therefore this was unusual. Since the investigation began, a total of six cases of HCV infection among patients receiving treatment at the same clinic have been identified. After months of investigating, it was also determined that the four years of unsafe procedures practiced by the Endoscopy Center had resulted in more than 53,000 patients being exposed to Hepatitis B, Hepatitis C, and HIV.

Introduction

Hepatitis C (HCV) is a disease of the liver transmitted primarily through contact with the blood of an infected person. Persons can most likely become infected through sharing needles, syringes, or other works for injecting drugs; needle stick injuries in healthcare settings; or through neonatal transmission from an infected mother. Other less- common ways of transmitting HCV are through sharing personal items that may have been contaminated with someone's blood such as razors or through having intercourse with an infected person (*1*). Before the US began widespread screening of the blood supply, HCV was primarily spread through blood transfusions and organ transplants. Currently, the most common transmission is through sharing needles.

The effects of HCV can either be acute or chronic. Acute HCV infection occurs within the first 6 months after exposure. Although approximately 70-80% of people with acute HCV are asymptomatic, some people can experience symptoms such as "fever, fatigue, loss of appetite, nausea, vomiting abdominal pain, dark urine, clay-colored bowel movements, joint pain, or Jaundice" (*1*). For most people, acute infection will lead to chronic infection. Chronic HCV infection occurs when the virus remains in a person's

body. This can eventually lead to problems with liver functioning such as liver scarring (cirrhosis), liver cancer, and in some cases, death.

Currently, there is no vaccine for HCV or medication available to treat acute HCV infection. Doctors usually recommend rest, adequate nutrition, and fluid. For chronic HCV, people are monitored regularly for signs of liver disease and are usually prescribed “a combination of two medicines, interferon and ribavirin. However, not every person . . . will benefit from treatment.” (1).

HCV, hepatitis A, and hepatitis B are caused by three different viruses. They each have modes of transmission and affect the liver differently. Hepatitis A appears only as an acute infection and does not become chronic. Similar to HCV, hepatitis B can also begin as an acute infection and lead to chronic infection. However, there are vaccines for both hepatitis A and hepatitis B, whereas there is no vaccine for HCV. Prior to its discovery in 1989 by Chiron, Inc., infection not caused by hepatitis A or hepatitis B was referred to as ‘non-A, non-B hepatitis’ (2).

Case Study

Key Players:

Sally Bobally.....	CD Nurse employed b the SNHD
Megan Drendle.....	NSHD Epidemiologist
Dr. Joe Dirt.....	Chief Health Officer, SNHD
Josh Orngutan.....	Nevada’s Governor
Sophie Sophophaphos.....	Nevada Assemblywoman
Ed Fred.....	Nevada Senate Minority Leader

January 02, 2008 – Outbreak Detection

Sally Bobally, a registered nurse with the Southern Nevada Health District (SNHD), checked her computer. Every morning at about this time, she would log into Nevada’s Health Alert Network and look for disease outbreak reports for residents in her district. It was one of her duties to monitor the health status of the community and investigate unusual disease occurrences. She was accustomed to receiving notification every day from doctors and local clinic staff with reports of common communicable diseases. It was early January, so Sally expected the majority to be reports of flu.

She looked through the list on her computer screen for anything unusual. She was very surprised to see reports of two people diagnosed with acute Hepatitis C (1,2). In her career, she had not ever seen two cases of Hepatitis C reported in one day. As a matter of fact, Southern Nevada Health District typically confirms four or fewer cases over the course of an entire year. This was very unusual.

Sally began her initial investigation by making calls to the patients that were diagnosed with the disease. She followed her usual routine, asking the customary questions and looking for trends or any other data that might point to a discovery. She was surprised that one common factor between the two reported cases was that they all underwent an

endoscopy procedure at the Endoscopy Center of Southern Nevada between 35-90 days prior to showing symptoms of Hepatitis C (1,2). This was troubling. If this disease was somehow being transmitted in the clinic, there was the potential that a very large number of people could be infected as a result.

She decided to contact Megan Drendle, the Nevada State Epidemiologist, and go over her findings. Sally was always quick to notify the State as soon as possible in special situations like these. With rapid notification, Megan could watch for other outbreaks in different areas of the state and if there were other reports, they could quickly alert other agencies and they all could appropriately adjust their investigations. During Sally's conversation with the Megan, she learned that her Hepatitis C cases were the first reported that seemed to have any link to the endoscopy clinic. It was agreed that SNHD would begin assembling an outbreak investigation team (OIT) and that Megan on behalf of the State Health Department will issue a formal request for technical assistance from the Center's for Disease Control and Prevention (CDC) as soon as possible (2).

Sally was in the process of assembling her team when reports of a third case of acute Hepatitis C appeared. The initial interview revealed again that this individual had undergone an endoscopy procedure at this same clinic. Since all evidence was pointing to the clinic in question, Sally contacted the Nevada State Bureau of Licensure and Certification as they are the agency that licenses the clinic (2). She wanted to make sure that any and all key players involved were aware of this situation.

January 4, 2008

Megan Drendle, Epidemiologist with the Nevada State Health District issues a formal request for technical assistance to the CDC. CDC responds and indicates that they will send investigators to assist in the investigation. They are to arrive on the 9th of January (2).

January 9-17, 2008 – The Initial Clinic Investigation

The health officials began their investigation at the clinic. In addition to the members of the SNHD's OIT (with Sally at the helm) this group now included members of the CDC investigation team for technical support. The health investigators spent several days reviewing files and operating procedures as well as interviewing former and currently employed staff of the clinic (2).

A few days into the review of the clinic records, Sally noticed that the number of single use anesthetic vials (that would be used in endoscopy procedures) was frequently different than the number of patients logged to receive the dose in a given day. The OIT learned from staff that it was common practice in this clinic that when a patient required more sedation, an additional vial of anesthetic was used. Staff explained that the old, anesthetic vial and needle were discarded and a new needle was attached to the old syringe and was then used to draw medication from a second vial. The remaining anesthetic solution in this vial was then used on the next patient requiring such a procedure (1).

The health investigators were astonished. They realized that the reused syringe barrel could have become contaminated with HCV laden backwash from an infected patient. This infected syringe barrel, now with a new needle, may have passed the virus into the partially used vial of anesthetic, which was subsequently injected into the next patient. Discarding used tools and single use vials was a very basic communicable disease prevention process. Sally herself thought of it as “nursing 101”.

During the staff interviews, the OIT learned that some staff had made complaints about these procedures to clinic management, but nothing was ever done to correct this issue. The OIT was notified by some former staff members that it was unsafe practices such as these that caused them to resign their positions. The interviews and record research further revealed that this dangerous practice had been followed since the clinic was remodeled in 2004 (2). This meant that potentially thousands of patients could have been exposed to all sorts of communicable diseases.

Timeline of events:

07/15-31/07

1 endoscopy procedure performed. Single use vials of anesthesia reused on multiple patients (1)

09/16-31/07

5 endoscopy procedures performed. Single use vials of anesthesia reused on multiple patients (1)

10/16-31/07

Symptoms of Hep C onset in patient undergoing endoscopy procedure in July '07. 3 patients who underwent endoscopy procedures at clinic in September '07 demonstrate Hep C symptoms (1)

11/1-30/07

2 more patients who underwent procedure in September '07 demonstrate symptoms (1)

01/02/08

Southern Nevada Health District (SNHD) receives surveillance reports from area doctors that indicate that 2 people recently diagnosed with acute hepatitis C (an additional case added the next day). Nevada State Health Division (NSHD) contacted and informed CDC.

Initial inquiries indicated that all patients had undergone procedures at the same endoscopy clinic 35-90 days before onset.

01/09/08

Joint investigation (SNHD, NSHD, and CDC) of the clinic was initiated. Investigation revealed that transmission likely occurred because of reusing syringes on individual patients and use of single use medication vials on multiple patients (8)

01/31/08

Field investigation concludes (5)

02/27/08

SNHD issues formal announcement that 6 identified cases of hepatitis C had been identified and urges testing for approximately 40,000 patients. Health Department website FAQ page dedicated to the outbreak put online (8)

03/28/08

SNHD OIT memo sent to Dr. Joe Dirt, Chief Health Officer, and SNHD. Dr. Dirt appears in 2 videotaped public service announcements explaining the outbreak, urging the public to be tested and asking that they do not avoid routine medical care as a reaction to their possible loss of trust in the staff of health clinics(8)

04/11/08

SNHD announces it will host special community forum on Hepatitis C on 19th of April (7)

04/21/08

News release: SNHD advises of an eighth acute Hepatitis C case, the seventh linked to clinic (7)

04/25/08

2 Nevada lawmakers, Assemblywoman Sophie Sophophaphos and Senate Minority Leader Ed Fred send a formal request to Nevada's governor, Josh Orangutan, asking for an independent investigation into the doctors linked to the outbreak.

05/08/08

News release: Health District identifies 77 potential clinic associated infections (7)

05/14/08

Nevada Governor, Josh Orangutan refuses to order an independent probe to investigate doctors employed at the clinic linked to the Hepatitis outbreak. Instead, the state is to rely on their Board of Medical Examiners. The 2 lawmakers that authored the 04/25/08 letter asking for the independent investigation ask in another letter that this board conduct a thorough, unbiased investigation. Assemblywoman Sophophaphos suggests restructuring the board in order to restore confidence in it. (6)

06/05/08

News release: SNHD concludes investigation and announces implementation of Hepatitis C Exposure Registry (7)

07/24/08

News release: SNHD issues news release identifying source cases for HCV outbreak. The Exposure Registry now includes 6,000 enrollees (7)

10/23/08

Las Vegas Sun publishes article "Nevada hepatitis C outbreak largest in U.S.; Health officials report 105 possible cases" (5)

Results of Hepatitis C outbreak

After months of investigating, it was determined that the four years of unsafe procedures practiced by the Endoscopy Center of Southern Nevada and an affiliated clinic, the Desert Shadow Endoscopy Center, had resulted in more than 53,000 patients being exposed to Hepatitis B, Hepatitis C, and HIV. Nine patients diagnosed with Hepatitis C were directly linked to the clinics because of the hard work of Sally Bobally of the Southern Nevada Health District, Megan Drendle of the Nevada State Health District, and staff from the Centers for Disease Control and Prevention. Another 105 patients diagnosed with Hepatitis C could have possibly contracted the disease from the clinics, although they also had other identified risk factors. No cases of Hepatitis B or HIV were identified in patients of the clinics that had procedures performed during the timetable in question. Both medical clinics were closed and two physicians that worked in the facilities had their licenses temporarily suspended. A malpractice complaint was filed against a third physician.

This case study addresses the core competency of policy development. The Nevada Hepatitis C outbreak is the largest Hepatitis C outbreak in United States history. The outbreak was not just a public health investigation, but a criminal investigation. Therefore, sharing information between agencies was difficult. However, the Southern Nevada Health District proposed new policy to ensure that investigative agencies have the ability to share information. They proposed policy to institute fines for violations by medical facilities to include costs for public health investigations and outbreaks. They also proposed giving the Southern Nevada Health District's Chief Health Officer, Dr. Joe Dirt, the power to order a cease and desist order in cases when medical facilities are found to be performing unsafe medical practices. In addition, they recommended that the State of Nevada Health Division create an Ombudsman Program to assist the public in filing complaints against health professionals or medical facilities that may be performing unsafe practices.

To a lesser degree, this case study also addresses assessment through diagnosis, reporting, and investigation of a communicable disease. The quick reporting of physicians and investigation by infection control staff in medical facilities and public health professionals is critical in the detection of disease outbreaks. Effective surveillance systems can not be a one way flow of information from medical provider to public health department. Therefore, the teamwork and information sharing between Sally Bobally of the local health department, Megan Drendle of the Nevada State Health District, and investigative staff from the Centers for Disease Control and Prevention was very effective in this outbreak investigation.

This outbreak also had financial and political implications. Nevada Senator, Ed Fred, attempted to obtain over five million dollars in federal funding for Southern Nevada Health District due to their involvement in the Hepatitis C investigation. The funding was to be used to reimburse expenses incurred by the Southern Nevada Health District during the outbreak, fund a Hepatitis C awareness campaign in Nevada, and have the financial resources to provide blood tests and additional follow-up for patients of the Endoscopy

Center of Southern Nevada and the Desert Shadow Endoscopy Center since the average lifetime cost of managing a patient with Hepatitis C is estimated to be \$100,000.

The need for Prevention, Control and Medical Management of Hepatitis C

With cases of Hepatitis C on the rise it is imperative we educate not only the health professionals but also the public. CDC fact sheets, articles, and Epidemic Control Tracking show us the need for medical management of Hepatitis C along with education and surveillance is greatly needed. Both the Senate and Congress currently have bills on the board addressing this need.

Some recommended practices are as follows:

For the public:

Make sure fact sheets are available at all times with basic safety information in simple terms.

For Healthcare providers:

- Strict asepsis must be maintained during preparation and administration of all parental medications
- Vial must state that the vial is appropriate for multiuse purposes
- Check for product expiration date
- Inspect vial for any evidence of contamination. If any exists, discard vial.
- Follow hand hygiene procedures before beginning any task
- Cleanse the stopper with 70% alcohol before inserting the needle or other device
- Ensure that the syringe and the needle or other device used to access the vial is sterile
- Avoid touching the stopper

For Surveillance purposes:

- Add the date of opening on the vial label
- Unless otherwise noted, secure the vial in refrigerator
- Note the usage in clinic log as directed

Conclusion

It is our hope that lessons learned from this study will help healthcare professionals as well as policy makers to better understand the importance of following policies and protocols that have been put in place to protect the health and safety of the citizens. The sheer negligence in medical practice protocols at the healthcare providers location exposed in this case study should serve as a learning lesson for readers and make them ponder on their own best practices for the health and safety of the community at large.

Study Guide/ Discussion Questions:

1. What control measures could have been put in place by the State or local government to prevent the initiation of the dangerous injection practices?
2. The OIT was comprised of members of the SNHD and the CDC. Do you agree with the makeup of the group? Why?
3. What was Sally's purpose in contacting the Nevada State Health Department epidemiologist? Why is this step critical?
4. If you were the Public Information Officer, in charge of making a statement to the media about this outbreak investigation, what are three main points you would want the public to know?
5. This investigation identified that many Nevada medical facilities are years overdue for State inspections that may have identified unsafe medical practices. What type of assurances can be put in place to ensure that health inspection agencies complete inspections in the required time frames?
6. Discuss the Incident Command structure design that could have been utilized in responding to this outbreak. What roles, if any, would the key players in the outbreak have had in the structure?
7. Do you feel that any action should be taken against the managers/employees of Clinic A? Why or why not?

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