Outbreak Investigation of Healthcare-Associated Hepatitis C Virus Infections  North Dakota, 2013

A Report to the State Health Officer
October 2016

Division of Disease Control
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Summary
This report contains the findings regarding an investigation into an outbreak of health-care related hepatitis C virus infections in Ward County, North Dakota which was initiated in 2013. Content includes the details of the investigative and surveillance activities and recommendations made by NDDoH to reduce the ongoing risk of transmission. The investigation initiated when an outbreak was discovered and found to be associated with residency in a long term care facility (LTCF A). Forty-eight cases of HCV infections were identified to be genetically identical by quasi-species analysis among individuals who had resided at LTCF A during the period January 1, 2011 through September 9, 2013. The median age for these cases is 83.5 years (range: 38-100 years), with 62% of cases being female. The epidemiologic and on-site investigation did not reveal a single exposure or source that could explain all of the cases. The epidemiologic data shows that the outbreak likely resulted from breakdowns of proper infection control procedures in LTCF A for these cases. Results from a case-control study found nail care, foot care and phlebotomy performed at LTCF A to be statistically associated with having hepatitis C. Inconsistencies in protocols and procedures to prevent the transmission of pathogens as well as other infection control breaches were identified during the investigation.

Additional screening for hepatitis C in the community in early-2014 resulted in four additional outbreak cases. The quasi-species analysis revealed that these additional four cases were likely associated with the transmission among other outbreak associated cases. The cases fit the epidemiologic profile of other cases in terms of age, living in a congregate setting, but had no history of residency at LTCF A. An additional case of hepatitis C related to this outbreak was identified in January of 2015, however was a former resident of LTCF A during the time period that other cases were also residents of that facility. Ongoing active surveillance has not shown evidence of any ongoing transmission based on likely time periods of exposure since October 2013.

Setting and Background
Ward County is located in north central North Dakota with an estimated population of 67,000 people in 2013. The county has one major population center, Minot, which is a community of about 46,000. The community has one acute care hospital (hospital X) and two long term care facilities. If patients are found to require long-term care after hospital discharge, it was determined that often bed availability and/or patient preference were the main determining factors considered in patient placement.

In February 2013, two HCV cases were reported to the North Dakota Department of Health (NDDoH), Division of Disease Control (DC) through the standard passive reporting system from a clinical laboratory in Minot. In March 2013, the infectious disease specialist in Minot contacted DC and indicated that he was diagnosing both with acute infection. By definition, acute HCV infection is a case in which laboratory evidence and clinical criteria are met where the likely infection occurred in the last 12 months. Both cases were diagnosed in patients aged
older than 60 years. The physician was asked to report any additional cases of acute HCV infections upon diagnoses to DC. In May 2013, a third report of an acute HCV case also greater than 60 years of age was received. In June 2013, serum samples from two of the three cases were collected; the third case had expired but a blood sample was found in storage and forwarded for testing. All three specimens were positive for HCV antibody and sent for genotyping and quasi-species analysis at the Centers for Disease Control and Prevention (CDC), Atlanta, GA.

DC began gathering epidemiologic information on these initial cases in spring 2013. It was found that of these first three cases, they all held in common current or former residence of LTCF A. The DC surveillance system was cross referenced with the names of recent or current residents of LTCF A to determine if there were other previously reported cases that shared the same exposure to LTCF A. This search identified four additional HCV cases aged 60 years and older. Blood samples were collected on these four additional cases and were found to have antibodies to HCV. These four additional samples were sent to CDC for further analysis, and found to share the similar quasi-species results.

Medical record chart abstraction for these original seven cases was conducted to look for procedures, providers or injectable medications that the seven cases may have had in common. No single common acute care, inpatient or outpatient procedure was identified; neither were exposures to a single healthcare provider administering injectable medications identified.

To further our understanding of the distribution of cases, the Department initiated several activities to help assess the scope of this outbreak. LTCF A produced a register of all current and former residents of that facility, dating back to January 2011. This date was chosen based on the analysis of the initial cases where laboratory evidence, when assessed retroactively, was suggestive of a time period in which acute infections may have been likely. This list of residents was compared with laboratory-based surveillance data maintained by DC. Eight additional current or former residents were identified that had been previously reported to DC with either past or current HCV infection.

In September 2013, targeted screening of current and former residents of LTCF A identified 19 additional persons with similar quasi-species of HCV as the outbreak strain. On September 9, 2013, testing of current residents of LTCF A yielded a HCV prevalence of 28% for this facility. This prevalence was much higher than what was to be expected. According to the Centers for Disease Control and Prevention (CDC), the estimated prevalence rates for the general population in the United States for hepatitis C range from one to two percent. Prevalence of hepatitis C in long term care facilities is less understood. A single meta-analysis of data shows prevalence ranging from 1.4% to 11.8%. (Attachment A) To help understand if this high prevalence was unique to LTCF A or if this outbreak extended beyond LTCF A, a targeted screening was performed at the second long term care facility (LTCF B) in the same community. In this screening, an HCV prevalence of about 3% was found. Further laboratory analysis indicated
only one case from LTCF B matched the outbreak strain. This case was also a former resident of LTCF A. The other two cases that were HCV positive were found to have had traditional risk factors that are likely to have explained their infection.

Additional cases were identified through subsequent testing in the community. Testing events were conducted from September 2013 through February 2016, and an additional 26 cases related to the outbreak were identified. This yielded a total of 52 cases having the same HCV as determined by quasi-species analysis. Forty-eight (92.3%) occurred among current or former residents of LTCF A. Of the remaining four, three (75.0%) occurred among current residents of a single assisted living facility (ALF Y) and one case at a second assisted living facility (ALF Z). Four samples from patients with hepatitis C, genotype 1b infections from the general community were tested to determine if there was quasi-species match to the outbreak strain of the virus. None of the general community viruses matched the outbreak virus. Testing events where blood was collected for hepatitis C testing also included screening for human immunodeficiency virus (HIV) and hepatitis B (HBV) in addition to HCV testing. All HCV testing included antibody testing with reactive samples subsequently tested for HCV RNA and genotyping. No HIV or HBV infections were detected as a result of the testing events. Attachment B outlines all screening and surveillance activities conducted from September 2013 through February 2016.

Further Investigation

On October 12, 2013, the State Epidemiologist issued an EPI-AID request to CDC for assistance in the investigation. The EPI-AID team, which was comprised of two medical officers, two Atlanta-based Epidemic Intelligence Service (EIS) officers, and the EIS officer assigned to North Dakota, arrived in Minot on October 15, 2013. CDC and state personnel conducted chart abstraction, data entry and data analysis in the field. A case-control analysis found that HCV case status was significantly associated with exposure to nail care at LTCF A, as well as, receipt of podiatry and phlebotomy services at LTCF A. Both podiatry and phlebotomy services at LTCF A were provided through contracts with outside providers. The results of this case control study were published in the American Journal of Infection Control in October 2016. The abstract can be found referenced in Attachment C.

Investigation Activities

Objectives

The objectives for the EPI-AID and the NDDoH investigation were as follows:

1. To perform case finding activities to better characterize the outbreak; including screening at-risk persons for HCV and analysis of outbreak serum specimens from persons affected by the outbreak to identify viral genetic relatedness;
2. To observe infection control practices at LTCF A and hospital X;
3. To perform a case-control analysis of LTCF A and hospital X medical records to assess potential modes of transmission and risk factors for HCV infection in this population; and
4. To develop infection prevention recommendation to stop ongoing transmission.

Methods
The investigation included the following elements:

- Serologic screening of current and former residents (January 1, 2011-September 9, 2013) of LTCF A.
- Observation of:
  - Processes and procedures at LTCF A, LTCF B, outreach phlebotomy, podiatry and hospital X
  - Work flows and protocols at LTCF A and Hospital X
- A case-control study focused on residents at LTCF A who were residents on September 9, 2013.
- Serologic screening among a similar population within the community to assess the scope of the outbreak.
- An infection control consultation for LTCF A and ALF Y by the Association of Professional in Infection Control (APIC)
- General infection control education for all community providers by APIC.

Observations and Interviews
In September and October of 2013, the DC Healthcare Associated Infections activities coordinator and the EIS officer assigned to North Dakota conducted observations in LTCF A. Observations included all three shifts over the course of four days. In October, observations and interviews were conducted by the NDDoH’s Division of Health Facilities survey staff at Hospital X. Observations and interviews were also conducted to better understand the protocols and procedures pertaining to controlled substances. Observations were also conducted of the single-local EMS services.

LTCF A
Observations revealed that a single set of nail care clippers was being used on each floor of LTCF A for non-diabetic patients. LTCF A staff members who were conducting nail care were not able to consistently describe the protocol for cleaning the clippers. Staff were reminded to follow the manufacturer’s instructions for cleaning and disinfection of point of care glucose monitoring devices. In February of 2014, APIC conducted on onsite assessment of infection control practices and procedures. Among the findings, there was inconsistent understanding of how point of care glucose monitoring devices should be cleaned and disinfected and a single instrument was used for multiple patients.

Hospital X
Several areas were observed at hospital X. These observations and interviews focused on the movement of controlled substances within the hospital and infection control practices. Areas observed included: hospital pharmacy, the emergency department, the operating room,
anesthesiology, radiology, intensive care, the GI laboratory, orthopedics, neurology, same day surgery, and the post anesthesia care unit.

Hospital X Central Processing
Observations were conducted at both of the central processing areas used by hospital X and its associated clinics by the DC Health Care Associated Infections (HAI) activities coordinator in November 2013. Central Processing is the department where instruments are cleaned, disinfected and sterilized. No major lapses were noted.

Outreach Phlebotomy
Observation and interviews of outreach phlebotomy services occurred in September and October of 2013. At LTCF A, a phlebotomist was observed in September 2013, however, this phlebotomist was not the same individual that was consistently providing care to the facility during the time period in which disease transmission was believed to have occurred. The primary phlebotomist was not available on the day observations were made. Of note, the phlebotomist who was observed did not wash hands or conduct hand hygiene after removing gloves, however did so upon entry into a resident’s room. There were no disposal bags attached to the tray. A sharps container was noted to be attached to the tray; however, the observed phlebotomist, after performing the procedure, would walk across the room to dispose of materials into either the garbage in the resident’s bathroom or the sharps container in the resident’s bathroom.

The primary phlebotomist for LTCF A was assigned through a contractual agreement between LTCF A and Hospital X. This individual was interviewed, with her supervisor present, in August 2013. Answers provided were consistent with accepted standards of practice. This phlebotomist was observed in practice at an assisted living facility in October 2013. The phlebotomist had a large tray with a hinged cover. The tray was well stocked. Glove changes were made between patients but no hand hygiene was performed between patients. It was noted that the phlebotomist had long nails or an acrylic manicure during both an interview in August and during observation in October.

Podiatry
The podiatrist providing most of the care in LTCF A since January 2011 had moved out of state in September 2012. Interviews at the outpatient podiatry clinic failed to identify a breakdown in procedures that may have resulted in transmission of HCV. However, through interviews with healthcare staff in November 2013, it was noted that procedures, conducted onsite at LTCF A, involving the treatment of ingrown nails and calluses would occasionally result in bleeding.

The podiatrist providing much of the care during the critical time period was interviewed by phone in November 2013. Although there were occasional procedures dealing with ingrown toenails or callous removal, these were infrequent and most visits to LTCF A were for routine
nail care. There were no notable breaches in infection control reported during this interview. Direct observation of this provider did not occur.

Observations of current podiatry services were made in October 2013 and February 2014.

**Patient Interviews**

Interviews with HCV infected cases and non-cases were conducted, when feasible. If cases could not be interviewed, a proxy, often a family member, was interviewed. Current and former residents of LTCF A were interviewed. These interviews provided limited information in assisting with the investigation. Anecdotal reports from some of the family members indicated that the sharing of razors and toothbrushes between residents occurred in LTCF A, but were not directly observed during the investigation.

**Assisted Living Facility Y (ALF Y)**

Observations and interviews were conducted at all of the assisted living facilities in the community. As a result of the additional cases found residing at ALF Y, APIC was hired to provide consultation to ALF Y as well as provide education to the staff of all the assisted living facilities in the community. It was documented that insulin injections are given by medication technicians and each resident has his/her own insulin pen and lancets that are stored separately. The medication technicians also conduct the point of care glucose monitoring. Residents have their own instruments and are kept in their respective apartments, with the exception of one resident’s instrument, which is stored in the central medication room. Instruments are not routinely cleaned by staff, except when visibility soiled. In that case, they are wiped down with an alcohol swab.

Either the registered nurse or the licensed practical nurse give vitamin B injections as prescribed. Staff indicate that nail care is not performed by staff.

There is a salon that rents space at ALF Y. The salon provides hair and cosmetic nail care to clients by appointment. The salon has a single operator, who is a cosmetologist licensed by the state of North Dakota. Of note, there were several lapses in infection control procedures observed by DC staff. Among these were failing to keep dirty supplies separate from clean supplies, inadequate cleaning of instruments, failure to measure the concentration of disinfectant and lack of knowledge regarding how much disinfectant to mix with water or the amount of contact time needed for proper disinfection. This operator was also witnessed giving advice to a client regarding an ingrown toenail. The operator stopped working on the current client and handled the foot, which had an open wound. Without any hand hygiene, the operator went back to work on the other client’s nails. The client with the ingrown nail commented that the toe is pretty tender but she would come back next week and let the operator “dig in it”.

Of note, observations were conducted at all the salons that were located within assisted living facilities in the community. Common findings included inadequate cleaning of instruments prior to disinfection. Also, there was lack of knowledge about the label directions regarding proper
concentrations of disinfectant or contact time for disinfection as well as a lack of knowledge for proper cleaning and disinfection if contamination of the instruments with blood occurred. These issues were addressed with the North Dakota Board of Cosmetology in July of 2014.

Case-Control Study
After observation and preliminary analysis of patient flow and exposures failed to identify a single source of infection, a case-control study was conducted. This study involved the gathering of detailed health care information for 30 HCV infected individuals (cases) and 62 individuals with similar exposure potential, but not infected (controls). Data was collected for outpatient services, inpatient services, Emergency Medical Services and long term care. Chart abstraction using both state and federal assets took 30 days to complete. The case definition for the case-control study was any person being in residence at LTCF A on September 9, 2013 and having HCV infection with HCV quasi-species analysis indicating a virus related to the outbreak strain.

Significant difference between cases and control were observed for sex, age and length of residency at LTCF A. The percentage of females in the control group was greater than in the case group (79% versus 60%). The median age for cases was significantly greater than that for controls (87 versus 83 years) and the median length of stay at LTCF A was significantly greater for cases than controls (2.6 versus 0.5 years). See Table one for a summary.

Bivariate analysis revealed that exposure to podiatric care, phlebotomy services, international normalized ration (INR) monitoring, wound care and any nail care at LTCF A were significantly associated with HCV infection. The table below summarizes those findings.

Table 1. Characteristic of the Study Population at LTCF A

<table>
<thead>
<tr>
<th>Study Participant Characteristic</th>
<th>Cases N=30</th>
<th>Controls N=62</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex: Female</td>
<td>18</td>
<td>49</td>
<td>0.05 (chi square)</td>
</tr>
<tr>
<td>Median Age (range)</td>
<td>87 (38-100)</td>
<td>83 (62-101)</td>
<td>0.21 (Kruskal-Wallis)</td>
</tr>
<tr>
<td>Median Length of Residence</td>
<td>2.6 years (0.7-7)</td>
<td>0.5 years (.06-6.3)</td>
<td>&lt;0.01 (Kruskal-Wallis)</td>
</tr>
</tbody>
</table>

Table 2. Bivariate Analysis of risk factors associated with case status

<table>
<thead>
<tr>
<th>Exposure</th>
<th>No. of Cases N=30</th>
<th>No. of Controls N=62</th>
<th>Odds Ratio</th>
<th>95% Confidence Intervals for the Odds Ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any podiatry</td>
<td>23</td>
<td>8</td>
<td>22.2</td>
<td>7.2-68.4</td>
</tr>
<tr>
<td>Phlebotomy services</td>
<td>30</td>
<td>50</td>
<td>9.7*</td>
<td>1.9-infinity</td>
</tr>
<tr>
<td>INR monitoring</td>
<td>15</td>
<td>8</td>
<td>6.8</td>
<td>2.4-18.9</td>
</tr>
<tr>
<td>Wound care</td>
<td>25</td>
<td>28</td>
<td>6.1</td>
<td>2.1-17.9</td>
</tr>
</tbody>
</table>
When adjusting for length of residence and other exposures, multivariate analysis found that exposure to only podiatry and International Normalization Ratio (INR) monitoring by phlebotomy was significantly associated with HCV infection. Table 3 summarizes the multivariate analysis.

Table 3. Multivariate Analysis, Controlling for Length of Residence and Other Exposures

<table>
<thead>
<tr>
<th>Model Terms</th>
<th>Adjusted Odds Ratio</th>
<th>95% Confidence Intervals for the Adjusted Odds Ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td>Podiatry</td>
<td>11.6</td>
<td>2.4-57.2</td>
</tr>
<tr>
<td>INR monitoring</td>
<td>6.7</td>
<td>1.7-26.6</td>
</tr>
<tr>
<td>Wound Care</td>
<td>2.4</td>
<td>0.6-10.4</td>
</tr>
<tr>
<td>Any Nail Care</td>
<td>3.5</td>
<td>0.8-14.2</td>
</tr>
</tbody>
</table>

In addition, analyses failed to reveal any statistically significant association with HCV case status and any inpatient procedures at hospital X, or any care received in any outpatient settings, any EMS services or having received injectable medications.

Surveillance
Active surveillance looking for new cases was implemented at LTCF A and ALF Y following a protocol recommended by the NDDoH and the CDC Division of Viral Hepatitis. Enhanced passive surveillance occurred in the community with providers being asked to report acute cases immediately.

Active surveillance at LTCF A included testing all new admissions for antibodies to hepatitis C. Those found to have reactive antibody results were tested for the presence of ribonucleic acid (RNA) and were genotyped. Any genotype 1b viruses would require samples to be sent to CDC for quasi-species analysis. With the exception of known cases, the entire census at LTCF A was tested on a monthly basis and testing was conducted on all patients being discharged. This surveillance was conducted from October 2013 through October 2015. No evidence of hepatitis C transmission related to this outbreak was observed during this surveillance period.

Surveillance at ALF Y included monthly testing of all residents on a voluntary basis. In general, the number of residents electing to be tested on a monthly basis was low. No new cases or new evidence of ongoing transmission was detected through the testing at ALF Y.

Community based testing also occurred during 2014, 2015 and early 2016. During these events, targeting other long term care and assisted living centers, more than 1,800 tests were performed.
on more than 1,300 people. This testing detected 19 infections; four of which had similar virus types when compared to the outbreak by quasispecies analysis but had no history of residency at LTCF A. The last community testing event was conducted in January and February of 2016. More than 470 people were tested with no new infections identified.

Of the four out of the 52 cases not having a history of residency at LTCF A, three resided in ALF Y and one in ALF Z. All are in an older age group (>60 years) and have complicated health histories. Three had received phlebotomy through outreach services. The HCV status (acute or chronic infection) could not be reliably determined for any of these four cases. Because of these findings, DC continued to conduct HCV screening in the community. Also as a result of these cases, the APIC consultant was brought in to review infection control policies and protocols at ALF Y and to provide general education for all assisted living and long term care facilities in the community. Furthermore as a result of these case findings, all the assisted living facilities and their associated beauty salons were visited by DC staff to review procedures, infection control policies and observe infection control practices.

**Discussion**

This outbreak of HCV infections is the largest hepatitis outbreak and only hepatitis C outbreak associated with a long term care facility reported in the United States. Healthcare-associated exposures are a recognized route of transmission for HCV. According to information compiled by the CDC, from 2008 through 2014 there have been 44 healthcare-associated outbreaks of hepatitis B or C. Of these, 22 were hepatitis C outbreaks resulting in 239 outbreak associated infections. With the exception of this outbreak, none of these were associated with a long term care facility. For five (22%) of these outbreaks, the actual breach in infection control protocol or mode of transmission is unknown or only suspected.

Our case control study found an association between being HCV infected and receiving wound care, nail care, INR testing by phlebotomy, phlebotomy and podiatry care at LTCF A. Because of the significant difference in the length of residency in LTCF amongst cases versus controls, odds ratios were calculated using a multivariate analysis. In this analysis, only phlebotomy for INR monitoring and podiatry remained significantly associated with infection.

This investigation has not identified any single breach in infection control that can explain the transmission of HCV for all of the cases. Observations at LTCF A did show that a single nail clipper was used on each floor, in the shower areas, for nail care of non-diabetic patients. Furthermore, a single nail clippers was used by staff nurses to perform nail care on diabetic patients. Interviews with staff members providing nail care resulted in inconsistent answers about how and when nail clippers should be disinfected. At the time of the APIC consultation, LTCF A was transitioning to using single-use, disposable nail clippers. During the observations however, it was noted that each patient had a dedicated clipper kept in a zip-lock back stored in a “very dirty wash basin.” LTCF A was utilizing a single point of care instrument for blood
glucose monitoring for all patients. Evidence-based guidelines recommend that a single instrument not be used for multiple patients. There were also inconsistent answers concerning how point of care glucose monitoring systems should be cleaned and disinfected among staff. Hand sanitizer at the facility was not widely available to staff providing patient care.

In both bivariate and multivariate analysis, receiving podiatry care was found to be associated with hepatitis C infection. Although podiatry has not previously been implicated in the transmission of HCV, it has been associated with transmission of hepatitis B, which has similar routes of transmission (www.cdc.gov/hepatitis/outbreaks/healthcarehepoutbreaktable.htm). The podiatric care in LTCF A was provided by an outside provider. By the time this outbreak was recognized, the primary provider of podiatry services was no longer practicing in North Dakota. As a result, direct observations of this provider’s practices could not be completed. However the provider was interviewed by phone to help understand the scope of care and how it was performed. The APIC consultant observed a different podiatrist providing care at LTCF A. Observations or interviews found that the space used for examination was small and poorly lit. There was no clear separation of clean and dirty work spaces. Most care consisted of nail care, with occasional procedures involving bleeding. Gloves were not always changed between patients, however if bleeding did occur, gloves were changed between patients. There was no sink to use for hand hygiene however, alcohol based hand sanitizer was available.

In bivariate analysis, phlebotomy was found to be associated with HCV infection. Although phlebotomy has not been implicated in previously reported outbreaks of HCV, it remains a significant epidemiological finding in this investigation. Up until November 2013, phlebotomy services in LTCF A were provided through an arrangement with hospital X’s laboratory. In November of 2013, LTCF A trained a small number of its own nurses to perform phlebotomy services for its own residents. The t consultant observed the phlebotomy practices conducted by LTCF A staff and had no recommendations for improvement.

INR testing was significantly associated with HCV infection in both the bivariate and the multivariate analyses. During the suspected outbreak period (January 2011 – October 2013) at LTCF A, INR laboratory analysis was provided by an outside laboratory. Thus, phlebotomy was required to collect appropriate specimens, which were then submitted to laboratory for analysis. In November of 2013, LTCF A initiated point of care testing to monitor INR. In-house staff were trained to conduct this testing.

The investigation has been marked by various challenges and complexities. Of note:

- All of the cases have complex health conditions requiring complex medical needs, including inpatient care, outpatient care or long term care.
- In the absence of symptoms, timing of HCV infection is difficult to ascertain. Because HCV is often a chronic infection, a positive antibody test, in the absence of symptoms or supporting liver function tests, does not inform how long a person has been infected.
Furthermore, in persons who have other underlying health conditions, relying on liver function tests may be of limited value for determining if a person has a HCV infection, particularly in this outbreak population where many of the cases had other health conditions that may have explained abnormal liver function tests.

- In this outbreak, only nine cases had symptoms, elevated liver function tests or documented seroconversion that provided enough information to classify them as acute cases or to estimate when these cases may have been exposed to HCV.
- For the remaining cases, review of medical records failed to identify when infection with HCV may have occurred.
- Interviews with the cases in this outbreak were difficult because of the age and cognitive impairment of the individuals and the complexity of the care they received. The interviews that were completed did not indicate any risk factor for community acquired infections.
- The burden of chart abstraction averaged 4.5 hours per record given the age and complex nature of care received by this population. In addition, the numerous procedures that could result in HCV transmission for all the cases and controls needed to be abstracted. In all, more than 625 forms were completed during chart abstraction for 94 different individuals. Further complicating data extraction was the difficulty in finding the needed information in the charts as documentation was not always found to be consistent.

Although the exact mechanism or breach in infection control has not been identified that can explain all of the cases, several breaches in infection control practices were observed and addressed. This includes observations of those exposures identified by epidemiologic analysis to be associated with hepatitis C infection in this outbreak. Bivariate analysis of a case control study for current residents of LTFC A found exposure to wound care, phlebotomy, INR testing, podiatric care and nail care to be associated with HCV infection. Multivariate analysis found that podiatric care and INR monitoring remain significantly associated with HCV infection. The following actions were undertaken:

1. Active surveillance at LTFC A was initiated in October 2013 and continued through October 2015. This surveillance found no evidence of transmission of HCV during this time period.
2. The NDDoH promoted meticulous adherence to standard precautions for infection control among all involved health care facilities and associated staff.
3. A certified infection preventionist was contracted to review infection control policies and conduct observations of procedures to ensure strict compliance with infection control policies. This consultation occurred in February 2014. This consultant was also contracted to provide similar services to ALF Y in August of 2014.
Attachment A

Burden of Hepatitis C Virus Infection Among Older Adults in Long-Term Care Settings: a Systematic Review of the Literature and Meta-Analysis.

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Abstract

Hepatitis C virus (HCV) infection is a significant cause of morbidity and mortality worldwide. The magnitude of the HCV burden has previously been the subject of debate, as representative data tend to exclude high-risk populations, including institutionalized persons. The purpose of this systematic review and meta-analysis was to estimate the prevalence of HCV infection among older adults in long-term care (LTC) and assess factors associated with the prevalence of HCV in this setting. The Preferred Reporting Items for Systematic Review and Meta-Analyses checklist was used as the methodological guide. Two reviewers independently assessed the study quality using a validated modified quality assessment tool. Six articles met inclusion criteria; the majority were cross-sectional studies (93.3 %) designed to estimate HCV infection prevalence rates and identify associated risk factors. HCV prevalence ranged from 1.4 to 11.0 %. A pooled HCV infection prevalence of 3.3 % (95 % confidence interval: 1.5 - 7.2 %) was estimated based on 1920 LTC residents with substantial heterogeneity noted (I² = 51.1, p < 0.001, I(2) = 90.2). Three of six studies reported statistically significant factors associated with an increased risk for HCV infection, including older age, female gender, history of blood transfusions, short duration of LTC residence, and hepatitis B virus positivity. This study reports a higher prevalence of HCV infection among older adults in LTC settings compared to community-dwelling older adults; however, accurate estimation of prevalence is limited by heterogeneity between and within studies, variation in sampling and recruitment methodologies, and absence of the HCV-RNA test to confirm active infection.
<table>
<thead>
<tr>
<th>Date</th>
<th>Testing Population</th>
<th>Rationale</th>
<th>Number Tested</th>
<th>No. of Currently Infected Hepatitis C Cases Identified</th>
<th>No. of Newly Identified Hepatitis C Outbreak Cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sept. 9, 2013</td>
<td>Current Residents – LTCF A</td>
<td>Determine prevalence of HCV at LTCF A</td>
<td>99</td>
<td>17</td>
<td>15</td>
</tr>
<tr>
<td>Sept. 2013</td>
<td>Former Residents – LTCF A</td>
<td>Additional case finding among previous LTCF A residents</td>
<td>14</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>Sept. 2013</td>
<td>HCV Cases Reported to NDDoH</td>
<td>Testing of Cases Reported in ND Surveillance System</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Sept. 2013</td>
<td>LTCF A - Current and Former Employees</td>
<td>Mandatory Current and Former LTCF A Employee Testing</td>
<td>139</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Sept. 19, 2013</td>
<td>Current Residents – LTCF B</td>
<td>Prevalence in Facility Similar to LTCF A</td>
<td>95</td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>Oct. 22, 2013</td>
<td>Current LTCF B Residents</td>
<td>LTCF B Residents with ALF Exposure</td>
<td>14</td>
<td>0</td>
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</tr>
<tr>
<td>Nov. 2013</td>
<td>Former LTCF A Residents</td>
<td>Former LTCF A Residents Since 1/1/2011</td>
<td>142</td>
<td>5</td>
<td>4</td>
</tr>
<tr>
<td>Nov. 6, 2013</td>
<td>Current LTCF A Residents</td>
<td>Current Residents Not Previously Tested</td>
<td>13</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Dec. 2013</td>
<td>Two Assisted Living Facilities – ALF X &amp; ALF W – Current Residents</td>
<td>Similar Phlebotomy Exposures to LTCF A Residents</td>
<td>57</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Dec. 2013 – Jan. 2014</td>
<td>LTCF C – Current and Former Residents</td>
<td>Similar Podiatry Exposures to LTCF A Residents</td>
<td>9</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Jan. 29, 2014</td>
<td>LTCF D – Current Residents</td>
<td>Similar Podiatry Exposures to LTCF A Residents</td>
<td>12</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>June - July 2014</td>
<td>ALF Y – Current Residents</td>
<td>Facility with Known Cases and Potential Exposures</td>
<td>64</td>
<td>4</td>
<td>4</td>
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<tr>
<td>June 6, 2014</td>
<td>ALF Y – Employees Requested</td>
<td>Per Employee Request</td>
<td>7</td>
<td>0</td>
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<tr>
<td>July 9, 2014</td>
<td>LTCF D – Current Residents</td>
<td>Similar Exposures to LTCF A</td>
<td>54</td>
<td>1</td>
<td>1</td>
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<tr>
<td>Aug. – Sept. 2014</td>
<td>Employees of Above Facilities</td>
<td>Employee Request</td>
<td>27</td>
<td>0</td>
<td>0</td>
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<tr>
<td>Jan. – Feb. 2016</td>
<td>Employees of Above Facilities</td>
<td>Employee Request</td>
<td>32</td>
<td>0</td>
<td>0</td>
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<tr>
<td>Sept. 2013 – Jan. 2016</td>
<td>Community Samples</td>
<td>Possible Exposures to Cases or Community Samples</td>
<td>19</td>
<td>2</td>
<td>0</td>
</tr>
</tbody>
</table>
Attachment C

Hepatitis C virus transmission in a skilled nursing facility, North Dakota, 2013

Dinorah L. Calles, PhD, MPH, Melissa G. Collier, MD, MPH, Yury Khudyakov, PhD, Tonya Mixson-Hayden, PhD, Lindsey VanderBusch, MPH, Sarah Weninger, MPH, Tracy K. Miller, PhD, MPH for the North Dakota Hepatitis C Virus Investigation Team

Highlights

• A large outbreak of hepatitis C virus occurred among residents of a long-term skilled nursing facility.
• Molecular analysis of hepatitis C virus from residents linked the cases by transmission.
• Breaches in infection control during phlebotomy, podiatry, and other nail care procedures led to the outbreak.
• This investigation highlights the importance of good infection control practices in skilled nursing facilities to prevent hepatitis C outbreaks.

Background
From March-May 2013, 3 cases of acute hepatitis C virus (HCV) infection were diagnosed among elderly patients residing at the same skilled nursing facility (facility A) and who received health care at hospital X during their likely exposure period.

Methods
We performed HCV testing of at-risk populations; quasispecies analysis was performed to determine relatedness of HCV in persons with current infection. Infection control practice assessments were conducted at facility A and hospital X. Persons residing in facility A on September 9, 2013, were enrolled in a case-control study to identify risk factors for HCV infection.

Results
Forty-five outbreak-associated infections were identified. Thirty cases and 62 controls were enrolled in the case-control study. Only podiatry (odds ratio, 11.6; 95% confidence interval, 2.4-57.2) and international normalized ratio monitoring by phlebotomy (odds ratio, 6.7; 95% confidence interval, 1.7-26.6) at facility A were significantly associated with case status. Infection control lapses during podiatry and point-of-care testing procedures at facility A were identified.

Conclusions
HCV transmission was confirmed among residents of facility A. The exact mode of transmission was not able to be identified, but infection control lapses were likely responsible. This outbreak highlights the importance of prompt reporting and investigation of incident HCV infection and the need for adherence to basic infection control procedures by health care personnel.