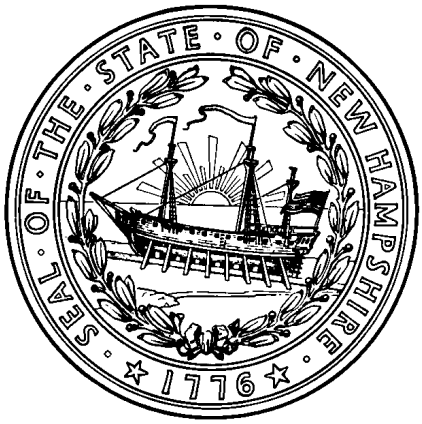
State of New Hampshire
HEPATITIS C OUTBREAK INVESTIGATION
EXETER HOSPITAL
PUBLIC REPORT



Prepared by

New Hampshire Department of Health and Human Services

Division of Public Health Services

June 2013

Hepatitis C Outbreak Investigation Exeter Hospital
Public Report
Table of Contents

Content	Pages
List of Appendices	3
Abbreviations Used	4
Contributors	5
Summary	6-7
Chapter 1: Introduction	8-12
Chapter 2: Notification of Potential Cluster to DPHS and Initial Steps	13-15
Chapter 3: CCL Investigation	16-38
Chapter 4: Investigation of Other Units at Exeter Hospital	39-43
Chapter 5: Expansion of Testing to ICU and OR Patients	44-49
Chapter 6: Multi-State Outbreak Investigation	50-51
Chapter 7: Laboratory Response	52-57
Chapter 8: Communications and Information Sharing	58-62
Chapter 9: Conclusions and Final Recommendations	63-69
References	70

List of Data Tables and Figures within the Report

Table 1: HCV Outbreak Investigation CCL and RR Initial Patient Testing Summary, May 15, 2012–May 1, 2013	34
Table 2: HCV Outbreak Investigation OR and ICU Initial Patient Testing Summary, May 15, 2012–May 1, 2013	48-49
Figure 1: Monthly CCL/RR Procedures among Persons Testing Positive for HCV, October 2010–May 2012	35
Figure 2: Monthly CCL/RR Procedures among Confirmed and Probable Cases vs. Patients with Unrelated HCV Infection, October 2010–May 2012	37

List of Appendices

Appendix 1: Case Questionnaire
Appendix 2: CCL Employee Questionnaire
Appendix 3: Incident Command System Organizational Chart
Appendix 4: Superior Court Notice of Decision
Appendix 5: Testing Algorithm
Appendix 6: Analysis of CCL Staff (Unit and Medical) Attendance at CCL on Days with Confirmed or Probably HCV Transmission
Appendix 7: Standard Case Definitions
Appendix 8: Summary of Case Characteristics
Appendix 9: Criminal Affidavit
Appendix 10: OR/ICU Employee Questionnaire
Appendix 11: OSC/ENDO Employee Questionnaire
Appendix 12: Patient Letter
Appendix 13: Phase II Map
Appendix 14: Clinics Testing Algorithm
Appendix 15: Clinic Evaluation Summary
Appendix 16: Phylogenetic Tree
Appendix 17: Risk Notification Template
Appendix 18: HCV Outbreak Investigation Summary of Initial Testing

Abbreviations Used in This Document

AZ	Arizona	ICU	Intensive Care Unit
CCL	Cardiac Catheterization Lab	ID	Infectious Disease
CDC	U.S. Centers for Disease Control and Prevention	IR	Interventional Radiology
CEO	Chief Executive Officer	IRMS	Integrated Resource Management System
CLIA	Clinical Laboratory Improvement Amendments	IV	Intravenous
CMC	Catholic Medical Center	KS	Kansas
CMS	Centers for Medicare and Medicaid Services	KS DHE	Kansas Department of Health and Environment
DHHS	New Hampshire Department of Health and Human Services	LIMS	Laboratory Information Management System
DMV	Department of Motor Vehicle	LRN	Laboratory Response Network
DNA	Deoxyribonucleic Acid	MD	Maryland
DPHS	NH Division of Public Health Services	MI	Michigan
ED	Emergency Department	MMRS	Metropolitan Medical Response System
EH	Exeter Hospital	NH	New Hampshire
EIA	Enzyme Immunoassay	NS5B	Non-Structural 5B
ESU	Emergency Services Unit	NY	New York
EU	Endoscopy Unit	OR	Operating Room
FAQ	Frequently Asked Questions	OSC	Outpatient Surgical Center
FDA	U.S. Food and Drug Administration	PA	Pennsylvania
FTP	File Transfer Protocol	PCP	Primary Care Provider
GA	Georgia	PCU	Progressive Care Unit
GI	Gastrointestinal	PHL	NH Public Health Laboratories
HAN	Health Alert Network	PHR	Public Health Region
HBV	Hepatitis B Virus	PIO	Public Information Office
HCV	Hepatitis C Virus	POD	Point of Dispensing
HCW	Healthcare Worker	QS Analysis	Quasispecies Analysis
HeP	NH Code of Administrative Rules (Public Health)	RNA	Ribonucleic Acid
HIPAA	Health Insurance Portability and Accountability Act	RR	Recovery Room
HIV	Human Immunodeficiency Virus	RSA	Revised Statutes Annotated
HVR1	Hyper Variable Region 1	RT-PCR	Reverse Transcriptase-Polymerase Chain Reaction
ICD	Implantable Cardioverter-Defibrillator	SST	Serum Separator Tube
ICS	Incident Command Structure	U.S.	United States

Contributors

The Division of Public Health Services wishes to acknowledge the following entities who assisted in the response:

Centers for Disease Control and Prevention (CDC)

- Division of Viral Hepatitis – Surveillance and Epidemiology Branch and Viral Hepatitis Laboratory Branch
- Division of Healthcare Quality Promotion

Seacoast Public Health Network
Greater Derry Public Health Network
Greater Manchester Public Health Network
Strafford County Public Health Network

Department of Health and Human Services
- Emergency Services Unit

Manchester Health Department
Nashua Health Department

Leadership Preventive Medicine Residency (LPMR), Dartmouth-Hitchcock Medical Center

For questions about this report, please contact:

Bureau of Infectious Disease Control

Division of Public Health Services

NH Department of Health and Human Services

29 Hazen Drive, Concord, NH 03301-6504

Phone: (603) 271-4496

Summary

This report summarizes the events of a large outbreak of hepatitis C at Exeter Hospital in Exeter, New Hampshire in 2012. The New Hampshire Department of Health and Human Services, Division of Public Health Services (DPHS) was first notified on May 15, 2012 by Exeter Hospital (EH) of four patients with newly diagnosed hepatitis C virus (HCV). The initial investigation revealed that one of these recently diagnosed patients was also a healthcare worker (HCW), a technician in the Cardiac Catheterization Lab (CCL), at EH. On May 25, 2012, laboratory testing conducted at the New Hampshire Public Health Laboratories (PHL) confirmed that all four patients shared a genetically similar virus, indicating a common source of infection and confirming an HCV outbreak. DPHS initiated an investigation to determine the cause of the outbreak and impede further HCV transmission as well as to identify those who had been infected and connect them with appropriate care.

The DPHS investigation determined, based on extensive evidence detailed in this report, that the cause of the outbreak was drug diversion (the stealing of narcotic pain medication intended for patients for self use) by the infected HCW. A criminal investigation was also commenced. In July 2012, the infected HCW was charged by federal law enforcement authorities and, at the time of the writing of this report, is awaiting trial.

Testing of potentially exposed patients was conducted in two phases:

Phase 1–CCL patient testing: DPHS recommended the testing of more than 1,200 patients who had procedures in the CCL at EH from October 1, 2010–May 25, 2012. Of the 1,074 who were tested, 32 patients were identified with active HCV infection with the NH HCV outbreak strain. 27 additional patients had evidence of past HCV infection (and their virus could not be tested) and 9 of them were categorized as probable cases (n=4) and suspect cases (n=5) based on epidemiological information.

Phase 2–Operating Room and the Intensive Care Unit patient testing: After receiving information that the infected HCW had access to the Operating Room (OR) and the Intensive Care Unit (ICU), DPHS recommended the testing of patients who received care in those units at the time of his employment (April 2011–May 2012). More than 3,500 patients were indicated for testing. DPHS and local partners organized public clinics in August 2012 to assist with phase 2 testing and utilized, for the first time in an outbreak setting, rapid HCV testing on site. In phase 2, 2,679 patients were tested and, as of the writing of this final report in May 2013, no additional cases of active HCV infection matching the outbreak strain were identified. Additional investigation of other units in EH did not reveal sufficient evidence to suggest risk from the infected HCW.

Since the infected HCW used to work as a traveling technician and was assigned to multiple hospitals in several states, the information about his activities was shared with the relevant states, which initiated independent investigations. The multi-state investigation was coordinated and led by the Centers for Disease Control and Prevention (CDC). As of May 2013, 13 other cases of the NH HCV outbreak strain were identified and confirmed in two other states (Kansas and Maryland).

The outbreak investigation revealed multiple areas of concern regarding access, handling, and oversight of narcotics at Exeter Hospital and lack of appropriate follow up on concerns that were raised regarding the infected HCW at the time of his employment. Several public health recommendations are outlined as a result of this investigation in order to help reduce the likelihood of outbreaks of a similar nature occurring in the future. Given the access to narcotics in facilities and the increasing rates of prescription drug abuse in the U.S., healthcare facilities

should monitor for drug diversion in their facility. They are encouraged to construct a comprehensive and multifaceted program with a formalized approach to decrease the opportunities for drug diversion to occur and identify drug diversion incidents early.

This was a complex and prolonged public health investigation, which could not have been possible without the cooperation and expertise of many other individuals, and public health partners, acknowledged above, and DPHS would like to thank them for their support and assistance throughout the investigation.

Chapter 1: Introduction

On May 15, 2012, the New Hampshire Department of Health and Human Services (DHHS), Division of Public Health Services (DPHS) received a report of a possible cluster of hepatitis C virus (HCV) infections from Exeter Hospital (EH). This initiated an extensive investigation that spanned the course of a year. This public report is intended to provide details of the DPHS activities during the investigation and the findings. DPHS recognizes the significant social, emotional, and physical impact this outbreak has had, especially on those infected due to the outbreak and their loved ones, but also on all those who were exposed, and the entire community. To prevent future patient harm and suffering from an outbreak of a similar nature, this report includes recommendations to healthcare facilities based on the findings of the DPHS investigation. In addition to the public health investigation, an independent criminal investigation was conducted by the United States Attorney, which resulted in criminal charges; facts gathered in that investigation that have been made available through publicly disclosed documents are included in this report.

I. Hepatitis C Background

A. Natural History and Virology

Hepatitis C is an infection caused by a virus that attacks the liver and may cause liver damage, liver failure, and even cancer. HCV belongs to the flavivirus family that causes human infections worldwide. The virus has the ability to mutate easily since there is high viral turnover and a lack of viral "proofreading" to keep all viral copies the same. Because of this, there are at least six major viral genotypes (numbered 1–6) and within the genotypes there are subtypes (such as 1a or 1b). Within an individual, there is a smaller amount of viral diversity that occurs with viral replication over time, and these are known as viral quasispecies. In the United States, a majority of individuals with hepatitis C are infected with genotype 1 (70%), and most (2/3) have subtype 1a.

Hepatitis C is a blood-borne infection. Acute infection is often asymptomatic, although a minority of individuals (<20%) may experience malaise, fatigue and abdominal discomfort after an incubation period of 2–12 weeks. Approximately 15% of those with acute infection will clear the virus on their own and have no lasting effects, but most people will develop chronic active hepatitis C with persistent viral replication in the liver. Without therapy, and after 2–3 decades, an average of 10–20% of those infected may go on to develop cirrhosis of the liver. Certain groups are at risk of more rapid development of serious liver disease and these include those with Human Immunodeficiency Virus (HIV) coinfection, heavy alcohol consumption, males, and new infection acquired after age 40. Among those with HCV cirrhosis, up to 20% can go on to develop the most serious manifestations of hepatitis C, specifically end-stage liver disease with liver failure or liver cancer (hepatocellular carcinoma).

B. Epidemiology

As of May 2013, the Centers for Disease Control and Prevention (CDC) estimated that there are approximately 4.1 million persons in the U.S. who have been infected with HCV and 3.2 million with active infection. Seroprevalence (evidence of past or current hepatitis C infection) ranges widely, but in the general U.S. population it is estimated at 1.6% with a range from 1–4%, depending on the population tested. Worldwide, there are approximately 180 million people

infected with HCV. Risk factors for acquiring hepatitis C include injection drug use, tattoos with contaminated supplies, use of infected blood products or occupational needlestick injury, transmission during pregnancy, and sexual transmission (which is usually very uncommon). The CDC website on hepatitis C is useful and up-to-date and is available at http://www.cdc.gov/hepatitis/C/.

The risk of acquiring HCV from a needlestick injury with blood from an HCV-infected patient is approximately 1–2%, but it depends on the level of virus in the blood and the nature of the injury. In contrast, if a blood transfusion with HCV-infected blood is given to an HCV-negative donor, the incident infection rate is 90%. [1,2]

C. Testing

The usual diagnostic testing for HCV includes two types of tests:

1. A serology test to identify whether HCV antibodies can be found in the patient's blood. Evidence of antibodies is an indication that the patient had been infected with HCV at some point in their life.
2. A Reverse Transcriptase-Polymerase Chain Reaction (RT-PCR) test to identify whether the virus itself is circulating in the patient's blood. A positive RT-PCR test indicates an active infection. RT-PCR tests can be either qualitative (yes/no) or quantitative, providing a viral load, i.e., the number of circulating viral copies detected.

Patients with positive serology (evidence of antibodies) but negative RT-PCR are usually assumed to have cleared their infection (the exception being in a recent exposure when levels of circulating virus can fluctuate). In rare instances this may be a false positive result. Patients with positive RT-PCR (evidence of circulating virus) will have additional testing to determine the genotype and subtype of the virus. That information is important especially for decisions regarding treatment.

In an outbreak setting, there are two additional tests that may be performed when an epidemiologic investigation suggests possible linkages by transmission. These tests help identify whether HCV strains from different patients are genetically similar and therefore may suggest a common source of infection:

1. HCV Viral Sequencing—Two regions of the virus genome are sequenced and compared between the strains. These regions are the nonstructural 5B (NS5B) region that identifies the subtype of the HCV strain and the hypervariable region 1 (HVR1) which is highly susceptible to frequent changes and mutations and can help determine relatedness. If two HCV strains from two different people are highly similar in both NS5B and HVR1 regions, and an epidemiologic investigation indicates potential relatedness by transmission, the two infected people most likely have been infected by the same strain, i.e., have a common source of infection, since that high level of similarity would happen very rarely by chance.
2. Quasispecies Analysis (QS Analysis)—This is a test that identifies several different sequences that may normally be found in a patient with chronic HCV infection and, based on HVR1 analysis, compares all those different variants from the patient to the sequence sets found in other patients. The benefits of QS analysis are: a) high accuracy of identification of genetic relatedness between HCV strains and b) the ability to identify patients who have been co-infected with more than one HCV strain.

D. Treatment

There are multiple effective therapies available to treat HCV today. The current standard regimen is weekly interferon injections along with ribavirin pills and direct-acting antiviral pills called protease inhibitors. These medications are costly and must be given for a period of months. There are also many associated side effects that warrant careful medical monitoring. Specialists who treat people with HCV include gastroenterologists (GI) and infectious disease (ID) physicians. They normally begin with a general assessment of health to determine all other medical conditions and possible contraindication to medical therapy.

The expected response rate to treatment depends on the genotype (genotype 1 is more difficult to treat than genotypes 2 and 3) as well as other patient characteristics. For those who are eligible for therapy and have not been treated in the past, the likelihood of cure is very good in acute infection (80–90%). With newer available agents, the response rate is very good in chronic infection as well (60–80%). There are many ongoing studies looking at newer agents, different combinations of medications, all oral regimens, and a shorter duration of therapy to treat hepatitis C, and this is an active area of medical research.

II. Healthcare-Associated HCV Transmission

HCV transmission in a healthcare setting has been reported previously, and CDC provides a useful summary of the outbreaks that had been reported to the CDC, for both hepatitis B and C, from 2008–2012.

(http://www.cdc.gov/hepatitis/Outbreaks/HealthcareHepOutbreakTable.htm).

Lapses that have been associated with transmission of viral hepatitis in healthcare setting include:

1. Reuse of syringes for more than one patient or to access medication containers used for more than one patient;
2. Sharing of contaminated equipment, like point of care or podiatry equipment; and/or
3. Drug diversion by an infected healthcare worker (HCW). Transmission can occur when the infected HCW self-administers an injectable narcotic, intended for patient administration, fills the syringe with saline, and places the used syringe back into the circulation for patient administration.

The CDC report outlines 15 outbreaks of HCV in that time frame (in addition to the outbreak detailed in this report) accounting for 117 outbreak-associated cases and notification of over 80,000 exposed patients.

Previous reports describing specifically hospital-acquired hepatitis C infection include the following:

1. Report from Florida by Hellinger et al. [(3)]: 3 cases of hepatitis C among radiology patients who had received intravenous narcotic medication (Fentanyl) over a one-year period between 2007 and 2008. Laboratory testing with viral sequencing showed a common source of infection. Employee testing revealed that a radiology technician had active hepatitis C infection with a matching virus. This technician eventually admitted to narcotic diversion. He admitted to using the "used" sharps bin as a source of narcotics. He also admitted to self-administration of a patient's Fentanyl from a syringe, which he later replaced with saline before it was administered to the patient. During the exposure period of his employment from 2004–2010, 6,132 patients were determined to be at risk and recommended for testing. Among the 3,444 patients who underwent testing, 2 additional linked cases of hepatitis C were identified.

2. A report from Israel by Shemer-Avni et al. [4]: a cluster of HCV noted at a hospital in 2003 with an early link established to a physician (an anesthesiologist) with chronic hepatitis C infection who had been let go due to excessive use of anesthetics. The hospital contacted 1,344 patients with possible exposure and set up a special screening clinic. They screened 2,073 persons over 14 days, including exposed persons and "worried well" patients. They identified 28 patients with active hepatitis C infection who matched the virus from the source physician. [4]

3. A report from California by Cody et al. [5]: an anesthesiologist was the source of an outbreak. He was diagnosed with acute HCV infection and one of his patients was diagnosed with acute HCV 8 weeks later with a matching virus. Nearly 800 patients were exposed and two others patients with active infection were matched to the outbreak. The route of transmission was not established.

4. A report from Germany by Ross et al. [6]: 4 patients were diagnosed with hepatitis C and all had undergone surgery 6–18 weeks prior. They collected blood from all surgical staff and reviewed all patients with procedures over the prior 6 months. They were able to identify six patients with newly acquired HCV infection as well as an anesthesiology assistant who had acquired acute hepatitis C who had administered narcotics to all six patients, but denied any drug use or diversion.

6. Additionally, in the past several years there has been an extensive public health investigation in Colorado at Rose Medical Center and Audubon Surgical Center due to a former HCV-infected surgical technician who was diverting drugs. Colorado issued a public health order and sent letters to patients who could have been exposed between 2008 and 2009. Available data as of May 2010 shows that among 5,248 patients who underwent testing, 18 had matching hepatitis C virus and were determined to be related to the outbreak. The website for this investigation can be found at: http://www.chd.dphe.state.co.us/Resources/cms/dc/Hepatitis/hepc/HepCInvestigation.html.

III. Reportable Diseases in New Hampshire

In New Hampshire, hospitals, laboratories, healthcare providers, childcare centers, schools, and local boards of health are required to report diagnosis of certain infectious diseases to DPHS. There are approximately 60 of these reportable conditions with over 8,000 reports received each year. The Council of State and Territorial Epidemiologists and the CDC meet annually to determine the national list of reportable diseases. This list serves as a recommendation for which diseases should be voluntarily reported by states to the CDC, and each state determines which diseases to include in their own reporting laws. In New Hampshire, the reporting of these conditions is mandated under RSA chapter 141-C, and the specific list of conditions is provided in New Hampshire Administrative Rules HeP 300. [7] A full list of reportable infectious diseases is available at: http://www.dhhs.nh.gov/dphs/cdcs/documents/reportablediseases.pdf.

Reported infections are investigated by public health nurses and epidemiologists at DPHS. The purpose of the investigation is to prevent additional illness in the population, which may be accomplished through a variety of methods, depending on the specific disease. Some examples of how public health works to prevent additional illness include identifying close contacts to the infected person and recommending prophylaxis medication to prevent them from becoming ill (antibiotics, antivirals, vaccine, etc.), providing disease prevention recommendations (washing hands, covering cough, etc.), recognizing outbreaks, and identifying and controlling their source (healthcare-associated outbreaks, foodborne outbreaks, etc.). In New Hampshire, HCV infection

is not in and of itself a reportable disease. However, any suspected outbreak, i.e., the occurrence of illness or disease in a community at a rate clearly in excess of what is normally expected, is reportable to DPHS under the mandatory reporting law. [8] As such, any suspected outbreak of HCV must be reported to be investigated by DPHS.

Chapter 2: Notification of Potential Cluster to DPHS and Initial Steps

On the afternoon of May 15, 2012, DPHS received a report from the Infection Preventionist at Exeter Hospital (EH) regarding four individuals who had been recently diagnosed with HCV. All four individuals had been patients at EH and had received care between January and March of 2012. One of the individuals was also a healthcare worker (HCW) employed as a technician at the Cardiac Catheterization Lab (CCL) at the Hospital. The other three individuals, as part of their care, were treated at the EH CCL. The report was made to DPHS within the context of an unusual occurrence or possible cluster of illness as required by RSA chapter 141-C, given the close proximity of patient diagnoses, similarity in their healthcare exposures, and no known or apparent HCV risk factors (see Chapter 1). Upon notification, DPHS immediately initiated an investigation to determine whether this was an outbreak, i.e., whether these HCV infections were recently acquired from a common source.

The initial investigation included the following steps:

1. May 16: DPHS investigators reviewed the medical records of the four potential cases.
2. May 16: The NH Public Health Laboratories (PHL) prepared for all HCV testing needs and ordered supplies to allow testing.
3. May 17: DPHS investigators met with the EH Chief Executive Officer (CEO), EH management team, and the CCL supervisor to learn about the organization and operations of the CCL and related units and to identify any additional relevant information about the HCW.
4. May 17–18: The PHL adjusted existing mechanisms in its information management system (test ordering, results entering, tracking, and reporting) to be outbreak specific and developed an HCV outbreak-specific requisition form.
5. May 18–21: DPHS investigators reviewed the available literature on HCV transmission in a healthcare setting.
6. May 22: DPHS arranged for blood samples from all four individuals to be sent to PHL for HCV sequence analysis.
7. May 24: DPHS conducted an additional site visit to the CCL and continued medical record review.
8. May 24: DPHS initiated active surveillance. DPHS reached out to all gastrointestinal (GI) and infectious disease (ID) providers in the area (email followed by a call to each practice), explaining that there was an HCV cluster investigation and asking them to report to DPHS cases of new HCV diagnosis in their practice since August 1, 2011. The specific providers were chosen based on specialty (the providers who are likely to follow patients with HCV) and geography (those who were likely to treat patients who receive care at EH).
9. May 25: DPHS investigators created:
    a. A standardized questionnaire to capture relevant information from potential cases. This included demographic information, HCV risk factors, and healthcare exposures (see Appendix 1: Case Questionnaire).
    b. A standardized questionnaire to interview employees of the CCL in order to collect information on infection control practices and assess other potential mechanisms for HCV transmission (see Appendix 2: CCL Employee Questionnaire).

The findings from the initial investigation were highly suggestive of new HCV diagnoses in the three individuals who received care at the EH CCL. They had no known or apparent risk factors for HCV infection, and all three had evidence of worsening liver enzymes within 3 months of the CCL procedure. In two patients this was accompanied by hepatitis-related symptoms. In one patient there was convincing evidence of acute HCV infection with antibody seroconversion (positive serology test after documented negative serology). As for the fourth individual, the healthcare worker, the HCV diagnosis was documented in the medical record as new, there was no prior HCV testing documented in the chart, and interviews with the HCW and his treating physicians at EH supported a new diagnosis of HCV. The HCW had experienced several healthcare exposures as a patient at EH but never received care in the CCL.

EH reported that the HCW had been working at EH since April 11, 2011. The HCW first worked as a traveling technician at the CCL and was later hired as a permanent employee of that unit in October 2011. EH management and the CCL supervisor denied any concerns about the performance or behavior of the HCW while at work, including concerns about possible drug or alcohol abuse. After thorough review and investigation of all possible links between the four potentially related cases, it was determined that the only common link was their exposure to the EH CCL or the adjacent Recovery Room (RR).

On May 25, 2012, the PHL completed the NS5B and HVR1 sequencing and sequence analysis on the four HCV-infected individuals. All four were infected with the same HCV subtype based on sequence analysis of the NS5B region. The four specimens had 100% similarity in the HVR1 region. These data confirmed that all four individuals shared the same strain of HCV (NH HCV outbreak strain), indicating a common source of infection.

With the confirmation of the outbreak on May 25, 2012, the following steps were taken:

1. DPHS recommended closing the CCL/RR at EH until the source of the outbreak was revealed and contained to ensure no further transmission could occur to other patients. This included recommendations to test all CCL/RR employees and medical staff for HCV and exclude them from invasive procedures until they had been cleared for work by testing performed at the PHL.
2. DPHS asked EH to contact patients who received care at the CCL/RR since August 2011 (6 months prior to the first confirmed case), notify them of their potential exposure, and recommend HCV testing by the PHL. Patient notification was accomplished through telephone contact (using a call center operated by EH) and a letter that was drafted by both DPHS and EH and mailed to these patients. The PHL coordinated courier service to regularly transport specimens from EH to the PHL.
3. DPHS notified the Centers for Disease Control and Prevention (CDC) and consulted with experts in both the Division of Viral Hepatitis (and the Viral Hepatitis Laboratory) and the Division for Healthcare Quality Promotion. From then on both divisions continued to play an important consultant role throughout the investigation.
4. After obtaining consent from all four cases, blood samples were also tested for hepatitis B virus (HBV) and Human Immunodeficiency Virus (HIV) to rule out transmission of other common blood-borne pathogens. The four specimens tested negative for HBV surface antigen and HIV antibody in the PHL. These four specimens were also sent to the Rhode Island Public Health Laboratory (serving as a reference lab) and tested negative for HIV antigen/antibody, a more sensitive test to rule out early infection.

5. DPHS activated the Incident Management Team using the Incident Command System (ICS) to structure and organize the outbreak response (see Appendix 3: Incident Command System Organizational Chart).
6. DPHS initiated daily conference calls with EH management to coordinate communications and facilitate the outbreak investigation.

Chapter 3: CCL Investigation

I. Public Health Goals

The primary public health goals in the EH CCL outbreak investigation, as in other outbreak investigations, were the following:

1. Determine the source of the outbreak, identify the risk and the persons exposed;
2. Understand the mode of transmission in order to stop the spread of disease;
3. Provide guidance and recommendations to control the spread of infection;
4. Diagnose all exposed patients and connect patients with active infection to appropriate care; and,
5. Understand the circumstances that allowed the outbreak to occur and provide recommendations to prevent future outbreaks of similar nature.

To achieve these goals DPHS conducted the following activities:

A. Investigation of the CCL/RR

1. Site visits to observe processes and procedures at the CCL.
2. Medical record review.
3. Review of complete equipment list to evaluate the potential spread through contaminated equipment.
4. Review infection control policies.
5. Review narcotic oversight policies.
6. Review of controlled substance usage at the CCL.
7. Interview CCL staff and medical staff who worked at the CCL and other relevant EH employees with information relevant to the investigation.
8. Review of relevant personnel files of CCL staff.
9. HCV testing of CCL staff (current and past), medical staff who worked at the CCL, and pharmacy employees.
10. HCV testing, review of employment history, and interviews of relevant employees from other units at EH.
11. Review of incidents involving controlled substances at the CCL.
12. Review of work schedule and card key access records of staff working at the CCL.
13. Investigation of prior HCV positive test results for the infected HCW.
14. Notification of potentially exposed patients.
15. HCV testing of potentially exposed patients.
16. Interviews of cases.
17. Development of standard case definitions.
18. Cause of death investigation of potentially exposed CCL patients who have expired.

B. Investigation of Other Potential Links between Cases

1. Investigation of a tattoo parlor that provided services to the HCW and an additional case.
2. Evaluation of social links between cases using publicly available information resources.

C. Surveillance Activities

1. Active Surveillance:
   a. Notification of providers and request for reporting new HCV cases.

   b. Record review of patients who tested positive for HCV at EH.
2. Routine Surveillance:
   a. Review of Emergency Department (ED) visits.
   b. Investigation of death certificates of New Hampshire residents whose deaths were attributed to hepatitis.

II. Investigation—Methods

A. Investigation of the CCL/RR

During the CCL investigation, DPHS followed standard disease investigation methods, which included the following.

Site Visits

DPHS conducted multiple site visits to learn about the setting in which transmission of HCV occurred, observe processes and procedures that could have placed patients at risk, and conduct employee interviews and review of medical records. On May 30, 2012, DPHS conducted a site visit to observe a CCL procedure. Given that the CCL was closed at the time, DPHS investigators observed a mock-up procedure where relevant unit and medical staff demonstrated and explained the processes of the CCL. On June 12, 2012, after the re-opening of the CCL (the criteria for which are detailed later in this chapter) DPHS investigators returned to observe real procedures. During site visits, DPHS interviewed key roles at EH (e.g., the pharmacy director and nursing leadership) to learn about the available systems and common procedures and practices.

Site visits were conducted as needed to advance the investigation between May 24, 2012 and July 28, 2012, after which EH sought judicial intervention prior to complying with DPHS's requests for information to continue its investigation. Following the court ruling affirming DPHS's authority on October 31, 2012 (see Appendix 4: Superior Court Notice of Decision), DPHS resumed site visits to complete the investigation.

Medical record reviews were conducted for any person suspected to be related to the outbreak, either as an exposed patient or as a potential source. DPHS developed an electronic tool to collect a standard set of relevant patient information from the electronic medical records, including demographics, past history of HCV, HCV and liver function test results, HCV risk factor information, underlying medical conditions, medications, and information on EH exposures since January 1, 2009, that may have put the patient at risk for acquiring blood borne infection (ED visits, hospitalizations, medical procedures) and any related controlled substance administration associated with these exposures. This electronic database was created in EpiInfo, a CDC software program, loaded on State of New Hampshire issued encrypted and secure laptops and brought to EH where the DPHS investigation team entered data directly into the database. In addition, other tools were created to collect additional relevant information that was stored in other EH systems and required review of hard copies (see below for details on documentation systems). These included procedure notes, nursing notes, anesthesia notes, and information about medications dispensed under a patient's name.

Controlled Substance Use at the CLL

Controlled substances include pain medications (narcotic) and sedative medications that require strict oversight to prevent misuse, abuse, and addiction. The controlled substance use at

the EH CCL was reviewed in aggregate comparing use in January–March 2012 to January–March 2011. This review was conducted in order to assess any unexpected increase in narcotics use after the infected HCW was hired compared with baseline data to determine any indication of drug diversion. Given that controlled substance actual use appears only in individual patients' records, and is not available as an aggregate number, DPHS calculated the estimated amount of controlled substance use from the amount dispensed in the CCL, subtracting the amount that was unused and either wasted (discarded) or returned to the pharmacy. To adjust for patient volume at different periods of time, the monthly use was divided by the number of procedures that month to get an average use per procedure for each of the controlled substances that are used at the CCL (specifically, Fentanyl, Midazolam, and Morphine), and that number was used to compare usage over different periods of time.

Employee Interviews

Interviews of employees were conducted using a standard questionnaire that was developed for this outbreak (see Chapter 2). All current EH employees working at the CCL (unit staff and medical staff including cardiologists, vascular surgeons, and anesthesiologists) as well as past employees who worked at the CCL when HCV transmission occurred, were interviewed. Current CCL employees were interviewed more than once, some multiple times, as more information became available and the need arose (or upon their request). In addition, DPHS investigators interviewed other EH employees who had information on leads that could further the investigation. This included employees from other units who had specific information on the infected HCW or on incidents concerning drug diversion at the CCL.

Review of Relevant Personnel Files of CCL Staff

In cases where the investigation uncovered concern about staff behavior suggestive of possible drug abuse, DPHS reviewed personnel files to confirm the reporting of an event, its associated documentation, and to analyze the enforcement and disciplinary patterns as a result of those events.

HCV Testing for All Employees Working in the CCL/RR and Pharmacy Staff

All staff working at the CCL at the time of the investigation (n=12), medical staff who worked at the CCL (cardiology, vascular surgery and anesthesiology from EH n=22, cardiologists from Catholic Medical Center [CMC] who had access to the CCL during weekend call coverage, n=6), past employees who worked at the CCL during periods when HCV transmission occurred (n=7), and pharmacy staff (n=29) were tested for HCV. The purpose of the testing was to rule out both another potential source of infection and to identify HCV transmission to other staff members. All testing was voluntary, and EH assumed the responsibility for collecting blood from all current employees and sending it to the PHL for HCV testing. For past employees (who were out of state at the time of the investigation) and the six CMC cardiologists who provided weekend coverage for emergency cases at EH CCL, DPHS coordinated the blood draw to be performed at their current location and sent to the PHL or received the final test results for testing performed at an official laboratory.

Testing of Other EH Employees

HCV testing, review of employment history, and interviews of relevant employees from other units at EH were also conducted. Based on information discovered during the investigation,

additional testing of other units' employees became critical in order to rule out their involvement. The need, and rationale, for additional testing was communicated to EH management on July 23 and 24, 2012 and provided in an official memo on July 26, 2012. As requested by EH management, DPHS wrote a letter to the relevant employees explaining the need for their HCV testing as part of the outbreak investigation and provided it on August 3, 2012 to EH management for appropriate distribution. The distribution occurred on August 21, 2012. DPHS requested that EH assume responsibility for the blood draw for HCV testing of the current employees indicated for testing, continuing the approach used for the CCL/RR and pharmacy staff. EH management was willing to offer blood draw services for interested employees but declined to assure completion of employees' testing. To reserve mandatory testing as a last resort, DPHS asked EH to provide the employment history of employees who were indicated for testing but did not provide a specimen. DPHS investigators reviewed the employment history and compared it with that of the infected HCW. If the review did not alleviate concerns about potential involvement in the outbreak, the employee (and travel agency for traveling staff) was interviewed, with the goal of compelling HCV testing only when involvement of the employee could not be ruled out in any other way.

Review of Incidents Involving Controlled Substances at the CCL

Early on in the investigation, DPHS inquired about concerns or reports of drug diversion in the CCL. EH officials denied any reports of that nature. Based on employees' interviews, which reported specific incidents suspicious for drug diversion that had been reported to an online reporting system, DPHS asked EH management on June 27, 2012 to provide the specific reports as described by the employees. After repeated requests for that information over the course of two months, EH's legal counsel provided a verbal summary to DPHS's legal counsel. Despite DPHS's assurances that it would not assert that disclosure for purposes of the outbreak investigation would be construed to waive any privilege for any other purpose, EH did not provide the full original reports and asserted that those were confidential and privileged under the activity of a quality assurance committee (pursuant to RSA 151:13-a, II).

Work Schedule and Card Key Access Records

Work schedules and card key access records were reviewed to identify whether specific staff working at the CCL (unit staff and medical staff) were more likely to be at the CCL on days when HCV transmission occurred. This information was analyzed in conjunction with data retrieved from the patients' procedure notes that indicated which staff members were assigned to the case (physician, nurse, and technician). DPHS also requested that EH provide video surveillance footage from motion-activated cameras located around the CCL that were taken at specific time periods relevant for the investigation. This, however, was not available as the cameras would continuously overwrite previous footage and the recordings from the relevant time periods were no longer available.

Investigation of Prior HCV Status for the Infected HCW

Review of the EH medical record of the infected HCW did not identify prior HCV test results. Information on prior HCV status was important to determine whether the infected HCW could have been the source of the outbreak. To determine his HCV status prior to arriving in New Hampshire, the following activities were conducted:

1. DPHS requested the employment history of the infected HCW and reached out to HCV coordinators in other states' Public Health Departments (where HCV is reportable) to determine whether he was reported as HCV positive in other states.
2. DPHS investigators contacted previous out-of-state providers who cared for the infected HCW (based on information that was available in the EH record). The infected HCW's past medical records were reviewed to determine prior HCV testing.

Notification of Potentially Exposed Patients

With the confirmation of the outbreak on May 25, 2012, DPHS asked EH to provide a list of the patients who might have been exposed at the CCL/RR and contact them to recommend testing. The criteria to consider a patient as potentially exposed included any patient who received care at the CCL/RR from the time of the first known transmission of HCV to a patient until the closure of the CCL on May 25, 2012. In addition, to ensure earlier cases were not missed, and to determine when the outbreak started, DPHS also recommended testing patients who received care 6 months prior to the earliest known HCV transmission in the CCL/RR. Those recommendations persisted throughout the investigation and with additional identification of earlier cases of transmission, more patients were recommended for testing. Eventually, all patients who received care at the CCL/RR between October 1, 2010 and May 25, 2012, were recommended for testing. Given the possibility of infection by more than one HCV strain, patients with prior known HCV infection were not excluded from the testing recommendation. The process for notification included a letter, written jointly by DPHS and EH, that was mailed to the patients and posted on both organizations' websites. In addition, EH contacted all patients by phone utilizing a call center that was established for this purpose.

HCV Testing for Potentially Exposed Patients

EH assumed responsibility for blood draws for CCL/RR patients and formed special blood draw clinics. Specimens collected at EH were picked up by a special courier sent by the PHL on a daily basis. On June 19, 2012, in response to requests from patients, DPHS announced additional local drawing sites, outside EH's network, to allow patients more blood drawing options. Specimens collected at those drawing sites were also picked up by the courier and delivered to the PHL for testing.

All specimen testing was done at the PHL. DPHS, in consultation with the Centers for Disease Control and Prevention (CDC), developed a patient testing algorithm (see Appendix 5: Testing Algorithm) to account for the limitations of the various tests in the setting of recent HCV exposure. Patients who had a recent exposure (tested within 3 months of exposure) were tested by both serology and Reverse Transcriptase-Polymerase Chain Reaction (RT-PCR), while patients with a more remote exposure (over 3 months prior) required serology testing alone. Any positive test was sent for additional testing to CDC, which was blinded to the epidemiological information and the previous PHL test results of the specimen. Patients with positive serology but negative PCR were sent for repeat PCR testing. Patients with positive PCR had viral sequencing done at the PHL to determine whether or not their strain matched the NH HCV outbreak strain. A sequence with NS5B matching the subtype of the outbreak strain that had over 98% similarity in the HVR1 region was considered a match. Any positive PCR specimen (matching and non-matching) was sent to CDC for quasispecies (QS) analysis. In cases of co-infection (i.e., patient found by QS analysis to have two different HCV strains), a second blood draw was coordinated with the patient and/or their primary care provider (PCP), and all tests

were repeated, both at the PHL and the CDC. In such cases, CDC was also blinded to the information that this was a repeat draw.

Based on information gathered from patients' testing, and out of an abundance of caution, the algorithm was updated during the investigation to include sending specimens to CDC of patients who were negative for HCV but had a recent exposure (within 3 months) to confirm their negative PCR test. In addition, all patients whose initially negative HCV testing was done less than six months from the time of the exposure were recommended for repeat HCV serology, even if initial testing included PCR. This recommendation, along with a request to report to DPHS any result (positive or negative), was sent to providers using a Health Alert Network (HAN) message on October 15, 2012.

Six-month follow up testing was carried out by patients' PCPs and EH. Any patient whose follow-up specimen tested positive for HCV had their blood redrawn and sent to the PHL for repeat testing. DPHS continued to monitor the six-month follow-up results and reminded both indicated patients and their providers of the recommendation if test results had not been received by DPHS.

Case Interviews

Case interviews were conducted using the standard questionnaire that was developed for this outbreak for all patients who were found to have the NH HCV outbreak strain and any patients with past evidence of HCV. DPHS also attempted to interview all patients with active HCV infection that did not match the NH HCV outbreak strain.

Investigation of Cause of Death for Potentially Exposed CCL/RR Patients

Due to age and health status, some patients indicated for testing had already died. With every update in testing recommendation, the list of potentially exposed patients, provided by EH, was cross-matched with the New Hampshire death certificate database to identify all patients who had died since receiving care at EH. In addition to these formal searches, some deaths were identified through family members, PCPs, and returned mail. These deaths usually occurred out of state and were not included in the New Hampshire death certificate database. In addition, death certificates of patients who tested positive for HCV as part of the outbreak investigation (either by serology or by PCR) and later died were also investigated.

Death certificates were reviewed for primary cause of death and any contributing diagnoses. If a New Hampshire death certificate was not available, a medical record review at EH was performed in order to determine where, when, and why the person died. If additional information was required, the PCP was contacted. Finally, the state in which the death occurred was contacted and the final death certificate from the respective state was obtained for review.

Death certificates and other relevant clinical documentation for all persons were reviewed to determine if the death was due specifically to HCV. Deaths were separated into four categories of etiologies: cardiac, cancer, other (including diabetes, renal failure, pneumonia), and liver/hepatitis. Any liver/hepatitis death (e.g., hepatitis was listed as the cause or contributing cause of death) was reviewed further. Deaths with the cause clearly noted to be other than HCV (such as alcoholic cirrhosis or hepatitis B) did not require further investigation. Any death clearly attributed to HCV and cases with unspecified liver-related causes of death ("liver failure" or "hepatitis") underwent medical record review at EH to determine if the death was due to HCV. If additional information was required after medical record review, the patient's PCP was contacted.

B. Investigation of Other Potential Links between Cases

During the investigation, DPHS continued to explore all options that could have led to HCV transmission to patients and followed any lead that suggested a different or an additional source of infection for cases that had been identified as carrying the NH HCV outbreak strain.

Tattoo Parlor Investigation

Based on information gathered during case interviews, a concern regarding an additional mode of transmission from the infected HCW to another case was raised when it was discovered that both individuals may have received tattoos at the same tattoo parlor around the same time. In coordination with the Town's health officer and the code enforcement officer, a DPHS investigator conducted an unannounced site visit to the tattoo parlor. During the site visit, the investigator reviewed infection control policies and procedures as well as approximately 1,000 hard copy records of clients who received tattoos between June 1, 2011 (the earliest records available) and May 20, 2012.

Publicly Available Information Resources

DPHS reviewed all publicly available sources of online information to identify potential connections between cases outside the exposure at EH.

C. Active Surveillance

The purpose of active surveillance was initially to confirm the outbreak and later to identify new cases that might be connected to the outbreak (especially those patients who would not be discovered during CCL/RR patient testing) by performing special, targeted activities that are not done on a regular basis. These targeted activities included the following.

Outreach to Providers Requesting Reports of New HCV Diagnosis

Seacoast Provider Surveillance

On May 24, 2012, as part of the initial steps in the investigation (see Chapter 2), DPHS reached out (via email followed by a phone call to each practice) to eight seacoast area ID and GI specialists requesting that they report to DPHS all cases of new HCV diagnosis in their practices since August 1, 2011. The request included a reporting form asking for certain details, including whether the patient had any known HCV risk factors. Each reported case was cross-matched against the list of CCL patients who had received care at EH since October 1, 2010. In addition, each reported case was reviewed to rule out connection to the outbreak.

State-wide Provider Outreach

On May 31, 2012, following confirmation of the outbreak, a HAN message was sent to all the providers in the State who are signed up with the HAN system. The HAN message informed providers about the outbreak and included a request to report recently diagnosed HCV cases (in the past 12 months) to DPHS, especially when the patient lacked traditional risk factors for HCV or had healthcare exposure at EH.

Review of Positive Serology Records from EH Lab

On June 22, 2012, DPHS requested a list of all positive HCV test results conducted at EH since October 1, 2010 to identify potential transmission of HCV in other units at EH (outside the

CCL/RR location). DPHS reviewed each case using a standardized form to collect the relevant information from the medical record, including demographics, HCV diagnosis and testing history, HCV risk factors, and information on exposures at EH that could have put the patient at risk for acquiring a blood-borne pathogen (ED visits, hospitalizations, medical procedures). Following this review, patients whose HCV infection could have been related to the outbreak were contacted, interviewed, and asked to provide a specimen to the PHL for HCV sequencing testing.

D. Routine Surveillance

The purpose of the routine surveillance was to identify new cases that might be connected to the outbreak, and who would not be discovered during CCL/RR patient testing, using routine methods of surveillance that are performed on a regular basis for early identification of health hazards. These routine methods of surveillance are listed below.

Review of ED Visits

From June 7, 2012 through October 12, 2012, ED data from all 26 acute care hospitals in New Hampshire were queried daily for either key terms (Hepatitis C, Hepatitis, Hep, Liver, Jaundice) in the chief complaint text or for a hepatitis C–related ICD-9 code (070.41, 070.44, 070.51, 070.54, 070.70, 070.71). Hepatitis-related ED visits were reviewed to determine if further investigation was warranted (for example, liver abscesses were not further investigated). In encounters where hepatitis C could not be ruled out as the cause of the visit, DPHS contacted the hospital where the encounter occurred and requested the following information: patient demographic, diagnosis, HCV risk factors, and any information about potential exposure at EH. If the hospital was unable to provide this information, the patient's PCP was contacted. A medical record review was conducted at EH for any patient who had received care at EH to identify potential connection to the outbreak.

Death Certificate Surveillance

From June 7, 2012 through October 12, 2012, death certificates were reviewed daily to identify hepatitis-related deaths among New Hampshire residents. Death certificate review was similar to the review described above for potentially exposed CCL patients who died prior to testing. Any death with HCV diagnosis or unspecified liver-related causes of death underwent medical record review at EH to determine if the deceased received care at EH, and if so, information regarding infection, healthcare exposures, and death was reviewed. If additional information was still required, the patient's PCP was contacted.

II. Investigation—Results

A. CCL Organization and Operations

The CCL at EH had a procedure room (with an attached control room separated by a large window) and an adjacent recovery room (RR). The procedures performed in the CCL were cardiac and vascular catheterization procedures. The RR was used to hold patients prior to and after CCL procedures but was also used as a recovery room for patients undergoing interventional radiology (IR) procedures in the IR suite.

Access to the CCL/RR was available through multiple doors, some but not all of which required the use of a personal card key (either after hours only or 24 hours/day). There was open access between the CCL and RR.

Personnel

At the time of the investigation, 41 staff members had regular access to the CCL, including unit staff (nurses, technicians), medical staff (cardiology, vascular surgery, anesthesiology), and the CCL supervisor. In addition, 6 cardiologists from CMC had access to the CCL at EH when providing weekend on-call coverage.

Process Flow

CCL Procedure

Patients could be admitted for a CCL procedure from an outpatient or inpatient setting. During a typical procedure (process could change during emergency procedures) the patient would first be held in the RR for preparation by the nurse as needed (pre-medication, insertion of intravenous [IV] line, glucose monitoring, etc.). Generally, the same nurse who was assigned to the case would care for the patient during the CCL procedure. A technician who had completed required competencies (as defined by EH) could assist with placing an IV line. During the preparation of the patient at the RR, the technician assigned to the case would prepare the equipment in the procedure room using a sterile kit.

Once the patient and room were ready, the patient would be transferred awake, on a stretcher, to the procedure room and the assigned nurse would prepare the medications for the procedure. This usually included Fentanyl, a powerful narcotic medication to prevent pain during the procedure, and Versed, a sedative medication. All controlled substances (narcotic/sedation) required for the procedure were given in the procedure room. All medications were stored in an automated storage cabinet called a Pyxis that usually required a fingerprint and a password to allow access by authorized personnel only (i.e., nurses, anesthesiologists). The type of Pyxis machine in the CCL procedure room was a "non-profiled station," i.e., it allowed medications to be removed for a single patient without a written order or prior approval through the pharmacy. This type of Pyxis machine was available in procedure areas and the emergency department (ED); the assumption was that in those locations, where emergency needs may arise, an ordering physician was present to make verbal orders and witness removal and administration of the medications. In all other locations in the hospital (including the RR), a "profiled" station was available and only medications that had been prescribed in writing, and approved by the pharmacy, could be dispensed for that patient.

When preparing for the CCL procedure, the nurse would obtain the medication vials from the Pyxis, draw them into syringes, label the syringes with pre-prepared stickers and arrange them on top of the Pyxis cabinet for anticipated use. During the procedure, medications would be given per verbal order by the physician, administered by the nurse, and documented by another staff member, typically a nurse, located in the control room of the CCL. Staff assignments to a case were usually clear and documented in the patient record, but access to the procedure room was not restricted to assigned staff only and was not properly and regularly documented.

At the end of the procedure, one of three available types of closure devices was placed at the site to control bleeding. All three types of closure devices were for single use. Two required insertion by a physician and one could be inserted by the technician assigned to the case. Following the procedure, the patient would usually be monitored in the RR to be later discharged

home or to another unit in the hospital. In cases of emergency, a patient could be transferred directly from the CCL to the Intensive Care Unit (ICU), Operating Room (OR), or another hospital. All the single-use equipment would be discarded. Any remaining controlled substance was "wasted."

The waste process required the nurse who dispensed the medication, witnessed by another nurse or physician, to empty the syringe into an inaccessible location and document in the Pyxis machine under the patient's name the type of medication and how much was wasted. The witness was also required to sign in the Pyxis machine attesting to the waste (medication and dose). Physicians without access to the Pyxis were required to manually document the waste and send it by fax to the pharmacy. About a year prior to the start of the investigation, the rules had changed to disallow technicians to witness wasting. The reason for that change was not made clear during interviews.

IR Procedure

Patients could be admitted from an outpatient or inpatient setting. The patient would be held in the RR for preparation as needed, and one nurse would be assigned to their care. Technicians had no role in the care process for patients undergoing IR procedure. For the procedure, the nurse would obtain a mobile medication box called a "stress box" from the pharmacy and would take it with him/her as s/he escorted the patient to the IR procedure. Any medications needed at the time of the procedure would be prepared from the stress box and administered at the bedside. At the end of the procedure, the patient would return to the RR and the stress box would be returned to the pharmacy, unless it was kept for additional patients.

Documentation Systems

The information about the care provided to CCL/RR patients was maintained in several silo systems:

1. Meditech[1]: the electronic medical record that contained documentation regarding most of the care provided to patients at EH.
2. Mac-Lab: a separate electronic system to document details regarding the CCL procedures including the amount of narcotic administered.
3. Pyxis: information regarding medications dispensed and returned under a patient name.
4. Paper records: some information was kept separately in paper records, for example anesthesia records with documentation of medications given by anesthesia.

In addition, a Live Patient Activity System was available and used to track the status of patients' location during their hospitalization.

B. Potential Sources of Transmission within the CCL

The following findings are based on the investigation conducted by DPHS. The DHHS Healthcare Facilities Administration performed an independent investigation, including three

[1] Initially this was the only type of record provided to DPHS investigators upon request for the cases' medical records. After review of the available information in Meditech, and based on information gathered from EH employees, the additional data sources became known to DPHS investigators and were provided by EH after specifically requesting them.

surveys, and their reports, released on July 11, July 13, and September 18, 2012, will be posted on the Centers for Medicare & Medicaid Services (CMS) Website.

DPHS' investigation of all potential modes of HCV transmission in the CCL/RR revealed the following information.

Equipment

The equipment used for the CCL procedures was mostly single use. It was organized in sterile kits, opened prior to a procedure and discarded after the procedure. Multiple use equipment that can come in direct contact with patients was routinely covered with a special nylon provided in the single-use kits. In cases requiring insertion of a pacemaker or Implantable Cardioverter-Defibrillator (ICD), a multi-use surgical kit was utilized. That kit underwent sterilization at the EH central sterilization unit prior to each use.

Glucose monitoring was performed mainly in the RR using single-use lancets that were not shared between patients. Staff provided inconsistent reports regarding the procedure for cleaning the glucometer. Given the use of that device at the end of the testing process (i.e., the glucometer itself did not touch the patients), this could not have been the route of HCV transmission.

Medications

Most of the medications used in the CCL/RR were single-use vials and were not misused for multiple patients. The exception was a nitroglycerine spray, used sublingually (beneath the tongue), that did not come in contact with blood. Employee interviews did identify areas for improving medication administration processes but none that could have resulted in transmission of blood borne infections between patients.

Infection Control Practices

The CCL had clear and organized infection control policies and procedures that were followed by most staff, but eight employees did witness lapses in infection control that were of concern. Four staff members noted that the infected HCW did not always follow appropriate scrubbing techniques when assigned as the technician for the case. There had been incidents when the HCW "broke scrubs," compromised his sterility, and left the room unexpectedly in the middle of a procedure for a restroom break. When returning to the procedure, he did not always follow the protocol to regain sterility. In addition, four staff members noted that he was working at times with open and draining wounds that would leak through the scrubs. Evaluating this as a potential source of infection was crucial. The evidence that allowed ruling out this mode of transmission was:

1. The number of infected patients. HCV is not easily transmitted without deep penetrating blood-to-blood exposure (for example using a needle) (see Chapter 1). Infecting dozens of patients via this route has not historically been possible.
2. Fifteen of the 32 patients who were found to have the NH HCV outbreak strain did not have the infected HCW assigned to their CCL procedure and so could not have had contact with his open wounds during their procedure. The infected HCW was not documented as providing direct care to these patients.
3. Five of 32 patients who were found to have the outbreak strain had procedures done prior to any reports of the infected HCW having open and draining wounds.

Controlled Substance Use and Oversight

Multiple pieces of evidence gathered in the CCL investigation raised concerns regarding the use and oversight of controlled substances:

1. Access
   a. All controlled substances were locked in the Pyxis and most authorized users required biometric verification (finger print). Several individuals, however, were approved for access via password only for various reasons.
   b. There was no restriction in access to the procedure room for staff who were not assigned to the case. Other staff members could go in and out of the procedure room without that access being restricted or documented. Four employees, unsolicited, indicated that the infected HCW was commonly seen in the procedure room, "assisting" the staff, when not assigned to cases, but this was never documented on the procedure record.
   c. The stress box used for the administration of medications (including controlled substances) during IR procedures was locked in a vault in the pharmacy, but once given to a nurse it was not locked, which conflicted with EH policy that required controlled substances to be under double locks.
   d. The processes for receiving the stress box and returning it to the pharmacy varied among nurses. Some nurses would return the box directly to the pharmacy after the procedure and would not take the box to the RR with the patient while others did. Some nurses would return the box themselves to the pharmacy while others might have requested other team members (usually another nurse) to do this for them. This could have allowed access to unlocked controlled substances not only in the IR but also in the RR.
2. Medication Preparation and Use
   a. Controlled substances were prepared at the start of the procedure and placed on the Pyxis machine for future use. There was no procedure to lock the drawn up medications until actual use, and when the nurse was caring for the patient in the room (with potential multiple distractions) those medications could have been out of sight.
   b. After initial use of a controlled substance, while the procedure was still ongoing, there was no practice to lock up the syringe with the remaining medication to ensure it was never out of the nurse's sight. The syringe would be kept on top of the Pyxis machine.
   c. There were variations in the approach to controlled substance leftovers at the completion of the procedure. Some nurses followed "waste" procedure while others allowed the remaining medication to follow the patient to the RR for future administration as needed. This latter practice could have allowed unauthorized access to controlled substances in the RR.
   d. In most Pyxis machines (profiled), a nurse dispensing controlled substances is required to count the number of vials of that medication available in the Pyxis, note how many vials are removed for the current patient, and confirm the final number remaining. The same level of reconciliation of controlled substances did not occur for the stress box used for the IR procedure. Nurses confirmed that there was no updating of an inventory list after every use. DPHS investigators observed the stress box disorganized, with empty wrappers, and no inventory list.

3. Controlled Substance Waste
   a. There was variation in the description of the waste process by different nurses. Some indicated wasting into the sink while others felt the appropriate process was wasting into the sharps container (where needles are discarded).
   b. The nurse or physician who was asked to witness the wasting did not necessarily have independent knowledge of what was in the syringe. At times, the nurse witnessing the wasting was not involved in any way in that patient's care and was called in specifically for wasting purposes.
   c. DPHS' record review revealed 16 cases in which a total of 21 full vials were wasted, indicating that the vials should not have been drawn in the first place. Eighteen of those were wasted by Nurse A, a nurse who was reported to have a close relationship and previously resided with the infected HCW. Nurses working with Nurse A indicated that they reported this concern to management but there was no documentation found of corrective actions by the CCL, pharmacy, or nursing management.
   d. There was no follow up on cases in which a physician supposedly witnessed waste to ensure that the documentation (by fax) was received by the pharmacy.

4. Controlled Substance Oversight
   a. The CCL had an adjacent control room with a large glass window. This setting could have assisted in monitoring the preparation and use of controlled substances. However, the Pyxis was located at the far end of the room. It was not easily visible from the control room and at times completely obscured by imaging equipment or personnel during the procedure.
   b. The process of drug administration during a CCL procedure involved different silo recording systems that did not allow for automated identification of discrepancies.
      i. The Pyxis machine contained information about the amount of medication dispensed, returned, and wasted. For non-profiled Pyxis stations, such as in the CCL, there was a weekly audit to ensure the expected amount of controlled substances matched the actual count in the machine.
      ii. MAC-Lab records contained information about the amount of medication ordered and given.
      iii. Anesthesia paper records included documentation of controlled substance administration in cases where sedation was performed by anesthesia.

      In order to ensure that the amount assumed to be used for the patients, based on the Pyxis information (the amount dispensed minus the amount returned and the amount wasted), is the amount that was actually ordered and given to the patient, a manual audit of records was required. This process happened occasionally in other units with non-profiled Pyxis machines, but had "fallen by the wayside" in the CCL based on interviews with EH pharmacy officials, and had not been audited for several months prior to the investigation. DPHS medical record review revealed the following concerns that could have been found in an audit:
      - Out of 74 procedure records that were reviewed, 9 procedures (12%) had discrepancies in controlled substances (the amount dispensed did not match

the amount administered, wasted and returned), including 4 cases where full vials of controlled substance were missing.

- Two cases in which the controlled substance was dispensed after the procedure ended. One of them had documentation of a full vial being wasted (although an unopened vial could have been returned to the pharmacy). In the other case, EH later clarified that in retrospect the controlled substance was probably intended for another patient and incorrectly dispensed under the prior case's name.
- At least three occasions were documented where controlled substances that were withdrawn from the CCL Pyxis were either wasted or administered in the RR, indicating medication movement between rooms.
- On at least three other occasions, the individual withdrawing medication from the Pyxis was not the same person subsequently administering or wasting the medication, which was against EH policy.
- One case occurred where a scrub technician was listed as administering a controlled substance, an activity that only a licensed nurse or a physician is allowed to do. EH believed this to have been a documentation error.

c. Any incident, including those concerning controlled substance misuse, should have been reported to an online reporting system. The information gathered during the investigation suggested that this reporting system may not have been as reliable as it should have been as an oversight tool for controlled substance use.
   i. Many concerns related to controlled substances that were raised during the investigation were never reported to the system (the infected HCW's behavior, concerns about full vial wastage, an incident of an unattended Fentanyl syringe that was reported to DPHS, etc.).
   ii. There was at least one report from an employee who insisted on having reported an incident to the system and of the information being "lost."
   iii. There was at least one account from an employee who wanted to report a concern to the system and was told by her supervisor not to do so.
   iv. Since EH did not provide the full incident reports to DPHS, questions regarding the thoroughness of follow up remain unanswered. These include:
      - A report regarding a syringe found in the restroom near the CCL (see full description below in "Evidence to Support Drug Diversion at the CCL"). DPHS learned that following this finding a camera was installed to capture activities in that area. No unannounced drug testing of employees was conducted. It is unclear whether the camera recording was reviewed, by whom, and how often.
      - A report on a CCL nurse returning two vials of Fentanyl, one of which seemed to have been tampered with, was documented in the system. When questioned by the pharmacy, the nurse denied any involvement in tampering and was concerned about the allegations. Based on the nurse's interview, the pharmacist in charge decided to dismiss the event saying that on second look both vials appeared fine. In her interview the nurse indicated that she felt her concerns that someone might have tampered with the medications and returned it under her name were dismissed.

- A report was documented regarding an empty Fentanyl vial found in the EH parking garage.

d. There was no clear oversight of the stress box content by the pharmacy. It is not clear how often the stress box content was checked. There was no process to verify the content of the box with the nurse, either upon releasing the stress box from the pharmacy or upon return of the box after the procedure (the latter did not require a nurse's signature).

e. EH did have a narcotic oversight policy that defined drug testing to be "for cause," i.e., to be performed when an employee was suspected of drug use. However, the policy was not followed in the incidents that were revealed during the DPHS investigation. Most importantly, significant concerns of drug use by the infected HCW, raised by co-workers, were not investigated, and his only drug test on file was his initial negative drug test upon hire as a traveler in April 2011.

C. Findings to Support Drug Diversion at the CCL as the Source of the Outbreak

In addition to the multiple system issues that were found around the use and oversight of controlled substances, providing opportunities for drug diversion, the following specific evidence directly supports drug diversion as the mode of HCV transmission in the CCL outbreak:

1. Evidence of ongoing transmission of a single HCV strain to 32 patients over a period of more than a year. Based on the biology of the virus, the only plausible explanation is transmission from an infected individual through penetrating exposure (such as a contaminated needle). The virus can only survive in the environment for up to 5 days [(9)] and in a contaminated syringe for up to 63 days. [(10)] The occurrence of cases over time does not support patient-to-patient transmission.
2. Incidents that were concerning for drug diversion in the CCL/RR include:
   a. In late 2011, an empty Fentanyl syringe was found in the restroom between the CCL and the Intensive Care Unit (ICU). The label on the syringe was a Fentanyl sticker from the CCL (which differed in color from the ICU Fentanyl sticker).
   b. During the course of the investigation, an empty Fentanyl syringe/vial was found underneath a Pyxis machine in the RR.
   c. An incident of a Fentanyl vial that appeared initially to be tampered with and returned to the Pyxis.
   d. An incident where a vial containing a controlled substance was left sitting out on the counter in a locked medication room but unattended.
3. Evidence from interviews and medical record review of cases include:
   a. Seven of 28 patients reported experiencing higher than usual pain during the procedure, 3 of whom underwent a previous procedure and could compare the level of pain between their procedures.
   b. The usual narcotic use in patients undergoing CCL procedure was on average 72 µg of Fentanyl based on January–March 2011 aggregate data and 101 µg of Fentanyl based on January–March 2012 aggregate data. The use of Fentanyl for confirmed cases in the outbreak was 226 µg of Fentanyl, three times higher than 2011 aggregate and two times higher than the 2012 aggregate.
   c. When reviewing Fentanyl use in confirmed cases that had prior CCL procedures, the use of Fentanyl was 2–8 times higher during the procedure at the time of HCV transmission compared with a previous CCL procedure for the same individual.

D. Findings to Support Drug Diversion by the Infected HCW

1. Despite initial denial of behavior/performance concerns regarding the infected HCW by EH management, 7 staff members described instances of concerning behavior, including slurred speech, profuse sweating, blood shot eyes, disheveled appearance, foaming at the mouth, and erratic behavior. They all concluded that the HCW appeared under the influence of drugs/alcohol. Each of those concerns was reported to management, even prior to the HCW's employment as a permanent employee in October 2011, and documented in the infected HCW's personnel file; however, there was no documentation of an investigation or any disciplinary action.
2. At least one family member of a confirmed case remembered erratic behavior by a technician at the time their loved one was at the RR post procedure. That family member was able to provide the infected HCW's name, prior to his name being publicly known.
3. Despite a vivid description of the infected HCW being surprised by his positive HCV test results in New Hampshire, a prior positive HCV test was confirmed by testing done in Kansas in 2010.
4. All patients who received care at the CCL/RR between October 1, 2010 and May 25, 2012 were recommended for testing. This included a period of 6 months prior to April 11, 2011 when the infected HCW started to work at EH. Thirty-one of 32 patients in whom HCV transmission was confirmed had CCL/IR procedures after the infected HCW started working at EH. The only patient who had a procedure prior to that had a prolonged hospital stay that did overlap with the infected HCW's employment at EH (see additional information in the investigation related to this case in the following section).
5. In the review of work assignments, work schedule, and card key access, the infected HCW was documented as present in all 31 confirmed cases of transmission that occurred after his hire, and in all 4 cases of patients with evidence of cleared infection whose infection was categorized as likely to be related to the outbreak (probable cases, see Scope of Outbreak section for definitions). For confirmed cases, the infected HCW:
   a. Worked as the technician assigned to the case (or at least to one procedure for patients with multiple procedures): 17 cases
   b. Was scheduled to be at work but not assigned to the case: 11 cases
   c. Was not scheduled to be at work, but proved to be present based on card key access records: 3 cases

   The infected HCW was the most common CCL staff to be present on days transmission of HCV occurred. In addition, the second most common staff member (after the unit supervisor) was Nurse A (see Appendix 6: Analysis of CCL Staff (Unit and Medical) Attendance at CCL on Days with Confirmed or Probable HCV Transmission).
6. Four employees indicated that the infected HCW was at work many times when not scheduled and was quick to volunteer for work in the procedure room. One specific example was an urgent weekend procedure, when he was not on call and volunteered to work. That procedure resulted in HCV transmission to the patient. Additional concerns were voiced about the HCW going in and out of the CCL procedure room when not specifically assigned for any work with some co-workers asking him to leave. Employees reported the infected HCW being around the Pyxis, "assisting" the nurses (mainly Nurse A) in preparation for the procedure, with some of his actions purposefully obscuring the view of the Pyxis for other members of the team.

7. Some CCL nurses reported that the infected HCW would follow them to see IR procedures performed on patients who were held at the RR. For those patients, there was no role for a technician, but the infected HCW indicated that he would like to accompany the nurse because he was "interested in learning new things." In one case, the nurse felt uncomfortable and, after this happened several times, asked him to stop doing this.
8. A phlebotomist, who cared for the infected HCW as a patient, reported noticing track marks on his arms when trying to draw his blood. When this task proved difficult, the HCW pointed out to her the best location for IV access and admitted to having used that location successfully a few hours prior.
9. After asserting the mode of transmission as being drug diversion by the infected HCW and providing this information to other states' public health authorities, additional evidence of prior drug diversion events came to light (see Chapter 6).

E. Evidence to Rule out Other Employees as the Source of the Outbreak

Other CCL Employees

All other employees working at the CCL when HCV transmission occurred (including past employees) were tested and found to be negative for the NH HCV outbreak strain, ruling them out as the source. On May 31, 2012, after all other current employees were ruled out as the source of infection, and after the CCL was closed for over 5 days, eliminating the risk for transmission through contaminated equipment, DPHS authorized reopening of the CCL. On June 15, 2012, after learning about the relationship that the infected HCW had with Nurse A, and discovering evidence suggesting questionable practices regarding her narcotic use, DPHS recommended to EH that they remove the nurse from patient care until her involvement could be ruled out. EH replied that Nurse A was put on administrative leave starting June 14, 2012.

Employees in Other Units

With the confirmation of HCV transmission to a patient whose CCL procedure occurred prior to the infected HCW start day at EH, concerns regarding the involvement of other employees increased. The possible explanations for that finding were:

1. Lab error: The patient was re-drawn and the specimen underwent a repeat process, including blinded CDC testing, confirming the results of the first round of testing, and ruling out the possibility of a lab error.
2. Transmission by other CCL workers: All CCL staff and medical staff were tested as described above. Testing included all past CCL staff who worked at the time of the patient's CCL procedure and none were found to have the NH HCV outbreak strain.
3. Transmission by the infected HCW:
    a. During care at the CCL/RR: based on all the information available to DPHS investigators, the infected HCW was out of state at the time the patient underwent the CCL procedure, ruling out transmission by him at that time.
    b. During the days of overlap between the infected HCW's start day and the patient's hospitalization: based on the information available in the patient's medical record, no narcotics were given to the patient on or after April 11, 2011 (when the infected HCW was first documented to be at EH). A possibility that the infected HCW was present at EH prior to his start date (allowing diversion by him to occur when the patient was documented as receiving narcotics) was raised during interviews but

could not be proven. Documentation error regarding the administration of narcotics on or after April 11, 2011, when the infected HCW was present, was also possible but could not be proven.

c. Transmission during a different admission for the patient when the infected HCW was at EH and could have diverted narcotics: DPHS investigators reviewed all healthcare exposures at EH for the patient after April 2011 and no other administration of narcotics was documented.
d. Cross-contamination between the infected HCW, when receiving care as a patient himself, and the patient: the medical record of the infected HCW was compared with the patient's record and no common link was found in their healthcare exposure (i.e., receiving care in the same unit at the same time).
e. Transmission outside the hospital: DPHS investigated potential connections between the patient and the infected HCW using publicly available information resources. No direct (or indirect through other confirmed cases) connections could be established. In addition, the patient indicated in his interview that he was incarcerated in one of the states where the infected HCW previously worked. DPHS investigated the potential of connection between the two individuals in a medical facility in that state. All state and county correctional facilities in that state searched their databases for any information on this individual but none was found.

4. Transmission by employees in other units: The patient's hospital admission, during which the CCL procedure was performed, was a prolonged stay. The patient was admitted through the Emergency Department (ED) and, in addition to the CCL/RR, received care at the Intensive Care Unit (ICU), Operating Room (OR), Progressive Care Unit (PCU), and 4 North. Since no evidence was found to support transmission by the infected HCW, and given repeated administration of narcotics to the patient in other units, the need to rule out transmission by another HCW was crucial.

   On July 23, 2012, DPHS requested that EH provide a list of employees who could have been involved or present for the care of the affected patient in the units where he received care. On July 30, 2012, EH provided a list of 624 names of any unit and medical staff who might have been in those units "even for an hour," as described by EH officials. One hundred forty of the 624 employees indicated for testing at that time voluntarily provided samples and were negative for the NH HCV outbreak strain. With the continuation of the investigation (both in state and out of state), new information became available and DPHS was able to narrow the list of employees indicated for testing. That information included documentation of a negative HCV test for the infected HCW in 2006 and confirmation of outbreak-related HCV transmission to a patient who received care in Kansas while the infected HCW worked there.

   The updated information indicated any employee who provided care in the above-mentioned units and was a traveler or started working at EH after 2006. The indication for testing stemmed from the concern that a prior connection to the infected HCW, when his HCV status was unknown or known to be positive, in a previous mutual workplace, could have allowed transmission between the two. The refined criteria were provided to EH on August 3, 2012, and on August 28, 2012 EH provided a list of 78 employees who met the updated testing requirement, of whom 15 were already tested. To rule out involvement of the others, DPHS reviewed other's prior work history data and compared this with the infected HCW's work history. After that review, 51 employees were ruled

out for potential prior connection with the infected HCW in a worksite. The remaining 12 staff members were ruled out after interviewing them and/or their traveler agencies.

Based on the investigation, DPHS concluded that transmission to the patient likely occurred from the infected HCW during the days of the overlap between the patient's hospital stay and the infected HCW start of employment. There was no evidence to suggest another HCW as the source of the patient's infection.

F. Scope of CCL Outbreak

One thousand and two hundred fourteen patients who received care at the CCL/RR between October 2010 and May 25, 2012 were recommended for testing, and those testing results are provided below.

Table 1: HCV Outbreak Investigation CCL and RR
Initial Patient Testing Summary, May 15, 2012–May 1, 2013

Summary	Exeter Hospital CCL and Recovery Area Patients Indicated for Testing October 1, 2010 - May 25, 2012
People[1] indicated for testing	1,214
People tested	1,074
People unable to test[2]	132
People with no evidence of active HCV infection	997
People with past HCV infection (cleared infection)	27
People with active HCV infection matching outbreak	32
People with active HCV infection unrelated to outbreak	18
People still to be tested	8

Notes

1. Individuals indicated for testing refers to patients having a procedure in the cardiac catheterization lab at Exeter Hospital in Exeter, New Hampshire from October 1, 2010 to May 25, 2012 based on data provided by Exeter Hospital.
2. Includes patients who have died since their procedure date and persons who have refused testing to date.

All the patients who were found by the PHL to have active HCV infection matching the outbreak strain were also identified as such by the CDC. Three confirmed cases had co-infection with two different strains of HCV (one matching the outbreak strain and one non-matching) and were confirmed by CDC.

Six-Month Follow-up Testing

Three hundred fifty-four patients who tested negative for HCV had their testing done less than 6 months from the time of their exposure at the CCL/RR and were recommended for repeat serology 6 months after the exposure. On January 22, 2013, DPHS sent letters to 48 providers'

offices of 286 CCL patients, for whom 6-month follow-up testing was not yet reported to DPHS. On March 21, 2013, DPHS sent letters to 157 patients whose 6-month follow-up testing was still not available to remind them of the follow-up testing recommendation.

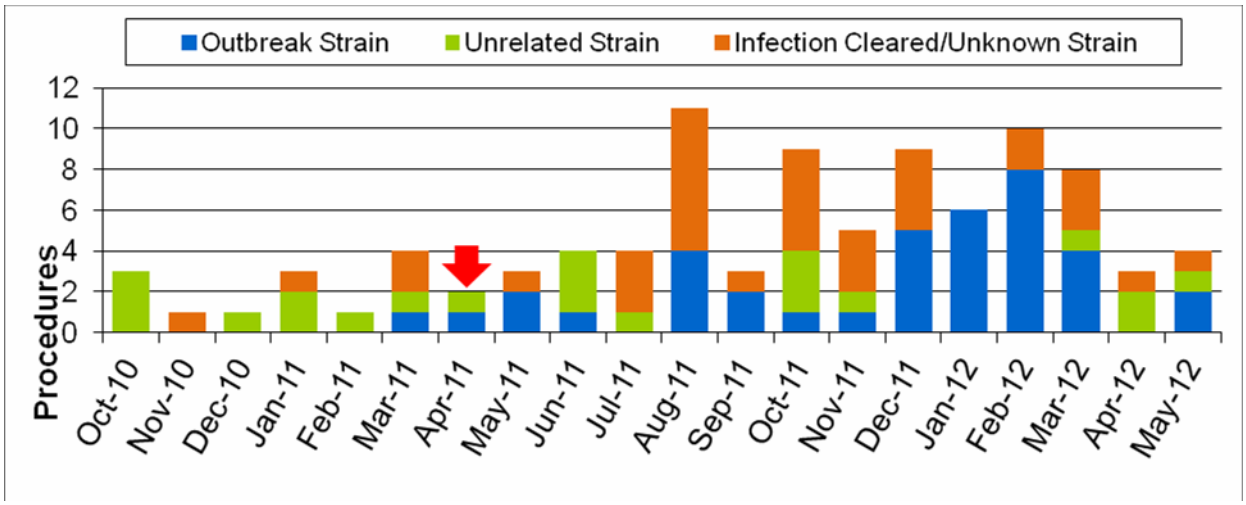
At the time of the writing of this report, 271 patients have completed 6-month follow-up testing and no additional cases of active HCV infection have been diagnosed. Six-month follow-up testing results have been unavailable for 83 patients (including 15 patients who died before repeat testing could be completed and 2 patients who refused repeat testing).

Occurrence of Cases over Time

The figure below provides a visual description of the occurrence of CCL/RR exposure for all patients who tested positive for HCV in relation to the employment of the infected HCW.

Figure 1: Monthly CCL/RR Procedures among Persons Testing Positive for HCV, October 2010–May 2012

[Outbreak Strain: 32 cases, n=38 procedures*; Unrelated Strain: 11 cases, n=21 procedures; Infection Cleared/Unknown Strain: 27 cases, n=35 procedures. The red arrow indicates the infected HCW start date at EH.]



*There were 42 CCL procedures among the 32 cases infected with the NH HCV outbreak strain (confirmed cases), however four procedures were eliminated from the figure because no narcotics were administered during the procedure (1), the procedure occurred after HCV diagnosis (1), or procedure occurred prior to HCW employment (2). All four cases had other procedures during the timeframe of HCW employment.

To describe the scope of the outbreak, DPHS developed standard case definitions (see Appendix 7: Standard Case Definitions) to classify HCV positive patients (outside the infected HCW) based on the likelihood of their infection being related to the outbreak. In patients who cleared their infection, the classification was based on information to suggest other sources of infection (review of HCV risk factors and past HCV testing) and lab evidence to suggest HCV acquisition at EH (liver function tests abnormalities within 12 weeks of the CCL/IR procedure and evidence of clearing the HCV infection within 6 months of the EH exposure). Based on the standard case definitions, patients with evidence of HCV infection were classified into 5 categories:

1. Confirmed cases (n=32): Patients with active HCV infection who have been confirmed by testing (PHL or CDC) to have the NH HCV outbreak strain.
2. Probable case (n=4): Patients who have cleared their infection (positive serology and negative PCR, or positive PCR with very low viral load who could not be sequenced) but likely acquired HCV as part of the outbreak
3. Suspect case (n=5): Patients who have cleared their infection and could have acquired it as part of the outbreak.
4. Unknown case (n=15): Patients who were known to have HCV prior to the outbreak or who had high risk factors for HCV infection but given the possibility to acquire, and clear, a second strain, their association to the outbreak could not be completely ruled out. Patients for whom sufficient information for classification was not available were also considered unknown cases.
5. Not a case: A patient with an active HCV infection with a strain different from the NH HCV outbreak strain by CDC QS analysis (n=18) or a patient who cleared the infection but did not meet the definition of exposed patient to be considered a probable, suspect, or unknown case (n=3).

Summary of Cases' Characteristics

For a comprehensive summary of the characteristics of cases, see Appendix 8.

Confirmed Cases (n=32)

The median age was 63.3 (range 43–83 years); 11 females (34.4%) and 21 males (65.6%). All but one received care at the CCL procedure room and one underwent an IR procedure but was cared for in the RR prior to and post procedure. For that patient, other healthcare exposures and social connections to the infected HCW outside EH were investigated and ruled out.

Three patients were found to be co-infected with two strains of HCV. All patients with co-infections were investigated for potential social connection to the infected HCW and transmission outside the hospital, but those connections were not found.

Probable Cases (n=4)

The median age was 68.5 years (range 58–73 years); 3 females (75%) and 1 male (25%). No patients in this group had any significant risk factors to suggest a different etiology for their HCV infection.

Suspect Cases (n=5)

The median age was 58 years (range 42–76 years); 2 females (40%) and 3 males (60%). Four had never had testing for HCV prior to this event and one patient had a documented negative test 10 years prior.

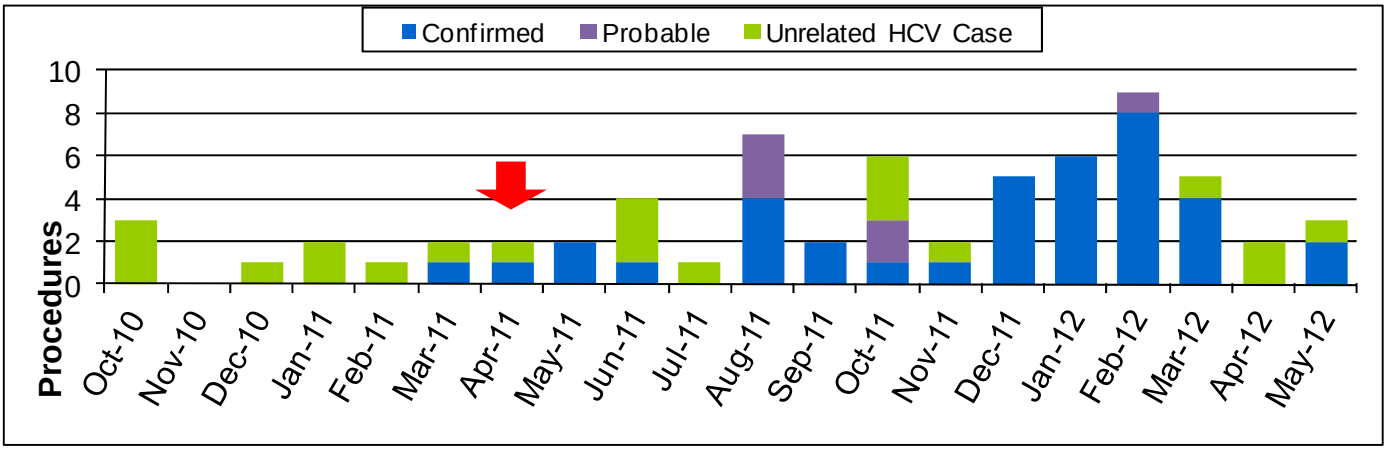
Unknown Cases (n=15)

The median age was 58 years (range 34–80 years); 4 females (26.7%) and 11 males (73.3%). Twelve of the patients had been positive for HCV prior to their exposure to the CCL/RR and three had never been tested previously but had risk factors to suggest another etiology of their HCV infection.

Below in Figure 2 is a visual representation of the occurrence of the CCL/RR exposure for confirmed cases and probable cases compared with patients with active HCV infection unrelated to the outbreak.

Figure 2: Monthly CCL/RR Procedures among Confirmed and Probable Cases vs. Patients with Unrelated HCV Infection, October 2010–May 2012

[Outbreak Cases: 32 Confirmed, 4 Probable, n=44 procedures; Unrelated Cases: 11, n=21 procedures. The red arrow indicates the infected HCW start date at EH.]



*There were 42 CCL procedures among the 32 cases infected with the NH HCV outbreak strain (confirmed cases), however four procedures were eliminated from the figure because either no narcotics were administered during the procedure (1), the procedure occurred after HCV diagnosis (1), or the procedure occurred prior to HCW employment (2). All four cases had other procedures during the timeframe of HCW employment.

Results of Death Certificate Review of Potentially Exposed CCL/RR Patients

A total of 142 potentially exposed CCL/RR patients died prior to completing HCV testing as recommended. This included 111 patients who died prior to notification and 31 patients who were notified but unable to complete testing prior to death. Medical record review of 21 deaths (including the request and review of 14 out-of-state death certificates) required additional investigation due to either unknown cause of death or liver/hepatitis-related conditions listed on the death certificate. All deaths were determined not to be HCV related.

In addition, 30 potentially exposed CCL/RR patients died after completing testing and by February 28, 2013, when the final death certificate cross-match was performed. Of those, 27 tested negative for HCV infection and three tested positive for HCV: two patients with cleared infection and one with active HCV infection matching the NH HCV outbreak strain. All three deaths were investigated and determined not to be related to their HCV status.

In summary, death certificate review of exposed CCL/RR patients did not identify outbreak-related deaths.

G. Results of Investigation Efforts outside the CCL

Identifying Other Links between Cases

Despite active investigation of other potential links between cases, none were found. Based on case interviews, there were no common healthcare exposures other than receiving care at the CCL/RR. Investigation of the tattoo parlor did not reveal an additional source of exposure, since

only one record of service provided to one of the cases was found. The review of the infection control policies at the tattoo parlor was satisfactory, raising no concerns for transmission of blood-borne pathogens. Review of all publicly available resources did not reveal any connections between cases that might explain transmission outside EH.

Surveillance Activities

Active Surveillance Activities

- Outreach to providers yielded a total of 55 reports of patients with HCV. After thorough review of the medical information on all cases, no outbreak-related HCV infections were identified through this process.
- EH HCV positive lab records included 37 patients, of whom 4 were already known to be associated with the outbreak. Information for the remaining 33 patients was entered into a database to analyze risk factor and potential common exposures at EH. After thorough review, 31 were ruled out for connection to the outbreak. The remaining 2 patients were further investigated by interview and HCV sequencing at the PHL and were determined not to be related to the outbreak based on testing results. No outbreak-related HCV infections were identified through this process.

Routine Surveillance Activities

- ED encounter data review: A total of 2,942 hepatitis-related ED visits were identified from all 26 acute care hospitals in New Hampshire. Of these, 2,864 encounters were ruled out for potential connection to the outbreak based on initial encounter review. Seventy-eight encounters required further investigation, of whom 3 encounters were related to patients already known to be CCL patients. The remaining 75 patients were determined not to be associated with the outbreak, as they had no exposure at EH at the time of the infected HCW's employment. No new outbreak-related HCV infections were identified through this process.
- Death certificate surveillance: A total of 181 hepatitis-related deaths statewide were identified through review of electronically filed death certificates. One hundred fifty-two were determined to be non-HCV related and 29 were further investigated. Of those requiring further investigation, 26 decedents had no contact with EH while three received care at Exeter Hospital but their infection was determined to be unrelated to the outbreak due to evidence of long-standing HCV infection that could not have been acquired as part of the outbreak. No outbreak-related HCV infections were identified through this process.

Chapter 4: Investigation of Other Units at Exeter Hospital

With all evidence in the CCL/RR investigation pointing toward drug diversion, the need to ensure that the infected HCW did not endanger other patients, in other units, became critical. Additional information that supported the concern for patients' safety outside the CCL/RR was:

1. The finding of a confirmed case whose CCL procedure preceded the infected HCW's documented employment dates but whose entire hospital stay overlapped with this time period, raising concern for the infected HCW's access to patients receiving narcotics in other units.
2. Findings from the investigation in other states where the infected HCW worked (see Chapter 6), some of which became public knowledge in the criminal affidavit (see Appendix 9: Criminal Affidavit). The affidavit described at least one situation where the infected HCW was caught stealing a narcotic-containing syringe in the OR while working as a catheterization lab technician.

DPHS asked EH repeatedly, throughout the early stages of the investigation, whether the infected HCW worked in other units in the hospital and was repeatedly told he did not. With the above concerning information, DPHS inquired again about his access to other units and learned that, in his role as a CCL technician, he could have had access to a specific OR (OR 3) where vascular procedures were performed, either to deliver supplies or to assist with the procedure. Moreover, he was indeed documented as being in the OR on at least one occasion. In addition, concerns arose regarding his access to the ICU, a unit close to the CCL where some CCL patients were monitored and treated post procedure with possible assistance from CCL technicians.

I. Investigation of Other Units–Methods

Assessment of risk for patients in other units of the hospital was based on two key points:

1. The availability of narcotic medications in the units
2. Evidence of access to the unit by the infected HCW

A. General Investigation Activities

Review Floor Plans and Card Key Access Records

DPHS requested card key access logs from EH for review for the duration of employment of the infected HCW and Nurse A and correlated them with floor plans of the hospital. The purpose of requesting the data was to document the presence of the infected HCW and/or Nurse A and look for any unusual patterns or access to areas that were not typical or expected for the role of a CCL employee.

B. Unit-Specific Investigation Activities

In addition, DPHS developed a tiered approach based on assessment of access and the opportunity for drug diversion by the infected HCW, as given below.

Tier 1

Units where controlled substances were frequently administered as part of routine care and to which the infected HCW had access as part of his duties–OR, ICU.

To assess the level of risk in those units, DPHS conducted the following activities:

1. Site visits to assess the processes for handling (preparation, administration, wastage) of controlled substances.
2. Private interviews of staff to inquire about the narcotic oversight and the infected HCW access to the units. The managers in the respective units provided a list of employees who worked regularly in the units (OR, 27 staff; ICU, 44 staff). DPHS staff interviewed a convenience sample (all staff working on the date of the site visit) on July 11, 2012 and July 16, 2012 (OR, 12 staff; ICU, 11 staff), and DPHS used a standard questionnaire that was developed for that purpose (see Appendix 10: OR/ICU Employee Questionnaire) and the infected HCW security photograph for identification.

Tier 2

Units where controlled substances were frequently administered as part of routine care and to which the infected HCW had access on specific days–Endoscopy Unit (EU) and Outpatient Surgical Center (OSC). To assess the level of risk for patients, DPHS conducted the following activities:

1. Record review –On August 7, 2012, DPHS requested that EH provide specific medical records of the patients who received care in the EU and OSC on the specific days the infected HCW was known to have access to the unit. DPHS requested only records related to administration of controlled substances during the procedure of interest (procedure notes, nursing notes, Pyxis records, anesthesia notes) to identify narcotic discrepancies that could suggest drug diversion. EH management agreed at first to provide the detailed medical records and on August 22, 2012, provided a list of patients for the requested dates, which included 12 EU and 21 OSC patients. Later, on August 28, 2012, EH declined to send the records or to allow on-site medical record review and insisted on waiting for the court ruling regarding DPHS' authority to review medical records. After the court ruling in DPHS' favor, DPHS requested again on November 5, 2012 to review the records, to which EH consented. This review occurred on November 21, 2012.
2. Employee interviews–Initially requested in mid-July (with repeated requests over the course of 5 months), DPHS asked to conduct private interviews (as previously done in the investigation) with selected employees to inquire about the infected HCW's access to certain units. At this phase of the investigation, however, EH management insisted on the presence of an EH management representative or legal counsel during the interview. Since previous experience in both CCL/RR investigation and Tier 1 units investigation revealed significant differences between the information gathered directly from EH management (or from staff in the presence of management) and information gathered in staff private interviews, DPHS insisted on conducting the interviews in private, offering to provide EH, at the end, an aggregate, de-identified summary of findings. On December 21, 2012, EH agreed to allow private interviews, and those were conducted using the standard questionnaire (see Appendix 11: OSC/EU Employee Questionnaire) either on-site (January 3, 2013) or by phone (through February 11, 2013). In total, 10 employees were interviewed (4 EU and 6 OSC). Despite repeated attempts at contact, DPHS was not able to interview an EU current staff member who did not return calls.

Tier 3

All other EH units. To assess the level of risk for patients, DPHS conducted the following activities:

1. Site visit to the ED where narcotic medications were administrated occasionally and to which the HCW could have access. The purpose of the visit was to assess whether occasional access with lower frequency of narcotic administration could have allowed the opportunity for drug diversion.
2. Communication with all EH employees asking them to report to DPHS concerns regarding drug diversion by the HCW in other units. On August 3, 2012, DPHS asked EH management to send out a memo, from DPHS, to all EH employees asking them to report to DPHS any concerns about the activities of the infected HCW in their units and providing them contact information. This request was denied at first by EH management, claiming that the hospital had an existing internal reporting system that did not require duplication. Given prior concerning findings regarding the ability of the system to capture concerning behavior, the follow up on the reports by EH and the timely availability of the reports to the DPHS investigators (see Chapter 3), DPHS insisted on its request, and on August 28, 2012 the memo was posted on the EH internal intranet.

II. Investigation of Other Units—Results

A. General Investigation Activities

Card Key Access

Upon review, there were several card key swipes that raised concern, mainly in the CCL. There were repeated attempts to access the CCL med room door, some of which were unsuccessful. On most attempts (approximately twice the number of times of being denied access), the infected HCW was allowed access to the CCL medication room door. EH officials cited changes in the HCW's duties and subsequent access to this area upon inquiry by DPHS. There were repeated attempts to access various locations throughout the hospital that could not be clearly explained after questioning EH officials. Based upon the review of the access, there was not a significant concern for a specific patient care area as documented by card key access, outside the CCL.

B. Unit-Specific Investigation Activities

Tier 1: OR and ICU

<u>OR</u>

The main inpatient OR unit was located on the ground floor and consisted of four separate rooms built in a square around one shared central space. Access to the OR required registration at the entrance by the reception staff member. However, documentation of who entered the OR was on paper record and inconsistent. Employees who may have accessed the OR only to deliver supplies were not necessarily documented. Once entrance to the OR complex was obtained, access between the rooms and the central space was unrestricted. Staff observing or assisting in the procedure were documented in the anesthesia or nursing notes but, again, staff present for short periods of time (e.g., delivering supplies) were not necessarily documented. Controlled

substances in the OR were prepared and administered by anesthesia. Each room had a non-profiled Pyxis machine (with an additional Pyxis station available at the central common space), and the process to prepare controlled substances was similar to the CCL process and included drawing the medication from a vial to a syringe, labeling the syringe, and placing it either on top of the Pyxis or the anesthesia work station. Although narcotic control seemed tighter at the OR compared with the CCL, there was no practice to secure the narcotic during the procedure, and ensuring it was never out of sight was impossible.

Among the 12 OR staff interviewed, 4 employees indicated seeing the infected HCW in the OR. All 4 reported that his presence in the OR was rare (staff only recalled seeing him once or twice either to deliver a piece of equipment or on one occasion to observe a procedure). The main OR nurse manager was interviewed and asked how supplies needed from the CCL during a procedure were brought to the main OR. The manager said that supplies were always delivered to the unit secretary at the front desk and not to the OR itself. During interviews with other OR staff, 5 of the 6 non-manager employees reported that supplies could be dropped off at the front desk or brought directly to the OR by CCL staff.

ICU

The ICU was adjacent to the CCL and contained several patient rooms. The Pyxis machine, where controlled substances were stored, was located in a med room that required a badge to enter. Despite the initial report of the ICU manager that there was complete separation between the ICU and CCL units and no CCL staff would ever enter the ICU, interviews with ICU staff revealed that CCL technicians had, at times, a role in following up on patients in the ICU. Moreover, when asked specifically about the presence of the infected HCW in the ICU, 9 of 11 interviewed ICU staff indicated seeing him repeatedly in their unit, generally checking on patients who he had cared for in the CCL. Among the 9 who had seen the infected HCW on the unit, 2 reported concerns regarding his frequent use of the public bathroom near the ICU, especially given the fact that CCL staff had access to an employee bathroom in their unit.

Tier 1 Risk Assessment

Based on the information gathered during the OR and ICU investigation, DPHS determined that patients could have been at risk, albeit low, in those units and recommended testing. Given free access within those units, and no reliable documentation to assert where the infected HCW might have been (which could have narrowed the list of patients indicated for testing), the recommendation for testing included any patient who received care at the main OR or the ICU during the time of the infected HCW's employment (April 2011 to May 2012). The recommendation to expand testing was discussed with EH through phone and conference calls daily from July 21, 2012 through July 24, 2012 and was provided in writing to EH on July 26, 2012. EH's initial estimation of impacted patients was 6,000. On July 25, 2012, DPHS received the actual list that included 3,505 ICU and OR patients who met the criteria for testing, and after cross matching with the death certificate database, DPHS identified 3,288 patients who were still alive and indicated for testing. Additional information on the testing expansion to OR and ICU patients is provided in Chapter 5.

Tier 2: EU and OSC

The review of medication administration records of 33 patients undergoing procedures in the EU and the OSC on the same dates (one date in each unit) the infected HCW had access to the

respective unit revealed:

1. Two discrepancies in the EU out of the 21 reviewed procedures, one involving an entire Fentanyl vial unaccounted for.
2. Two possible discrepancies in the OSC out of the 12 procedures reviewed; however, due to the handwritten nature of records in this unit, these records were very difficult to audit. It is difficult to say with certainty whether there were true discrepancies.
3. Evidence of differences in the use of Pyxis machines and protocols for return and withdrawal of controlled substances within these units. EH confirmed that prior to July 2012 (and during the outbreak timeframe), rather than returning unused, unopened vials to the Pyxis machine, vials withdrawn for one patient could be transferred for use on another patient with a physician order for the same medication. This provides a possible explanation for a whole, unopened vial being left out between patients, compromising the security of controlled substances.

OSC and EU staff indicated that the narcotic oversight processes had changed following the investigation to minimize the chance of narcotics being left unattended. Prior to May 2012, OSC staff reported that controlled substances had been kept on top of the Pyxis machine or in a drawer of the anesthesia machine. If anesthesiologists turned their attention to another matter, medications were kept in an unlocked drawer of the anesthesia machine. Staff reported that these processes had changed following identification of the drug diversion–associated outbreak at EH to include locking of narcotics during a procedure. All staff interviewed attested that the infected HCW could not, and did not, have access to their units other than the two dates he was known to be on the unit for a limited time and felt he did not pose a threat to patients who received care there.

Tier 2 Risk Assessment

Based on the information gathered during the EU and OSC investigation, DPHS determined that there was not sufficient evidence to suggest patients were at risk from the infected HCW and there was no need to recommend testing in those units.

Tier 3: Other Units in Exeter Hospital

Investigation activities to assess the risk in other units revealed no significant concerns to suggest drug diversion by the infected HCW in other units. DPHS received no reports from EH employees regarding concerns over the infected HCW's access to and behavior in other units. DPHS did receive a report on a prior, unrelated drug diversion incident at EH ICU that was reported to the New Hampshire Board of Nursing.

Tier 3 Risk Assessment

Based on the information gathered, DPHS determined that there was not sufficient evidence to suggest that patients were at risk in other units and no need to recommend additional testing.

Chapter 5: Expansion of Testing to ICU and OR Patients

In this phase of the response, additional resources and State agencies were engaged, and the New Hampshire Department of Health and Human Services (DHHS) Emergency Services Unit (ESU) coordinated the mobilization of those resources in support of the DPHS outbreak response. Based on the risk assessment for HCV exposure in the ICU and OR at EH (see Chapter 4), DPHS recommended HCV testing for patients who received care in those units during the time of the infected HCW's employment. DPHS made the decision to set up public health clinics to support timely testing and prompt lab results. This was based on the cardiac catheterization lab/recovery room (CCL/RR) testing experience, which included the testing of roughly 1,000 patients and took approximately six to eight weeks, as well as the recognition of the high level of concern that the new recommendation would cause for the patients and the community.

I. Testing Expansion—Public Health Goals

1. To offer timely and convenient HCV testing for patients who may have been exposed in the ICU/OR.
2. To alleviate as much as possible the anxiety and concern associated with the testing and wait for results.
3. To define the scope of the outbreak.
4. To establish and conduct public health clinic operations to support the expansion of testing.

II. Notification of Potentially Exposed Patients

With the expansion of testing to ICU/OR patients, DPHS and EH decided to modify the method of notification and DHHS assumed primary control of patient notification. The criteria to consider a patient as potentially exposed included any patient who received care at the ICU or main OR between April 1, 2011 and May 25, 2012. On July 25, 2012, EH provided a list of 3,505 patients who met the exposure definition. After cross matching the list to the death database, the list was narrowed to 3,288 patients to contact.

The notification process included a letter (see Appendix 12: Patient Letter) that was mailed to the patients explaining the reason for the testing recommendation and the testing options available. In addition, DHHS conducted targeted outreach to each individual through a special call center set up at the New Hampshire Department of Motor Vehicles (DMV). The call center was coordinated by the ESU. The timing to initiate the calls was planned for approximately two days after the mailing to allow for delivery of the letters and to promote an understanding among individuals receiving the notification. The ESU then recruited and trained volunteers at the call center at the DMV building in Concord, New Hampshire. Training sessions were held for call center staff on the evening prior to the call center opening.

The call center managed a total of 6,968 calls, 4,745 of which were outbound to notify patients and 2,223 of which were inbound from patients with questions, concerns, or those returning calls. Call center staff successfully contacted 2,667 individuals, 1,197 of whom were scheduled for appointments at the public clinics. Of the remaining group, 1,470 preferred alternative testing options, and a small number of persons (14) declined to be tested. These call center operations occurred from August 6-13, 2012.

III. Approach to Patient Testing

In this testing phase of the outbreak investigation, DHHS offered multiple options for patients to be tested. Since most patients were in the southern tier of the State (see Appendix 13: Phase II Map), clinics were planned in this geographic area in order to offer the most convenient options and minimum travel time for persons being recommended for testing. Testing options included:

1. DHHS public clinics: Cooperative Middle School, Stratham, (2 clinics), Timberlane Regional High School, Plaistow (2 clinics), Rochester Middle School (1 clinic), and Manchester Health Department (3 clinics). Appointments were scheduled by the call center and walk-ins were accepted.
2. Additional local drawing sites coordinated by DPHS: Portsmouth Regional Hospital, Hampton and Pease Trade Port locations. For the Hampton and Pease sites, no appointment was necessary, but individuals were asked to provide their notification letter and proper identification in order to be tested.
3. Exeter Hospital operated clinics by appointment at Exeter Hospital.
4. DHHS encouraged any individual who preferred to be tested by their healthcare provider to do so and recommended that those individuals use the laboratory requisition form located on the DHHS website in order to facilitate specimen submission and testing at the PHL.
5. A medical team activated for the response by ESU, the Metropolitan Medical Response System (MMRS), did home visit calls for homebound persons. Two teams visited a total of 13 individuals.

A. Testing Methods

Given the time that had elapsed at this point in the investigation from the date of potential exposure, the testing algorithm, developed by DPHS in consultation with the CDC, was simplified with HCV antibody testing done as a first step and PCR testing done in cases of positive antibody results (see Appendix 14: Expansion Testing Algorithm). All testing was done by the PHL. Positive test results were sent for additional blinded testing at the CDC, similar to the testing of the CCL patients. Patients who were tested less than six months from the time of their exposure were recommended for repeat testing after 6 months. Additional outreach to reinforce this recommendation was provided to patients and to clinicians through patient letters and HAN messages.

DHHS made every effort to alleviate the anxiety associated with this testing. It was well understood that patients, families, and the community were concerned for their health. Therefore, DHHS purchased and offered a rapid HCV test option in the public clinics to provide prompt on-site initial results. Since the rapid test had not been used previously in the setting of a sizable outbreak and because the positive result could not serve as a confirmatory test and would require blood draw for additional viral sequencing, DHHS, in consultation with the CDC, decided to add the rapid test to the routine testing that had been done for the CCL/RR patients, rather than replacing the routine testing with the rapid test. Therefore, several tubes were obtained from a single blood draw from each patient to complete the testing.

IV. Investigation Activities Related to OR/ICU Exposed Patients

DPHS conducted medical record reviews to investigate the cause of death of patients who were potentially exposed in the ICU/OR and who died prior to the recommendation for testing.

The process for the death record review followed the process detailed in Chapter 3 that was conducted for the CCL/RR patients.

V. Organization and Execution of Public Health Clinics

New Hampshire has a unique infrastructure as compared with other states for establishing public clinics in response to public health emergency events or large outbreaks. The majority of public health services are delivered by DPHS. The cities of Manchester and Nashua have local health departments that provide broad public health services, and the city health departments work collaboratively with DPHS. Further, New Hampshire has supported and implemented a process of regionalization for public health services that has largely focused on public health preparedness and response coordination for several years. To that end, 13 Public Health Regions (PHRs) were established to facilitate emergency planning and response. Each PHR has successfully planned and implemented the capacity to conduct clinic operations, as evidenced by prior successful public clinics (2009 H1N1 public vaccination clinics). The plans, referred to as Point of Dispensing (POD) plans, are aimed at dispensing countermeasures (medications or vaccine in response to a public health emergency event, such as an influenza pandemic). Since the HCV outbreak required laboratory testing rather than medication dispensing, regional and local partners adapted their POD plans to establish these clinics. This type of POD use was the first of its kind.

A. Declaration of a Public Health Incident

The Commissioner of DHHS has the authority under RSA 508:17-a to declare a public health incident. On August 9, 2012, a Public Health Incident was declared for the purposes of responding to the HCV outbreak investigation. This was done primarily to be able to extend worker's compensation and liability protections under State law to volunteers who assisted in the public health clinics.

B. Clinic Planning

DHHS coordinated with regional and local partners to focus on the expansion of testing and implementation of the clinics. DHHS requested activation and support from the PHRs to conduct the clinics. The selected PHRs and corresponding geographic location of the clinics as discussed was guided by where most individuals indicated for testing resided. The PHRs in the Seacoast and Derry, along with other regional partners, met this request to support the outbreak response. A regional team was assembled to develop and implement the action plan for modified POD operations.

For the purpose of clinic planning and execution, DHHS assumed responsibility for staffing and implementing the clinical and laboratory services. State, regional, and local partners coordinated efforts to recruit phlebotomists to work in the clinics with a primary responsibility of drawing patients' blood samples. The recruitment of skilled phlebotomists posed a challenge in the clinic planning process. PHL staff assumed responsibility for assessing the clinic locations for feasibility and ensuring a safe environment to execute patient testing, for both patients and laboratory workers.

The clinical supplies required to support testing services were not routinely available in the regional caches, and purchasing these supplies was coordinated by the PHL through known laboratory vendors. The PHRs did successfully deploy several resources (screens, refrigerators, and volunteers) to support the regional clinics. Staff were recruited and scheduled for clinic

shifts ranging from four to eight hours. Clinic planning included conference calls with state, regional, and local partners serving the greater Exeter area. Laboratory testing staff included sentinel laboratory partner volunteers from hospital laboratories as well as PHL staff. DHHS developed patient consent forms and identified the process for providing confidential onsite results as well as making plans for call backs if patients chose not to wait at the clinic for their results.

C. Postponement of Clinics

DHHS had planned to begin clinics in late July 2012. The clinics were an unprecedented undertaking, and several factors had the potential to compromise the clinic operations. DHHS' goal was to provide the best and safest experience for persons being tested. While a difficult decision, DHHS opted to postpone the clinics for approximately two weeks in order to continue planning, work out additional details, and ensure an optimal outcome for patients. DHHS staff attended a community meeting planned to discuss the clinics and explained the reasons for the delay to the Exeter community and the general public.

D. Clinic Staffing

As noted, DHHS staffed the clinical and laboratory services component of the public clinics. These staff provided pre- and post-test counseling on site. The State Epidemiologist or Deputy State Epidemiologists (infectious disease physicians) were on site for every clinic to answer questions and provide test results and post-test counseling. Each clinic had established confidential areas for this purpose. DPHS staff in the Bureau of Infectious Disease Control offered their expertise and training to provide results to patients and appropriate counseling, regardless of a positive or negative result. PHL staff was on site to perform testing, and the PHL Quality Manager was present to assure high-quality testing outcomes.

A total of 143 State employees worked approximately 1,600 hours on the execution of the clinics. State agencies supporting the DHHS response included the New Hampshire Department of Safety, Department of Information Technology, Department of Transportation, Attorney General's Office, and the NH National Guard. Additionally, 224 non-State employees worked in the clinics for a total of approximately 1,500 hours, and most of these staff were volunteers.

E. Clinic Operations

State, regional, and local partners conducted a total of seven clinics over the course of eight days, beginning August 10, 2012 and concluding on August 18, 2012. Clinic areas included greeting, registration, phlebotomy, laboratory, waiting area, and results areas. Water and snacks were available for patients being tested and for those waiting for results. Signage was placed to facilitate the flow of individuals entering and moving through the clinic areas. Each clinic identified staff to monitor flow, and observe and promptly address any areas of bottleneck, the goal being to provide the best possible clinic experience. Integral to the clinic planning and operations was ensuring that accommodations for persons with specific needs, such as those with mobility limitations, at each site ensured the security and safety for persons being tested as well as workers. Public Information Officers (PIOs) for DHHS managed all media requests related to the outbreak investigation and the clinical aspects of the response, as they had throughout the investigation. In each region, a local PIO was tasked with managing media requests related to site-specific operations.

The PHL performed as a laboratory unit for every clinic. PHL staff also provided oversight of the intake process to ensure that specimens and requisitions were correctly labeled and all specimens were handled appropriately and safely. All laboratory staff appropriately wore personal protective equipment, such as masks, gloves, and eyewear during phlebotomy, rapid testing, and the transportation of specimens.

DPHS staff comprised the clinical services whose primary role was managing results. Patients arrived at the clinic at their appointed time and met with registration staff to complete the registration form and receive a unique number as their identifier. Patients were called by their assigned POD number and provided confidential post-test counseling in a separate room/location. Client documentation was managed electronically using the Integrated Resource Management System (IRMS). IRMS is a system procured by DHHS that provides inventory management and patient tracking. The POD number was used to track patients throughout their time at the clinic, including having their form scanned as they exited the site.

DHHS conducted clinic satisfaction surveys at each of the clinics. These surveys were routinely used to make service and process improvements at sites with multiple days of testing. Overall, the completed satisfaction surveys (478) provided positive feedback on the clinic experience (see Appendix 15: Clinic Evaluation Summary).

VI. Testing Results and Related Investigation

DHHS scheduled 1,197 people for testing at the clinics and 1,190 kept their appointments and had their blood drawn. Of the 1,190, 1,167 received rapid testing and 23 did not. Those who could not be tested with rapid tests included patients who were younger than 15 years of age or pregnant (n=14), populations which have not been validated for rapid testing from the manufacturer. The remaining nine were difficult draws and did not have sufficient blood sample to conduct rapid testing. All 23 received follow-up testing at the PHL in Concord, New Hampshire. EH tested an additional 1,028 persons indicated for testing and 72 persons who were not indicated for testing but were concerned and requested testing. Approximately 146 persons elected to be tested elsewhere. Medical volunteers tested 13 homebound patients during home visits. DHHS and EH identified additional persons, some hospitalized at the time or residents of nursing homes who required coordination with those healthcare facilities to complete testing (n=50). All activities accounted for 2,449 persons being tested at the time of the clinic response. A current summary of this phase of testing as of May 1, 2013 is provided in the table below.

Table 2: HCV Outbreak Investigation OR and ICU Initial Patient Testing Summary, May 15, 2012–May 1, 2013

Summary	Exeter Hospital OR and ICU Patients April 1, 2011–May 25, 2012
People[1] indicated for testing	3,505
People tested	2,679
People unable to test[2]	254
People with no evidence of active HCV infection[3]	2,622

People with past HCV infection (cleared infection)	28
People with active HCV infection matching outbreak	0
People with active HCV infection unrelated to outbreak	29
People still to be tested	572

Notes

1. Individuals indicated for testing refers to patients undergoing procedures in the operating room, or patients admitted to the intensive care unit at Exeter Hospital in Exeter, New Hampshire from April 1, 2011 to May 25, 2012 based on data provided by Exeter Hospital.
2. Includes patients who have died since their procedure date and persons who have refused testing to date.

A. Follow-up Testing

DPHS recommended that any person testing earlier than six months from the last potential exposure be retested, as routinely recommended with recent exposure. DPHS also requested that providers report both positive and negative results to DPHS. As of May 1, 2013, 237 patients were reported to DPHS as completing 6-months follow-up testing, all with no evidence of HCV infection. Reports were not available for the remaining 406 patients who were indicated for follow-up testing from the ICU/OR patients.

Chapter 6: Multi-State Outbreak Investigation

On May 29, 2012, EH provided to DPHS the infected HCW's employment history as it appeared in his file. The list included employment in 14 hospitals in 6 states, either as a temporary employee (through one of five listed travel agencies) or as a direct hire. At those sites, the infected HCW was employed as a technician in the catheterization lab, intervention radiology unit, or the emergency department (ED). On June 14, 2012, the New Hampshire State Epidemiologist contacted peers in the corresponding 6 states with initial concerns about drug diversion in New Hampshire by a HCW who worked previously in their states. Due to confidentiality restrictions at the time, the ability to share the infected HCW's identified information was limited. On June 26, 2012, after the accumulation of sufficient evidence to support a drug diversion allegation, the HCW's identity and details of employment were shared with the other states whose involvement was known to DPHS. The information was provided to each State Epidemiologist who initiated a local investigation as deemed necessary. To assist in the investigation efforts in other states, DPHS shared the tools it had developed during the CCL/RR investigation (e.g., questionnaires, patient letter, Frequently Asked Questions, etc.).

CDC took the lead on coordinating the multi-state aspects of the investigation early on and coordinated information gathering and sharing during weekly conference calls. There was open communication and great collaboration and information sharing among the different state health departments and the CDC. As the investigation continued, it became evident that the original employment list as provided by the employee to EH was not accurate. Assignments in some hospitals were missing, including a hospital in an additional state, and the dates of employment were inaccurate for some employment sites. Significant effort was focused on ensuring that accurate employment history (locations and timeline) was available to all the affected states. After a thorough investigation by CDC and the states, the infected HCW's prior employment list was finalized and revealed employment in 16 hospitals prior to EH, in a total of 7 states in addition to New Hampshire (Michigan, New York, Pennsylvania, Maryland, Arizona, Kansas, and Georgia).

Each state conducted its own investigation independently with the involved hospital(s) to determine the access the infected HCW may have had in the hospital and the volume of potentially exposed patients. The investigation in some states revealed evidence of highly concerning prior incidents of drug diversion by the HCW, as early as 2008, some of which have been documented in the criminal affidavit (see Appendix 9: Criminal Affidavit). On July 19, 2012, based on information gathered in New Hampshire and other involved states, the infected HCW was arrested and taken into custody. At the time of the write up of this report, he is scheduled for trial on the criminal charges in January 2014.

The prior HCV status of the HCW was critical in order to establish the risk for HCV transmission to patients in other states and to determine the need for patient testing. A considerable effort was made by CDC and affected states to locate any previous HCV testing on the infected HCW, including reaching out to blood banks that test blood donors for HCV. Despite all available documentation at EH suggestive of a new HCV diagnosis, a prior positive HCV test for the infected HCW was found from May 2010 in Kansas. Additional documentation of a negative test was available from January 2006. No other HCV test was found between those dates.

With the identification of a positive HCV status for the HCW in May 2010, the hospital in Kansas, where he worked at the time, along with the Kansas Department of Health and

Environment (KS DHE), promptly decided to notify patients who might have been exposed to the infected HCW and recommend testing. Given the unique capabilities at the NH PHL to conduct HCV sequence testing, the KS DHE reached out asking whether specimens positive for HCV from Kansas patients could be sequenced at the PHL to determine relatedness to the infected HCW. The PHL agreed to assist with HCV sequencing of any specimen of a patient who might have been exposed to the infected HCW and found to be HCV positive, from any interested state, with additional quasispecies (QS) analysis performed as a second step by CDC. PHL received 18 specimens from Kansas, positive by serology, for RT-PCR and sequencing. Five specimens were found to have a high degree (over 95%) of similarity to the NH HCV outbreak strain, suggesting a common source of infection. For additional information on the PHL testing see Chapter 7. The PHL was not involved in testing specimens from other affected states who conducted patient notification and testing. Those specimens were sent directly to CDC for QS analysis testing.

Based on CDC testing as of May 28, 2013, 13 additional cases were confirmed as related to the infected HCW in three other hospitals: 6 patients in one hospital in Kansas, where the infected HCW was employed during 2010 and 7 cases in two hospitals in Maryland where the infected HCW was employed in 2008-2009.

Chapter 7: Laboratory Response

This chapter provides a detailed and highly technical summary of the New Hampshire Public Health Laboratories (PHL) testing procedures and protocols performed in response to this large-scale outbreak. For a basic explanation of HCV testing see Chapter 1. Many technical terms and descriptions are included in this section in order to provide a comprehensive understanding of the scope and complexity of the response, specifically the extent of laboratory testing that was required to effectively manage the outbreak.

To respond to the EH outbreak, the PHL utilized laboratory diagnostic tools including serologic assays for detecting human antibodies against the hepatitis C virus (anti-HCV) and reverse transcriptase-polymerase chain reaction (RT-PCR) assay for detecting HCV Ribonucleic Acid (RNA) as well as Deoxyribonucleic Acid (DNA) sequencing of HCV genome for determining HCV subtype and genetic relatedness.

I. PHL Goals

The goals of the laboratory response included:

1. Identify HCV infected individuals from the potentially exposed patients.
2. Determine HCV genetic relatedness to identify HCV-infected individuals who are associated with the outbreak.
3. Perform testing following quality assurance guidelines and best laboratory practice.

II. Quality Assurance

The NH PHL holds a certificate of compliance to operate from the Centers for Medicare and Medicaid Services (CMS). CMS regulates all laboratory testing (except research) performed on humans in the U.S. through the Clinical Laboratory Improvement Amendments (CLIA). As such, all human diagnostic testing must be performed under strict quality assurance conditions. These conditions include, but are not limited to, quality control measures for all procedures; appropriate education and training for all staff who perform testing and handle specimens; successful participation and completion of approved proficiency testing program; and oversight by laboratory supervisors and the laboratory director.

III. Initial Laboratory Response

On May 15, 2012, when DPHS received the report from EH regarding four individuals who were recently diagnosed with HCV, the PHL used molecular procedures to sequence NS5B and HVR1 regions of the HCV genome to determine if the four individuals were infected with HCV from the same source. Early steps taken at the NH PHL include:

1. May 15, 2012, PHL prepared laboratory procedures for sequencing
2. May 16, 2012, PHL ordered primers for NS5B and HVR1 RT-PCR and sequencing
3. May 22, 2012, the ordered RT-PCR and sequencing primers arrived in the PHL
4. May 22-23, 2012, PHL verified the RT-PCR and sequencing primers using the archived known HCV positive specimens.
5. May 23-24, 2012, PHL performed NS5B and HVR-1 RT-PCR and sequencing on the four specimens.

On May 25, 2012, the NH PHL analyzed the sequences obtained from the four HCV-infected individuals; all four were found to be infected with the same HCV subtype based on sequence analysis of the NS5B region, and the similarity among the HVR1 sequences from the specimens

obtained from the four individuals was 100%. These data confirmed that all four individuals shared the same strain of HCV (NH HCV outbreak strain) indicating a common source of infection.

IV. Specimen Collection, Transport, and Receiving

With the notification of patients for HCV testing, the PHL coordinated specimen collection and transport from EH and other health care providers to the PHL for HCV testing. The PHL made arrangements for a local courier to pick up and deliver specimens daily Monday–Friday through September 2012. PHL employees were scheduled for weekend pickups. Starting in October 2012, specimens were picked up and delivered three days per week until November. After that, special arrangements for specimens were made. Other delivery methods for specimens were the use of the U.S. Postal Service or other commercial companies such as FedEx.

Upon receipt, specimens were checked against a master list of patients who had been indicated for HCV testing to ensure appropriateness of testing. All specimens received at the PHL were entered into the PHL's Laboratory Information Management System (LIMS), which was utilized to track and manage specimens and results during the outbreak. Early tasks related to specimen management in LIMS included:

- Creation of a unique specimen requisition form designed to capture patient data specific to this outbreak.
- Development of an outbreak-specific specimen tracking tool. This ensured that outbreak specimens followed the appropriate testing algorithm and allowed the PHL to collectively report testing data on the grouped samples using specific outbreak queries.
- New data fields were created to capture and track unique information that was specific to this outbreak including: date of CCL procedure, date of OR/ICU procedure, whether the patient was indicated for testing, rapid HCV test result, etc.
- Addition of an HCV-specific shipping test code for those specimens shipped to the CDC for further testing.
- Addition of a specimen storage test code to track freezer storage of specimens.

In order to minimize patient inconvenience and avoid delays in testing, the laboratory did not refuse testing of any specimens that met PHL submission criteria. Specimens from patients who were not indicated for testing underwent HCV testing as requested on the specimen requisition, and final laboratory reports included a comment that "the patient was not indicated for testing as part of the EH outbreak at this time." A total of 95 patients not meeting the indications for testing were tested and results reported.

Following entry into LIMS, specimens were transferred to the laboratory for testing. Specimens were stored at 4–8°C until testing commenced. If testing was not completed within 48 hours of receipt, specimens were frozen at -70°C. All residual specimens were frozen at -70°C following completion of testing.

V. Laboratory Testing Methods

A. Enzyme Immunoassay

The PHL utilizes an enzyme immunoassay (EIA), the ORTHO® HCV Version 3.0 ELISA Test System as the initial screening test for specimens submitted to the PHL for HCV antibody testing. This assay is a U.S. Food and Drug Administration (FDA) cleared, *in vitro* diagnostic

assay. Tests are run on the ETI-Max 3000 automated enzyme immunoassay analyzer. This test detects antibody to HCV virus in serum or plasma. Specimens are defined as reactive for antibody to HCV if the signal to cutoff ratio is greater than or equal to 1.0. The sensitivity and specificity of the test are estimated at 98.9% and 100%, respectively, in patients with chronic HCV infection. [11]

B. RT-PCR

The PHL utilizes an FDA cleared, *in vitro* molecular diagnostic method, the Roche Molecular Systems Cobas Amplicor HCV v2.0 to detect HCV RNA as a supplemental test for specimens with reactive HCV antibody tests, or for patients whose anti-HCV antibody levels may be undetectable due to early infection. This assay is a semi-automated method, run on the Cobas Amplicor platform, an automated amplification and detection analyzer. The lower limit of detection of this method is 50–100 IU/ml. An HCV RNA positive result is an indicator of active HCV infection regardless of anti-HCV antibody positive or negative results.

C. DNA Sequencing

DNA sequencing for the NS5B and HVR1 regions of the HCV genome as well as HVR1 QS analysis have commonly been used to determine HCV subtypes and HCV relatedness to assist in hepatitis C outbreak investigations. [12] During the initial investigation of the four HCV-infected individuals in the EH outbreak, the NH PHL adopted a modified NS5B and HVR1 sequencing procedure that has been used at the CDC Hepatitis Laboratory. The following steps are included in the procedure:

- Conventional RT-PCR to amplify the NS5B region of the HCV genome using the One-Step RT-PCR kit (Qiagen).
- Performance of gene sequencing on the amplified NS5B RT-PCR products on an ABI 3130xl DNA Analyzer (Life Technologies).
- Analysis of the NS5B region sequence data to determine HCV subtypes.
- Conventional RT-PCR to amplify the HVR1 region of the HCV genome using Qiagen One-Step RT-PCR kit.
- Sequencing of the amplified HVR1 RT-PCR products.
- Analysis of HVR1 sequence data to determine genetic relatedness of HCV among investigated individuals.

For sequence analysis, a multiple alignment of HCV sequences was constructed using Alignment Explorer/CLUSTAL. Phylogenetic trees were constructed with UPGMA using the sequence analysis tool MEGA4.0. Because patients included in this investigation had recent exposure to HCV, sequences with ≥98% similarity in the HVR-1 were defined as "genetically linked" to the NH HCV outbreak strain.

VI. Testing Algorithm

As mentioned in Chapter 3, DPHS developed a laboratory testing algorithm to account for the limitations of the various tests in settings of recent HCV exposure (see Appendix 5). All specimens that tested positive for anti-HCV antibody were subsequently tested by RT-PCR for HCV RNA. HCV RNA positive specimens were sequenced in both the NS5B and HVR1 regions. Specimens determined to be the same subtype as the NH HCV outbreak strain in NS5B sequence testing and with ≥98% similarity in the HVR1 were considered "genetically linked,"

i.e., matching the NH HCV outbreak strain. Specimens determined to be of other HCV subtypes, or the same subtype but <98% similarity in the HVR1 region, were reported as non-matching to the NH HCV outbreak strain.

Considering the possibility of mixed infection of HCV, all RT-PCR positive specimens (matching and non-matching) were sent to CDC for QS analysis. In cases of mixed-infection (i.e., patient found by QS analysis to have two different HCV strains), a second blood sample was collected and all tests were repeated, both at the PHL and the CDC. In these cases, the CDC was blinded to the information that this was a repeat draw.

Because the CDC Hepatitis Laboratory utilizes a RT-PCR (Roche COBAS® TaqMan® HCV Quantitative Test) with a lower detection limit (15 IU/ml) than that utilized by the PHL (50–100 IU/ml), the PHL sent the following specimens to CDC for repeat RT-PCR testing:

- Specimens with positive serology (evidence of antibodies) but negative RT-PCR results at the PHL.
- Specimens from patients who were anti-HCV antibody and RT-PCR negative at the NH PHL but had recent CCL procedure (within 3 months of testing).

VII. Laboratory Testing Results

The results in this section provide information on the specimens processed by the PHL (and potential follow up testing by CDC). These include testing that was done for individuals not indicated for testing and does not include testing done out of state (not at the PHL), which accounts for the differences in the numbers provided in this section compared with those provided in other testing summaries in this report.

A. Testing for the CCL Group

A total of 1,142 individuals were screening for HCV infection, including 1,066 patients and 76 employees. 52 individuals were identified with active HCV infection and 49 of them could undergo genotyping and three specimens were unable to be amplified due to low viral titer.

The Phylogenetic analysis of HVR1 sequences identified a distinct cluster (NH HCV outbreak strain) in 27 HVR1 sequences from specimens of HCV-infected individuals including 26 patients and the HCW. The sequence similarity in the HVR1 region among the sequences in the cluster was ≥98% (see Appendix 16: Phylogenetic Tree).

The PHL compared the HVR1 sequences of the NH HCV outbreak strain with Genbank and the Los Alamos hepatitis C sequence database and found the highest sequence similarity in HVR1 between the NH HCV outbreak strain and any other publicly available sequences was <90%.

All HCV RNA positive specimens were tested at the CDC Hepatitis Laboratory by QS analysis, which sequences multiple clones from each infected individual. Specimens from 27 genetically related individuals identified by the PHL were also determined to be linked at the CDC by QS analysis. The CDC Hepatitis Laboratory was able to identify six additional matched cases:

- Three cases were infected with two HCV subtypes, including one matching the NH HCV outbreak strain. The PHL only detected one of them, the strain that was not matching the NH HCV outbreak strain.
- Three cases that had low viral titers and could not be amplified by the PHL.

In total, 33 HCV infected individuals including 32 CCL patients and 1 HCW were determined to be linked to the outbreak based on HVR1 region analysis.

B. Laboratory Testing for the OR/ICU Group

Out of 2,905 individuals who were screened for HCV infection as part of the testing expansion, 2,747 were patients and 158 employees. Thirty were identified with active HCV infection. No patients from the OR/ICU group were identified as being linked to the outbreak.

VIII. Testing at the Public Clinics

During the public clinics for the OR/ICU testing expansion, rapid HCV tests were utilized. The PHL was assigned the responsibility of setting up a testing laboratory at off-site locations. Plans were developed to include best laboratory practices of integrating quality throughout the patient process, to control laboratory inventory, assign and train testing personnel, and to manage all specimens from receipt to disposal, including transport, and to oversee the biohazardous waste generated at each testing site.

Before testing could occur under the domain of the NH PHL, a certificate of compliance from CLIA was needed to enable the laboratory to perform testing in a location other than the main facility in Concord, New Hampshire. Receiving this certificate was accomplished from the Region I office in Boston within 48 hours of the request.

Eight clinics were set up in seven days to accommodate over 3,000 patients to obtain their HCV antibody status using a rapid test. The first FDA-approved, CLIA-waived rapid HCV test by OraSure Technologies, Inc. (OraSure), called OraQuick® HCV Rapid Antibody test, was used and can detect HCV antibodies in fingerstick and venipuncture whole blood. OraSure states this test platform enables healthcare providers to deliver a 98% accurate diagnosis in 20 minutes. The NH PHL chose to perform venipuncture, and phlebotomists obtained two serum separator tubes (SST) and one lavender (anti-coagulant) tube from each patient. The lavender tube was used for the rapid testing. Both SST tubes were sent to the NH PHL for testing as defined in the CCL testing. There were 1,190 patients who had phlebotomies at these sites. Patients who were pregnant or under the age of 15 years of age were not tested, because OraSure has not performed validation testing on these populations. These patients were drawn using just the SST tubes that were sent to the NH PHL for testing. Any difficult draws were prioritized using the SST tubes so the serum could be tested following the in-house HCV testing algorithm at the PHL.

The rapid test is a waived test and by CLIA regulations can be performed by anyone who has the ability to read and demonstrate performance and interpret results correctly. The PHL chose to use testers who had extensive laboratory experience and were all trained to perform with a high level of competency. Competency assessment was documented for all trained testing staff.

To recruit testers and phlebotomists, the PHL contacted the NH Laboratory Response Network (LRN). Many hospital laboratory medical technologists also agreed to volunteer their skills and time. Twenty-four testers were recruited and trained to perform testing at the clinics. OraSure Technologies, Inc. representatives made themselves available at the Stratham site as a technical resource. At each site, a PHL laboratory manager was assigned to oversee all testing activities. Positive and/or questionable test results were repeated by a different tester on-site for verification prior to the release of the results. The laboratory manager reviewed all results and transcriptions before they were released to the clinical services staff to provide to patients.

The POD number that was assigned at registration to all patients was used for all paperwork, including the labeling of blood samples. Phlebotomists were instructed to check that the patient name, date of birth, and POD number all matched in both paper work and tube labels. Laboratory testers also assured that all paperwork and blood samples were labeled correctly prior to testing.

Test results were given to a healthcare professional such as a nurse or a doctor in the Results Group to call the patient by their POD number to provide confidential post-test counseling.

Temperatures of the testing site were taken twice daily and quality control was performed at each shift. A courier service transported specimens and requisitions back to the PHL in Concord, New Hampshire for follow-up testing. A contracted medical waste company retrieved the biohazardous waste at each site at the end of each clinic.

The manufacturer states a 98% sensitivity and specificity agreement between the HCV antibody rapid test result and HCV status of the patient, [15] which correlated with the testing results. All specimens drawn at the public clinic sites underwent HCV EIA testing at the PHL. Following the previously established algorithm, specimens testing positive by EIA underwent supplementary testing by RT-PCR. Specimens testing positive by RT- PCR underwent NS5B and HVR1 sequencing and were sent for additional testing by CDC.

IX. HCV Testing for Kansas Patients

To assist the Kansas Department of Health and Environment (KS DHE) in investigating the HCV outbreak in Kansas, the NH PHL performed RT-PCR and DNA sequencing. The PHL received 18 specimens that were serology positive for HCV from the KS DHE, and 14 of them tested positive for HCV RNA by RT-PCR at the PHL. NS5B sequencing was performed on the 14 HCV RNA positive specimens. Based on analysis of NS5B sequences, seven were determined to have the same subtype as the NH HCV outbreak strain. Of these seven, five were determined to be closely related to the NH HCV outbreak strain by phylogenetic analysis of HVR1 sequences. Of the five sequences, three had ≥98% similarity at HVR1 and two had HVR1 similarity between 95.4–97.8% compared with the NH HCV outbreak strain.

Chapter 8: Communications and Information Sharing

I. Public Health Communication Goals

Public health goals regarding communications and information sharing of the outbreak investigation were:

1. To ensure all information gathered as part of the outbreak investigation was compliant with the Health Insurance Portability and Accountability Act (HIPAA) and consistent with RSA 141:C (New Hampshire State law that addresses Communicable Disease).
2. To provide concise risk communication to the general public, patients, and healthcare providers and to update these communications continually as new information became available.
3. To inform and educate people about HCV.
4. To maintain ongoing situational awareness throughout the duration of the outbreak.

To achieve these goals, DPHS conducted the following activities:

1. Requested patient data and any and all relevant information from EH to conduct the outbreak investigation.
2. Established a mechanism to exchange information securely and confidentially.
3. Collaborated with the DHHS PIO to develop and disseminate public messaging materials and maintain awareness of the outbreak status.
4. Engaged subject matter experts to develop and disseminate patient messaging and clinical (healthcare provider) messaging materials.
5. Maintained availability for and responded to media inquiries.
6. Planned and led two community forums to provide information and answer questions about the outbreak.
7. Provided regular communication and timely sharing of investigation information with CDC and out-of-state health departments.

II. Communication with Exeter Hospital

After the initial notification from EH, DPHS staff requested to meet with EH management and key clinical staff to review the situation and outline the steps that DPHS would take to investigate. Hospital staff offered assistance and extended their commitment verbally to fully cooperate with DPHS in information gathering in order to promptly identify additional patients who may be at risk and manage the initial cluster of infections. At the preliminary meetings, DPHS identified its role and the need to gather information to conduct the public health investigation. DPHS gave its commitment verbally at these meetings to devote its entire scope of resources and epidemiological expertise to promptly and thoroughly investigate to the fullest extent of public health's statutory authority and bring the investigation to a prompt closure.

DPHS and EH continued to communicate in person through site visits, via conference calls, and by sharing documents, data, and memos through a secure website. The primary means of communication early in the investigation was daily conference calls, which were routinely attended by DPHS lead investigators and the EH CEO and senior management team. DPHS used a recently developed Risk Notification Template (see Appendix 17: Risk Notification Template) as a means to summarize the content of conference calls, establish documentation for information requests, and monitor developments and the status of the outbreak. In general, the frequency of conference calls, emails, and communication was greater earlier in the investigation

and less frequent later in the course of the investigation. EH was promptly notified, by a phone call, of every matching case once identified.

At the beginning of the investigation, clinical and management staff at EH fully cooperated with requests from DPHS to conduct the public health investigation, including making arrangements for DPHS investigators to privately interview employees and securing a location within EH to review patients' medical records. As more cases were identified, the scope of the outbreak expanded and the outbreak became widely publicized. DPHS expected to continue its ongoing investigation precisely as it had previously been conducted, including the review of patient records and conducting private interviews of employees. EH administration slowed the expediency of their responses and significantly curtailed the level of access to DPHS staff.

In late August 2012, DHHS was notified of legal action taken by EH against DHHS, which suspended direct communications between DPHS investigative staff and EH. This delayed the public health outbreak investigation even further. Once the legal action was resolved in October 2012, DPHS resumed requests for data and information from EH to complete the outbreak investigation. On October 31, 2012, the court provided its ruling affirming DPHS's authority and its valid exercise of such authority in its investigation activities, allowing DPHS to resume its investigation. On April 30, 2013, DPHS concluded its investigation of the HCV outbreak.

A. Establishment of an Information Exchange Site

In order to facilitate the investigation while upholding confidentiality, DPHS established a secure environment for information exchange. The State of New Hampshire's Secure File Exchange Server is a file transfer protocol (FTP) website that allows designated users to access it using a username and password. DPHS staff holds administrative roles, and the site is maintained by the New Hampshire Department of Information Technology.

On June 12, 2012, a folder was created for EH on the FTP site to support the outbreak investigation. Both DPHS and EH designated staff to access and manage the documents on the FTP site. Once established, the FTP site was checked a minimum of twice a day for any downloads from EH. When DPHS uploaded documents, a notice was sent via email to designated EH staff to notify them of the upload and to whom it was addressed. DPHS established a process to guide use that was routinely practiced during the outbreak investigation between DPHS and EH.

III. Communication with Patients

Messaging targeted to patients who may have been exposed to HCV as a part of this outbreak was provided in the form of general information described below in "Messaging to the General Public." In addition, there were several questions on the Frequently Asked Questions (FAQs) information sheet that were for calls from exposed persons. There were also scripts written for telephone calls to patients to give them their laboratory results. The initial plan for providing test results for patients included calling those with positive results and mailing both positive and negative test results to providers. However, the concern among individuals waiting for their test results was high and DPHS decided to call all patients with positive or negative results as soon as they were available. Public health medical or nursing staff contacted individuals with positive results. Scripts were also written for delivery of test results in person at the public clinics.

Every effort was made to address each patient question, and if the person on the phone did not know the particular answer, the question was passed to others with additional information and they called the patient back as soon as possible. Some questions relative to the criminal

investigation, legal questions, or personal medical information (e.g., with regards to predictions around individual prognoses) could not be answered by DPHS but appropriate referrals were made to other services as needed.

IV. Communication with Medical Providers

The HAN is a messaging and notification system primarily for healthcare providers used by New Hampshire and many states to conduct risk notification and messaging. DHHS broadly communicated with healthcare providers throughout the course of the investigation.

DPHS developed and disseminated six HAN messages during the HCV outbreak and included information about the outbreak and recommendations for providers. The first HAN message was sent on May 31, 2012. All HAN messages related to the outbreak are available at http://www.dhhs.nh.gov/dphs/cdcs/hepatitisc/hepc-investigation.htm#NHHAN.

The HAN messages have broad reach in the provider community and were sent to the system list for individuals who had signed up for these messages. Each of these HAN messages was sent to approximately 4,400 recipients, which included system physicians, physician assistants, nurses, infection control practitioners, ID specialists, hospital emergency departments, hospital CEOs, the Laboratory Response Network, local health departments in Manchester and Nashua, the New Hampshire Hospital Association, and Community Health Centers. Currently a total of 8,000 partners are included in the system. All healthcare providers in New Hampshire are encouraged to participate in the system to receive HAN messages about important health information from DPHS. Additional information pertaining to this, including how to sign up, is available on DHHS website at the following link: http://www.dhhs.nh.gov/dphs/cdcs/alerts/index.htm.

Other messaging for patient providers included a provider letter that was sent along with patient lab results to help with interpretation of laboratory results and to become a part of each patient's medical record. Formal written reporting was provided for FDA approved testing methods. For non-FDA approved HCV testing (such as viral QS analysis), written results were not sent in the mail but providers received a telephone call with these results for their patients. Scripts were written for telephone calls to providers as well to help with laboratory result interpretation. These scripts and letters were updated as new information became available during the course of the investigation.

V. Communication with CDC and Out-of-State Health Departments

DPHS communicated with CDC very early on in the investigation through conference calls and emails. CDC experts were extremely helpful in providing information and resources available from previous investigations (patient interview forms, site infection control assessment forms, etc). These initial informal inquiries progressed to standing weekly conference calls in June 2012. The purpose of the conference calls was to share information about the outbreak investigation with CDC and to discuss the laboratory response, for which CDC was assisting. Once the multistate investigation was initiated, weekly conference calls with the CDC and the other affected states, coordinated by the CDC, were also conducted.

Other State Health Departments were communicated with frequently throughout the investigation, and the successful New Hampshire and multistate responses relied heavily on the free flow of information across state lines. State Health Departments are very experienced in multistate investigations and they support one another in accomplishing the common goal of protecting the public's health.

In the very earliest days of the investigation, DPHS reached out to several state health departments asking for specific information and resources available from previous investigations. Once the outbreak was confirmed and testing of CCL patients was recommended, DPHS broadly communicated with all State Health Departments on May 31, 2012 through the Epidemic Information Exchange (Epi-X), the nationwide communication and alerting system maintained by CDC. This message announced the outbreak and requested that states report any potentially related HCV infections to DPHS. As the investigation progressed, DPHS posted several updated messages (on June 21, July 22, and August 8, 2012). With the evolution to a multistate investigation, CDC posted an additional Epi-X notification.

In addition to these broad communications to all states, DPHS sent state-specific notification letters that provided a list of EH patients recommended for testing who were residents of each respective state. Among CCL patients, there were 59 non–New Hampshire residents who lived in 7 states and Canada. Two of those were confirmed as matched cases, and the New Hampshire State Epidemiologist notified the peers in those states. On June 19, 2012, DPHS mailed letters to each of the 8 jurisdictions with a list of their resident patients, which included test results for those patients who had already been tested. The State Health Departments were asked to assist with locating patients who had not been tested. Among OR and ICU patients during the expanded testing, there were 213 non–New Hampshire residents who lived in 21 states and Canada. On August 27, 2012, DPHS mailed letters to each of the 22 jurisdictions with a list of their resident patients, which included test results for those patients who had already been tested and asking the State Health Department to assist with locating patients who had not. Other health departments assisted with locating patients, communicating with healthcare providers, arranging specimen collection, and transporting specimens to the PHL if indicated.

In addition to the sharing of exposed patient information for residents of each respective state, DPHS relied on the open sharing of information across state lines to conduct the epidemiologic investigation. As previously mentioned in other chapters, other health departments shared information on (1) prior HCV testing for the infected HCW and other past CCL employees who lived or worked in other states either before or after their employment at EH, (2) death certificates for exposed patients who died outside of New Hampshire, and (3) testing information for exposed patients who had evidence of prior HCV infection.

VI. Communication with the General Public

A. Press Releases

The DHHS PIO issued a total of 18 press releases between May and August 2012. DPHS and EH officials conducted a press conference on May 31, 2012 to announce the finding of the initial four cases with a similar strain of HCV, to notify the public of testing to take place, and to answer questions from the media. DHHS hosted two media availabilities and updates were provided and questions answered by Dr. José Montero, Director, DPHS. Dr. Montero also participated in a television segment in a local TV station (WMUR) on June 6, 2012 to discuss the initial HCV outbreak investigation activities.

B. Social Media

DHHS established a webpage about the event in Early June, 2012. A website slider on the homepage was launched June 29, 2012 linking people to the HCV outbreak investigation page. Comprehensive information was posted on the website including: FAQs, HCV testing summaries, clinic information, press releases, and information for medical providers. DPHS

recorded three short videos to provide information to the public. The first video was on the basics of hepatitis C recorded by the Deputy State Epidemiologist in June 2012. The State Epidemiologist recorded the second and third videos. One provided information on the initial steps that DPHS took and how the outbreak was managed and the other provided an explanation of the expanded testing, use of the rapid test for HCV, and the public clinics. The DHHS PIO also posted messages and shared information about the outbreak on Facebook and the public could follow the outbreak on Twitter @NHDHHSPIO or look for #NHHepC.

C. Call Center for the General Public

DHHS staffed phone lines throughout the response and remained available to patients and the general public for questions and concerns about HCV. When HCV testing was expanded to OR/ICU patients, DHHS established, in addition, a public inquiry line staffed by volunteers that operated between July 24 and August 17, 2012. The staff was provided with patient messaging materials (specific to the testing expansion recommendation as well as general HCV FAQs). A total of 1,012 calls were received in the inquiry line and 3,055 were made to patients who asked for callbacks or information.

D. Community Meetings

DHHS planned and conducted two community meetings to provide an opportunity to discuss the outbreak investigation, including the process and rationale for decision-making, with community members, and to be available to answer questions and concerns of the public in general. DPHS invited EH officials to attend the community meetings. The first meeting was held June 15, 2012 in Exeter. The purpose of the meeting was to explain the process of the investigation by DPHS and answer questions. At that point, 20 cases of HCV were associated with the outbreak. Speakers included DHHS Commissioner Nicholas Toumpas, Dr. José Montero, Director of DPHS, Dr. Sharon Alroy-Preis, State Epidemiologist, and Dr. Jodie Dionne-Odom, Deputy State Epidemiologist. The meeting was well attended by approximately 80–100 individuals and was two hours in length. DHHS officials remained on hand until all questions from the public were answered, including from individuals after the public meeting ended.

The second community meeting was conducted July 26, 2012, also in Exeter. The purpose of the meeting was to explain the process of the clinics, why the testing was recommended, to explain the process for providing test results, and to discuss the reasons for delaying the clinics. At that date, 31 cases were associated with the outbreak. The same speakers attended this meeting. The meeting was attended by approximately 80–100 individuals and was slightly over two hours in length. DHHS officials again remained onsite answering all questions until there were no more. DHHS used social media tools for this second meeting; it was live streamed to accommodate community members who may not have been able to attend in person. Additionally, DHHS PIO staff monitored questions and content live on Facebook and Twitter for the duration of this public meeting.

Chapter 9: Conclusions and Final Recommendations

I. Conclusions

Based on the initial report of a suspected HCV cluster on May 15, 2012, the NH DPHS initiated an investigation that spanned the course of one year and put an end to one of the most serious healthcare associated outbreaks in New Hampshire. In addition to the local impact, the investigation uncovered a multi-state outbreak involving at least three other hospitals in two other states, and some investigation efforts are still ongoing.

DPHS concluded that the outbreak resulted from drug diversion by an HCV-infected CCL technician at Exeter Hospital (EH).

The New Hampshire outbreak investigation included testing of 3753 patients and 131 employees. 33 cases, 32 patients and 1 HCW, were confirmed as related to the outbreak. See Appendix 18: HCV Outbreak Investigation Summary of Initial Testing Results. Nine (9) additional patients with cleared infections were determined to be probable cases (4) and suspect cases (5) based on epidemiological information. Investigation efforts were ongoing for 12 months and were hindered by EH management, including review of medical records, private interviews of staff, and employee testing. Despite this, many EH employees were instrumental in the investigation and provided the information that allowed DPHS to quickly discover the source of the outbreak and prevent ongoing patient harm.

The investigation and response efforts involved approximately 150 staff and included epidemiologists, public health nurses, laboratory workers, emergency service unit workers, administrators, support staff, and many others. The investigation and response efforts cost over $384,000. The majority of the costs were incurred for supplies for laboratory testing and overtime hours for staff working on the investigation.

DPHS routinely conducts critical reviews and evaluation of its work, particularly for a large-scale, long-duration outbreak response such as this. Staff is committed to the principles of performance improvement and as a result will identify gaps as well as lessons learned in order to build capacity to better respond to future outbreak events.

II. Final Recommendations:

The extensive outbreak investigation revealed multiple gaps and areas for improvement in the following three domains:

A. Increase regulation and improve information sharing regarding allied healthcare workers.
B. Strengthen healthcare systems to promote prevention and early detection of drug diversion.
C. Assure optimal response to healthcare associated outbreaks to protect patient safety.

Domain A

Increase Regulation and Improve Information Sharing Regarding Allied Healthcare Workers.

The multi-state aspects of the investigation revealed several high level barriers to early identification of drug diversion activities by the HCW and the ability to share concerning information once identified. These barriers allowed the infected HCW to continue with drug

diversion activities while moving from hospital to hospital and from state to state. Being an unlicensed HCW prohibited the reporting of his activities to a formal board. Being a traveling technician facilitated his movement from location to location with minimal regulation and oversight.

Recommendations for future improvement include:

1. Ensure a comprehensive and effective national system to capture concerns about HCWs' activities that can put patients at risk, including allied HCWs. The current available system, the Data Bank, should be improved to capture different types of concerns on all types of HCWs and the reporting to this system should be made mandatory.
2. Support legislation to allow past employers, concerned about potential drug diversion by a HCW, to share these concerns (i.e., the reason for early termination) with future employers, whether within the state or across state lines.
3. Improve the process of background checks prior to hiring an employee.
4. Improve regulation and scrutiny when hiring traveling staff.
5. Enact regulation and oversight of staffing agencies that place traveling technicians for temporary assignments.

These issues have been the focus of investigation by the Maryland Department of Health and Mental Hygiene and detailed findings and recommendations are available in their report (http://dhmh.maryland.gov/pdf/Public%20Health%20Vulnerability%20Review.pdf). More work is needed to address these issues both on a state and national level.

Domain B

Strengthen Healthcare Systems to Promote Prevention and Early Detection of Drug Diversion.

One of the main public health goals in the investigation was to shed light on the specific systems gaps that allowed drug diversion to occur at the CCL. The following recommendations are based on the outbreak investigation findings at EH and can serve as a list to guide gap analysis and improvement efforts in healthcare facilities.

1. Assure Limited Access to Controlled Substances

a. Procedure areas where controlled substances are being administrated on a regular basis should be closed and require a card key for access. Restriction of access at that level can assist in minimizing unwanted traffic but can also aid in tracking that access. In the CCL investigation, it became clear that the infected HCW accessed the CCL on days when he was not scheduled to be at work. Automatic integration of the card key access database with employees' schedules could be beneficial in flagging unusual patterns of unexplained access. In healthcare facilities where such technology cannot be implemented, it would not be realistic to expect that employees' movements in the hospital be constantly monitored, but upon suspicion of unusual behavior a tracking system could provide additional information worth investigating.

b. Access to the procedure room itself during a procedure should be restricted to include only the specific employees who have a clear role in the procedure. The presence of those employees should be documented in the patient's record, even if they were present for a short period of time. Based on the CCL investigation, staff members who were assigned to the case were documented, but other staff, including the infected HCW, had free

access and their presence was never documented. In the OR investigation, there was a policy to document any staff presence in the room but that policy was not adhered to at all times.

c. Controlled substances should be locked, preferably in an automated medication cabinet, such as a Pyxis, with access provided only to those employees who have a role in administering controlled substances. The access should preferably be biometric to allow the highest degree of personal identification.

2. Improve Processes Related to the Preparation and Use of Controlled Substances

a. Controlled substances should not be prepared ahead of their anticipated use.
b. When controlled substances are prepared and not administrated immediately, the syringe should be stored in a locked drawer. After initial use, if the remaining controlled substance is kept for future use, the syringe should be maintained in a locked drawer. Keeping a syringe with a controlled substance on top of a Pyxis machine is easier for workflow but does not guarantee that the syringe is always in the nurse's sight, especially in a procedure room with many distractions.
c. Controlled substances should not follow patients when they are being transferred at the end of the procedure. The nurse who drew and administered the medication during the procedure should waste the remainder at the end of the procedure as the patient is leaving the procedure room. If additional medication is needed thereafter, in the recovery room (RR), a new vial should be used.

3. Ensure Real Time Accountability for Controlled Substances

a. At the end of the procedure there should be a timeout to account for all the controlled substances that have been dispensed under the patient's name, similar to what is done in surgeries to assure all instruments are accounted for. That process should include reviewing the amount that was dispensed, the amount that was administered, and the amount that was not used, which should be either returned (unopened vials) or wasted (opened vials). The timeout should include the nurse and physician who were assigned to the case and know the details of what was ordered and administered to ensure a meaningful review.
b. In the case where a discrepancy is found during a timeout, there should be a "lockdown" procedure to locate the missing controlled substance prior to staff leaving the room. If controlled substances cannot be accounted for, all employees who were in the procedure room during the procedure should undergo drug testing.
c. The process for controlled substance waste should be clear and repeatedly communicated to staff.
d. When controlled substances are used in a non-procedure setting, it is preferable for the nurse to have a witness to all three steps of preparation and use (dispensing, administration, and wasting). If the second staff member (nurse or physician) is only witnessing the wasting they have no independent knowledge of the appropriate content of the syringe and cannot serve as a meaningful observer.
e. In cases where a physician is witnessing the waste, there should be follow up on the documentation of that process. Alternatively, physicians who usually don't need Pyxis access could be provided with one for wasting purposes only, which will allow better oversight of that process at the pharmacy level.

f. Any case of wasting of a full vial should be investigated. Repeated incidents by the same staff should initiate a comprehensive investigation to rule out drug diversion. This should include drug testing of the staff member and others who are suspected of being involved. Aborting the process of wasting the next time a full vial is about to be wasted in order to test the content of the syringe should be done if possible.

4. Enhance Controlled Substances Oversight

a. Pyxis machines in procedure rooms that have a control room should be positioned as close as possible to the glass window that separates the two rooms to allow oversight of the Pyxis by the staff in the control room.
b. Controlled substances should be closely tracked to ensure accountability for every vial. In profiled Pyxis stations (not in procedure areas), where upon request the whole drawer with vials is opened, the nurse should count the vials prior to and after removing additional doses and enter those numbers into the Pyxis. Pharmacy should closely monitor the Pyxis content using Pyxis reports and manual Pyxis checks. Non-profiled stations (in procedure areas such as the CCL) in which only the requested dose is dispensed (and can be dispensed without prior pharmacy verification) require an even tighter oversight by pharmacy with frequent audits and Pyxis checks. In this scenario, the nurse is not able to check how many vials are left within the Pyxis to detect discrepancies. Although the expected scenario is for one vial to be dispensed at a time, this is not always the case. The nurse may try to dispense one vial and get two or none and have a discrepancy in the amount of vials expected to be in the Pyxis. Frequent audits of the Pyxis by the pharmacy, comparing reports on controlled substances dispensed/returned to the machine to the actual number of vials in the machine, would allow the proper oversight.
c. Controlled substance oversight could be significantly enhanced if all patient information is integrated into a single system. This allows automatic checks to see if the amount of controlled substance dispensed under a patient's name equals the amount given, wasted, and returned and whether this matches up with the amount ordered. It could also be programmed to alert staff if a single patient is getting a significantly higher dose of a controlled substance compared with the usual average use for that procedure and, if so, can serve to initiate an investigation. If using a single system to document patients' care is not possible, every effort should be made to connect the freestanding systems to allow those automatic checks. Most of the information regarding controlled substances is already in the Pyxis (the amount dispensed, wasted, and returned). If the Pyxis can be programmed to prompt the user at the time of wasting to document the amount of controlled substance that was given to the patient during the procedure, this could also assist in discovering discrepancies. Lacking the ability to leverage technology in integrating different information systems requires frequent manual audits, on a regular basis, to compare Pyxis records to patients' charts.

5. Strengthen Procedural Management for Use of a Mobile Medication Box

Storing controlled substances in a mobile box should be minimized as much as possible. If the use of such a box is needed on a regular basis for a certain procedure areas (such as the IR procedures at EH), consideration should be made to locate a Pyxis station in that area in order to

avoid the need for a mobile box. If despite all efforts a mobile box is still needed, the processes around the use of the box should be clear, concise, and tightly supervised:

a. The box must be locked at all times.
b. The box should reside in the pharmacy (under a second lock) and be signed out only to the nurse who is expected to administer the controlled substances, and at that time s/he should be provided with the key/code required to open the box.
c. The box should also be sealed. Upon delivery of the box to the nurse in the pharmacy, the seal should be broken and both the nurse and the pharmacist should check the contents of the box against an inventory list within the box. That information should be documented with both staff signing their names.
d. The box should be opened outside the pharmacy only when medication is needed, and it should be promptly locked thereafter.
e. Controlled substances should not be drawn in advance of their need, and if that has occurred, the syringe should be locked within the box until its use.
f. Wasting of controlled substances should be done, and documented, in the pharmacy by the nurse and the pharmacist when the mobile box is returned. If the mobile box was used for more than one patient, a clear wasting process should occur after each patient. This would require wasting to occur where the controlled substance was given. In those cases, two team members (nurse or physician) should complete the wasting procedure with clear documentation in a designated paper record within the box. That documentation should be brought back and kept in the pharmacy.
g. When the box is no longer needed, the same nurse should return the box to the pharmacy and the same process, where both the nurse and the pharmacist are checking the content of the box against the inventory list, should be performed. The nurse should waste any unused controlled substance that was already drawn in the presence of the pharmacist (in case the box was used for only one patient) or go over any wasting documentation that has occurred outside the pharmacy (if multiple patients were treated).
h. After the inventory list is updated, the nurse and pharmacist should sign off, and the box should be sealed again and locked in the pharmacy.

6. Implement a Comprehensive Approach to Proactive Impeding of Drug Diversion

Since drug diversion is a real and constant threat in healthcare settings, the approach to prevention and early detection should be one of active planning, implementation, and oversight rather than being reactive to an event.

a. Dedicated staff should be in charge of coordinating drug diversion prevention efforts in every healthcare system where drug diversion could occur. That can range from a task force of several employees for large institutions to a single staff position filling that role. That role should report directly to the hospital CEO or the director of the quality and patient safety unit.
b. The dedicated drug diversion staff should review processes and procedures related to controlled substances in each unit with each unit supervisor, assess for any gaps that need to be addressed, and create a plan to do so. The plan and its implementation should be reviewed on a regular basis.
c. All staff should be educated on an ongoing basis on the risk of drug diversion and the possible presentation to look for. Signs and symptoms (consistent with a person being under the influence of drugs/alcohol) as described for the infected HCW by his co-

workers should have been investigated early on. Educational information is available at: http://www.deadiversion.usdoj.gov/pubs/brochures/drug_hc.htm.

d. A formal process of reporting drug diversion concerns to the dedicated staff should be in place. This should include concerns due to staff behavior, controlled substance discrepancies, any findings of unattended syringes containing controlled substances (especially in non-patient care areas), wasting of full vials of controlled substances, etc. All staff should be educated about their role in prevention and be empowered to report any concerns. The reporting process should allow for anonymous reporting, provide multiple ways to reach the dedicated staff (email, hotline, letter box, etc.), and be as easy as possible to encourage staff to use this process to raise concerns.
e. A clear policy regarding drug diversion should be in place and each staff member should be required to review and sign the document. The policy should include mandatory drug testing for any suspicion of drug mishandling. This clearly should apply for specific concerns regarding staff behavior. Moreover, in cases where an empty syringe that contained a controlled substance is found unexpectedly in a unit (without prior concerns about a specific employee) the policy should require drug testing of all staff in that unit. The policy should also describe the approach that will be taken if suspicion of drug diversion is confirmed. However, having a policy in place is not enough, and the dedicated drug diversion staff, along with management, should ensure the policy is enforced.
f. Camera surveillance should be considered in areas where controlled substances are given on a regular basis, but even more so when a drug diversion concern arises in a specific unit. Again, having the camera itself would not solve the problem if the data from this surveillance device is not being closely monitored.

7. Develop a Clear and Concise Action Plan for Suspected Cases of Drug Diversion

a. The drug diverter should be placed immediately on leave and kept away from patient care areas.
b. Drug diversion is a criminal activity and as such should be reported to law enforcement. Maintaining close working relationships between the dedicated drug diversion staff and local law enforcement can assist in coordinating activities to investigate drug diversion suspicions even prior to confirmation.
c. The law enforcement community should consider creating/assigning one centralized entity to receive reports of suspected drug diversion.
d. Drug diversion incidents should be considered adverse events and be reported as such.
e. The drug diverter should be tested for blood-borne pathogens (for example HIV, HBV, and HCV) and if found to be positive, the drug diversion should also be reported to NH DPHS, who will initiate an independent investigation to determine the risk to public health.
f. In case of a licensed provider, the licensing board should be notified (NH Board of Nursing, Board of Medicine, Board of Pharmacy, etc.).
g. For any HCW, both licensed and unlicensed providers (such as technicians), the information should be reported to the Data Bank and this reporting should be made mandatory.

Domain C

Assure Optimal Response to Healthcare Associated Outbreaks to Protect Patient Safety.
In their respective roles, health care providers and public health have the same core mission: protecting people's health, whether on an individual basis by healthcare providers or on a population basis by public health. In an outbreak setting, the need to protect the public intensifies because the risk for continued transmission and harm is ongoing until the source of the outbreak is identified and eliminated or mitigated.

a. Maintain prompt reporting of any unusual occurrence of illness, suspect cluster or outbreak to DPHS. This should include cases of drug diversion by a HCW when there is a concern for transmission of a blood borne pathogen.
b. Ensure effective communications between public health and hospitals/ healthcare providers during an investigation.
c. Provide timely and complete reporting of outbreak related data to public health during an investigation in order to promote efficient outbreak response, minimize patient risk and ensure prompt resolution of the situation.

The quality of healthcare in New Hampshire is among the best in the country and the criminal actions of one individual are not reflective of the system as a whole. They do, however, demonstrate that the system is not perfect and requires both healthcare and public health to remain vigilant for ways to improve the care provided to patients. The NH Health Care Quality Assurance Commission is an entity in New Hampshire designated to do just that. The Commission was established in 2005 with the passage of HB514 by the State Legislature and was reauthorized in State law RSA chapter 151-G in 2010. The Commission includes rrepresentatives from all hospitals, ambulatory surgical centers, and public health, working together to ensure the care provided to patients is safe and of the highest quality. There could be no better platform to share experiences, learn from one another, and coordinate efforts among the different partners, in order to decrease patient risk from one of the most difficult challenges facing healthcare, drug diversion.

REFERENCES

1. Mandell GE, Bennett JE, Dolin R. Mandell, Douglas and Bennett Principles and Practice of Infectious Diseases. 7th edition. 2010. Chapter 154.
2. Betts RF, Chapman SW, Penn RL. Reese and Betts' Practical Approach to Infectious Diseases. 5th edition 2003. Chapter 14. pg 484–487.
3. Hellinger WC, Bacalis LP, Kay RS, et al. Health Care-Associated Hepatitis C Virus Infections Attributed to Narcotic Diversion. Annals of Internal Medicine 2012;156:477–482.
4. Shemer-Avni YS, Cohen M, Keren-Naus A, et al. Iatrogenic Transmission of Hepatitis C Virus (HCV) by an Anesthesiologist: Comparative Molecular Analysis of the HCV-E1 and HCV-E2 Hypervariable Regions. Clinical Infectious Disease 2007;45:e32–38.
5. Cody SH, Nainan OV, Garfein RS, et al. Hepatitis C Virus Transmission From an Anesthesiologist to a Patient. Archives of Internal Medicine 2002;162:345–350.
6. Ross RS, Viazov S, Gross T. Transmission of Hepatitis C Virus from a Patient to an Anesthesiology Assistant to Five Patients. New England Journal of Medicine 2000;343(25):1851–1854.
7. State of NH RSA Title X Public Health, Chapter 141-C Communicable Disease available at: http://www.gencourt.state.nh.us/rsa/html/X/141-C/141-C-mrg.htm.
8. NH Code of Administrative Rules. PART He-P 301 Communicable Diseases. He-P 301 #9172 effective 06-06-08. Available at: http://www.gencourt.state.nh.us/rules/state_agencies/he-p300.html.
9. Doerrbecker J, Friesland M, Ciesek S, et al. Inactivation and Survival of Hepatitis C Virus on Inanimate Surfaces. Journal of Infectious Diseases, 2011;204:1830–1838.
10. Paintsil E, He H, Peters C, et al. Survival of Hepatitis C Virus in Syringes: Implication for Transmission among Injection Drug Users. Journal of Infectious Diseases, 2010; 202:984–990.
11. Colin C, Lanoir D, Touzet S, et al. Sensitivity and specificity of third-generation hepatitis C virus antibody detection assays: an analysis of the literature. J Viral Hepat 2001; 8:87–95.
12. Tugwell BD, Patel PR, Williams IT, et al. Transmission of hepatitis C virus to several organ and tissue recipients from an antibody-negative donor. Ann Intern Med. 2005;143(9):648–54.
13. OraSureTechnologies, Inc., 220 East First Street, Bethlehem, Pa 18015; www.orasure.com.

Appendix 1: Case Questionnaire

New Hampshire Department of Health and Human Services **Interviewer Name: _____**
Bureau of Infectious Disease Control **Date: _____/____/_____**

Hepatitis C Virus Case Investigation Form

After introduction and confirming the patient knows of his or her hepatitis C diagnosis: *I am calling to ask you questions about your recent hepatitis C diagnosis. We are trying to determine how you became infected with hepatitis C. We have received reports of other people with hepatitis C and we are concerned that these infections are related or connected in some way. I would like to ask you some questions about your illness and how you may have gotten it. These questions will take about 20 minutes to answer. You don't have to answer any question that you don't want to answer, but your answers might help us find the source of your illness and help prevent other people from getting sick. The information you give me will remain confidential.*

Interviewee: ☐ Self ☐ Spouse ☐ Other:_____

1. Patient Information:

LAST NAME	FIRST NAME	MI

ADDRESS	CITY	STATE	ZIP

HOME PHONE	WORK PHONE	CELL PHONE
( )	( )	( )

DATE OF BIRTH	AGE	SEX (CIRCLE ONE)	RACE	ETHNICITY
		MALE FEMALE		○ Hispanic ○ Non-Hispanic

OCCUPATION

2. Did you have any of the following symptoms before you were diagnosed with hepatitis C:

☐Jaundice (yellowing of the eyes or skin ☐Fever
☐Dark urine ☐Fatigue
☐Clay-colored stool ☐Joint pain
☐Abdominal pain ☐Nausea
☐Loss of appetite ☐Vomiting

3. Do you remember when you started becoming ill with symptoms of hepatitis?

☐Yes If yes, date**:**_____/_____/_____ ☐No ☐Did not have symptoms

4. Have you ever been diagnosed with hepatitis in your lifetime before this most recent diagnosis:

☐Yes if yes, date**:**_____/_____/_____ ☐No ☐Unsure

If yes, type: ☐Hepatitis A ☐Hepatitis B ☐Hepatitis C ☐non-viral

5. Do you ever remember being tested for hepatitis C before this most recent diagnosis:

☐Yes If yes, date**:**_____/_____/_____where:_____ ☐No ☐Unsure

If yes, why were you tested:

6. In the 2 weeks – 6 months before onset of symptoms/diagnosis were you hospitalized: ☐ Y ☐ N ☐ U

If yes:

Reason:_____Dates:____/____/_____ to ____/____/_____Where:_____

Reason:_____Dates:____/____/_____ to ____/____/_____Where:_____

Reason:_____Dates:____/____/_____ to ____/____/_____Where:_____

7. Did you have surgery or other invasive medical procedures during these hospitalizations: ☐ Y ☐ N ☐ U

If yes:

Type of Procedure:_____Date:____/____/_____Where:_____

Type of Procedure:_____Date:____/____/_____Where:_____

Type of Procedure:_____Date:____/____/_____Where:_____

8. In the 2 weeks – 6 months before onset of symptoms/diagnosis did you have any other surgery or other invasive medical procedure outside of a hospitalization: ☐ Y ☐ N ☐ U

If yes:

Type of Procedure:_____Date:____/____/_____Where:_____

Type of Procedure:_____Date:____/____/_____Where:_____

Type of Procedure:_____Date:____/____/_____Where:_____

9. In the 2 weeks – 6 months before onset of symptoms/diagnosis did you have endoscopy such as colonoscopy: ☐ Y ☐ N ☐ U

If yes:

Type of Procedure:_____Date:____/____/_____Where:_____

Type of Procedure:_____Date:____/____/_____Where:_____

10. In the 2 weeks – 6 months before onset of symptoms/diagnosis did you receive any IV infusions or injections outside of your hospitalizations (such as in an outpatient clinic, emergency room, or doctor's office): ☐ Y ☐ N ☐ U

If yes:

Type of IV/Injection:_____Date:____/____/_____Where:_____

Type of IV/Injection:_____Date:____/____/_____Where:_____

11. In the 2 weeks – 6 months before onset of symptoms/diagnosis did you have any dental work or oral surgery: ☐ Y ☐ N ☐ U

If yes:

Type of Dental Work:_____Date:____/____/_____Where:_____

Type of Dental Work:_____Date:____/____/_____Where:_____

12. In the 2 weeks – 6 months before onset of symptoms/diagnosis did you/were you:

Undergo hemodialysis	☐ In the last 2-6 months	☐ Y ☐ N ☐ U	Details:
	☐ Ever in lifetime	☐ Y ☐ N ☐ U	Details:
Have an accidental stick or puncture with a needle or other object contaminated with blood	☐ In the last 2-6 months	☐ Y ☐ N ☐ U	Details:
	☐ Ever in lifetime	☐ Y ☐ N ☐ U	Details:
Receive a blood transfusion or other blood products	☐ In the last 2-6 months	☐ Y ☐ N ☐ U	Details:
	☐ Ever in lifetime	☐ Y ☐ N ☐ U	Details:
Have exposure to someone else's blood	☐ In the last 2-6 months	☐ Y ☐ N ☐ U	Details:
	☐ Ever in lifetime	☐ Y ☐ N ☐ U	Details:
Employed in a medical or dental field	☐ In the last 2-6 months	☐ Y ☐ N ☐ U	Details:
	☐ Ever in lifetime	☐ Y ☐ N ☐ U	Details:
Receive a tattoo or body piercing	☐ In the last 2-6 months	☐ Y ☐ N ☐ U	Details:
	☐ Ever in lifetime	☐ Y ☐ N ☐ U	Details:
Self inject drugs prescribed by a doctor	☐ In the last 2-6 months	☐ Y ☐ N ☐ U	Details:
	☐ Ever in lifetime	☐ Y ☐ N ☐ U	Details:
Self inject drugs not prescribed by a doctor	☐ In the last 2-6 months	☐ Y ☐ N ☐ U	Details:
	☐ Ever in lifetime	☐ Y ☐ N ☐ U	Details:
Used any other drugs not prescribed by a doctor	☐ In the last 2-6 months	☐ Y ☐ N ☐ U	Details:
	☐ Ever in lifetime	☐ Y ☐ N ☐ U	Details:
Incarcerated in a jail or prison	☐ In the last 2-6 months	☐ Y ☐ N ☐ U	Details:
	☐ Ever in lifetime	☐ Y ☐ N ☐ U	Details:
Have contact with a person diagnosed with hepatitis C	☐ In the last 2-6 months	☐ Y ☐ N ☐ U	Details: ☐ Sexual ☐ Household (non-sexual) ☐ Other:_____
	☐ Ever in lifetime	☐ Y ☐ N ☐ U	Details: ☐ Sexual ☐ Household (non-sexual) ☐ Other:_____
Have unprotected sex with any new partners	☐ In the last 2-6 months	☐ Y ☐ N ☐ U	Details:

If this patient had a procedure in a procedure room at Exeter hospital ask question 13. If not, skip to question 14.

13. You had a _____procedure performed at Exeter Hospital on _____/_____/_____.
(*filled in first by interviewer using information in medical record*)

a. What parts of the procedure do you remember?

- ☐ Being prepared for the surgery before going into the procedure room
- ☐ The procedure itself
- ☐ Waking up after the procedure
- ☐ Do not remember the procedure at all

b. Have you ever had this procedure before? ☐ Y ☐ N ☐ U

c. Do you remember anything unusual about this procedure at the hospital? (only if asked for an example, prompt them with: such as the procedure was particularly painful, the procedure was longer than expected, they had to call extra people to the room to help, etc.) ☐ Check if prompt was used.

d. Did you have any complications with your procedure such as problems with the place they put the catheter in or extra bleeding?

e. Do you remember having your blood sugar tested with finger sticks? ☐ Y ☐ N ☐ U

If yes, where (check all that apply):

☐ In procedure room ☐ Post procedure room ☐ On the unit ☐ Emergency room ☐ Other:_____

14. Is there anything else that you feel would be important to tell me?

Thank you for taking the time to speak with me. I may need to call you back to ask additional questions at a later time. If we determine that you are connected to other people with hepatitis C, you will be contacted by either our department or your healthcare provider.

Appendix 2: CCL Employee Questionnaire

New Hampshire Department of Health and Human Services **Interviewer Name: _____**
Bureau of Infectious Disease Control **Interview Date:_____/_____/_____**

Hepatitis C Virus Employee Interview Form

I am meeting with you to discuss your role at the hospital and to ask you questions about procedures used in your unit. We have received reports of patients developing hepatitis C after receiving care at Exeter Hospital and we are concerned that these infections are related or connected in some way. These questions will take about 45 minutes to answer. Some of these questions may be difficult to answer, but your answers might help us identify the source of these patients' infections and help prevent other people from getting sick.

1. Employee Information:

LAST NAME	FIRST NAME	MI

ADDRESS	CITY	STATE	ZIP

HOME PHONE	WORK PHONE	CELL PHONE
( )	( )	( )

DATE OF BIRTH	AGE	SEX (CIRCLE ONE)
		MALE FEMALE

2. Which units do you work on at Exeter Hospital (check all that apply):

☐ Cardiovascular procedure room ☐ PACU associated with cardiovascular procedure room

☐ Other:_____

3. What is your job position at Exeter Hospital:

☐ Nurse ☐ LNA ☐ Other:_____

☐ Physician Type:_____ ☐ Tech Type:_____

Additional Comments:

4. Are you a licensed health care provider? ☐ Yes License Type: _____ ☐ No

5. Have you ever worked in another state as a healthcare provider? ☐ Yes ☐ No

If yes, what state(s):

6. Do you currently work as a healthcare provider at any other healthcare facility? ☐ Yes ☐ No

If yes, what healthcare facility(s):

7. When did you begin working at Exeter Hospital: _____/_____/_____

8. What was your previous workplace before you worked at Exeter Hospital:_____

9. How many hours did you typically work per week at Exeter Hospital from January to March, 2012: _____

Any comments:

10. In the last year did you ever stop working at Exeter Hospital for a period of time and return or were you on leave for any reason other than a vacation or short term sick leave? ☐ Yes ☐ No

If yes, provide details:

11. Can you please generally describe your job responsibilities and describe your role during a typical procedure?:

12. Do you have direct patient care responsibilities? ☐ Yes ☐ No

13. Do you do glucose monitoring on patients? ☐ Yes ☐ No

14. Do you start IVs? ☐ Yes ☐ No

15. Do you prepare or administer IV or injected <u>narcotic</u> medications (exclude oral administration)? ☐ Yes ☐ No ☐ Unknown

If yes, please list:

Medication Name	Single- or multi-dose vial	In which procedures is it used?	Where does the medication come from	When and where is the med prepared	Who prepares the medication	Where is vial and syringe kept between prep and admin	When and where is it administered	Who administers it	Where does the vial go after it is used	Does left over med go to PACU with patient
Versed										
Fentanyl										
Morphine										
Other										

16. What non-narcotic multidose vials do you use on the unit? List name of medications:

17. During a procedure, are syringes with medication for sedation left attached to the IV line or are they removed and then reattached as more medication is needed?

18. Can you describe in detail how contrast is used, including how is it prepared, who administers it, and when?

19. Can the same contrast material container be used for multiple patients? ☐ Yes ☐ No ☐ Unknown

20. Can you describe to me how the PYXIS works in the procedure room?

a. When is the PYXIS opened?

b. Who opens the PYXIS?

c. When is the PYXIS closed?

d. Who closes the PYXIS?

21. Can you describe to me how the PYXIS works in the post-procedure room/PACU?

22. Can you put things back into the PYXIS, for example if you didn't end up using it?

Now I am going to ask you several questions around practices in the procedure room.

23. Have you ever observed someone reusing a needle or needle/syringe unit to draw medication for the same patient? ☐ Yes ☐ No ☐ Unknown

If yes, describe circumstances:

a. When: ___/___/____ b. By whom: _____

c. Was the vial: ☐ single dose vial ☐ multidose vial used for one patient ☐ multidose vial used for >1 patient

d. Additional comments:

24. Have you ever reused a needle or needle/syringe unit to draw medication for the same patient?

☐ Yes ☐ No ☐ Unknown

If yes, describe circumstances:

a. When was the first time you did this? ___/___/____

b. Was the vial: ☐ single dose vial ☐ multidose vial used for one patient ☐ multidose vial used for >1 patient

c. Additional comments:

25. Have you ever observed someone reusing a syringe after changing the needle to draw medication for the same patient? ☐ Yes ☐ No ☐ Unknown

If yes, describe circumstances:

a. When: ___/___/____ b. By whom: _____

c. Was the vial: ☐ single dose vial ☐ multidose vial used for one patient ☐ multidose vial used for >1 patient

d. Additional comments:

26. Have you ever reused a syringe after changing the needle to draw medication for the same patient?

☐ Yes ☐ No ☐ Unknown

If yes, describe circumstances:

a. When was the first time you did this? ___/___/____

b. Was the vial: ☐ single dose vial ☐ multidose vial used for one patient ☐ multidose vial used for >1 patient

c. Additional comments:

27. Have you ever observed the same syringe being used for more than one patient even if the needle on the syringe is changed? ☐ Yes ☐ No ☐ Unknown

If yes, describe circumstances:

a. When: ___/___/____ b. By whom: _____

c. Was the vial: ☐ single dose vial ☐ multidose vial used for one patient ☐ multidose vial used for >1 patient

d. Additional comments:

28. Have you ever reused the same syringe being used for more than one patient even if the needle on the syringe is changed? ☐ Yes ☐ No ☐ Unknown

If yes, describe circumstances:

a. When was the first time you did this? ___/___/____

b. Was the vial: ☐ single dose vial ☐ multidose vial used for one patient ☐ multidose vial used for >1 patient

c. Additional comments:

29. Have you ever observed the same needle being used for more than one patient? ☐ Yes ☐ No ☐ Unknown

If yes, describe circumstances:

a. When: ___/___/____ b. By whom: _____

c. Was the vial: ☐ single dose vial ☐ multidose vial used for one patient ☐ multidose vial used for >1 patient

d. Additional comments:

30. Have you ever reused the same needle being used for more than one patient? ☐ Yes ☐ No ☐ Unknown

If yes, describe circumstances:

a. When was the first time you did this? ___/___/____

b. Was the vial: ☐ single dose vial ☐ multidose vial used for one patient ☐ multidose vial used for >1 patient

c. Additional comments:

31. Have you ever observed the <u>same</u> needle or syringe being used to flush the line first <u>and</u> then use the same needle or syringe to draw medication and administer to the patient? ☐ Yes ☐ No ☐ Unknown

If yes, describe circumstances:

a. When: ___/___/____ b. By whom: _____

c. Was the vial: ☐ single dose vial ☐ multidose vial used for one patient ☐ multidose vial used for >1 patient

d. Additional comments:

32. Have you ever used the <u>same</u> needle or syringe to flush the line first <u>and</u> then use the same needle or syringe to draw medication and administer to the patient? ☐ Yes ☐ No ☐ Unknown

If yes, describe circumstances:

a. When was the first time you did this? ___/___/____

b. Was the vial: ☐ single dose vial ☐ multidose vial used for one patient ☐ multidose vial used for >1 patient

c. Additional comments:

33. How are patient blood glucose levels monitored in the procedure room or PACU?

a. Which patients are monitored?

b. Where in the unit is the blood glucose testing done?

c. How is the blood collected from the patient and what type of lancet is used?

d. Please describe how the blood goes on the strip and when the strip gets placed in the monitor (with blood or without?).

e. How and when is the machine cleaned after use?

34. Who starts IVs on the unit?

35. Do phlebotomists ever come to the unit to draw blood or start IVs? ☐ Yes ☐ No ☐ Unknown

If yes, provide general details:

36. What types of medical or surgical equipment that touches the patient is reused in this unit:

Equipment	How is it used	Who uses it	How is it reprocessed or cleaned	Who is responsible for reprocessing or cleaning it

37. Have you witnessed any lapses in infection control processes or any practices that are concerning to you from a patient or healthcare worker safety perspective in your unit? ☐Yes (provide details below) ☐No

38. Do you have any concerns about any coworkers that may have ever worked while under the influence of drugs or alcohol? ☐Yes (provide details below) ☐No

39. Have you ever worked while under the influence of drugs or alcohol?

☐Yes (provide details below) ☐No

40. Do you have knowledge of any coworker that has ever used a medication intended for a patient?

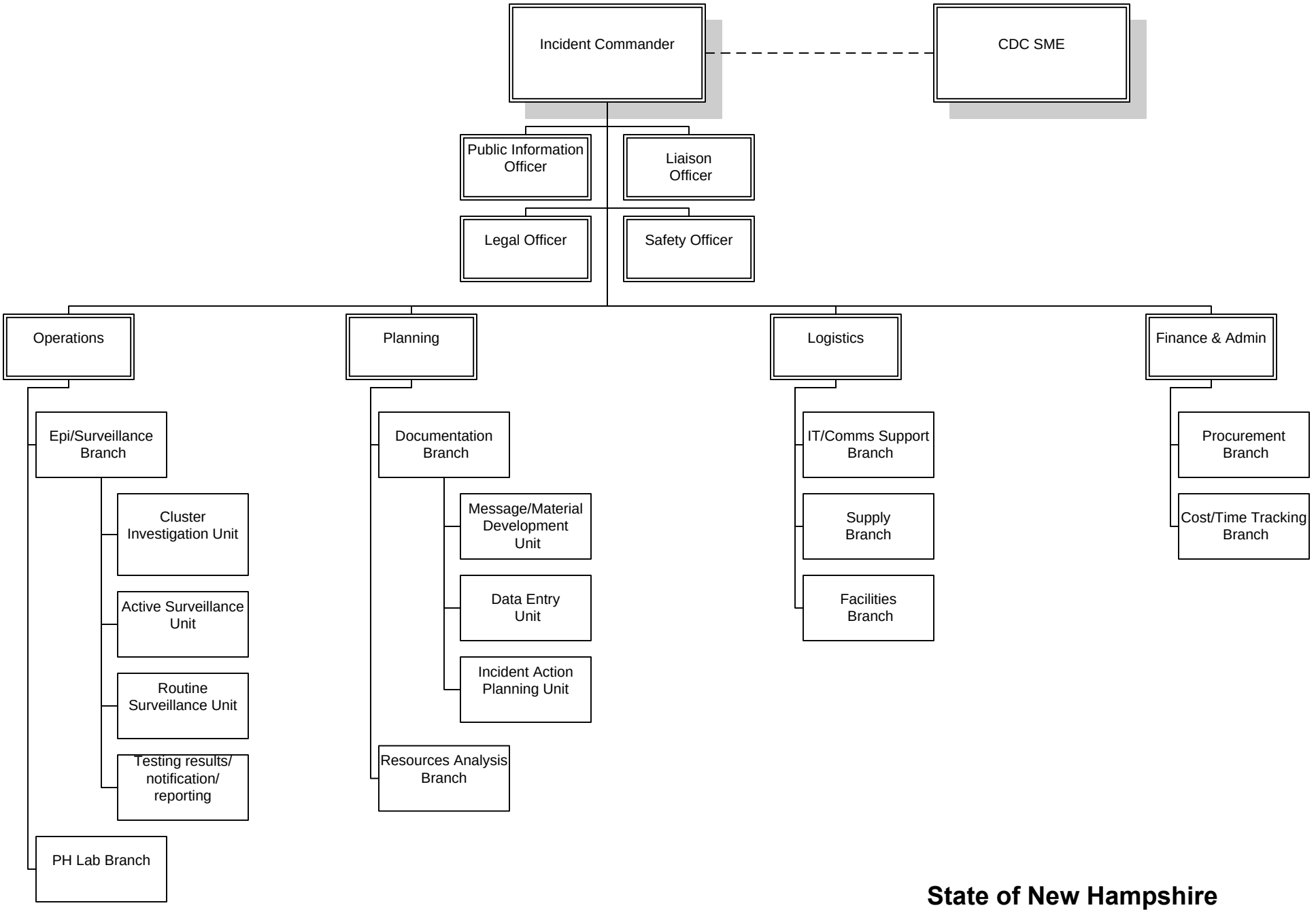
☐Yes (provide details below) ☐No

41. Have you ever used a medication intended for a patient? ☐Yes (provide details below) ☐No

42. Is there anything else you would like to tell me?

Thank you for taking the time to speak with me. I may need to contact you again to ask additional questions at a later time. At this point we are just doing a lot of information gathering and the next steps will be determined as we collect information. I have asked you a lot of questions today so if you think of anything you forgot or anything else you would like to share with me at any point please feel free to contact me.

Appendix 3: Incident Command System Organizational Chart



State of New Hampshire
Department of Health and Human Services
Division of Public Health Services
Exeter HCV Incident

Appendix 4: Superior Court Notice of Decision

THE STATE OF NEW HAMPSHIRE
JUDICIAL BRANCH
SUPERIOR COURT

Merrimack Superior Court
163 North Main St./PO Box 2880
Concord NH 03302-2880

Telephone: (603) 225-5501
TTY/TDD Relay: (800) 735-2964
http://www.courts.state.nh.us

NOTICE OF DECISION

Jeanne P. Herrick
NH Attorney Generals Office
33 Capitol Street
Concord NH 03301

Case Name: **Exeter Hospital, Inc. v Dr. Sharon Alroy-Preis, et al**
Case Number: **217-2012-CV-00617**

Enclosed please find a copy of the court's order of October 31, 2012 relative to:

Order

November 01, 2012

William S. McGraw
Clerk of Court

(629)

C: Anthony J. Galdieri; Anne M. Edwards

The State of New Hampshire

MERRIMACK, SS **SUPERIOR COURT**

Exeter Hospital, Inc.

v.

Dr. Sharon Alroy-Preis,
Dr. Jose Montero, and
New Hampshire Department of Health and Human Services

NO. 2012-CV-617

ORDER

This case involves a New Hampshire Department of Health and Human Services ("DHHS") investigation into the Hepatitis C outbreak at Exeter Hospital. The Petitioner, Exeter Hospital, Inc., ("Exeter"), seeks a Declaratory Judgment that the Respondents, Dr. Sharon Alroy-Preis, Dr. Jose Montero, and DHHS, (also collectively, "DHHS"): (1) do not have unfettered access to all paper and electronic records of Exeter's patients; (2) may only access portions of medical records that are not protected by State and Federal law; (3) may only acquire the minimum amount of information necessary to conduct their investigation pursuant to RSA 141-C; (4) must provide Exeter with some information necessary to determine which patient records they wish to review; and (5) must provide Exeter with an opportunity to review said medical records prior to the Respondents' review of the same records. The Petitioner also seeks a Protective Order that would require the DHHS Respondents to provide certain information before being allowed access to patients' medical records. The DHHS Respondents object. Because Petitioner has produced no evidence to suggest that DHHS is not complying with state and federal law in its investigation at Exeter Hospital, the Petitioner's Motion for a Protec-

tive Order is **DENIED.**

I

DHHS initiated an investigation on May 15, 2012 after the Petitioner reported a cluster of recently diagnosed cases of Hepatitis C at its hospital. DHHS proceeded pursuant to the provisions of RSA 141-C:1, entitled "communicable diseases." RSA 141-C:1, entitled "Policy," states in relevant part that:

> The outbreak and spread of communicable disease cause unnecessary risks to health and life, interfere with the orderly workings of business, industry, government and the process of education, and disrupt the day-to-day affairs of communities and citizens... [I]t is hereby declared to be the policy of this state that communicable diseases be prevented, and that such occurrences be identified, controlled, and, when possible, eradicated at the earliest possible time by application of appropriate public health measures and medical practices.

In order to effectuate the purposes of the chapter, the Commissioner of DHHS has been given broad authority by statute to investigate incidents of communicable disease. RSA 141-C:7 required Petitioner to report the cluster of diagnoses and, as part of the report, to disclose certain protected health information of its patients.

After receiving Petitioner's report, pursuant to RSA 141-C:9, DHHS conducted an initial investigation to determine whether the cluster of diagnoses was truly an outbreak. Since the time that DHHS acquired enough information to determine that the cases are related, "the goals of the investigation have been: (1) to stop transmission of the infection by establishing, and disrupting, the mode of transmission; and (2) to determine the scope of the outbreak by identifying all those impacted and to allow linkage to appropriate care." Respondents' Memorandum of Law in Support of Objection to Motion for Protective Order ("Respondents' Memo in Support of Objection"), 2.

Early on in the investigation, DHHS personnel visited Exeter Hospital on nine occasions and accessed medical records through use of the hospital's electronic medical

records database ("EMR"). Members of the investigation team were provided access to computer terminals within the hospital to conduct their review of records. During this time, the Petitioner did not request information regarding which medical records were being reviewed, but rather, provided DHHS with "open access" after being informed that the review was related to the investigation for the Hepatitis C outbreak.

To help facilitate the investigation, DHHS used software "that creates an electronic database for storage of the relevant information extracted by [DHHS's] investigators] and allows analysis of the data." Respondents' Supplemental Memorandum of Law in Further Support of Objection to Motion for Protective Order ("Respondents' Supplement"), 3. The Centers for Disease Control and Prevention (CDC) designed the software and it is used by trained Public Health Professionals to collect information provided in the EMR. Further, the DHHS used additional software to collect information related to exposed patients that had died and other patients that died from a Hepatitis C related cause.

In early August, members of the investigation team signed an "End User Security Agreement – Outside Individual Access," ("Security Agreement") so that each investigator could obtain a username and password that would provide access to the EMR. The Security Agreement ensured that each user would only access those records as allowed by privacy/security policies and as allowed by law. Further, the Security Agreement ensured that each user would be accountable for his/her work conducted under their username and ensure that users would not intentionally access any information not authorized by their password. Because each investigator now had their own username and password, the Petitioner could audit each investigator's use of the EMR after their review.

According to the Respondents, the investigation led to information that indicated the healthcare worker suspected of causing the outbreak, in addition to being located in the cardiac catheterization laboratory, may have also been located in the main inpatient operating room and the intensive care unit at the hospital. Because of this information, "outstanding questions remain regarding the mode of transmission and the scope of the outbreak." Respondents' Memo in Support of Objection, 7.

Sometime beginning in July and extending to August, the Petitioner began requesting that DHHS provide information related to what facts it had learned in the investigation. DHHS, however, maintained that it could not share information obtained throughout the course of the investigation pursuant to RSA 141-C:10. After this, on August 24, 2012, the Petitioner refused DHHS access to medical records, stating that DHHS must provide additional information about the review, including information about the connection of the patient to the Hepatitis C investigation. The instant Petition for Declaratory Judgment and Motion for Protective Order followed.

II

The Petitioner advances two main arguments in support of its Motion: (1) the Petitioner contends that the Respondents have not ensured that they are only obtaining the minimum amount of information necessary in their investigation, as required by law to protect patient privacy (RSA 141-C:10, IV); and (2) the Petitioner contends that the Respondents' access to entire medical records is in violation of federal and state laws that provide privileges for certain medical information. Petitioner submits that before any review of records, the Respondents shall be required to provide the Petitioner with the following information: the patient's name; the approximate dates of the medical records sought; the portion of the medical record for which review is sought; and an ex-

planation regarding why the information sought is the minimum necessary.

The Respondents object and make three points: (1) Respondents assert that they are only obtaining the minimum information necessary to conduct the investigation, evidenced by the fact that they are using a scientific approach to define collection requirements and using tools to develop forms and databases to determine relevant information; (2) Respondents contend that the state laws cited by the Petitioner do not prohibit DHHS's access to records for the purpose of a communicable disease investigation; and (3) Respondents maintain that they are prohibited from providing the Petitioner information relative to the investigation pursuant to RSA 141-C:10. The Court agrees with Respondents.

A

New Hampshire RSA 141-C:10, IV provides in pertinent part that when the DHHS is conducting an investigation for an outbreak of a communicable disease, it "shall acquire and retain only the minimum amount of information . . . necessary to carry out its obligations under this chapter." The Petitioner contends that "it is inconceivable that an entire patient's file is 'the minimum amount of information necessary' for [DHHS] to conduct its investigation into the Hepatitis C outbreak." Petitioner's Memorandum of Law in Support of Verified Motion for a Protective Order, 5. However, Petitioner, the moving party, has provided no expert medical testimony to support its position. In fact, at oral argument, Petitioner argued that records prior to the incident in question could not be relevant. Respondent pointed out, though, that Hepatitis C could be obtained from blood transfusions and that blood transfusions have only been screened for Hepatitis C relatively recently. The record before the Court suggests, a blood transfusion that occurred in the past could well be relevant because it could ex-

plain the presence of Hepatitis C in a hospital patient and, therefore, could rule that patient out as part of the current incident.

Respondents, on the other hand, have provided an offer of proof that demonstrates that DHHS is only acquiring the minimum amount of information necessary. The Respondents explain what evidence indicates that they are obtaining the minimum information necessary in the following ways:

> For the Exeter Hospital Hepatitis C outbreak, medical information on patients possibly associated with the outbreak that was necessary to collect to carry out the public health response included the following: documentation of Hepatitis C risk factors or prior Hepatitis C diagnosis, relevant underlying medical conditions and medications, and information on encounters at Exeter Hospital that might have exposed the patient to Hepatitis C. Forms and databases were developed to collect this information in a systematic and standardized way. Trained public health professionals (physicians, nurses, and epidemiologists) collected medical information by reviewing medical records at Exeter Hospital to extract the relevant data originally decided on into the database that was uniquely developed for this outbreak investigation. During medical record review only the information in the unique tool developed for this outbreak was collected and nothing more. Initially, these professionals were oriented to the EMR system by Exeter Hospital staff and were shown how to navigate the EMR to identify relevant patient information . . . Standardized collection of data by public health professionals analyzing and extracting information from the EMR has: (1) allowed for a consistent, complete, and efficient public health investigation; (2) prevented the collection of volumes of non-relevant medical records being provided in hard copy to public health; and (3) ensured that public health received all relevant information related to the patient given the complexity of an EMR and the difficulty with identifying certain pieces of information.

Respondents' Supplement, 8. The Respondents have provided a detailed explanation of how they ensure that only the minimum information necessary is acquired during this investigation and demonstrate that they are not abusing their access to sensitive medical records. The Respondents have demonstrated that this is a professional, regulated, and lawful investigation into a potentially serious health threat. Petitioner's *ipse dixit* is not persuasive.

The Petitioner attempts to analogize this case to cases in which the New Hamp-

shire Supreme Court has developed specific procedures to protect patient medical records in instances where the records are the subject of a search warrant in a criminal investigation. See In Re Search Warrant (Medical Records of C.T.), 160 N.H. 214, 226 (2010). However, this analogy is unpersuasive for several reasons. The medical records for a criminal investigation differ in several ways from the reasons for obtaining medical records regarding communicable diseases investigations. First, the search warrant for an individual's medical records presents a circumstance in which the interest of the State is in ensuring that criminal conduct of a target criminal defendant is detected and punished, and that interest is, in most circumstances adverse to the holder of the privilege. This is not ordinarily the case in an investigation into a communicable disease by DHHS. An investigation into an outbreak of a communicable disease uncovers direct and specific harm occurring to individuals who contract a communicable disease.

Second, and perhaps more important, once information is obtained pursuant to the criminal procedures, there is a high likelihood it will eventually become public. Information obtained pursuant to RSA 141-C is not turned over to police and prosecutors and reviewed by criminal juries. Unlike law enforcement officials that do not have medical training and may not be aware of the sensitive nature of information contained within medical records, DHHS investigators have significant medical training and its statutes and rules provide for limited use of the information obtained. RSA 141-C:10, I.

Further, there are other areas of the law where the "minimum information necessary" standard is implicated. 18 U.S.C. §2518(5), the Federal wiretap statute, requires that when a governmental agency conducts a wiretap in a criminal investigation, the listen-in "shall be conducted in such a way as to minimize the interception of communica-

tions not otherwise subject to interception."[1] As the First Circuit has noted, "[t]his minimization requirement spotlights the interest in confining intrusions as narrowly as possible so as not to trench impermissibly upon the personal lives and privacy of wire-tap targets and those who, often innocently, come into contact with such suspects." United States v. Hoffman, 832 F.2d 1299, 1307 (1st Cir. 1987). Although the intrusion must be confined, "[t]he statute does not forbid the interception of all non-relevant conversations, but rather instructs the agents to conduct the surveillance in such a manner as to 'minimize' the interception of such conversation." Scott v. United States, 434 U.S. 128, 140 (1978). Under this framework, "[d]uring the early stages of surveillance[,] the agents may be forced to intercept all calls to establish categories of non-pertinent calls .... Interception of those same calls might be unreasonable later on, however, once the non-pertinent categories have been established and it is clear that this particular conversation is of that type." Id. at 141. Courts recognize that police officers listening to intercepted communications often deal with individuals who use code language, "the terms of which ma[k]e it difficult to identify immediately those calls that [are] inquiries into [the defendant's] legitimate business interests...." State v. Andrews, 125 N.H. 158, 167 (1984).

While the analogy to review of medical records is not entirely congruent, there are certainly similarities. An electronic intercept intrudes into calls, not only of the target of the investigation, but of those innocent persons who call the target. Some of those communications, for example, physicians and other health care providers, might well be privileged. RSA 141-C:10, IV does not prohibit DHHS investigators from ever *seeing*

[1] The same minimization requirement is set forth in RSA 570-A:9, V, the State's cognate statute, which provides in relevant part "every order and intercept shall contain a provision that the authorization to intercept shall be... conducted in such a way as to minimize the interception of communications not otherwise subject to interception under this chapter..." See State v. Moccia, 119 N.H. 169, 172 (1979).

non-relevant information, but rather requires that they only acquire and retain the minimum necessary information. This process may involve determining what information is not necessary to the investigation and may involve observations of information not relevant to the investigation. However, as in the case of a wiretap, once the non-relevant information is identified, the DHHS may not retain it. Further, as apparent from DHHS's explanation, it has already taken steps to ensure that instances of observing non-relevant information are few and far between through the use of its software and tools. Similar to wiretap investigations, the investigators from DHHS are professionals trained to identify relevant and non-relevant information to the investigation. See Andrews, 125 N.H. at 167.

Since DHHS has demonstrated that it is only obtaining the minimum amount of information necessary for its investigation, the Court cannot find Petitioner has established a violation of the minimization requirement.

B

In a related argument, Petitioner also contends that if it allows Respondents access to entire medical records, then the Petitioner will necessarily be in violation of certain federal and state laws. Specifically, the Petitioner cites the following New Hampshire statutes requiring patient consent before records are released: RSA 151:21, X (Patient's Bill of Rights); RSA 141-H:2 (Genetic Testing); RSA 141-F:8 (Testing for HIV); RSA 135-C:19-a (Mental Health Treatment); RSA 173-C:2 (Rape Crisis and Domestic Violence Counseling); and RSA 172:8-a (Alcohol or Drug Abuse Treatment). The Petitioner also cites federal regulations interpreting the Heath Insurance Portability and Accountability Act of 1996 ("HIPAA"). Because HIPAA provides a floor for privacy in medical records, the Court need only address the more stringent state law requirements.

See 42 C.F.R. §160.203.

Significantly, Petitioner has cited no authority for the proposition that state evidentiary privileges can thwart the efforts of a public health investigation into communicable diseases. Examination of the privileges themselves illustrates why.

First, the Patient's Bill of Rights, while it requires consent to release information, also explicitly provides an exception for records released to persons authorized by law to receive them, *i.e.* the DHHS in a communicable disease outbreak investigation. RSA 151:21, X. As to the remaining statutes the Petitioner cites, the Respondents provide a comprehensive summary of why the purpose behind each of these statutes is not frustrated when medical records are released in conjunction with a DHHS investigation of a communicable disease outbreak. Respondents' Supplement, 4–7. The Court need not repeat that summary here. It suffices to say that it is well settled that all statutes relating to a particular subject must be read together, to effectuate all of their terms.[2] Opinion of the Justices, 135 N.H. 543, 545 (1992).

Finally, even if the privileges recognized in the statutes the Petitioner cites were absolute and were meant to apply in all contexts, the privileges still would need to give way in the face of other compelling justifications for release of the privileged information. Analogously, "New Hampshire law makes clear that even so-called absolute [evidentiary] privileges are subject to overriding concerns when the competing claim is suf-

[2] Additionally, the Respondents point out that the Petitioner has not provided any evidence that the statutes even apply to its facility: it has not shown that it conducts genetic testing; operates New Hampshire Hospital or one of its designated receiving facilities; operates a rape crisis center or a domestic violence center; or operates a federally-funded drug or alcohol rehabilitation facility. Id. at 6. If any patients at Exeter Hospital did divulge information pertaining to any of these categories to a physician at the hospital so that the information is now contained in the medical records, the release of those records to DHHS would still be permitted under RSA 141-C:10, III ("The physician-patient privilege shall not apply to information required to be reported or provided to the commissioner under this chapter.").

ficiently compelling," *e.g.* the constitutional right of confrontation or compulsory process or the constitutional right to a fair trial. A PRACTICAL GUIDE TO DISCOVERY AND DEPOSITIONS IN NEW HAMPSHIRE, Vol. 1 §11.26 (2011). For example, both the physician-patient privilege and the attorney-client privilege must give way in circumstances where constitutional rights must be upheld or where "there is a compelling need for the information and no alternate source is available." State v. Farrow, 116 N.H. 731, 733 (1976); McGranahan v. Dahar, 119 N.H. 758, 764 (1979). As the Court recently noted, any statutory privilege may yield when disclosure of the information "is considered essential." In re Search Warrant, 160 N.H. at 225.

Similarly, statutory privileges must give way to the DHHS's compelling interest in investigating communicable disease outbreaks. As the Policy of RSA chapter 141-C states:

> The outbreak and spread of communicable disease cause unnecessary risks to health and life, interfere with the orderly workings of business, industry, government, and the process of education, and disrupt the day-to-day affairs of communities and citizens.

The DHHS is the entity charged with the responsibility of determining the scope of outbreaks and determining how an outbreak started. The entity is comprised of trained professionals equipped to design the best way to carry out these investigations. Certain privileges contained in medical records may need to give way to the DHHS's compelling interest in discovering information related to the investigation. This will permit the DHHS to fulfill the policy of RSA 141:C and to protect public health. Notably, the DHHS is not on a hunt for privileged information, but rather, as discussed *supra*, is trained to avoid acquiring unnecessary medical records and to only acquire the minimum necessary to complete the investigation. Information it obtains will not be disclosed to the

public, as in the criminal context, but will be kept confidential. RSA 141-C:10, I.

C

Finally, the Petitioner's proposed compromise, suggesting that the DHHS investigators shall provide the patient's name, approximate dates of the medical records sought, the portion of the medical record for which review is sought, and an explanation regarding why information sought is the minimum necessary before the Petitioner releases any medical records, is not necessary nor required by law. The Court agrees with the Respondents that RSA 141-C:10, I should be construed to prohibit the DHHS from re-disclosing information obtained during its investigation to the Petitioner. RSA 141-C:10, I provides, in relevant part, the following:

> Any protected health information provided to or acquired by the department under this chapter shall be released only with the informed, written consent of the individual or to those authorized persons having a legitimate need to acquire or use the information and then only so much of the information as is necessary for such persons to provide care and treatment to the individual who is the subject of the protected health information, investigate the causes of disease transmission in the particular case, or control the spread of the disease among the public.

The Petitioner has not alleged that it requires the information requested in order to provide treatment, investigate the cause of the disease transmission, or to control the spread of the disease among the public. Instead, the Petitioner has only suggested it requires this information to protect the privacy of the patients involved. RSA 141-C does not permit other use of re-disclosed information. Even if the Respondents provided the names of the patients, this would communicate to the Petitioner that these patients are connected to the outbreak or have Hepatitis C related symptoms and spent time in a questioned portion of the hospital.

III

In sum, the Petitioner's duty to protect its patients' privacy must give way to the

DHHS's interest in investigating communicable disease outbreaks. RSA 141-C explicitly bestows the responsibility of conducting outbreak investigations while simultaneously protecting certain health information to the trained professionals of the DHHS. See RSA 141-C:6 (providing that the commissioner of the DHHS shall adopt rules to carry out the policies and purposes of the chapter). Petitioner has made no showing that DHHS is not carrying out its duties appropriately or within the limits of the law as it conducts its investigation. For these reasons, the Petitioner's Motion for a Protective Order must be **DENIED**.

SO ORDERED.

10/31/12
Date

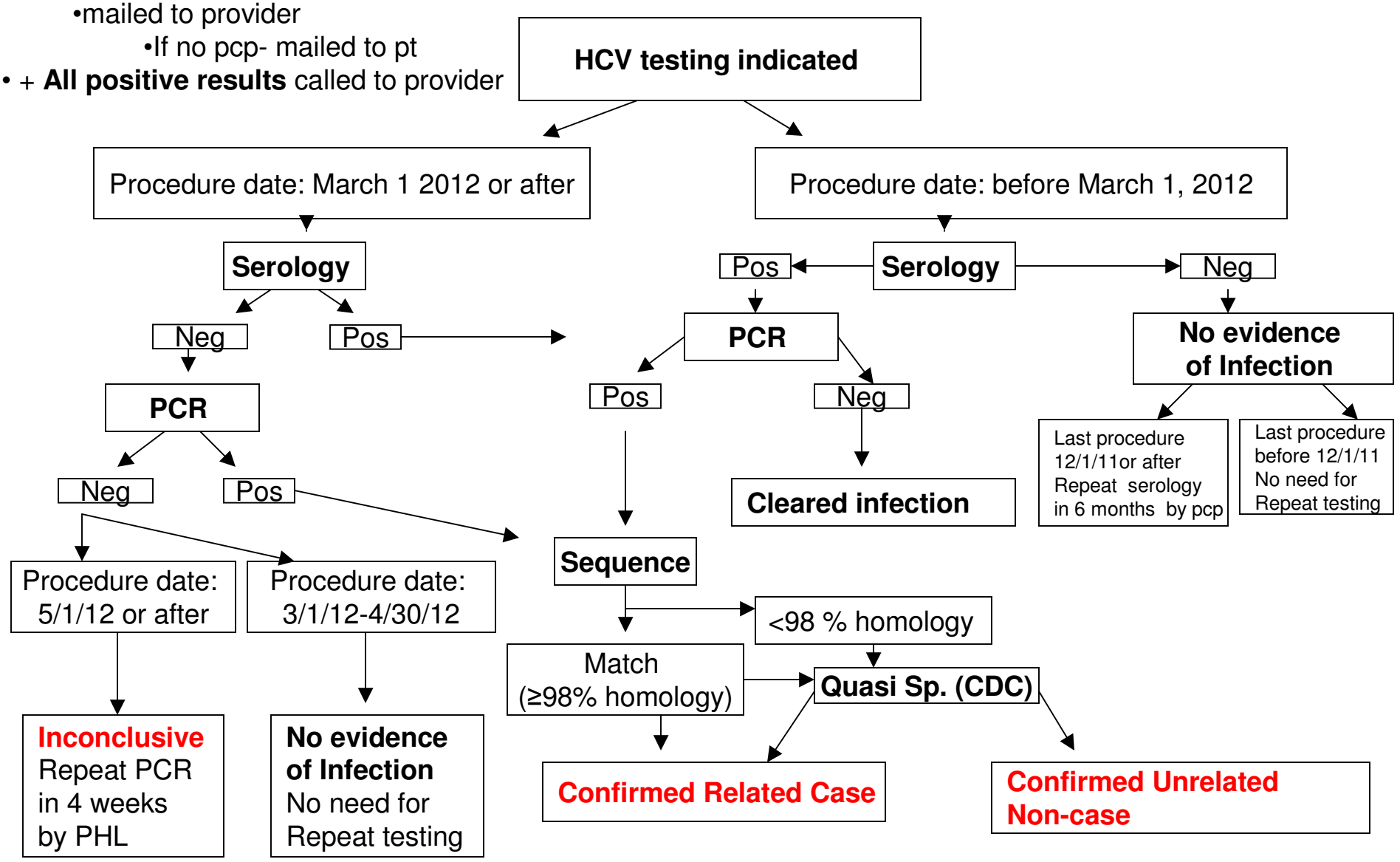
Richard B McNamara
Richard B. McNamara
Presiding Justice

Appendix 5: Testing Algorithm

- **All results**
  - called to patient
  - mailed to provider
    - If no pcp- mailed to pt
- \+ **All positive results** called to provider

HCV Testing Algorithm

UPDATE – 6.20.12



Algorithm Logic

Facts and assumptions:	Decision:
Positive serology appears after 4-10 w of virus acquisition	If time interval between procedure day and blood collection < 12 w test PCR even if serology is negative
>97% of patients will have pos serology 6 month after virus acquisition	If serology negative repeat serology after 6 month
PCR would be positive after 2-3 weeks of virus acquisition	If time interval between procedure day and blood collection <4w and PCR negative need to repeat PCR in 4 weeks
Sensitivity of PCR in NH PHL is 100 IU/ml	If PCR is neg with pos serology send specimen for CDC for hypersensitive PCR (15 IU/ml)
Assumption for simplification – collection date 5/25/12 (close date of cath lab)	Can base decisions on date of procedure
Questionable results will be f/u by BIDC	Cases to f/u: Repeat PCR for inconclusive

Appendix 6: Analysis of CCL Staff (Unit and Medical) Attendance at CCL on Days with Confirmed or Probable HCV Transmission

Name for Report	For confirmed cases (n=31*)				For probable cases (n=4)				Total (n=35*)
	Assigned to work on ≥1 case procedure	On schedule for ≥1 case procedure date	Present in CCL based on card key records for ≥1 case procedure date	Total Cases with Potential Contact	Assigned to work on ≥1 case procedure	On schedule for ≥1 case procedure date	Present in CCL based on card key records for ≥1 case procedure date	Total Cases with Potential Contact	
Tech 1- Infected HCW	17	27	29	31 (100%)	1	4	4	4 (100%)	35 (100%)
Unit Supervisor (Tech2)	5	28	29	29 (94%)	0	3	3	3 (75%)	32 (91%)
Nurse 1 – Nurse A	17	26	26	27 (87%)	3	4	4	4 (100%)	31 (89%)
Unit Secretary	0	0	26	26 (84%)	0	0	4	4 (100%)	30 (86%)
Nurse 2	12	24	24	26 (84%)	2	3	3	3 (75%)	29 (83%)
Nurse 3	10	24	21	26 (84%)	0	3	3	3 (75%)	29 (83%)
Tech3	16	23	22	23 (74%)	4	4	4	4 (100%)	27 (77%)
Cardiologist 1	12	19	21	22 (71%)	3	3	4	4 (100%)	26 (74%)
Nurse 4	14	22	21	22 (71%)	1	3	3	3 (75%)	25 (71%)
Tech 4	6	16	20	20 (65%)	0	4	4	4 (100%)	24 (69%)
Cardiology NP 1	0	0	20	20 (65%)	0	0	3	3 (75%)	23 (66%)
Cardiologist 2	7	15	19	20 (65%)	1	1	2	2 (50%)	22 (63%)
Director of Outpatient Surgical Services	0	0	19	20 (65%)	0	0	1	1 (25%)	21 (60%)

* Excludes one confirmed case-patient with a procedure date of 03/24/2011

Note: Table only includes HCW that had contact with ≥20 case-patients

Appendix 7: Standard Case Definitions

Exeter Hospital Hepatitis C Outbreak – Standard Case Definitions

1. **Confirmed cases:** Exposed patient* with HCV strain matching the NH HCV outbreak strain (by PHL or CDC testing)
2. **Probable case:** Exposed patient* with evidence of cleared HCV infection (positive serology, negative PCR**) and *all* of the following:
    a. No prior history of HCV infection
    b. No HCV risk factors OR evidence of HCV risk factors in the past but negative HCV test thereafter
    c. Documentation of negative HCV test in the 5 years prior to the exposure at EH OR lab evidence of clearing the HCV infection within 6 months of the exposure at EH.
3. **Suspect case:** Exposed patient* with evidence of cleared HCV infection and *all* of the following a-c:
    a. No prior history of HCV infection
    b. HCV risk factors:
        i. None OR
        ii. Low-risk[#] risk factors OR
        iii. Evidence of high-risk[#] risk factors in the past but
            1. Negative HCV test after risk factors ended OR
            2. 5 fold increase in liver enzyme test (alanine aminotransferase, ALT, ≥ 300 units/L) within 12 weeks of the exposure at EH OR
    c. No documentation of negative HCV test within 5 years prior to the exposure at EH.
4. **Unknown case:** Exposed patient* with evidence of cleared HCV infection and *any* of the following:
    a. Prior positive history of HCV infection
    b. History of high-risk RF's without documented negative HCV test after exposure AND not meeting liver enzyme test definition for suspect case
    c. Patient reported "unknown" for high-risk RF
    d. Inability to obtain enough information to classify further (for example, blood transfusion in the past but unknown date)
5. **Not a case:**
    a. A patient with an active HCV infection with a strain different than the outbreak strain by CDC QS analysis OR
    b. A patient with evidence of cleared infection who is not considered an exposed patient. .

*Exposed patient: a person who received intravenous controlled medication(s) in the CCL or RR at EH and his/her procedure (or associated hospital stay) occurred between April 11,2011 and May 25,2012.

** Cases with positive serology and positive PCR but very low viral load that could not be sequenced for matching were also considered cleared infection

High-risk risk factors: Intravenous drug use (ever), blood transfusion or blood products before 1992

Low-risk risk factors: Needle –stick blood exposure (ever), tattoo or non-ear body piercing (ever), hemodialysis (ever)

Appendix 8: Summary of Case Characteristics

Summary characteristics of confirmed, probable, suspect, and unknown cases associated with Exeter Hospital HCV outbreak, NH, 2012.

	Confirmed (n=32)*	Probable (n= 4)	Suspect (n= 5)	Unknown (n= 15)
Proportion Male	65.6 % (21)	25% (1)	60% (3)	73.3% (11)
Age				
Median	63.3 years	68.5 years	58 years	58 years
Range	43-83 years	58-73 years	42-76 years	34-80 years
Residence				
NH	93.7 % (30)	100.0 % (4)	80.0 % (4)	100.0 % (15)
ME	3.1 % (1)	0.0 % (0)	0.0 % (0)	0.0 % (0)
MA	3.1 % (1)	0.0 % (0)	0.0 % (0)	0.0 % (0)
FL	0.0 % (0)	0.0 % (0)	0.0 % (0)	0.0 % (0)
MI	0.0 % (0)	0.0 % (0)	20.0 % (1)	0.0 % (0)
Pre-procedure HCV History				
Previous positive test	9.4 % (3)	0.0 % (0)	0.0 % (0)	80.0 % (12)
Previous negative test	12.5 % (4)	75.0 %(3)	20.0 % (1)	0.0 % (0)
Unknown	78.1 % (25)	25.0 % (1)	80.0 % (4)	20.0 % (3)
Post-procedure HCV diagnosis prior to outbreak testing	21.9% (7)	25.0% (1)	20.0 % (1)	0.0 % (0)
High-risk Risk Factors**				
Intravenous Drug Use	0.0 % (0)	0.0 % (0)	0.0 % (0)	13.3% (2)
Blood transfusions/products prior to 1992	6.9 % (2)	0.0 % (0)	0.0 % (0)	26.7% (4)
Blood transfusions/products prior to 1992 unknown date	3.4 % (1)	0.0 % (0)	0.0 % (0)	13.3% (2)
Low-risk Risk Factors**				
Needle-stick blood exposure	10.3 % (3)	25.0 % (1)	0.0 % (0)	0.0 % (0)
Tattoo/non-ear body piercing	28.6 % (8)	0.0 % (0)	40.0 % (2)	25.0 % (1)
Hemodialysis	9.4 % (3)	0.0 % (0)	0.0 % (0)	25.0 % (1)
Procedure Type				
Cardiac	78.1 % (25)	100.0 % (4)	100.0 % (5)	60.0 % (9)
Vascular***	18.8 % (6)	0.0 % (0)	0.0 % (0)	26.7 % (4)
Interventional radiology/Other	3.1 % (1)	0.0 % (0)	0.0 % (0)	6.7 % (1)
Not documented/transferred	0.0 % (0)	0.0 % (0)	0.0 % (0)	6.7 % (1)
Procedure Location				
CCL	96.9 % (31)	100.0 % (4)	80.0 % (4)	93.3 % (14)
RR	3.1 % (1)	0.0 % (0)	20.0 % (1)	6.7 % (1)

*This does not include the HCW matching the outbreak strain.
** Out of those who agreed to answer the questions
***Vascular procedures include; diagnostic PV, fistula access, right leg claudication, and dialysis access.

AO 91 (Rev. 11/11) Criminal Complaint **Appendix 9: Criminal Affidavit** **SEALED DOCUMENT**

UNITED STATES DISTRICT COURT

for the

District of New Hampshire

DISTRICT OF N.H.
FILED
2012 JUL 19 A 10:27

United States of America
v.

David Kwiatkowski

Defendant(s)

Case No. 12-mj56-01

CRIMINAL COMPLAINT

I, the complainant in this case, state that the following is true to the best of my knowledge and belief.

On or about the date(s) of from April 2011 to May 2012 in the county of Rockingham in the _____ District of New Hampshire, the defendant(s) violated:

Code Section	*Offense Description*
21 U.S.C. 843(a)(3)	Acquiring a controlled substance by misrepresentation, fraud, forgery, deception or subterfuge;
18 USC 1365(a)(3)	Tampering with a consumer product and the container for such product that affected interstate and foreign commerce with reckless disregard for the risk that another person will be placed in danger of death or bodily injury and under circumstances manifesting extreme indifference to such risk, resulting in serious bodily injury to another individual

This criminal complaint is based on these facts:

See attached Affidavit

☑ Continued on the attached sheet.

Marcie DiFede
Complainant's signature

Marcie DiFede, Special Agent
Printed name and title

Sworn to before me and signed in my presence.

Date: 7-19-12

Judge's signature

City and state: Concord, New Hampshire

Landya B. McCafferty, U.S. Magistrate Judge
Printed name and title

AFFIDAVIT OF SPECIAL AGENT MARCIE DIFEDE

I, Marcie DiFede, being first duly sworn, hereby depose and state as follows:

INTRODUCTION

1. I am a Special Agent of the Federal Bureau of Investigation ("FBI"). I have been employed as a Special Agent of the FBI for over seventeen years. I am currently assigned to the Portsmouth, New Hampshire Resident Agency, which is part of the FBI's Boston Division. In this assignment, I work numerous criminal violations, including economic crimes, violent crimes, and health care fraud. I was previously assigned to the FBI's headquarters, as well as Field Offices in New York and Washington, D.C. I have gained experience conducting these investigations through training and everyday work. As a federal agent, I am authorized to investigate violations of United States laws and to execute warrants issued under the authority of the United States.

2. I make this affidavit in support of an application for a criminal complaint against David Kwiatkowski ("Kwiatkowski") charging him with violations of: (1) 21 U.S.C. § 843(a)(3) (acquiring a controlled substance by misrepresentation, fraud, forgery, deception or subterfuge) and (2) 18 U.S.C. § 1365(a)(3) (tampering with a consumer product and the container for such product that affected interstate and foreign commerce with reckless disregard for the risk that another person will be placed in danger of death or bodily injury and under circumstances manifesting extreme indifference to such risk, resulting in serious bodily injury to another individual).

3. The facts in this affidavit come from my personal observations, my training and experience, and information obtained from other law enforcement agents and witnesses. This

affidavit is intended merely to show there is sufficient probable cause for the criminal complaint and does not set forth all the facts learned during this investigation.

4 The evidence detailed below establishes probable cause to believe that Kwiatkowski has illegally taken controlled substances intended for use by patients of the Cardiac Catheterization Lab ("CCL") at Exeter Hospital in Exeter, New Hampshire ("Exeter Hospital") for his personal use. In addition, the evidence also establishes probable cause to believe that Kwiatkowski tampered with a consumer product (prescription drugs used in the CCL), causing patients to become infected with a particular strain of Hepatitis C. This is the same strain with which he is infected.

BACKGROUND OF DAVID KWIATKOWSKI

5. As part of my investigation, I have attempted to gather background information on Kwiatkowski. Kwiatkowski was raised in Michigan and worked as a health care worker there for several years. Records that I have reviewed indicate that since approximately 2007, Kwiatkowski has worked as a traveling technician at catheterization labs in approximately six different states.

6. Based upon interviews of multiple witnesses, investigators have learned that traveling workers such as Kwiatkowski are hired to work at hospitals on a contract basis for short durations of time, often approximately 13 weeks. Such traveling workers can be used to provide short-term staffing assistance. For example, a traveler could be hired to temporarily replace a full-time worker who is on a medical leave of absence.

7. Other investigators have spoken with staff members at some of the hospitals where Kwiatkowski has previously worked. Those individuals have advised that Kwiatkowski often told stories about himself that have proven to be false. For example, Kwiatkowski frequently

claimed to have played baseball at the University of Michigan and that his fiancée had died under tragic circumstances. A supervisor from a hospital in another state indicated that Kwiatkowski was terminated for falsifying timesheet information. Multiple witnesses have stated that Kwiatkowski has told them that he has cancer, but I have been unable to locate any records to support this assertion.

8. A supervisor from a hospital in another state where Kwiatkowski worked has reported that on at least two occasions while Kwiatkowski was working at the hospital, needles were found in a restroom outside the CCL at the hospital. This individual reported that there were no further such incidents after Kwiatkowski left the hospital.

9. Records show that Kwiatkowski first came to Exeter Hospital in or about April of 2011, as a traveling employee. He was subsequently hired by Exeter Hospital as a full-time employee in approximately October of 2011.

10. In May of 2012, Kwiatkowski disclosed to an employee of Exeter Hospital that he had been recently diagnosed with Hepatitis C. However, at least two individuals have advised investigators that Kwiatkowski was aware of this diagnosis well before May of 2012. In fact, an individual in another state has advised that in 2011, Kwiatkowski contacted her, disclosed that he had Hepatitis C, and recommended that she get tested. The individual did get tested based upon Kwiatkowski's suggestion and that testing was performed on or about May 24, 2011.

11. I have obtained records indicating that Kwiatkowski tested positive for Hepatitis C in June of 2010.

12. While working for Exeter Hospital, Kwiatkowski resided in Exeter, New Hampshire. However, he is no longer employed at Exeter Hospital and is no longer living in

Exeter. I do not believe he has any permanent residence at this time. I believe he has been residing at hotels.

13. On July 11, 2012, Kwiatkowski was scheduled to appear in state court to respond to charges of conduct after an accident. Kwiatkowski did not appear on July 11, 2012, and a bench warrant has been issued for his arrest.

14. On or about July 13, 2012, officers of the Marlborough, Massachusetts Police Department located Kwiatkowski at a hotel room in an intoxicated state. He was transported to a medical facility and an officer has advised me that, based upon Kwiatkowski's condition, he believed that Kwiatkowski may have been attempting to harm himself.

THE HEPATITIS C OUTBREAK AT EXETER HOSPITAL

15. In or about May of 2012, staff at Exeter Hospital learned that several patients had tested positive for Hepatitis C. Since that time, the hospital staff has been providing information relevant to the investigation at the request of the New Hampshire Department of Health and Human Services, Division of Public Health Services ("DPHS"). The DPHS has issued several public announcements about the status of its investigation. In addition to the DPHS investigation, federal, state, and local law enforcement agencies have been conducting an investigation of this matter.

16. As of July 13, 2012, the DPHS has publicly announced that 31 people associated with Exeter Hospital have tested positive for the same strain of Hepatitis C. [1] All but one of those individuals was a patient who underwent a procedure at the CCL or its recovery room, where

[1] I recently became aware of another potentially infected patient whose hospital stay partially overlapped with Kwiatkowski's employment at Exeter Hospital. However, it is my understanding that this individual may require further testing.

Kwiatkowski was employed. The remaining individual was Kwiatkowski, a former Exeter Hospital employee who worked in the CCL.

17. DPHS officials have conducted an extensive investigation of the Hepatitis C outbreak at Exeter Hospital. They have conducted laboratory testing to identify patients and healthcare workers who were infected with Hepatitis C and have conducted an extensive epidemiological investigation to determine the source of the outbreak. I have discussed this matter with representatives of the DPHS, including Dr. Sharon Alroy-Preis, New Hampshire's state epidemiologist for public health.

18. According to Dr. Alroy-Preis, Hepatitis C is a blood-borne viral disease that primarily is transmitted by exposure to infected blood. This illness causes inflammation of the liver. It can lead to protracted impairment of the liver and other chronic health issues. In fact, it can be deadly. The federal Centers for Disease Control and Prevention ("CDC") has reported that more Americans die annually from Hepatitis C infections than from HIV-related causes.

19. According to Dr. Alroy-Preis, Hepatitis C is known to have six genotypes. The DPHS investigation at Exeter Hospital has identified multiple individuals who have genotype 1 subtype b, which is one of the more common strains of Hepatitis C. Identifying the appropriate genotype is important for treatment decisions.

20. According to Dr. Alroy-Preis, the DPHS and the CDC have been conducting further analysis of the infected patients' blood samples, tests that are done only in outbreak settings to determine the source of the outbreak. The DPHS lab is sequencing a certain part of the viral genome (Hyper Variable Region 1, HVR1) that is known to be prone to mutations. Because of the high rate of mutation, finding the same genetic sequence in samples from multiple patients can

strongly suggest that patients obtained Hepatitis C from the same source.

21. Because of the mutations that happen with the virus replication over time, multiple different variants (quasispecies) can develop within an infected individual over time. CDC is performing an additional test, quasispecies analysis, to find the different variants in each of the patients with hepatitis C. That test helps to analyze the relationships between the different patients' infections.

22. Dr. Alroy-Preis has advised me that in each of the 31 cases that has been publicly identified, the DPHS lab or CDC have found a very high similarity of genetic sequencing. In the opinion of Dr. Alroy-Preis and staff at the CDC, this provides strong evidence that each of these infected individuals obtained Hepatitis C from a common source.

23. Although the epidemiological investigation by the DPHS has involved testing of patients who were treated at the CCL prior to Kwiatkowski's employment at Exeter Hospital and has found other patients who were infected with Hepatitis C, all of the infected patients that appear to share a common source had procedures performed at Exeter Hospital between April of 2011 and May of 2012. This is the time period when Kwiatkowski was at Exeter Hospital.

24. Dr. Alroy-Preis has advised that a review of medical literature related to large-scale outbreaks of Hepatitis C has identified several general reasons for such outbreaks. The first involves breaches of infection control practice like: (a) re-use of single dose vials for multiple patients or (b) the re-use of tainted equipment (such as a glucose monitoring device) between patients. In these cases, the infection is spread from patient to patient. The other general reason is drug diversion by an infected health care worker. Because the Hepatitis C virus can only survive outside of blood for a few days, the patient-to-patient scenarios would only explain an

outbreak cluster within a brief period of time. These scenarios are not plausible explanations for this outbreak. Here, the infected patients were treated at the CCL over the course of a time period that exceeded one year. Even if a tainted syringe or tainted equipment had been used on a patient, there is no known way that all 30 patients could have been infected by the same equipment.

25. According to Dr. Alroy-Preis and other information I have reviewed, there have been several incidents where Hepatitis C outbreaks in health care facilities have been linked to infected health care workers diverting drugs. For example, there have been incidents where workers infected with Hepatitis C have taken a syringe filled with medication that is intended for a patient, injected the medication into their own bodies, and then refilled the syringe with saline or another liquid. When the patient receives the liquid in the syringe that has been tainted by its contact with the health care worker's blood, the patient can receive the Hepatitis C virus. Another manner in which drug diversion can occur is when a health care worker removes medication from a vial using a syringe, injects the drug into his or her body, and then uses the same tainted syringe to refill the vial with saline or another liquid. When the fluid in the vial is later administered to a patient, the patient could then contract Hepatitis C.

26. According to information obtained from the CDC, there is one known case where transmission of Hepatitis C occurred when an infected physician performed invasive procedures on patients. However, this would not explain all of the related cases identified in Exeter Hospital because there are incidents where Kwiatkowski never physically touched the patient who became infected.

THE CCL AT EXETER HOSPITAL

27. The CCL at Exeter Hospital is a location where invasive cardiac procedures are performed. According to multiple witnesses and records, staffing for these procedures ordinarily includes at least one physician, one nurse, and one scrub technician. There is usually at least one additional individual (who can be a technician or a nurse), who sits in a control room and documents what takes place during the procedure for the medical record.

28. Controlled substances, such as Fentanyl and Versed, are often used in procedures in the CCL. According to the Drug Enforcement Administration, Fentanyl is a Schedule II controlled substance that is substantially more potent than morphine. Versed (also known as Midazolam) is a Schedule IV controlled substance. Both are drugs within the meaning of the Food, Drug, and Cosmetics Act and are sold in interstate commerce. Representatives of Exeter Hospital have advised that these drugs are ordinarily obtained from Massachusetts. Accordingly, these drugs are consumer products within the meaning of 18 U.S.C. § 1365(h)(1)(A). The drugs usually are administered to the patient via an intravenous line.

29. The CCL contains two secured devices referred to as Pyxis machines that dispense controlled substances, including Fentanyl and Versed. The first Pyxis is maintained in a secured room that is adjacent to the area where patients are prepped for the procedure and recover from the procedure. The second Pyxis machine is located in the room where CCL procedures are performed. Nurses (or other authorized individuals) can access the Pyxis to obtain the medication for a procedure. In order to access the machine, the nurse ordinarily must enter an appropriate username and provide biometric information via a fingerprint. As a scrub technician, Kwiatkowski did not have access to the Pyxis machine.

30. According to multiple witnesses, at the beginning of a procedure, a nurse will ordinarily remove vials of medication, such as Fentanyl or Versed, from the Pyxis and draw these drugs into a syringe using a blunt needle so that they are ready for use during a procedure. When the medications are drawn into the syringe, the nurse affixes a label identifying the medication to the syringe. At Exeter Hospital, syringes containing Fentanyl are labeled with a blue sticker bearing the name of that drug.

31. According to witnesses, during the procedure, the physician and the scrub technician are considered sterile and are the only individuals who come in contact with the portion of the patient's body that is involved in the procedure (which is usually the groin area). The nurse who administers the medications is not sterile and stands at a different location behind a screen. It is not uncommon for other technicians or nurses who are not "scrubbed in" to enter the procedure room to assist in the procedure. Individuals who participate in the procedure wear lead aprons to protect them from radiation exposure. When the procedure is underway, the room is dark so that the physician can look at a series of video screens that are located above the patient. At the conclusion of the procedure, the nurse (while witnessed by another individual) will "waste" or dispose of any leftover narcotics from the procedure. These drugs and any needles or syringes are deposited in a "sharps" container for medical waste. A scrub technician, such as Kwiatkowski, would not administer narcotics to a patient and would have no reason to possess a syringe containing Fentanyl or a needle that was used in a procedure at the CCL.

UNUSUAL BEHAVIOR BY KWIATKOWSKI

32. Interviews with multiple employees at Exeter Hospital have suggested that Kwiatkowski engaged in behavior that was unusual and is consistent with the activities of an

individual who is using or abusing controlled substances.

33. On June 15, 2012, an employee of the Exeter Hospital CCL was interviewed by law enforcement officers. The employee said that she had worked with Kwiatkowski in the CCL and on one particular day, she observed Kwiatkowski sweating and having bloodshot eyes. She further said that she thought Kwiatkowski "was on something" and in her opinion, he was unfit for patient care. She said that she expressed this concern to the CCL Director.

34. On June 18, 2012, the Director of the Exeter Hospital CCL was interviewed by law enforcement officers. He acknowledged that he received a complaint from another staff member about Kwiatkowski. He recalled calling Kwiatkowski into his office where he observed that his eyes were bloodshot. Kwiatkowski told him that his aunt had died and that he had been up since 3:00 in the morning crying about his aunt's death. The Director could not console Kwiatkowski and sent Kwiatkowski home from work in light of his condition. The Director also said that the employee who had originally complained about Kwiatkowski approached the Director after Kwiatkowski had been sent home. The employee stated that she really thought Kwiatkowski was "on something" and, based on her experience, it looked as if he was overly medicated. During this investigation, Kwiatkowski's parents were interviewed and have indicated that there have been no family deaths in recent years. Accordingly, Kwiatkowski's behavior cannot be attributed to the death of a relative.

35. On June 15, 2012, a hospital employee at the Exeter Hospital was interviewed by law enforcement officers. He acknowledged that he worked at the CCL with Kwiatkowski. He recalled an incident at the CCL when he observed that Kwiatkowski had a red face, red eyes, and white foam around his mouth while he was on duty.

36. On June 18, 2012, an employee of the Exeter Hospital was interviewed by law enforcement officers. The employee said that a patient's family member had found a syringe labeled "Fentanyl" in a public bathroom outside the CCL at the Exeter Hospital, and turned the syringe over to her. Other employees from the hospital have also described an incident occurring in the latter part of 2011 where a syringe labeled "Fentanyl" was recovered in a public restroom in the vicinity of the CCL. A different employee later had a conversation with Kwiatkowski after the syringe had been recovered in a restroom. In the conversation, Kwiatkowski was upset and claimed that the employee had accused him of stealing drugs and was trying to get him fired.

37. On June 19, 2012, an individual who worked at the Exeter Hospital CCL was interviewed by law enforcement officers. The worker indicated that she sometimes had seen Kwiatkowski get shaky and very sweaty. The worker indicated that Kwiatkowski would rush out of the CCL at the conclusion of some procedures. The worker also indicated that there were occasions when Kwiatkowski would bring her lead apron into the CCL for her.

38. On June 19, 2012, a phlebotomist was interviewed by law enforcement officers. She indicated that on May 30, 2012, she drew Kwiatkowski's blood. She said when she was attempting to draw Kwiatkowski's blood, she observed marks on Kwiatkowski's arms which she described as "fresh track marks" and large needle marks consistent with a 21-22 gauge needle on Kwiatkowski's arms. Such a large needle is not ordinarily used for injections into the skin. She said that based on these observations and her prior experiences treating intravenous drug users, she concluded that Kwiatkowski was an intravenous drug user.

39. Investigators conducted interviews with CCL employees who worked with Kwiatkowski, many of whom commented that he often sweated profusely through hospital scrubs.

An individual who had resided with Kwiatkowski said that Kwiatkowski often complained of abdominal pain and had to go to the bathroom frequently while at work, but that he did not seem to have to rush to the bathroom at other times. This individual also said that Kwiatkowski frequently vomited. In addition, another individual who was interviewed also described seeing Kwiatkowski vomiting.

40. According to DPHS officials, abdominal pain and nausea are side effects associated with both Hepatitis C and Crohn's Disease. These officials also informed investigators that profuse sweating is not a symptom related to either Hepatitis C or Crohn's Disease. However, according to the website WWW.DRUGS.COM, several withdrawal symptoms associated with Fentanyl abuse include abdominal cramps, vomiting, and sweating, common symptoms that witnesses have said were displayed by Kwiatkowski.

41. On June 19, 2012, Kwiatkowski's parents were interviewed by agents in Michigan. They told the agents that Kwiatkowski had Crohn's disease and took a lot of prescription medications, but that they were unaware of any illegal drug use. They indicated that he did have issues with alcohol, anger, and depression. They stated that Kwiatkowski was diagnosed with Hepatitis C about a year ago. Kwiatkowski had told them that he became infected when he was pricked by a needle at work. Also, they indicated that no relatives of Kwiatkowski had died in the last three years. The parents on a later date stated that they believed that Kwiatkowski has had Hepatitis C for one to two years.

42. On June 22, 2012, investigators spoke with an individual who had previously resided with Kwiatkowski. She advised that Kwiatkowski had departed from their residence in Exeter and that he had taken personal belongings with him. She indicated that she had found

needles in Kwiatkowski's laundry on several occasions and confronted Kwiatkowski about them. These needles were the type of needles used to inject medications. According to her, Kwiatkowski told her the needles were related to his B-12 injections that he had been receiving as part of cancer treatments at Portsmouth Regional Hospital. Investigators have found no evidence suggesting that Kwiatkowski had cancer or that he was ever treated by doctors at Portsmouth Regional Hospital.[2] This same individual subsequently advised law enforcement that she had found a blunt needle under a bed used by Kwiatkowski. I have observed this blunt needle and it is similar to the needles used in the CCL to draw medication from vials of medication after they are removed from the Pyxis machine.

43. On June 15, 2012, a Lab Technician Supervisor was interviewed by law enforcement officers. He acknowledged that he was Kwiatkowski's supervisor at the CCL and had received a complaint from another employee that Kwiatkowski was unfit for patient care and had bloodshot eyes. He also said that Kwiatkowski would often "break scrub" and attributed this to his Crohn's disease. Based upon my conversations with health care workers, "breaking scrub" refers to situations where a health care worker who has become sterile for a procedure leaves the procedure room and then is no longer sterile.

44. The Lab Technician Supervisor, while trying to imagine how so many patients became infected with the same strain of Hepatitis C, explained that Kwiatkowski would bring the employees lead aprons into the procedure room, even if he was not assigned to the case. He further said that Kwiatkowski would set the lead aprons down on the table right next to the Pyxis

---

[2] This individual, who also is referenced in paragraph 39, submitted to a polygraph examination following an interview by law enforcement officials. It is my understanding that the individual failed the polygraph exam.

machine (located in the procedure room of the CCL). The Supervisor said that oftentimes Kwiatkowski brought the lead aprons and set them down on this table after the nurses had drawn up the medications from the Pyxis machine. The Supervisor speculated that upon setting the lead apron on this table, Kwiatkowski may have been able to take a syringe containing Fentanyl and replace it with a tainted syringe containing saline or another substance. The Supervisor also said there would be no reason for a technician to be in the nursing area where the medications are located. He noted that it was unusual for an employee to bring in lead aprons for other employees.

PATIENT TREATED IN THE CCL ON FEBRUARY 25, 2012

45. The Supervisor also recalled a Saturday in February of 2012 when he and several other staff members were "on call" and were asked to come into the CCL to perform a procedure. He noted that although Kwiatkowski was not "on call," he was present and remained at the hospital while the call team worked on two different patients. The Supervisor said that a nurse had asked Kwiatkowski to come to the CCL because other members of the call team had not arrived. Kwiatkowski provided some assistance preparing for a procedure before the call team arrived. Once the team was ready for the procedure, the Supervisor thanked Kwiatkowski and told him he could leave, but Kwiatkowski remained and watched the procedure, as well as a second procedure. Often, Kwiatkowski stood at the head of the table near where the nurse was standing. The Supervisor stated that Kwiatkowski, who was not scrubbed in for the procedure, never touched the patient. The Supervisor noted that he believes that the second patient had contracted Hepatitis C. Several additional witnesses have also described situations where Kwiatkowski entered the CCL even though he was not on the "team" assigned to work on the procedure being performed.

46. On June 20, 2012, law enforcement officers interviewed a physician who performs

many procedures in the CCL. The physician noted that syringes are never re-used at the CCL and that there are no multi-use vials of medication. The physician stated that he recalled a situation that occurred on a Saturday where Kwiatkowski was present at the CCL even though he was not "on call." The physician recalled that Kwiatkowski was told that he could go home, but that he stayed for the treatment of both patients who were seen that day. The physician believed that the second patient treated that day contracted Hepatitis C.

47. On July 18, 2012, law enforcement officers interviewed this physician again. The physician confirmed that the date he had previously described was February 25, 2012. He stated that Kwiatkowski was not "scrubbed in" to the second procedure on February 25, 2012, and that he entered and exited the CCL during the procedure. The physician reviewed the medical records related to the second procedure and noted that the amount of Fentanyl that was administered to the patient seemed high. The physician said that the blunt needles that are used in the CCL to withdraw Fentanyl from vials would not ordinarily be used to inject drugs directly into the body. He noted, however, that he had observed abscesses on Kwiatkowski's body that would be consistent with the use of a blunt needle to inject medication.

48. On June 21, 2012, law enforcement officers interviewed a nurse who performs many procedures at the CCL. That nurse stated that Kwiatkowski would bring in lead aprons for the nurses. The nurse also noted that Kwiatkowski spent more time near the nurse's area in the CCL than other technicians. The nurse stated that Kwiatkowski had stated that he had cancer, that Kwiatkowski sweated profusely, and that it was common for him to "break scrub" and leave the CCL during a procedure. This nurse also described an event when Kwiatkowski came to the CCL when he was not on call and did not participate in the procedure but remained at the CCL despite

being asked to leave.

49. I have reviewed the medical records of a patient who was treated during the second procedure at the CCL on Saturday, February 25, 2012, as well as other records obtained from Exeter Hospital. Those records show that at approximately 7:12 p.m., 100 micrograms of Fentanyl were removed from the Pyxis machine by a nurse. The CCL can be accessed via an electronic swipe card. At approximately 7:20 p.m., card access information indicates that Kwiatkowski entered the CCL. It appears that he then left the CCL and returned because card access information showed him entering the room again at approximately 7:29 p.m., shortly before the first Fentanyl was administered to the patient. At approximately 7:52 p.m., a nurse withdrew 100 micrograms of Fentanyl from the Pyxis machine. It appears that Kwiatkowski departed the room and returned again because card key access information showed him entering the room again at approximately 8:06 p.m. The patient left the CCL at approximately 8:10 p.m. The medical records do not contain any information suggesting that Kwiatkowski ever touched the patient in any way. As mentioned above, he was not one of the workers assigned to be "on call" that day.

50. The patient described above is one of the 30 patients whose Hepatitis C appears to be from the same source as the type of Hepatitis C that has been found in Kwiatkowski. Based upon the medical and epidemiological information, the witness statements, my conversations with other law enforcement officers, and my training and experience, I believe that Kwiatkowski tampered with the medications that were intended for this patient and diverted the medication for his personal use. As discussed above, Hepatitis C is a blood-borne virus. In light of the fact that Kwiatkowski had no physical contact with the patient, the commonality between his Hepatitis C and that of this patient could only have occurred if he somehow tainted the medication that was

administered to this patient. As a result, the patient received tainted medication that caused the patient to contract Hepatitis C.

SEARCH WARRANT IN MASSACHUSETTS

51. On June 23, 2012, a family member of Kwiatkowski contacted the Exeter Police Department to express concern that Kwiatkowski might be suicidal and that he had a gun. Officers from the Boxborough, Massachusetts Police Department subsequently located Kwiatkowski at a hotel in Boxborough, Massachusetts. The officers conducted a brief protective sweep and did not observe any weapons, but did observe prescription bottles and clothing in the room. Kwiatkowski later agreed to be transported to a hospital for evaluation.

52. A federal search warrant was executed on Kwiatkowski's vehicle. Among the items recovered was an empty syringe bearing a blue sticker stating "Fentanyl." This sticker appears to be consistent with the stickers used to label syringes at the Exeter Hospital CCL. The syringe also was made by the same manufacturer from which Exeter Hospital purchases syringes. Several needles also were recovered. As discussed earlier, because Kwiatkowski did not administer narcotics to patients at the CCL, there would be no legitimate reason for him to possess a syringe of Fentanyl.

STATEMENTS BY KWIATKOWSKI

53. On June 13, 2012, Kwiatkowski was interviewed by law enforcement officers. Kwiatkowski said that he has been employed as a scrub technician at the CCL since March or April of 2011. He stated that he had Crohn's disease and had undergone several surgeries at Exeter Hospital. He further stated that he recently was informed by a doctor that he had tested positive for Hepatitis C. Kwiatkowski described this news as a "time bomb" and that he had not

previously known that he was infected with Hepatitis C. He stated that he "had no idea" that he had the disease "until a couple weeks ago." Kwiatkowski stated that he was aware that the disease was transmitted by blood to blood contact. Kwiatkowski denied that he diverted any drugs, denied knowing how he contracted Hepatitis C, and stated that he was allergic to Fentanyl.

54. Investigators have reviewed Kwiatkowski's medical records. Although the records show a self-reported allergy to Fentanyl, he nevertheless received approximately 200 micrograms of this drug during a procedure on December 11, 2011. On July 18, 2012, law enforcement officers interviewed the physician who performed this procedure. The physician indicated that she had not been able to find evidence that Kwiatkowski had active Crohn's disease. She further advised that Kwiatkowski advised her that Fentanyl made him itchy, sweaty, and nervous. The physician indicated that these are common side effects of the medication and not evidence of an allergy. The physician saw no signs of an allergic reaction when Kwiatkowski received the Fentanyl. Moreover, she noted that the amount of Fentanyl administered (200 micrograms) had not been sufficient to sedate him. The physician stated that some individuals have issues with metabolizing the drug and that the fact that this amount of Fentanyl did not have a sedating effect could be an indication that he had built up a tolerance to the drug.

55. In further investigating Kwiatkowski's statements, I learned on July 18, 2012, that Kwiatkowski was involved in a drug diversion incident when he worked as a contract employee in another state in 2008. According to information obtained from a hospital, an employee in an operating room observed Kwiatkowski enter an operating room, lift his shirt, put a syringe in his pants, move his arms quickly near a medication care, and exit the room. A subsequent review of the narcotics in the room showed that a syringe containing Fentanyl was missing and that it had

been replaced by a syringe containing a different liquid (which was later found not to be Fentanyl). Kwiatkowski, who was acting erratically and sweating, was confronted and agreed to be searched shortly after the incident. Three empty syringes bearing Fentanyl labels were found on his person. An empty morphine sulfate syringe and a needle were later found in his locker. A drug test found Fentanyl and opiates in Kwiatkowski's urine.

56. Investigators have obtained and reviewed Kwiatkowski's medical records from Exeter Hospital and other health care facilities. Those records reflect differing statements about who is aware of his Hepatitis C diagnosis. For example, in one medical note, Kwiatkowski told a health care provider that, as a result of his diagnosis, his family believed that he was a drug addict. In a subsequent note, a provider documented that Kwiatkowski stated that his father had recently visited and that Kwiatkowski had not told him about the diagnosis.

57. On July 2, 2012, Kwiatkowski was interviewed by law enforcement officers. Although he was not placed under arrest, he was advised of his *Miranda* rights. During the interview, Kwiatkowski admitted that he had "lied to a lot of people" and "fabricated my life." He stated that two of the biggest lies he had told were claiming he played baseball at the University of Michigan and that his fiancée had died. He stated that he had been a traveling technician and had worked at a number of locations, including New York. He denied having track marks and claimed he is "not a shooter" and that he is scared of needles.

58. Kwiatkowski claimed that he first became aware of his Hepatitis C diagnosis in approximately May of 2012. Kwiatkowski stated that he was a victim and that he did not know how he contracted Hepatitis C. When asked how the patients at the CCL had contracted Hepatitis C, Kwiatkowski stated "You know, I'm more concerned about myself, my own well being." He

later said "That's all I'm really concerned about and I've learned here to just worry about myself and that's all I really care about now." As mentioned earlier, I have obtained information indicating that Kwiatkowski tested positive for Hepatitis C in June of 2010.

59. In discussing drug use, Kwiatkowski said "I've already said it. I did not take any drugs or do any drugs . . . and I'm gonna stick to that." When he was advised that a syringe bearing a Fentanyl label was found in a bag in his vehicle, Kwiatkowski claimed that it was not his and suggested that it had been planted by a co-worker at the CCL.

60. When asked about needles that were found when he was working in another state, Kwiatkowski said that he found one and another person found one, but they were not the type of needles that would be used to inject drugs.

61. When he was questioned about the individual who said that she had been tested for Hepatitis C in May of 2011 based upon his suggestion and the fact that his parents had said that he had Hepatitis C, Kwiatkowski asked for a lawyer and terminated the interview.

CONCLUSION

62. Based upon my training and experience and my discussions with other law enforcement officers, I know that some of the behaviors that witnesses described observing (bloodshot eyes, excessive sweating, and foaming at the mouth) are associated with narcotics use and/or withdrawal. In addition, it is my understanding that drug-using health care workers have been known to attempt to divert controlled substances that are intended for patients. Based upon all of the above facts, I believe there is probable cause to believe that Kwiatkowski diverted controlled substances for his personal use and tampered with consumer products, such as Fentanyl, intended for patients at Exeter Hospital, thus exposing and infecting multiple patients with

Hepatitis C, an illness that involves a substantial risk of death and protracted loss or impairment of a bodily organ (the liver).

63. Based upon all of the above facts, there is probable cause to believe that from in or about April of 2011 through in or about May of 2012, Kwiatkowski: (1) knowingly and intentionally acquired and obtained possession of a controlled substance by misrepresentation, fraud, forgery, deception, and subterfuge, in violation of 21 U.S.C. § 843(a)(3) and (2) with reckless disregard for the risk that another person will be placed in danger of death or bodily injury and under circumstances manifesting extreme indifference to such risk, tampered with a consumer product that affected interstate and foreign commerce and the container for such product, resulting in serious bodily injury to another individual, in violation of 18 U.S.C. § 1365(a)(3).

Dated: July 19, 2012

Respectfully submitted,

Marcie DiFede

Marcie DiFede
Special Agent
Federal Bureau of Investigation

Subscribed and sworn to before me on July 19, 2012

UNITED STATES MAGISTRATE JUDGE

Appendix 10: OR/ICU Employee Questionnaire

New Hampshire Department of Health and Human Services **Employee Name: _____**
Bureau of Infectious Disease Control

Hepatitis C Virus Employee Interview Form

I am meeting with you to discuss your role at the hospital and to ask you questions about personnel that may have worked in your unit. We are investigating an outbreak of hepatitis C in patients that received care at Exeter Hospital. These questions will take about 10 minutes to answer. Some of these questions may be difficult to answer, but your answers may help us understand how these patients became infected.

1. Employee Information:

LAST NAME	FIRST NAME	MI	DATE OF BIRTH

ADDRESS	CITY	STATE	PREFERRED PHONE FOR ADDITIONAL QUESTIONS

2. Which units do you work on at Exeter Hospital (check all that apply):

☐ Cardiovascular procedure room ☐ Recovery area associated with cardiovascular procedure room
☐ Main Operating room ☐ Outpatient Operating Room ☐ Endoscopy Suite
☐ Interventional Radiology ☐ Other:_____

3. What is your job position at Exeter Hospital:

☐ Nurse ☐ LNA ☐ Other:_____
☐ Physician Type:_____ ☐ Tech Type:_____
Additional Comments:

4. Do CCL staff ever come to your unit to assist with patients (patient care, transport, etc)?

☐ Yes ☐ No ☐ Unknown

If yes,
a. How frequently:
c. Why do they come:
d. What do they do do:

5. Do CCL staff ever come to your unit to observe procedures or other activities?

☐ Yes ☐ No ☐ Unknown

If yes,
a. How frequently:
c. Why do they come:
d. What do they do do:

6. Do CCL staff ever come to your unit to deliver supplies?

☐ Yes ☐ No ☐ Unknown

If yes,

a. How frequently:

c. Why do they come:

d. What do they do do:

Now I am going to ask you several questions specifically about David Kwiatkowski.

7. Have you ever seen David on your unit?

☐ Yes ☐ No ☐ Unknown

If yes, please provide details:

a. When, or if multiple times how frequently:

b. Where:

c. Why was he there:

d. What did you see him do:

e. Did he exhibit any behavior that was concerning to you? ☐ Yes ☐ No ☐ Unknown

If yes, please provide details:

8. Is there anything else you would like to tell me?

Thank you for taking the time to speak with me. I may need to contact you again to ask additional questions at a later time. If you think of anything you forgot or anything else you would like to share with me at any point please feel free to contact me.

Appendix 11: OSC/ENDO Employee Questionnaire

New Hampshire Department of Health and Human Services **Interviewer Name:_____**
Bureau of Infectious Disease Control **Interview Date: _____/_____/_____**

Hepatitis C Virus OSC and Endoscopy Employee Interview Form

I am meeting with you to discuss your role at the hospital and to ask you questions about hospital employees that may have worked or visited in your unit. This is part of the hepatitis C Investigation These questions will take about 20 minutes to answer. Some of these questions may be difficult to answer, but we ask you to be as accurate and honest in your answers as you can. It will help us assess if patients in your unit may have been at risk for acquiring hepatitis C as part of the outbreak. This interview is done in private to provide you the opportunity to discuss any concerns you may have. Only a summary of the general responses (without disclosing names of interviewees) will be provided to Exeter Hospital.

1. Employee Information:

LAST NAME	FIRST NAME	MI	DATE OF BIRTH

ADDRESS	CITY	STATE	PREFERRED PHONE FOR ADDITIONAL QUESTIONS

2. Which units do you work on at Exeter Hospital (check all that apply):

☐ Cardiovascular procedure room ☐ Recovery area associated with cardiovascular procedure room
☐ Main Operating room ☐ Outpatient Operating Room ☐ Endoscopy Suite
☐ Interventional Radiology ☐ Other:_____

3. What is your job position at Exeter Hospital:

☐ Manager ☐ Nurse ☐ LNA ☐ Other:_____
☐ Physician Type:_____ ☐ Tech Type:_____
Additional Comments:

4. When did you begin working in this unit? _____/_____/_____

5. How many hours a week do you usually work in this unit?

6. In the past, or currently, do CCL staff ever come to your unit to assist with patients (patient care, transport, etc)?

☐ Yes ☐ No ☐ Unknown
If yes,
a. How frequently:
c. Why do they come:
d. What do they do do:

7. In the past, or currently, do CCL staff ever come to your unit to observe procedures or other activities?

☐ Yes ☐ No ☐ Unknown

If yes,

a. How frequently:

c. Why do they come:

d. What do they do do:

8. In the past, or currently, do CCL staff ever come to your unit to deliver supplies?

☐ Yes ☐ No ☐ Unknown

If yes,

a. How frequently:

c. Why do they come:

d. What do they do do:

The next few questions will be related to how narcotics were handled in your unit ***prior to May 2012****:*

9. How many medication Pyxis machines were on this unit, and where were they located?

10. Can you describe when and where the controlled substances/narcotics were prepared?

11. Can you describe who prepared the controlled substances/narcotics?

12. Where were the vial and syringe kept between preparation and administration?

13. When and where were the controlled substances/narcotics administered?

14. Who administered the controlled substances/narcotics?

15. Were unused controlled substances/narcotics kept for future administration for that patient?

☐ Yes ☐ No ☐ Unknown

If yes, describe where they were kept and how they moved with the patient?

16. Were syringes or vials containing controlled substances/narcotics ever left unattended such as in the medication preparation/PYXIS area or at the bedside? As an example, if medication is drawn up and the nurse or physician turns their attention to another activity in the room?

☐ Yes ☐ No ☐ Unknown

If yes, provide details:

If no, How is it ensured that medication is never left unattended, are medications carried with the person administering?

17. Can you describe how unused controlled substances/narcotics were being wasted if not used?

18. Can you describe how controlled substances/narcotics were returned if not used?

19. Have there been any changes (policy, or otherwise) to the handling of narcotics in your unit since May 2012?

☐ Yes ☐ No ☐ Unknown

If yes, provide details:

20. Please describe the process of how narcotic discrepancies are reported and remedied.

Now I am going to ask you specifically about David Kwiatkowski.

21. Have you ever seen David on your unit?

☐ Yes ☐ No ☐ Unknown

If yes, please provide details:

a. When, or if multiple times how frequently:

b. Where:

c. Why was he there:

d. What did you see him do:

e. Did he exhibit any behavior that was concerning to you? ☐ Yes ☐ No ☐ Unknown

If yes, please provide details:

22. Is there anything else you would like to tell me?

23. Is there anyone else you would suggest that we talk to from your unit?

Thank you for taking the time to speak with me. I may need to contact you again to ask additional questions at a later time. If you think of anything you forgot or anything else you would like to share with me at any point please feel free to contact me. Also, you can leave an anonymous tip if there was anything that you did not want to discuss during this interview. Our office number is 603-271-4496.

Appendix 12: Patient Letter

STATE OF NEW HAMPSHIRE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

29 HAZEN DRIVE, CONCORD, NH 03301-6503
603-271-4612 1-800-852-3345 Ext. 4612
Fax: 603-271-4827 TDD Access: 1-800-735-2964

NH DIVISION OF Public Health Services
Improving health, preventing disease, reducing costs for all

Nicholas A. Toumpas
Commissioner

José Thier Montero
Director

Date

Name
Address
Address

Dear _____,

The Division of Public Health Services has been investigating a Hepatitis C outbreak at Exeter Hospital. We believe that you may have been exposed as part of this outbreak and we recommend you to be tested for hepatitis C. With this notification we are providing to you several testing options. We have set up public clinics that you can schedule an appointment to be tested. The clinics dates and times are provided below:

Cooperative Middle School, Stratham	August 10, 10 AM-6 PM August 11, 10 AM-6 PM
Timberlane Regional High School	August 14, 10 AM-1 PM August 15, 4 PM-7 PM
Rochester Middle School	August 16, 2 PM-7 PM
Manchester Health Department	August 16, 8 AM-12 PM August 17, 1 PM-5PM August 18, 8 AM-12 PM

We will call you to schedule your appointment. You may also call us at 603-271-6617 between 8 AM-8 PM to schedule. At the above sites, you will have a blood draw that will be tested on site using a rapid test (with results available within 30-45 minutes). The sample will also be tested at our Public Health Lab in Concord with final results sent to you and your provider. This confidential testing will be free of charge to you. We encourage you to come to the above public clinics.

Other testing options are also available. These include the following locations:

Exeter Hospital, August 13-15, 7 AM-6 PM.

You must schedule an appointment directly with Exeter Hospital by calling 603-580-6124

Portsmouth Regional Hospital – Hampton, Monday-Thursdays, 8 AM-4 PM

Portsmouth Regional Hospital – Pease Trade Port, Monday-Thursdays, 8 AM-4 PM

For the Hampton and Pease sites, no appointment is necessary, but you will be asked to provide this letter and proper identification.

In these sites you will have a blood draw and the sample will be sent to our Public Health Lab in Concord. We will contact you with the results of your test. Rapid test will not be conducted at those sites.

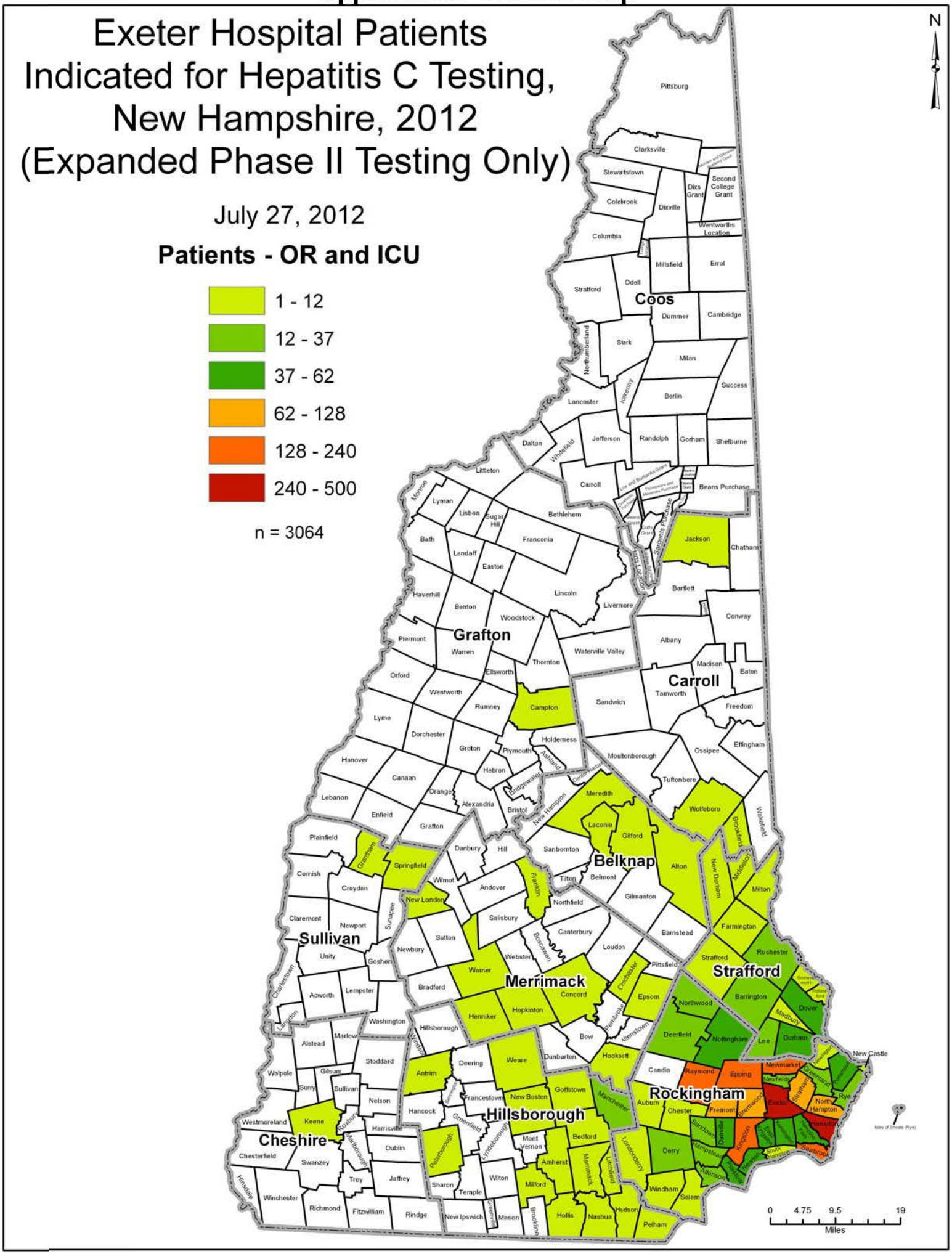
You may choose to go to your primary care provider who can send your blood sample to the NH Public Health Labs for testing. The healthcare provider should call the Lab at 603-271-4661 to coordinate this testing. (Test Requisition Form is available on our website at http://www.dhhs.nh.gov/dphs/cdcs/hepatitisc/hepc-investigation.htm.)

We realize this notification may raise your concern. Please understand that your risk of exposure is low but as a precaution we are recommending this testing. We remain available to you at 603-271-4496 for any questions or concerns you may have.

Respectfully,

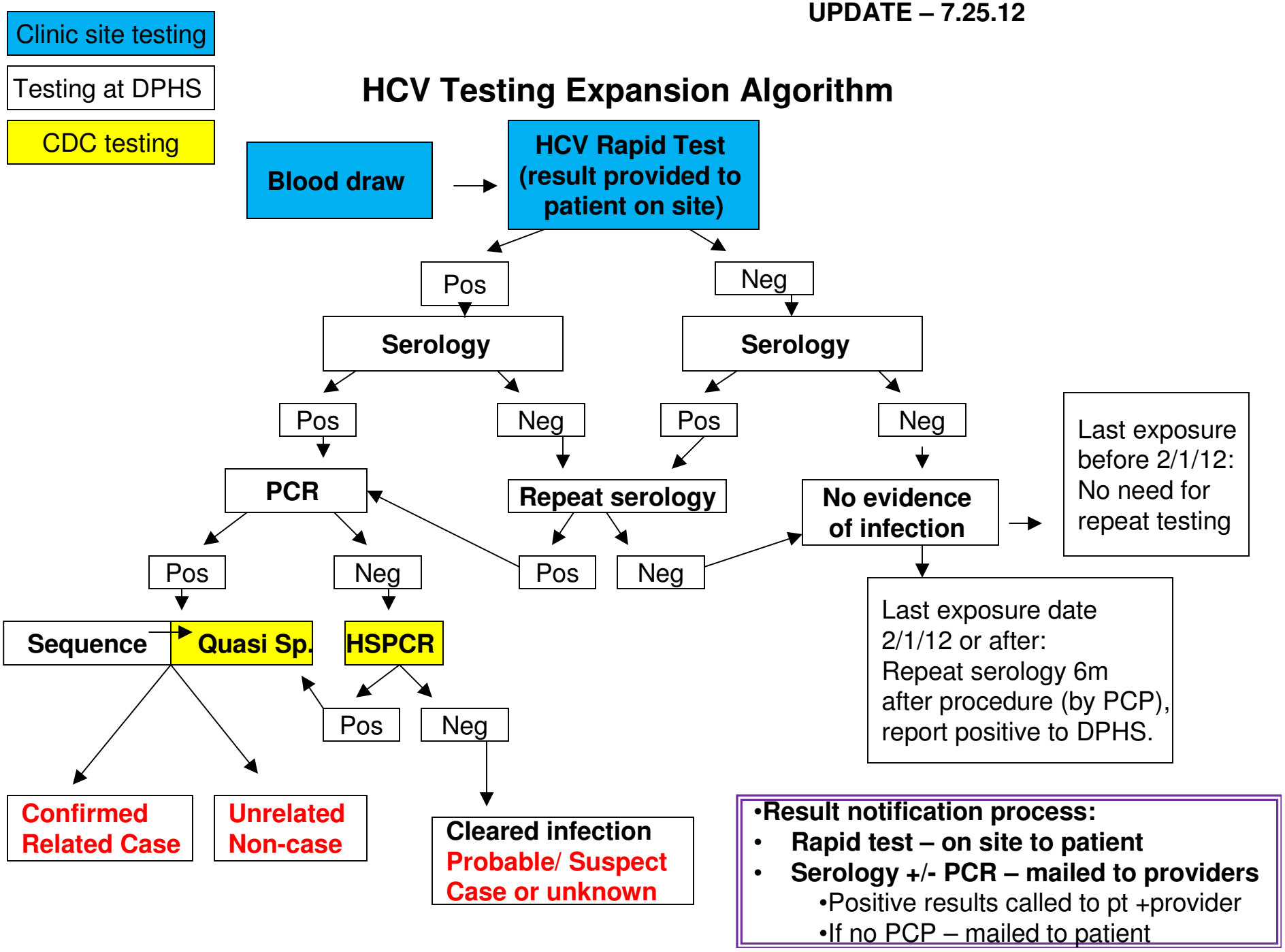
Sharon Alroy-Preis, MD, MPH
NH State Epidemiologist
Division of Public Health Services
Department of Health and Human Services.

Appendix 13: Phase II Map



Appendix 14: Clinics Testing Algorithm

UPDATE – 7.25.12



Algorithm Logic

Facts and assumptions:	**Decision:**
Rapid test = serology in sensitivity but not confirmatory for positive result	Replace serology with rapid test (finger stick). If positive continue with blood draw
Positive serology appears after 4-10 w of virus acquisition.	If time interval between exposure day and blood collection < 12 w – could be window period for serology.
Based on first tier of testing – with recent exposure no one with negative serology had positive PCR.	No default serology + PCR testing for recent exposure (only rapid test and if negative repeat serology after 6 month)
>97% of patients will have pos serology 6 month after virus acquisition	If serology negative repeat serology after 6 month
Sensitivity of PCR in NH PHL is 100 IU/ml	If PCR is neg with pos serology - send specimen for CDC for hypersensitive PCR (15 IU/ml)
Assumption for simplification – collection date 8/1/12 (first clinic 7/28/12)	Can base decisions on date of procedure
Patients could have repeated exposures (repeated procedures, prolong ICU stay, etc)	Take last exposure as the date used for algorithm.
Questionable results will be f/u by BIDC	Cases to f/u: Repeat serology for patient with exposure date during May 2012 (within window period for serology)

Appendix 15: Clinic Evaluation Summary

TESTING CLINICS SURVEY SUMMARY

CLINIC ATTENDEES: **1252**
TOTAL NUMBER OF SURVEYS: **478**

1. How did you hear about this public health clinic today? (Check all that apply)

		Response Precent	Response Count
DPHS Letter	81%	81%	372
DPHS Telephone Call	32%	32%	149
Public Announcement	6%	6%	29
Social Media	5%	5%	22
Television	26%	26%	120
Radio	4%	4%	20
Newspaper	13%	13%	60
Other	2%	2%	11

Answered question 460
Skipped question 18

RATING AVERAGE BY LOCATION:

2. On a scale from 1-5 please rate you level of satisfaction with the process to schedule your appointment today:

Stratham 10-Aug	Stratham 11-Aug	Plaistow 14-Aug	Plaistow 15-Aug	Rochester 16-Aug	Manchester 16-Aug	Manchester 17-Aug	Manchester 18-Aug	**OVERALL RATING**
4.33	4.70	4.05	4.82	4.40	4.42	4.44	4.58	**4.47**

3. On a scale from 1-5 please rate your of satisfaction with having your questions answered:

Stratham 10-Aug	Stratham 11-Aug	Plaistow 14-Aug	Plaistow 15-Aug	Rochester 16-Aug	Manchester 16-Aug	Manchester 17-Aug	Manchester 18-Aug	**OVERALL RATING**
4.16	4.38	4.18	4.71	4.48	4.04	4.35	4.80	**4.39**

4. On a scale from 1-5 please rate your level of satisfaction with the rapid testing today:

Stratham 10-Aug	Stratham 11-Aug	Plaistow 14-Aug	Plaistow 15-Aug	Rochester 16-Aug	Manchester 16-Aug	Manchester 17-Aug	Manchester 18-Aug	**OVERALL RATING**
3.95	4.59	3.64	4.69	4.33	4.45	4.38	4.94	**4.37**

5. On a scale from 1-5 please rate your overall level of satisfaction with the clinic today:

Stratham 10-Aug	Stratham 11-Aug	Plaistow 14-Aug	Plaistow 15-Aug	Rochester 16-Aug	Manchester 16-Aug	Manchester 17-Aug	Manchester 18-Aug	**OVERALL RATING**
4.21	4.54	3.76	4.79	4.36	4.48	4.41	4.84	**4.42**

Stratham Testing Clinic
8/10/2012

CLINIC ATTENDEES: **537**
TOTAL NUMBER OF SURVEYS: **163**

1. How did you hear about this public health clinic today? (Check all that apply)

		Response Precent	Response Count
DPHS Letter	89%	89%	138
DPHS Telephone Call	24%	24%	37
Public Announcement	7%	7%	11
Social Media	5%	5%	7
Television	29%	29%	45
Radio	4%	4%	6
Newspaper	15%	15%	23
Other	2%	2%	3

Answered question 155
Skipped question 8

2. On a scale from 1-5 please rate you level of satisfaction with the process to schedule your appointment today:

Very Unsatisfied	Unsatisfied	Neutral	Satisfied	Very Satisfied	Rating Average	Response Count
10	5	11	48	86	4.33	156

Comments: 28

Answered question 156
Skipped question 7

3. On a scale from 1-5 please rate your of satisfaction with having your questions answered:

Very Unsatisfied	Unsatisfied	Neutral	Satisfied	Very Satisfied	Rating Average	Response Count
5	6	26	58	62	4.16	153

Comments: 14

Answered question 153
Skipped question 10

Stratham Testing Clinic (continued)
8/10/2012

4. On a scale from 1-5 please rate your level of satisfaction with the rapid testing today:

Very Unsatisfied	Unsatisfied	Neutral	Satisfied	Very Satisfied	Rating Average	Response Count
12	11	23	45	54	3.95	140

Comments:	48
Answered question	140
Skipped question	23

5. On a scale from 1-5 please rate your overall level of satisfaction with the clinic today:

Very Unsatisfied	Unsatisfied	Neutral	Satisfied	Very Satisfied	Rating Average	Response Count
10	7	16	51	71	4.21	150

Comments:	48
Answered question	150
Skipped question	13

6. For future use, we would like to know how we can improve:

Answered question	72
Skipped question	91

Stratham Testing Clinic (continued)
8/10/2012

COMMENTS SYNOPSIS

2. On a scale from 1-5 please rate you level of satisfaction with the process to schedule your appointment today:

I found the entire staff incredibly friendly and helpful, and theprocess was streamlined and well-directed.
Except it was extremly hot in building
No problem at all-rec'd the call and message. I returned call and scheduled immediately
In hold for a long time to schedule
Thank you to nurse Donna
Long wait for "appointment" that was very specific timewise
Was told the letter was needed as well as ID but explained I didn't have access to the letter and was given a waiver
Schedule could have been better in formed on how process worked
Scheduled for appt and was held in line 40 min & they lost my pre-registration papers. So talked to others who had same experience
I had makde my appt on Monday, 8/6/12 that went fine. I don't understand why I made an appt, it didn't matter it was 1st come 1st served
Appt time was a joke, one-hour later
Everyone was very nice
The people calliing to schedule my appointment were polite and caring. Willing to do what they could to expedite the process
Got a call on Sun from DPHS
Well organized and friendly volunteer
Got time I wanted
I didn't schedule an appointment
Scheduling the appt was the easy part
Kind & Pro
My name was not on the list
Very organized
Given an appt time that was not honored
Made appt & scheduled personal time to avoid wait. Was mixed in w/large volumnof people w/o appts.
Total time (start-finish) took 2.5 hours. Was told to plan of 1 hr.
Was phoned 4x - 4 days
Very organized & location & lines were speedy, but I really don't understand why the appt were scheduled @ specific times since we weren/t seen then
No problem scheduling, very nice on phone
Seemed very disorganized. Registration took over 1/2 hr
I called DPHS to schedule an appointment-quite easy

3. **On a scale from 1-5 please rate your of satisfaction with having your questions answered:**

I'm also reading on-line about prognosis and transmission information.
Trouble getting answer to question regarding follow-up testing
Could have had more take away info on process of all tests & how long things will take
Rcd non
The handouts were very helpful
They kept me informed of all the steps taken. Kristen, the young woman with me, stayed throughout the whole process
I felt bad for the workers. I know they must have stayed late!!
Didn't wait for results
None
What education?
Only education received was pamphlet
What education?
Contradictory information re: final results. Told by educator I had to call lab to request a copy of results IF negative-results would only go to PCP. Told at registration & in letter from DHHS-final results to provider and ME!! She questioned who told me I'd get a copy. (Implying I was misinformed.) A gentleman next to me waited 2 hrs & was there @ 10:15A!
Did not take advantage of Media Center

4. **On a scale from 1-5 please rate your level of satisfaction with the rapid testing today:**

Great job handling a really unpleasant situatin for potentially infected patients of Exeter Hospital.
Wait for results a little long-understandable being 1st day
Two sticks, Yuk!
Longer wait then though it would be
Did not choose to wait
Results for rapid testing a little slow but circumstances are understandable
People didn't come at appointment time-long line
Understandble-but so slow-waited over an hour
Did not wait
Not eligible for Rapid Test
Length of wait for results
Not sure how much stock I put in results
Too long-lines & wait especially since given an Appointment
Rapid???
Wait time went from 45 as wer were 1st told to a 2 hour wait time
Issue with pregnant women not being told that we can't do rapid
We had to wait about 2 hours. We were mislead on the wait time
Not very rapid. People very nice
The workers werked as fast as they could. Everyone was pleasant & helpful
Passed on it
WAITED TWO 2 HRS! ALONG WITH MANY OTHERS
Didn't stay for results
Happy to get results today, but the wait is a little long and stressfull

4. **On a scale from 1-5 please rate your level of satisfaction with the rapid testing today (continued):**

Too slow-I was told on phone it would take 1 hr. (I assumed entire process). I took 1 hr just to get my blood drawn so would have been 2 hrs.
I chose not to wait for the results. They told me what to do and what is going to happen
It was a long wait but I was so relieved at the negative results.
Needmore lab techs. Rapid tests should be done before all other testing
Not very rapid
Did not wait for results
Wasn't 30-45 minutes-more like 2 hours
3+ hours plus, from time of appt
The phlebotomist was excellent
Blue band was on way too tight and way too long. Left bruise
Didn't wait for results
Long line-told 10 min took >1hr. Lot of volunteers standing around
took a long time but that's understandable with the amount of people
N/A
Slow, but all volunteers & technicians very polite
Testing okay but those volunteers (flobotomists) should have been paid
Glad to have results on the same day
A bit slow wait for results
Did not wait
There was NOTHING RAPID about it!!
Didn't wait
Wait time more than what was projected (30-45 min) number indicated on fact sheet "5160"-told it was my ID number. Number on sticker "892"???
Backed up abouat 2 hours
Very well organized
Didn't stay to hear the results because was told initially they would call w/results assuming it would be Sat, not Monday.

5. **On a scale from 1-5 please rate your overall level of satisfaction with the clinic today:**

Very organized and quickly went through the process
Well organized
Check out needs to be better prepared and more staff two people are not enough
Thank you to everyone for making this scary experience as pleasant as possible
Ran quite smoothly
More Air
Too slow, too hot. Some of cannot stand in heat for 20 mins
Very satisfied + +. Very organized-smooth!
anonymous testing and public clinic are oxymorons
All the staff was very helpful and kind
Phlebotomist was very gentle I didn't even feel the needle go in/out and I not only donate blood but also have it drawn several times a year
Results process seems unorganized, long, hot

5. **On a scale from 1-5 please rate your overall level of satisfaction with the clinic today (continued):**

Test ALL Hospital Personnel!!
Handled so badly I was ashamed of the organization
Everyone on staff was kind, polite, helpful, caring and knowledgeable. The girl who drew my blood was great!
Not told that pregnant women wouldn't be able to get Rapid Results. I would have gone to my personal Dr if I had know I couldn't participate in rapid results
Long lines, much standing
Volunteers were all very courteous & halpful although it was a long weight it was very satisfactory
Thank you fro setting up this testing and being open about the whole situation
Everyone was very friendly and knowledgeable & helpful
I found the organization to be outstanding
Just the wait ws too long!!
Efficient and kind
Wait was far too long-for registration and the line for blood draws
Waited too long in line & too long for results
Organization
Should not have to wait this long, not staffed properly (hot here, no soap in mens room! No hand sanitizer here!
I expecgted to be seen within 15 min of my scheduled appt. There was a long delay-therefore the scheduling was not sufficient I'm guessing. I didn't get out of here until an hour later!
It takes way too long. The longer I wait the madder I get!!
Corinn & Carol (nurse) were excellent.
Takes too long to know test results
Why the appointment when you have to wait 45 minutes
Thanks to all the volunteers giving up their time to support the community. My prayers to Exeter Hospital…. May it last to continue offering their services.
Would have liked to know that the wait was extremely long too many people scheduled at once
Unacceptabel wait in bad waiting conditions (too hto & standing for 45 min)
They didn't have me registered even though I had an appointment
As I knew instinatively, far more pople showed up than planned
Long process, felt unorganized.
Far too many people were scheduled for the same time slot. While waiting in line for almost an hour, workers would push through us without saying "excuse me." I wouldn't have minded waiting so long if I
I feel the best was done that could be done regarding this situation
Because it was th efirst day, it was running about an hour behind-It didn't matter whether you had an appointment; emotionally it ws upsetting to wait longer, but understandable I guess
Very well organized, with a friendly, positive staff-couldn't have been better. I just wish I didn't have to be here today…..
The lady that took my blood was really good. A lot of the volunteers wre helpful to make sure we didn't have any questions
People were very professional, courteous, and kind to those of us who had to go through this. I appreciate this!
Unbelievably well run and organized-bravo!

5. **On a scale from 1-5 please rate your overall level of satisfaction with the clinic today (continued):**

Overall process was smooth and coordinator were helpful and kept things organized & moving. Back up was in the wait for rapid results. Counselor contradicted info by registrar and letter from DHHS.
Reduce wait by adding more ck-ins @ initial point of contact organize by A-d, E-H, etc

6. **For future use, we would like to know how we can improve:**

The only fault I could find would be the lack of air conditioning! I chose to wait for results, so the air-conditioned library was welcome. Phlebotomists will be overheated, though! Marcella has an infectious personality and kept the waiting crowd happy. Thanks for yoru humor Marcella.
Tell New's Media to respect people's privacy
Both staff members I came in contact with were very professional- given the fact this was fairly new process went well
Everything went well
Because of extreme heat and fumidity more fans would have helpful
Populate form with patient info and have patient verify vs asking patient to recall info on file and who may be under stress
I think Director Toumpas made the right decision to cancel the first clinic series in order to make a more efficient clinic. Well done!
More Air
If appt says 11:45, do it at 11:45
For the size and scale of the problem-good job. I feel bad for all involved-great job for all of you!!! Thank you
Provide better estimate of waiting time for results. Call numbers in numerical sequence!
People who can draw blood
If rapid testing being used-need many more technicians
You are doing just fine
Length of time waiting for results
Better organized. More info @ registration
Have two lines one for appts and one for walkins

Overall everything seemed to go smoothly. Air Cond would have been a big help. The fans were great. The making of appts issue should be changed or explained to those who had one and still had to wait. I hdad make an appt, but at the first click in my paperwork couldn't be found. I felt uneasy about that

Better communication, no one could answer my question as to when I would find out since I'm pregnant
Don’t tell people the wait is 30-45 minutes when it is will over an hour
Have NH hospitals screen their employees with a drug test before hiring
Need more trash containers spread around

It didn't seem to make a difference if you had an appointment or not, so I didn't understand the point of making the appointment and the wait was a little long. Thank you to all the volunteers though!
I think everything was running very smoothly

6. **For future use, we would like to know how we can improve (continued):**

This clinic was very impressive and well-organized. It felt like being at Disneyworld with a volunteer every 3 feet. The personal consultation was excellent and the process ws very efficient. I think overall the State did an excellent job.
Clinic was very good processing & education, with all the people they did a great job
I can think of nothing to improve the process
Schedule less at one time! Everything was well organized & everyone was very helpful.
This was well run both medically & from a person to person/educational stand point. Thanks for this huge effort.
Keep a closer check on the medical profession
Do the same
more space between appointments. More phlebotomy techs. More lab techs. Empty water bottles and dirty bandaids were scattered throughout school-a lot of staff just hanging around when they should be tending to "trash". Haven't found soap or hand sanitizer in the building.
The DHHS should have known that the Stratham Clinic would be the busiest based on the fact that it is closest to the hospital
(A.C), very humid & hot today. Talk about anxiety! Over 2 1/2 hours, watching people after me getting results
The clinic is very, very well organized for the magnitude of this issue
If after 45 minutes, the same numbers are being called for when we are waiting for results, it's time to "retire" these numbers; it seems this is unnecessary when the patient doesn't respond.
Nothing
Everything went fast and smooth. Thank you
because of a dirty situation but not be clean here! Plus nobody told me to sign consent, after 2 hours they call me and ask to sign consent! Still waiting 3 hrs.
Better shceduling
money. DHHS or someone needs to monitor hospital procedures better! Hospital Management should be held accountable for this nightmare of a situation!
Have more people drawing blood. Lots of areas to draw, but only 4 drawing blood. Discharge line was longer then blood draw. Uncalled for!
Schedule fewer individuals per hour
It is good
Thank you!
Those individuals w/appointments should be in a separate line from the walkins w/o appt.
Everyone was so pleasant !!
Air Conditioning
I think you did the best you could
Coordination of appointments & sufficient staff
Better staffing-more realistic expectations
It seemed pretty smoothunder circumstances
Make sure everyone is registered and maybe less people at once so wait is shorter. Everyone warking here was very very nice and helpful
Less wait time-more numerical consistancy-not random
Be sure all hospital staff are tested for drugs <u>before</u> hiring
No way possible-they were all just great

6. For future use, we would like to know how we can improve (continued):

Seemed disorganized for the level of testing needed
1. Have appts available sooner after notice (letter Monday, first appt Friday) 2. A lto of staff "standing" around. Putmore staff on "doing the job". 3. If you Request/Require appts, those w/o them should be scheculed for a future visit.
Move seniors & people with small children thru first
Not so many people scheduled at one time
Long wait

3:15 Everyone was super nice, from beginning to end. Very organized. P.S. It's now 4:10-2+ hours after I got here-getting ridiculous. 4:25 DONE!! YEAH
Make sure all people are on the same page. Having to pull all the registration people at the same time to have a "Pow-Wow" was not very re-assuring. Turn on the A.C!!
Test every person before they work in a hospital or public place dealling with situations

You should have a sseparate area for the lederly and disabled. I am not elderly or disabled myself but their were a lot here todday and they should have had their own area instead of being conjested in w/the others. Thgere was no rool for people in wheel chairs
Keep doing what you are doing

Advice for Exeter Hospital: Prescreen employees - background check-anyone who works with public in a hospital-should have a complete physical-blood work including drug testing-shame on those other hwspialts who fired "this man" knowing he had Hepititatis C-this could have all been prevented
For screening clinics in the future-final results should go to PCP and individual being tested. Process should be communicated clearly and consistent across all media-not contradictory. Raises frustration and anxieity levels that are already hightened

*saw one of the supervisors take a pen in her mouth & pull off the cap, not good hygiene. *Nobody has talked about the HIV risk for anyone, should this have been included in the screening? *the greeters wre a nice touch but "have a nice day"? We are @ s HepC clinic! some other greeting should have been said. *computer glitches should have been take care of before patients came in

Unfortunately I was one of the many who had to be tested for Hepatitis C. Thankfully my results were negative but was told that I needed to be re-tested again, 6 months after my surgery date. I was also informed that the expense of the re-testing would be my responsibility. This is not something that I caused or something that just happened to me.....Exeter Hospital caused this---- and needs to take full responsibility! Very unsatisfied!!!

The overall responses by DPHS were very good in general, and that was a stark contrast with inept non-responsive manners exhibited by Exeter Hospital and its affiliated doctors. However, the rapid test results could have been obtained a bit quicker

Stratham Testing Clinic
8/11/2012

CLINIC ATTENDEES: **338**
TOTAL NUMBER OF SURVEYS: **132**

1. How did you hear about this public health clinic today? (Check all that apply)

		Response Precent	Response Count
DPHS Letter	77%	77%	102
DPHS Telephone Call	36%	36%	47
Public Announcement	6%	6%	8
Social Media	7%	7%	9
Television	25%	25%	33
Radio	6%	6%	8
Newspaper	15%	15%	20
Other	2%	2%	2

Answered question 128
Skipped question 4

2. On a scale from 1-5 please rate you level of satisfaction with the process to schedule your appointment today:

Very Unsatisfied	Unsatisfied	Neutral	Satisfied	Very Satisfied	Rating Average	Response Count
2	0	3	24	98	4.70	127

Comments: 16

Answered question 127
Skipped question 5

3. On a scale from 1-5 please rate your of satisfaction with having your questions answered:

Very Unsatisfied	Unsatisfied	Neutral	Satisfied	Very Satisfied	Rating Average	Response Count
1	2	15	37	70	4.38	125

Comments: 8

Answered question 125
Skipped question 7

Stratham Testing Clinic (continued)
8/11/2012

4. On a scale from 1-5 please rate your level of satisfaction with the rapid testing today:

Very Unsatisfied	Unsatisfied	Neutral	Satisfied	Very Satisfied	Rating Average	Response Count
1	3	3	30	82	4.59	119

Comments:	18
Answered question	119
Skipped question	13

5. On a scale from 1-5 please rate your overall level of satisfaction with the clinic today:

Very Unsatisfied	Unsatisfied	Neutral	Satisfied	Very Satisfied	Rating Average	Response Count
1	2	2	31	82	4.54	120

Comments:	27
Answered question	120
Skipped question	12

6. For future use, we would like to know how we can improve:

Answered question	39
Skipped question	93

Stratham Testing Clinic (continued)
8/11/2012

COMMENTS SYNOPSIS

2. **On a scale from 1-5 please rate you level of satisfaction with the process to schedule your appointment today:**

Smooth
People were great
Very simple-scheduler called back w/in minutes
Very organized
Very accommodating. Was able to come prepared with needed ID and paperwork to keep me busy while I waited!
I was happy to see I could call until 8 p.m.
The only bad thing was all the initial confusion about when to be tested and then it being canceled. That was not good. But from that point it has been fine.
Registration woman was vry rude about accommodation for blood platelet disease
Was called to make appt after I already scheduled it 1-2 days before
Very courteous, I had to change my appt & they were very accommodating
Fast, organized
Great
Left message…DPHS called right back
Everyone was very very courtious & pleasant, helpful

3. **On a scale from 1-5 please rate your of satisfaction with having your questions answered:**

Good, clear fact sheet
Gave me a Fact Sheet
Good reading material
Was not anything about the disease of other informatino regarding the why factor
Fact Sheet
I didn't receive any education outside of the fact sheet. I already knew that info.
Didn't receive anything other the piece of paper

4. **On a scale from 1-5 please rate your level of satisfaction with the rapid testing today:**

Did not wait, will call Monday
Incredibly organized, very good clinic flow, process-staffing was exceptional-would like more than 1 volunteer to each person to be tested
But my surgery was 4 1/2 months ago and now Im told I need to be retested when I reach 6 months after surgery. I did not kow that

4. **On a scale from 1-5 please rate your level of satisfaction with the rapid testing today (continued):**

Thankyou for the H2O and the snacks while in waiting. Please better screen your employees. Also teest during employment periodically

One person said late appts could wait, another staff down the line said it was too late; then another said I could

Very organized

Would have liked more immediate results left to call Monday as they said it would be an hour wait for results.

Waited for results for an hour but I was told ahead of time it would take an hour to an hour and a half
Wait time is longer thabn it should have been
Very efficient and pleasant process
Was told several different wait lengths: 30 min, 45 min…1.5 hr(s)
Walked in to done blood draw in approx 10 minutes
slow
Waited 2 hours to find that my number had already been called
Thank you for offering the rapid test
Very organized, very pleasant volunteers, excellent phlebotomist! (Michael)

Very impressed with how fast everything moved. From station to station, there was always seomeone ready to move you along!

5. **On a scale from 1-5 please rate your overall level of satisfaction with the clinic today:**

Dept people did a good job
Very very impressive
Very smooth
Very well run-staff very professional, helpful and respectful
The RN which drew my blood was informative
Very well organized
Many volunteers-Very organized. Volunteers were very helpful & police & Caring

Staff was so caring and helpful! Woman in wheelchair was hyper ventilating after leaving building and staff was kindly helping her breath and talking her through her anxiety. Wonderful!
Well organized

Things went more smoothly than anticipated. All the people helping & directing were wonderful.
Everybody was very helpful and nice. My nurse Lynda exceptionally good, very nice
it was very organized
Poor setup for network and the person who signed me in did not receive proper training
Very organized
Very well organized & very friendly volunteers & staff
All people involved were extremely helpful and pleasant-thank you
Went <u>much</u> smoother than expected!
Everyone very helpful, friendly & supportive.

5. **On a scale from 1-5 please rate your overall level of satisfaction with the clinic today (continued):**

People were very comforting, kine & attentive. Very efficient process. Didn't feel rushed, everyone was empathetic & took the time to talk & explain
None, was good as it could be
Everyone ws very nice and considerate
Had to do 2 arms
Great Job! Didn't even hurt!
Well staffed. Well organized. Staff very helpful
Everyone was so pleasant & helpful

6. **For future use, we would like to know how we can improve:**

I missed the initial call and when I then called back the woman said I was not on her list until I gave my date of birth
Invent machine for faster results
get that cool license scanning technology to work!
Margaritas at the end??
Walking from aprking lot to door was a bit intimidating. I would say-don't have so many folks watching you walk up-Yikes!!
Nothing to suggest
Please hire people with AA, BA, BS, MS or higher education.
Make sure everyone has clear information for how to obtain results
The process was very smooth and attendent were pleasant and knowledgable

Staff and services were top shelf. Directions, ssafety, cleanliness and # system made me feel safe and cared for. How one person could put so many at risk-and employees also. Breaks by heart.
Considering its Saturday, I expected mayhem-quite the opposite. Well done, thank you.
Better communication from start. Don't change testing plans.
None
Very well organized!
It was very good

for as unpleasant a situation as we are all in today it was very organized, respectful, & the best it could be-
Nurse should not be rude when I am trying to explain my blood disease and possible accommodations.
Better education for nurses about handling pre existing medial conditions. Orange juide should be provided for folks that need rapid blood sugar increased levels
Make sure staff know how to draw blood
Seemed very well organized-patient comfort & directions here much appreciated. Appreciate the volunteers. Despite the delay from the initial test dates - probably less frustration since took time to organize the clinics @ today's level.

I wished the clinics were organized before word got out. The waiting to be tested was very nerve wracking. Otherwisse, Welldone!! The clinic was well put together and <u>all</u> the staff were wonderful. I was very impressed with all the caring folks, staff and volunteers alike!! Thank you!!

6. **For future use, we would like to know how we can improve (continued):**

Don't need to did great

Perfect!
Put Exeter Hospital under and close the butcher help. This would have never happened if they would have paid attention to strict regulations
Spread the word when waiting period changes
Excellent service all around. Thanks for the coffee & snacks!!
So many volunteers, it went very smooth. Amazing how people can come together to help!
Juice
The whole process was very efficient and all the volunteers were very welcoming and friendly. IN light of a potentially scary situation, you all did a very good job.
Went on Saturday and everything was running very smoothly
Having snacks and drinks was very nice. Thank you
No suggestions-It was organized, friendly and quick
Mandatory testing of ALL health care workers
I think you people did just fine. I got right in for my 10:15 am appointment
Trained people
I think it was very well organized, and all the people were very hellpful & friendly

Have a newspaper reporter-come to show the rapid community response network of a veriety of volunteer groups that mobilized to make the testing process as warm calming and compassionate for the individuals who could feel stressed and vulernable-instead they were welcomed and hands held by their follow citizens of all ages. such as NH Response (Citizens of Community not involved) Americo and others.
People should be make aware of the "Good News" and selfless service to community
Not only spanish for entrance, etc, how abouat doing french also?
Nothing to improve. A great job done for such an unfortunate mess.

Plaistow Testing Clinic
8/14/2012

CLINIC ATTENDEES: **95**
TOTAL NUMBER OF SURVEYS: **39**

1. How did you hear about this public health clinic today? (Check all that apply)

		Response Precent	Response Count
DPHS Letter	87%	87%	33
DPHS Telephone Call	21%	21%	8
Public Announcement	5%	5%	2
Social Media	3%	3%	1
Television	42%	42%	16
Radio	5%	5%	2
Newspaper	11%	11%	4
Other	3%	3%	1

Answered question 38
Skipped question 1

2. On a scale from 1-5 please rate you level of satisfaction with the process to schedule your appointment today:

Very Unsatisfied	Unsatisfied	Neutral	Satisfied	Very Satisfied	Rating Average	Response Count
4	0	3	14	17	4.05	38

Comments: 6

Answered question 38
Skipped question 1

3. On a scale from 1-5 please rate your of satisfaction with having your questions answered:

Very Unsatisfied	Unsatisfied	Neutral	Satisfied	Very Satisfied	Rating Average	Response Count
4	0	1	13	20	4.18	38

Comments: 2

Answered question 38
Skipped question 1

Plaistow Testing Clinic (continued)
8/14/2012

4. On a scale from 1-5 please rate your level of satisfaction with the rapid testing today:

Very Unsatisfied	Unsatisfied	Neutral	Satisfied	Very Satisfied	Rating Average	Response Count
4	3	7	6	13	3.64	33

Comments: 8

Answered question 33
Skipped question 6

5. On a scale from 1-5 please rate your overall level of satisfaction with the clinic today:

Very Unsatisfied	Unsatisfied	Neutral	Satisfied	Very Satisfied	Rating Average	Response Count
5	2	4	12	14	3.76	37

Comments: 9

Answered question 37
Skipped question 2

6. For future use, we would like to know how we can improve:

Answered question 16
Skipped question 23

Plaistow Testing Clinic (continued)
8/14/2012

COMMENTS SYNOPSIS

2. **On a scale from 1-5 please rate you level of satisfaction with the process to schedule your appointment today:**

   A Little slow, but nice people
   Should have more drawers
   Great Job!!
   Very organized - but too many people scheduled - my appt. was 12:30 - left after test at 1:35
   Girl on phone was not especially cooperative or professional
   Call and a letter, friendly helpful staff.

3. **On a scale from 1-5 please rate your of satisfaction with having your questions answered:**

   She was very helpful
   only complaint is I would have liked this done sooner

4. **On a scale from 1-5 please rate your level of satisfaction with the rapid testing today:**

   Need professionals capable of dealing with narrow or difficult veins. I had to wait until Steve was available.
   Instead of EMTs use Red Cross or VNA nurses to draw blood
   Results took much longer than told they would.
   Did not do Rapid Testing
   N/A - under 15 could not do rapid test

   They could not get my blood to flow. The supervisor was able to , but I never had this problem before!!
   Way longer than the "20" minutes we were told.

5. **On a scale from 1-5 please rate your overall level of satisfaction with the clinic today:**

   Intake process very slow. Information could have been otained from Exeter Hospital.
   They did it in an orderly way and they me feel very comfortable.
   Too many people - not enough phlebotomost
   Volunteers were great - some of the people at the clinic well, they should have just stayed home.
   Long wait but not unexpected
   Everyone was very kind and professional
   People are moving very slowly thru the process because they are having trouble drawing blood. I almost walked out!
   Phlebotomist made me feel that the process being followed was not clearly explained to her. Touched prior pts. Viles while doing mine
   Appointment was 12:45p, its now 2:11p and Im still waiting

6. **For future use, we would like to know how we can improve:**

Very well organized
Things went as well as can be for the situation we are in.

Request intake info in advance. Too much time for results. Ruined day wait for intake, for draw, for results. If this is disaster preparedness, NH fails. What happens in a devastating disaster???
More drawers - when it comes to 500 or more people.
My phlebotomist/nurse was EXCELLENT!
Flow was very organized - everyone made you feel more at ease. Very pleasant and helpful
Speed!

I believe you did the best you could under the circumstances - the volunteers were very pleasant and that was very helpful.
More information. I was not aware that my son could not do rapid test.
Great

Make sure to have really good people do the blood draws. Notification was terrible! The original date was cancelled without contacting people. Exeter hospital has everyone's records, we should have been contcted rather than having to call. Also, this test could have been done the last time I had blood drawn (about a month ago)
Moderate temperature for comfort - it was freezing in clinic.
Need clocks at table. Need to have sanitizeer at table. Very stressful and unnerving.

When asked about appointment it seemed more like a scheduled time then the wait. Was not anticipating a wait.

Smaller amount of people more clinics, Overall, great, supportive and friendly staff. Process was smooth, just slow.

I received a letter in the mail telling me about the testing dates and times and called for an appointment and come to find out that they are taking walk-ins. Made for an 1.5 hr delay. I took time off from work to do this. Testing should be done by appontment, most of us work!

Plaistow Testing Clinic
8/15/2012

CLINIC ATTENDEES: **99**
TOTAL NUMBER OF SURVEYS: **38**

1. How did you hear about this public health clinic today? (Check all that apply)

		Response Precent	Response Count
DPHS Letter	79%	79%	30
DPHS Telephone Call	32%	32%	12
Public Announcement	3%	3%	1
Social Media	3%	3%	1
Television	24%	24%	9
Radio	5%	5%	2
Newspaper	16%	16%	6
Other	0%	0%	0

Answered question 38
Skipped question 0

2. On a scale from 1-5 please rate you level of satisfaction with the process to schedule your appointment today:

Very Unsatisfied	Unsatisfied	Neutral	Satisfied	Very Satisfied	Rating Average	Response Count
1	0	0	3	34	4.82	38

Comments: 6

Answered question 38
Skipped question 0

3. On a scale from 1-5 please rate your of satisfaction with having your questions answered:

Very Unsatisfied	Unsatisfied	Neutral	Satisfied	Very Satisfied	Rating Average	Response Count
1	0	0	7	30	4.71	38

Comments: 4

Answered question 38
Skipped question 0

Plaistow Testing Clinic (continued)
8/15/2012

4. On a scale from 1-5 please rate your level of satisfaction with the rapid testing today:

Very Unsatisfied	Unsatisfied	Neutral	Satisfied	Very Satisfied	Rating Average	Response Count
2	0	0	2	28	4.69	32

Comments:	8
Answered question	32
Skipped question	6

5. On a scale from 1-5 please rate your overall level of satisfaction with the clinic today:

Very Unsatisfied	Unsatisfied	Neutral	Satisfied	Very Satisfied	Rating Average	Response Count
1	0	0	3	30	4.79	34

Comments:	8
Answered question	34
Skipped question	4

6. For future use, we would like to know how we can improve:

Answered question	10
Skipped question	28

Plaistow Testing Clinic (continued)
8/15/2012

COMMENTS SYNOPSIS

2. **On a scale from 1-5 please rate you level of satisfaction with the process to schedule your appointment today:**

   Staff was amazing. Very helpful and understanding
   Very Easy
   Very efficient and friendly
   Very organized
   Excellent Setup!
   It was quick and easy, I was treated by courteous staff members.

3. **On a scale from 1-5 please rate your of satisfaction with having your questions answered:**

   The on hand doctor anwered all of my questions.
   Very knowledgeable and helpful
   Precise right to the point

4. **On a scale from 1-5 please rate your level of satisfaction with the rapid testing today:**

   did not wait for result
   Quick and easy, friendly people
   Did not opt for rapid testing
   no one told me about the # they would call or what # I had
   Kelly was very nice and did a great job
   In and out very quickly

5. **On a scale from 1-5 please rate your overall level of satisfaction with the clinic today:**

   Very well organized! Friendly people!
   Went great
   very organized process
   volunteer staff excellent in all respects
   very efficient and friendly personnel
   Very smooth process staff made us very comfortable. Thak you to all who volunteered for us.
   Everyone was very nice
   We went to Timberland High School and the service was excellent, could not be better

6. **For future use, we would like to know how we can improve:**

Well managed.
Use of email to get info and test results.
Everything went well, and very orderly
Everything was finee except when I was registering. My DOB was wrong on your list. The month was wrong. Not sure if that's a big deal.
Can't/none needed
No suggestions everything was wonderful, during this difficult time.
Great job by all I encountered! Very friendly & professional
Excellent!! Very Quick and polite
Stay the course.
No way could you be better. I'm 87 years old. Have been in six different hospitals and I do like Exeter very much. Thank you very kindly.

Rochester Testing Clinic
8/16/2012

CLINIC ATTENDEES: **77**
TOTAL NUMBER OF SURVEYS: **42**

1. How did you hear about this public health clinic today? (Check all that apply)

		Response Precent	Response Count
DPHS Letter	69%	69%	27
DPHS Telephone Call	41%	41%	16
Public Announcement	3%	3%	1
Social Media	0%	0%	0
Television	18%	18%	7
Radio	0%	0%	0
Newspaper	5%	5%	2
Other	8%	8%	3

Answered question 39
Skipped question 3

2. On a scale from 1-5 please rate you level of satisfaction with the process to schedule your appointment today:

Very Unsatisfied	Unsatisfied	Neutral	Satisfied	Very Satisfied	Rating Average	Response Count
3	0	3	7	29	4.40	42

Comments: 5

Answered question 42
Skipped question 0

3. On a scale from 1-5 please rate your of satisfaction with having your questions answered:

Very Unsatisfied	Unsatisfied	Neutral	Satisfied	Very Satisfied	Rating Average	Response Count
2	0	1	12	27	4.48	42

Comments: 1

Answered question 42
Skipped question 0

Rochester Testing Clinic (continued)
8/16/2012

4. On a scale from 1-5 please rate your level of satisfaction with the rapid testing today:

Very Unsatisfied	Unsatisfied	Neutral	Satisfied	Very Satisfied	Rating Average	Response Count
2	1	3	9	24	4.33	39

Comments: 5

Answered question 39
Skipped question 3

5. On a scale from 1-5 please rate your overall level of satisfaction with the clinic today:

Very Unsatisfied	Unsatisfied	Neutral	Satisfied	Very Satisfied	Rating Average	Response Count
2	0	3	11	23	4.36	39

Comments: 2

Answered question 39
Skipped question 3

6. For future use, we would like to know how we can improve:

Answered question 12
Skipped question 30

COMMENTS SYNOPSIS

2. On a scale from 1-5 please rate you level of satisfaction with the process to schedule your appointment today:

The only day for testing in my area was an inconvenient day, but that was ok.
Really appreciate the phone call to schedule appt.
Staff very polite and caring, helpful. Moved through process quickly.
Very nice and helpful
Need telephone book or a list of primary Drs for area.

Rochester Testing Clinic (continued)
8/16/2012

3. **On a scale from 1-5 please rate your of satisfaction with having your questions answered:**

   Friendly

4. **On a scale from 1-5 please rate your level of satisfaction with the rapid testing today:**

   Should not be called rapid test, waited a while - should be called while you wait test
   Good Job!!! :)
   She called numbers several times in case you stepped out or didn't hear.
   Had to wait too long
   No rapid under 15

5. **On a scale from 1-5 please rate your overall level of satisfaction with the clinic today:**

   All staff were very helpful and efficient

   This clinic was VERY well run, plenty of knowledgable staff to assist with ANY questions and/or concerns

6. **For future use, we would like to know how we can improve:**

   This works perfect.
   Everything went as smooth as you could get.
   More water
   Everything was great, thanks! :)
   Do one in Dover. Carol was great.
   Nothing
   Pizza
   All good
   Less wait time overall. More convenient scheduling times.
   With so many unstabled people in this world I was surprised no one was screened for fire arms nor did I see any police on the premises - unless they had uncovered police.
   Appointment I made the 1st appt of the day - yet had to wait for 5-6 others :). Fortunately, I was able to wait.

Manchester Testing Clinic
8/16/2012

CLINIC ATTENDEES: **43**
TOTAL NUMBER OF SURVEYS: **26**

1. How did you hear about this public health clinic today? (Check all that apply)

		Response Precent	Response Count
DPHS Letter	75%	75%	18
DPHS Telephone Call	42%	42%	10
Public Announcement	8%	8%	2
Social Media	4%	4%	1
Television	21%	21%	5
Radio	0%	0%	0
Newspaper	4%	4%	1
Other	8%	8%	2

Answered question 24
Skipped question 2

2. On a scale from 1-5 please rate you level of satisfaction with the process to schedule your appointment today:

Very Unsatisfied	Unsatisfied	Neutral	Satisfied	Very Satisfied	Rating Average	Response Count
1	0	2	6	15	4.42	24

Comments: 4

Answered question 24
Skipped question 2

3. On a scale from 1-5 please rate your of satisfaction with having your questions answered:

Very Unsatisfied	Unsatisfied	Neutral	Satisfied	Very Satisfied	Rating Average	Response Count
1	0	5	8	9	4.04	23

Comments: 2

Answered question 23
Skipped question 3

Manchester Testing Clinic (continued)
8/16/2012

4. On a scale from 1-5 please rate your level of satisfaction with the rapid testing today:

Very Unsatisfied	Unsatisfied	Neutral	Satisfied	Very Satisfied	Rating Average	Response Count
1	0	1	5	13	4.45	20

Comments:	2
Answered question	20
Skipped question	6

5. On a scale from 1-5 please rate your overall level of satisfaction with the clinic today:

Very Unsatisfied	Unsatisfied	Neutral	Satisfied	Very Satisfied	Rating Average	Response Count
2	0	1	3	19	4.48	25

Comments:	5
Answered question	25
Skipped question	1

6. For future use, we would like to know how we can improve:

Answered question	11
Skipped question	15

Manchester Testing Clinic (continued)
8/16/2012

COMMENTS SYNOPSIS

2. **On a scale from 1-5 please rate you level of satisfaction with the process to schedule your appointment today:**

   Excellent foll up to contact pt.
   A very scary, nerve wtacking process but staff were attentive & friendly
   Considering the unpleasant reason that I am here, everyone was very kind & helpful.

3. **On a scale from 1-5 please rate your of satisfaction with having your questions answered:**

   Staff was very accommodating & friendly

4. **On a scale from 1-5 please rate your level of satisfaction with the rapid testing today:**

   Do not have results yet
   did not perform yet

5. **On a scale from 1-5 please rate your overall level of satisfaction with the clinic today:**

   Nice touch with snacks & coffee
   The services & people who provided them were so personable. They make you so comfortabel. It was actually fun & enjoyable, from beginning to end.
   I think the saff were great, did everything to make you as comfortable as possible.
   Helpful and informative
   Very professional staff

6. **For future use, we would like to know how we can improve:**

   The whole process today was efficient and very well organized. Every single person whom I came in contact with today was very kind. Thank you so such for making a scary situation a lot less daunting….you have a great group of people here.

   No need, everytying very smooth, very efficient staff. Extra nice touch to accommodate the children
   Do not say things like "good luch", and "you should be pretty satified & confident in the results" in response to the query "how sure will I be of the results of the rapid test." Otherwise, process went smoothly and staff were sensitive and efficient
   Keep up the good work!
   Everything was great!
   You really could not in my opinion
   Warn patients about the packet of paperwork and to arrive earlier

6. **For future use, we would like to know how we can improve (continued):**

I think it would be good when you call people to make appointments, you mention that you have to go to the back of the building. It was difficult for us as we parked on Elm St, and walk was difficult for my husband.

I was one of the first here @ 8:15a.m. There seemed to be an over-abundance of volunteers/workers, though all were very nice. They all seemed a little nervous and confused. Perhaps because I was the first of the day. I hope the process became more streamlined andn efficient as the day went on. Perhaps too many volunteers

No ideas

In the case of large scale testing-more phone lines need to be added to make sure people can get through- I received a fast busy call circuits busy for over an hour

Manchester Testing Clinic
8/17/2012

CLINIC ATTENDEES: **34**
TOTAL NUMBER OF SURVEYS: **18**

1. How did you hear about this public health clinic today? (Check all that apply)

		Response Precent	Response Count
DPHS Letter	67%	67%	12
DPHS Telephone Call	39%	39%	7
Public Announcement	6%	6%	1
Social Media	6%	6%	1
Television	17%	17%	3
Radio	0%	0%	0
Newspaper	11%	11%	2
Other	0%	0%	0

Answered question 18
Skipped question 0

2. On a scale from 1-5 please rate you level of satisfaction with the process to schedule your appointment today:

Very Unsatisfied	Unsatisfied	Neutral	Satisfied	Very Satisfied	Rating Average	Response Count
1	0	2	2	13	4.44	18

Comments: 4

Answered question 18
Skipped question 0

3. On a scale from 1-5 please rate your of satisfaction with having your questions answered:

Very Unsatisfied	Unsatisfied	Neutral	Satisfied	Very Satisfied	Rating Average	Response Count
1	0	2	3	11	4.35	17

Comments: 1

Answered question 17
Skipped question 1

Manchester Testing Clinic (continued)
8/17/2012

4. On a scale from 1-5 please rate your level of satisfaction with the rapid testing today:

Very Unsatisfied	Unsatisfied	Neutral	Satisfied	Very Satisfied	Rating Average	Response Count
1	0	1	4	10	4.38	16

Comments:	1
Answered question	16
Skipped question	2

5. On a scale from 1-5 please rate your overall level of satisfaction with the clinic today:

Very Unsatisfied	Unsatisfied	Neutral	Satisfied	Very Satisfied	Rating Average	Response Count
1	0	1	4	11	4.41	17

Comments:	3
Answered question	17
Skipped question	1

6. For future use, we would like to know how we can improve:

Answered question	2
Skipped question	16

Manchester Testing Clinic (continued)
8/17/2012

COMMENTS SYNOPSIS

2. **On a scale from 1-5 please rate you level of satisfaction with the process to schedule your appointment today:**

   Was out of town when phone calls were left. I called when back in town
   They were efficient over the phone to schedule a time for me to be tested
   Process was fast, staff was friendly. Atmosphere was made to be as comfortable as possible given the circumstances.
   Everyone was very helpful

3. **On a scale from 1-5 please rate your of satisfaction with having your questions answered:**

   I didn't ask any questions to have answered

4. **On a scale from 1-5 please rate your level of satisfaction with the rapid testing today:**

   I only wish that they had told me I could wait for rapid results when I set up the appt.

5. **On a scale from 1-5 please rate your overall level of satisfaction with the clinic today:**

   All of the staff were friendly and great towards my 2 yr old that came with me
   Everyone was very nice
   Susan & Kris wwere wonderful. Everyone made me feel very welcome!

6. **For future use, we would like to know how we can improve:**

   Continue to utilize the woman who drew my blood. Kris B. Due infertility treatments, small, uncooperative veins. I tend to be an extremely hard stick. She took her time, listened to what I hd to say, took excellent direction, was super sweet and very understanding. She also got me on the first stick. If I could have her draw my blood everytime it needed to be done I would. She was absolutely awesome.
   The only problem I had was when I was trying to make an appointment there was a little communication problem

Manchester Testing Clinic
8/18/2012

CLINIC ATTENDEES: **29**
TOTAL NUMBER OF SURVEYS: **20**

1. How did you hear about this public health clinic today? (Check all that apply)

		Response Precent	Response Count
DPHS Letter	60%	60%	12
DPHS Telephone Call	60%	60%	12
Public Announcement	15%	15%	3
Social Media	10%	10%	2
Television	10%	10%	2
Radio	10%	10%	2
Newspaper	10%	10%	2
Other	0%	0%	0

Answered question 20
Skipped question 0

2. On a scale from 1-5 please rate you level of satisfaction with the process to schedule your appointment today:

Very Unsatisfied	Unsatisfied	Neutral	Satisfied	Very Satisfied	Rating Average	Response Count
0	0	1	6	12	4.58	19

Comments: 5

Answered question 19
Skipped question 1

3. On a scale from 1-5 please rate your of satisfaction with having your questions answered:

Very Unsatisfied	Unsatisfied	Neutral	Satisfied	Very Satisfied	Rating Average	Response Count
0	0	0	4	16	4.80	20

Comments: 2

Answered question 20
Skipped question 0

Manchester Testing Clinic (continued)
8/18/2012

4. On a scale from 1-5 please rate your level of satisfaction with the rapid testing today:

Very Unsatisfied	Unsatisfied	Neutral	Satisfied	Very Satisfied	Rating Average	Response Count
0	0	0	1	17	4.94	18

Comments:	5
Answered question	18
Skipped question	2

5. On a scale from 1-5 please rate your overall level of satisfaction with the clinic today:

Very Unsatisfied	Unsatisfied	Neutral	Satisfied	Very Satisfied	Rating Average	Response Count
0	0	0	3	16	4.84	19

Comments:	8
Answered question	19
Skipped question	1

6. For future use, we would like to know how we can improve:

Answered question	10
Skipped question	10

Manchester Testing Clinic (continued)
8/18/2012

COMMENTS SYNOPSIS

2. **On a scale from 1-5 please rate you level of satisfaction with the process to schedule your appointment today:**

   Kris was fantastic!

   I received a latter, called the number, made appt, got another call an hr later to confirm. Great service
   I wasn't happy with the cancelation of the initial testing palnned-I understand not being ready for this large testing, but why put it out there just to cancel
   Everyone was so nice!
   I did not like sign out front Hep C testing, embarrassed, daughter asked what is Hep C

3. **On a scale from 1-5 please rate your of satisfaction with having your questions answered:**

   I have read the info available so I have not had many questions-If I am found positive, I will have many more questions
   Just did not like the signs, felt like I have a disease and everyone knows-but I am glad the State stepped in….

4. **On a scale from 1-5 please rate your level of satisfaction with the rapid testing today:**

   I was notified in 20 minutes of the results
   The phlebotomist was very friendly and put people @ ease
   Not waiting
   Everyone I have talked to waked by have been very friendly, helpful and supportive
   I am very happy the State stepped in!! They did a great job and the people were great!!

5. **On a scale from 1-5 please rate your overall level of satisfaction with the clinic today:**

   Everyone was kind and helpful. It helped to ease the stress of a tough situation
   The whole staff, was very helpful, friendly. The nurses (Lisa & Chris) were wonderful and eased any nervousness I had during the process. Very professional staff.
   -10
   Kris was very helpful and professional when drawing blood-made me feel comfortable.
   Everyone was very pleasant. They really cared about my experience here.
   Everything has been on-time quick even. The nurse who took my blood was especially nice and very easy to talk to Carey (I believe) also did a great job finding a vein, etc…..
   I was treated very nice. Kris taking blood was great!
   I am happy the State stepped in 2 1/1 months ago. Exeter told me don't worry about it

Manchester Testing Clinic (continued)
8/18/2012

6. **For future use, we would like to know how we can improve:**

Just thanks for being here
N/A
Everyone was very nice and informative, thank you
This was so easy, comforting and quick-fabulous staff!!! My only wish would be signage for where to park.
Again, fabulous staff!!!!!!
Very quick with my draw, was satisfied
Maybe get some infant arm guards for wormy babies
Very organized

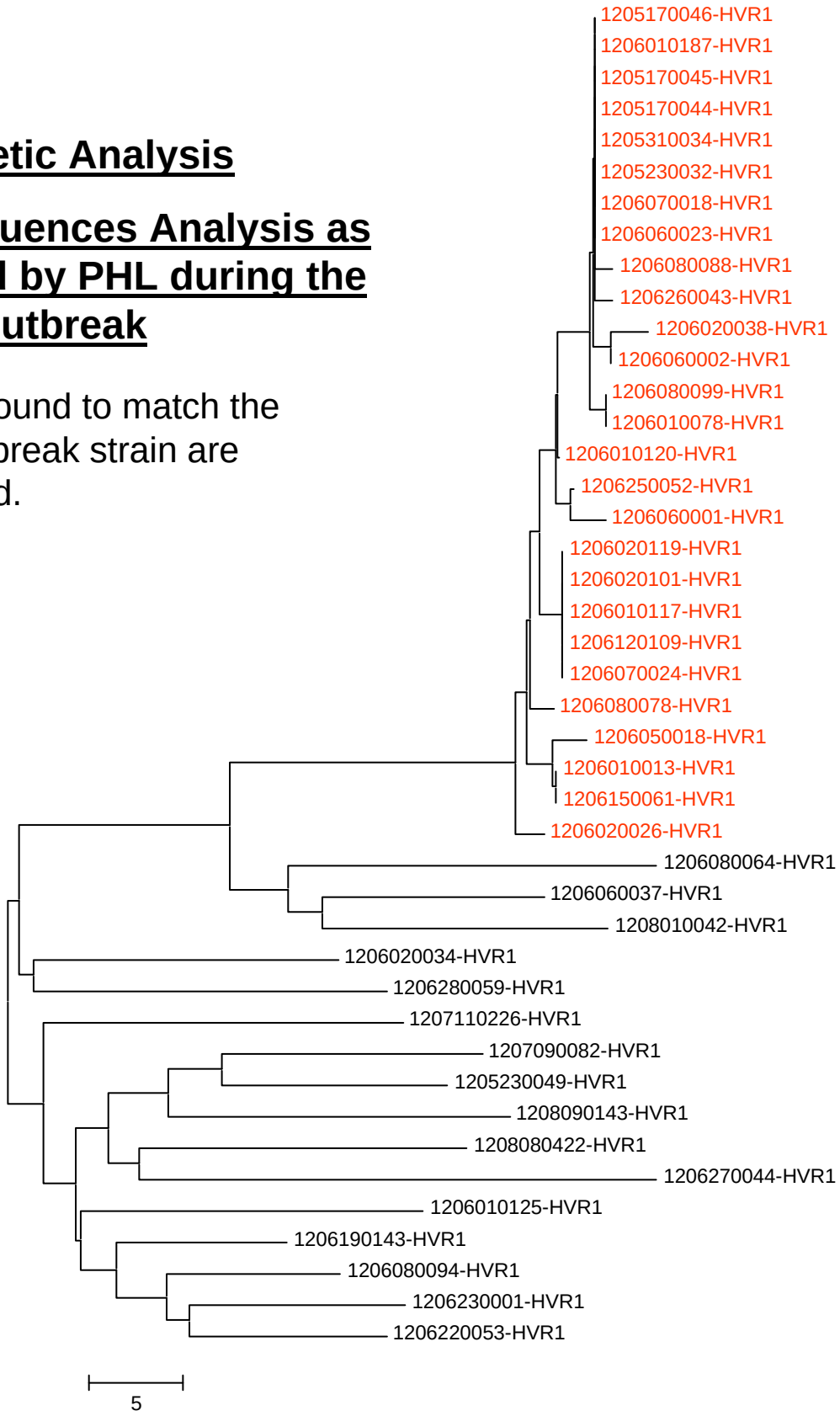
The signs-maybe a sign that said Exeter Hospital testing not Hepatitis C testing. Feels uncomfortable.
Very pleased w/Kris

Appendix 16: Phylogenetic Tree

Phylogenetic Analysis

HVR1 Sequences Analysis as Performed by PHL during the EH HCV Outbreak

Sequences found to match the NH HCV outbreak strain are marked in red.



Appendix 17: Risk Notification Template

STATE OF NEW HAMPSHIRE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

29 HAZEN DRIVE, CONCORD, NH 03301-6527
603-271-4496 1-800-852-3345 Ext. 4496
Fax: 603-271-0545 TDD Access: 1-800-735-2964

Nicholas A. Toumpas
Commissioner

José Thier Montero
Director

Bureau of Infectious Disease Control
Risk Communication Notification (RCN)

DATE: April 20, 2012 TIME: EDT

TO:

FROM: Bureau of Infectious Disease Control

SUBJECT:

Current Situation:

Potential Risk(s):

The NH Division of Public Health Services (DPHS) Recommends:

- Prophylaxis:
- Resources/References:

Requested Action(s):

Response Requested:

Time of Response:

Public / Media Outreach:

- ☐ Public Meeting
- ☐ Press Release
- ☐ Press Conference
- ☐ Closed Informational Meeting
- ☐ _____

DPHS Key Contact Information:

Attachments:

Appendix 18: HCV Outbreak Investigation Summary of Initial Testing

Hepatitis C Virus (HCV) Outbreak Investigation Initial Testing Summary, May 15, 2012 – May 1, 2013

Summary	Exeter Hospital CCL and Recovery Area Patients October 1, 2010 - May 25, 2012	Exeter Hospital Main OR and ICU Patients April 1, 2011 – May 25, 2012	Total Among Indicated Patients	Exeter Hospital Employees Indicated For Testing[4]	Total Among Indicated People	Patients not Indicated for Testing
People[1] Indicated for Testing	1214	3505	4719	294	5013	N/A
People Tested	1074	2679	3753	231	3984	95
People unable to test [2, 3]	132	254	386	63	449	N/A
People with no evidence of active HCV infection	997	2622	3619	226	3845	93
People with past HCV infection (cleared infection)	27	28	55	3	58	0
People with active HCV infection matching outbreak	32	0	32	1	33	0
People with active HCV infection unrelated to outbreak	18	29	47	1	48	2
People still to be tested	8	572	580	0	580	N/A

Notes:

1. Individuals indicated for testing refers to patients having a procedure in the cardiac catheterization lab or the recovery area from October 1, 2010 to May 25, 2012 and patients undergoing procedures in the main operating room and patients admitted to the intensive care unit from April 1, 2011 to May 25, 2012 at Exeter Hospital in Exeter, New Hampshire based on data provided by Exeter Hospital. Results include specimens tested at NH PHL and other laboratories.
2. Patients unable to test include patients who died prior to testing and persons who have refused testing to date.
3. Employees unable to test include persons who did not submit a specimen but whose involvement was ruled out in another way.
4. Employees indicated for testing refers to all Exeter Hospital employees recommended for testing at some point during the investigation. After testing recommendations were narrowed the indication included 154 employees.