TO: Physicians, Physician Assistants, Nurses, Infection Control Practitioners, Infectious Disease Specialists, Practice Managers, Bordering State Epidemiologists, Hospital Emergency Departments, Hospital CEOs, Laboratory Response Network, Manchester Health Department, Nashua Health Department, NHHA, Community Health Centers, EWIDS, DHHS Outbreak Team, DPHS Investigation Team, Public Health Network, and DPHS Management Team

FROM: Jodie Dionne-Odom, MD, Deputy State Epidemiologist

SUBJECT: Update #2 on Hepatitis C Virus (HCV) Outbreak

NH Division of Public Health Services (DPHS) recommends:

- Awareness of investigation updates on the hepatitis C outbreak at Exeter Hospital.
- Familiarity with new testing guidelines and follow up testing recommendations for potentially exposed individuals
- Awareness of networks of care to assist with the management of patients with newly diagnosed hepatitis C

Epidemiology:

NH DPHS Bureau of Infectious Disease Control was notified on May 15, 2012, of four persons with recently diagnosed hepatitis C virus (HCV) at Exeter Hospital. Further testing revealed that all cases shared an identical HCV strain, indicating a common source of infection. The common exposure among all cases was the cardiac catheterization laboratory in Exeter Hospital.

Based on investigation findings, we have recently extended our testing window and are recommending HCV testing for any individual who received care in the Exeter cardiac catheterization laboratory or its post procedure room between October 1, 2010, and May 25, 2012. This includes approximately 1200 potentially exposed patients and Exeter Hospital has sent letters to these individuals and contacted them by telephone with the testing recommendation. As of June 20, 2012, we have received 931 specimens at the NH Public Health Laboratories and we have finalized results on 868 of them.

We have identified a total of twenty individuals (one of whom is a healthcare worker) with the outbreak strain. We have also identified eight individuals with active HCV infection that is not related to the outbreak strain.
Based on the investigation thus far, the most likely cause of this outbreak is drug diversion. Appropriate state and federal partners are involved and the public health investigation is ongoing.

**Laboratory Testing:**
There are now several options for patient blood draws:

A) Blood can be drawn at Exeter Hospital. Their Information and Referral Center line is 603-580-6124.

B) The second option (as of June 20th, in response to requests for additional sites), is to go to one of the two drawing stations listed below. Patients have been instructed to bring the letter they received from Exeter Hospital stating that they need bloodwork in order to verify indication for testing.

1. PRH Collection Station  Monday-Thursday 8 am-4 pm  Closed 1-1:30 pm
   55 High Street Suite 104
   Hampton, NH 03842

2. PRH Collection Station  Monday-Thursday 8 am-4 pm  Closed 1-1:30 pm
   Pease International Tradeport
   26 Manchester Square
   Portsmouth, NH 03801

C) The third option we are giving patients is to have their bloodwork ordered and drawn by their provider. If you have a patient who prefers this option, specimen collection guidelines are attached and you can print out the requisition form online at http://www.dhhs.nh.gov/dphs/cdcs/hepatitisc/hepc-investigation.htm

The blood will be tested by NH Public Health Laboratories (PHL) and the initial test performed will be hepatitis C antibody. If the serology is positive, HCV viral sequencing and genotyping will be performed. Results will be available within 10 days and all results will be directly called to patients by DPHS staff. Positive results will be called to provider offices and copies of all lab results (positive or negative) will be sent directly to the listed primary care provider (PCP). Any blood test with positive results will be sent to CDC (Centers for Disease Control and Prevention) Laboratories for confirmatory testing.

**For Primary Care Providers of Exposed Persons**

Some of the individuals tested may have listed you as their PCP. If so, we will be contacting you by mail with any test results within 10 days of blood draw (see the attached updated provider letter that will go out with all laboratory results). We will call you directly with any positive results on your patient. We can mail you results of HCV antibody and PCR testing (positive or negative) for your records, but not the results of sequencing tests since these are only approved for public health purposes (identifying an outbreak strain), not for clinical use. Final sequencing results, performed by CDC laboratories, may take a few weeks. Patients without a primary care provider will receive a direct call and letter from NH DPHS with laboratory results and additional information.

We have recommended that all patients have medical follow up with their primary care provider. We also recommend referral to a hepatitis specialist for any with newly detected active hepatitis
C infection (PCR positive) given the benefits of early therapy and complicated decision making around assessing eligibility and monitoring for adverse effects from therapy.

Exeter Hospital has created a Hepatitis C Task Force to coordinate care for those individuals with newly diagnosed hepatitis C infection. This group is in the process of contacting all patients with matching infection and they are a resource for non-matching cases as well. For any patient who prefers to seek medical care from an alternate provider or network, we have a hepatitis C resource guide that can be used to help identify other local resources for the management of hepatitis C. If you (or your patient) are interested in this resource, please contact DPHS directly at (603) 271 4496.

There is also a general resource available for NH HIV/STD/Viral Hepatitis on our website: http://www.dhhs.nh.gov/dphs/cdcs/hepatitisc/documents/resource-guide.pdf

**Follow Up Testing**

See the attached provider letter and algorithm for recommendations about follow up testing. The algorithm is complicated and shows that testing is dependent on most recent procedure dates in the Exeter Cardiac Catheterization Laboratory or post-procedure unit. The following patients need follow up testing (at no charge):

- Those with negative HCV serology on the first test and their latest procedure dated December 1, 2011 through March 1, 2012, need follow up HCV serology tests in 6 months time. We kindly request for you to order this testing and contact us if any of these follow up serology tests are positive.

- Those with negative HCV serology and negative HCV PCR but with a recent procedure dated May 1st-May 25th, 2012 will need a follow up PCR in four weeks. Patients will be contacted directly by Exeter Hospital to arrange this.

**Mental Health Support**

If you have any patients who are having a difficult time with this ongoing situation and would like to talk to someone about it, a few good resources are Community Mental Health Centers in Portsmouth (603 431 6703) or in Exeter (603 772 2710). They are aware of the situation and the testing recommendations for this sizable group of individuals. They are available 24/7 with an answering service for off hours to help direct calls to the right person.

**Additional Requested Actions:**

In order to help us identify other cases of recent hepatitis C, we continue to request that you contact us directly at the number below if you have seen cases of recently diagnosed hepatitis C in your medical practice since January 2011. Please contact our office so that we may coordinate receipt of this information.

This is an ongoing investigation and we will continue to update you with changes in clinical recommendations or requests for additional information. Do not hesitate to contact us anytime with questions or concerns related to this investigation or your patients.

For additional information and resources on the investigation:
http://www.dhhs.nh.gov/dphs/cdcs/hepatitisc/hepc-investigation.htm
Attachments:
1) Updated HCV Testing Algorithm
2) Updated Provider Letter
3) Specimen Collection Guidelines

For any questions regarding the contents of this message, please contact NH Department of Health and Human Services, Division of Public Health Services’ Bureau of Infectious Disease Control at 603-271-4496.

After hours or toll free (in NH), call 800-852-3345, ext. 4496 or 603-271-5300 and ask for the public health professional on call.
DEFINITION OF TERMS AND ALERTING VOCABULARY

Message Type
- Alert: Original alert
- Update: Prior alert has been updated and superseded
- Cancel: Prior alert has been cancelled
- Error: Prior alert has been retracted

Status
- Actual: Refers to a live event
- Exercise: Designated recipients must respond to the communication or alert
- Test: Related to a technical and/or system test

Severity
- Extreme: Extraordinary threat to life or property
- Severe: Significant threat to life or property
- Moderate: Possible threat to life or property
- Minor: Minimal threat to life or property
- Unknown: Unknown threat to life or property

Sensitive
- Sensitive: Indicates the alert contains sensitive content
- Not Sensitive: Indicates non-sensitive content

Message Identifier
A unique alert identifier that is generated upon alert activation

Delivery Time
Indicates the time frame for the delivery of the alert

Acknowledgement
Indicates whether an acknowledgement on the part of the recipient is required to confirm that the alert was received, and the time frame in which a response is required.

Originating Agency
A guaranteed unique identifier for the agency originating the alert.

Alerting Program
The program sending the alert or engaging in alerts and communications using PHIN Communication and Alerting (PCA) as a vehicle for their delivery.

You have received this message based upon the information contained within our emergency notification database.

If you have a different or additional e-mail or fax address that you would prefer to be used, please contact:

Denise M. Krol, MS
NH HAN Coordinator
Denise.Krol@dhhs.state.nh.us

Business Hours: 8 AM – 4 PM
Tel: 603-271-4596
Fax: 603-271-0545
HCV Testing Algorithm

HCV testing indicated

Procedure date: March 1 2012 or after

Serology

Pos

PCR

Neg

Procedure date: 5/1/12 or after

Inconclusive
Repeat PCR in 4 weeks by PHL

Pos

No evidence of Infection
No need for Repeat testing

Procedure date: 3/1/12-4/30/12

Neg

PCR

Repeat serology in 6 months by pcp

Procedure date: before March 1, 2012

Serology

Pos

PCR

Neg

No evidence of Infection

Last procedure before 12/1/11
No need for Repeat testing

Sequence

<98 % homology

Match (=98% homology)

Quasi Sp. (CDC)

Confirmed Related Case

Confirmed Unrelated Non-case

Update – 6.20.12

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

• + All positive results called to provider
June 21, 2012

Dear Provider,

You are receiving this letter because your patient was identified as potentially exposed to hepatitis C virus (HCV) as part of a Department of Health and Human Services outbreak investigation at Exeter Hospital (laboratory report enclosed). The patient has undergone HCV testing which was completed at the NH Public Health Laboratories. Our testing methodologies include HCV antibody, HCV RNA PCR and viral sequencing. The sequencing tests are available to public health professionals and are very useful in outbreak situations but these tests are not available or approved for clinical use. We are contacting patients by telephone with their laboratory results and we are also calling providers directly with any positive laboratory results.

The reports we can provide you with (serology and PCR) for your patient are attached and our interpretation is as follows:

- If the HCV antibody result report reads "Hepatitis C Antibody: Positive" AND the HCV PCR report result reads "Hepatitis C Virus RNA: Negative": This patient was infected with HCV at some point and has cleared the infection. The laboratory has no virus to sequence to determine if it matches the outbreak strain of HCV. The timing of infection cannot be determined from these laboratory results, although prior serology results would be useful, if available. Follow up HCV testing as part of this outbreak investigation is not necessary.

- If the HCV antibody result report reads "Hepatitis C Antibody: Positive" or "Hepatitis C Antibody: Negative" AND the HCV PCR report result reads "Hepatitis C Virus RNA: Positive": This patient has an active HCV infection and additional tests are being performed to determine if this strain matches the outbreak strain of HCV. These patients with active hepatitis C infection should be referred to a hepatitis specialist for consideration of early antiviral therapy.

NH DHHS will call you as well as the patient to discuss sequencing results and inform you both whether or not they were likely infected as part of the current outbreak. This additional testing may take several weeks and for technical reasons, not every virus that is detected with PCR will be able to be sequenced. We will not be able to provide you with a written report of sequencing findings since it is only approved for public health purposes.

- If the HCV antibody result report reads "Hepatitis C Antibody: Negative" AND HCV PCR report result reads "Hepatitis C Virus RNA: Negative": This combination of testing results requires also considering the patient’s procedure date at the Exeter Hospital.
If the procedure was done May 1, 2012 or after, this should be considered inconclusive, and the patient should have a repeat HCV PCR 4 weeks after the first test. Exeter Hospital will be calling these patients to help schedule this follow up testing and you do not need to schedule or order this testing. If your patient prefers to have their blood drawn at an alternate location, we have made these arrangements and they can call us at (603) 271 4496 for details. We will be contacting the patient with their subsequent results and providing you with results as well.

If the procedure was done between March 1st and April 30th, 2012, no additional testing is necessary.

- If the HCV antibody result report reads "Hepatitis C Antibody: Negative" AND there is no HCV PCR report included, this patient currently shows no evidence of infection. However, this patient should undergo repeat testing by serology in 6 months if their most recent care in the Exeter Hospital cardiac catheterization laboratory (or post procedure unit) was on or after December 1st, 2011. We kindly request for you to order this testing and contact us if any of these follow up serology tests are positive. If their procedure was before December 1st, 2011, no additional testing is necessary.

Please refer to the Health Alert Network (HAN) Messages for testing algorithms and additional information targeted to New Hampshire providers about this ongoing hepatitis C investigation at http://www.dhhs.nh.gov/dphs/cdcs/alerts/han.htm. Contact Denise Krol at (603) 271 4596 or denise.krol@dhhs.state.nh.us if you would like to be added to the HAN distribution list.

If you have any questions, please contact Division of Public Health Services, Bureau of Infectious Disease Control, 603-271-4496.

Christine Bean, Ph.D., MBA, MT(ASCP)
NH Public Health Laboratory Director

Sharon Alroy-Preis, MD, MPH
NH State Epidemiologist.

The Department of Health and Human Services’ Mission is to join communities and families in providing opportunities for citizens to achieve health and independence.
HEPATITIS C BLOOD SPECIMENS: INSTRUCTIONS FOR COLLECTION AND TRANSPORTATION

**MUST BE DELIVERED TO THE PHL WITHIN 48 HOURS OF COLLECTION**
Specimen: 3 – 5 ml serum

**Procedure for Collection:**
1. Identify the patient and perform venipuncture using standard aseptic technique.

2. Fill SST Vacutainer tubes with the correct amount of blood (preferably two 10 ml tubes).

3. **Label the tubes with the patient’s name and date and time of collection.**

4. **Verify that the name on the tube and the name on the requisition are the same and correlate with the patient whose blood was drawn.** Verify that spelling is the same on the tubes and the requisition form.

5. ***Fill out all the requisition form completely and legibly. Assure complete Primary Care Physician information is included with address and phone number.***

6. **Assure the date(s) of the cardiac/vascular procedure is noted and the patient has signed the consent section. If specimen collection is from an employee, please note that on the requisition. If specimen is for testing following an initial negative test result (4 weeks or 6 months after initial testing), please note that on the requisition.**

**Procedure for Transport***:
7. **SAMPLES MUST BE RECEIVED AT THE NH PUBLIC HEALTH LABORATORIES WITHIN 48 HOURS OF COLLECTION. SPECIMENS RECEIVED BEYOND 48 HOURS AFTER COLLECTION WILL BE REJECTED. IF YOU HAVE ANY QUESTIONS ABOUT THIS, PLEASE CALL THE LAB AT 603-271-2764 OR 603-271-4661.**

8. SST tubes MUST be centrifuged prior to transport.

9. All specimens must be shipped in a leak-proof container. Place the properly labeled blood tubes into a leak-proof container. (Make sure there is enough absorbent material available to cushion tubes and contain specimen should there be any breakage of the tubes.)

10. **Secure the requisition form on the outside of the leak-proof container.**

11. Insert the leak-proof container into a rigid outer container suitable for transport.

12. Store specimens at 4-8° C until transport.

13. If transporting via courier, place specimens in cooler with cold pack. If shipping via US Mail or FedEx, please provide a cool pack within the rigid outer container.

14. For any questions concerning specimen collection or transportation call 603-271-2764 or 603-271-4661

*All specimens including blood from patients known or suspected of being infected with Hepatitis must be packaged and shipped as "Biological Substances, Category B" according to IATA Packing Instruction 650.*