Hepatitis C

June 2010

1) THE DISEASE AND ITS EPIDEMIOLOGY

A. Etiologic Agent

Hepatitis C (HCV) is caused by an RNA virus in the Flaviviridae family. Multiple HCV genotypes exist, with type 1 being most common in the United States.

B. Clinical Description and Laboratory Diagnosis

Hepatitis C is a disease with varying rates of progression. In general, its course is slowly progressive. For people who are recently infected, only about 20% will experience any related acute symptoms. Therefore, it is uncommon for people to be diagnosed with HCV infection in the acute stage. About 15% to 25% of HCV-infected individuals recover spontaneously, and reasons for this are still unknown. The remainder develops chronic infection.

Most people are asymptomatic during the first decade or two of chronic HCV infection. Some patients will experience a range of symptoms including fatigue, headaches, joint aches, muscle aches, nausea, jaundice, loss of appetite, and/or abdominal pain. Of those chronically infected, about 10% to 20% may eventually develop cirrhosis or cancer of the liver. Cirrhosis can lead to liver failure in some people and predispose them to liver cancer. Factors related to more serious clinical outcomes include drinking alcohol, co-infection with hepatitis A, hepatitis B, or HIV, and medications or food supplements that harm the liver.

Laboratory diagnosis is based upon an anti-HCV screening test (EIA) positive with a signal to cut-off ratio considered diagnostic, or a positive recombinant immunoblot assay (RIBA), or a positive Nucleic Acid Test for HCV RNA, or a report of a HCV genotype.

C. Reservoirs

Infected humans are the only known source of this disease.

D. Modes of Transmission

HCV is a bloodborne pathogen and is predominantly spread via percutaneous exposure to contaminated blood or blood products. Currently, the most prevalent mode of transmission is the sharing of needles or syringes among intravenous drug users. Blood transfusions pose an extremely limited risk now, but for those patients who received a blood transfusion before June 1992, the risk was approximately 1 in 200 transfused units. Sexual transmission of HCV does occur but is not common. Recently outbreaks of HCV associated with breaches of infection control standards in healthcare settings have been reported. Other potential risks for transmission include long-term hemodialysis, sharing straws for intranasal cocaine use, vertical (mother-to-infant) transmission, occupational blood exposure, and tattooing or body piercing with nonsterilized equipment. HCV is not spread via casual contact, kissing, sneezing, hugging, sharing glasses or utensils, or breast milk.

E. Incubation Period

The incubation period for HCV ranges from 2 weeks to 6 months, with an average incubation period of 6 to 7 weeks.

F. Infectious Period

The infectivity of HCV is variable; anyone with a positive test for HCV antibody should be considered infectious. The virus can usually be detected in an infected person's blood within 1 to 3 weeks after the initial exposure. The degree of correlation between quantity of circulating virus and infectivity is not clearly established.

G. Epidemiology

Hepatitis C has a worldwide distribution. In the United States an estimated 4 million people are infected with HCV. It is thought that there are currently about 30 000 new cases of HCV infection each year. HCV infection occurs among persons of all ages, with the highest incidence of acute HCV (new cases) occurring among persons aged 20 to 39 years. Prevalence is highest among groups with specific risk factors, especially injection drug users, patients with hemophilia or on long-term hemodialysis, prisoners, and people who received blood or organ products prior to June 1992. The risk of occupational exposure for health care workers has been estimated to be similar to that of the general population, at 1.8% among hollow-bore needlestick exposures to HCV-infected blood. Perinatal transmission is estimated as being about 5%, although if the mother is co-infected with HIV, the risk may be increased to approximately 15% to 25%.

There has been a sharp increase in reporting of HCV infection in New Jersey recently. Most of these newly diagnosed cases are not people with new (acute) disease, but those with newly reported chronic infection. There is a large population of undiagnosed people who were infected in the past but only recently reported.

2) Case Definition

A. New Jersey Department of Health and Senior Services (NJDHSS) Case Definition

ACUTE HEPATITIS C

1. Clinical Description

An acute illness with a discrete onset of any sign or symptom consistent with acute viral hepatitis (e.g., anorexia, abdominal discomfort, nausea, vomiting), and either a) jaundice, or b) serum alanine aminotransferase (ALT) levels >400 IU/L.

2. Laboratory Criteria for Diagnosis

One or more of the following three criteria:

1. Antibodies to HCV (anti-HCV) screening-test-positive with a signal to cut-off ratio predictive of a true positive as determined for the particular assay as defined by the Centers for Disease Control and Prevention (CDC) (URL for the signal to cut-off ratios: http://www.cdc.gov/ncidod/diseases/hepatitis/c/sc_ratios.htm),

OR

2. HCV Recombinant Immunoblot Assay (HCV RIBA) positive,

OR

3. Nucleic Acid Test (NAT) for HCV RNA positive (PCR)

AND, meets the following two criteria:

1. IgM antibody to hepatitis A virus (IgM anti-HAV) negative, AND

2. IgM antibody to hepatitis B core antigen (IgM anti-HBc) negative

3. Case classification

Confirmed: a case that meets the clinical case definition, is laboratory confirmed, and is not known to have chronic HCV.

Possible: Cases involving an infant born to a mother with HCV infection may be classified as "POSSIBLE" in CDRSS pending the completion of the investigation. See note below for additional details.

NOTE: Children born to a mother with HCV should be tested for anti-HCV no sooner than age 18 months because anti-HCV from the mother might persist until this age. If diagnosis is desired before the child turns 18 months, testing for HCV RNA could be performed at or after the infant's first well-child visit at age 1–2 months. HCV RNA testing should then be repeated at a subsequent visit, independent of the initial HCV RNA test result.

CHRONIC HEPATITIS C

1. Clinical Description

Most HCV-infected persons are asymptomatic. However, many have chronic liver disease, which can range from mild to severe including cirrhosis and liver cancer. For the purposes of HCV surveillance in New Jersey, all cases of laboratory-confirmed HCV (see section below for laboratory criteria for diagnosis) which have NOT been reported as ACUTE, can be designated as CHRONIC-confirmed (ie, if the local health department was not notified that the case is acute, it can be assumed to be chronic).

2. Laboratory Criteria for Diagnosis

- Anti-HCV positive (repeat reactive) by EIA, verified by an additional more specific assay (e.g. RIBA for anti-HCV or nucleic acid testing for HCV RNA),

OR

- HCV RIBA positive,

OR

- Nucleic acid test for HCV RNA positive

OR

- Report of HCV genotype

OR

- Anti-HCV screening-test-positive with a signal to cut-off ratio predictive of a true positive as determined for the particular assay as determined and posted by CDC (e.g., >3.8 for the enzyme immunoassays).

3. Case classification

Probable: a case that is anti-HCV positive (repeat reactive) by EIA and has alanine aminotranferase (ALT or SGPT) values above the upper limit of normal, but the anti-HCV EIA result has not been verified by an additional more specific assay or the signal to cutoff ratio is unknown.

Confirmed: a case that is laboratory confirmed and that does not meet the case definition for acute HCV.

B. Difference from CDC Case Definition

The NJDHSS and Council of State and Territorial Epidemiologists (CSTE)/(CDC) surveillance case definitions for HCV are essentially the same. The NJDHSS case definition for acute HCV has been modified slightly (ie, it includes a case classification category of "Possible") to promote follow-up of infants born to mothers with HCV.

3) LABORATORY TESTING AVAILABLE

The NJDHSS Public Health and Environmental Laboratories do not provide routine HCV antibody testing for the general public. Testing is generally conducted through hospitals and commercial clinical laboratories. For the purposes of suspected or confirmed outbreak investigations, molecular sequencing (genetic typing) may be performed after consultation with NJDHSS Communicable Disease Service staff.

4) PURPOSE OF SURVEILLANCE AND REPORTING REQUIREMENTS

A. Purpose of Surveillance and Reporting

- To provide information to HCV-infected persons on how to prevent exposing others.
- To identify HCV-infected patients to ensure that they are educated on the need for medical evaluation and how to reduce disease progression, and to provide referrals to medical or support services.
- To identify cases and determine the prevalence of HCV in specific populations and geographic locations to better inform HCV prevention and service activities.

B. Laboratory and Health Care Provider Reporting Requirements

NJAC 8:57-1 et seq. stipulates that laboratories and health care providers must report (by telephone, confidential fax, over the Internet using the confidential and secure Communicable Disease Reporting and Surveillance System [CDRSS], or in writing) all cases of newly diagnosed acute illness of hepatitis C and newly diagnosed chronic cases of HCV within 24 hours of diagnosis to the NJDHSS Infectious and Zoonotic Diseases Program (IZDP) at 609.826.5964 or fax 609.826.4874.

Mailing address:

New Jersey Department of Health and Senior Services
Communicable Disease Service
Infectious and Zoonotic Disease Program
PO Box 369
Trenton, NJ 08625-0369

NOTE: If a health care provider is reporting, ask him or her to inform the patient that someone from the local health department will be contacting the patient for follow-up.

C. Local Departments of Health Reporting and Follow-Up Responsibilities

1. Reporting Requirements

NJAC 8:57-1 et seq. stipulates that each local health officer must report the occurrence of any case of HCV, as defined by the criteria in section 2A above. Case reports received by a local health department should be reported to NJDHSS IZDP electronically via the Internet using CDRSS. Most HCV reports will go directly to NJDHSS from labs/health care providers, but some may continue to go to the local health department.

2. Case Investigation

a. It is the health officer's responsibility to investigate a reported **acute** case of HCV by interviewing the patient and others (such as the diagnosing health care provider who may be able to provide the pertinent information). Use the CDS-17 form to capture pertinent information about the case. Much of the information required on the form can be obtained from the patient's health care provider or the medical record.

b. Use the following guidelines to assist in completing a case report for **acute HCV:**

(1) Begin the investigation by contacting the diagnosing health care provider to verify the diagnosis. This will ensure that the health care provider has an opportunity to provide the test results to the case-patient before the local health officer contacts him or her.

(2) If the health care provider cannot be reached, leave a message indicating that the local health department will be contacting the case-patient and the case-patient should be informed of the diagnosis or test results. If the report came from a laboratory and the health care provider is not known, contact the laboratory (before contacting the case-patient) in order to identify which specific tests were used for the diagnosis and physician name prior to contacting the patient.

(3) Be sure to record accurately the date of diagnosis, what related lab work was performed, and demographic information. If possible, document when the person may have been infected. The confirmatory tests are PCR for viral RNA, RIBA tests, and **EIA with S/Co provided as a numeric value and determined positive for that particular assay.** If the laboratory test information comes from the medical provider and a hard copy of the test results is not available, indicate in the "Comments" section of the "Laboratory" tab that lab results were provided or confirmed by the patient's health care provider.

(4) Pay special attention to possible risk factors (eg, health care procedure, tattoo, unprotected sex, injection drug use) in the past six months. Ideally this information should be obtained on all cases. It may be possible to stop transmission of HCV in certain instances (eg, health-related procedures) through prompt identification of acute cases. In CDRSS, risk factor and symptom information can be documented as dropdown box options.

(5) Quantitative PCRs (QN PCRs) can usually be assumed to be follow-up tests for patients chronically infected with HCV. Contact the patient for follow-up only if there is a positive EIA and/or supplementary test. If an initial EIA is shown to be false-positive via negative supplementary testing, do not contact the case-patient.

(6) Reassure the patient that all information is kept strictly confidential. For all of the risk-related questions on the report form, it is essential that the investigator not assume the case-patient's risk factors. Get the information concretely from the individual or his/her medical provider(s) or indicate that the risk is unknown for that case. Other than obtaining the information (when possible) and providing related health education, the local health department (LHD) does not have further responsibility in relation to this information.

(7) Educate the patient about preventing transmission and ways to protect his or her liver (eg, role of alcohol, hepatitis A/B vaccination). Encourage the patient to speak to any people who may have been

exposed to his or her blood since the time he or she was estimated to have been exposed, infected, or seroconverted.

(8) Inform patient about role of sexual behavior and injection drug use in transmission of HCV.

(9) If there have been 3 attempts to obtain patient information (eg, the patient or health care provider does not return calls or does not respond to a letter, or the patient refuses to divulge information or is too ill to be interviewed), please fill out the form with as much information as possible. Please note the reason why it could not be filled out completely.

For Chronic HCV- No investigation need be done for cases not diagnosed as "acute" illness unless there is a suspected or confirmed outbreak of HCV under investigation. If the health department was not notified that the case is acute, it can be assumed to be chronic. Case subcategory in CDRSS should be marked "chronic," and the health care provider should be informed by the LHD that the patient will be contacted to ensure he or she is aware of the diagnosis and how to reduce transmission risk to others (see section 4D).

3. **Entry into CDRSS**

The mandatory fields in CDRSS include: disease, last name, county, municipality, gender, race, ethnicity, case status, report status.

The following table can be used as a quick reference guide to determine which CDRSS fields need to be completed for accurate and complete reporting of HCV cases. The "Tab" column includes the tabs which appear along the top of the CDRSS screen. The "Required Information" column provides detailed explanations of what data should be entered.

CDRSS Screen	Required Information
Patient Info	In the Disease Information section, enter the disease name ("Hepatitis C"), the date the case was reported to the local health department (LHD), and illness onset date. In the Demographics section, enter the patient's date of birth. There are two subgroups for HCV*: acute illness* (for cases representing acute illness/new onset of symptoms) and *chronic infection* (for cases representing infections diagnosed in the current reporting year, but are not associated with symptoms suggestive of acute infection). Note: reported cases that are not newly diagnosed can be marked as described in Section 4.D.3. below.
Addresses	Enter any alternate address (e.g., an address for a pain management clinic). Use the Comments section in this screen to record any pertinent information about the alternate address (e.g., the frequency by which the case-patient visits the pain management clinic). Entering an alternate address will allow other disease investigators access to the case if the alternate address falls within their jurisdiction.

Clinical Status	Enter any treatment that the patient received and record the names of the medical facilities and physician(s) involved in the patient's care. If the patient received care from two or more hospitals, be sure that all are entered so the case can be accessed by all infection preventionists (IP) covering these facilities. If immunization status for hepatitis A and B is known, it should also be entered here. If the patient died, date of death should be recorded under the Mortality section.
Signs/Symptoms	Check appropriate boxes for signs and symptoms and indicate their onset. Make every effort to get complete information by interviewing the physician, family members, ICP, or others who might have knowledge of the patient's illness. Also, information regarding the resolution of signs and symptoms should be entered.
Risk Factors	Enter complete information about risk factors to facilitate study of HCV in New Jersey.
Laboratory Eval	Select the appropriate laboratory test that indicates what type of test was performed.
Contact Tracing	Information regarding contacts is not required for this disease.
Case Comments	Enter general comments (i.e., information that is not discretely captured by a specific topic screen or drop-down menu) in the Comments section. **NOTE:** Select pieces of information entered in the Comments section CANNOT be automatically exported when generating reports. Therefore, whenever possible, record information about the case in the fields that have been designated to capture this information; information included in these fields CAN be automatically exported when generating reports.
Case Classification	Case status options are: "REPORT UNDER INVESTIGATION (RUI)," "CONFIRMED," "PROBABLE," "POSSIBLE," and "NOT A CASE." All cases entered by laboratories (including LabCorp electronic submissions) should be assigned a case status of "REPORT UNDER INVESTIGATION (RUI)." Cases still under investigation by the

	LHD should be assigned a case status of "REPORT UNDER INVESTIGATION (RUI)." Upon completion of the investigation, the LHD should assign a case status on the basis of the case definition. "CONFIRMED" and "NOT A CASE" are the only appropriate options for classifying a case of HCV (see section 2A), except for newborn infants in which case "POSSIBLE" is an acceptable option.
Report Status	Report status options are: "PENDING," "LHD OPEN," "LHD REVIEW," "LHD CLOSED," "DELETE," "REOPENED," "DHSS OPEN," "DHSS REVIEW," and "DHSS APPROVED." Cases reported by laboratories (including LabCorp electronic submissions) should be assigned a report status of "PENDING." Once the LHD begins investigating a case, the report status should be changed to "LHD OPEN." The "LHD REVIEW" option can be used if the LHD has a person who reviews the case before it is closed (e.g., health officer or director of nursing). Once the LHD investigation is complete and all the data are entered into CDRSS, the LHD should change the report status to "LHD CLOSED." "LHD CLOSED" cases will be reviewed by DHSS and be assigned one of the DHSS-specific report status categories. If additional information is needed on a particular case, the report status will be changed to "REOPENED" and the LHD will be notified by e-mail. Cases that are "DHSS APPROVED" cannot be edited by LHD staff (see Section C below).

D. Other Reporting/Investigation Issues

1. The LHD/LINCS agency will only need to complete or send out investigation forms (ie, the CDS-17 form) as needed to clinicians reporting ACUTE cases (if the healthcare provider did not provide enough information

upon initial report), thereby greatly decreasing the amount of time spent attempting to obtain information from healthcare providers on chronic cases. LHDs **will be expected** to investigate **all** acute cases to determine possible routes of transmission so that further transmission can be prevented (e.g., assure proper infection control practices in medical provider office/hospital) in instances where infection is secondary to a healthcare procedure.

2. Cases of HCV (whether acute or chronic) which are lost to follow-up after three attempts (e.g., phone calls to patients/providers on three separate days at different times of the day, or letters faxed or mailed to healthcare provider three separate times) to obtain information should be classified as **CHRONIC - CONFIMED** in the Communicable Disease Reporting and Surveillance System (CDRSS) provided the laboratory criteria specified in section for laboratory criteria for diagnosis for chronic HCV is met.

3. Laboratory-confirmed or health care provider-reported cases of chronic HCV infection diagnosed prior to the current reporting year, and not reported previously in CDRSS, should be managed as follows in CDRSS:

1) Enter the patient's illness onset date as reported by the provider. If the exact illness date is unknown, enter January 1st if the month and day are not known, followed by the year that the HCV diagnosis was made.
2) Select the "CONFIRMED" option under Case Status.
3) Select "CASE DIAGNOSED IN A PREVIOUS YEAR" from the "Reason for Update" drop-down menu that appears next to "Case Status" box.

4. The local health agency will either send an informational letter/ fact sheet to ALL HCV-infected individuals (acute and chronic) which will contain explanation of risks of transmission and need for medical follow-up, or provide such information by telephone (unless you ascertain that the healthcare provider has already provided sufficient information). PLEASE NOTE: Dropdown boxes under the "CDRSS Clinical Status" page are to be utilized to document assurance that the patient is aware of his/her diagnosis and that disease-related education was provided.

5. NJDHSS will then review all CDRSS "LHD closed" acute and chronic cases prior to data submission to CDC.

6. Although NJDHSS will focus attention on investigating acute HCV cases, local health departments may investigate ALL cases of HCV if they desire and have the resources.

5) CONTROLLING FURTHER SPREAD

A. Isolation and Quarantine Requirements (NJAC 8:57)

Minimum Period of Isolation of Patient

No restrictions except for exclusion from organ and blood donation and counseling to modify activities in order to prevent transmission.

NOTE: Sexual transmission of HCV does occur, but it does not appear to be efficient. Donating blood, organs, tissue, or sperm can spread HCV to others.

Minimum Period of Quarantine of Contacts

None.

B. Protection of Contacts of a Case

Standard precautions for cases are recommended to prevent exposing others to blood and body fluids. Immunoglobulin prophylaxis is not effective and is not recommended for contacts of HCV-infected individuals.

C. Managing Special Situations

There are no specific regulations regarding HCV infection in daycare, school, or community residential programs. HCV is not spread via casual contact or through food or water. As long as standard precautions are maintained, HCV will not be spread to others in these settings. No one who is HCV-infected should be excluded from attending or working in any of these settings on the basis of his/her HCV infection.

D. Preventive Measures in Acute and Chronic Hepatitis C

The role of the local health department in managing HCV largely is educating infected persons how to care for themselves and avoid spreading infection to others. Little epidemiologic investigation is required except data collection for case reports of acute disease. Prevention and education includes information on how the disease is transmitted, how to avoid transmitting it, and how patients can protect themselves from other potential sources of liver damage.

Offer the information and support below to newly identified case-patients.

1. Provide basic instruction on transmission of HCV and emphasize the need for ongoing medical evaluation. Treatment is available, and the case-patients should be referred to their health care provider for treatment options.
2. Educate on the need to completely abstain from alcohol to help protect the liver. If a case-patient needs or wants support to stop drinking, provide referrals to appropriate treatment or support services.
3. Discuss medications that should be avoided (eg, acetaminophen) as high doses of these can damage the liver. All case-patients should discuss any medications (including over-the-counter medications) and dietary supplements and herbs with a health care provider before taking them to be certain the medications will not impair liver function.
4. Provide information on the importance of hepatitis A and B immunization. Refer to the Hepatitis A and Hepatitis B chapters in this manual.
5. Discuss sexual transmission of HCV. Indicate that HCV may be transmitted during sex, but that the risk is low. All contact with blood during sex should be avoided. Emphasize latex barrier protection as a way to prevent the spread of HCV, as well as a way to prevent the exposure to and transmission of other pathogens.
6. Discuss household transmission of HCV. Household transmission is rare, but to ensure that it does not happen, the case-patient should not share razors, toothbrushes, nail clippers, or any other item that could be contaminated with blood. Inform the case-patients that they should not be restricted from working, preparing food, or taking part in their daily activities unless they have specific symptoms that make it difficult to do so. There are no recommendations suggesting that HCV-infected persons change their exercise routines or have any dietary restrictions.

ADDITIONAL INFORMATION

A copy of the Hepatitis C Fact Sheet can be obtained at the NJDHSS Web site at http://www.state.nj.us/health/cd/f_hepac.htm.

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