

	Division of Community and Public Health	
	Section: 4.0 Diseases and Conditions	Page 1 of 18
	Subsection: Hepatitis C	Updated 6/2008

Hepatitis C Table of Contents

Overview

[Signs and symptoms](#)

[Cause](#)

[Transmission](#)

General Reporting Requirements

Responsibilities of the Local Public Health Agencies (LPHA)

[Reporting Requirements](#)

[MOHSIS Clarifications](#)

[MOHSIS Entry and Disease Investigation](#)

[Hepatitis C Associated Laboratory Tests](#)

[Guidelines for: Interpreting Antibody to Hepatitis C Virus \(anti-HCV\) Test](#)

[Results](#)

[Case Definitions](#)

Acute Hepatitis C

Chronic Hepatitis C

[Hepatitis C Case Definition Algorithm](#)

Responsibilities of the Bureau of HIV, STD and Hepatitis (BHSB)

State Public Health Laboratory Procedures

Control Measures

Links

References

Communicable Disease Case Report (CD-1) Form

PDF version: <http://www.dhss.mo.gov/CommunicableDisease/CD-1.pdf>

Word version: <http://www.dhss.mo.gov/CommunicableDisease/CD-1.dot>

Viral Hepatitis Case Report Form

<http://www.cdc.gov/hepatitis/PDFs/vhsp02.pdf>

MOHSIS Entry from Laboratory Reports Flow Chart

Pamphlets

<http://www.cdc.gov/ncidod/diseases/hepatitis/c/index.htm#materials>

Fact Sheet

<http://www.cdc.gov/ncidod/diseases/hepatitis/c/fact.htm>

Frequently Asked Questions

<http://www.cdc.gov/ncidod/diseases/hepatitis/c/faq.htm>

	Division of Community and Public Health	
	Section: 4.0 Diseases and Conditions	Page 2 of 18
	Subsection: Hepatitis C	Updated 6/2008

Overview

Hepatitis C virus (HCV) is one of the most significant health problems affecting the liver. More than 4 million Americans (1.6% of the U.S. population) and 180 million individuals in the world (3% worldwide) have been infected with HCV. About 15 to 25% of persons with acute hepatitis C resolve their infection without further problems. The remainder develops a chronic infection and about 55 to 80% of these persons develop chronic hepatitis. Cirrhosis of the liver develops in 10 to 20% of persons with chronic hepatitis C over a period of 20-30 years, and hepatocellular carcinoma (liver cancer) in 1% to 5%. For individuals with cirrhosis, however, the rate of development of liver cancer might be as high as 1% to 4% per year.

The propensity of HCV to cause chronic infection is explained by the extraordinary ability of this virus to avoid destruction by the body's immune system. Once established, HCV infection causes an inflammation of the liver called chronic hepatitis. This condition can progress to scarring of the liver, called fibrosis, or more advanced scarring, called cirrhosis. Some individuals with cirrhosis go on to develop liver failure or complications of cirrhosis including liver cancer.

Signs and symptoms:

Signs and symptoms of HCV infection are indistinguishable from other types of hepatitis. Acute disease tends to be mild and insidious in onset and without appreciable symptoms. The incubation period for HCV ranges from 2 weeks to 6 months, commonly 6 to 9 weeks. Only about 25% of those infected exhibit symptoms of acute hepatitis in the beginning of their illness. Symptoms commonly associated with acute hepatitis include: fatigue, muscular aches, poor appetite, vague abdominal discomfort, nausea, vomiting and low-grade fever. A yellowing of the skin and or eyes (jaundice) can occur when liver damage from the infection interferes with normal production and discharge of bile. Development of jaundice occurs in less than 20%. Abnormalities in liver function tests are generally less pronounced than in patients with hepatitis B virus (HBV). At the onset of HCV infection about 75% of those infected experience minimal or no symptoms. Many remain asymptomatic even when their HCV infection progresses to a chronic condition. A chronic hepatitis C infection is often discovered through routine blood work or while being medically evaluated for unrelated issues. HCV infected individuals may not exhibit symptoms even with significant liver damage and disease. Others may experience chronic or intermittent fatigue and a diminished sense of wellbeing with advanced liver disease. HCV infected individuals who have developed cirrhosis of the liver, may have muscle wasting, generalized weakness, and bruise easily. As cirrhosis progresses, complications in liver function are evident by symptoms including: fluid retention with edema (swelling of the lower extremities,) ascites (fluid in the abdominal cavity), internal bleeding (usually from dilated esophageal veins), and mental confusion or sleepiness (due to hepatic encephalopathy). Cirrhosis frequently leads to cancer of the

	Division of Community and Public Health	
	Section: 4.0 Diseases and Conditions	Page 3 of 18
	Subsection: Hepatitis C	Updated 6/2008

liver (hepatocellular carcinoma or hepatoma), although someone may develop hepatitis C related liver cancer without first developing cirrhosis. Abdominal pain, weight loss, and fever associated with HCV infection should be medically evaluated. Other HCV related conditions of concern include: cryoglobulinemia (abnormal antibody development known as cryoglobulins that cause inflammation of small blood vessels), B-cell non Hodgkin’s lymphoma, and skin conditions such as lichen planus and porphyria cutanea tarda.

Cause:

HCV is a small, single-stranded RNA virus biologically classified in the Flavivirus family and the Hepacavirus genus. From the time of exposure to development of viremia is generally 1 to 2 weeks. Although symptoms may not be evident during initial HCV infection, a high percentage of those infected progress to chronic infection. Chronic infection may persist for up to 20 years before cirrhosis or hepatoma develops or is evident. Of those chronically infected, about half will eventually develop cirrhosis and/or cancer of the liver.

Transmission:

Hepatitis C is a blood borne pathogen, which is transmitted primarily by large or repeated direct percutaneous exposures (direct skin puncture). Exposure risk factors include, but are not limited to:

1. use of injection or street drugs, with needles and/or drug “works” used to prepare or inject the drug(s) that may have had someone else’s HCV contaminated blood on them.
2. receipt of blood (prior to 1992), blood products (prior to 1987), or solid organs (prior to 1992) from a donor whose blood contained HCV.
3. receipt of long-term kidney dialysis in which HCV contaminated supplies/equipment, blood, or body fluid may have unknowingly been used.
4. an occupational exposure as a health care worker by contact with blood on the job or accidental needle sticks.
5. born to a HCV infected woman.
6. engaged in sex with a person infected with HCV.
7. live(d) with someone who is infected with HCV and shared personal items (i.e., toothbrushes, dental appliances, nail grooming equipment or razors) that might have had HCV infected blood on them.

A person with hepatitis C can transmit the virus to others one (1) or more weeks prior to the onset of symptoms and may continue to be infectious indefinitely. All patients with chronic hepatitis C should be vaccinated against hepatitis A. Unvaccinated or non-immune persons with risk factors for hepatitis B virus (HBV) should be vaccinated against hepatitis B. Current Federal Drug Administration (FDA) approved treatments for

	Division of Community and Public Health	
	Section: 4.0 Diseases and Conditions	Page 4 of 18
	Subsection: Hepatitis C	Updated 6/2008

HCV include interferon α (alpha) alone or combination therapy interferon with ribavirin. Combination therapy with ribavirin and pegylated interferon has achieved the highest response rates and better outcomes than treatment with monotherapy. HCV genotypes are critical factors in treatment decisions. A sustained virological response (SVR) is currently the best indicator of effective treatment.

General Reporting Requirements

According to Chapter 19 of the Code of State Regulations (CSR) 20-20.020 the Reporting of Communicable Environmental and Occupational Diseases, hepatitis C is a category II disease and shall be reported to the local health authority or to the Missouri Department of Health and Senior Services (DHSS) within three (3) days of first knowledge or suspicion. (See next section for LPHA reports responsibilities.)

1. For all cases, complete a Disease Case Report form (CD-1).
2. Mail or fax the completed CD-1 to the Bureau of HIV, STD and Hepatitis (BHS) in c/o the Hepatitis Quality Assurance Coordinator, at PO Box 570, Jefferson City, MO 65102, or fax to (573) 751-6417 or to your local public health agency.
3. Chapter 19 CSR 20-20.070, Duties of Local Health Departments. “All local health authorities shall forward reports of all diseases and conditions mentioned in 19 CSR 20-20.020 to the Missouri Department of Health. These reports shall be forwarded within twenty-four (24) hours after they are received, according to procedures established by Department of Health Director.”
4. Missouri is a dual reporting state. Chapter 19 CSR 20-20.020 Report Communicable Environmental and Occupational Disease Rule states that physicians are to report. Chapter 19 CSR 20-20.080 Duties of Laboratories, states that laboratories are also to report.
5. All **outbreaks** or “suspected” outbreaks must be reported as soon as possible to BHS. This can be accomplished by completing the Missouri Outbreak Surveillance Report (CD-51). The contact number is (573) 526-5271 and the fax number is (573) 751-6417.

	Division of Community and Public Health	
	Section: 4.0 Diseases and Conditions	Page 5 of 18
	Subsection: Hepatitis C	Updated 6/2008

Responsibilities of the Local Public Health Agencies (LPHA)

Reporting Requirements

It is important for the LPHA to promote disease case reporting according to Chapter 19 of the Code of State Regulations (CSR) 20-20.20. (See General Reporting Requirements)

1. Chapter 19 CSR 20-20.70, Duties of Local Health Departments. “All local health authorities shall forward reports of all diseases and conditions mentioned in Chapter 19 CSR 20-20.020 to the Missouri Department of Health. These reports shall be forwarded within twenty-four (24) hours after they are received, according to procedures established by Department of Health Director.” Entry of laboratory and/or disease case reports (CD-1) into MOHSIS negates the need to forward hardcopy results to DHSS.
2. All **outbreaks** or “suspected” outbreaks must be reported as soon as possible to BSHS. This can be accomplished by completing the Missouri Outbreak Surveillance Report (CD-51). The contact number is (573) 526-5271 and the fax number is (573) 751-6417.
3. Submit the final outbreak reports to BSHS within 90 days from the conclusion of an outbreak.
4. LPHAs may create customized HCV surveillance reports that are available online through Crystal Reports. LPHA staff may also run reports to monitor jurisdictional HCV prevalence and MOHSIS disease notifications. Contact BSHS for information on how to run reports online.

MOHSIS Clarifications:

1. MOHSIS was designed to be a notification and surveillance database system for State and Local Health Departments to monitor all communicable diseases for epidemiological purposes. This database is not to be used as a medical case management system.
2. Each person can have only one condition for acute hepatitis C in a lifetime.
3. Each person can have only one condition for chronic hepatitis C in a lifetime.

MOHSIS Entry and Disease Investigation

1. It is recommended that the LPHA check MOHSIS notifications for “acute” or “chronic” hepatitis C cases daily. The following link <http://dhssnet/ehcdp/Help13.pdf> will give you directions on how to run the notifications from MOHSIS.
2. It is recommended that the LPHA run Crystal Reports daily to learn of any newly entered HCV laboratory results. The following link

	Division of Community and Public Health	
	Section: 4.0 Diseases and Conditions	Page 6 of 18
	Subsection: Hepatitis C	Updated 6/2008

<http://dhssnet/ehcdp/Help31.pdf> will give directions on how to run the reports in Crystal's from the web.

3. Enter any hepatitis C laboratory results and/or CD-1's received in your office into MOHSIS within 24 hours of receipt.
4. It is not necessary to enter additional laboratory reports received that do not change the case definition for a case already in MOHSIS. The address of the case could be updated at this time.
5. Verify the clinical diagnosis and establish the extent of illness to determine the condition status.
 - a. Determine what laboratory tests were conducted.
 - b. Determine the results.
 - c. Determine the patient's clinical symptoms.
 - d. Determine whether the case is an acute or chronic hepatitis C case according to the lab work.
 - e. Determine the vaccination status and needs of the individuals and contacts. (i.e. Hepatitis B vaccine and Hepatitis A vaccine).
 - f. Determine the risk of infection to others and contact those who may be at risk.
 - g. Document disease education provided.
6. Attempt to establish the source of the infection. Determine if the patient has any of the following risk factors for this disease:
 - a. received clotting factor concentrates before 1987
 - b. received transfusions of blood or blood components before 1992
 - c. notified that they had received blood from a donor who later tested positive for HCV infection
 - d. received an organ transplant before 1992
 - e. remote or recent needle sticks, sharps or mucosal exposure to HCV positive blood
 - f. engaged in injecting drug use or any activity that may involve the sharing or re-use of contaminated needles such as tattooing/body piercing
 - g. sex with hepatitis C-infected person
 - h. shared personal items (toothbrush, razor, nail clippers, cuticle scissors, etc.) with an individual infected with hepatitis C
7. Complete the supplemental CDC Viral Hepatitis Form for:
 - a. acute confirmed
 - b. chronic confirmed – aged 30 years and younger. (See pages 14 & 15 for case definition.)

Rationales: These individuals have generally been infected a shorter period of time. Prevention education may be more effective and epidemiological links may be identified more readily than for those who are older and may have contracted the disease 20 to 30 years earlier.

	Division of Community and Public Health	
	Section: 4.0 Diseases and Conditions	Page 7 of 18
	Subsection: Hepatitis C	Updated 6/2008

8. Mail or fax the completed CDC Viral Hepatitis form to DHSS BSHS within 10 working days. Fax: (573) 751-6417.
9. Assure provision of appropriate counseling to the infected individual in regard to National Hepatitis C Prevention Strategy Program Guidelines including:
 - a. HCV disease and transmission information
 - b. risk reduction of HCV transmission to others
 - c. medical referral to determine the extent of liver disease and antiviral treatment options
 - d. limiting alcohol intake to reduce further liver distress and/or damage
 - e. immunization for hepatitis A, hepatitis B, pneumococcal disease, and influenza
 - f. evaluate need of treatment for alcohol and/or drug abuse
 - g. notification and referral of sex and/or needle sharing partners
 - h. document date, time, and content of counseling information and client response.
10. If the case is an offender within the Missouri Department of Corrections (MDOC), close all new hepatitis C conditions (acute and chronic) with “no investigation needed.” MDOC shall conduct the investigation of these cases.
11. When there are issues concerning MOHSIS such as, if the system is down, running too slow and/or locks up, please contact the Help Desk at (800) 347-0887 or email them at support@dhss.mo.gov. This information will ensure that all MOHSIS users will have access to the system.
12. LPHA’s may create customized HCV surveillance reports that are available online through Crystal Reports. LPHA staff may also run reports to monitor jurisdictional HCV prevalence and MOHSIS disease notifications. Contact BSHS for information on how to run reports online.

Hepatitis C Associated Laboratory Tests (Supplement information)

HCV Screening Tests

EIA – Enzyme Immunoassay

Screening test for anti-HCV (i.e. Abbott HCV 2.0 and Ortho HCV Version 3.0 Elisa and VITROS Anti-HCV). Some EIA tests provide a signal to cut off ratio (S/Co). (Alternate names used by some laboratories: Anti-HCV, Hep C, Hep C Antibody, Acute Hepatitis Panel, Hepatitis C Virus IgG AB).

S/Co - Signal to cut off ratio. This ratio measures the strength of the EIA reaction. Each brand of HCV antibody tests has a specific signal to cut off-ratio reference. Antibodies to hepatitis C virus (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 CDC can be found on their web-site, (URL for the signal to cut-off ratios:

http://www.cdc.gov/ncidod/diseases/hepatitis/c/sc_ratios.htm

	Division of Community and Public Health	
	Section: 4.0 Diseases and Conditions	Page 8 of 18
	Subsection: Hepatitis C	Updated 6/2008

Screening test negative - Screening immunoassay test result interpreted as negative on the basis of criteria provided by the manufacturer.

Screening test positive – Screening immunoassay test result interpreted as positive on the basis of criteria provided by the manufacturer.

Despite previous recommendations for supplemental testing of all anti-HCV screening test-positive results, the majority of laboratories report positive anti-HCV results based on a positive screening assay. Confirmatory testing provides more reliable results. Further counseling and clinical evaluation are intended for those confirmed to have been infected with HCV, to minimize unnecessary medical visits and psychological harm from reporting a false-positive screening test result.

HCV False-Positive

Screening immunoassay tests are highly specific, however the proportion of false-positives averages 35% among immunocompetent populations with anti-HCV prevalence of less than 10%, and averages 15% among immunocompromized populations. Because of this it is recommended that HCV screening tests report the signal-to-cut off (s/co) ratios of screening-test-positive results.

HCV Supplemental Serologic Tests (Confirmatory Tests)

RIBA – Recombinant Immunoblot Assay, a more specific serologic anti-HCV assay. It is considered a confirmatory test. When positive, it meets one of the CDC 2007 Case Definition laboratory criteria. (Alternate Names – Immunoblot, SIA, Red Cross “XQ₁”)

An anti-HCV (RIBA) positive test result indicates active infection.

The significance of a single HCV-RNA result is unknown.

An anti-HCV negative person is considered Uninfected as defined as:

1. anti-HCV screening-test-negative or
2. anti-HCV screening-test positive, RIBA-negative or
3. NAT-negative, RIBA-negative

HCV Nucleic Acid Tests (NAT or PCR) – detects HCV-RNA by amplification of viral genetic sequences. Also known as PCR or RT-PCR. Generally used in clinical practice for evaluating and managing patients with chronic HCV. When positive, it meets one of the CDC 2007 Case Definition laboratory criteria. (Alternate names RNA, DNA, Genotype, Red Cross “XQ₃”)

	Division of Community and Public Health	
	Section: 4.0 Diseases and Conditions	Page 9 of 18
	Subsection: Hepatitis C	Updated 6/2008

RT-PCR – Reverse Transcriptase-polymerase chain reaction amplification, a nucleic acid testing method for detection of HCV-RNA.

Qualitative – reports results as either positive or negative for HCV-RNA

A positive qualitative HCV-RNA test result indicates the presence of HCV-RNA.

It is useful in confirmation of HCV-positivity before ordering quantitative HCV tests.

Quantitative – reports results in a numerical form according to a reference value in IU/mL, or log IU.

A numeric value reported below the lower limit of detection of the assay indicates that either the specimen contain no HCV-RNA, or that the level of HCV-RNA is below the lower detection limit of the assay; this result does not rule out the presence of HCV-RNA.

SVR – Sustained virological response - defined as undetectable HCV-RNA six (6) months after termination of antiviral therapy.

ALT - alanine aminotransferase, also known as SGPT (serum glutamic pyruvic transminase) – an enzyme found predominately in the liver. Most ALT elevations are often associated with liver injury or damage. Refer to the reference range provided on the laboratory report for abnormal values.

AST – aspartate aminotransferase, also known as SGOT (serum glutamic-oxaloacetic transaminase), an enzyme is found in high concentration within the heart muscle, liver cells, skeletal muscles, and to a lesser degree in the kidneys and pancreas. This enzyme is often compared to the ALT. The AST/ALT ratio less than 1.0 may be seen with hepatitis. Refer to the reference range provided on the laboratory report for abnormal values.

HCV RNA (by PT-PCR) provides the most sensitive and specific method available for the direct detection of HCV-RNA in the patient’s blood. This test is useful in determining early infection when HCV antibody is not detectable during the early months following infection. In clinical practice, the usual approach is to test initially for HCV antibody and then use HCV-RNA testing to document viremia.

Qualitative and quantitative HCV-RNA tests are helpful in monitoring chronic infection. Qualitative tests are sensitive to determine HCV at low levels and quantitative tests generally provide the HCV viral load. Both of these tests are useful for physicians to determine candidacy for treatment or for monitoring a patient response to treatments.

	Division of Community and Public Health	
	Section: 4.0 Diseases and Conditions	Page 10 of 18
	Subsection: Hepatitis C	Updated 6/2008

A quantitative HCV-RNA test that is “below the detectable limits of the assay” does not always indicate the absence of HCV infection. Since these two tests are generally associated with monitoring of chronic HCV infection, these values more often reflect an infected person’s response to treatment. A physician will be monitoring the results of these tests over periods of time to look for log reduction in viral load during treatment or a sustained viral response following treatment.

	Division of Community and Public Health	
	Section: 4.0 Diseases and Conditions	Page 11 of 18
	Subsection: Hepatitis C	Updated 6/2008

Guidelines for: Interpreting Antibody to Hepatitis C Virus (anti-HCV) Test Results (CDC MMWR, Recommendations and Reports Guidelines for Laboratory Testing and Result Reporting of Antibody to Hepatitis C Virus. Volume 52, No. RR-3, February 7, 2003)	
Anti-HCV Positive	<p>An anti-HCV–positive result is defined as:</p> <ol style="list-style-type: none"> 1.) anti-HCV screening-test-positive* and recombinant immunoblot assay (RIBA®)- or nucleic acid test (NAT)-positive; or 2.) anti-HCV screening-test–positive, NAT-negative, RIBA-positive. <ul style="list-style-type: none"> • An anti-HCV–positive result indicates past or current HCV infection. <ul style="list-style-type: none"> —An HCV RNA-positive result indicates current (active) infection, but the significance of a single HCV RNA-negative result is unknown; it does not differentiate intermittent viremia from resolved infection. • All anti-HCV–positive persons should receive counseling and undergo medical evaluation, including additional testing for the presence of virus and liver disease. <ul style="list-style-type: none"> —Anti-HCV testing usually does not need to be repeated after a positive anti-HCV result has been confirmed.
Anti-HCV Negative	<p>An anti-HCV–negative result is defined as:</p> <ol style="list-style-type: none"> 1.) anti-HCV screening-test–negative*; or 2.) anti-HCV screening-test–positive, RIBA-negative; or 3.) anti-HCV screening-test–positive, NAT-negative, RIBA-negative. <ul style="list-style-type: none"> • An anti-HCV–negative person is considered uninfected. • No further evaluation or follow-up for HCV is required, unless recent infection is suspected or other evidence exists to indicate HCV infection (e.g., abnormal liver enzyme levels in an immunocompromised person or a person with no other etiology for their liver disease).
Anti-HCV Indeterminate	<p>An indeterminate anti-HCV result is defined as anti-HCV screening-test–positive, RIBA-indeterminate:</p> <ol style="list-style-type: none"> 1.) indeterminate anti-HCV result indicates that the HCV antibody status cannot be determined. <ul style="list-style-type: none"> • Can indicate a false-positive anti-HCV screening test result, the most likely interpretation among those at low risk for HCV infection; such persons are HCV-RNA-negative. • Can occur as a transient finding in a recently infected person who is in the process of seroconversion; such persons usually are HCV-RNA-positive. • Can be a persistent finding among persons chronically infected with HCV; such persons usually are HCV-RNA-positive. 2.) If NAT is not performed, another sample should be collected for repeat anti-HCV testing (>1 month later).
<p>*Interpretation of screening immunoassay test results based on criteria provided by the manufacturer</p>	

	Division of Community and Public Health	
	Section: 4.0 Diseases and Conditions	Page 12 of 18
	Subsection: Hepatitis C	Updated 6/2008

Case Definitions:

Based on 2007 CDC Case Definitions

Hepatitis C (Acute)

For surveillance purposes, a confirmed case of acute hepatitis C is one that meets both clinical and laboratory criteria, and is not known to have chronic hepatitis C.

Clinical case definition:

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.

Laboratory criteria for diagnosis:

One or more of the following three criteria:

1. Antibodies to hepatitis C virus (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 CDC. (URL for the signal to cut-off ratios: http://www.cdc.gov/ncidod/diseases/hepatitis/c/sc_ratios.htm;) **OR**
2. Hepatitis C Virus Recombinant Immunoblot Assay (HCV RIBA) positive; **OR**
3. Nucleic Acid Test (NAT) for HCV RNA positive

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

Case classification:

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

Reference:

Division of Viral Hepatitis. Guidelines for Viral Hepatitis Surveillance and Case Management. Centers for Disease Control and Prevention.

Note: “Acute” hepatitis C cases cannot have a condition status of “suspect” or “probable”.



Division of Community and Public Health

Section: 4.0 Diseases and Conditions

Page 13 of 18

Subsection: Hepatitis C

Updated 6/2008

Hepatitis C (Chronic)

Clinical description:

Cases in these categories may or may not have an acute onset of illness or symptoms and may or may not have elevated liver enzyme test results. The presence or absence of other viral markers of hepatitis is not relevant to these classifications.

Laboratory criteria for diagnosis:

1. 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**
2. HCV RIBA positive; **OR**
3. Nucleic acid test for HCV-RNA positive; **OR**
4. Report of HCV genotype; **OR**
5. Anti-HCV screening-test-positive with a signal to cut-off ratio predictive of a true positive as determined for the particular assay. Each brand of HCV antibody tests has a specific signal to cut off-ratio reference. Antibodies to hepatitis C virus (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 CDC can be found on their web-site, (URL for the signal to cut-off ratios:
http://www.cdc.gov/ncidod/diseases/hepatitis/c/sc_ratios.htm

Chronic HCV Case Classification:

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

1. Positive antibody to hepatitis C virus (anti-HCV) by EIA verified with a S/CO ratio predictive of a true positive as determined for the particular assay as defined by CDC, or by a supplemental test (e.g. RIBA, PCR) **OR**
2. Positive RIBA or PCR test in the absence of other tests.
3. Report of HCV genotype.

Probable: A case that is anti-HCV positive (repeat reactive) by EIA and has alanine aminotransferase (ALT or SGPT) value above the upper limit of normal, but the anti-HCV EIA result has not been verified by an additional more specific assay or the S/CO ratio is unknown.

Suspect*, **: Positive anti-HCV by EIA test and does not meet the “confirmed” or “probable” chronic case classifications for HCV infection.

* When DHSS receives a hepatitis C case report (either a CD-1 or a verbal statement from the physician that the patient is chronic) without supporting diagnostic laboratory tests, the case will be entered into MOHSIS as a hepatitis C chronic with a condition status of “suspect”. The LPHA may change the case status when supporting information or laboratory tests are received.

	Division of Community and Public Health	
	Section: 4.0 Diseases and Conditions	Page 14 of 18
	Subsection: Hepatitis C	Updated 6/2008

** When DHSS receives an isolated HCV-RNA tests with a result of “less than the lower detection limit of the assay”, the case will be entered into MOHSIS as a hepatitis C chronic with a condition status of “suspect”. The LPHA may change the case status when supporting additional information or laboratory tests are received. The LPHA is encouraged to contact the provider to find out whether or not there are additional hepatitis C laboratory tests or clinical information to substantiate or reject a confirmed condition status. The provider should be able to provide information to determine either:

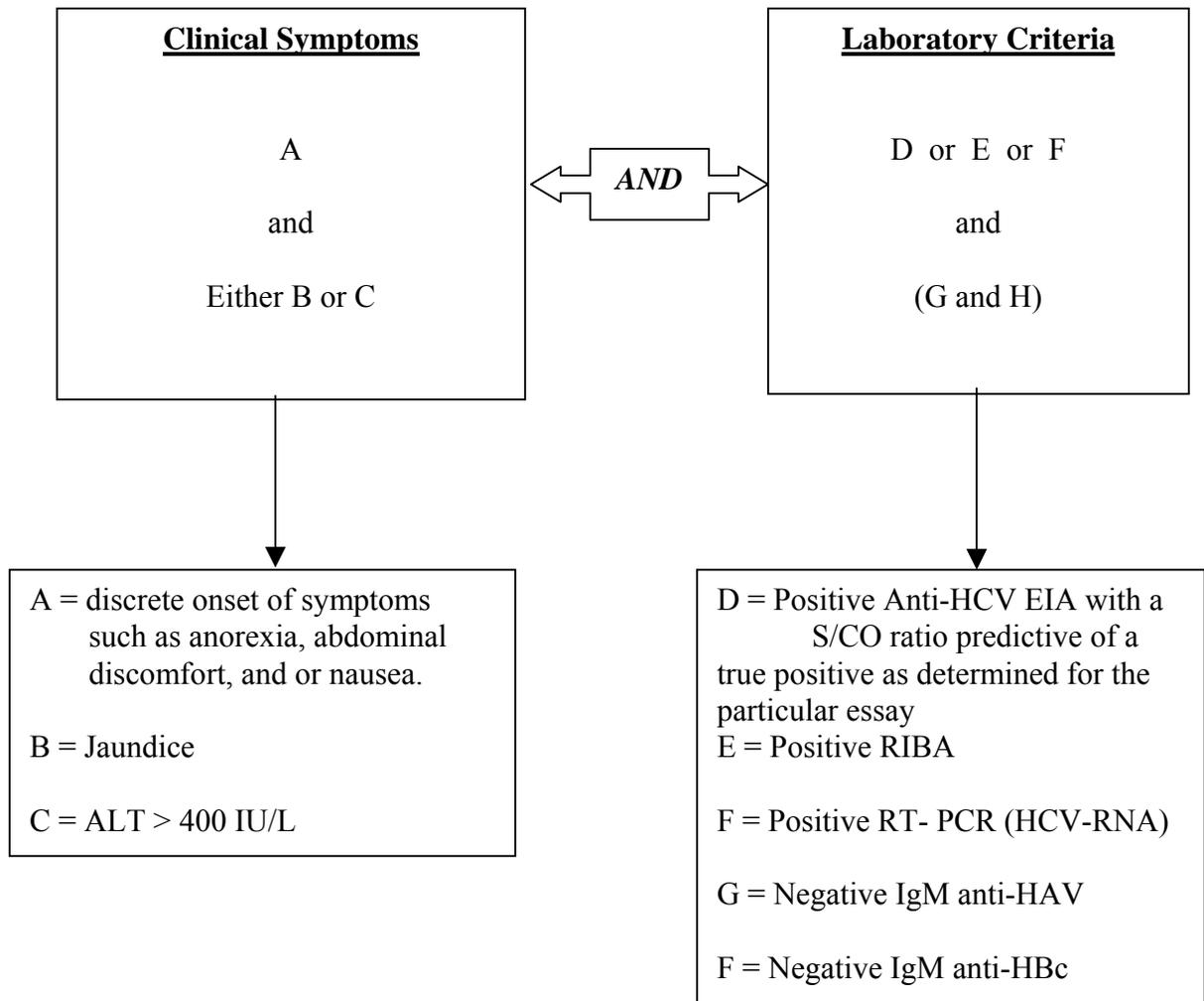
- a.) the case is not considered a case of HCV based on subsequent screening, clinical or laboratory evaluation, or
- b.) this patient is a chronic hepatitis C case being monitored for treatment purposes.

Answers to these questions will help the LPHA to determine the appropriate case disposition and whether any further follow-up is warranted. In this case, request a copy of the confirmatory laboratory test results. When the copies are received, enter them into MOHSIS, update the condition status, diagnostics, and case disposition as appropriate.

Contact with the patient is **NOT** recommended unless the LPHA determines the additional information from the provider supports the need for a full disease investigation for a confirmed unreported hepatitis C case in need of contact identification and/or disease and transmission prevention counseling, or medical referral.

Hepatitis C Case Definition Algorithm:

Algorithm for Determination of Confirmed Acute Hepatitis C Condition



Clinical Symptoms + Laboratory Criteria = Confirmed Acute Hepatitis C*

[A + {Either: B or C}] + positive [(D or E or F) + negative {G and H}] = Confirmed Acute HCV

*Complete the CDC Viral Hepatitis Case Report for all confirmed Acute Hepatitis C cases.

Algorithm for Determination of Suspect, Probable or Confirmed Hepatitis C Condition

	Division of Community and Public Health	
	Section: 4.0 Diseases and Conditions	Page 16 of 18
	Subsection: Hepatitis C	Updated 6/2008

Confirmed =
D or
E or
F or
I or
J (verified by E or F)

D = Positive Anti-HCV EIA (screen test) with S/CO ratio predictive of a true positive as determined for the particular assay

E = Positive RIBA

F = Positive RT-PCR (HCV-RNA)

I = HCV genotype identified

Probable = J
(not verified by RIBA, RT-PCR, or S/CO is not known)
and C

J = Positive Anti-HCV (repeat reactive)

C = ALT or SGPT > ULN

Suspect = J (without other supplemental HCV tests) or K*

K = Isolated HCV-RNA less than the detectable limits of the assay without any other information*

*This scenario requires the LPHA to obtain additional information prior to the determination of condition status (e.g. Ask physician why the test was ordered. Find out if this patient is HCV chronic? If so request copies of confirmatory laboratory results, document the additional information into MOHSIS, determine whether to close the case or that further investigation is warranted.)

Laboratory Criteria = Chronic

[(D or E or F or I or (J verified by E or F))]

Complete the CDC Viral Hepatitis Case Report for all confirmed chronic hepatitis C cases aged 30 years or younger.

	Division of Community and Public Health	
	Section: 4.0 Diseases and Conditions	Page 17 of 18
	Subsection: Hepatitis C	Updated 6/2008

Responsibilities of the Bureau of HIV, STD and Hepatitis (BHSB)

1. Provide case-management and investigation consultation.
2. Data entry of information into MOHSIS within 3-5 days from reporting laboratories when received by the BHSB first.
3. DHSS shall utilize MOHSIS to notify LPHA of HCV reports rather than forwarding traditional hard copies.
4. Quality Assurance and oversight case review to ensure the cases meet current CDC case definitions.
5. Provide educational materials and presentations.
6. Integrate HCV counseling into HIV Counseling, Testing, and Referral (CTR).

State Public Health Laboratory Procedures

Testing for hepatitis C is currently not performed at the Missouri State Public Health Laboratory.

Control Measures

For specific control measures consult the current reference manuals listed below:

American Academy of Pediatrics. "Hepatitis C." In: Pickerton, LK. ed. *Red Book 2006: Report of the Committee on Infectious Diseases*. 27th ed. Elk Grove Village, IL. American Academy of Pediatrics; 2006: 355-359.

Heymann, D., MD, ed. "Hepatitis C." *Control of Communicable Diseases Manual (CCDM)*, 18th ed. Washington, D.C.: American Public Health Association, 2004: 261-264

Links

CDC Viral Hepatitis C Information:

<http://www.cdc.gov/ncidod/diseases/hepatitis/c/index.htm>

American Liver Foundation:

<http://www.liverfoundation.org/>

	Division of Community and Public Health	
	Section: 4.0 Diseases and Conditions	Page 18 of 18
	Subsection: Hepatitis C	Updated 6/2008

References

1. American Academy of Pediatrics. "Hepatitis C." In: Pickerton, LK. ed. *Red Book 2006: Report of the Committee on Infectious Diseases*. 27th ed. Elk Grove Village, IL. American Academy of Pediatrics; 2006: 355-360.
2. Centers for Disease Control and Prevention. *Case Definitions for Infectious Diseases Web Site*, http://www.cdc.gov/EPO/DPHSI/casedef/hepatitis_viral_acute_current.htm
3. Centers for Disease Control and Prevention. *Recommendations for Prevention and Control of Hepatitis C Virus (HCV) Infection and HCV-Related Chronic Disease*. MMWR 1998;47 (No. RR-19): 1-39.
4. Evans, A. S. and Kaslow, R.A., Eds. *Viral Infections of Humans Epidemiology and Control*; 4th ed. Eds. New York: Plenum, 1997: 387-394.
5. Centers for Disease Control and Prevention. *Guideline for Laboratory Testing and Result Reporting of Antibody to Hepatitis C Virus*. MMWR 2003;52 (No. RR-3): 1-13.
6. Hepatitis Control Report, *Big Changes are Coming for Hepatitis C Surveillance*, Summer 2001, Volume 6, Number 2.
7. Heymann, D., MD, ed. "Hepatitis C." *Control of Communicable Diseases Manual (CCDM)*, 18th ed. Washington, D.C.: American Public Health Association, 2004: 261- 264
8. Mandell, G. L., Bennett, J. E., & Dolin, R., Eds. *Principles and Practice of Infectious Diseases*, 5th. Ed. New York: Churchill Livingstone, 2000: 1279-1295, 1736-1753.
9. Mayo Medical Laboratories, *Interpretive Handbook*. Rochester, Minnesota, Mayo Medical Laboratories 2005.
10. Strader, D. B., Wright, T., Thomas, D. L., and Seeff, L. B. AASLD Practice Guideline; Diagnosis, Management, and Treatment of Hepatitis C. Hepatology. 2004. <https://www.aasld.org/eweb/docs/hepatitisc.pdf>