Hepatitis C Guidelines for Local Health Departments

Wisconsin Department of Health Services
Division of Public Health
Bureau of Communicable Diseases
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Acronyms

AASLD	American Association for the Study of Liver Disease
ALT	Alanine aminotransferase
AST	Aspartate aminotransferase
BCD	Bureau of Communicable Diseases
CDC	Centers for Disease Control and Prevention
CIA	Chemiluminescence immunoassay
CSTE	Council for State and Territorial Epidemiologists
DAA	Direct-acting antiviral
DHS	Department of Health Services
DPH	Division of Public Health
EIA	Enzyme immunoassay
FDA	Food and Drug Administration
HAV	Hepatitis A virus
HBV	Hepatitis B virus
HCV	Hepatitis C virus
HIV	Human immunodeficiency virus
IDSA	Infectious Disease Society of America
LHD	Local health department
NAT	Nucleic acid test
NAAT	Nucleic acid amplification test
PCR	Polymerase chain reaction
RNA	Ribonucleic acid
STI	Sexually transmitted infection
WEDSS	Wisconsin Electronic Disease Surveillance System

Introduction

The purpose of this document is to provide local health departments (LHDs) information on following up, preventing, and identifying cases of hepatitis C virus (HCV) infection.

This introduction describes the purpose of disease reporting for HCV, provides a brief overview of the disease, and describes the epidemiology of HCV in the U.S. and Wisconsin.

Disease Reporting

The Wisconsin Department of Health Services (DHS), Division of Public Health (DPH), Bureau of Communicable Diseases (BCD), coordinates statewide communicable disease surveillance and control activities under the authority of Wis. Stat. ch. 252. Hepatitis C is to be reported to the patient's local health officer or to the local health officer's designee within 72 hours of recognition of a case or suspected case, per Wis. Admin Code § DHS 145.04(3)(b). It is to be reported electronically through the Wisconsin Electronic Disease Surveillance System (WEDSS) or by mailing or faxing a completed Acute and Communicable Disease Case Report (F-44151) to the address on the form. According to Wis. Admin Code § DHS 145.04(1), reporting is the responsibility of persons licensed under Wis. Stat. ch. 441 or 448, laboratories, health care facilities, teachers, principals, or nurses serving a school or day care center, and any person who knows or suspects that a person has a communicable disease identified in Appendix A.

The purpose of disease reporting and surveillance is to:

- Identify sources of infection and prevent further transmission.
- Identify new groups at risk and reduce the number of new cases.
- Inform cases about treatment options and prevent additional liver damage.
- Educate individuals about transmission of HCV and how to reduce the risk of transmission.
- Better understand the epidemiology of HCV infection and the burden of disease.

HCV Disease

Hepatitis C is a liver infection caused by the hepatitis C virus, which is a ribonucleic acid (RNA) virus in the Flavivirus family. HCV is a blood borne virus. Disease caused by HCV can be acute, short term, or can become chronic, prolonged, or lifelong. Chronic hepatitis can lead to cirrhosis, liver failure, or cancer.

Symptoms

Most persons with newly acquired HCV infections are either asymptomatic or experience mild symptoms that do not result in a health care visit. Only 20–30% of newly infected persons experience symptoms, which may include:

- Fatigue
- Abdominal pain
- Poor appetite
- Jaundice
- Fever
- Dark urine
- Clay-colored stool
- Nausea or vomiting
- Joint pain

Because the majority of people with HCV infection do not experience any symptoms, many do not know they have HCV.

Transmission

HCV is transmitted primarily through exposure to HCV-infected blood. HCV can survive outside the body at room temperature on environmental surfaces for up to three weeks. Examples of common methods of HCV transmission include:

- Sharing needles, syringes, or other equipment used to prepare or inject drugs (sometimes referred to as "works").
- Occupational exposures, such as a needle stick injury in a health care setting.
- Birth to a mother who has HCV.
- Receipt of blood, blood products, or organs from a donor with HCV. (Before 1992, when HCV blood screening became available, this was a common method of transmission).

Although less common, HCV can be spread through:

- Sharing personal care items that have come into contact with the blood of a person who has HCV (for example, toothbrushes, razors, nail clippers).
- Sexual contact with a person who has HCV.
- Tattoos and body piercings done somewhere other than a licensed tattoo facility or with nonsterile instruments.

Testing Recommendations

In 2020, the CDC updated their testing guidelines to recommend the following:

Universal hepatitis C screening:

- Hepatitis C screening at least once in a lifetime for **all adults** aged 18 years and older, except in settings where the prevalence of HCV infection (HCV RNA-positivity) is less than 0.1%*
- Hepatitis C screening for **all pregnant women during each pregnancy**, except in settings where the prevalence of HCV infection (HCV RNA-positivity) is less than 0.1%*

One-time hepatitis C testing regardless of age or setting prevalence among people with recognized conditions or exposures:

- People with HIV
- People who ever injected drugs and shared needles, syringes, or other drug preparation equipment, including those who injected once or a few times many years ago
- People with selected medical conditions, including:
    - people who ever received maintenance hemodialysis
    - people with persistently abnormal ALT levels
- Prior recipients of transfusions or organ transplants, including:
    - people who received clotting factor concentrates produced before 1987
    - people who received a transfusion of blood or blood components before July 1992
    - people who received an organ transplant before July 1992
    - people who were notified that they received blood from a donor who later tested positive for HCV infection
- Healthcare, emergency medical, and public safety personnel after needle sticks, sharps, or mucosal exposures to HCV-positive blood
- Children born to mothers with HCV infection

Routine periodic testing for people with ongoing risk factors, while risk factors persist:

- People who currently inject drugs and share needles, syringes, or other drug preparation equipment
- People with selected medical conditions, including:
    - people who ever received maintenance hemodialysis

Any person who requests hepatitis C testing should receive it, regardless of disclosure of risk, because many persons may be reluctant to disclose stigmatizing risks to their healthcare providers or at outreach testing sites.

*Determining prevalence: In the absence of existing data for hepatitis C prevalence, healthcare providers should initiate universal hepatitis C screening until they establish that the prevalence of HCV RNA positivity in their population is less than 0.1%, at which point universal screening is no longer explicitly recommended but may occur at the provider's discretion.

In addition, the United States Preventive Services Task Force recommends HCV screening for all adults age 18 to 79 years. Grade: B Recommendation

Treatment

Acute HCV infection may clear naturally without treatment. Chronic HCV can be cured with treatment. Since 2011, new treatments, known as direct-acting antivirals (DAAs), have become available and have been shown to cure 95% of HCV-infected persons with 8–12 weeks of oral therapy. A complete list of FDA-approved HCV medications can be found on Hepatitis C Online, a free educational website by the University of Washington National Hepatitis Center.

As new HCV therapies are available, health care professionals can access timely guidance from HCVGuidelines.org, an online resource created through a partnership between the American Association for the Study of Liver Diseases (AASLD) and the Infectious Disease Society of America (IDSA).

Epidemiology of HCV in the U.S. and Wisconsin

In the U.S., an estimated 2.4 million people have chronic HCV infection. However, it is estimated that only half of these people are aware of their diagnosis.

In Wisconsin, as many as 70,000 adults are living with HCV. However, only approximately half of these people have received testing and are aware of their HCV status. The majority of HCV reports in Wisconsin are among baby boomers (born between 1945 and 1965) and young people who inject drugs. In recent years, several states, including Wisconsin, have reported that the number of infants born to women who have HCV has increased. In 2018, to monitor the number of children infected with HCV through perinatal exposure, the CDC implemented a new case definition for HCV perinatal infection.

For more information on the epidemiology of HCV in the U.S. and Wisconsin, see Centers for Disease Control and Prevention (CDC) Viral Hepatitis or the Wisconsin Hepatitis C Virus Surveillance Annual Review.

Hepatitis C Testing

Testing is the only way to identify HCV infection. There are two types of tests used in the diagnosis of HCV infection: 1) screening tests that detect hepatitis C antibody, and 2) confirmatory tests that detect HCV RNA. The CDC-recommended testing sequence (see Figure 1, page 9) consists of an initial hepatitis C antibody test. A positive or reactive hepatitis C antibody test is followed by an HCV RNA test.

Tests reportable to Wisconsin DHS and LHDs:

- **Positive HCV antibody test**
- **Positive HCV RNA test**
- **Negative HCV RNA test**

1. Screening Test—Detects Hepatitis C Antibody

Tests that detect hepatitis C antibodies are screening tests for HCV infection. Hepatitis C antibody tests indicate infection at some point in time; they do not differentiate between resolved infection and current infection.

Types of tests

The following are the most commonly used HCV antibody tests. The name and type of test may vary by laboratory or laboratory system.

- **Enzyme Immunoassay (EIA):** The EIA test is a laboratory-conducted assay. In the U.S., it is the most commonly used test for initial HCV antibody testing.
- **Chemiluminescence Immunoassay (CIA):** The CIA test is a laboratory-conducted assay. It is comparable to the EIA test but is used much less frequently.
- **Point-of-Care Rapid Immunoassays (HCV Rapid Antibody Tests)**: The OraQuick® HCV Rapid Antibody Test (OraSure Technologies Incorporated) is FDA-approved for detecting HCV antibodies in finger stick and venipuncture whole blood. The test provides an accurate result in 20 minutes. In Wisconsin, this test is used by syringe service providers and local health departments.

The signal-to-cut-off ratio is no longer used in the HCV testing algorithm. However, it may still be reported on laboratory reports. To interpret laboratory results, always read the reference range reported on that laboratory report and determine if the reported results for that patient fall outside the reference range (indicating a positive/reactive result) or fall within the reference range (indicating a normal or negative result).

Positive antibody test

If the HCV antibody test is positive or reactive, HCV antibody is detected. The presence of HCV antibody indicates one of the following:

1. Current HCV infection.
2. Past HCV infection that has resolved.
3. False positivity.

Further testing needs to be done to identify if there is current HCV infection.

Negative antibody test

If the HCV antibody test is negative or non-reactive, there is no HCV antibody detected. No further testing needs to be done.

For people who might have been exposed to HCV within the past six months, testing for HCV RNA or follow-up testing for HCV antibody at a later time is recommended. For people with compromised immune systems, an HCV antibody test may not work and testing for HCV RNA should be considered.

2. Confirmatory Test—Detects Hepatitis C RNA

A positive or reactive HCV antibody test should be followed by testing for HCV RNA. Tests that detect HCV RNA are confirmatory tests that determine whether a person has current HCV infection.

Types of tests

There are several different names for tests that detect HCV RNA, including polymerase chain reaction (PCR) test, nucleic acid test (NAT) and the nucleic acid amplification test (NAAT). The name and type of test may vary by laboratory or laboratory system. In addition, the results produced by these tests might be qualitative, quantitative or genotype results.

- **Qualitative HCV RNA**: Qualitative HCV RNA tests indicate whether detectable HCV RNA is present in the sample or not. These tests do not provide a quantitative level or viral load of HCV and are not used for baseline HCV RNA levels or for monitoring response to treatment.
- **Quantitative HCV RNA**: Quantitative HCV RNA tests generate an actual HCV RNA level (viral load) that may provide useful information as a baseline HCV RNA or to monitor response to treatment.
- **Genotyping**: There are seven distinct genotypes and more than 67 subtypes of HCV. Genotype information may be important for deciding which medications will be used to treat the patient's HCV.

Positive (detected) confirmatory test

If the test indicates that HCV RNA was detected or the viral load is higher than the reported reference range, then there is current HCV infection and the patient should be linked to care. To interpret laboratory results, always read the reference range reported on that laboratory report and determine if the reported results for that patient fall outside the reference range (indicating a positive/reactive result) or fall within the reference range (indicating a normal or negative result).

Negative (not detected) confirmatory test

If the test indicates that HCV RNA was not detected or viral load <15 IU/mL, there is no current HCV infection. This may be a past case of HCV that resolved itself or the patient may have had a false positive HCV antibody test.

To differentiate past resolved HCV infection from biologic false positivity for HCV antibody, testing with another HCV antibody assay can be considered.

A person should have repeat HCV RNA testing if the person is suspected to have had HCV exposure within the past six months, has clinical evidence of HCV disease, or if there is concern regarding the handling or storage of the test specimen.

Additional HCV-Related Tests

When possible, LHDs are encouraged to gather ALT and bilirubin results from the patient's healthcare provider on any suspected HCV cases.

Alanine aminotransferase (ALT):

Elevated ALT results may indicate HCV infection. ALT levels greater than 200 IU/mL are included in the CDC case definition for HCV. It is common for patients with chronic hepatitis C to have liver enzyme levels that fluctuate, with periodic returns to normal or near normal levels. Liver enzyme levels can remain normal for over a year despite chronic liver disease.

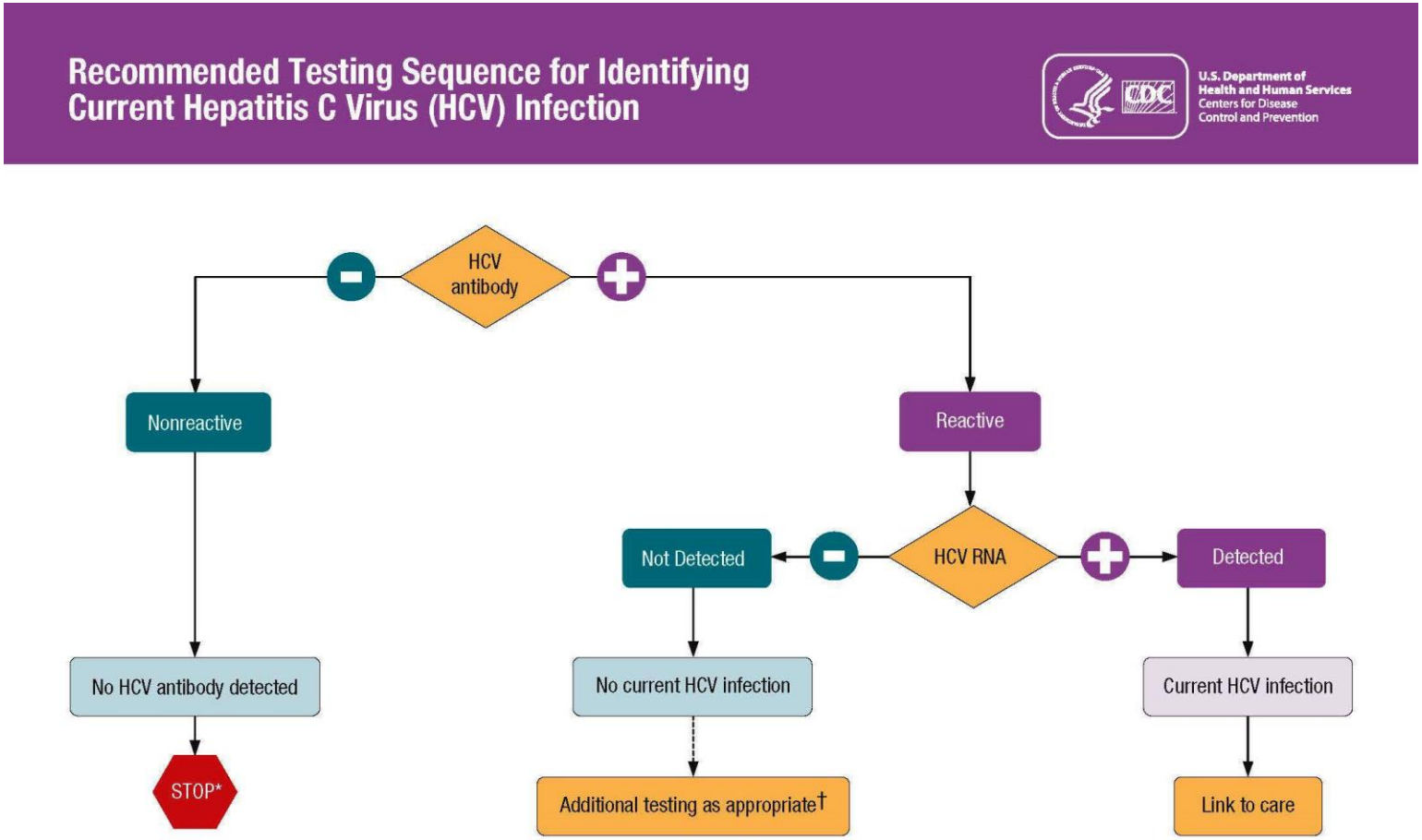
Aspartate aminotransferase (AST):

Elevated AST levels may indicate liver disease and can be used to monitor the disease and assess the effectiveness of treatment.

Bilirubin:

Jaundice (yellow color in the skin or eyes) can be a sign of acute HCV infection. This yellow color is caused by elevated bilirubin levels because the liver is not functioning properly. Elevated bilirubin levels (≥3.0 mg/dL) are included in the CDC case definition for HCV as a laboratory measure of jaundice.

Figure 1. HCV Testing Sequence



* For persons who might have been exposed to HCV within the past 6 months, testing for HCV RNA or follow-up testing for HCV antibody is recommended. For persons who are immunocompromised, testing for HCV RNA can be considered.

† To differentiate past, resolved HCV infection from biologic false positivity for HCV antibody, testing with another HCV antibody assay can be considered. Repeat HCV RNA testing if the person tested is suspected to have had HCV exposure within the past 6 months or has clinical evidence of HCV disease, or if there is concern regarding the handling or storage of the test specimen.

Source: CDC. Testing for HCV infection: An update of guidance for clinicians and laboratorians. MMWR 2013;62(18).

Interpretation of Results of Tests for Hepatitis C Virus (HCV) Infection and Further Actions

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

TEST OUTCOME	INTERPRETATION	FURTHER ACTIONS
HCV antibody nonreactive	No HCV antibody detected	Sample can be reported as nonreactive for HCV antibody. No further action required. If recent exposure in person tested is suspected, test for HCV RNA.*
HCV antibody reactive	Presumptive HCV infection	A repeatedly reactive result is consistent with current HCV infection, or past HCV infection that has resolved, or biologic false positivity for HCV antibody. Test for HCV RNA to identify current infection.
HCV antibody reactive, HCV RNA detected	Current HCV infection	Provide person tested with appropriate counseling and link person tested to care and treatment.†
HCV antibody reactive, HCV RNA not detected	No current HCV infection	No further action required in most cases. If distinction between true positivity and biologic false positivity for HCV antibody is desired, and if sample is repeatedly reactive in the initial test, test with another HCV antibody assay. In certain situations,§ follow up with HCV RNA testing and appropriate counseling.

* If HCV RNA testing is not feasible and person tested is not immunocompromised, do follow-up testing for HCV antibody to demonstrate seroconversion. If the person tested is immunocompromised, consider testing for HCV RNA.

† It is recommended before initiating antiviral therapy to retest for HCV RNA in a subsequent blood sample to confirm HCV RNA positivity.

§ If the person tested is suspected of having HCV exposure within the past 6 months, or has clinical evidence of HCV disease, or if there is concern regarding the handling or storage of the test specimen.

Source: CDC. Testing for HCV infection: An update of guidance for clinicians and laboratorians. MMWR 2013;62(18).

Local Health Jurisdiction Guidelines for Conducting HCV Case Investigations

The following information outlines the process for hepatitis C case investigation. If these steps cannot be completed for all HCV cases, guidance on prioritizing cases has been included. Prioritization of HCV cases may vary across jurisdictions due to capacity limitations determined by the local health department. To view all newly reported HCV cases, in WEDSS regularly review: (1) the Staging environment and (2) Jurisdiction Review for cases with a process status of "New" and a disease of "Hepatitis C, Acute", "Hepatitis C, Chronic", Hepatitis C, Perinatal", "Hepatitis C, Suspected Reinfection – Acute" or "Hepatitis C, Suspected Reinfection – Chronic".

Routine case investigation

Step 1

Determine if the patient was previously reported to the Wisconsin Electronic Disease Surveillance System (WEDSS) as an HCV case of any type (see list in paragraph above as well as "Hepatitis C").

A. If the patient **was** previously reported, attach all new lab reports (positive antibody and positive/negative RNA results) to the existing WEDSS incident for the patient. There should only be one disease incident of HCV per person in their lifetime. The only exception to this rule is if there is a suspected reinfection.

1. If the patient was previously reported as a ***confirmed chronic case***, no further investigation is needed. Do not proceed with the following steps.
2. If the patient was previously reported as a ***probable chronic case,*** the case was reported during the current calendar year and has not been finalized in WEDSS, and the new laboratory evidence *confirms* infection, update the resolution status to **confirmed** and complete the investigation if not previously completed.
3. If the patient has been previously investigated, no further investigation is needed and you do not proceed with the following steps.

B. If the patient **was not** previously reported in Wisconsin, further investigation is needed. In particular, if the case is assigned to you by DHS and has a disease name of "Hepatitis C, Acute" or "Hepatitis C, Suspected Reinfection", further investigation is requested. Proceed with the following steps.

Step 2

Contact the medical provider (or laboratory, if needed) to collect information to determine the correct HCV case definition.

A. Ask about:

1. The reason for testing.
2. Results of any previous HCV testing, including previous negative results and previous genotype results.

If Step 2 cannot be completed for all patients, prioritize the following groups:

- **Those reported with test conversion, symptoms or other indications it may be a new (acute) infection**
- **Suspected reinfection**
- **People age less than 40 years**

3. Symptoms: jaundice, fever, malaise (general feeling of being unwell), nausea, diarrhea, headache, anorexia, vomiting, abdominal pain, or joint pain.
4. Liver enzyme (ALT) test results.
5. Bilirubin test results.
6. The date of illness onset.
7. The possible source of infection and risk factors during the period two weeks to six months (14-180 days) before onset of illness.
8. Does the provider think this is a new (acute) HCV infection or an existing (chronic) HCV infection?
9. Was there an alternate diagnosis that explains any of the symptoms or other clinical findings (elevated ALT, elevated bilirubin)? For example, does the person have liver disease due to alcohol exposure or hemochromatosis? Or does the person have advanced liver disease due to a pre-existing chronic HCV infection? Or does the person have a different acute viral hepatitis infection (hepatitis A virus or hepatitis B virus)?
10. Has the patient received HCV treatment recently or in the past? If so, when was that treatment completed?

B. **For cases of suspected reinfection**, does the provider think that the recent positive RNA results are because of reinfection? Or does the provider think the patient experienced treatment failure? What evidence does the provider give to support the answer?

C. **If no RNA test has been done**, discuss the importance of confirming the diagnosis with an RNA test. This may be a good time to talk to the healthcare provider about the importance of ordering an HCV test that 'reflexes' to RNA. This means that the specimen is first tested for HCV antibody, and if the specimen is positive for HCV antibody then an HCV RNA test is automatically conducted on the specimen.

Step 3 Contact the patient to collect information.

A. If no RNA test has been done, discuss the importance of confirming the diagnosis with an RNA test through their healthcare provider or other testing site

B. If an acute HCV infection or reinfection is suspected, attempt to determine:
   1. The date of onset of any symptoms.
   2. Symptoms: jaundice, fever, malaise (general feeling of being unwell), nausea, diarrhea, headache, anorexia, vomiting, abdominal pain or joint pain.
   3. The source of infection by asking about potential exposures. Pay particular attention to the period two weeks to six months (14-180 days) before onset of illness. Exposure Information should include:
      a. Injection drug use.
      b. Occupational or other needle stick injuries.
      c. Receipt of blood transfusion or other blood products, organs or tissues.
      d. Potential medical or dental exposures within six months prior to onset of current illness.
      e. Other exposures within the six months prior to onset of current illness, including but not limited to tattooing, piercing, or acupuncture.
      f. Accidental exposure of skin, eyes, mucous membranes, or a wound to the blood of another person.
      g. High-risk sexual contact (multiple partners, history of other sexually transmitted infections [STIs], anal sex, etc.).

C. If a chronic HCV infection is suspected, collect as much information as possible, including the information on the lab clinical and risk tabs in WEDSS.

If Step 3 cannot be completed for all cases, prioritize the following groups:

- **Suspected reinfection**
- **Injection drug use (within the last 6 months)**
- **Symptoms of acute hepatitis, including jaundice**
- **Elevated liver enzymes (ALT >200 IU/L) or elevated bilirubin (≥3.0 mg/dL)**
- **Pregnant women**
- **Age <40**
- **Known HIV diagnoses**
- **Known STI diagnoses**
- **HCV testing and diagnosis in an emergency room or urgent care facility**
- **Health care blood exposure (needle stick or sharps exposure) to HCV positive blood**
- **Hemodialysis (within the last 6 months)**

Step 4 Educate the patient about hepatitis C.

Focus on:

- **Testing**: For people who might have been recently infected with HCV within the past six months, testing for HCV RNA at a later time is recommended.
- **Treatment**: There are treatments available that can cure HCV. Patients should talk with their primary care provider about treatment options. For patients eligible for Medicaid, remind them that Wisconsin Medicaid has removed all HCV treatment restrictions.
- **Minimizing disease progression.**
  - Avoid or reduce alcohol intake.
  - Be evaluated for other conditions that may accelerate liver damage, such as hepatitis B or HIV.
  - Get vaccinated against hepatitis A and hepatitis B.
- **Reducing risk of transmission**
  - Remember: HCV is not spread by sharing eating utensils, breastfeeding, hugging, kissing, holding hands, coughing, or sneezing. It is also not spread through sharing food or drink.
  - Do not donate blood, body organs, other tissues, or semen.
  - Do not share personal care items that might have blood on them, such as toothbrushes, razors, nail clippers, blood testing equipment, etc.
  - Cover cuts and sores on the skin to keep from spreading infectious blood or secretions.
  - Use protection if sexually active.
  - Do not share needles, syringes, water, cleaning materials, "works" or other equipment used to prepare or inject drugs. Refer to local syringe service programs (SSPs) in order to access sterile supplies, testing and education.
  - If you are a health care worker, always follow routine barrier precautions and safely handle needles or other sharps.
  - Only get tattoos or body piercings from licensed facilities.
  - Persons with HCV should **not** be excluded from work, school, play, child care, or other settings on the basis of their HCV infection status. The risk of transmission is low.

Step 5 If possible, identify and manage contacts of the patient.

- People with whom the patient has shared equipment used to prepare or inject drugs and long-term sexual contacts should be educated about transmission of HCV and be tested. One option is to refer them for testing at syringe service programs (SSPs).
- If the patient is a health care worker, evaluate the potential for exposing their patients. Encourage the person to seek out counseling from employee health services regarding risk reduction strategies and to practice standard precautions.
- Determine if the patient has donated blood or plasma in the six months prior to onset or any time thereafter. If so, notify the blood bank or plasma center with particulars (date, etc.).

- Recommend that the patient's contacts that are not already immune be vaccinated against other forms of hepatitis—hepatitis A virus and hepatitis B virus—to prevent dual infections.
- Household (nonsexual) contacts of HCV infected patients do not need to be tested for HCV unless personal care items have been shared.

Managing Special Situations

Case age is younger than 36 months at positive HCV test result (possible perinatal case)

- If RNA test has not been done, contact health care provider to encourage RNA testing at age 2 months or later. **Note**: HCV antibody testing is not recommended for infants under age 18 months.
- If the mother has not been tested for HCV, recommend HCV testing for the mother to determine if the child was infected perinatally.
- If mother has HCV, educate and follow up as for a normal case.
- Inform the birth mother that women with HCV infection have a 5% risk of transmitting HCV to future children during future pregnancies and deliveries.
- Recommend hepatitis A and hepatitis B vaccines for the infant (hepatitis B vaccine series starting at birth and the hepatitis A series starting at age 1 year), the mother, and for future children.

Case is pregnant

- Inform the pregnant patient that the risk of transmitting HCV to a fetus during a pregnancy and delivery is about 5%.
- Recommend pregnant women talk to their health care provider about hepatitis A and hepatitis B vaccination.
- Recommend pregnant women speak to their health care provider about receiving HCV treatment after delivery and before any subsequent pregnancies.

Case has a needle stick or similar exposure, is a health care worker, has a suspected iatrogenic infection, or is a recent blood donor or recipient

Questions about significant exposure should be directed to the Wisconsin Healthcare-Associated Infection (HAI) Prevention Program at 608-267-7711.

HCV Prevention Messages

- Currently there is not a vaccine for HCV. Recommend that people get vaccinated against other forms of hepatitis—hepatitis A virus (HAV) and hepatitis B virus (HBV). (Questions about vaccines and immunizations should be directed to the Wisconsin Immunization Program at 608-267-9959.)
- Avoid sharing or reusing needles, syringes, or other equipment to prepare or inject drugs, steroids, hormones, or anything else.
- Do not use personal items that may have come into contact with the blood of a person with HCV, such as toothbrushes, razors, nail clippers, needles, syringes, blood testing equipment, etc.
- Only get tattoos or body piercings from licensed tattoo facilities. Avoid getting homemade tattoos or tattoos in jail or prison.

- Any blood spills—including dried blood, which can still be infectious—should be cleaned using a dilution of one part household bleach to 10 parts water. Gloves should be worn when cleaning up blood spills.

Hepatitis C Case Definitions

After the 'Local Health Jurisdiction Guidelines for Conducting HCV Investigations' have been followed, the case should then be classified in WEDSS (in the Resolution Status) using the CDC definitions below.

Acute Case (CDC 2020)

Clinical Criteria:

All hepatitis C virus cases in each classification category should be > 36 months of age, unless known to have been exposed non-perinatally.

One or more of the following:

Jaundice
OR
Peak elevated total bilirubin levels ≥ 3.0 mg/dL
OR
Peak elevated serum alanine aminotransferase (ALT) levels >200 IU/L

AND

The absence of a more likely diagnosis (which may include evidence of acute liver disease due to other causes or advanced liver disease due to pre-existing chronic Hepatitis C virus (HCV) infection or other causes, such as alcohol exposure, other viral hepatitis, hemochromatosis, etc.)

Laboratory Criteria for Diagnosis:

Confirmatory laboratory evidence:

- Positive hepatitis C virus detection test: Nucleic acid test (NAT) for HCV RNA positive (including qualitative, quantitative, or genotype testing)
  OR
- A positive test indicating presence of hepatitis C viral antigen(s) (HCV antigen)

Presumptive laboratory evidence:

- A positive test for antibodies to hepatitis C virus (anti-HCV)

Criteria to Distinguish a New Case from an Existing Case:

- A new acute case is an incident case that is over the age of 36 months and has not previously been reported meeting case criteria for chronic hepatitis C or for whom there is laboratory evidence of re-infection. Cases under the age of 36 months should be classified under the Perinatal HCV Position Statement (17-ID-08) unless the exposure mode is not perinatal (e.g., healthcare acquired).
- Acute cases determined via anti-HCV test conversion do not need to have a positive HCV viral detection test reported to be considered confirmed acute cases.
- For probable acute cases, the presence of a negative HCV viral detection test result, in the absence of criteria that would allow for confirmation, indicates that a case should not be classified as probable acute and should not be reported to CDC.

Case Classification:

Probable

- A case that meets clinical criteria and has presumptive laboratory evidence
  AND
- Does not have a hepatitis C virus detection test reported
  AND
- Has no documentation of anti-HCV or HCV RNA test conversion within 12 months

Confirmed

- A case that meets clinical criteria and has confirmatory laboratory evidence
  OR
- A documented negative HCV antibody followed within 12 months by a positive HCV antibody test (anti-HCV test conversion) in the absence of a more likely diagnosis
  OR
- A documented negative HCV antibody OR negative hepatitis C virus detection test (in someone without a prior diagnosis of HCV infection) followed within 12 months by a positive hepatitis C virus detection test (HCV RNA test conversion) in the absence of a more likely diagnosis

Chronic Case (CDC 2020)

Clinical Criteria:

All hepatitis C virus cases in each classification category should be > 36 months of age, unless known to have been exposed non-perinatally.

One or more of the following:

Jaundice
OR
Peak elevated total bilirubin levels ≥ 3.0 mg/dL
OR
Peak elevated serum alanine aminotransferase (ALT) levels >200 IU/L

AND

The absence of a more likely diagnosis (which may include evidence of acute liver disease due to other causes or advanced liver disease due to pre-existing chronic Hepatitis C virus (HCV) infection or other causes, such as alcohol exposure, other viral hepatitis, hemochromatosis, etc.)

Laboratory Criteria for Diagnosis:

Confirmatory laboratory evidence:

- Positive hepatitis C virus detection test: Nucleic acid test (NAT) for HCV RNA positive (including qualitative, quantitative, or genotype testing)
  OR
- A positive test indicating presence of hepatitis C viral antigen(s) (HCV antigen)

Presumptive laboratory evidence:

- A positive test for antibodies to hepatitis C virus (anti-HCV)

Criteria to Distinguish a New Case from an Existing Case:

- All jurisdictions are encouraged to track negative HCV viral detection tests to document both spontaneous clearance of infection or sustained viral response to HCV treatment. Cases that have evidence of having cleared the infection at time of initial report or are considered false positive should not be reported to CDC.
- If evidence indicating resolution of infection is received after a confirmed chronic case has been reported to CDC, the case report does not need to be modified as it was a confirmed case at the time of initial report. However, negative HCV viral detection test results received on confirmed chronic cases, subsequent to an initial positive result, should be appended to case reports, as feasible, and considered for the purpose of data analysis by each jurisdiction.
- **Evidence for re-infection may include a case of confirmed chronic HCV infection that has at least two sequential negative HCV viral detection tests reported, indicative of treatment initiation and sustained virologic response, followed by a positive HCV viral detection test.** Under current treatment recommendations, those two negative tests should be at least three months apart, however, the timing may change as standard of care for HCV treatment evolves. **Other evidence of reinfection should be considered, including a report of a new genotype on a case that has previously cleared a different genotype**. Jurisdictions are encouraged to ensure that cases of HCV treatment failure are not classified as new cases of HCV infection to the extent that it can be determined. Jurisdictions tracking re-infection should also consider collecting data on prior treatment completion (when relevant and possible to document), treatment failure, change in reported genotype if that applies, and the known time frame for reinfection.
- For probable chronic cases, the presence of a negative HCV viral detection test result, in the absence of criteria that would allow for confirmation, indicates that a case should not be classified as probable chronic and should not be reported to CDC.
- A new chronic case is a newly reported case that does not have evidence of being an acute case of HCV infection.
- Jurisdictions are also encouraged to track and classify possible re-infection cases that may have been previously submitted to CDC as a confirmed or probable chronic HCV infection case. Jurisdictions tracking re-infection should also consider collecting data on prior treatment completion (when relevant and possible to document), treatment failure, change in reported genotype if that applies, and the known time frame for reinfection.

Case Classification:

Probable

- A case that does not meet OR has no report of clinical criteria
  AND
- Has presumptive laboratory evidence
  AND
- Has no documentation of anti-HCV or RNA test conversion within 12 months
  AND
- Does not have an HCV RNA detection test reported

Confirmed

- A case that does not meet OR has no report of clinical criteria
  AND
- Has confirmatory laboratory evidence
  AND
- Has no documentation of anti-HCV or HCV RNA test conversion within 12 months

Perinatal Infection (CDC 2018)

Clinical Criteria:

Perinatal hepatitis C in pediatric patients may range from asymptomatic to fulminant hepatitis.

Laboratory Criteria for Diagnosis:

- HCV RNA positive test results for infants between 2 to 36 months of age
  OR
- HCV genotype test results for infants between 2 to 36 months of age or greater
  OR
- HCV antigen test results for infants between 2 to 36 months of age or greater.

Epidemiologic Linkage:

Maternal infection with HCV of any duration, if known. Not known to have been exposed to HCV via a mechanism other than perinatal (for example, not acquired via health care).

Criteria to Distinguish a New Case from an Existing Case:

Test results prior to 2 months of age should not be used for classification. Test results after 36 months of age should be reported under the 2020 Acute and Chronic HCV Infection case classification and not as perinatal HCV infection. Cases in the specified age range that are known to have been exposed to HCV via health care, and not perinatally, should be reported under the 2020 case definition. Event date should be based on earliest relevant laboratory test date within the 2 to 36 month window.

Case Classification:

Confirmed

Infant who has a positive test for HCV RNA nucleic acid amplification test (NAAT), HCV antigen, or detectable HCV genotype at ≥2 months and ≤36 months of age and is not known to have been exposed to HCV via a mechanism other than perinatal.

Hepatitis C Case Classification Table

	Clinical criteria Jaundice ***or*** ALT >200 IU/L ***or*** total bilirubin ≥3.0 mg/dL **AND** the absence of a more likely diagnosis[1]	
HCV test results	**No,** does not have enough information to meet clinical criteria above	**Yes,** meets clinical criteria above
Perinatal Cases The classification below is for persons age ≥2 months and ≤36 months at the time of specimen collection who are suspected to have been exposed perinatally.		
Meets age requirement and had positive HCV RNA or detectable HCV genotype results.[2]	Disease = Hepatitis C, Perinatal Resolution Status = Confirmed	Disease = Hepatitis C, Perinatal Resolution Status = Confirmed
Acute and Chronic Cases The classifications below are for persons age >36 months only, unless a person age ≤36 months was known to have been exposed non-perinatally.		
HCV antibody positive[3] only, without a positive HCV RNA result in the same calendar year.	Disease = Hepatitis C, Chronic Resolution Status = Probable	Disease = Hepatitis C, Acute Resolution Status = Probable
Any HCV RNA (nucleic acid) test positive[4] or HCV antigen test[5] positive.[*]	Disease = Hepatitis C, Chronic Resolution Status = Confirmed	Disease = Hepatitis C, Acute Resolution Status = Confirmed
HCV antibody positive[3] followed by a negative[6] HCV RNA in the same calendar year. (And never had a positive HCV RNA test result.)	Disease = Hepatitis C, Chronic Resolution Status = Not a Case	Disease = Hepatitis C, Chronic Resolution Status = Not a Case
A documented negative HCV antibody test result followed within 12 months by a positive HCV antibody test result (anti-HCV test conversion).[7]	Disease = Hepatitis C, Acute Resolution Status = Confirmed	Disease = Hepatitis C, Acute Resolution Status = Confirmed
A documented negative HCV antibody test result OR negative HCV RNA test result followed within 12 months by a positive HCV RNA test result (HCV RNA test conversion), in the absence of a more likely diagnosis.[8]	Disease = Hepatitis C, Acute Resolution Status = Confirmed	Disease = Hepatitis C, Acute Resolution Status = Confirmed

Suspected Reinfection Cases The classifications below are for people who were previously reported to WEDSS and to the CDC as a confirmed or probable case of HCV. DHS will monitor WEDSS throughout the year to identify cases of reinfection and assign them to jurisdictions (with a process status of "New") when they are found.		
In the years following the initial report as a confirmed or probable case either: (1) two documented negative[6] HCV RNA results >28 days apart, followed by a positive[4] HCV RNA result or (2) documentation of clearance of one genotype and subsequent infection with a different genotype.	Disease = Hepatitis C, Suspected Reinfection – Chronic Resolution Status = Confirmed	Disease = Hepatitis C, Suspected Reinfection – Acute Resolution Status = Confirmed
In the years following the initial report as a confirmed or probable case, documentation of one negative[6] RNA result followed by a positive[4] HCV RNA result	Disease = Hepatitis C, Suspected Reinfection – Chronic Resolution Status = Suspect	Disease = Hepatitis C, Suspected Reinfection – Acute Resolution Status = Suspect

[1]A more likely diagnosis may include evidence of acute liver disease due to causes that are not acute HCV. A more likely diagnosis may include advanced liver disease due to a pre-existing chronic HCV infection or other causes, such as alcohol exposure, other viral hepatitis, hemochromatosis, etc.

[2]And not known to have been exposed to HCV via a mechanism other than perinatal.

[3]Any antibody result, regardless of the signal-to-cutoff ratio; includes rapid tests.

[4]Nucleic acid tests for HCV RNA include quantitative, qualitative and genotype testing.

[5]When and if a test for HCV antigen is approved by FDA and available.

[6]A test result for HCV RNA or antigen that indicates 'HCV RNA not detected', 'Negative', or below the level of detection for the test.

[7]A case with documented anti-HCV test conversion is automatically classified as 'Confirmed, Acute' regardless of clinical criteria.

[8]A case with documented HCV RNA test conversion, in a person without a prior diagnosis of HCV infection and without a more likely diagnosis, is classified as 'Confirmed, Acute' regardless of clinical criteria.

**WDPH is not reclassifying HCV cases in which spontaneous clearance of infection or sustained viral response to treatment has occurred. Therefore, a previously 'Confirmed, Chronic' or 'Confirmed, Acute' case that has a negative HCV RNA result will remain a 'Confirmed' case in WEDSS.*

Resources

For Health Care Professionals

Continuing Education

- Hepatitis C: Basic Facts – Wisconsin Hepatitis C Program and University of Wisconsin HIV Training System
- Viral Hepatitis Serology Training – Centers for Disease Control and Prevention
- Hepatitis C Online - University of Washington National Hepatitis Center
- Harm Reduction Trainings and Issues – National Harm Reduction Coalition

Hepatitis C Testing

Centers for Disease Control and Prevention (CDC), Viral Hepatitis, Hepatitis C

- Testing Recommendations for Hepatitis C Virus Infection
- Recommended Testing Sequence for Identifying Current Hepatitis C Virus (HCV) Infection
- Interpretation of Results of Tests for Hepatitis C Virus (HCV) Infection and Further Actions

Hepatitis C Treatment

- **FDA-approved medications**—This link provides information on all HCV treatment medications. Source: *Hepatitis C Online*, University of Washington National Hepatitis Center.
- **Association for the Study of Liver Diseases and Infectious Diseases Society of America (AASLD – IDSA)**—This link provides recommendations for testing, managing, and treating Hepatitis C.

Wisconsin and National Agencies

Wisconsin Department of Health Services, Division of Public Health, Hepatitis C Program—
Hepatitis C Fact Sheet (Available in English, Hmong and Spanish)
Hepatitis C in Wisconsin: Increase among Young People Who Injection Drugs

Wisconsin State Laboratory of Hygiene

Wisconsin Electronic Disease Surveillance System (WEDSS)

Centers for Disease Control and Prevention (CDC), Viral Hepatitis, Hepatitis C

- HCV Case Definitions: Acute, Chronic, and Perinatal Infection
- Hepatitis C FAQs for Health Professionals
- Hepatitis C FAQs for the Public

National Viral Hepatitis Roundtable (NVHR)
This national coalition's goal is to eliminate hepatitis B and C in the U.S. The website includes patient and provider resources, and continuing education opportunities.

For Patients

Help 4 Hep
This nonprofit provides a peer-to-peer helpline for patients.

Hep
A print and online brand for people living with and affected by viral hepatitis, Hep and HepMag.com offer educational and social support for people living with hepatitis.

American Liver Foundation
This foundation provides patient education resources for people living with liver disease.

Vivent Health (formerly known as AIDS Resource Center of Wisconsin / ARCW)
This organization is an HIV medical care home in Wisconsin with prevention services, including syringe exchange services and HIV, hepatitis C and STI testing. The services available vary based on location. Call the location for details on services provided..

Wisconsin Treatment Directory for Opioid Use Disorder
This directory for opioid treatment programs provides information on medications combined with counseling and other services.

Wisconsin NARCAN® Direct Program
NARCAN® is the nasal spray formulation of naloxone, a drug used to reverse opioid overdoses. The agencies highlighted on this map are providing NARCAN® at no cost to people at risk for an opioid overdose and people who may witness an opioid overdose. Contact the agency near you to learn where and when they provide NARCAN® and NARCAN® trainings.

Acknowledgements

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