Utah Department of Health & Human Services

Hepatitis C (chronic, acute, perinatal)

Disease plan

Quick links

Last updated: 08/22/2022, by Amelia Salmanson, MPH

Questions about this disease plan?

Contact the Utah Department of Health and Human Services, Office of Communicable Diseases: 801-538-6191.

Acute and chronic hepatitis C virus (HCV) critical clinician information

Clinical evidence

Signs/symptoms

- Acute infection is often asymptomatic (~80% of cases) or mild; it is uncommon for people to be diagnosed in the acute stage. If symptoms occur, they begin about 7 weeks after infection and can include: jaundice, fatigue, dark urine, abdominal pain, loss of appetite, and nausea.
- People with chronic infection may be asymptomatic for 1–2 decades. Some patients may intermittently experience a range of symptoms, including fatigue, headache, joint aches, muscle aches, nausea, jaundice, loss of appetite, and/or abdominal pain.

Period of communicability

- Anyone with a positive test for anti-HCV antibody is considered infectious until ruled out by negative HCV detection tests.
- HCV can usually be detected by the presence of viral RNA in an infected person's blood 1–3 weeks after initial exposure.

Incubation period

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

Mode of transmission

- Blood to blood
- The highest risk is through sharing drug injection equipment.

Laboratory testing

Type of lab test	Also known as	Type of specimens	Collection timing
HCV RNA	PCR, NAAT, NAT, Viral Load	Serum or plasma	≥2 weeks after suspected exposure
HCV antigen (when available)	HCV Ag	Serum or plasma	≥2 weeks after suspected exposure
HCV antibody	Anti-HCV, HCV Ab	Serum or plasma	≥2 weeks after suspected exposure
HCV genotype	Genotype by PCR	Serum or plasma	≥2 weeks after suspected exposure

Treatment recommendations

Type of treatment

- Direct-acting antivirals (DAAs)
- Most new DAAs are pangenotypic (simplified treatment algorithm).

Prophylaxis

- There is currently no post-exposure prophylaxis for HCV.

Case and contact management

Isolation of case: None
Hospital: Standard precautions
Quarantine: None
Contact management: Drug use partners, specifically injection drug use, should be tested for HCV and linked to care

Infection control procedures

- Standard precautions

Perinatal HCV (≤ 36 months of age) critical clinician information

Clinical evidence

Signs/symptoms

- Newborns with HCV are usually asymptomatic, with a substantial proportion who have normal or mildly elevated serum alanine aminotransferase (ALT) concentrations.

Period of communicability

- Anyone with a positive anti-HCV antibody test should be considered infectious until ruled out by negative HCV detection tests.
- Prior to 18 months of age, anti-HCV antibody testing is not specific for infection since a positive test can reflect maternal IgG antibodies that have passively crossed the placenta.

Incubation period

- Timing of transmission can be reflected by results of PCR testing for HCV RNA, which may not be positive until several weeks after infection, when levels of viremia reach the detection threshold.
- In most infants, HCV RNA levels become detectable several weeks after birth, suggesting perinatal infection. However, detection of HCV RNA within a few days of delivery has also been described, which suggests in utero infection earlier in pregnancy can occur.

Mode of transmission

- Vertical transmission, both intrauterine and perinatally.
- There is no evidence that breastfeeding spreads HCV, but HCV-positive breastfeeding parents with cracked or bleeding nipples should consider precautions.

Laboratory testing

Type of lab test	Also known ss	Type of specimens	Collection timing
HCV RNA	PCR, NAT, viral load	Serum or plasma	2–36 months of age
HCV antigen (when available)	HCV Ag	Serum or plasma	>2 months of age
HCV antibody	Anti-HCV, HCV Ab	Serum or plasma	>18 months of age
HCV genotype	Genotype by PCR	Serum or plasma	>2 months of age

Treatment recommendations

Type of treatment

- When a child is diagnosed with HCV, further evaluation is needed to inform treatment decisions and monitor for progression of liver disease.
- Currently available curative HCV therapies are not recommended for pediatric patients younger than age 12.
- Treatment for children aged 3–11 years with chronic HCV should be deferred until interferon-free regimens are available.
- If direct-acting antiviral (DAA) regimens are available for a child's age group, treatment may be recommended for HCV-infected children >3 years as they will benefit from antiviral therapy, independent of disease severity.

Prophylaxis

- There is currently no post-exposure prophylaxis for HCV.

Case and contact management

Isolation of case: None

Hospital: Standard precautions

Quarantine: None

Contact management: Gestational parent should be tested for HCV and linked to care

Infection control procedures

- Standard precautions

Why is hepatitis C virus important to public health?

Hepatitis C virus (HCV) infection is a serious disease that can result in long-term health problems, including liver damage, liver failure, liver cancer, or even death. It is the leading cause of cirrhosis and liver cancer and the most common reason for liver transplants in the U.S. Approximately 15,000 people die every year from HCV-related liver disease. HCV affects a diverse proportion of the population because prior to identification, HCV can spread with little control through blood and organ tissue during transfusion and tissue transplant. Most individuals are unaware of their HCV infection status, which increases the probability of developing long-term health problems. Public health works to control HCV through increased community awareness, testing recommendations, and education. With the recent advent of highly effective treatments that can cure many persons with chronic HCV infection, public health has a role in assessing the distribution and characteristics of persons who may be in need of treatment.

Perinatal hepatitis C

From 2009–2014, the prevalence of hepatitis C among pregnant people in the United States significantly increased by 89%, from 1.8 to 3.4 per 1,000 live births based on maternal HCV infection status reported on birth certificates from the National Vital Statistics System (NVSS). Additionally, the proportion of infants born to HCV-infected gestational parents increased by 68% nationally from 2011 through 2014 (CDC, 2021).

CDC recommends healthcare providers test all pregnant persons during each pregnancy for HCV. CDC also recommends testing all children born to gestational parents living with HCV. About 4–7% of these babies are infected with the virus during pregnancy or childbirth, and risk doubles if the gestational parent is co-infected with HIV or has high levels of HCV in their body. No curative treatment has been determined safe for use by pregnant persons or infants (CDC, 2021).

Prior to 2017, a case definition had not been established for classification of perinatal HCV infection. In 2018, the Council of State and Territorial Epidemiologists (CSTE) developed guidelines for HCV testing in children younger than 36 months born to HCV positive gestational persons. Additionally, case definitions were developed to support case classification of perinatal HCV.

Screening recommendations and interpretation of HCV laboratory results for infants born to HCV-positive gestational parents differ from those for adolescents and adults. There has been a reported increase of HCV infection among persons of childbearing age in numerous jurisdictions in the U.S., increasing the likelihood that perinatal transmission will increase as a result (CSTE, 2017).

Goals of surveillance:

- Improve assessment of the scope of the problem of perinatal HCV transmission.
- Identify infants who become infected with HCV via exposure from a gestational parent with HCV infection.
- Use perinatal HCV surveillance data for determination of linkage to care for infants with confirmed HCV infection.
- Evaluate health outcomes of infected infants.
- Reduce HCV transmission from mother to baby.

Disease and epidemiology

Clinical description

Symptoms—acute

Initial infection with HCV is often asymptomatic (~80% of cases) or mild; it is uncommon for people to be diagnosed with HCV infection in the acute stage. If clinical illness occurs, symptoms begin about 7 weeks after infection and can include: jaundice, fatigue, dark urine, abdominal pain, loss of appetite, and nausea. About 15–25% of HCV-infected individuals clear infection without treatment; the rest develop chronic infection. Hepatitis C is a disease with varying rates of progression; however it generally progresses slowly.

Symptoms—chronic

Most people are asymptomatic during the first decade or 2 of chronic HCV infection. Some patients may intermittently experience a range of symptoms, including fatigue, headache, joint aches, muscle aches, nausea, jaundice, loss of appetite, and/or abdominal pain.

For many people with chronic HCV, signs and symptoms appear only when liver disease is advanced. Almost 70% of those with chronic HCV infection develop chronic liver disease (CLD), a situation in which the virus damages the liver. The damage may progress to severe disease, including cirrhosis, liver cancer, and liver failure.

Severe disease or cirrhosis symptoms include fatigue, muscle weakness, poor appetite, nausea, weight loss, itching, dark urine, fluid retention, and abdominal swelling.

Symptoms—perinatal

Newborn infants with HCV infection are usually asymptomatic; a substantial proportion have normal or mildly elevated serum alanine aminotransferase (ALT) concentrations. Progression to

chronic infection occurs with most infants who acquire HCV through vertical transmission, however liver disease is typically mild throughout childhood (UpToDate, 2020).

Causative agent

HCV is a spherical, enveloped, single-stranded RNA virus belonging to the Flaviviridae family and Hepacivirus genus. HCV is related to hepatitis G, dengue, and yellow fever viruses. HCV can produce at least 10 trillion new viral particles each day. Six major HCV genotypes and numerous subtypes have been identified.

Table 1: HCV genotypes and subtypes

	Genotype 1	Genotype 2	Genotype 3	Genotype 4	Genotype 5	Genotype 6
Subtypes	a, b, c	a, b, c, k	a, b, k	a	a	a, b, d, g, h, k
North America prevalence	75%	10%	11%	2%	<1%	<1%

Note. Estimated U.S. Genotype (all subtypes) prevalence, as described in "Global epidemiology of hepatitis C virus infection: An up-date of the distribution and circulation of hepatitis C virus genotypes." World J Gastroenterol. 2016 Sep 14; 22(34): 7824-7840. doi: 10.3748/wjg.v22.i34.7824

Genotypes

- The major HCV genotype worldwide is genotype 1, which accounts for 40–80% of all isolates.
- Genotypes 1a and 1b are most prevalent in the U.S. and worldwide.
    - HCV genotype 1, particularly 1b, does not respond to therapy as well as genotypes 2 and 3. Recent HCV treatments have increased the response rate to genotype 1 therapy.
    - Genotype 1 may be associated with more severe liver disease.
- Genotypes 2 and 3 are found worldwide. However in the U.S., they account for a minority of infections.
- Genotypes 4, 5, and 6 are found worldwide, but are uncommon in the U.S. The largest proportions of genotypes 4 and 5 occur in lower-income countries, primarily Africa.

  Genotype 6 is most prevalent in Vietnam, Cambodia, and the Philippines.

Differential diagnosis

Major conditions can be confused clinically with **acute hepatitis C**:

- Acute hepatitis A and B
- Drug-induced hepatitis
- Alcoholic hepatitis
- Autoimmune disorders

Major conditions can be confused clinically with **chronic hepatitis C**:

- Autoimmune hepatitis
- Chronic hepatitis B and D
- Alcoholic hepatitis
- Non-alcoholic steatohepatitis (fatty liver)
- Sclerosing cholangitis
- Wilson's disease
- Alpha-1-antitrypsin-deficiency-related liver disease
- Drug-induced hepatitis

Perinatal hepatitis C

Prior to 18 months of age, anti-HCV antibody testing is not specific for infection since a positive test can reflect maternal IgG antibodies that have passively crossed the placenta (UpToDate, 2022). The virus can usually be detected by the presence of viral RNA in an infected person's blood within 1–3 weeks after initial exposure. The degree of correlation between quantity of circulating virus and communicability is not clearly established. Passively acquired maternal antibodies against HCV are cleared in 95% of infants by 12 months, although some take longer than 12 months to clear.

Laboratory identification

Anti-HCV antibody (total antibody) testing is recommended for routine screening of asymptomatic persons based on their risk for infection, or based on a recognized exposure. For such persons, testing for HCV infection should include the use of an FDA-approved test for antibodies to HCV. Nucleic acid testing, including reverse transcriptase polymerase chain reaction (RT-PCR) to detect HCV RNA (viral load), is necessary to confirm the diagnosis of current HCV infection, and an elevated ALT level is biochemical evidence of chronic liver disease (CLD) (See Appendix A). It is recommended that labs and healthcare systems implement HCV reflex RNA testing for all HCV antibody positives in order to identify current versus previous infection without additional sample collection.

Persons tested for HCV infection and determined to be anti-HCV positive should be evaluated (by referral or consultation, if appropriate) for the presence of active infection, presence or development of CLD, and possible treatment.

Several blood tests are available to test for HCV infection (See Appendix B). Guidance for entering hepatitis C lab results into EpiTrax can be found in Appendix B, which will help investigators interpret various tests. These tests can be characterized into 2 categories, anti-HCV antibody tests and HCV detection tests.

Anti-HCV antibody tests

- Screening tests for total antibody to HCV (anti-HCV)
    - Enzyme immunoassay (EIA)
    - Enhanced chemiluminescence immunoassay (CIA)

HCV RNA detection tests

- Qualitative tests to detect presence or absence of virus (HCV RNA polymerase chain reaction [PCR])
- Quantitative tests to detect amount (titer) of virus (HCV RNA PCR)
- Genotype testing

Anti-HCV antibodies can be detected as early as 4–10 weeks after infection and can be detected in >97% of persons by 6 months.

False positive anti-HCV antibody tests appear more often when persons at low risk for HCV infection (e.g., blood donors) are tested. Therefore, it is important to follow-up all positive anti-HCV antibody tests with an HCV detection test to establish current infection.

Table 2: Laboratory test interpretation

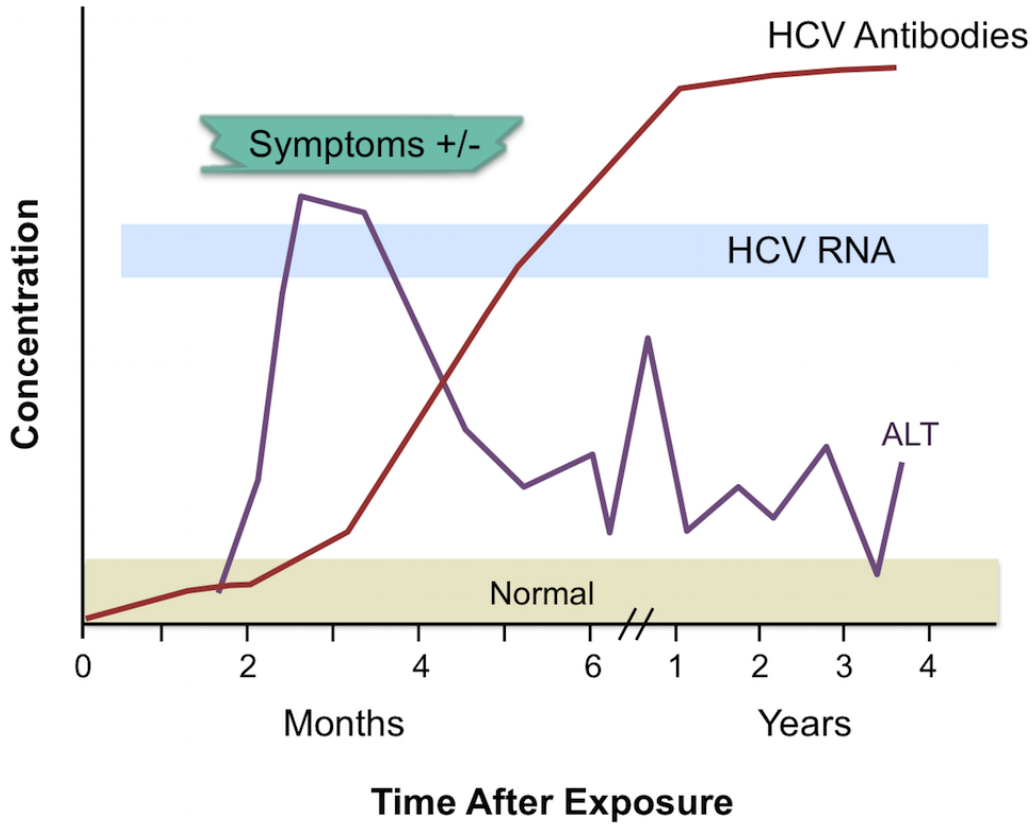
Anti-HCV antibody	Qualitative PCR	Quantitative PCR	Genotyping	Testing interpretation
+	-	<n* and/or not detected	Negative or Indeterminate	Previously exposed, not currently infected or false positive antibody
+	+	Quantified viral load	Genotype identified	Current infection

*<n will be dependent upon the detectable range of laboratory methodology used.

Persons with early HCV infection might not yet have developed anti-HCV antibody levels high enough for the test to detect (termed the “window” period). In addition, some persons might lack the immune response necessary for the test to work well. In these persons, further testing such as

PCR for HCV RNA may be considered. HCV RNA appears in blood and can be detected as early as 2–3 weeks after infection (see Figure 1).

Figure 1: Laboratory markers with acute HCV infection



Note. From *Diagnosis of Acute HCV Infection* by R. K. Fox and M. A. Corcorran, 2021, Hepatitis C Online (https://www.hepatitisc.uw.edu/go/screening-diagnosis/acute-diagnosis/core-concept/all). Copyright 2022 by Hepatitis C Online.

In acute HCV, liver enzymes may be elevated up to, and in excess of, 10 times greater than normal values. This elevation is typically observed after 2 weeks of infection and will return to normal levels within 12 weeks. Fifteen to 25% of acute infections will self-resolve; the majority of acute cases (75–85%) will progress to chronic HCV infection.

It is common for patients with chronic HCV to have liver enzyme levels that go up and down, with periodic returns to normal or near normal levels. Liver enzyme levels can remain normal for more than a year despite CLD.

Most patients with chronic HCV have a viral load between 100,000 ($1X10^5$) and 10,000,000 ($1X10^7$) copies per mL. Expressed as IU, these averages are 50,000 to 5 million IU.

Viral levels as measured by viral load do not correlate with hepatitis severity or with a poor prognosis (as in HIV infection). However, viral load inversely correlates with the likelihood of a response to antiviral therapy (e.g., cases with low initial viral load levels have a better therapeutic outcome than cases with high initial viral load levels.)

Utah Public Health Laboratory (UPHL): UPHL has the ability to perform anti-HCV antibody and HCV NAAT on collected specimens.

Perinatal hepatitis C

There are recommended timelines for HCV RNA screening of infants born to HCV-positive gestational parents. These include not testing until at least 2 months of age and, in some cases, recommending repeat serial testing of infants if they test positive on 1 test, if done prior to 12 months of age (CSTE, 2017).

Testing for anti-HCV at <18 months of age is not recommended as a positive result could be caused by trans-placental maternal anti-HCV.

HCV screening recommendations (CDC, 2020)

Universal screening

All adults aged 18 years and older, except in settings where the prevalence of HCV infection (HCV RNA-positivity) is less than 0.1% should receive a hepatitis C screening at least once in their life. Additionally, all pregnant persons should receive a hepatitis C screening once during **each** pregnancy.

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

- People with HIV
- People who ever injected drugs and shared needles, syringes, or other drug preparation equipment (even if many years ago)
- People with selected medical conditions, including people who:
    - Received maintenance hemodialysis
    - Have persistently abnormal ALT levels
- Prior recipients of transfusions or organ transplants, including people who:
    - Received clotting factor concentrates produced before 1987
    - Received a transfusion of blood or blood components before July 1992
    - Received an organ transplant before July 1992

    - Were notified that they received blood from a donor who later tested positive for HCV infection
- Healthcare personnel, emergency medical, and public safety personnel after needle sticks, sharps, or mucosal exposures to HCV-positive blood. For more details see CDC's Testing of source patients after potential exposure of health care personnel to hepatitis C virus.
    - After a needlestick or sharps exposure to HCV-positive blood, the risk of HCV infection is approximately 1.8% (range: 0%–10%); though a few cases of HCV transmission via blood splash to the eye have been reported, the risk for such transmission is expected to be very low.

Children born to persons with HCV infection

For information, see the perinatal hepatitis C section.

Routine periodic testing for people with ongoing risk factors:

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

Any person who requests HCV testing

Any person who requests testing should receive it regardless of risk. Many people may be reluctant to disclose stigmatizing risks.

Treatment

The landscape of treatment for HCV infection has evolved substantially since the introduction of highly effective HCV protease inhibitor therapies in 2011. The pace of change is expected to increase rapidly, as numerous new drugs with different mechanisms of action will likely become available over the next few years. To provide healthcare professionals with timely guidance as new therapies are available and integrated into HCV regimens, the Infectious Diseases Society of America (IDSA) and American Association for the Study of Liver Diseases (AASLD), in collaboration with the International Antiviral Society–USA (IAS–USA), developed a web-based process for the rapid formulation and dissemination of evidence-based, expert-developed recommendations for HCV management. The IAS–USA provided the structure and assistance to sustain the process that represents the work of leading authorities in hepatitis C prevention, diagnosis, and treatment in adults, from 2013 to 2015.

The American Association for the Study of Liver Disease/Infectious Diseases Society of America (AASLD/IDSA) Guidance on Hepatitis C (www.hcvguidelines.org) addresses management issues

ranging from testing and linkage to care, crucial first steps toward improving health outcomes for HCV-infected persons, to optimal treatment regimens in particular patient situations. Recommendations are based on evidence and are rapidly updated as new data from peer-reviewed evidence becomes available. For each treatment option, recommendations reflect the best possible management for a given patient and a given point of disease progression. Recommendations are rated with regard to the level of evidence and strength of the recommendation. The guidance should be considered a "living document" in that it will be updated frequently as new information and treatments become available. This continually evolving report provides guidance on FDA-approved regimens. At times, it may also recommend off-label use of certain drugs or tests or provide guidance for regimens not yet approved by FDA. Readers should consult prescribing information and other resources for further information. Of note, the choice of treatment may, in the future, be further guided by data from cost-effectiveness studies.

Most new direct acting antivirals (DAAs) are pangenotypic and a simplified treatment algorithm has been designed.

Treatment duration

Treatment duration depends on genotype, liver health, previous treatment, and other factors. Most treatments range from 8–24 weeks. The goal of treatment is to eliminate HCV RNA and achieve a sustained virologic response (SVR). An SVR has been demonstrated to result in a 97 to 100 percent chance of remaining HCV RNA negative after long-term follow-up. Individuals who achieve SVR are considered cured of the infection. The definition of SVR is an absence of HCV RNA 24 weeks after treatment.

Treatment response and success

Each treatment has a different response rate and successful treatment depends on several factors, including: genotype, race, age, weight, extent of liver damage, viral load, HIV Infection, previous treatment, alcohol use, length of infection, and adherence.

A person reaching SVR after completing treatment suggests HCV infection has been cured. SVR can result in decreased cirrhosis and complications of liver disease, decreased rates of liver cancer (hepatocellular carcinoma), and decreased mortality. Most new medications are showing a SVR of 93–100%.

Treatment for pediatric patients

Curative DAA treatment can be provided to children as young as 3 years of age. When HCV infection is diagnosed in a child, further evaluation is warranted to inform treatment decisions and monitor for progression of liver disease (UpToDate, 2021). The main strategy to reduce the risk of vertical HCV transmission is identification and treatment of HCV-infected persons prior to conception. Of note, gestational persons who were treated with a ribavirin-containing regimen should avoid pregnancy for at least 6 months afterward (UpToDate, 2022).

Treatment side effects

Each treatment has the potential for a variety of adverse effects. However, most new medications that are interferon- and ribavirin-free seem to be easily tolerated with few minor side effects including headache, fatigue, and insomnia.

Pegylated or standard interferon: Fatigue, flu-like symptoms, mood changes, drop in platelet count, drop in white blood cell count, drop in neutrophil count, loss of appetite, nausea or change in bowel habits, weight gain or weight loss, hair loss, changes in thyroid function, increase in blood sugar level, and insomnia may be associated with these medications.

Ribavirin: Drop in red blood cell count, sore throat, cough, shortness of breath, rash, and birth defects may be associated with use of ribavirin.

Clinical trials

Research facilities conduct clinical trials on hepatitis medications and often look for individuals to participate. For further information on current trials and qualifications, visit www.clinicaltrials.gov. Local agencies with a history of HCV medication clinical trials include: The University of Utah Medical Center (http://healthcare.utah.edu/clinicaltrials) and Jean Brown Research (https://www.jbrclinicalresearch.com), or contact the Utah Department of Health and Human Services, Office of Communicable Diseases at 801-538-6191 for additional resources.

Case fatality

The age-adjusted hepatitis C-related mortality rate increased each year from 2010 through 2013 but began to decline in 2014. The age-adjusted hepatitis C-related mortality rate decreased from 4.13 per 100,000 population in 2017 to 3.33 in 2019, below the 2019 target rate of 3.75 (CDC, 2021).

Reservoir

Humans are the only known reservoir of HCV.

Transmission

HCV is a bloodborne pathogen predominantly spread via exposure to contaminated blood or blood products. Currently, the highest risk of transmission is through sharing needles or syringes to inject drugs. Continued injection drug use increases the risk of HCV infection. Studies have shown up to a 33% seroprevalence among 18–30 year-old injection drug users (IDUs) which increases substantially (70–90%) among older and former IDUs.

Blood transfusions pose an extremely limited risk now. But, for patients who received a blood transfusion prior to June 1992, the risk of infection was approximately 1.5% per transfusion recipient.

Sexual transmission of HCV is very low, but can occur. The risk of sexual transmission increases with multiple partners, co-infection with HIV, MSM, anal sex, and any other sexual activity where blood may be exchanged.

Other potential risks for transmission include:

- Long-term hemodialysis
- Sharing straws for intranasal drug use
- Vertical (mother to infant) transmission (the risk of perinatal transmission is estimated to be about 6%, although if the mother is co-infected with HIV, the risk may be approximately 15–25%)
- Occupational blood exposure (the risk of occupational exposure for healthcare workers has been estimated to be 1.8% per incident of hollow-bore needle stick exposure to HCV-infected blood)
- Various medical procedures with non-sterile equipment (including dental)
- Tattooing or body piercing with non-sterile equipment

HCV is not spread through casual contact, kissing, sneezing, hugging, and sharing glasses or utensils, or breast milk.

Vertical transmission

Vertical transmission of HCV has been documented in numerous studies, but estimates on the rate of transmission vary. Overall, it appears the risk of vertical transmission is approximately 6% in viremic women, with higher rates in certain subgroups, namely women who are coinfected with HIV (UpToDate, 2022). Unfortunately, much is still unknown about vertical transmission of HCV. With the increase in the number of HCV positive persons of childbearing age it is critical to implement tracking and screening of children born to HCV positive persons in order to better understand transmission rates. Additionally, there is no evidence that breastfeeding spreads HCV,

but HCV-positive breastfeeding parents with cracked or bleeding nipples should consider precautions (CDC, 2020).

Susceptibility

HCV infection occurs among persons of all ages. The highest incidence of acute HCV infection (new cases) occurs among persons aged 20–40 years. Cases may be infected by more than 1 genotype, but this is rare. Patients can be treated for 1 genotype, and be re-infected via the same or another genotype.

Incubation period

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

Perinatal hepatitis C

The timing of transmission can be reflected by results of polymerase chain reaction (PCR) testing for HCV RNA, which may not be positive until several weeks following infection, when levels of viremia reach the detection threshold. In most infants, HCV RNA levels only become detectable several weeks after birth, suggesting perinatal infection. However, detection of HCV RNA within a few days of delivery has also been described, suggesting that in utero infection earlier in pregnancy can also occur.

Period of communicability

Communicability of HCV is variable; anyone with a positive test for anti-HCV antibody should be considered infectious until ruled out by negative HCV detection tests. The virus can usually be detected by the presence of viral RNA in an infected person's blood within 1–3 weeks after the initial exposure. The degree of correlation between quantity of circulating virus and communicability is not clearly established.

Epidemiology

HCV has a worldwide distribution. In the U.S., an estimated 2.4 million people were infected with HCV during 2013–2016. The CDC estimates approximately 50,300 acute HCV cases (newly infected individuals) occurred in 2018. Prevalence is highest among groups with specific risk factors, especially IDUs, patients with hemophilia, persons on long-term hemodialysis, prison inmates, and people who received blood or organ products prior to June 1992.

Most of these newly reported cases are not people with new (acute) disease, but those with chronic infection who have been newly diagnosed. There remains a large population of undiagnosed people who were infected in the past. It is estimated that only 25% of individuals with HCV know they are infected.

Public health control measures

Public health responsibility

- Provide information to HCV-infected patients on the importance of medical evaluation, why continued care is needed, how to reduce disease progression, and referrals to medical or supportive facilities for services.
- Provide current treatment information and resources.
- Provide information to HCV-infected persons on how to prevent transmitting infection to others.
- Provide education to HCV-infected pregnant persons on the importance of prenatal care and strategies to reduce transmission risk to their child.
- Determine incidence and prevalence of HCV in specific populations and geographic locations to help guide HCV prevention and education activities, and other public health interventions.
- Identify clusters of HCV cases or outbreaks.
- Investigate all suspect acute cases of disease, as explained in the investigation protocol.
- Investigate individuals co-infected with HIV/AIDS or hepatitis B without evidence of previously documented investigation.
- Provide education to the general public, clinicians, and first responders about disease transmission and prevention.
- Identify sources of exposure and prevent further transmission.

Prevention

The goals of HCV prevention and control efforts include:

- Reduce incidence of new infections by reducing HCV transmission.
- Reduce risk of chronic liver disease in HCV-infected individuals through appropriate medical management and counseling, by ensuring linkage to care.
- Educate infected persons on how to care for themselves and how to avoid spreading infection to others.

Chemoprophylaxis

There is currently no post-exposure prophylaxis for HCV, although treatment is available for infected individuals.

Vaccine

There is currently no vaccine for HCV. It is recommended that HCV infected individuals receive hepatitis A and hepatitis B immunizations to prevent further liver disease.

Isolation and quarantine requirements

Isolation: None.
Hospital: Standard Precautions
Quarantine: None.

No restrictions except exclusion from organ and blood donation.

Case investigation

Reporting

All cases of HCV infection are reportable to public health, including:

- The clinical or laboratory diagnosis of hepatitis C infections in an infant between 2 months and 36 months of age, and
- The clinical or laboratory diagnosis of hepatitis C infection in a pregnant person.

Additionally, all cases of hepatitis C among females of chilbearing age should be reported with pregnancy status documented and, when possible, in order to verify infection source for an infant that has been reported as having evidence of HCV infection status, the HCV status of the gestational parent should be determined, using the acute and/or chronic HCV infection case definition as a guideline for which cases would be considered confirmed.

Criteria for reporting HCV acute and chronic

Criterion	Reporting
Laboratory criteria for reporting	
Antibodies to hepatitis C virus (anti-HCV)	S
Nucleic Acid Test (NAT) for HCV RNA positive	S
Positive test for hepatitis C antigen(s)*	S

Vital records criteria for reporting	
Death certificate lists hepatitis C	S
Birth certificate lists birth mother as having hepatitis C	S
Other criteria for reporting	
Healthcare record contains a diagnosis of hepatitis C	S

Notes:
S = This criterion alone is sufficient to report a case.
*When and if a test for HCV antigen(s) is approved by FDA and available.

Additional criteria for determining whether a case should be reported to public health

Criterion	**Reporting**			
Clinical evidence				
Diagnosis of HCV infection		N		
Pregnant				N
Born to a gestational parent with evidence of hepatitis C infection (positive HCV RNA, antigen, or genotype)				
Laboratory evidence				
Positive HCV RNA	O			O
Positive HCV antigen**	O			O
Positive HCV genotype	O			O
Positive HCV antibody			N	
Demographic evidence				
Between 2 and 36 months of age		N		
Younger than 36 months of age	N			
Between 18 and 36 months of age			N	

Notes:
S*= This criterion alone is sufficient to report a case.
N= All "N" criteria in the same column are necessary to report a case.
O= At least one of these "O" (one or more) criteria in each category (i.e., clinical evidence and laboratory evidence) in the same column—in conjunction with all "N" criteria in the same column—is required to report a case.
*A requisition or order for any of the "S" laboratory tests is sufficient to meet the reporting criteria.
** When and if a test for HCV antigen(s) is approved by FDA and available.

Clinical descriptions

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

Acute or chronic clinical criteria

- Illness with either jaundice, **or**
- Peak elevated serum alanine aminotransferase (ALT) level >200 IU/L, **or**

- Peak elevated total bilirubin levels (Tbili) ≥ 3.0 mg/dL, **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 HCV infection or other causes, such as alcohol exposure, other viral hepatitis, hemochromatosis, etc.)

Illness can occur with or without discrete onset of any sign or symptom consistent with acute viral hepatitis (e.g., fever, headache, malaise, anorexia, nausea, vomiting, diarrhea, and abdominal pain).

Perinatal clinical criteria

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

Laboratory criteria

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)

Epidemiologic linkage

No epidemiologic linkage is required for case classification.

Case classification

Acute, 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 virus detection test (HCV RNA test conversion) in the absence of a more likely diagnosis.

Acute, 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.

Chronic, 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.

Chronic, 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.

Criteria to distinguish a new case of HCV

A new acute case is an incident case who is older than 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 younger than 36 months should be classified under the perinatal HCV case classification unless the exposure mode is not perinatal (e.g., healthcare acquired).

A new probable acute case may be reclassified as confirmed acute if a positive HCV viral detection test is reported in the same reporting year. If evidence indicating resolution of infection is received after a confirmed acute or 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 acute and chronic cases, subsequent to an initial positive result, should be appended to case reports, as feasible.

Evidence for re-infection may include a case of confirmed chronic HCV infection that has at least 2 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 2 negative tests should be at least 3 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 who previously cleared a different genotype.

A new chronic case is a newly reported case who does not have evidence of being an acute case of HCV infection. A confirmed acute case may be classified as a confirmed chronic case if a positive HCV viral detection test is reported 1 year or longer after acute case onset. A confirmed acute case may not be reported as a probable chronic case (i.e., HCV antibody positive, but with an unknown HCV viral detection test).

Criteria for classification of HCV

	Acute				Chronic	
Criterion	**Confirmed**			**Probable**	**Confirmed**	**Probable**
Clinical evidence						
Jaundice	O			O		
Total bilirubin >3.0 mg/dL	O			O		
ALT >200 IU/L	O			O		
The absence of a more likely diagnosis	N	N	N	N		
>36 months of age, unless known to have been exposed non-perinatally	N	N	N	N	N	N
Does not meet or has no report of clinical criteria					N	N
Laboratory evidence						
Positive anti-HCV antibody				N		N
Positive NAT for HCV RNA test (including quantitative, qualitative, and genotype)	O				O	
Positive HCV antigen test	O				O	
Absence of a negative HCV viral detection test				N		N
A documented negative HCV antibody test result followed within 12 months by a positive HCV antibody or positive HCV viral detection test result		N				
A negative HCV viral detection test result followed within 12 months by a positive HCV viral detection test if not previously reported as having HCV infection			N			
Criteria to distinguish a new case						
Not previously reported as an acute case within one year	N	N	N	N	N	N
Not previously reported as a chronic case unless there is evidence of having cleared HCV infection since the initial report					N	N

Notes:
N = All “N” criteria in the same column are necessary to classify a case. A number following an “N” indicates this criterion is only required for a specific disease/condition subtype (see below). If the absence of a criterion (i.e., criterion not present) is required for the case to meet the classification criteria, list the absence of criterion as a necessary component.
O = At least one of these “O” (one or more) criteria in each category (categories=clinical evidence, laboratory evidence, and epidemiologic evidence) in the same column—in conjunction with all “N” criteria in the same

column—is required to classify a case. A number following an "O" indicates this criterion is only required for a specific disease/condition subtype.

Perinatal hepatitis C

Perinatal, confirmed

- Is not known to have been exposed to HCV via a mechanism other than perinatal, **and**
- 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 older; **or**
- HCV antigen* test results for infants between ≥2 to ≤36 months of age or older
  * When and if a test for HCV antigen(s) is approved by FDA and available.

Perinatal, suspect

- Is not known to have been exposed to HCV via a mechanism other than perinatal, **and**
- HCV positive antibody test for infants ≤36 months of age, WITHOUT evidence of a HCV RNA positive test, HCV genotype test, or HCV antigen* test
  * When and if a test for HCV antigen(s) is approved by FDA and available.

For purposes of perinatal HCV surveillance, infant and maternal status should be ascertained.

Infants 36 months of age and younger should only be assessed for perinatal HCV infection and not according to the 2015 Surveillance Case Definition of Hepatitis C. The laboratory and epidemiologic criteria described in the 2015 case definitions for acute and chronic HCV should only apply to individuals 36 months of age or older. However, if there is evidence the case was exposed to HCV via a mechanism other than perinatal (i.e., acquired via healthcare or other means), and is younger than 36 months of age, it can and should be classified under the 2015 position statement.

Clinical criteria

Perinatal HCV in pediatric patients may range from asymptomatic to fulminant hepatitis. Most children with HCV infection are asymptomatic, with minor abnormalities such as hepatomegaly or mild non-specific symptoms occasionally reported. Despite this, most perinatally infected infants will have intermittently or persistently abnormal liver enzymes (AST/ALT), particularly in the first 6–12 months of life.

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 (i.e., not acquired via healthcare or other means).

Criteria to distinguish a new case of this disease or condition from reports or notifications which should not be enumerated as a new case for surveillance.

Test results prior to 2 months of age should not be used for classification. All 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 known to have been exposed to HCV via healthcare and not perinatally should be reported under the 2020 position statement. Event date should be based on earliest relevant laboratory test date within the 2–36 month window. Antibody tests for anyone younger than 18 months of age should be considered suspect until further testing is available.

When should a child be tested for hepatitis?	
Either	
After 18 months	Test for hepatitis C antibody—if the test is positive, follow up with hepatitis C RNA (viral load) confirmatory test
Or	
After 2 months	Test for hepatitis C RNA confirmatory test, **and**
After 12 months	Test 1 more time for hepatitis C RNA confirmatory test

Case classification

Confirmed perinatal hepatitis C infection: infant who has a positive test for HCV RNA (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.

Criteria for perinatal hepatitis C case classification (CSTE, 2017)

Criterion	Confirmed	Suspect (Utah definition only)
Clinical evidence		
Infant between 2 and 36 months of age	N	
Infant ≤36 months of age (Utah definition only)		N
Laboratory evidence		
Positive for HCV RNA	O	
Positive for HCV genotype	O	
Positive for HCV antigen*	O	
Positive for HCV antibody		O
Epidemiologic evidence		
Not known to have acquired HCV via a mechanism other than perinatal	N	N
Criteria to distinguish a new case		

Never previously reported as a case of perinatal HCV infection	N	N

Notes:
S= This criterion alone is sufficient to classify a case.
N = All "N" criteria in the same column are necessary to classify a case. A number following an "N" indicates this criterion is only required for a specific disease/condition subtype (see below). If the absence of a criterion (i.e., criterion not present) is required for the case to meet the classification criteria, list the absence of criterion as a necessary component.
O = At least one of these "O" (one or more) criteria in each category (i.e., clinical evidence and laboratory evidence) in the same column—in conjunction with all "N" criteria in the same column—is required to classify a case. (These "O" criteria are alternatives, which means that a single column will have either no O criteria or multiple O criteria; no column should have only one O.) A number following an "O" indicates this criterion is only required for a specific disease/condition subtype.
* When and if a test for HCV antigen(s) is approved by FDA and available.

Nosocomial outbreaks

Nosocomial outbreaks are uncommon with hepatitis C, but could occur with lack of infection control. Contact the Utah Department of Health and Human Services, Office of Communicable Diseases at 801-538-6191 for assistance with any suspect or confirmed nosocomial HCV outbreaks or occurrences.

Resolved infection: 'treated and cured' or 'self resolved'

Treated HCV infected patient

When a patient completes HCV treatment and receives a negative HCV detection test ≥24 weeks after treatment (SVR), that individual is considered 'treated and cured.' 'Treated and cured' individuals can become re-infected with HCV. When a 'treated and cured' individual is determined to be re-infected, as evident through a positive HCV detection test, the case will be treated as a new event and managed according to the investigation algorithm in Appendix D.

Untreated HCV infected patients

Individuals who are not known to have been treated, who through laboratory evidence demonstrate negative results on an HCV detection test will be considered 'self-resolved' after 2 negative HCV detection tests on different collection dates or collected on the same date, but tested using different HCV detection laboratory methodologies. 'Self-resolved' individuals can become re-infected with HCV. When a 'self-resolved' individual is determined to be re-infected, as evident through a positive HCV detection test, the case will be treated as a new event and managed according to the investigation algorithm in Appendix D.

Case investigation process

All acute cases will be investigated (asymptomatic cases with documented seroconversion in the past 12 months, and cases with elevated ALT (>200 IU/L), Tbili (>3.0 mg/dL) and/or jaundice).

Chronic cases and cases determined not to be acute are considered surveillance events.

The HCV surveillance system is designed to focus investigator efforts on likely acute cases based on the first reported laboratory test. This is accomplished by first identifying likely acute cases based on the test type (e.g., acute hepatitis panel) or diagnostic facility (e.g., blood component donor facilities). Individuals who do not meet investigation criteria are not investigated. Individuals who are reported as HCV positive (either anti-HCV antibody or HCV detection test) from the likely acute categories have met investigation criteria and are investigated by 1 of 2 methods:

1) Individuals reported as HCV positive from a blood component donation center will have their last negative test date ascertained from the donor center. If the donor's last negative HCV test was less than 12 months from their HCV positive test, the donor meets investigation criteria and will be contacted by public health to assess exposure risks and provide education. If the donor was a first-time donor, or the last negative donation was longer than 12 months prior, the case will be considered a surveillance event with no further investigation given clinical criteria is not met.
2) Individuals reported from an acute hepatitis panel will have their ALT and/or total bilirubin (Tbili) requested from the reporting lab. If ALT is greater than 200 IU/L or Tbili is greater than 3.0 mg/dL, the case meets investigation criteria. Clinical information should be gathered to ascertain if there is/was jaundice present and to ensure there is not another more likely diagnosis that is contributing to clinical presentation. If the case meets acute case definition criteria, the case will be contacted by public health to assess exposure risks and provide education. If the acute HCV case definition criteria is not met (due to a more likely diagnosis), the case will be considered a surveillance event with no further investigation.

DHHS enhanced reports: The Utah Department of Health and Human Services (DHHS) Office of Communicable Diseases (OCD) receives an automated report providing ALT and Tbili from individuals identified as HCV positive from acute hepatitis panels at some medical facilities, as available. This information is entered into UT-NEDSS/EpiTrax to assist investigators. DHHS OCD will continue to work with medical providers to expand the use of automated data collection to support investigational efforts.

Outbreaks

An outbreak is defined as:

- 2 or more cases of HCV clustered in time, **and**
- At least 1 confirmed acute case, **and**

- At least 1 of the following:
    - A common exposure
    - Laboratory evidence of highly related viral sequences

Occasionally, a healthcare-associated outbreak may be identified by a single sentinel case, e.g., a frequent blood donor with no identified risk who has had contact with the healthcare system where parenteral exposure to blood or blood-contaminated products may have occurred. Investigation of such outbreaks can be quite complex and requires strong collaboration among involved parties and expert advice.

Case contact identification

Identification of case contacts for an acute case should focus on individuals who may have been exposed to the case's blood (e.g., sharing needles, sharing drug preparation equipment [i.e., spoons, cotton, syringes, water bottles], or tattoo equipment and supplies). Otherwise, encourage the case-patient to speak to people who may have been exposed to their blood since the time the case-patient was estimated to have been exposed, infected, or seroconverted.

Case contact management

Percutaneous and mucosal exposure to HCV infection

Recommend baseline anti-HCV antibody testing and HCV detection test if indicated. If baseline testing is negative, recommend testing for anti-HCV antibody and ALT 4-6 months after exposure. Recommend HCV detection testing at 4–6 weeks if earlier diagnosis of HCV is desired. Reactive anti-HCV antibody tests should be confirmed with an HCV detection test to identify current infection. Contacts with a positive anti-HCV antibody and/or HCV detection test should be reported and investigated according to the HCV disease plan.

Pregnant persons

Routine one-time screening for all pregnant persons for each pregnancy is recommended. All HCV positive pregnant persons should be reported for pregnancy surveillance, and provided resources/education for infant follow-up testing. In several studies, high maternal viral load and positive HCV-RNA were predictors for increased risk of vertical transmission, as well as maternal co-infection with HIV. Co-infection with HIV both accelerates the clinical progression of HCV and increases the risk of perinatal HCV transmission from 6% (range, 3–8%) to 17% (range, 7–36%).

Infants born to HCV positive gestational parents

The American Academy of Pediatrics (AAP) recommends screening infants born to HCV-positive gestational parents. The AAP recommends testing for anti-HCV antibodies be performed after 18

months of age, as passively acquired maternal antibodies can last up to 12 months. A negative HCV detection test strongly suggests the infant is not infected, although a confirmatory re-test at least 3 months after the initial test is advised. A positive HCV detection test increases the post-test probability that the infant is infected with HCV.

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Version control

V.01.15: This disease plan contains updated testing, treatment, and investigation processes and information. The major changes in the investigation process change the investigation criteria from age-based investigation criteria to acute case investigation.

V.02.15: Updated plan with new CSTE position statement classification tables and narrative descriptions.

V.03.16: HCV disease plan workgroup updates. Complete guidance and investigation revamp. Chronic case definition included and shifted to acute case investigation. Added guidance for 'treated and cured' and 'self-resolved.'

V.03.19: Added critical clinician Information for chronic and acute hepatitis C.

V.01.20: Updated plan with new CSTE position statement classification tables and narrative descriptions. Updated investigation algorithm to reflect new CSTE position statement. Added clinical description for acute and chronic HCV.

V.02.20: Updated ELR processing rules.

V.04.20: Updated links and formatting and included recommendation for testing of pregnant women.

V.01.22: New table for perinatal HCV critical clinician information. New table for criterion for reporting HCV perinatal. New sections for perinatal hepatitis C in *why is hepatitis C important to public health*, *clinical description, differential diagnosis, laboratory identification, treatment, transmission, incubation period, case investigation, case classification.* Removed outdated investigation algorithm flow chart.

V.06.22: Updated formatting and writing style to match new departmental guidelines. Updated references to conform to APA 7th edition citation style.

UT-NEDSS/EpiTrax minimum/required fields by tab

Demographic

- Age
- Area code
- Birth gender
- City
- County
- Date of birth
- Ethnicity
- First name
- Last name
- Phone number
- Race
- State
- Street
- Zip code

Clinical

- Clinician first name
- Clinician last name
- Date diagnosed
- Date of death
- Diagnostic facility (DF)
- DF state
- DF city
- DF county
- Died
- Disease
- Pregnant
- Does patient have jaundice?
- ALT (SGPT) results:
- ALT interpretation:
- Hepatitis B?, date of diagnosis
- HIV/AIDS?, date of diagnosis

Laboratory

- Collection date
- Lab
- Organism
- Result value
- Test result
- Test type
- Units
- Bilirubin results
- ALT (SGPT) results
- ALT interpretation

Epidemiological

- None

Contacts

- None

Reporting

- Date first reported to public health

Administrative

- LHD investigation/intervention started
- State case status
- Outbreak name
- Outbreak-associated

Electronic laboratory reporting processing rules

Hepatitis C rules for entering laboratory test results

The following rules describe how laboratory results reported to public health should be added to new or existing events in UT-NEDSS/EpiTrax. These rules have been developed for the automated processing of electronic laboratory reports, although they apply to manual data entry, as well.

Test-specific rules

Test-specific rules describe what test type and test result combinations are allowed to create new morbidity events in UT-NEDSS/EpiTrax, and what test type and test result combinations are allowed to update existing events (morbidity or contact) in UT-NEDSS/EpiTrax.

Test type	Test result	Create a new event	Update an existing event
Genotype by sequencing	Positive	Yes	Yes
	Negative	No	Yes
	Other	No	Yes
	Equivocal	No	Yes
PCR/amplification	Positive	Yes	Yes
	Negative	No	Yes
	Other	No	Yes
	Equivocal	No	Yes
Total antibody	Positive	Yes	Yes
	Negative	No	Yes
	Other	No	Yes
	Equivocal	No	Yes
Viral load – Qualitative bDNA	Positive	Yes	Yes
	Negative	No	Yes
	Other	No	Yes
	Equivocal	No	Yes
Viral load – Qualitative RT-PCR	Positive	Yes	Yes
	Negative	No	Yes
	Other	No	Yes
	Equivocal	No	Yes
Viral load – Quantitative RT-PCR	Positive	Yes	Yes
	Negative	No	Yes
	Other	No	Yes
	Equivocal	No	Yes
Western (immuno) blot	Positive	Yes	Yes
	Negative	No	Yes
	Other	No	Yes
	Equivocal	No	Yes

Genotype 1a	Positive	Yes	Yes
	Negative	No	Yes
	Other	No	Yes
	Equivocal	No	Yes
Genotype 1a or 1b	Positive	Yes	Yes
	Negative	No	Yes
	Other	No	Yes
	Equivocal	No	Yes
Genotype 1b	Positive	Yes	Yes
	Negative	No	Yes
	Other	No	Yes
	Equivocal	No	Yes
Genotype 1c	Positive	Yes	Yes
	Negative	No	Yes
	Other	No	Yes
	Equivocal	No	Yes
Genotype 1 (undifferentiated)	Positive	Yes	Yes
	Negative	No	Yes
	Other	No	Yes
	Equivocal	No	Yes
Genotype 2a	Positive	Yes	Yes
	Negative	No	Yes
	Other	No	Yes
	Equivocal	No	Yes
Genotype 2b	Positive	Yes	Yes
	Negative	No	Yes
	Other	No	Yes
	Equivocal	No	Yes
Genotype 2c	Positive	Yes	Yes
	Negative	No	Yes
	Other	No	Yes
	Equivocal	No	Yes
Genotype 2 (undifferentiated)	Positive	Yes	Yes
	Negative	No	Yes
	Other	No	Yes
	Equivocal	No	Yes
Genotype 3a	Positive	Yes	Yes
	Negative	No	Yes
	Other	No	Yes
	Equivocal	No	Yes
Genotype 3 (undifferentiated)	Positive	Yes	Yes
	Negative	No	Yes
	Other	No	Yes

	Equivocal	No	Yes
Genotype 4a	Positive	Yes	Yes
	Negative	No	Yes
	Other	No	Yes
	Equivocal	No	Yes
Genotype 4k	Positive	Yes	Yes
	Negative	No	Yes
	Other	No	Yes
	Equivocal	No	Yes
Genotype 4 (undifferentiated)	Positive	Yes	Yes
	Negative	No	Yes
	Other	No	Yes
	Equivocal	No	Yes
Genotype 5 (undifferentiated)	Positive	Yes	Yes
	Negative	No	Yes
	Other	No	Yes
	Equivocal	No	Yes
Genotype 6a	Positive	Yes	Yes
	Negative	No	Yes
	Other	No	Yes
	Equivocal	No	Yes
Genotype 6e	Positive	Yes	Yes
	Negative	No	Yes
	Other	No	Yes
	Equivocal	No	Yes
Genotype 6h	Positive	Yes	Yes
	Negative	No	Yes
	Other	No	Yes
	Equivocal	No	Yes
Genotype 6l	Positive	Yes	Yes
	Negative	No	Yes
	Other	No	Yes
	Equivocal	No	Yes
Genotype 6 (undifferentiated)	Positive	Yes	Yes
	Negative	No	Yes
	Other	No	Yes
	Equivocal	No	Yes
Liver function tests (ALT, AST, bilirubin)	All	No	Yes

Whitelist rules

Whitelist rules describe how long an existing event can have new laboratory data appended to it. If a laboratory result falls outside the whitelist rules for an existing event, it should not be added to that event, and should be evaluated to determine if a new event (CMR) should be created.

Hepatitis C virus morbidity whitelist rule: Never a new case.
Hepatitis C virus contact whitelist rule: Always added to contact.

Graylist rule

Lab results are often received through ELR that cannot create cases, but can be useful if a case is created in the future. These laboratory results go to the graylist. The graylist rule describes how long an existing event can have an old laboratory result appended to it.

Hepatitis C virus graylist rule: If the specimen collection date of the laboratory result is 18 months before to 7 days after the event date of the morbidity event, the laboratory result should be added to the morbidity event.

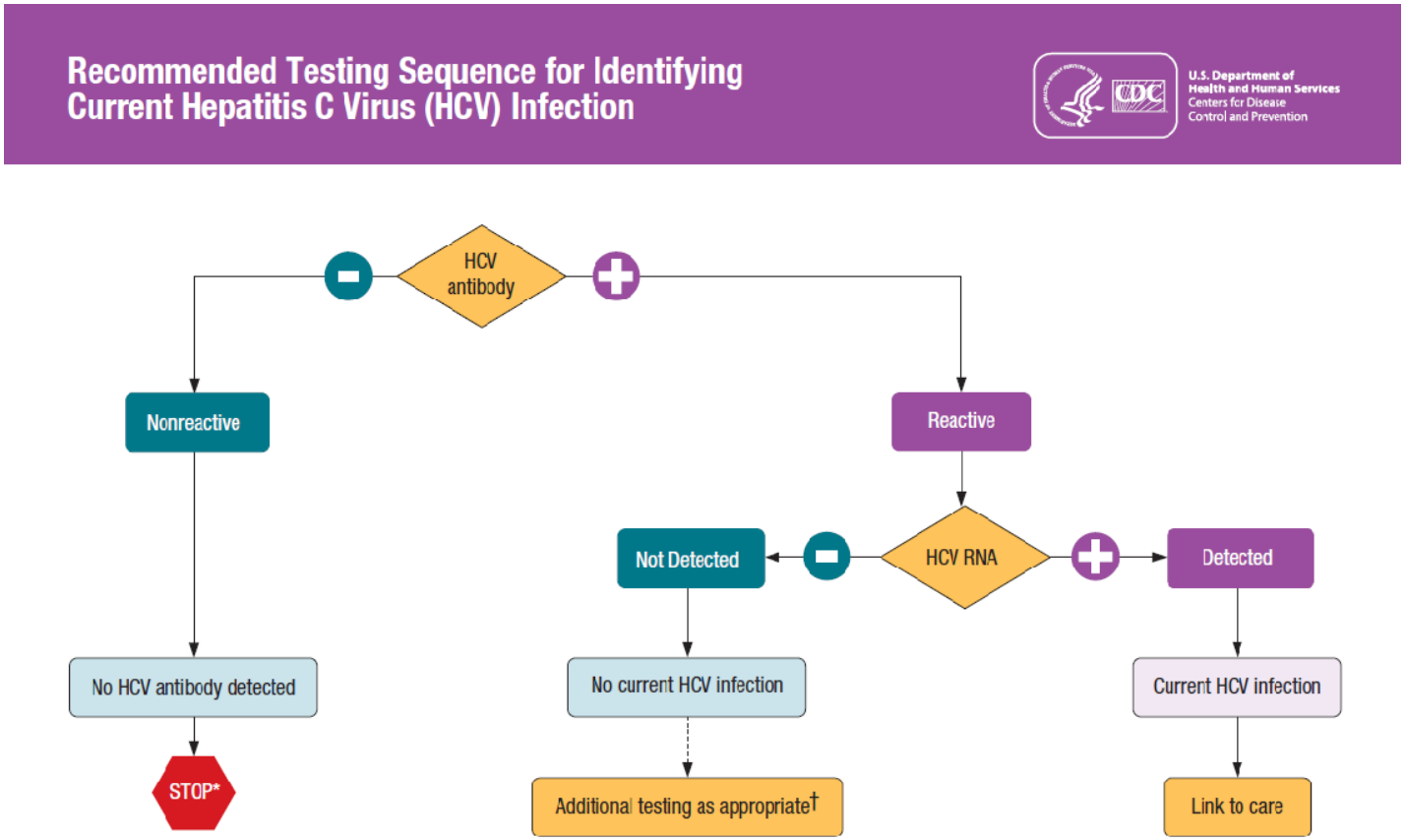
Liver function graylist rule: If the specimen collection date of the laboratory result is 6 months before to 6 months after the event date of the morbidity event, the laboratory result should be added to the morbidity event.

Other electronic laboratory processing rules

If an existing event has a state case status of “not a case,” ELR will never add additional test results to that case. New labs will be evaluated to determine if a new CMR should be created.

Appendices

Appendix A: HCV testing algorithm



* 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).

Appendix B: HCV laboratory report guidance

Test type	Total Ab (EIA, IFA, TRF, Etc.)	Western (immuno) blot (RIBA)	Viral load	Genotype	ALT	AST	Bilirubin
Common test codes	HCV ab, HCVDA, hepatitis C ab, hepatitis C antibody, Ab S/CO, s/co	RIBA	PCR, NAT, NAAT, qualitative, quantitative	Genotype sequencing	• (ALT) alanine aminotransaminase • (AST) aspartate aminotransaminase • (Bilirubin), Tbili, Bili		
Reporter	Local hospitals, Cat-C, donor centers, reference laboratories	Reference laboratories	Reference laboratories, donation centers, some local hospitals	Reference laboratories	Local hospitals, some reference laboratories		
Results	Reactive, positive, equivocal, indeterminate, ≥11, reactive HI, low positive, reactive (number), low s/com, HI s/co	Positive, negative, reactive, non-reactive	Numbers, reactive, non-reactive, positive, negative, HI, detected, no detected, <43**	Genotype 1a, 1b, 2a, 2b, 2c, 2d, 3a, 3b, 3c, 3d, 3e, 3f, 4a, 4b, 4c, 4d, 4e, 4f, 4g, 4h, 4i, 4j, 5a, 6a	Number	Number	Number
Units	None, IV, s/co	None	IU/mL, LOG IU/mL, Copies, copies/mL	None	U/L	U/L	mg/dL
Hints	All antibody tests are considered equivalent and must be confirmed by a more specific assay.	This lab test is not routinely used anymore, so it will be very rare to see one.	Tests that have numbers over 10,000 is a clue that it is a viral load.	Some laboratories do not differentiate between similar genotypes and will report both (e.g., 1a and 1b).	These three tests are components of clinical testing. They can be found in laboratory panels called: Liver Function Panel, Liver Function Test (LFT), and Comprehensive Metabolic Panel (CMP).		

**Viral loads may result <43, but state HCV RNA detected. This is a positive test. The quantity of IU was less than the test's sensitivity range.

Appendix C: Patient education

Prevention and education include providing information on how the disease is transmitted, how to prevent spread of infection, how patients can protect themselves from other potential sources of liver damage, and available treatment options. Offer the information and support below to newly identified cases:

- Provide basic instruction on transmission of HCV and emphasize the need for ongoing medical evaluation. Treatment is available and effective, and the case should be referred to their healthcare provider for a discussion of treatment options.
- Discuss sexual transmission of HCV. Indicate HCV may be transmitted during sex. Monogamous sexual partners are at lower risk of transmission than those with multiple partners. 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 exposure to and transmission of other pathogens.
- Discuss household transmission of HCV. Household transmission is rare, but to ensure it does not happen, the case should not share razors, toothbrushes, nail clippers, or any other item that could be contaminated with blood.
- If the patient is a current injection drug user, provide referrals to drug treatment and needle exchange programs if the case needs, or wants, support to stop using. This will help prevent the spread to other individuals.
- Educate the case on the need to abstain from alcohol to help protect the liver. If a case needs, or wants, support to stop drinking, provide referrals to appropriate treatment or support services.
- Discuss medications that should be avoided (e.g., acetaminophen) as high doses can damage the liver. All cases should discuss medications (including over-the-counter medications), dietary supplements, and herbs with a healthcare provider to be certain they will not damage their livers.
- Determine hepatitis A and B immunization status. If not immunized, provide information on hepatitis A and hepatitis B immunization. (Refer to the hepatitis A and hepatitis B disease plans for more information.)
- Inform the case that he/she 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 should change their exercise routines or have any dietary restrictions.
- Encourage them to consult with their healthcare provider, or suggest involvement in a research study. Research facilities conduct clinical trials on hepatitis medications and often look for individuals to participate. For further information on current trials and qualifications, visit www.clinicaltrials.gov. Local agencies with a history of HCV medication clinical trials include: The University of Utah Medical Center

(http://healthcare.utah.edu/clinicaltrials), and Jean Brown Research (https://www.jbrclinicalresearch.com or contact the Utah Department of Health and Human Services (DHHS), Office of Communicable Diseases (OCD) at 801-538-6191 for additional resources.

Appendix D: Local health department action steps

This quick reference guide is designed for local health departments (LHDs) to use for HCV case investigation activities and is a suggested sequence of investigation and information that should be reviewed with each case. This guidance corresponds with the investigation algorithm included below.

Upon receiving a report of acute HCV infection from DHHS, a laboratory, or a healthcare provider, please follow the process detailed below:

1) Decide if report meets investigation criteria:
    - Anti-HCV antibody positive from an acute hepatitis panel
    - HCV detection test from donor screening
    - HCV+ suspect acute—based on circumstantial evidence and/or health department discretion
    - Co-infected (HIV/AIDS, HBV), if not previously investigated

2) Call or fax a request for ALT, Tbili, or last negative donation result from the lab or donation center respectively. The following are criteria for moving to step 3 (or 4):
    - ALT >200 IU/L
    - Tbili >3.0 mg/dL
    - Negative HCV <12 months **(move directly to step 4)**

3) Request medical records to review clinical presentation. The following are criteria for moving to step 4:
    - Co-infected (HIV/AIDS, HBV), if not previously investigated, **or**
    - Jaundice, **or**
    - Absence of other etiologies/underlying conditions to explain clinical elevated LFT, Tbili

If investigation criteria are not met, no investigation is needed.

For individuals who meet investigation criteria, proceed with investigation.

4) Contact case for full investigation as described:
    - Complete form (risk factor) questionnaire
    - Attempt to identify place exposure and contacts
    - Assist with education to disrupt transmission

Hepatitis C investigation algorithm