

Merlin disease code: 07054 Hepatitis C, Chronic

[Paper case report form](#)  
Merlin extended data required

## Background

Persons with chronic hepatitis C may have no evidence of liver disease or may have a spectrum of disease ranging from chronic hepatitis to cirrhosis or liver cancer. Most persons with chronic infection are asymptomatic until later in the disease process when significant damage has been done to the liver.

Nucleic acid tests for HCV RNA (HCV NAT) include quantitative, qualitative, or genotype testing. No HCV antigen tests are currently approved by FDA. These tests will be acceptable laboratory criteria if and when an FDA-approved test becomes available.

## Clinical criteria for case classification

### Reclassifying chronic hepatitis C as acute:

Cases with any of the following will be reclassified as acute hepatitis C:

- Bilirubin  $\geq 3.0$  mg/dL,
- **Or** alanine aminotransferase (ALT)  $> 200$  IU/L,
- **Or** a person  $< 18$  years old (unless case reviewer verified that clinical criteria are not met).

## Laboratory criteria for case classification

### Confirmatory:

A person  $\geq 1$  year old with either of the following:

- Positive HCV NAT
- **Or** positive HCV antigen.

### Presumptive:

A person  $\geq 1$  year old with both of the following:

- Positive HCV antibody (anti-HCV)
- **And** absence of a negative HCV NAT.

### Reclassifying chronic hepatitis C as acute:

Cases with any of the following will be reclassified as acute hepatitis C:

- Negative anti-HCV and positive NAT with the same specimen event date (unless case reviewer verified that clinical criteria are not met),
- **Or** negative HCV NAT in the absence of a positive HCV NAT or anti-HCV with the same or earlier specimen event date followed within 365 days by positive HCV NAT,
- **Or** negative anti-HCV in the absence of a positive anti-HCV with the same or earlier specimen event date followed within 365 days by positive anti-HCV,
- **Or** negative HCV antigen in the absence of a positive HCV antigen or anti-HCV with the same or earlier specimen event date followed within 365 days by positive HCV antigen,
- **Or** a person  $> 36$  months old with a positive HCV NAT result followed by 2 negative HCV NAT results  $\geq 30$  days apart,  $\geq 30$  days after the last positive HCV NAT followed within 365 days by positive HCV NAT.

## Epidemiological criteria for case classification

A person who does not meet the case definition for acute hepatitis C and meets one or more of the following:

- A child  $\leq 36$  months old known to be exposed to HCV via a mechanism other than perinatal transmission (e.g., acquired via health care exposure or household contact),
- **Or** a child  $\leq 36$  months old with 2 positive HCV NAT results  $\geq 180$  days apart,
- **Or** a person  $> 36$  months old with no previous diagnosis or Merlin case of chronic hepatitis C,
- **Or** a person  $> 36$  months old with a previous case of chronic hepatitis C with a positive HCV NAT result followed by 2 negative HCV NAT results  $\geq 30$  days apart,  $\geq 30$  days after the last positive HCV NAT.

## Case classification

### Confirmed:

A person with confirmatory laboratory criteria and epidemiological criteria.

### Probable:

A person with presumptive laboratory criteria and epidemiological criteria.

## Criteria to distinguish a new case from previous reports

**See epidemiological criteria for classification.** If positive results are received for specimens collected more than 365 days after an acute hepatitis C case occurred, a new chronic hepatitis C case should be created. If a person has a previous chronic hepatitis C diagnosis or Merlin case, a new chronic hepatitis C case should **not** be created.

### **Reinfection**

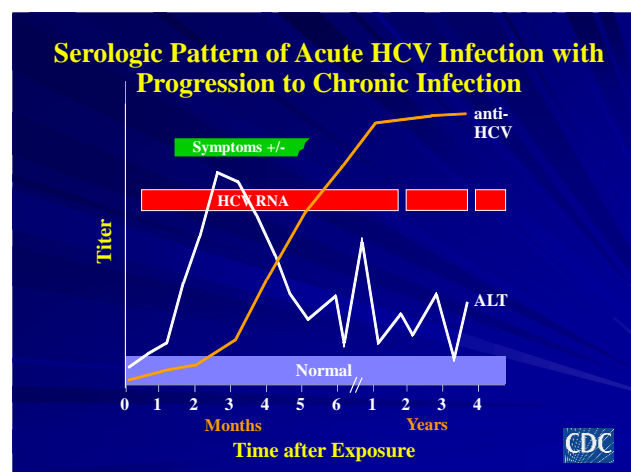
For individuals with a previous acute or chronic hepatitis C with a positive HCV NAT result, a new confirmed chronic case may be created for persons  $> 36$  months old when there are two negative HCV NAT results followed by a new positive HCV NAT result, each of which are  $\geq 30$  days apart. Reinfection cases should be investigated and interviewed.

## Comments

Children  $\leq 36$  months old should only be reported as perinatal hepatitis C (Merlin disease code: 07058), not acute hepatitis C (Merlin disease code: 07051) or chronic hepatitis C (Merlin disease code: 07054) **unless** there is evidence that the case was exposed to HCV via a mechanism other than perinatal transmission (e.g., was acquired via health care exposure) or the child has 2 positive HCV NAT results  $\geq 180$  days apart. Test results prior to 2 months of age should not be used for classification. Anti-HCV testing prior to 18 months of age should not be used for classification.

Report all available liver enzyme results for every case under liver function tests (Merlin disease code: 00000).

See graphic for additional information related to the serological course of disease.



Merlin disease code: 07058 Hepatitis C, Perinatal

No paper case report form  
No Merlin extended data

## Background

Perinatal hepatitis C virus (HCV) infection in pediatric patients may range from asymptomatic to fulminant hepatitis.

## Clinical criteria for case classification

Not applicable.

## Laboratory criteria for case classification

### Confirmatory:

Either of the following:

- Positive nucleic acid test (NAT) for HCV RNA (including quantitative, qualitative, or genotype testing)
- **Or** positive HCV antigen test (if and when an FDA-approved test for HCV antigen is available).

### Supportive:

Both of the following:

- Positive HCV antibody (anti-HCV)
- **And** the absence of a negative HCV NAT.

## Epidemiological criteria for case classification

A child  $\leq 36$  months old not known to be exposed to HCV via a mechanism other than perinatal transmission (e.g., not acquired via health care exposure or household contact). This would include situations where the mother's HCV infection status is unknown (e.g., closed adoptions).

## Case classification

### Confirmed:

A child  $\geq 2$  months old and  $\leq 36$  months old with confirmatory laboratory criteria and epidemiologic criteria.

### Probable:

A child  $< 2$  months old with confirmatory laboratory criteria and epidemiologic criteria.

### Suspect:

A child  $\geq 2$  months old and  $\leq 36$  with supportive laboratory criteria and epidemiological criteria.

## Criteria to distinguish a new case from previous reports

Not applicable.

## Comments

There is no safe and effective intervention known to prevent vertical transmission of HCV from mother to fetus or baby during pregnancy or childbirth. Approximately 75% of children who are vertically infected with HCV will develop chronic hepatitis C and should be referred for further evaluation and follow-up. HCV vertical transmission is higher in those who are born to HIV-infected mothers.

**Follow-up testing should be prioritized for all suspect cases to identify true perinatal infections.** Antibody testing alone can reflect the mother's infection rather than true infection in an infant. Follow-up should include contacting the primary care giver and provider to ensure confirmatory testing is conducted.

Children  $\leq 36$  months old should only be reported as perinatal hepatitis C (Merlin disease code: 07058), not acute hepatitis C (Merlin disease code: 07051) or chronic hepatitis C (Merlin disease code: 07054) **unless** there is evidence that the case was exposed to HCV via a mechanism other than perinatal transmission (e.g., was acquired via health care exposure). Test results prior to 2 months of age should not be used for classification.

Event date should be based on earliest relevant laboratory test date within the 2 to 36 month window.