

Ontario Public Health Standards:
Requirements for Programs, Services and Accountability

Infectious Diseases Protocol

Appendix 1:

Case Definitions and Disease-Specific Information

Disease: Hepatitis C

Effective: January 2026

Hepatitis C

Communicable

Virulent

[Health Protection and Promotion Act \(HPPA\)](#)¹

[Ontario Regulation \(O. Reg.\) 135/18 \(Designation of Diseases\)](#)²

Provincial Reporting Requirements

Confirmed case

Probable case

As per Requirement #3 of the “Reporting of Infectious Diseases” section of the *Infectious Diseases Protocol, 2023* (or as current)³, the minimum data elements to be reported for each case are specified in the following:

- [O. Reg. 569](#) (Reports) under the HPPA:⁴
- The iPHIS User Guides published by Public Health Ontario (PHO); and
- Bulletins and directives issued by PHO.

Also refer to the [Sexual Health and Sexually Transmitted/Blood-Borne Infections Prevention and Control Protocol, 2018](#) (or as current).⁵

For additional information, refer to the *Data Entry Scenario Guide: Hepatitis C Cases in iPHIS* (this resource is intended to help boards of health classify cases of hepatitis C and enter information into iPHIS when receiving additional laboratory information during and after a case investigation).⁶

Type of Surveillance

Case-by-case

Case Definition

For adults, adolescents and children >36 months of age AND for children ≤36 months of age whose suspected mode of exposure is not perinatal

Confirmed case – Acute or recent infection

- Detection of hepatitis C virus ribonucleic acid (HCV RNA) **or** detection of hepatitis C virus antigen (HCV Ag)

AND

- Clinical hepatitis (jaundice **or** peak elevated total bilirubin levels in serum $\geq 50.0 \mu\text{mol/L}$ **or** peak elevated serum alanine aminotransferase [ALT] $>200 \text{ IU/L}$) **and** no other known cause for clinical hepatitis

AND

- Negative anti-hepatitis A virus IgM (anti-HAV IgM) **and** negative anti-hepatitis B core IgM (anti-HBc IgM)

OR

- Detection of HCV RNA **or** HCV Ag in a person with a documented negative test* within the preceding 12 months for hepatitis C virus antibodies (anti-HCV) **or** HCV RNA

OR

- Detection of anti-HCV in a person with documented negative anti-HCV* within the preceding 12 months

Confirmed case – Chronic infection

Does not meet criteria for "Confirmed case - Acute or recent infection"

AND

- Detection of HCV RNA

OR

- Detection of HCV Ag

* A documented negative point-of-care test or negative dried blood spot test is not considered sufficient to meet surveillance case definition criteria.

Confirmed case – Resolved infection[†]

Does not meet criteria for "Confirmed case - Acute or recent infection" or "Confirmed case – Chronic infection"

AND

- Negative HCV RNA test result

AND

- Detection of anti-HCV

Confirmed case – Unspecified hepatitis C[‡]

Does not meet criteria for "Confirmed case - Acute or recent infection" or "Confirmed case - Chronic infection" or "Confirmed case - Resolved infection"

AND

- Detection of anti-HCV

For children ≤36 months of age whose suspected mode of exposure is perinatal

Confirmed case – Perinatal infection[§]

- Detection of HCV RNA

OR

[†] The "Confirmed – Resolved infection" case classification is intended to include cases that have cleared spontaneously or through treatment.

[‡] The "Confirmed – Unspecified infection" case classification is intended to include cases of hepatitis C where anti-HCV is the only available test result. Whenever possible, such cases should be re-classified as additional information is obtained.

[§] The "Confirmed – Perinatal infection" case classification is intended to include infants who become infected with HCV via exposure from a mother or birthing parent with HCV infection (referred to in this Case Definition as "perinatal transmission").

- Detection of anti-HCV at ≥ 18 months of age

Notes

Case classifications are for surveillance purposes and are not intended to be used for making a clinical diagnosis.

Cases should be reported in the context of their initial identification and **not** be reclassified with longitudinal change in status except when information becomes available for Confirmed - Unspecified infection case.

Individuals who have achieved sustained virologic response (SVR) after treatment through documented undetectable HCV RNA at least 12 weeks post-end-of-treatment (SVR-12), then have a subsequent detectable HCV RNA result within 12 months of SVR-12 date should be considered as a new confirmed case of acute or recent infection for surveillance purposes, even though these cases may, albeit rarely, represent late post-treatment relapses.⁷

Outbreak Case Definition

The outbreak case definition varies with the outbreak under investigation. Please refer to the [Infectious Diseases Protocol, 2018](#) (or as current) for guidance in developing an outbreak case definition as needed.³

The outbreak case definitions are established to reflect the disease and circumstances of the outbreak under investigation. The outbreak case definitions should be developed for each individual outbreak based on its characteristics, reviewed during the course of the outbreak, and modified, if necessary, to ensure that the majority of cases are captured by the definition. The case definitions should be created in consideration of the outbreak definitions.

Outbreak cases may be classified by levels of probability (i.e., confirmed and/or probable).

Clinical Information

Clinical Presentation

Acute HCV Infection

Approximately 20% to 30% of acute HCV infections are symptomatic.^{8,9} If symptoms develop, the onset is slow and gradual with common symptoms including anorexia (loss of appetite), vague abdominal discomfort, nausea and vomiting, dark urine, fever,

fatigue and jaundice.¹⁰ Symptoms may last for 2 to 12 weeks.⁸ Some individuals spontaneously clear the infection without treatment (approximately 30% of infections within 6 months).¹⁰

Chronic HCV Infection

The majority of individuals (~70%) infected with HCV will not spontaneously clear the infection and go on to develop chronic infection.

About 15-30% of individuals.¹⁰ Individuals with advanced liver disease may present with jaundice, ascites, hepatomegaly, splenomegaly, hepatic encephalopathy, oesophageal varices and/or blood in the stool or vomit.^{8,11} Approximately 1% to 5% of individuals with chronic HCV will develop hepatocellular carcinoma.⁸ Extrahepatic manifestations of hepatitis C can also occur, including but not limited to heart and blood vessel conditions, type 2 diabetes, neurological conditions, and immune related disorders.^{12,13}

Perinatal HCV infection

Approximately 20 to 30% of neonates infected perinatally clear the infection by age 3. Of those children who do not clear the infection, roughly two-thirds have asymptomatic infection with intermittent viremia and one-third have chronic active HCV infection with persistent viremia. Common symptoms include jaundice, failure to thrive, poor weight gain, and hepatomegaly.

Laboratory Evidence

Laboratory Confirmation

Clinical specimens that are tested by validated assays in an accredited laboratory with one of the following results:

- Reactive for anti-HCV (screening and supplemental assay, if required) in individuals ≥ 18 months of age

OR

- HCV RNA (including dried blood spot) detected

OR

- HCV Ag detected

Indications and Limitations

- Anti-HCV

- After exposure, HCV antibodies are detectable in blood within 5 – 10 weeks, on average. HCV antibodies typically remain detectable in the blood for life, even after the virus has been cleared from the body.⁸
- For inconclusive HCV antibody results (e.g., indeterminate screening test or reactive screening test followed by a non-reactive supplemental test), the submitting healthcare provider should ask their patient to submit new samples for repeat HCV antibody testing **and** HCV RNA testing.
- HCV antibody testing should not be performed in infants ≤18 months of age because of detectable levels of maternal/birth parent antibody. A negative HCV serology result at greater than six months of age excludes HCV infection.
- Individuals with a reactive point-of-care (POC) HCV antibody test require confirmatory serological testing to meet surveillance case definitions for a confirmed HCV case.¹⁴
- HCV RNA
 - After exposure, HCV RNA is detectable in blood within 1-2 weeks.
 - Individuals with a reactive HCV antibody test should receive HCV RNA testing to determine their current infectious status and to guide treatment decisions.
 - Individuals with resolved or successfully treated infections generally require HCV RNA testing to confirm and diagnose a new infection.
 - In immunocompromised cases, if anti-HCV antibodies are negative or indeterminate then HCV RNA is recommended.
 - If HCV antibody testing is performed and found to be reactive in an infant ≤18 months of age, HCV RNA testing should be performed to determine if viremia is present.
 - Testing for HCV RNA earlier than 8 weeks of age is not recommended (to avoid false negative results).^{8,15}
 - Individuals with a positive POC HCV RNA test require confirmatory serological testing to meet surveillance case definitions for a confirmed hepatitis C case.¹⁶
 - Other considerations
 - Umbilical cord blood should not be used for testing in infants because of potential maternal/birth parent blood contamination.

- For surveillance purposes, individuals who test positive for anti-HCV or HCV RNA after receiving an organ transplant from a donor who was **known** to be anti-HCV or HCV RNA positive at the time of transplant should not be classified as a confirmed case of HCV. For data entry guidance, contact Public Health Ontario.
- For further information about diagnostic testing, contact Public Health Ontario's [laboratory](#).

Case Management

In addition to the requirements set out in the Requirement #2 of the “Management of Infectious Diseases – Sporadic Cases” and “Investigation and Management of Infectious Diseases Outbreaks” sections of the [Infectious Diseases Protocol, 2018](#) (or as current), the board of health shall investigate cases to determine the source of infection.³ Refer to Provincial Reporting Requirements above for relevant data to be collected during case investigation.

Case management may vary based on whether an individual has an acute or recent infection, a chronic infection, a resolved infection, or an infection that was acquired at an unspecified/unknown time.

The following cases should be prioritized for follow-up and counselling:

- All acute or recent infection cases;
- Currently infectious cases (i.e., RNA positive);
- Cases with an unknown RNA status**, and Individuals who have a documented negative anti-HCV POC test or a negative DBS test in the past 12 months and do not otherwise meet the case definition for acute or recent infection.

Cases with a resolved infection are of lower priority for follow-up unless they are known by the board of health to have ongoing high-risk activities and are at high risk of reinfection.

General principles of case management include the following:

** Individuals who have an unknown RNA status should receive complete follow-up and counselling as if they are RNA positive as the board of health may have only one opportunity to follow up with the case; they should be encouraged and supported to obtain RNA testing.

- Encourage anti-HCV positive individuals to seek HCV RNA testing if not already completed (e.g., through RNA reflex testing);
- Encourage testing for hepatitis B, HIV, and as appropriate, other sexually transmitted infections;
- Advise cases about the availability of hepatitis A and B vaccines and pneumococcal vaccine (Pneu-C-20) at no cost for persons with chronic liver disease including those with hepatitis C;
- Provide education and counselling to reduce risk of hepatitis C transmission and/or reduce impacts on liver function including:
 - Not sharing drug preparation or consumption equipment (e.g., needles, pipes, straws);
 - Not sharing personal hygiene or care equipment (e.g., toothbrushes, razors and nail clippers);¹⁷
 - Not sharing unsterilized materials or equipment used for tattooing and body piercings;
 - Not donating blood or blood products;
 - Utilizing safer sex practices using barrier protection (e.g., condom use);
 - Limiting alcohol use as per Canada's Low-risk alcohol drinking guidelines;¹⁸
 - Discussing prescription medication use (particularly those metabolized through the liver) with a health care provider;
 - Discussing HCV treatment considerations (e.g., availability, duration, cost) with a health care provider;
 - For those who clear the infection (e.g., spontaneously, through treatment) that there is potential for re-infection in the future; and
 - Available services to support individuals with HCV (e.g., harm reduction services, services through community support agencies and health care services).¹⁹
- Infants and children with a positive HCV RNA result should be referred to a pediatric specialist with experience in HCV management.¹⁵
- Licensed health care professionals who are infected with a bloodborne virus must follow applicable professional requirements/policies.

For management of cases refer to the [Sexual Health and Sexually Transmitted Infections/Blood Borne Infections Protocol, 2018](#) (or as current).⁵

For more information regarding case management refer to the following:

- *Case investigation form: Hepatitis C* (This form is designed to support public health unit staff as they collect information on hepatitis C cases and contacts).²⁰

Contact Management

Contact notification is recommended for acute or recent infection cases or any case that is RNA positive or RNA unknown. Contact notification can be completed by cases, health care providers or public health, depending on local resources and capacity. The responsibility for completing contact tracing and contact notification should be clear (e.g., whether public health staff, health care provider, and/or case is assuming responsibility).

The purpose of contact notification includes the following:

- Notification of the contact of the potential exposure;
- Providing the contact with general information on hepatitis C; and
- Providing the contact with information on testing resources.

When contact notification is undertaken by the case, the case should notify the contact of the potential exposure and encourage their contacts to see a health care provider who can provide them information on hepatitis C and counselling on testing.

Contacts to be considered for notification should include household and contacts who are likely to have blood-to-blood exposure to the case, including:

- Individuals with whom the case has shared drug preparation/consumption equipment or other personal hygiene/care items
- Sexual partners with known high risk sexual behaviour (e.g., condomless anal sex, sharing sex toys, multiple partners, chemsex, rough sex, and/or condomless sex in the presence of menstrual blood, open sores/wounds, or rectal mucous/semen/vaginal fluid containing blood) and long-term sexual partners;^{17,21} and
- Any other contact with a potential exposure to the case's blood.

The timeframe for contact follow-up includes:

- The outer time limit used to identify contacts is either from the onset of the identified risk behaviour or from the time of the case's previous negative antibody result, whichever is more recent; and

- If onset of risk behaviour is more than 12 months prior to diagnosis for chronic hepatitis C infection or hepatitis C unspecified cases focus on most recent contacts and expand based on capacity/resources.

For management of contacts refer to the [Sexual Health and Sexually Transmitted Infections/Blood Borne Infections Protocol, 2018](#) (or as current).⁵

For more information regarding management of contacts refer to the following:

- *Case investigation form: Hepatitis C* (This form is designed to support board of health staff as they collect information on hepatitis C cases and contacts).²⁰

Outbreak Management

Please see the [Infectious Diseases Protocol, 2018](#) (or as current) for the public health management of outbreaks or clusters in order to identify the source of illness, manage the outbreak and limit secondary spread.³

The occurrence of two or more cases of hepatitis C linked by time or a common exposure source or setting is suggestive of an outbreak.

Prevention and Control Measures

Personal Prevention Measures

Measures include:

- Provide counselling on risk reduction measures, including not sharing drug preparation or consumption equipment, or personal hygiene/care items;
- Provide counselling on safer sex practices using barrier methods especially with sexual partners of HCV-positive or HCV-status known persons where there is risk of blood exposure;
- HCV screening as per current national or provincial guidelines;⁸
- Access to HCV treatment to prevent complications of chronic infection and decrease the risk of transmission; and
- Availability of harm reduction strategies such as distribution of clean drug preparation/consumption equipment, needle exchange programs and needle drop off sites, supervised consumption services, and substance use treatment and rehabilitation services including opioid substitution therapy.²²

For additional prevention measures refer to the following:

- [Sexual Health and Sexually Transmitted/Blood-Borne Infections Prevention and Control Protocol, 2018](#) (or as current).⁵
- [Substance Use Prevention and Harm Reduction Guideline, 2018](#) (or as current).²³

Infection Prevention and Control Strategies

Strategies include:

- Use of Routine Practices and point of care risk assessment at all times;²⁴
- Ensuring reusable equipment/devices used in health care settings (e.g., medical, dental) or personal service settings (e.g., piercing, tattooing) are reprocessed using Spaulding's criteria to determine the level of cleaning, disinfection/sterilization required based on their intended use;^{25,26}
- Use of single use disposable equipment/devices, when reprocessing recommendations cannot be followed;
- Immediate containment of a blood spill and cleaning and disinfection of the area using a mycobactericidal disinfectant or a hypochlorite solution (diluted to 500-5000 ppm, equivalent to a 1:10-1:100 dilution of 5.25% sodium hypochlorite);²⁷ and
- Occupational exposures should be managed according to facility policy and legislative requirements.

Refer to [PHO's website](#) to search for the most up-to-date information on Infection Prevention and Control (IPAC).

Disease Characteristics

Aetiologic Agent - hepatitis C virus (HCV) is a single-stranded RNA virus belonging to the genus *Hepacivirus* in the family *Flaviviridae*.²⁸ At least 6 major genotypes and approximately 100 subtypes exist.²⁹ Genotype 1 predominates in Canada.; however, differences do exist in responses to antiviral therapy according to HCV genotype.²⁹

Modes of Transmission - HCV is primarily transmitted by blood-to-blood contact.

Parenteral transmission routes include sharing drug preparation or consumption equipment, exposure to inadequately sterilized instruments (i.e., contaminated with infected blood) or contaminated needles in medical and dental procedures (e.g., needle-stick exposures among health care workers) or other activities that break the skin (e.g.,

tattooing, ear or body piercing), sharing of personal hygiene/care (e.g., razors and toothbrushes).

Sexual transmission is less common, however, sex that involves an increased likelihood of contact with blood is higher risk for transmission. This includes condomless anal sex, fisting without a glove, sharing sex toys, group sex, rough sex, or sex in the presence of blood (e.g., menstrual blood, open sores, cuts, or wounds etc.). Co-infection with HIV or other sexually transmitted infection may also increase the likelihood of HCV transmission.^{30,31}

Vertical transmission of HCV occurs at a rate of approximately 6%. The risk of transmission increases in the presence of certain factors including: maternal/birth parent co-infection with HIV (if sub-optimally controlled), high HCV RNA viral load, elevated ALT in the year prior to pregnancy, birthing parent intravenous drug use, fetal scalp monitoring during labour, and prolonged rupture of membranes. Risk of transmission during delivery does not seem to differ between vaginal delivery or Caesarean section. HCV is not transmitted through breast milk.^{15,29,32}

Incubation Period – Ranges from 2 weeks to 6 months. On average, 5-10 weeks.²⁹

Period of Communicability – one or more weeks before onset of the first symptoms and may persist indefinitely among persons with chronic infection.²⁹ Communicability ends through spontaneous clearance (approximately 30% of infected persons within 6 months of infection) and with successful treatment.¹⁰ HCV can remain infectious on inanimate surfaces for up to 6 weeks.³³

Reservoir - Humans.²⁹

Host Susceptibility and Resistance - Individuals who have been successfully treated or have spontaneously cleared HCV are at risk of becoming re-infected.²⁸ Additionally, some patients may become co-infected (i.e. infected with two or more different HCV genotypes at the same time) or super-infected (i.e. a person infected with a different HCV genotype while chronically infected with another HCV genotype).³⁴

Please refer to [PHO's Reportable Disease Trends in Ontario reporting tool](#) for the most up-to-date information on infectious disease trends in Ontario.

For additional national and international epidemiological information, please refer to the Public Health Agency of Canada and the World Health Organization.

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Document History

Revision Date	Document Section	Description of Revisions
December 2025	Case Definitions	Updated to align with PHAC HCV Case Definitions (2024)
December 2025	Clinical Information	Clinical Evidence removed; updates to Clinical Presentation
December 2025	Laboratory Evidence	Approved/Validated Tests removed; updates to Indications/Limitations
December 2025	Case Management	Minor updates
December 2025	Contact Management	Minor updates
December 2025	Prevention and Control Measures	Minor updates
December 2025	Disease Characteristics	Minor updates
April 2022	Entire Document	New template. Appendix A and B merged. No material content changes.
April 2022	Epidemiology: Occurrence section	Removed.
April 2022	ICD Codes	Removed.