Ministry of Health

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

Infectious Disease Protocol

Appendix 1: Case Definitions and Disease-Specific Information

Disease: Hepatitis C

Effective: May 2022

Ontario

Hepatitis C

☒ Communicable
☐ Virulent

Health Protection and Promotion Act (HPPA)
Ontario Regulation (O. Reg.) 135/18 (Designation of Diseases)

Provincial Reporting Requirements

☒ Confirmed case
☐ Probable case

As per Requirement #3 of the "Reporting of Infectious Diseases" section of the *Infectious Diseases Protocol, 2018* (or as current), the minimum data elements to be reported for each case are specified in the following:

- O. Reg. 569 (Reports) under the HPPA;[6]
- 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).[7]

For additional information, refer to the Quick reference guide: Hepatitis C laboratory and diagnostic testing – iPHIS data entry scenarios (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).[8]

Type of Surveillance

Case-by-case

Case Definition

Confirmed Case – Newly Acquired (24 months of age or older)

Confirmation of a newly acquired infection in an individual requires:

- Detection of anti-hepatitis C virus (anti-HCV) antibody or hepatitis C virus ribonucleic acid (HCV RNA);

AND

- Less than 24 months between current positive and previous negative;

OR

- Detection of anti-HCV antibody or HCV RNA;

AND

- Clinically compatible signs and symptoms (see Clinical Evidence section) with no other known cause;

AND

- Exclusion of acute hepatitis A and B as follows:
    - Immunoglobulin M antibody to hepatitis A virus (IgM anti-HAV) negative;

    AND

    - Immunoglobulin M antibody to hepatitis B core antigen (IgM anti-HBc) negative.

Confirmed Case – Newly Acquired (less than 24 months of age)

- Detection of HCV RNA in those less than 18 months of age

OR

- Detection of anti-HCV antibody or HCV RNA in those 18 months to less than

24 months of age

Confirmed Case – Previously Acquired/Unspecified

- Detection of anti-HCV antibody or HCV RNA

AND

- 24 months of age or older

AND

- Doesn't meet criteria for Confirmed Case – Newly Acquired (24 months of age or older)

Infection Status

The infection status should be ascertained for any case meeting the definitions above:

- **Infectious** - if HCV RNA test reported as 'Detected'
- **Resolved** - if HCV RNA test reported as 'Not Detected' and anti-HCV antibody positive
- **Unknown** - if HCV RNA status is not known

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.

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 Evidence

Clinically compatible signs and symptoms are characterized by:

- Acute illness with discrete onset of any sign or symptom consistent with acute viral hepatitis (e.g., anorexia, abdominal discomfort, nausea, vomiting)

AND

- Jaundice

OR

- Elevated serum alanine aminotransferase (ALT) level

A clinical consultation is necessary for diagnosis.

Clinical Presentation

Approximately 20% to 30% of acute infections are symptomatic.[2] If symptoms develop the onset is slow and insidious and can include anorexia, vague abdominal discomfort, nausea and vomiting, fatigue and jaundice.[2]

Without treatment, a high percentage (75%-85%) of infected persons develop chronic infection. About 5% to 20% of those chronically infected will develop cirrhosis over a period of 20-30 years, and 1% to 5% will die from consequences of chronic infection (i.e., cirrhosis and hepatocellular carcinoma).[2]

Laboratory Evidence

Laboratory Confirmation

Any of the following will constitute a confirmed case of Hepatitis C:

- Reactive for HCV antibody

OR

- HCV RNA detected

Approved/Validated Tests

- Anti-HCV antibody screening and supplemental assays that are Health Canada approved;
- HCV RNA molecular assays that are Health Canada approved

Indications and Limitations

- In immunocompromised cases, if anti-HCV antibodies are negative or indeterminate then HCV RNA is recommended.
- If the HCV antibody screening test is reactive and the supplemental test is non-reactive, the overall interpretation for the two-test algorithm is "inconclusive". In these instances, the submitting clinician should ask their patient to submit new samples for repeat HCV antibody testing **and** HCV RNA testing if not already completed.
- Anti-HCV antibody testing should not be performed in infants ≤18 months of age because of detectable levels of maternal antibody. However, if 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.
- Cord blood should not be used for testing in infants because of potential maternal blood contamination.
- Testing for HCV RNA earlier than 6 weeks of age is not recommended.
- Cases newly confirmed as reactive for HCV antibody should receive HCV RNA testing to determine their current infectious status and to guide treatment decisions.
- For further information about human diagnostic testing, contact the Public Health Ontario Laboratories.

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. 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 a newly acquired HCV infection or if the HCV infection was previously acquired or acquired at an unspecified/unknown time and whether the individual's infection status is identified as infectious, resolved, or unknown.

Newly acquired cases, regardless of RNA status, are a priority for follow up and counselling:

- Currently infectious cases (i.e., RNA positive cases) are also a priority for follow-up;
- RNA negative cases who are previously acquired / unknown are of lower priority unless they are known by the board of health to have ongoing high risk activities; and
- 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.

General principles of case management include the following:

- Ensure anti-HCV positive individuals are tested for HCV RNA;[3]
- Ensure HCV cases are aware not to donate blood or blood products;[3]
- Ensure that people with hepatitis C are tested for hepatitis B and HIV and as appropriate, other STIs;
- Advise physicians about the availability of hepatitis A and B vaccines at no cost for persons with chronic liver disease including those with hepatitis C;
- Some regulatory professional colleges have developed policies addressing members who are infected with blood-borne viruses. Health care

professionals licenced by these regulatory colleges, who are infected with hepatitis C must be aware of and follow the requirements of their regulatory college; and

- Provide education and counselling about: not sharing illicit drugs or drug use equipment and personal hygiene equipment; harm reduction services; safer sex practices; alcohol and medication use; treatment availability etc., as well as information about community support agencies and health care services.

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

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).[11]
- Quick reference guide: Hepatitis C case and contact follow up (This guide provides boards of health with support for case and contact follow up based on the updated components of the case definition).[12]

Contact Management

Contact notification is recommended for cases who are RNA positive, RNA unknown or cases who are newly acquired. 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 above information can be

passed on to the case to provide to contacts.

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

- Individuals with whom the case has shared drug equipment;
- Individuals with whom they have shared other personal-use items such as razors and toothbrushes;
- Sexual partners with known high risk sexual behaviour involving blood-to-blood contact and long term sexual partners; and
- Others with a potential exposure to the case's blood.

The timeframe for contact follow up includes:

- Outer limit to identify contacts is onset of risk behaviour or previous negative antibody result (whichever is more recent); and
- If onset of risk behaviour is more than 24 months prior to diagnosis in cases who are "previously acquired/unspecified, RNA positive or RNA unknown", 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).

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).[11]
- Quick reference guide: Hepatitis C case and contact follow up (This guide provides boards of health with support for case and contact follow up based on the updated components of the case definition).[12]

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.

An outbreak is defined as the occurrence of two or more cases of Hepatitis C linked by time or a common exposure source or setting.

Prevention and Control Measures

Personal Prevention Measures

Measures include:

- Not sharing illicit drugs or drug use equipment, or personal hygiene articles such as tooth brushes and razors;
- Safer sex practices (e.g., using condoms) should be encouraged at all times, especially for sexual partners of HCV-positive persons; and
- Widespread availability of harm reduction strategies such as needle exchange programs, supervised injection services, and substance use treatment services including opioid substitution therapy.

For additional prevention measures refer to the following:

- *Sexual Health and Sexually Transmitted/ Blood-Borne Infections Prevention and Control Protocol, 2018* (or as current).[7]
- *Substance Use Prevention and Harm Reduction Guideline, 2018* (or as current).[9]

For more information, refer to Recommendations for the Public Health Response to Hepatitis C in Ontario.[3]

Infection Prevention and Control Strategies

Strategies include:

- Use of routine practices at all times;
- Single use disposable equipment or adequate sterilization of instruments used in invasive procedures including personal service settings such as piercing and tattooing;
- Appropriate disinfection measures following body fluid spills;

- Occupational exposures should be managed according to the Blood-Borne Diseases Surveillance Protocol for Ontario Hospitals;[10] and
- Widespread access to treatment of hepatitis C infection to decrease the risk of transmission of hepatitis C.

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

Disease Characteristics

Aetiologic Agent - The hepatitis C virus (HCV) is a small, single-stranded ribonucleic acid (RNA) virus belonging to the genus *Hepacivirus* in the *Flaviviridae* family.[1] At least 6 major genotypes and approximately 100 subtypes exist.[2] Genotype 1 predominates in Canada.[3] There is limited evidence about differences in clinical outcome between the various types, however, differences do exist in responses to antiviral therapy according to HCV genotype.[2]

Modes of Transmission - HCV is primarily transmitted by blood-to-blood contact. Parenteral transmission routes include sharing of needles or other injection drug use equipment, exposure to blood contaminating inadequately sterilized instruments and needles used in medical and dental procedures or other activities that break the skin (e.g., tattooing, ear or body piercing), sharing of personal items such as razors and toothbrushes, and accidental needle-stick exposures among health care workers. Sexual and mother-to-child transmission have both been documented but appear uncommon except for instances of HIV co-infection, especially HIV positive men who have sex with men.[2,3]

Incubation Period – Ranges from 2 weeks to 6 months, most commonly 6-9 weeks.[2]

Period of Communicability - Period of communicability is from one or more weeks before onset of the first symptoms and may persist indefinitely among persons with chronic infection.[2] Communicability can be ended with treatment.[3]

HCV can remain infectious on inanimate surfaces for up to 6 weeks.[4]

Reservoir - Humans.[2]

Host Susceptibility and Resistance - Individuals who have been successfully treated or have spontaneously cleared HCV are at risk of becoming re-infected.[2] Additionally, some patients may become co-infected (i.e. infected with 2 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).[5]

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
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.