

Hepatitis C



Public Health Branch

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Abbreviations

ALT	Alanine aminotransferase
Anti-HCV	Antibody to Hepatitis C virus
CBS	Canadian Blood Services
CMIA	Chemiluminescent microparticle immunoassay
CPL	Cadham Provincial Laboratory
DAA	Direct-acting antivirals
DBS	Dried blood spot
HAV	Hepatitis A virus
HBV	Hepatitis B virus
HCC	Hepatocellular carcinoma
HCP	Health care provider
HCV	Hepatitis C virus
HCV Ag	Hepatitis C antigen (aka HCV core antigen)
MCC	Mount Carmel Clinic
MHSLTC	Manitoba Health, Seniors and Long-Term Care
MHSU	Manitoba Health Surveillance Unit
MOH	Medical officer of health
MSM	Men who have sex with men
NAT	Nucleic acid testing
OAT	Opioid agonist treatment
PH	Public health
PHIMS	Public Health Information Management System
PHN	Public health nurse
POC	Point-of-care
PWID	People who inject drugs
STBBI	Sexually transmitted and blood-borne infection
SVR	Sustained virologic response
SVR-12	Sustained virologic response 12 weeks post-end-of-treatment
VHIU	Viral Hepatitis Investigative Unit
WHO	World Health Organization

Summary of Updates

July 2024

The July 2024 update to the *Hepatitis C Protocol* includes additional guidance for regional public health teams on the management of follow up hepatitis C serology. See Section 9.2.

December 2023

The December 2023 update to the *Hepatitis C Protocol* resulted in significant changes from the previous (2014) version.

Amendments that may result in a change in practice:

- Section 2: The case definitions for hepatitis C have been revised, with updated classification and staging.
- Section 3: Clarified the reporting requirements for each testing modality, including the requirements for reporting point-of-care test results. Clarified the specific requirements for notifying the Canadian Blood Services.
- Section 4: Removed outdated epidemiology, and included links to external hepatitis C epidemiology resources that are expected to remain up to date.
- Section 5: Consolidated clinical history information into one section.
- Section 6: Available testing options have been updated to reflect current practice, including emerging technologies such as dried blood spot and point-of-care testing. Added a comprehensive table for interpreting test results to stage cases.
- Sections 7 and 8: Revised to align with current practice and now reflect the current goals and expectations for hepatitis C management.
- Section 9: An all-new section for documenting in the Public Health Information Management System (PHIMS) has been added.
- Section 10: The list of additional resources has been updated.
- Section 11: The references list has been updated.
- Addendum letters to the previous version of the Protocol are found on the [Manitoba Health, Seniors and Long-Term Care website](#).

1. Etiology and Background

Hepatitis C virus (HCV), identified in 1989, is a small, single-stranded RNA virus that is a member of the family Flaviviridae.(1) At least seven genotypes exist and over 80 subtypes, with genotypes 1, 2 and 3 being the most common in North America.(2)

2. Case Definitions

For Adults, Adolescents and Children >36 Months of Age AND for Children ≤36 Months of Age Whose Suspected Mode of Exposure Was *Not* Perinatal

Note: Not perinatal=ruled out in birth parent.

2.1 Laboratory-confirmed case—acute

Fits the criteria for ONE of the following:

- i) Detection of HCV RNA or detection of HCV antigen (HCV Ag)

AND

Clinical hepatitis (jaundice or peak elevated total bilirubin levels in serum ≥ 50 $\mu\text{mol/L}$ or peak elevated serum alanine aminotransferase [ALT] >200 IU/L) within six months preceding the first positive HCV test.

AND

Negative Hepatitis A IgM antibody (anti-HAV IgM) and negative Hepatitis B core IgM antibody (anti-HBc IgM)

AND

No other known cause for clinical hepatitis

OR

- ii) New detection of HCV antibodies (anti-HCV) or HCV RNA or HCV Ag in a patient with previously documented negative anti-HCV or negative HCV RNA within the preceding 12 months

Note: Individuals who have achieved complete eradication of the virus, termed 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 having a new acute or recent infection for surveillance purposes, even though these cases may rarely represent late post-treatment relapses.

2.2 Laboratory-confirmed case—chronic

Does not meet criteria for acute or recent infection

AND

Detection of HCV RNA

OR

Detection of HCV Ag

2.3 Laboratory-confirmed case—resolved

Negative HCV RNA test result

AND

Detection of anti-HCV

Note: At the time of investigation in MB

2.4 Laboratory-confirmed case—unknown or undetermined

Does not meet criteria for acute, chronic or resolved infection

AND

Detection of anti-HCV

Note: Includes situations where anti-HCV positive, HCV Ag negative, and no/absent HCV RNA test result. This may be an interim stage where RNA test results are pending.

For Children ≤36 Months of Age Whose Suspected Mode of Exposure Was Perinatal

For infants who become infected with HCV via exposure from a mother/birth parent with HCV infection (perinatal transmission).

2.5 Laboratory-confirmed case—perinatal

Fits the criteria for ONE of the following:

i) Detection of HCV RNA

OR

ii) Detection of anti-HCV and ≥18 months of age (see laboratory comments)

Laboratory comments:

HCV infection is characterized by the appearance of HCV RNA, HCV Ag and anti-HCV. Following infection, HCV RNA is detectable within one to two weeks and HCV Ag within about two weeks, but it may take six to 10 weeks for anti-HCV to be detected. HCV RNA and HCV Ag can identify acute HCV infection even in the absence of anti-HCV. HCV Ag tests are generally less sensitive than HCV RNA tests. HCV RNA levels can fluctuate over the course of infection. Positive anti-HCV results should be confirmed with follow-up testing. Immunocompromised individuals may not develop anti-HCV and may require HCV RNA testing to confirm and diagnose infection.

HCV results (e.g., anti-HCV, RNA) from dried blood spot (DBS) specimens are considered confirmatory.

Spontaneous clearance of acute HCV is thought to occur in 15 to 30 percent of adults within six months.⁽³⁾ However, there is emerging evidence that spontaneous clearance may be more prevalent. Those who spontaneously clear an HCV infection will typically demonstrate anti-HCV without detectable HCV RNA or HCV Ag. For a minority of cases and typically after a prolonged time period, anti-HCV may become negative after spontaneous resolution or cure of hepatitis C. Individuals with resolved or successfully treated infections require HCV RNA testing to confirm and diagnose a new infection, as they will remain anti-HCV positive.

Between 20 and 30 percent of infants with perinatally-acquired hepatitis C infections experience spontaneous clearance by two to three years of age. Cord blood should not be used for infant testing. Positive anti-HCV results in infants younger than 18 months may represent placental transfer of maternal/birth parent antibodies. HCV RNA testing of infants is not routinely recommended, and if testing is required, should be delayed until eight weeks of age to avoid false negative results. Refer to Section 6.6.

3. Reporting and Other Requirements

3.1 Reporting to Manitoba Health, Seniors and Long-Term Care

All positive laboratory results noted in the case definition are reportable by laboratory to the Manitoba Health Surveillance Unit (MHSU) via [secure fax](#) or established electronic interface.

Confirmed cases are referred by Manitoba Health, Seniors and Long-Term Care (MHSLTC) to the health jurisdiction (i.e., Regional Health Authority, Indigenous Services Canada/First Nations Inuit Health) of residence for follow-up.

For all new cases, the *Provider Report Form for Sexually Transmitted and Blood-Borne Infections (STBBI) and STI Treatment (MHSU-6781)* (found on MHSU's [Surveillance Forms webpage](#)) should be completed by the testing practitioner and forwarded to the MHSU via [secure fax](#).

Operators of Manitoba clinical laboratories are required to submit the residual serum or plasma specimens from individuals who tested positive for HCV to Cadham Provincial Laboratory (CPL) within seven days of report for surveillance purposes.

Positive test results identified through the local Canadian Blood Services (CBS) are reportable to the MHSU via [secure fax](#).

Positive point-of-care (POC) tests for HCV are also required to be reported by the health care provider (HCP) by completing the *STBBI Case Report Form for Point of Care/Rapid Testing (MHSU-4487)* (found on MHSU's [Surveillance Forms webpage](#)) and forwarding to the MHSU via [secure fax](#) if confirmatory testing is not completed at the same time.

3.2 Reporting to Canadian Blood Services

All newly diagnosed HCV positive persons must be reported by the regional public health unit completing the investigation (public health nurse [PHN]/investigator, communicable disease coordinator, or medical officer of health [MOH]) to CBS within two working days of interview if the case reveals a history of donating blood during a potentially infectious period or receiving blood in Canada as a potential HCV acquisition source. However, CBS notification is not required if:

- the person donated blood in Canada more than six months prior to a confirmed negative anti-HCV laboratory test; or
- the person received blood in Canada and had a subsequent negative anti-HCV laboratory test six months or more after receipt.

Report submissions should include the donor's name, date of birth, where and when they donated blood (for donors), and the date/location of transfusion and other risk factors (for blood recipients where transfusion is one of the identified risk factors).

When notifying CBS, a copy of the positive test result must accompany all reports, and all information should be sent to CBS Transmissible Disease Notification via [confidential fax](#). Inquiries can be sent via [email](#).

For scenarios not described above (including donations of other tissues not involving CBS), the MOH should be consulted.

4. Epidemiology

4.1 Reservoir

Humans are the reservoir. Studies suggest that HCV may remain viable outside the body in serum on inanimate surfaces for days to several weeks depending on the environmental conditions,(4) and longer in liquids than on dry substrate.(5)

4.2 Transmission

HCV is primarily transmitted through direct percutaneous exposure to HCV-infected blood.(1, 3) Mucous membrane exposures to HCV-infected blood also can result in transmission, but this route is less likely to result in infection. Although HCV can be detected in other body fluids, they are not believed to be efficient vehicles of transmission.(3)

4.2.1 Parenteral or Percutaneous

Percutaneous transmission is most common through the use of blood contaminated drug injection or preparation equipment (e.g., used needles, syringes, cookers, filters, water).(6)

Exposure to contaminated blood products or transplantation was the most prevalent mode of transmission in Canada prior to 1992.(7) The estimated risk of HCV contamination in blood or blood products in Canada after current donor screening and viral inactivation/reduction processes were implemented is very low (approximately one in 6.7 million donations).(8)

Receipt of healthcare in HCV-endemic or resource-limited areas where basic infection control practices are not followed and/or blood supply is not tested, also accounts for significant proportion of global percutaneous transmission.

Although less common, HCV transmission can also occur through tattooing, piercing, scarification or acupuncture in settings (e.g., unlicensed settings) where unsterile equipment or improper technique is used.(1)

4.2.2 Sexual and Per mucosal

Sexual transmission between HCV-serodiscordant heterosexual partners has been estimated at less than five percent, and as low as 0.7 percent.(9) Sexual activity that involves blood exposure, mucosal trauma or genital ulcerative conditions may increase susceptibility or risk of HCV transmission.(1, 10) Higher rates of HCV transmission have been documented among men who have sex with men (MSM) and are living with HIV, although the role of HIV in mediating HCV transmission is not well understood.

Shared non-injecting drug use equipment (e.g., smoking, inhalation or intranasal drug consumption devices) where mucosal integrity is compromised is also associated with a higher odds of HCV infection.(11)

4.2.1 Vertical

Transmission to the infant from mothers/birth parents who are HCV RNA positive at the time of delivery occurs in approximately five to six percent of births. Mothers/birth parents co-infected with HIV have been associated with two-fold increased risk of perinatal transmission of HCV.(1) Both intrauterine and intrapartum transmission of HCV have been described.(12)

4.2.2 Horizontal/Household

Transmission among family contacts is documented but considered an inefficient mechanism for transmission. A practical recommendation is to avoid direct or inapparent percutaneous or mucosal exposure through shared hygiene devices with trace amounts of blood (e.g., razors, clippers, toothbrushes).(1) There is no evidence of HCV transmission with kissing, hugging, sneezing, coughing, food, water, sharing eating utensils or drinking glasses, casual contact, or other contact without exposure to blood.(13)

4.2.3 Occupational

HCV is not transmitted efficiently through occupational exposures to blood; the average incidence of anti-HCV seroconversion after accidental needlesticks or sharps exposures from an HCV-positive source is less than two percent, with one study indicating that transmission occurred only following injury with hollow-bore needles.(14, 15)

4.2.4 Breastfeeding/Chestfeeding

Although HCV RNA and anti-HCV have been detected in colostrum, HCV transmission from HCV-positive mothers/birth parents is not increased in breastfed/chestfed infants when compared to formula-fed infants.(1) Although breastfeeding/chestfeeding does not increase the risk of HCV transmission,(1) if the nipples are cracked and bleeding, it is recommended to abstain until healed.(16)

4.3 Epidemiological Information on Hepatitis C Virus Infection

4.3.1 World

Current global HCV epidemiology is available from the World Health Organization's (WHO) [website](#).

4.3.2 Canada

The most recent national epidemiology is available from the Public Health Agency of Canada's [Report on Hepatitis B and C Surveillance in Canada](#).

4.3.3 Manitoba

Provincial HCV epidemiology information is available on the MHS LTC's [Sexually Transmitted and Blood-Borne Infections \(STBBI\) Surveillance Report](#).

5. Clinical Presentation/Natural History

5.1 Acute Infection

Acute (initial) infection with HCV is asymptomatic or mildly symptomatic in most cases.(1, 17) Jaundice might occur in 20 to 30 percent of cases, and nonspecific symptoms (e.g., anorexia, malaise or abdominal pain) might be present in 10 to 20 percent of cases.(3) Spontaneous clearance of acute HCV infection occurs within six months of infection in approximately 15 to 30 percent of infected individuals in the absence of treatment,(18) although recent data suggests spontaneous clearance rates may be higher. Predictors of spontaneous clearance include presence of jaundice, elevated ALT level, hepatitis B virus surface Ag (HBsAg) positivity, female sex, younger age, HCV genotype 1 and host genetic factors. Spontaneous clearance is lower among people living with HIV.(3)

5.2 Chronic Infection

Most sources suggest approximately 70 to 85 percent of people who become infected with HCV become chronically infected, and most are asymptomatic.(3) Children with chronic infection are more often asymptomatic(1) than are adults. In the absence of treatment, approximately five to 25 percent of persons with chronic hepatitis C will develop liver cirrhosis over 10 to 20 years, which increases the risk for hepatocellular carcinoma (HCC). Cases who are male, are aged >50 years, use alcohol, have non-alcoholic fatty liver disease, have hepatitis B virus (HBV) or HIV co-infection or are undergoing immunosuppressive therapy have increased rates of progression to cirrhosis.(3)

5.3 Incubation Period

The average time from exposure to symptom onset is two to 12 weeks, although most cases are asymptomatic. The time from exposure to development of viremia (HCV RNA or Ag) is generally one to two weeks and indicates active infection. Anti-HCV can be detected six to 10 weeks after infection and are present in 97 percent of cases by six months.(3)

5.4 Host Susceptibility and Resistance

All humans are susceptible, and reinfection with HCV is known to occur among people following successful antiviral treatment as well as after spontaneous viral clearance.(19, 20) The overall risk of HCV reinfection is low,(21, 22) with the majority of people who are cured through treatment not experiencing HCV reinfection. However, reinfection can occur in individuals who have ongoing risks for hepatitis C after they have been treated and cured.

5.5 Period of Communicability

Viremia develops as early as one to two weeks after exposure,(17) at which point the individual would be considered infectious. All persons with a positive anti-HCV result are considered infectious unless there is documented evidence of a resolved infection.

6. Testing and Diagnosis

CPL performs serological and nucleic acid testing (NAT) for HCV (e.g., nucleic acid amplification test) in clinical specimens. The initial (screening) test for detection of HCV infection is chemiluminescent microparticle immunoassay (CMIA) test, which detects anti-HCV. A positive anti-HCV test may indicate an acute, chronic or resolved infection. A positive result from the CMIA test is confirmed with the HCV Ag test, a NAT for HCV RNA or immunoblot (Line immunoassay: INNO-LIA™). All confirmed positive anti-HCV results are reported to public health (PH), which should be assessed together with an HCV Ag or RNA test result for disease staging (see Table 1). Currently, reflex testing for HCV Ag is performed by CPL when there is a positive anti-HCV, unless it has been less than one year since an HCV Ag or RNA test has been done. The HCV Ag result is reported at the same time as the anti-HCV result. As of 2023, all HCV Ag and RNA results are available for viewing in eChart.

	Anti-HCV*	HCV RNA [#]	HCV Ag [#]	Most Likely Interpretation	Stage
1	–	+	+	Active infection. Early in the infection course, no anti-HCV detectable yet.	Acute hepatitis C (active infection)

Table 1 – Interpretation of Hepatitis C Virus Test Results for Individuals ≥18 Months of Age					
	Anti-HCV*	HCV RNA [#]	HCV Ag [#]	Most Likely Interpretation	Stage
2	–	No result available/Not requested	+	Active infection. Early in the infection course, no anti-HCV detectable yet. HCV RNA is recommended for confirmation.	Acute hepatitis C (active infection)
3	+	+	+	Active infection. Stage is based on evidence of recent infection. <u>Acute infection</u> – either based on (a) clinical hepatitis or (b) recorded negative anti-HCV test within the past 12 months or (c) reinfections with newly detectable HCV RNA within 12 months of a previously cleared infection. <u>Chronic infection</u> – based on no evidence of recent infection (does not meet acute infection definition). May include individuals with a previous negative HCV RNA or HCV Ag greater than 12 months ago and reinfections with newly detectable HCV RNA greater than 12 months after a previously cleared infection.	Acute hepatitis C (active infection) OR chronic hepatitis C (active infection)
4	+	No result available/Not requested	+	Active infection. Stage is based on evidence of recent infection. <u>Acute infection</u> – either based on (a) clinical hepatitis or (b) recorded negative anti-HCV test within the past 12 months or (c) reinfections with newly detectable HCV RNA within 12 months of a previously cleared infection. <u>Chronic infection</u> – based on no evidence of recent infection (does not meet acute infection definition). May include individuals with a previous negative HCV RNA or HCV Ag greater than 12 months ago, and reinfections with newly detectable HCV RNA greater than 12 months after a previously cleared infection.	Acute hepatitis C (active infection) OR chronic hepatitis C (active infection)

	Anti-HCV*	HCV RNA [#]	HCV Ag [#]	Most Likely Interpretation	Stage
5	+	+	No result available	Active infection. Stage is based on evidence of recent infection. <u>Acute infection</u> – either based on (a) clinical hepatitis or (b) recorded negative anti-HCV test within the past 12 months or (c) reinfections with newly detectable HCV RNA within 12 months of a previously cleared infection. <u>Chronic infection</u> – based on no evidence of recent infection (does not meet acute infection definition). May include individuals with a previous negative HCV RNA or HCV Ag greater than 12 months ago, and reinfections with newly detectable HCV RNA greater than 12 months after a previously cleared infection.	Acute hepatitis C (active infection) OR chronic hepatitis C (active infection)
6	+	–	N/A	Undetectable HCV RNA suggests a resolved infection.	Resolved hepatitis C infection
7	+	No result available/Not requested	-	Cannot determine whether there is an active or resolved infection. Recommend HCV RNA testing be completed.	Unknown or undetermined hepatitis C infection
8	–	N/A	N/A	If clinical suspicion that this is very early in the infection, recommend repeating HCV testing within six months	No hepatitis C infection
9	Indeterminate	N/A	N/A	If clinical suspicion that this is very early in the infection, recommend repeating HCV testing within six months	No hepatitis C infection

*A positive test result is followed by an HCV RNA or HCV Ag test to confirm active infection. It may take up to six months after infection for anti-HCV to be detected. Therefore, if infection is suspected to have occurred less than six months prior (e.g., one month ago), a negative test result should be followed up by retesting at ≥six months after suspected infection. In the absence of anti-HCV, any positive HCV Ag result must be confirmed by HCV RNA testing.

[#]Individuals having positive test results for one or more of these markers are considered to be infectious.

Detection of HCV RNA or HCV Ag is necessary to confirm the diagnosis of active HCV infection in a person who is anti-HCV positive. Either a positive HCV RNA test or a positive HCV Ag test is an indicator of active infection and therefore communicability, but neither differentiates between acute and chronic infection.

The HCV Ag test is less sensitive than NAT for HCV RNA to detect active HCV infection. Individuals who are anti-HCV positive and HCV Ag negative should have a confirmatory HCV RNA test.

The HCV RNA and HCV Ag tests can detect HCV infection within one to two weeks after exposure and may also be indicated in the following circumstances in individuals who are anti-HCV negative:

- For individuals undergoing testing who are suspected to be in the “window period” (i.e., infected but not yet producing detectable antibody);
- For immunocompromised individuals who may not develop detectable anti-HCV (e.g., HIV infection with CD4 counts <50, transplant recipients);
- For infants younger than 18 months of age (see Section 6.6) when the presence of maternal/birth parent antibody cannot be ruled out.

6.1 Window Period

The anti-HCV seroconversion window period is approximately six to 10 weeks; it is estimated that three percent of acute infections may be missed if anti-HCV is the only marker of infection used and only during this time period.⁽³⁾ HCV RNA can be detected as early as one to two weeks after infection and, in the context of clinical illness, can identify acute HCV infection even in the absence of anti-HCV. In immunocompromised individuals, seroconversion can be delayed for up to one year, and some may never develop anti-HCV. These individuals may need to undergo HCV RNA testing to confirm infection.

6.2 Acute Hepatitis C

Acute (initial) HCV infection is defined as the presence of HCV RNA or HCV Ag with evidence of clinical hepatitis or recorded negative anti-HCV test within the past 12 months, suggesting recent infection. It also includes reinfections (see Section 6.4).

Patients with acute hepatitis C may not be anti-HCV positive at initial testing. If clinical signs and symptoms are present, diagnosis in the acute phase can be established by detection of HCV RNA or HCV Ag. In the absence of anti-HCV, any positive HCV Ag result must be confirmed by HCV RNA testing.

6.3 Chronic Hepatitis C

The diagnosis of chronic hepatitis C is based on the detection of both anti-HCV and HCV RNA or HCV Ag and no evidence of recent infection (does not meet case definition for acute hepatitis C). This may include individuals with a previous negative HCV RNA or HCV Ag greater than 12 months ago. It also includes reinfections (see Section 6.4).

Spontaneous viral clearance is rare beyond six months from acute infection; therefore, if the virus can still be detected after six months, the clinical diagnosis of chronic hepatitis C can be made. However, for surveillance purposes, PH will stage based on the presentation at the time the case was reported to PH.

6.4 Hepatitis C Virus Reinfection

HCV infection does not confer protective immunity. Individuals who have cleared a previous infection either spontaneously or after treatment-induced clearance remain at risk for reinfection. After successful treatment or spontaneous clearance, people will remain anti-HCV positive lifelong. Reinfection is defined as the reoccurrence of HCV viremia (detection of HCV RNA) after a previously cleared infection. Reinfection is typically from a new exposure as relapses post-treatment are rare.

A diagnosis of HCV reinfection is based on new detectable HCV RNA after the SVR-12 date in those treated, or after documentation of negative HCV RNA in those who spontaneously cleared the infection. If the new detection of HCV RNA occurs within 12 months of the negative HCV RNA result, the reinfection should be considered acute. Although rare, some of these cases of new detection of HCV RNA after the SVR-12 may be post-treatment relapses. Detection of a new genotype of HCV is considered conclusive evidence of reinfection.

6.5 Genotyping

Determination of the viral genotype has been used to guide treatment choice and duration and to predict response to therapy. With newer treatment regimens being pan-genotypic, HCV genotyping is not used as frequently to guide treatment, but may be useful in certain situations (e.g., reinfections, individuals with cirrhosis, non-response to treatment). HCV genotyping in clinical specimens is performed by CPL, but it is not used to diagnose HCV infection.

6.6 Infants Younger Than 18 Months of Age

There is passive transfer of maternal/birthing parent anti-HCV to infants, so the diagnosis of HCV infection in an infant must be based on detection of HCV RNA if younger than 18 months of age or on the persistence of anti-HCV at or after 18 months of age. Cord blood should not be used to test for HCV because of potential cross-contamination with maternal/birth parent antibody. The recommended laboratory screening test for otherwise well infants born to HCV-infected mothers/birthing parents is anti-HCV performed at 12 to 18 months of age. If positive, HCV RNA testing is recommended. A positive anti-HCV test obtained prior to 18 months must be repeated at 18 months to confirm that it is still positive. HCV Ag detection is not considered standard protocol in infants.

HCV RNA testing might be considered after two months of age, in consultation with an appropriate specialist and in select circumstances (e.g., significant parental anxiety, concern that the infant will be lost to follow-up care). However, as false negatives may be observed with HCV RNA testing, a negative HCV RNA test should be confirmed by performing anti-HCV testing at or after 18 months of age.

6.7 Testing Recommendations for STBBI, Including Hepatitis C

In Manitoba, current recommendations include offering STBBI testing to all clients as part of routine care. If you test for one, consider testing for all STBBIs. Include:

- Anyone with consistent symptoms
- Sexual or blood-borne exposure contacts
- Pregnant people—STBBI testing at least three times during pregnancy
 - First trimester, 28 to 32 weeks and at delivery
 - More frequent testing if ongoing risk
 - Monthly testing for syphilis if new infection/treatment
 - Include HCV testing at least once. If selecting a panel test from the CPL requisition, check the information on the back of the requisition for tests included.
- People with new, multiple or anonymous sexual partners or with ongoing blood-borne exposures (offer STBBI testing every three to six months)
- Anyone requesting testing
- Anyone with any confirmed or suspected STBBI

HCV testing recommendations may vary across jurisdictions.(3, 8, 23)

6.8 Non-Traditional Specimen Collection and/or Testing Technologies

A number of new technologies have been, and continue to be, developed to expand access to testing and treatment. However, it should be noted that the gold standard specimen continues to be serum or plasma obtained by venipuncture.

DBS specimens have been validated and used successfully to expand access to HCV testing due to the relative ease of specimen collection with avoidance of venipuncture, and easier handling, transportation and storage options. The same DBS card can be used for HCV serology and NAT. Samples that are anti-HCV positive are followed up by the lab with NAT (RNA). Positive HCV results from DBS are considered confirmatory.

Recent developments in POC HCV testing using finger-prick blood samples have the potential to reduce barriers to hepatitis C care by providing one-step rapid results, expanding testing access to non-clinical settings and reducing loss to follow-up while awaiting results during the typical testing process. POC HCV tests may include anti-HCV only, or a combination of anti-HCV and HCV Ag or HCV RNA (e.g., GeneXpert HCV viral load). They may be included in combination, integrated multi-disease tests. POC tests are in various stages of development, approvals and validation, and vary by manufacturer. In general, positive HCV POC test results should be confirmed by standard test technologies, and cases should be classified as probable cases prior to confirmation when reported to PH, unless otherwise stated by the PH laboratory.

Self-testing is also an area of active research. In general, self-tests are not reportable to PH and should be confirmed by standard test technologies.

Positive test results received through POC testing must be reported to the MHSU by [secure fax](#) using the *STBBI Case Report Form for Point of Care/Rapid Testing (MHSU-4487)* (found in MHSU's [Surveillance Forms webpage](#)) if a confirmatory test is not completed.

6.9 Testing Pursuant to an Order

Where the testing for HCV is being done pursuant to an order issued under The Testing of Bodily Fluids and Disclosure Act, refer to MHSU's [Integrated Post-Exposure Protocol for HIV, HBV and HCV: Guidelines for Managing Exposures to Blood and Body Fluids](#).

7. Control

PH's primary objective in hepatitis C case management is to prevent ongoing disease transmission. This is achieved through case identification and notification, contact tracing and by ensuring newly identified cases are connected to initial and ongoing hepatitis C treatment. This is accomplished through collaboration among HCPs and community partners.

Collection of epidemiologic data by PH is also important to monitor trends, including risk factors for transmission, and to manage clusters and outbreaks when identified.

7.1 Prevention and Elimination

7.1.1 Blood-Borne Transmission Prevention

People who actively use injection drugs and persons who share drug-using equipment should be offered access to appropriate harm reduction, counseling and substance treatment options.

The effectiveness of publicly funded needle/syringe distribution programs for reducing hepatitis C and unsafe injection practices among people who inject drugs (PWID) has been established by systematic reviews, including evidence of cost-effectiveness.(24) Opioid agonist treatment (OAT) and supervised consumption services have been found to additionally prevent HCV transmission by reducing risk related to shared injection equipment.(25) Other harm reduction approaches can increase opportunities for engagement with health and other services, and early detection through low barrier STBBI testing.

CBS screens potential donors and tests donated blood for HCV and will exclude those testing positive. In addition, individuals who are known to be positive for HCV are excluded from donating blood in the future. Organ and tissue donors are also screened for HCV. Donors are notified of the positive test results, and positive results are also reported to MHSU.

Routine infection prevention and control practices should be followed for the handling, use and disposal of needles or other sharp instruments, for cleaning of blood, body fluids or spills, and for direct client care activities (e.g., avoiding sharing of personal hygiene supplies like razors, toothbrushes, etc.).

7.1.2 Harm reduction programs and services

The effectiveness of needle/syringe distribution programs and opioid agonist treatment for reducing blood borne infection transmission among PWID is established by systematic reviews.(24, 26, 27) Both types of programs are evidenced to reduce injection drug related exposure risk, although the impacts have been stronger for HIV reduction than HCV.(26) Harm reduction best practice recommendations support the unlimited distribution of needles and syringes, as well as access to drug preparation equipment such as cookers, filters and water, which may contribute to transmission of HCV when shared among PWIDs.(28) The *Canadian Network on Hepatitis C* identifies specific 2025 and 2030 prevention targets for the number of sterile needles/syringes distributed per PWID per year (500 and 750, respectively), and proportion of PWID receiving OAT (40 and ≥ 40 percent, respectively).(29)

Distribution of safer smoking devices may assist with hepatitis C prevention by: reducing equipment sharing thereby reducing permucosal transmission risk(30, 31); supporting change in consumption mode from injection to smoking(32); and improving engagement with health and social services through distribution encounters, including people who use drugs prior to initiation of injection use.(33)

7.1.3 Hepatitis C elimination goals

There are promising practices since the advent of interferon-free direct-acting antiviral (DAA) therapy for hepatitis C for “treatment as prevention” and HCV elimination. The WHO has set goals and targets that Canada has signed on to for HCV to be eliminated by 2030. The WHO targets include an 80 percent reduction in new chronic infections and a 65 percent reduction in deaths compared to levels in 2015. As efforts to increase screening and treatment are intensified, WHO predicts that it will be possible to eradicate HCV as a PH issue.

The *Canadian Network on Hepatitis C* provides 2025 and 2030 targets for hepatitis C prevention, testing and diagnosis, and HCV care and treatment.

- Objectives for testing and diagnosis include increasing the number of people living with HCV who have been diagnosed and increasing the proportion of people with positive anti-HCV test who receive testing for active HCV infection (HCV RNA).
- Objectives for care and treatment include increasing the number of diagnosed people who are linked to care, increasing the number of people with HCV who are initiating DAA treatment, and ensuring high treatment completion rates and documentation of SVR.

Canadian priority populations for HCV elimination strategies include: people who inject or use drugs; Indigenous peoples; immigrants and newcomers from countries where HCV is common; gay, bisexual, and other MSM; people with experience in the prison system; and the 1945–1975 birth cohort of adults living with HCV.(29) The elevated HCV rates experienced by priority populations are largely mediated by intersecting forms of structural disadvantage, stigma and oppression, and upstream policy responses are required to address root causes.

7.2 Management of Cases

New cases should be reported by the testing practitioner to the MHSU by [secure fax](#) using the *Provider Report Form for Sexually Transmitted and Blood-Borne Infections (STBBI) and STI Treatment (MHSU-6781)* (found in MHSU’s [Surveillance Forms webpage](#)) within five days of the interview with the case. The regional PH unit will contact the testing practitioner for further information if a report is not received.

7.2.1 Testing for active infection and other STBBIs

All results that are anti-HCV positive must be confirmed by a test for detection of HCV Ag or HCV RNA to make a diagnosis of active HCV infection, unless already recently performed. Either a positive HCV RNA test or a positive HCV Ag test is an indicator of active infection and therefore communicability but does not differentiate between acute and chronic infection.

All cases should be tested for other relevant STBBIs (e.g., HBV, HIV, syphilis).

7.2.2 Referral and treatment

Treatment for HCV infection has evolved substantially with the introduction of highly effective DAAs. As a result, the importance of HCV screening with the goal of linking clients to care is clear because of the known benefits of care and treatment in reducing the risk of cirrhosis, HCC and all-cause mortality from HCV, as well as the PH benefit of reducing transmission through early treatment, viral clearance and reduced risk behaviors.

It is recommended that all HCV-infected patients with active disease (HCV RNA or Ag positive), regardless of stage and ongoing risk factors, be referred to a hepatitis C treatment provider for consideration of treatment. Current hepatitis C treatment providers in Manitoba, who provide care in collaboration with primary care providers, include the following:

- [Viral Hepatitis Investigative Unit \(VHIU\)](#)
- [Mount Carmel Clinic \(MCC\)](#)

- Appropriate specialist (e.g., Pediatric Infectious Diseases or Pediatric Gastroenterology for clients 17 years and younger).

Note: People living with HIV generally have HCV treatment coordinated with the HIV care provider.

Even individuals with advanced disease have very high response rates to treatment, although further monitoring and care may be required for those with advanced fibrosis or cirrhosis. Data support considering all HCV-infected persons for DAA therapy, regardless of level of intake of alcohol or other substances. Growing data also support the treatment of incarcerated HCV-infected persons.(34, 35)

The primary objective of DAA therapy is SVR-12. Once achieved, SVR-12 is considered a true cure of the viral infection, as late relapses are very uncommon. Cure rates for treatment of HCV reinfections are similar to treatment of a primary HCV infection.(22)

Co-localization of HCV screening, evaluation and treatment with other medical(36) or social services (i.e., integrated care) is a strategy that addresses several treatment barriers. Co-localization has been applied to settings with high HCV prevalence (e.g., correctional facilities, needle exchange programs, substance use treatment centers and harm reduction programs) and has been demonstrated to increase the proportion of people who begin DAA therapy and achieve SVR-12 without serious adverse events.

Models of care involving close collaboration between primary care practitioners and subspecialists can address access issues to specialist care, particularly in remote geographies. Additional strategies that have been used for enhancing linkage to and retention in care include directly observed therapy, case managers, care coordinators and peer navigators.

In Manitoba, the VHIU and MCC both accept consultations from HCP, including PHNs, on individuals who have active hepatitis C infection. In order to facilitate access to therapy, visits may be done virtually or through Manitoba Telehealth. After a comprehensive review of baseline investigations, individuals are offered access to antiviral therapy and monitored by the team, which typically includes treatment nurses and physicians who are licensed to treat hepatitis C in the province.

The VHIU follows a care model where HCPs can evaluate, assess and treat individuals within their own community, which increases compliance and overall outcome. A central intake form is used to ensure all of the baseline investigations that are required for appropriate therapy are performed prior to the first visit.(37) Follow-up (e.g., blood work at three and six months) is performed by the primary care provider.

MCC is a community-based clinic that prioritizes harm reduction, self-determination and “meeting people where they are at.” The clinic team members have experience working with people who are not connected to a primary care provider and face barriers to treatment (e.g., active substance use, housing instability/lack of housing, poverty, stigma, mental health issues), and are committed to providing individualized support to help those with active HCV-infection get successfully treated.

7.2.3 Immunization

Immunization against hepatitis A virus (HAV) and HBV is recommended for all HCV cases who have not been previously immunized or infected with HAV and/or HBV as they may be at risk of more severe disease if infection occurs. Immunization should be completed as early as possible in the course of hepatitis C disease, as the immune response to vaccine is suboptimal in advanced liver disease.(38)

Individuals testing positive for HCV for the first time are routinely screened by CPL for HAV and HBV.

- Where testing indicates susceptibility to both HAV and HBV, the combined or bivalent hepatitis vaccine (offering protection against both hepatitis A and hepatitis B) is recommended.(38)
- Where the case is susceptible to HAV but not HBV, the monovalent hepatitis A vaccine is recommended.
- Where testing indicates that the case is susceptible to HBV, but not HAV, the monovalent hepatitis B vaccine is recommended.
- Other vaccinations should be offered based on client's eligibility (e.g., human papillomavirus, mpox, pneumococcal)

When indicated, MHS LTC provides the hepatitis A and hepatitis B vaccines at no charge to HCV-infected individuals. Refer to MHS LTC's [immunization website](#) as well as the most recent edition of the [Canadian Immunization Guide](#) for vaccine schedules and clinical use information.

Hepatitis A, B and combined A/B vaccines are available in adult and pediatric formulations. During regular business hours, contact the [Provincial Vaccine Warehouse](#). A current Biologics/Vaccine Order Form is available by calling the warehouse. After regular office hours, the on-call warehouse staff may be contacted.

For HCV cases with advanced liver disease, seroconversion should be assessed after hepatitis B vaccination.(38) Offering higher doses of vaccine should be considered as defined in the [Canadian Immunization Guide](#).

7.2.4 Preventative counselling for cases

All people with HCV infection should be considered infectious until there is evidence of resolved infection.

People diagnosed with resolved infection should be informed that they will have a positive anti-HCV test result for life, but this does not provide protection against HCV re-infection. Review transmission risks and inform that re-infection with HCV is possible. If the person remains at risk for exposure to HCV, follow up testing should be done by RNA PCR, if possible.

Newly diagnosed cases with active infection should be informed of the following:(39)

- The effectiveness of DAAs for treating hepatitis C and preventing transmission.

- How to avoid relevant transmission risks:
 - Do not donate blood, organs, tissue or semen.
 - For people who use drugs by injection, follow safer injection and drug preparation practices (i.e., do not reuse needles/syringes, nor share water, cookers or filters), and encourage safe sharps disposal. Discuss referral for Rapid Access Addictions Medicine (RAAM) and OAT, if appropriate.
 - There is low but present risk for transmission to sex partners. Use of condoms can minimize the risk of sexual transmission from an infected to an uninfected partner.
 - There is low but present risk of household transmission through sharing personal items that might come into contact with blood such as toothbrushes, dental appliances, razors or nail clippers. Prevent blood and other potentially infective body fluids from coming into contact with other individuals (e.g., cover open wounds until healed).
 - If pregnant or considering pregnancy, discuss risk of transmission to the infant. Treatment for HCV should be recommended prior to becoming pregnant.(40) Breastfeeding/chestfeeding is generally considered safe. If the nipples become cracked or bleed, breastfeeding/chestfeeding can be abstained from until they are healed. To prevent cessation of milk supply, consider expressing and discarding human milk until the nipples are healed.
- To minimize further damage to the liver, avoid or limit exposure to hepatotoxic products, such as alcohol, and check with an HCP before taking a new prescription, over-the-counter medication or herbal supplements.

For cases among children, reassure parents and caregivers that there is no known risk of transmission in saliva, urine or stool, and no need for special precautions at home. Child care attendance and participation in play activities and sports should be unrestricted, and parents are not obliged to notify day care staff or school authorities of their child's HCV infection.(40)

Successful treatment of chronic hepatitis C greatly reduces the risk of HCC. However, a proportion of clients, especially those with pre-existing cirrhosis, remain at risk for HCC despite achieving SVR-12. Diabetes mellitus, hepatic steatosis, alcohol consumption and lack of fibrosis regression are associated with risks of HCC after hepatitis C cure.(41)

7.2.5 Management of Hepatitis C Virus-infected infants younger than 18 months of age

Infected infants may be more likely than adults to have a transient infection that does not progress to chronic disease; therefore, no immediate intervention is recommended.

HCV-infected infants should be referred to a specialist with expertise in HCV infection for further assessment and monitoring.

7.3 Management of Contacts

A contact is an individual who has had a percutaneous or mucosal exposure to the blood or blood product(s) of an individual living with active HCV infection (HCV RNA or Ag positive). All people with HCV infection should be considered to be infectious until there is evidence of resolved infection. Percutaneous contacts, specifically those exposed through injection drug use, should be prioritized by PH. It is recommended that interviewing for contact information be done by the first health professional (e.g., physician, PHN) who interviews the case as there may not be a subsequent opportunity to do so.

The contact interview period generally extends back one year from the first positive test confirming active disease obtained from the index case. However, there may be situations where more distant contact identification and notification are indicated depending on the period of infectivity, the significance of the exposure, the feasibility of notification and prioritization of contacts at risk. Cases with resolved infection may be interviewed for contacts on a case-by-case basis if the period of communicability can be estimated, e.g., based on previous negative anti-HCV result or exposure risks.

- All contacts should be tested for HCV, along with other relevant STBBI screening (e.g., HBV, HIV, syphilis), and offered immunization against hepatitis A and B if not already immune or immunized.
- Consider HIV pre-exposure prophylaxis for all contacts who report injection drug use. There is currently no effective pre- or post-exposure prophylaxis available for HCV.(1)
- PWID who test negative for HCV should be advised to seek retesting every three to six months if exposure risk continues and supported to access harm reduction services and supplies.

As most long-term sex partners of people living with hepatitis C test anti-HCV negative, long-term sex partners need not be followed by PH. However, sexual contacts may choose to be tested for HCV by their HCP. People living with HIV who are exposed to HCV may be at higher risk for HCV infection.(3)

For follow-up of individuals who have sustained exposures to blood and/or body fluids (e.g., needlestick injury in a health care worker) and are deemed at risk of acquiring infection, see MHSLTC's [Integrated Post-Exposure Protocol for HIV, HBV and HCV: Guidelines for Managing Exposures to Blood and Body Fluids](#).

7.3.1 Perinatal contacts and pregnancy implications

It is recommended that asymptomatic perinatal contacts (i.e., infants) be tested for anti-HCV at 12 to 18 months of age. A positive anti-HCV test obtained prior to 18 months may reflect transferred maternal/birth parent antibody and must be repeated at 18 months to confirm that it is still positive. For more information, see Section 6.6.

Pregnant people should be advised that approximately five to six percent of infants born to HCV-infected mothers/birth parents become infected and that caesarian section delivery has not been demonstrated to decrease this risk. Breastfeeding/chestfeeding should generally be encouraged in the HCV context unless the nipples are cracked, damaged or bleeding, or if the mother/birth parent is co-infected with HIV.(40) Although breastfeeding/chestfeeding does not increase the risk of HCV transmission, parents may need support (i.e., ensuring a deep latch, addressing nipple pain) to prevent cracked/bleeding nipples as it is recommended to abstain from breastfeeding/chestfeeding until nipple cracks are healed.

7.3.2 Cluster and outbreak management

A cluster or outbreak may be declared if there is an increase in observed HCV transmission amongst a defined group of people or population. If an outbreak or cluster is identified, PH will initiate an outbreak investigation and form an outbreak response team. Refer to the [Regional PHIMS SOP](#).

8. Key Investigation Components for Public Health Response

Once a positive laboratory report of a newly detected case is received by the MHSU, an investigation is created and assigned to the appropriate PH unit.

Case investigation details can be obtained from the testing practitioner, hepatitis C care team, the case, or a combination of any of these. If the testing practitioner or external team (e.g., hepatitis C care team) completes the investigation, it is essential to share relevant information with PH using the *Provider Report Form for Sexually Transmitted and Blood-Borne Infections (STBBI) and STI Treatment (MHSU-6781)* (found in MHSU's [Surveillance Forms webpage](#)).

Cases are prioritized for follow up if they are currently infectious or known to be recently acquired regardless of HCV RNA status, and/or occur among individuals who inject drugs or have risk for onward transmission. The key objectives are determination of active or resolved infection, and referral and engagement with an HCV provider for all individuals with active infection, including reinfections.

8.1 Key Components of the Case Investigation

- Contact the testing practitioner prior to attempting to connect with the client
- Determine reason for testing, possible exposures (percutaneous exposure, medical/occupational)
- Determine case classification and staging according to Section 2. (Also see Section 8.2)
 - Facilitate HCV Ag or RNA testing if not performed
- Ensure referral to HCV treatment provider for all active cases, including reinfections. This may be accomplished through their HCP.
- Encourage or facilitate follow-up testing for co-infections, including other STBBIs
- Encourage or facilitate immunization for hepatitis A/hepatitis B and other vaccinations, if indicated (e.g., human papilloma virus, mpox, pneumococcal)
- Complete investigation components such as exposure and social risks

- Determine if client was donor or recipient of blood or blood contaminated products; follow up with CBS as required (see Section 3.2)
- Confirm pregnancy status for childbearing people
- Interview cases with active infection for percutaneous contacts that require follow-up (last 12 months).
 - Resolved cases may be interviewed for contacts on a case-by-case basis if the communicable period can be estimated from a previous negative anti-HCV or exposure risks.
- Provide harm reduction information/supplies/resources or referrals as indicated
- Counsel on preventive measures per Section 7.1, if not already completed by another provider.
- Document in Public Health Information Management System (PHIMS) and refer to the *Hepatitis B and C, HIV, and Syphilis Investigation Form (MHSU-6780)* (found in MHSU’s [Surveillance Forms webpage](#)) for the required investigation data elements. Service delivery organizations without PHIMS access can complete said investigation form and submit to the MHSU via [secure fax](#).

8.2 Guidance for Hepatitis C Case Classification and Staging

Classification from Person Under Investigation should generally be updated within three working days but may take up to four weeks to finalize. Staging should be consistent with the client’s condition at the time of the initial test and should be documented by four weeks from report date. If unable to confirm staging by four weeks, “unknown or undetermined” staging may be applied as an interim stage, or if there is insufficient information to update staging from “unknown or undetermined” prior to investigation closure.

Stage	Classification	Scenario Description
Acute*	Lab confirmed	New diagnosis with evidence of active disease (HCV Ag or HCV RNA positive), include reinfections (see Section 2)
Chronic*	Lab confirmed	New diagnosis with evidence of active disease (HCV Ag or HCV RNA positive), include reinfections; if new infection with active disease that does not meet acute case definition, stage as chronic (see Section 2)
Resolved	Lab-confirmed	New diagnosis, negative HCV RNA result at time of diagnosis (see Section 2) Referral to hepatitis C provider not required. Contact interview on case-by-case basis if infectious period can be roughly determined.
Unknown or undetermined	Lab confirmed	Interim stage—use as placeholder if staging not known by four weeks. Use if unable to confirm stage otherwise, e.g., new positive anti-HCV and HCV RNA or Ag result not performed at completion of investigation.

Stage	Classification	Scenario Description
Perinatal*	Lab confirmed	Detection of HCV RNA after eight weeks of age or detection of anti-HCV and ≥ 18 months of age (see Section 2)
Perinatal	Suspect	Interim stage—use as placeholder while awaiting confirmatory results, e.g., detection of HCV RNA after 8 weeks of age or detection of anti-HCV after ≥ 18 months of age. If waiting for 18-month test, investigation can be closed and recommendation provided that follow-up testing should be done at 18 months; if positive test result is obtained at a later date, can re-open and update classification, otherwise leave as suspect
Previous diagnosis – chronic	Lab-confirmed (not counted as new cases)	No existing investigation in PHIMS. Either known in MB prior to PHIMS or previously diagnosed elsewhere, and not a new reinfection. Evidence of active disease (HCV Ag or HCV RNA positive). Investigation/re-investigation of old cases is not required, but referral for treatment should be offered.
Previous diagnosis - resolved	Not a case	No existing investigation in PHIMS. Either known in MB prior to PHIMS or previously diagnosed elsewhere. Investigation/re-investigation of old cases is not required.
Blank	Lab confirmed or Person Under Investigation	Requires update to stage or classification
Blank	Not a case	Does not meet case definition

*If a previously staged hepatitis C case with active disease subsequently becomes resolved and known to PH, do not update the initial staging. Add an outcome “Recovered” with the date of the indicative laboratory result, and a comment describing the laboratory result. If a previously staged “acute” case later meets the definition for “chronic” – do not document any stage change or outcome as this is a natural progression of infection.

8.3 Key Components of the Contact Investigation

It is PH’s responsibility to ensure that contact notification and follow-up takes place (if possible), regardless of whether contact notification is performed by the index case, the HCP or PH (see Section 7.3).

- Notification of possible HCV exposure and testing, including testing for other STBBIs
- Immunization for HAV/HBV/human papilloma virus/mpox/pneumococcal, if indicated
- Harm reduction education/supplies as indicated and education on preventative measures; PWID who test negative for HCV should be advised to seek retesting every three to six months if exposure risk continues and supported to access harm reduction services and supplies.
- Completion of documentation in PHIMS or the STBBI Contact Investigation Form

9. Documentation Guidelines and Resources

9.1 Documentation Guidance and Timelines for New Cases and Contacts

Table 3 provides broad guidance and timelines for the majority of hepatitis C case investigations.

Table 3 – Timelines for Documenting Hepatitis C Cases in PHIMS		
Investigation Component	PHIMS Data Entry	Timeline from PH report date
Regions receive new investigation from MHSU or another source; responsible Org and Workgroup assigned by MHSU	Region to assign Primary Investigations or CD Coordinator. Connect with MHSU if investigation referred from another source. Investigation created.	One day
Primary investigator/CD Coordinators reviews investigation and lab results	Update Classification and classification date Update disposition from Pending (e.g., Follow up in progress) If other new STBBI investigations should be combined (e.g., if same contacts were exposed to more than one STBBI), see PHIMS process for Co Infections in User Guide of Completion of Surveillance Forms for Reportable Diseases and PHIMS QRCs. Add an additional disease to an Investigation.	Three days
Enter information received on the Hepatitis B and C, HIV, and Syphilis Investigation Form – Case Form. Contact testing practitioner if form not received. Includes: Symptoms Stage Pregnancy Risk Factors Interventions	Update PHIMS data with information available: Enter contact investigations (identified either by testing practitioner or by contact with client). Contact interview and creation of Transmission Event (TE) and Contact in PHIMS. If case plans to notify contacts, PH to hold case investigation open until notification confirmed. Author Note Upload relevant context documents as required (e.g., personal health information/correspondence sent to PH from an outside HCP, personalized letters). Non-critical fields (symptoms and non-required risk factors) should be documented whenever possible.	One to two weeks

Table 3 – Timelines for Documenting Hepatitis C Cases in PHIMS		
Investigation Component	PHIMS Data Entry	Timeline from PH report date
<p>Attempt to contact case directly if required (e.g., for additional information, contact interview, completion of investigation)</p> <p>All clients with active disease should be referred for treatment. If client not connected to primary care and consenting to treatment, facilitate connection to primary care in the region or refer directly to the VHIU/MCC or other hepatitis C care providers.</p> <p>Note: The VHIU welcomes referrals from PHNs so long as it is clear who is the primary HCP who will be doing the follow up (e.g., blood work at three and six months). If there is a provider involved, the referral should come from them, in order to establish their working relationship.</p>	<p>After contact/attempt with testing practitioner.</p> <p>Add intervention: Referral/Notification–Hepatitis C Provider.</p> <p>Start date=date of referral or date that investigator confirmed a referral has been made or received. Outcome “pending.”</p> <p>End date=date the client has attended an appointment. Outcome can be updated to “attended.” Confirming attendance with HCV provider is recommended for HCV cases experiencing barriers to care or with onward transmission risk.</p>	<p>One to three weeks</p>
<p>Follow up to complete critical data elements listed on Case Form</p>	<p>Complete PHIMS documentation</p> <p>Includes classification and staging. All cases should be staged by four weeks.</p> <p>Interventions relevant to key investigations.</p> <p>Complete critical/required fields. Required risk factors must have a response documented (e.g., yes, no, unknown, not asked, declined to respond)</p> <p>If unable to locate client and/or unable to meet basic care criteria (client not notified of results, not interviewed), continue with periodic attempts to locate. If subsequent testing shows ongoing active infection, continue attempts to re-offer treatment.</p> <p>Disposition: Follow up in Progress OR Unable to Locate, OR Lost to Follow up.</p>	<p>Four weeks for staging and classification</p>

Investigation Component	PHIMS Data Entry	Timeline from PH report date
Quality Assurance	Each region employs a Quality Assurance process (Classification, Staging, Critical/required fields) Consider use of PHIMS Quality Assurance report	Quarterly

*Unknown contacts (those whose identify cannot be confirmed) documented in PHIMS (TE Disposition Details) do not have the same options for data entry as PHIMS contact investigations. Follow the same basic investigation steps until two unique identifiers are confirmed.

Broad guidance and timelines for hepatitis C contact investigations is shown in Table 4.

Investigation Component	PHIMS Data Entry	Timeline from PH report date
Regions receive new investigation	Assign Primary Investigations, Responsible Organization, and Workgroup.	One day
Primary investigator attempts to locate and/or contact client for notification of exposure	Update Disposition: Follow up in Progress	Three days
Document testing	Update PHIMS Interventions. Author note.	One to two weeks
Critical data elements listed on form	Complete PHIMS documentation as soon as available. If contact tests positive, close contact investigations with Disposition: Contact Turned Case. Continue documentation in Case Investigations. If unable to locate client and/or unable to meet basic care criteria (client not notified or exposure, no treatment provided), hold open up to six months with periodic attempts to locate. Disposition: Unable to Locate, OR Lost to Follow up, OR Follow up in Progress. Status open up to six months	Two weeks to six months
Close investigation when investigation complete or if unable to complete (e.g., lost to follow up)	Disposition: Follow up in Progress OR Follow up Complete and OR Lost to Follow up/Unable to Locate. Status Closed.	Two weeks to six months

Table 4 – Timelines for Documenting Hepatitis C Contacts in PHIMS		
Investigation Component	PHIMs Data Entry	Timeline from PH report date
Quality Assurance	CD Coordinator Review by Quality Assurance Report level for minimal data elements only (Disposition, Treatment)	Quarterly

9.2 Management of Follow Up Serology for Previously Diagnosed Hepatitis C Cases

The goal of follow up serology management is to support individuals with active HCV infection to connect with HCV treatment provider. Otherwise, update staging if the previous case investigation was un-staged (unknown/undetermined or blank) or add outcome of recovered if additional information available.

Review referred serology and eChart (if required) for evidence of active infection (positive HCV Ag or HCV RNA), and/or history of resolved infection (negative HCV RNA). Testing history prior to 2017 may not be available in eChart.

If former HCV case investigation is available in PHIMS, review investigation, including classification and staging

- Check if former/original investigation in PHIMS was fully documented (e.g. risk factors, notes etc. complete)
 - If it is evident that client was never reached, referred to an HCV treatment provider, or notified of HCV result, pursue client as a new case.
 - If investigation was completed, follow steps below in Table 5.

If former/original investigation is not documented in PHIMS (e.g. note in investigation that HCV investigation completed prior to PHIMS)

- There will be limited information whether client aware of result and referred to HCV provider.
- Do not pursue paper file or original investigation, follow steps below in Table 5.

Table 5 – Management of Follow Up Serology for Previously Diagnosed Cases		
Infection Status	Follow Up	Staging/Documentation
If follow up serology received is linked to a previous HCV case Investigation in PHIMS		
<p>Active Infection: HCV Ag positive and/or HCV RNA positive</p>	<p>If client is already connected to an HCV treatment provider (e.g., ordering provider is hepatologist, HCV RNA lab result indicates treatment work up, Investigation Intervention = Referred to hepatitis C provider, with outcome = attended in last 12 months), no further follow up with client or provider required.</p> <p>If no evidence that client is in care of HCV treatment provider: Attempt to contact client and offer to connect to care for HCV treatment. Follow-up new contacts as required.</p> <p>If unable to contact client, fax letter (See Appendix A) to provider encouraging referral to HCV treatment provider. If same letter has been sent to the same provider within the last 12 months, do not send.</p>	<p>If PHIMS investigation formerly un-staged, update staging to Previous diagnosis – Chronic, Lab-confirmed.</p> <p>If follow-up HCV serology indicates a new reinfection, open a new case investigation in PHIMS and associate the new laboratory results with the new investigation/remove from the previous investigation.</p>
<p>Resolved Infection: HCV NA negative</p>	<p>No further public health follow-up required</p>	<p>Do not update previous staging. Add outcome of recovered to investigation if previous staging was not “resolved”. Author note in investigation and close.</p>
<p>Indeterminate Infection: No evidence of active infection but unable to rule out (e.g., HCV Ag negative or antigen not completed, no HCV RNA)</p>	<p>Do not pursue as unlikely to be active infection. Do not call CPL.</p> <p>If testing provider is reachable (e.g., not an Emergency Department) – PHN may send letter (See Appendix B) to provider advising that client has previous HCV infection, but we are unable to determine if the client has an active infection and recommend HCV RNA testing.</p>	<p>Do not update previous staging.</p> <p>Author note in investigation – e.g., no further follow up – previous investigation with no new evidence of active infection. Close investigation.</p>

Table 5 – Management of Follow Up Serology for Previously Diagnosed Cases		
Infection Status	Follow Up	Staging/Documentation
If new PHIMS HCV Case Investigation received for a client who was previously diagnosed in Manitoba (e.g., lab states “patient previously tested positive for HCV infection”, no prior HCV case investigation in PHIMS)		
Active Infection: HCV Ag positive and/or HCV RNA positive	<p>If evident that client is already connected to an HCV treatment provider (e.g., ordering provider is hepatologist, HCV RNA lab result indicates treatment work up), no further follow up with client or provider required.</p> <p>If no evidence that client is in care of HCV treatment provider: Attempt to contact client and offer to connect to care for HCV treatment. Follow-up new contacts as required.</p> <p>If unable to contact client, fax letter to provider (See Appendix A), encouraging referral to HCV treatment provider. If same letter has been sent to the same provider within the last 12 months, do not re-send.</p>	Stage as “previous diagnosis – chronic”, classify as “lab confirmed”
Resolved Infection: HCV RNA negative	No further public health follow-up required	Stage as “previous diagnosis – resolved”, classify as “not a case”.
Indeterminate Infection: No evidence of active infection but unable to rule out (e.g., HCV Ag negative or antigen not completed, no HCV RNA)	<p>Do not pursue client as unlikely to be active infection. Do not call CPL to request further testing.</p> <p>If testing provider is reachable (e.g., not an Emergency Department) – PHN may call or send letter (See Appendix B) to provider encouraging advising that client has previous infection, but we are unable to determine if the client has an active infection and recommend HCV RNA testing. Case can be closed.</p>	<p>Stage as “unknown or undetermined”, classify as “lab confirmed” – update classification date to first positive anti-HCV date.</p> <p>Author note in investigation – no further follow up – previously diagnosed case with no new evidence of active infection.</p>

10. Additional Resources

Cadham Provincial Laboratory

Forms and requisitions

<https://healthproviders.sharedhealthmb.ca/services/diagnostic-services/cpl/>

Guide to Services 2020

https://www.gov.mb.ca/health/publichealth/cpl/docs/guide_to_services.pdf

Canadian Blood Service Transmissible Disease Notification

Confidential fax: 844-836-6843

Email: lookback_traceback@blood.ca

Canadian Liver Foundation

www.liver.ca/Home.aspx

Canadian Association for the Study of the Liver

www.hepatology.ca

Education on preventive measures and/or connection to resources to support health outcomes

<https://www.catie.ca/essentials/hepatitis-c-basics>

<https://www.cdc.gov/hepatitis/HCV/PDFs/HepCGeneralFactSheet.pdf>

<https://www.cdc.gov/hepatitis/hcv/pdfs/FactSheet-PWID.pdf>

Manitoba Health, Seniors and Long-Term Care

Immunization Program

<https://www.gov.mb.ca/health/publichealth/cdc/div/index.html>

Surveillance Unit

Secure fax: 204-948-3044

Website:

STBBI Surveillance Forms: <https://www.gov.mb.ca/health/publichealth/surveillance/forms.html#stbbi>

STBBI Surveillance Report: <https://www.gov.mb.ca/health/publichealth/surveillance/stbbi/index.html>

Mount Carmel Clinic

Hepatitis C Clinic

Phone: 204-589-9428

Fax: 204-582-6006

Provincial Vaccine Warehouse

Phone: 204-948-1333 or 1-855-683-3306

On-call staff (after hours): 204-805-4096

Viral Hepatitis Investigative Unit

Phone: 204-787-3500;

Fax: 204-940-8176

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12. Appendix A: Provider Letter Previous Diagnosis Active Infection



Health, Seniors and Long-Term Care
Population and Public Health
4th Floor, 300 Carlton St
Winnipeg, MB R3B 3M9



Santé, Aînés et Soins de longue durée
Population et santé publique
4^e étage; 300, rue Carlton
Winnipeg, MB R3B 3M9

Dear Dr. _____,

Re: Your patient: _____

Date of Birth: ____ / ____ / ____
 YYYY / MM / DD

The above-named client was recently tested by you for hepatitis C infection. The results demonstrate active hepatitis C infection (HCV RNA or Ag positive). According to our records, this is not a new diagnosis as the client had previously tested positive for antibody to hepatitis C.

It is not evident from our records that the client is connected to a hepatitis C treatment provider. It is recommended that all HCV-infected patients with active disease, regardless of stage and ongoing risk factors, be referred to a hepatitis C treatment provider (e.g., HSC Viral Hepatitis Investigative Unit or Mount Carmel Clinic hepatitis C clinic) for consideration of treatment.

Manitoba's Hepatitis C Management Protocol can be found here for further management of this infection, including publicly-funded vaccine recommendations:

<https://www.gov.mb.ca/health/publichealth/cdc/protocol/hepc.pdf>

Please call me at _____ should you have any further questions.

Sincerely,

Public Health Nurse
(Office Address)

13. Appendix B: Provider Letter Previous Diagnosis Unknown Status



Health, Seniors and Long-Term Care
Population and Public Health
4th Floor, 300 Carlton St
Winnipeg, MB R3B 3M9



Santé, Aînés et Soins de longue durée
Population et santé publique
4^e étage; 300, rue Carlton
Winnipeg, MB R3B 3M9

Dear Dr. _____,

Re: Your patient: _____

Date of Birth: ____ / ____ / ____
 YYYY / MM / DD

The above-named client was recently tested by you for hepatitis C infection. While the antibody to hepatitis C results are positive, according to our records this is not a new diagnosis as the client had previously tested positive for antibody to hepatitis C in ____.

However, there is insufficient information to determine if the client has active hepatitis C infection (HCV RNA or Ag positive). Individuals who are anti-HCV positive and HCV Ag negative should have a confirmatory HCV RNA test. We encourage you to order hepatitis C RNA testing for this client.

If the client is subsequently demonstrated to have active infection, it is recommended that all HCV-infected patients with active disease, regardless of stage and ongoing risk factors, be referred to a hepatitis C treatment provider (e.g. HSC Viral Hepatitis Investigative Unit or Mount Carmel Clinic hepatitis C clinic) for consideration of treatment.

Manitoba's Hepatitis C Management Protocol can be found here for further management of this infection, including publicly-funded vaccine recommendations:

<https://www.gov.mb.ca/health/publichealth/cdc/protocol/hepc.pdf>

Please call me at _____ should you have any further questions.

Sincerely,

Public Health Nurse
(Office Address)