5.5 Hepatitis C REPORTABLE

ETIOLOGY

- Hepatitis C (HCV) is an enveloped RNA virus. It is a member of the *Flaviridae* family, genus *Hepacivirus*.
- At least 6 major genotypes and approximately 100 subtypes exist.
- Genotypes vary in pathogenicity and response to antiviral therapy.
- Genotype 1a and 1b are the most common types found in North America. However, all types have been reported in Canada.

CASE DEFINITIONS

Table 1: Case definitions of hepatitis C

Confirmed Case: Acute or Recent Infection	Detection of hepatitis C virus antibodies (anti-HCV) or hepatitis C virus RNA (HCV RNA) in a person with discrete onset of any symptom or sign of acute viral hepatitis within 6 months preceding the first positive HCV test* **AND** negative anti-HAV IgM, and negative anti-HBc IgM or HBsAg tests **AND** serum alanine aminotransferase (ALT) > 2.5 times the upper normal limit **OR** detection of anti-HCV in a person with a documented negative anti-HCV test within the preceding 12 months **OR** detection of HCV RNA in a person with a documented negative HCV RNA test within the preceding 12 months.
Confirmed Case: Unspecified (including chronic and resolved infections)	Detection anti-HCV **OR** detection of HCV RNA
Confirmed Case: Infants < 18 months**	PCR positive for HCV RNA.***
*HCV PCR is important as individuals who are viremic will be considered for antiviral treatment and PCR is a useful diagnostic tool in immunocompromised individuals who might not mount an antibody response.	
** In infants < 18 months of age, anti-HCV testing should not be performed as the presence of anti-HCV may represent passive maternal antibody. Cord blood should not	

be used because of potential cross-contamination with maternal antibody.
*** If testing for HCV RNA is done, it should be delayed beyond 4-12 weeks in order to avoid false negative HCV RNA test results

CLINICAL FEATURES

- Most people (more than 90%) infected with HCV have either no symptoms or exhibit only mild symptoms of illness, such as anorexia, vague abdominal discomfort, nausea and vomiting.
- In acute infections, the most common symptoms are fatigue and jaundice. A person with acute disease may have elevated serum ALT levels, often in a fluctuating pattern.
- Although initial illness may be asymptomatic or mild, a high percentage (50%–80%) go on to develop chronic HCV infection.
- Up to 70% of individuals with chronic HCV infection may have evidence of active liver disease, however, the majority of these individuals may not be aware of infection because they do not appear ill, and symptoms are often non-specific.
- Chronic HCV infection can manifest by changes in clinical symptoms and liver enzyme tests such as serum transaminases. Many people complain of chronic or intermittent fatigue. This fatigue can be debilitating however the degree of fatigue is not correlated with the severity of the liver disease.
- Most people with chronic HCV infection show few physical signs of the disease during the first 20 years of infection however half will develop complications such as cirrhosis or hepatocellular carcinoma (HCC) later in life. These long-term complications generally occur 20 years or more after infection and then rapid progression of disease is seen.
- HCV is the leading cause for liver transplants worldwide.
- Alcohol consumption, age at time of infection (>40 years old), male gender, and co-morbidities including obesity, co-infection with hepatitis B, and co-infection with HIV are factors that all accelerate liver disease progression in people with HCV infection.
- It is estimated that approximately 20% of HIV-positive people in Canada are also co-infected with HCV and the risk for cirrhosis in these individuals is nearly doubled in that of persons with HCV infection.

DIAGNOSIS

Laboratory Tests

Serology and nucleic acid testing (NAT) for HCV is done at the Provincial Public Health Laboratory. For confirmation on laboratory specimens, contact the NL Public Health Laboratory at 709-777-6583 or visit their website:

http://publichealthlab.ca/service/hcv-rna-hepatitis-c-virus-rna-nucleic-acid-amplification-test/

Figure 1: Recommended diagnostic approach to infectious hepatitis

Newfoundland Labrador
Public Health Laboratory

Government of Newfoundland and Labrador
Department of Health and Community Services

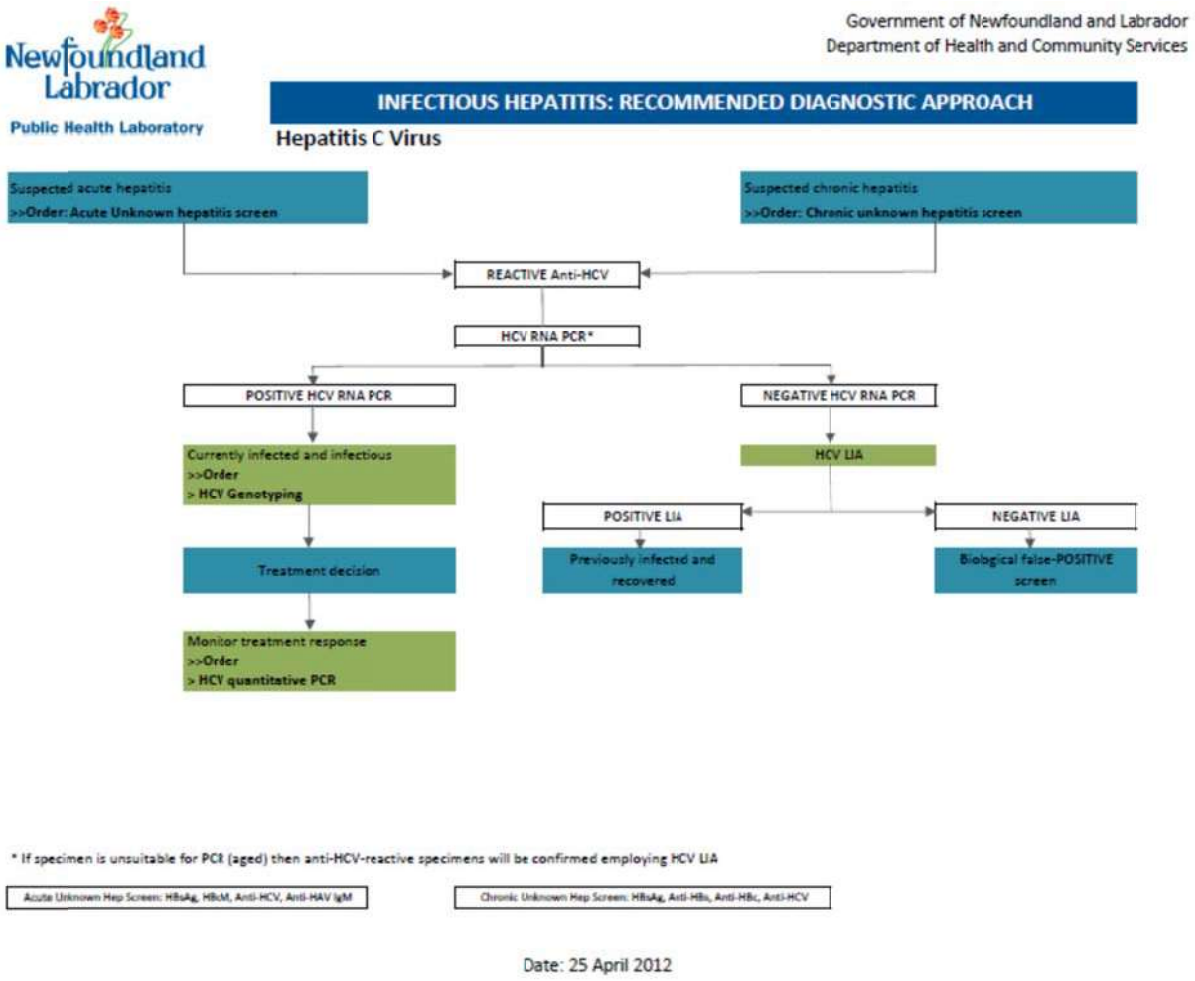
INFECTIOUS HEPATITIS: RECOMMENDED DIAGNOSTIC APPROACH

Infectious hepatitis serologic profile interpretation guidelines

	Profile Name	HBsAg	Anti-HBs	HBc total	HBc IgM	HBeAg	Anti-HBe	Anti-HAV total	Anti-HAV IgM	Anti-HVC	Interpretation
A	Acute uncown hepatitis	-			-				+	-	Acute Hepatitis A
		+		+	+	+			-	-	Acute Hepatitis B[1]
		-			-				-	+	Acute or chronic Hepatitis C
		-			-				-	-	Consider early hepatitis C or hepatitis E, CMV, or EBV[2]
B	Acute hepatitis B follow-up	+	+/-	+/-							Possible chronic hepatitis B
		-	+	+							Resolved past infection
		-	-	+	+						HBsAg-negative acute infection
C	Chronic hepatitis B monitoring					+	-				Actively replicating virus, infectious
						-	+				Evidence of previous active infection
D	Chronic unknown hepatitis screen	+	-	+	-					-	Chronic Hepatitis B
		-	-	-	NT					+	Chronic Hepatitis C
		-	-	-	NT					-	Consider Alternate Etiology*
		+	-	+	-					+	Chronic Hepatitis B and Hepatitis C co-infection
		-	+	+	+	-				+	Chronic HCV & exposure to HBV with recovery/immunity
E	Previous Hepatitis Exposure	-	-	-				+	-	-	Exposure to Hepatitis A with recovery / immunity
		-	-	-				+	+	-	Recent Hepatitis A
		-	-	-				-		+	Exposure to Hepatitis C with receovery or chronicity
		+	-	-				-		-	Exposure to Hepatitis B, early infection, asymptomatic
		+	-	+	-			-		-	Hepatitis B, chronic or carrier state
		+	-	+	+			-		-	Acute Hepatitis B
		-	+/-	+	-			-		-	Exposure to Hepatitis B with recovery / immunity
		-	-	+	+			-		-	Early acute Hepatitis B (core window)
		-	-	-				-		-	Consider Alternative Etiology

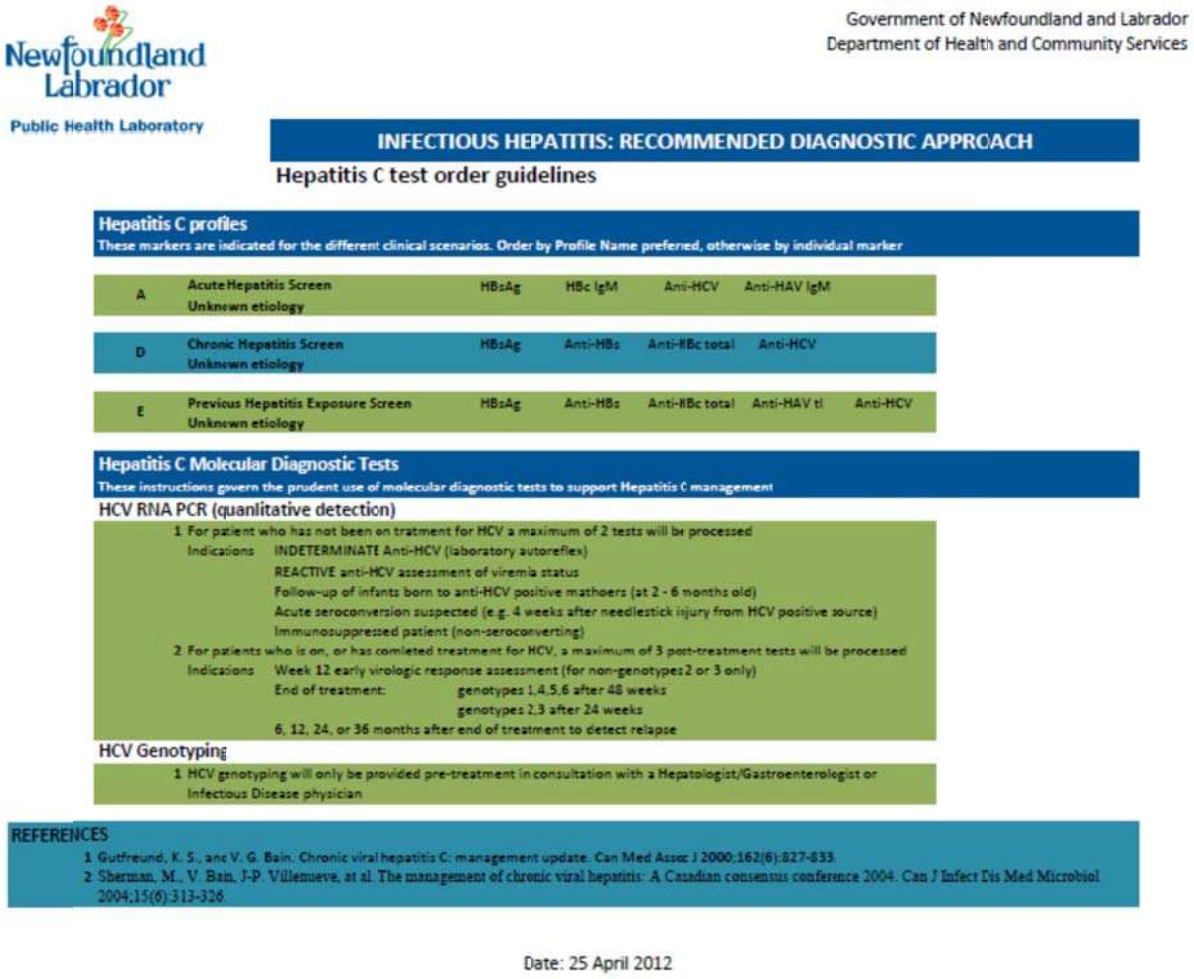
Source: NL Public Health Laboratory. http://publichealthlab.ca/wp-content/uploads/2012/10/Hepatitis-Interpretive.pdf

Figure 2: Recommended diagnostic approach for hepatitis C



Source: NL Public Health Laboratory. http://publichealthlab.ca/wp-content/uploads/2012/10/Hepatitis-Algorithm.pdf

Figure 3: Hepatitis C test ordering guidelines



Newfoundland Labrador
Public Health Laboratory

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INFECTIOUS HEPATITIS: RECOMMENDED DIAGNOSTIC APPROACH

Hepatitis C test order guidelines

Hepatitis C profiles
These markers are indicated for the different clinical scenarios. Order by Profile Name prefered, otherwise by individual marker

A	Acute Hepatitis Screen Unknown etiology	HBsAg	HBc IgM	Anti-HCV	Anti-HAV IgM	
D	Chronic Hepatitis Screen Unknown etiology	HBsAg	Anti-HBs	Anti-HBc total	Anti-HCV	
E	Previous Hepatitis Exposure Screen Unknown etiology	HBsAg	Anti-HBs	Anti-HBc total	Anti-HAV tl	Anti-HCV

Hepatitis C Molecular Diagnostic Tests
These instructions govern the prudent use of molecular diagnostic tests to support Hepatitis C management

HCV RNA PCR (quanlitative detection)

1 For patient who has not been on tratment for HCV a maximum of 2 tests will be processed
Indications INDETERMINATE Anti-HCV (laboratory autoreflex)
REACTIVE anti-HCV assessment of viremia status
Follow-up of infants born to anti-HCV positive mathoers (at 2 - 6 months old)
Acute seroconversion suspected (e.g. 4 weeks after needlestick injury from HCV positive source)
Immunosuppressed patient (non-seroconverting)
2 For patients who is on, or has comleted treatment for HCV, a maximum of 3 post-treatment tests will be processed
Indications Week 12 early virologic response assessment (for non-genotypes 2 or 3 only)
End of treatment: genotypes 1,4,5,6 after 48 weeks
genotypes 2,3 after 24 weeks
6, 12, 24, or 36 months after end of treatment to detect relapse

HCV Genotyping

1 HCV genotyping will only be provided pre-treatment in consultation with a Hepatologist/Gastroenterologist or Infectious Disease physician

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2 Sherman, M., V. Bain, J-P. Villeneuve, et al. The management of chronic viral hepatitis: A Canadian consensus conference 2004. Can J Infect Dis Med Microbiol 2004;15(6):313-326.

Date: 25 April 2012

Source: NL Public Health Laboratory. http://publichealthlab.ca/wp-content/uploads/2012/10/Hepatitis-Algorithm.pdf

Specimen Collection

Specimen Required

Serology: Suitable specimens are individual samples (human sera or EDTA plasma) obtained by standard laboratory techniques.

Blood:

Container/Tube: Serum separator (SST), EDTA plasma or Plain Red-top tube(s)

Specimen Volume: 5 mL of whole blood

Separate plasma or serum within 6 hours and store at 2-8°C and transport on ice packs within 72 hours.

Limitations of Hepatitis C Serology

Despite the value of serologic tests to screen for HCV infection, several limitations of serologic testing exist:

1. There may be a long delay (up to 6 months) between exposure to the virus and the development of detectable HCV antibodies.
2. False-reactive screening test results can occur.
3. A reactive screening test result does not distinguish between past (resolved) and chronic HCV infection.
4. Serologic tests cannot provide information on clinical response to anti-HCV therapy.

Interpretation of HCV RNA (Hepatitis C virus RNA nucleic acid amplification test)

DETECTED: Hepatitis C virus RNA detected indicative of viremia and infectiousness.

NOT DETECTED: Hepatitis C virus RNA was not detected indicating absence of viremia. A single negative HCV RNA PCR should not be used to exclude viremia. A repeat HCV RNA PCR should be ordered to confirm absence of intermittent viremia.

Interpretation of Results

Figure 4: Interpretation of results of HCV testing

Interpretation of hepatitis C virus (HCV) virological test results

Patient age	Born to HCV-infected mother	HCV antibodies	HCV RNA PCR	HCV RNA in liver or PBMCs*	Interpretation	Significance in paediatric patients
≤2 mo	Yes	Present	Not detected		Too early to interpret result because patient may not yet be viremic if transmission occurred at birth.	
2–17 mo	Yes	Present	Not detected		Vertical transmission of HCV did not occur, or the child has cleared HCV	Because the sensitivity of HCV RNA PCR may be <100%, antibodies should be tested at ≥18 months of age. If still present, HCV RNA PCR should be repeated to ensure HCV has been cleared. Children who clear HCV likely have no or very rare sequelae.
≥6 mo	Yes/No	Present	Detectable for >6 mo		Chronic HCV	Usually persists indefinitely in the absence of antiviral therapy, but spontaneous clearance likely more common in children than in adults.
≥18 mo	Yes/No	Present	Not detected	Small studies (15,16) in adults show virus almost always detectable in PBMCs and liver	Clearance of HCV†	Clearance occurs spontaneously with approximately 25% of acute HCV and an undetermined small percentage of chronic HCV, or occurs with successful antiviral therapy.
Any age	Yes	Absent	No need to test		Vertical transmission of HCV did not occur, or the child has cleared HCV	Children who clear HCV likely have no or very rare sequelae.
Any age	Yes/No	Present	Detectable in a child <6 mo of age, or detectable <6 mo after a negative antibody or PCR test		Acute HCV	An estimated 75% will develop chronic HCV and 25% will clear HCV.
Any age	Yes/No	Absent	Present		Seronegative (immunosilent) HCV, or very early acute HCV (infection typically occurred 20 to 60 days prior)	Seronegative HCV mainly described in HIV coinfected adults and other immunosuppressed patients with the incidence in children not known.
Any age	Yes/No	Absent	Absent	Present	Occult HCV	Described in adults with unexplained elevated transaminase levels (18), with there being no paediatric studies.

*Interpretation assumes the HCV RNA result is not a false-positive, which occurs on rare occasions. *Only available as a research tool; †Some experts label this 'occult HCV' if virus is detectable in peripheral blood mononuclear cells (PBMCs) or in the liver, and transaminases are normal; most reserve the term 'occult HCV' for seronegative patients. Mo Months; PCR Polymerase chain reaction*

Source: NL Public Health Laboratory.
http://publichealthlab.ca/wp-content/uploads/2012/10/Pediatric-HCV-Interpretation.pdf

EPIDEMIOLOGY

Occurrence

- Hepatitis C is a major public health concern around the world.
- It is estimated that approximately 3% of the world's population, or 180 million persons worldwide are infected with HCV, 130 million people are also chronic HCV carriers at risk of developing liver cirrhosis and/or liver cancer.
- It is estimated that 3-4 million people worldwide are newly infected with HCV each year.
- The majority of HCV cases in Canada are among people who inject drugs.
- Disease prevalence is considered low (<1%) in Canada. Many countries in Africa, Latin America, and Central and Southeastern Asia are considered high endemicity (>2%), with some countries in these areas reporting prevalence rates between 5 and 10%.
- Prior to 1989, when HCV was first identified, it was known that there was an association between hepatitis and transfusion of blood products. At that time it was originally known as "non-A, non-B" hepatitis.
- A test for HCV was introduced in Canada in 1990.
- Reported cases of HCV have declined in Canada in recent years. However, the health care burden presented by existing cases that progress to more serious sequelae continues to escalate.
- In 2009, 11,357 cases of HCV were reported through the Canadian Notifiable Disease Surveillance System (CNDSS), corresponding to a rate of 33.7 per 100,000 populations. This rate has decreased since 2005 (40.5 per 100,000).
- The majority of cases are over the age of 30 years and among males, but the gender gap is narrowing, which is mainly driven by increasing rates in younger females.
- Among newly acquired HCV cases with known risk factor information, injection drug use was associated with 61% of infections. HCV infection from transfusion of blood products accounts for only approximately 13 % of all cases. In Canada, approximately 20% of reported HCV infections are in immigrants. It is estimated that perhaps only 65% of the estimated cases in Canada have actually been diagnosed.

Reservoir

Humans: blood, blood products or any body fluid containing blood can be a source of infection.

Incubation

Ranges from 2 weeks to 6 months, but usually from 6 to 9 weeks.

Transmission

- HCV is primarily transmitted through parenteral exposure to HCV infected blood
- Transmission is most efficient through large or repeated percutaneous exposures to blood such as transfusion of blood from unscreened donors or through injection drug use.
- Highest rate of transmission of HCV is injection drug users who share drug paraphernalia (e.g. needles, spoons, bills, straws etc.); sexual transmission of hepatitis C is much less efficient than for hepatitis B (HBV).
- Perinatal transmission occurs less efficiently than HBV.
- Other activities involving inadequately sterilized equipment and needles, such as tattooing, piercing, electrolysis and acupuncture may pose a risk of HCV transmission.
- Household (non-sexual) transmission has been reported through sharing personal hygiene equipment with an infected person (e.g., toothbrushes, nail scissors and clippers, and razors).
- In Canada, since the early 1990s, the risk of transmission from screened and donated blood, manufactured blood products, and transplanted organs has been minimal due to strict screening and processing of all blood products.
- Individuals who were exposed to contaminated blood, blood products or transplantation prior to 1992 in Canada may be at risk of having HCV infection.
- HCV is not transmitted efficiently through occupational exposures to blood. The average incidence of anti-HCV sero-conversion after accidental percutaneous exposure (i.e. needle stick injury) from an HCV positive source is 1.8% (range 0 – 7%).

Communicability

A source is infectious from one (1) or more weeks before the onset of symptoms and can continue indefinitely.

CONTROL MEASURES

Management of Cases

- Determine the reason for testing (from case or physician).
- Assess risk factors for potential source of infection which include:
    - current or past injection drug use(even once)
    - needle sharing
    - incarceration,
    - homelessness and/or unstable housing
    - having resided in a country where HCV is common
    - having received a blood transfusion, blood products, or organ transplant before 1992
    - having received medical or dental care where basic infection control practices were not followed
    - having been on chronic(long term) hemodialysis

    - skin piercing procedures e.g., tattooing, body piercing, acupuncture,
    - work place or non-occupational exposure to HCV.
    - HIV-infected men who have sex with men.
    - Children born to HCV infected mothers

- Assess sexual relationships and high-risk sexual behaviors.
- Ascertain status of co-infection with other STBBIs
- If female, determine pregnancy status.
- Determine if client has donated blood, tissue, or organs.
- Identify household and other intimate contacts for potential blood exposure from the case. Contacts would include:
    - needle and drug-use equipment sharing partners
    - persons who share personal hygiene items e.g., razors, toothbrushes
    - long term and short term sexual partners
    - other persons with an identified exposure to the blood or other body fluids capable of producing HCV infection.

Treatment and Follow-Up

- Initiate correspondence to physician for appropriate follow-up and referral to specialist (gastroenterologist or hepatologist).
- Serological testing for Hepatitis A and B (to determine the need for hepatitis A and B vaccine).
- Immunization with Hepatitis A and/or B vaccine to prevent infection with either of these agents is strongly recommended.
- Test for other blood borne infections, HIV and syphilis.
- Discuss the importance of a healthy lifestyle to minimize liver damage e.g., avoid intake of alcohol and hepatotoxic drugs, eating a well-balanced diet, regular medical checkups, etc.
- Provide educational material that is suitable to the needs of the client where appropriate.
- Initiate linkages when appropriate to support services such as Mental Health & Addiction programs, and other harm reduction strategies aimed at reducing the risk of acquiring HIV infection.

Management of Contacts

Definition of Contact

A person who has shared drug use equipment or has had some relevant exposure to the case including sexual contact.

Notification

- Those persons who are identified as contacts of IDUs should be given priority for follow-up by public health personnel and should be notified of possible exposure to HCV by the case or by public health personnel.

- Sexual contacts should be assessed for risk behaviors and appropriate testing for STIs, hepatitis C and other BBIs should be recommended. They should be notified by the case or by public health personnel.
- Infants born to HCV positive mothers should be followed up by a pediatric infectious disease physician or another medical specialist/expert in HCV infection.

Management of Outbreaks

An outbreak management team should be established to address infection prevention and control matters.

PREVENTION

Education and Preventive Measures

Injection Drug Use (IDU)

- The identification of individuals who participate in injection drug use and sharing of drug use equipment should receive counselling around harm reduction measures. Harm reduction efforts may include participation in needle-exchange programs, participation in addiction programs and/or drug substitution.
- There is a need for HCV prevention strategies targeting new or potential injection drug users. More than half of the new injection drug users become positive for HCV within six to 12 months.

Skin Piercing Procedures

- Persons considering tattoos, body piercings, or acupuncture should be counseled to ensure that it is important that these practices be carried out using sterile equipment, specifically equipment appropriate for one-time-use.

Occupational Exposure

- Health care and emergency response workers should all be trained regarding the risk and prevention of bloodborne infections and should report any percutaneous or permucosal exposures to their respective occupational health and safety (OHS) representative for appropriate management.
- Prevalence of HCV infection among health care workers is about 1% to 2%, which is the same as the general population.

Sexual Activity

- Transmission from partner to partner in a long-term relationship is relatively low, however, the risk of transmission increases with multiple sexual partners, coinfection with HIV, and high-risk sexual behavior (i.e., where blood may be present).
- The infected person should inform sexual partners.
- Testing should be offered to all identified partners.

- Recommend use of condoms in short-term sexual relationships.
- Infected women should avoid unprotected sex during menstruation, as the virus may be present in menstrual blood which may increase the risk for transmission.

Vertical Transmission

- Transmission of HCV from mother to baby can occur at the time of birth.
- In general breastfeeding is recommended because of its proven health benefits and because the risk of HCV transmission by this means is only theoretical.
- Women who do not wish to breastfeed may choose alternative feeding methods. If the nipples are bleeding or cracked, it is recommended that breastfeeding be suspended until they are healed.

Household Exposure

- People with HCV should be advised not to share personal hygiene items such as razors, nail clippers or toothbrushes because of the possibility they may be contaminated with small amounts of blood.
- Cuts and open sores on the skin should be covered
- After a blood spill, removal of organic material must occur followed by cleaning with an appropriate disinfectant (usually 1:10 dilution of household bleach).

Screening for HCV

- Early detection of HCV infection is important so that treatment may be initiated if indicated, and so that infected persons may be given the opportunity to initiate lifestyle changes to reduce other risks that might lead to liver damage.
- Response to treatment may be enhanced in persons with a shorter duration of infection.
- Screening should be provided for persons with identified risks for infection and for individuals who request a test. Consideration of hepatitis C testing as a part of periodic routine medical screening should be discussed.
- Persons with liver dysfunction of unknown etiology or chronic liver disease should also be screened.
- All blood donations are screened by the Canadian Blood Services for HCV.
- All newly diagnosed hepatitis C cases are reported to Canadian Blood Services if they have donated blood.
- All donations of blood, blood products, tissues, organs, and semen are screened for HCV, and people infected with HCV should be counseled to not donate.

Health Care Workers

In any situation in which a health care worker, who is HCV positive, is uncertain about the potential transmission risks of HCV or proper practices to minimize the risk to patients/clients/residents, he or she should consult with employee health or an infection control practitioner or patient safety group responsible for the quality of care for the clients.

Immunization

- Hepatitis A and/or B vaccine are recommended for all Hepatitis C positive individuals.
- Individuals at high risk for hepatitis C should receive hepatitis A and/or hepatitis B vaccine.
- Pneumococcal-23 vaccine is recommended for HCV positive individuals.

Reporting Requirements and Procedures

- The laboratory (hospital or public health laboratories) will report case/s to the attending physician, the Chief Medical Officer of Health (CMOH) and the Medical Officers of Health (MOH).
- The MOH office will notify, as required, local physicians, nurse practitioners, environmental health officers, community health nurses, communicable disease control nurses (CDCNs) and Infection control practitioners (ICP), in the specific region as required for follow-up and case investigation.
- The CDCN will collect case details as required and will enter the case details into the Communicable Disease Surveillance System electronic reporting system and uses the CNPHI tool, if indicated, for alerts and/or outbreak summaries
- CDCN will advise Disease Control Nurse specialist in writing if Canadian Blood Services needs to be notified if case reports having donated blood that may require a trace back.

Provincial Disease Control

- Reports the aggregate case data to Public Health Agency of Canada
- Provides an analysis of the case/s with reports in the Quarterly Communicable Disease Report (CDR), which is also posted on the Public Health website.
- Coordinates the response if an outbreak crosses more than one RHA.

The link for the fact sheet on hepatitis C can be found here:

http://www.phac-aspc.gc.ca/hepc/pubs/getfacts-informezvous/index-eng.php

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