The HCV Guide

2nd edition

Everything you've always wanted to know about Hepatitis C (and more!)

A tool created by

CAPAHC

Centre Associatif Polyvalent d'Aide Hépatite C

Introduction

This *2024 HCV Guide* is for all people and health professionals who want to learn more about hepatitis C. It may be read in the suggested order or by the reader's preferred sequence.

This document aims to provide you with answers about hepatitis C, how it is transmitted, its diagnosis, consequences, the available treatments and prevention strategies.

We would like to extend our gratitude to all the professionals and specialists in the scientific committee who contributed in writing and revising the guide's initial version from the spring of 2018, as well as to **Sofiane Chougar** - Assistant Chief Nurse at the CHUM Drug addiction service, **Barbara Kotsoros** - nurse clinician at the CHUM Drug addiction service and **Émilie Roberge** - coordinator at Spectre de Rue (Spectre of the Street)..

The current version of this guide is an update of the 1st edition written by **Marjolaine Pruvost**, project coordonnator, under the direction of **Laurence Mersilian**, general director. The document layout was done by **Thomas Delbano**, project coordonnator. The English version of this document was translated by **Peter MacLean**, reviwed by **Bells Larsen**, head of Traning and **Esteban Lara**, communications manager.

The mission of CAPAHC (Centre Associatif Polyvalent d'Aide Hépatite C) is:

- To provide support to people living with hepatitis C and their caregivers.
- To promote global health in the community, through prevention and the acquisition of knowledge concerning the hepatitis C virus and other related diseases (HIV co-infection) and without discrimination.
- Design and implement information, awareness and education programs.

Founded in 2003, the organization has become over the years a reference in the field of hepatitis C and sexually transmitted and blood-borne infections in Quebec. CAPAHC's services include an information hotline at 1-866-522-0444, the creation and distribution of educational materials, the organization of workshops and training sessions, and the coordination of consultation committees.

Please note: the different procedures mentioned in this guide are in common use in Canada and especially in the province of Quebec.

CAPAHC
Centre Associatif Polyvalent d'Aide Hépatite C

Glossary

AHC: Action hepatitis Canada

ARV: Antiretrovirus

CAF: HIV and Hepatitis C Community Action Fund

DRSP: Regional public health department (Direction régionale de santé publique)

EHM: Extraepatic Manifestations of the hepatitis C virus

GBMSM: Gay and bisexual men who have sexual relations with other men

HAV: Hepatitis A Virus

HBV: Hepatitis B Virus

HCC: Hepatocellular carcinoma

HCV: Hepatitis C Virus

HDV: Hepatitis D Virus

HEV: Hepatitis E Virus

HIV: Human immunodeficiency virus

Iatrogenic: an illness caused by a medical procedure

Incidence: Number of new cases of a disease within a population over a given time period

INSPQ: Public Health Expertise and Reference (Institut National de Santé Publique du Québec)

MASH (formerly NASH): Metabolic dysfunction-associated steatohepatitis, formerly Non-alcoholic steatohepatitis

MSSS: Ministry of Health and Social Services (Ministère de la Santé et des Services Sociaux)

NIHB: Non-Insured Health Benefits

OAT: Opioid Agonist Therapy

PHAC: Public Health Agency of Canada

Portal tract: A complex in the liver that includes a bile duct, a branch of the hepatic artery, and lymphatic vessels or capillaries

PrEP: Pre-Exposure Prophylaxis

Prevalence: Number of cases of a disease within a population at a given time, encompassing new cases as well as on-going ones

PWUD: People who use drugs

PWID: People who inject drugs

Reportable diseases: Diseases that must be reported to public health officials

RNA: Ribonucleic acid

Septa: Name given in anatomy to describe a wall, dividing a cavity or structure into smaller ones

Serodiscordant: Relationship where one partner is infected by HIV (or another STBBI) and the other is not

Serosorting: Practice consisting of choosing one's sexual partner based on their serological status, particularly concerning HIV

STBBIs: Sexually transmitted and blood-borne infections

STI: Sexually Transmitted Infection

SVR: Sustained virological response

Viral load: Amount of virus in an infected person's blood.

Window period: Duration between the moment of viral transmission and the moment of screening during the test provides a reliable positive or negative result

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Overview of the situation in 2023

Epidemiology

Worldwide

In 2015, the viremic prevalence for hepatitis C (prevalence of HCV RNA) was estimated at 1% of the global population, or 71.1 million cases.

In 2022, the global viremic prevalence was estimated to be at 50 million. This number represents a considerable drop compared to the 2015 estimate, which may be explained by:

- Newer and lower estimates of prevalence in the region of Africa;
- Increased mortality rates linked to liver-related causes and aging populations.

Despite this decline, we are currently not on track to meet the WHO global elimination targets by 2030..[1] [2]

The global incidence rate for hepatitis C is 1.5 million new cases. Additionally, we estimate that HCV is responsible for 290,000 deaths every year.

The geographic distribution of hepatitis C is very heterogeneous.

In Canada

In Canada, the incidence for hepatitis C was estimated at 6736 new infections in 2020, a rate of 18.4 per 100,000 inhabitants.

In 2019, the prevalence of people in Canada with antibodies to hepatitis C was estimated at 1.03%, and those living with chronic (long term) hepatitis C was estimated at 41% of the population or 387,000 cases.[3]

We estimate that 24% of people living with chronic hepatitis C in Canada are not aware of their viral status[4]. The cohort of people born between 1945 and 1975 represent up to 75% of people carrying HCV in Canada. This cohort is therefore a priority as it is the most at risk for going undiagnosed.[5]

In Quebec

Since 1990, more than 45,000 cases have been registered in Quebec.

According to the INSPQ, the number of declared cases has gradually decreased over the last 20 years. However, the INSPQ points out in its report that this number is likely to be an underestimate due to the difficulty of distinguishing between acute and recent cases of HCV and calls for better and more precise data to accurately assess the incidence rate in Quebec.

Characteristics of cases reported in 2019

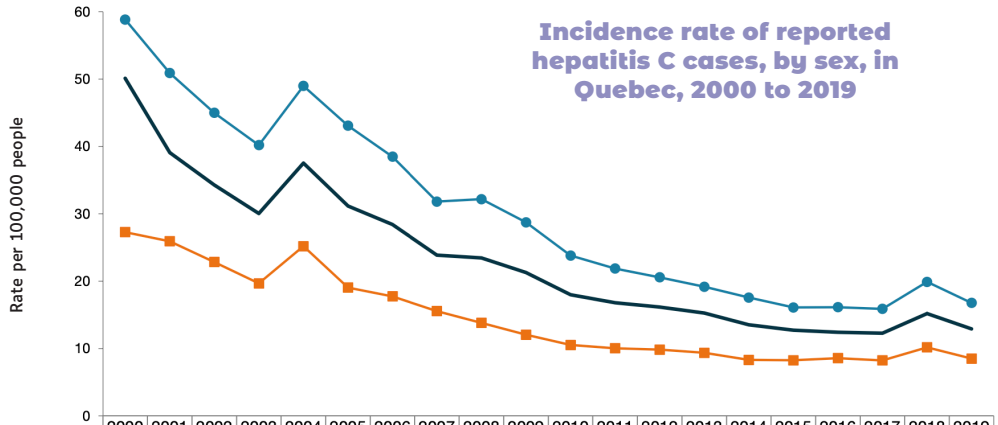
In 2019 in Quebec, 1,096 cases of hepatitis C (acute, recent or unspecified stage) were declared, or 13 cases per 100,000 people.

We observe an increased prevalence among men, who account for 66% of all reported cases. Men aged 50 to 54 and men aged 55 to 64 have the highest infection rates (33 and 32 cases per 100 000 persons, respectively).

Among women, the rate is relatively the same for all age groups between 30 and 64 years. The most affected regions in Quebec are:

- Montreal (22 cases per 100 000);
- Outaouais (20 per 100 000);
- Estrie (19 per 100 000);
- Nunavik (14 per 100 000);
- National Capital (14 per 100 000).

Incidence rate of reported hepatitis C cases, by sex, in Quebec, 2000 to 2019



	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019
Men	58,9	50,9	45,0	40,2	49,0	43,1	38,5	31,8	32,2	28,7	23,8	21,9	20,6	19,2	17,6	16,1	16,1	15,9	19,9	16,8
Women	27,3	25,9	22,8	19,7	25,2	19,1	17,7	15,6	13,8	12,1	10,5	10,0	9,8	9,4	8,3	8,3	8,6	8,2	10,2	8,5
Total	50,1	39,1	34,3	30,0	37,5	31,2	28,4	23,9	23,4	21,3	18,0	16,8	16,2	15,3	13,5	12,7	12,4	12,3	15,2	12,9

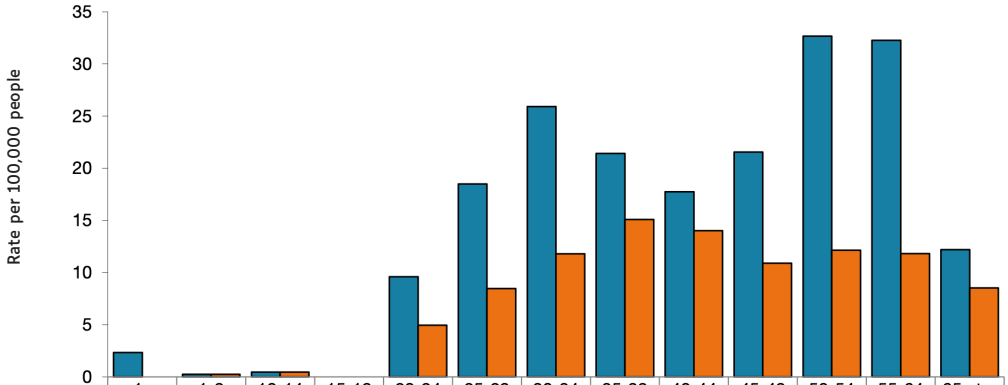
Notes: rate per 100,000 people.
Data taken from the *Fichier des maladies à déclaration obligatoire* (MADO)

Blouin (2021)

While the global rate of registered hepatitis C cases decreased by 74% between 2000 and 2019 (from 50 to 13 per 100,000 people), the provincial rate remained stable between 2015 and 2019. It even increased by 31% in the Outaouais region, by 25% in the National Capital region and by 16% in the Montreal region.[6]

It is important to emphasise that collecting and accessing data on hepatitis C is a matter of scale.

Incidence rate of reported hepatitis C cases, by age and sex, in Quebec in 2019

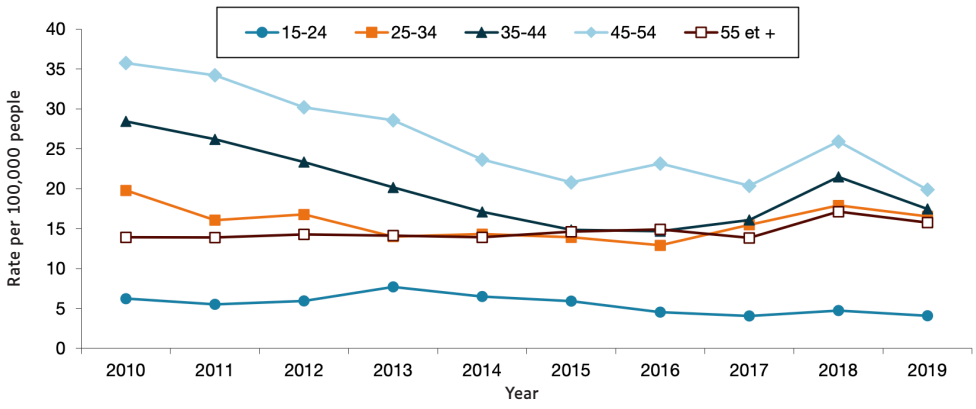


	< 1 an	1-9	10-14	15-19	20-24	25-29	30-34	35-39	40-44	45-49	50-54	55-64	65 et +
Men	2,3	0,2	0,4	0,0	9,6	18,5	25,9	21,4	17,7	21,5	32,7	32,3	12,2
Women	0,0	0,3	0,5	0,0	4,9	8,5	11,8	15,1	14,0	10,9	12,1	11,8	8,5

Notes: rate per 100,000 people.
Data taken from the *Fichier des maladies à déclaration obligatoire* (MADO)

Blouin (2021)

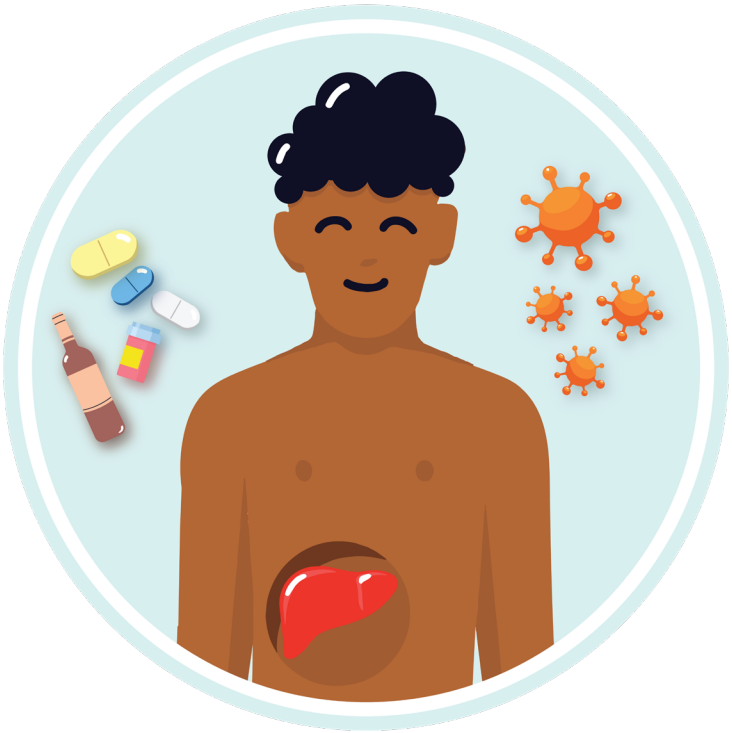
Incidence rates of reported hepatitis C cases, by age group, sexes combined, in Quebec from 2010 to 2019



Notes: rate per 100,000 people.
Includes all cases of hepatitis C (acute or recent and unspecified)
Data taken from the *Fichier des maladies à déclaration obligatoire* (MADO)

Blouin (2021)

What is hepatitis?



The term "hepatitis" means an inflammation of the liver.
This inflammation may have viral (caused by a virus) or non-viral origins.

Non-viral Hepatitis

Non-viral hepatitis is the often acute inflammation of the liver. It may be caused by exposure to medications, drugs, toxic substances or by an autoimmune disease.

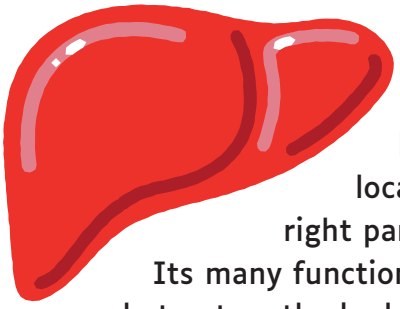
Other causes are possible, such as contaminated food or water, certain mushrooms and chemical products including metals, solvents or pesticides. Non-viral hepatitis may lead to hepatic insufficiency.[7]

Viral Hepatitis

Viral hepatitis is an inflammation of the liver caused by a virus. There are five viruses known to cause hepatitis, each identified by a letter: A, B, C, D and E. They have been named in the order of their discovery. It is important to note that other viruses, such as herpes, can also cause hepatitis. The hepatitis viruses differ in their mode of transmission, their risk of becoming chronic, and the drugs used to prevent or treat them.

Viral hepatitis can be acute or chronic.

The liver



The liver is a vital organ. It weighs about 1.4 kilograms and is located in the upper right part of the abdomen. Its many functions include filtering what enters the body, removing toxins and storing nutrients. The liver is connected to the gallbladder, which breaks down fats, and works with the spleen to clean the bloodstream.The liver is active 24 hours a day and performs more than 500 vital functions in the body, such as:

- Cleaning blood: the liver metabolizes alcohol and other drugs and chemical products, neutralising and destroying toxic substances;
- Regulating the body's energy intake: the liver produces, stores and provides rapid energy (glucose) and produces, stores and distributes fats;
- Creating proteins essential for transporting substances in the bloodstream, for blood coagulation and for infection resistance;
- Regulating hormones, including sexual hormones and thyroid hormones, cortisone and other adrenal hormones;
- Regulating cholesterol: the liver produces and excretes cholesterol and also converts cholesterol into other substances essential to the body;
- Regulating vitamins and essential minerals, including iron and copper.
- Producing bile, which removes toxic substances from the body and aids digestion.[8]

The liver has the ability to regenerate itself. This is why the disease caused by hepatitis C progresses slowly.

History of the hepatitis C virus

In the 1970s, cases of hepatitis associated with blood transfusions began to be reported. The majority of these infections became chronic, although they were not caused by the hepatitis A (HAV) or hepatitis B (HBV) viruses or any other source. This phenomenon was called hepatitis non-A, non-B (HNANB); it would be years before hepatitis C (HCV) was identified.

In 1989, Drs. Houghton, Choo, Weiner, Kuo, Overby and Granby discovered HCV. Following this discovery, a test was developed to detect HCV antibodies. The blood test helped to prevent iatrogenic transmission. Later, polymerase chain reaction (PCR) testing technology made it possible to identify the RNA of the virus in its early stages (during the first acute phase of hepatitis C).Strains of HCV are classified into six genotypes and numerous subtypes. In Canada, genotype 1a is the most common.

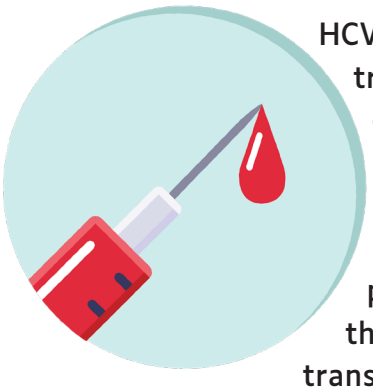
In 2020, the Nobel prize in Physiology or Medicine was awarded to biochemist Michael Houghton and virologists Harvey J. Alter and Charles M. Rice for their discovery of the hepatitis C virus and other associated work.[9]

Transmission modes

The **hepatitis C virus is most commonly transmitted through blood**. In some cases, the virus can be transmitted vertically or sexually.

HCV can survive in the open air for more than six weeks. To ensure that the HCV virus is completely eradicated, only autoclave sterilisation or ionising radiation machines are reliable.

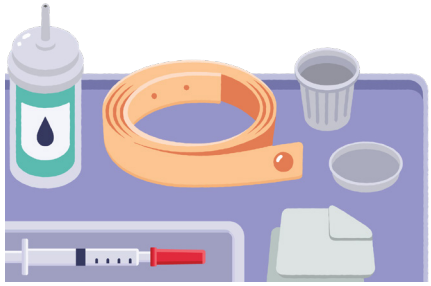
Transmission by blood



HCV is mainly transmitted through contact with blood. Transmission requires a point of exit from a person living with the virus, a mode of transmission and a point of entry to an uninfected person.

The main risk of transmission in Canada today is related to the sharing of injecting drug materials.

Sharing materials used for inhaling drugs (straws, pipes, etc.) is also a mode of transmission due to microdroplets of blood that may be present. Inhaling drugs erodes the mucous membrane (mucosa). Smoking crack, for example, dries out the mucosa and makes it susceptible to tearing.



Health care practices (medical, dental, surgical) that use non-sterile materials and/or unscreened tissues and blood transfusions are another mode of transmission of hepatitis C. In many countries, HCV was spread through large-scale health campaigns before there was widespread knowledge of the virus. In Egypt, for example, 15% of the population had HCV antibodies in 2008. The causes of this epidemic have been linked to campaigns to treat parasitic bilharzia (schistosomiasis) between 1950 and 1980. The use of reusable needles and other inadequately sterilized materials led to significant transmission of HCV[10]. Since 1992, the use of blood products, tissues and other medical materials in Canada has been highly controlled and safe.

Sharing personal hygiene items such as nail clippers, toothbrushes, or razors can also be a mode of transmission for HCV.

Certain practices involving piercing or skin cutting - such as tattooing, acupuncture, wet cupping therapy, or BDSM - also pose a risk of transmission if not performed with sterile, single-use equipment.

Sexual transmission

Sexual transmission of HCV is rare, and even rarer in the context of heterosexual sex. According to a 2013 study, transmission occurs at a rate of only 0.07% of serodiscordant monogamous heterosexual couples per year. This is considered a negligible risk.[11]

Nevertheless, it is important to note that gay and bisexual men who have sex with other men (GBMSM) face an increased risk of HCV transmission. Seropositive GBMSM who consume drugs (often by injection) in a sexual context are the most at risk of contracting HCV.[12]

Lastly, an increasing number of sexually transmitted HCV outbreaks has been reported recently--some of which are associated with drug use--which particularly impacts those living with HIV. According to a study, the prevalence of HCV is slightly higher among GBMSM who are HIV-negative (1.58%) and much higher among HIV-positive GBMSM without a history of drug use via injection (7%)[13]. This data is in comparison to the general population. A 2017 study estimates that, in wealthier countries, the incidence rate of HCV among HIV-positive GBMSM Is 19 times higher than those who are HIV-negative.[14]

The arrival of the HIV prevention drug PrEP (2012 in the United States) led to a change in practices during sex, notably a decrease in serosorting and condom use.[15] New cases of HCV have been declared among HIV-negative GBMSM who use PrEP.[16] Recent studies suggest that with increased PrEP usage, the risk of HCV transmission is also increasing.[17] Nonetheless, it is important to underline that such studies include GBMSM who self-identified as drug users and also that people who use PrEP are more likely to get tested for HCV.[18]

There are sexual practices that pose a higher risk to HCV exposure in the GBMSM community. The same is true for drug use within a sexual context.[19] These risk can include:

- The presence of another STBBI;
- Anal sex without a condom;
- Anal penetration with a fist (fisting) without protective gloves;
- Sharing sex toys;
- Multiple sexual partners;
- Group sex;
- Anal cleaning or douching;
- Practices involving skin cutting or piercing (e.g.: BDSM);
- Drug use prior to or during sex (Party'n Play or Chemsex).[20]

Oral sex is considered to pose a very low risk for transmission of HCV. There are no known cases of HCV transmission through oral sex, but the risk theoretically exists.[21]

Vertical transmission

A large scale meta-analysis reported the risk of vertical transmission of HCV to be at 5.8%. Data suggests both intra uterine and perinatal transmission.[22] For pregnant people with HIV/HCV coinfection, the risk of vertical transmission is much greater. Some stakes estimate it being from 10% to 30%[23·24·25·26]

Others modes of transmission

Unlike HBV, there is no documented transmission of HCV through household contact..[27]

The risk of percutaneous HCV transmission in a professional context is estimated at 0.5%.

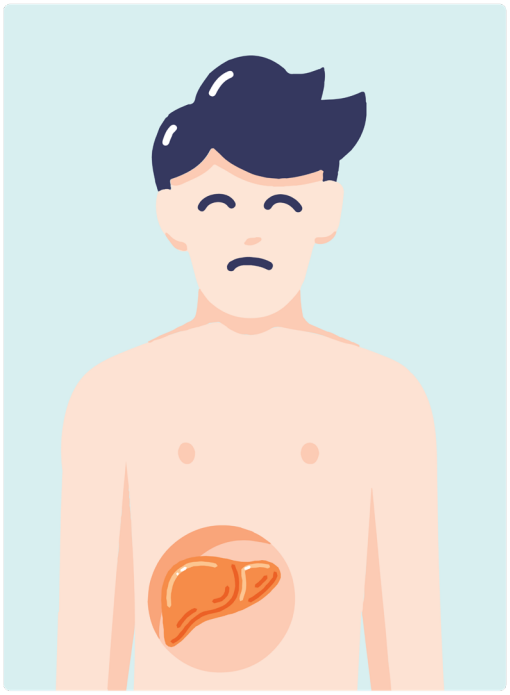
Acute or chronic

Hepatitis C is an inflammation caused by the hepatitis C virus (HCV) that attacks liver cells called hepatocytes. It is generally asymptomatic and can be acute or chronic, depending on the duration of the infection.

The acute phase of the infection manifests itself within six months of contracting the virus. In 15-40% of cases, the body eliminates the virus on its own within the first six months after primo infection (initial infection). This phenomenon is known as spontaneous HCV clearance. People who have had acute hepatitis retain anti-HCV antibodies for life, even though they are non-viremic. HCV RNA is undetectable, so there is no risk of viral transmission.

Hepatitis C is chronic when the virus stays in the body for more than six months after the initial infection; 60-85% of cases are chronic. Chronic hepatitis C is usually asymptomatic for many years (10, 20 and even 30 years).

Manifestations / Symptoms



Acute HCV infection may manifest as a viral syndrome (barely visible) or, more rarely, as jaundice, which in most cases goes unnoticed. Note that the presence of jaundice is associated with a higher probability of spontaneous HCV clearance (50%).

Chronic hepatitis is asymptomatic in most cases. The main manifestation is fatigue, but in rare cases other extrahepatic manifestations may be observed:

- Rhumatological: arthralgia, arthritis, myalgia;
- Renal: chronic renal insufficiency, glomerular involvement;
- Endocrine: insulin-resistance, type 2 diabetes;
- Cardiovascular: increased cardiovascular mortality, increased cerebral and cardiovascular events;
- Oncological: hepatocarcinoma, intrahepatic cholangiocarcinoma;
- Dermatological: purpura rash, Raynaud's disease, cutaneous vasculitis, pruritus.[28]

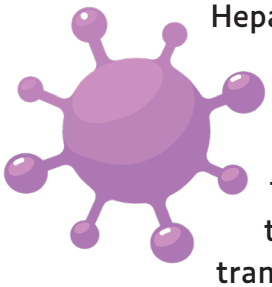
At advanced stages, there can be signs of decompensation associated with cirrhosis such as ascites, encephalopathy, jaundice or even gastrointestinal bleeding caused by ruptured esophageal varices.[29]

Hepatitis C is most often diagnosed by targeted screening based on risk factors or by chance discovery. Most hepatic diseases don't display major symptoms before the decompensated cirrhosis stage.

Other Viral Hepatitises

In addition to hepatitis C, there are four other viral hepatitises. They are identified by the letters A, B, D, and E. These viruses differ in their mode of transmission, risk of chronicity, and the medications used to treat them..

Hepatitis A



Hepatitis A virus (HAV) is transmitted by ingesting water or food contaminated with feces from a person who has the virus. It can also be transmitted through oro-anal sexual practices. Simply put, hepatitis A is fecal-oral transmission. Symptoms can be benign or severe, and the severity increases with the age of the person.

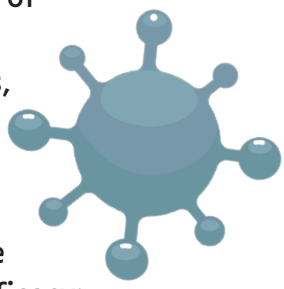
Symptoms include fever, fatigue, loss of appetite, diarrhea, nausea, abdominal pain, dark-colored urine, and jaundice. The illness usually lasts one to two weeks, but in some cases it can last several months.

There is an effective vaccine (two doses), and the disease also confers lifelong immunity after infection. There is no specific treatment for hepatitis A. Only supportive care is given.[30]

In Quebec, fewer than 50 cases of hepatitis A have been reported each year since 2011.

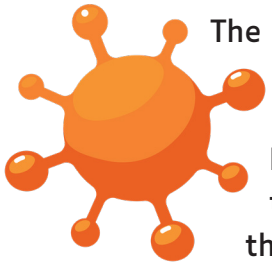
Hepatitis B

The hepatitis B virus (HBV) is transmitted primarily through the blood, sperm, or vaginal secretions of an infected person, even if the carrier is asymptomatic. Transmission can occur through unprotected sex, percutaneous contact with contaminated blood (sharing syringes, needles, or razors), contact between a mucous membrane and blood, contact with sperm or vaginal secretions, or even during pregnancy through vertical transmission.



Hepatitis B may be acute or chronic. It becomes chronic in 95% of carriers who are children versus only 5% of adults, which is why it's important to vaccinate newborns. There is currently a vaccine (three doses) with 98-100% efficacy; the disease also confers immunity after infection. There is no curative treatment for HBV, only supportive care to reduce the discomfort of those affected.[31]

Hepatitis D



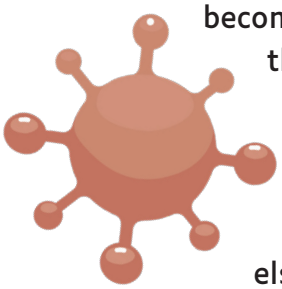
The hepatitis D virus (HDV) only affects people who already carry the hepatitis B virus. The modes of transmission are similar to those of hepatitis B (blood, percutaneous and, more rarely, vertical).

HBV/HDV is the most severe form of chronic viral hepatitis. HDV superinfection accelerates the development of cirrhosis by about 10 years compared to hepatitis B alone. Patients with cirrhosis caused by HBV are at high risk of developing hepatocellular carcinoma. Hepatitis D can be prevented by the hepatitis B vaccine..[32]

Hepatitis E

Hepatitis E (HEV) is transmitted by fecal-oral contact, usually through contaminated water. It can also be transmitted from animals by eating undercooked meat (especially liver and especially pork) or raw shellfish, mollusks, and fish from contaminated water.

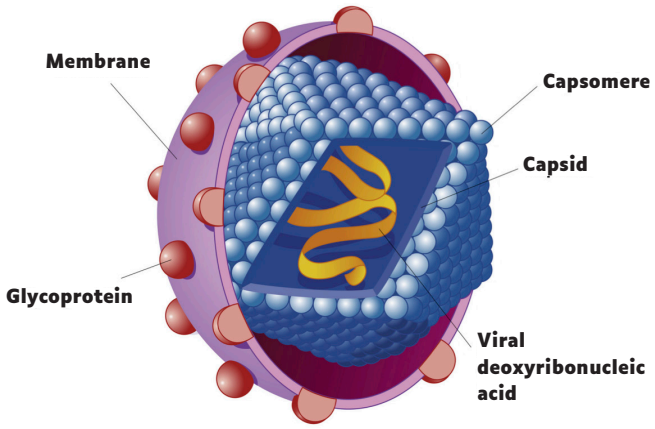
In most cases, the infection clears up in two to six weeks. In rare cases, HEV can lead to fulminant hepatitis (acute liver failure), which can be fatal. Pregnant women with hepatitis E, especially during the second or third trimester, have an increased risk of liver failure, fetal loss, and death. Up to 20-25% of pregnant women can die if they become infected with hepatitis E in the third trimester.



An effective HEV vaccine has been developed and licensed in China, but it is not yet available elsewhere..[33]

Structure and function

The hepatitis C virus genome consists of positive-polarity, single-stranded RNA contained in a capsid, which is surrounded by a lipid envelope.



The Hepatitis C virus[35]

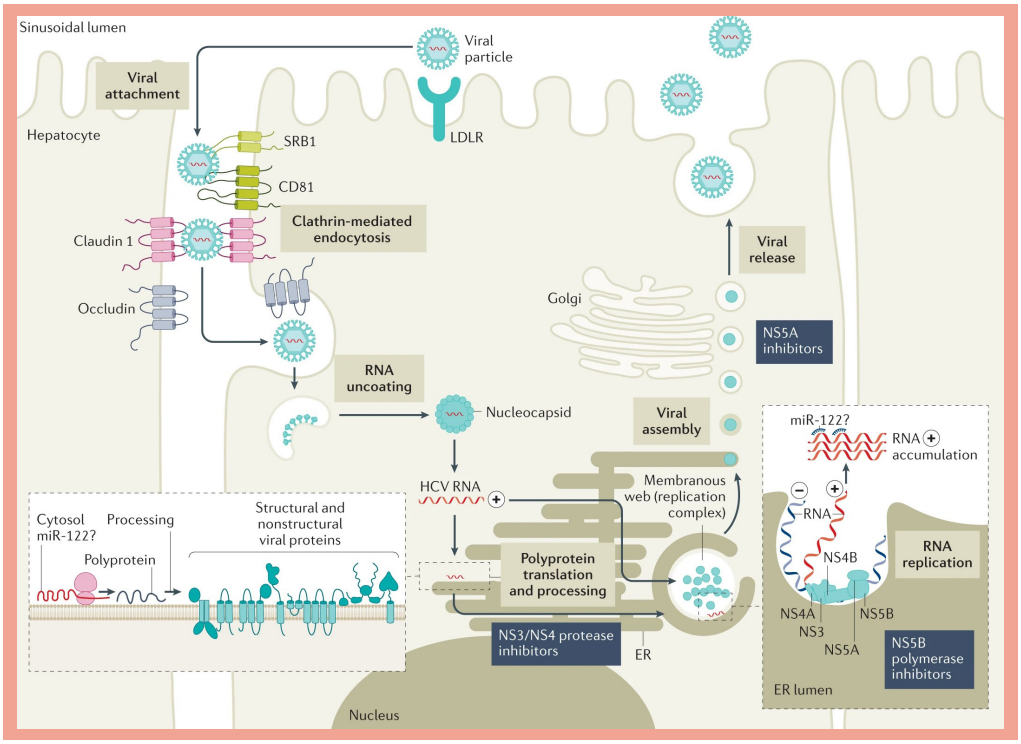
The viral particle attaches to receptors on the hepatocyte (liver cell) via glycoproteins in its envelope. The virus enters the hepatocyte via endocytosis (fusion of the viral envelope with the cell membrane).

This is followed by decapsidation, which releases viral RNA into the cell cytoplasm. In the endoplasmic reticulum, the released RNA is transformed into polyprotein by mechanisms within the hepatocyte (ribosomes and cellular proteins). Next, the virus replication complex takes form and the viral particles are assembled before the release of extracellular vesicles.[34]

Among others, the proteins involved in this process include:

- NS3/4 are involved in the formation of the replication complex;
- NS5B is involved in replication;
- NS5A is involved in the encapsidation of the viral genome.

These proteins are important because, as described below, they are the targets for antiviral treatment.



Life cycle of HCV[36]

Consequences of the virus

Fibrosis

After exposure to HCV, liver inflammation leads to fibrosis in 60-85% of people who develop chronic hepatitis. This is an accumulation of scar tissue in the extracellular matrix that replaces damaged liver cells.[37]

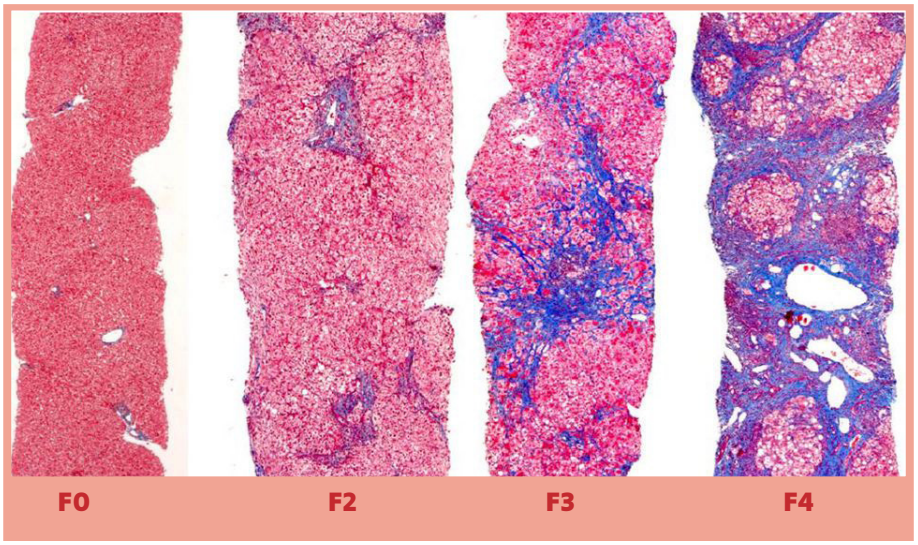
Depending on the extent of damage to the liver, fibrosis may be more or less extensive. There are five stages of fibrosis:

- F0 = healthy liver
- F1 = minor fibrosis, some deposition of scar tissue can be observed in portal areas
- F2 = moderate fibrosis, some septa (bands of scar tissue bridge together)
- F3 = severe fibrosis, portal-to-portal septa
- F4 = cirrhosis, septa form nodules that surround hepatocytes (regeneration nodules)

Fibrosis varies from one person to another, and certain factors can accelerate its development:

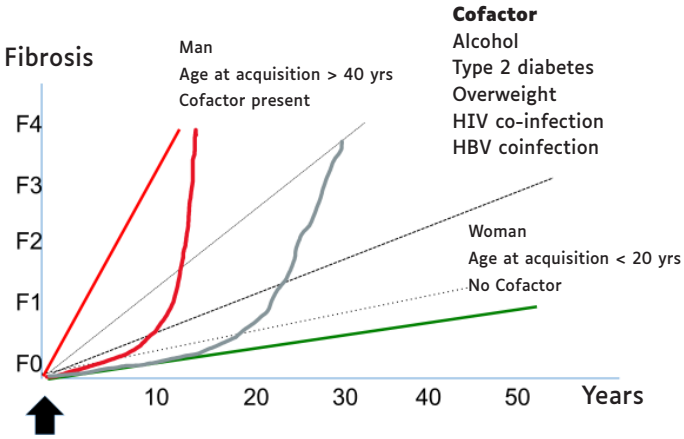
- Sex (M more than F)
- Contracting HCV at 40 years or older
- Cofactors such as excessive alcohol consumption, type 2 diabetes, excessive weight or obesity, and coinfection with HIV or HBV (which explains how people can develop cirrhosis within 10 years while others remain without fibrosis or at a minimum of F0-F1 for their whole lifetime.
- Age (the progression of fibrosis is not linear but rather accelerates with aging).

Views of different stages of fibrosis
Photos Z. Goodman[38]



Fibrosis (continued)

Variable progression of liver fibrosis



(Wartelle-Bladou, **2017**)[39]

Hepatic fibrosis may regress if the HCV is eradicated and no associated cofactors are present. This changes the prognosis.

Cirrhosis

Cirrhosis is characterised by the presence of regenerative nodules (scar tissue surrounding masses of regenerating liver cells). At this stage, damaged cells restrict liver function.

It is estimated that 20% of people living with hepatitis C will develop cirrhosis over a 20-year period. The main complications of cirrhosis are liver failure, portal hypertension and liver cancer.

Initially, cirrhosis is compensated (asymptomatic). It will evolve at a rate of 5% to 7% per year and patients will eventually develop complications.

A cirrhosis is decompensated when complications related to portal hypertension or liver failure develop (at a rate of 4% to 5% per year).

These complications include jaundice, ascites, encephalopathy or gastrointestinal bleeding caused by ruptured esophageal varices. This stage drastically reduces median survival from a prognosis of 12 years in the compensated stage to only 2 years in the decompensated stage.[40]

The Child-Pugh-Turcotte score is used for calculating the prognosis of a cirrhosis:

- A : survival for 1 year at 100%
- B : survival for 1 year at 80%
- C : survival for 1 year at 45%

The Model for End-Stage Liver Disease (MELD) score is also used to predict survival up to three months:

- MELD = 40: 71.3% probability of mortality within three months
- MELD = 30-39: 52.6%
- MELD = 20-29: 19.6%
- MELD = 10-19: 6.0%
- MELD = 9 or less: 1.9%

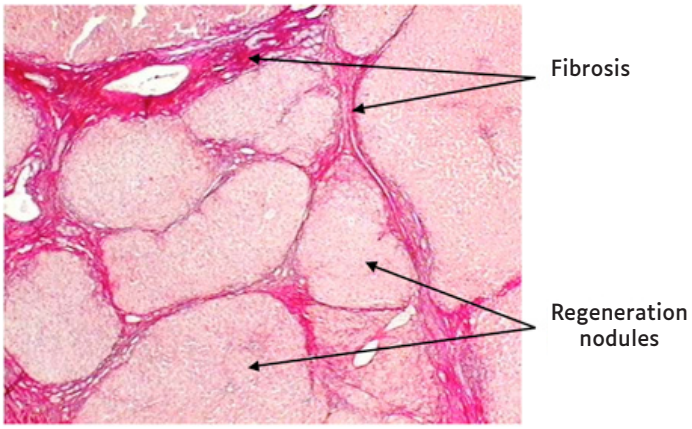


Photo of liver tissue fragment at fibrosis stage F4

In cases of liver failure or decompensated cirrhosis, a person may need a liver transplant.

Following alcohol-related liver disease and Metabolic dysfunction-associated steatohepatitis (MASH, previously called NASH), hepatitis C is the main cause of cirrhosis, liver transplantation and liver cancer in Canada. HCV is responsible for 7% of deaths of people affected by cirrhosis.[41] Sustained virologic response (SVR) treatment for hepatitis C can reduce the accumulation of fibrosis in the liver, possibly reverse cirrhosis (from decompensated to compensated) and prevent liver cancer.

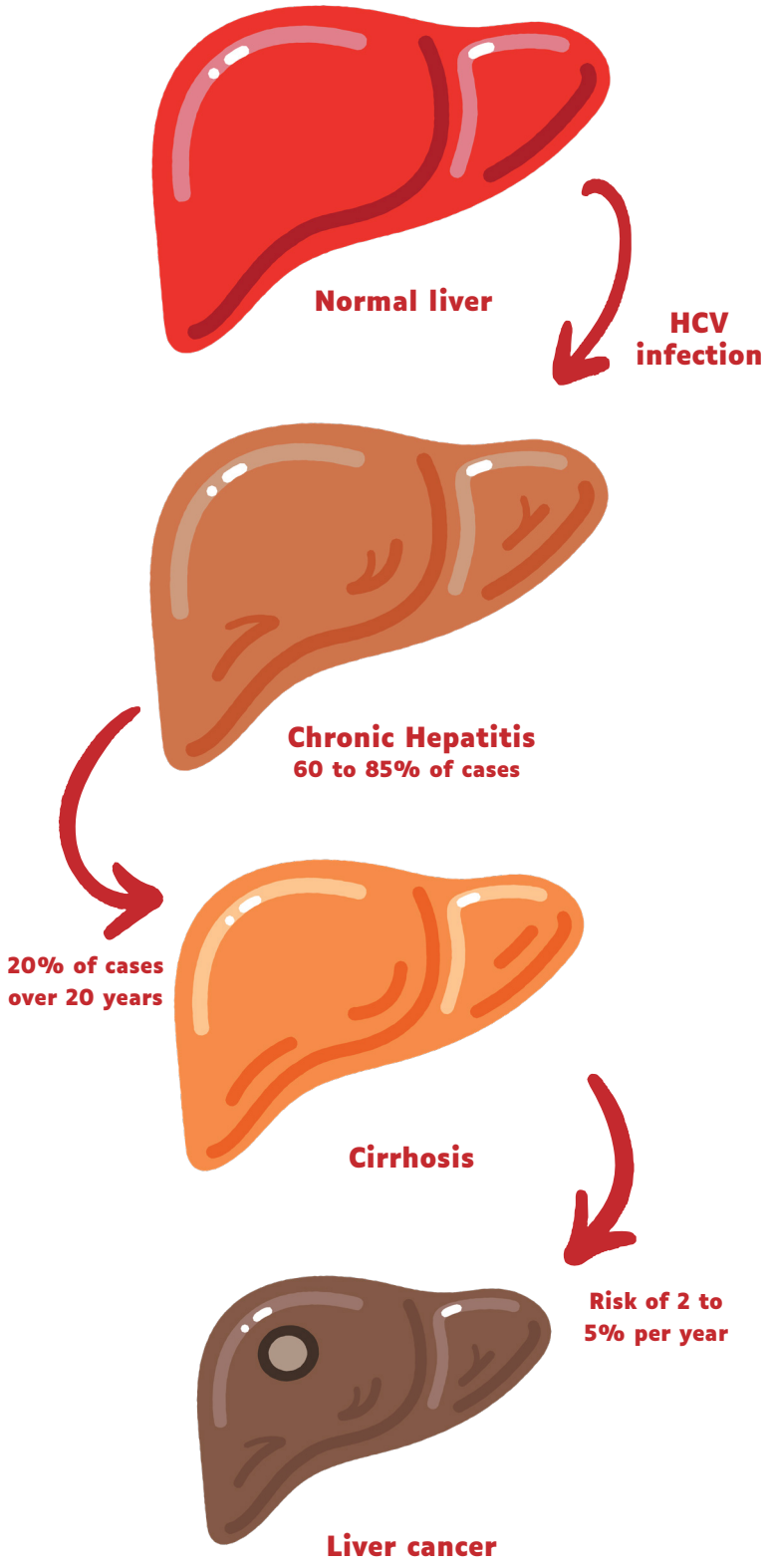
Hepatocellular carcinoma (HCC)

Hepatocellular carcinoma (HCC) is the most common form of liver cancer. People with cirrhosis have a 2% to 5% risk of developing HCC each year. It is important to note that people with stage F3 fibrosis are also more likely to develop HCC.

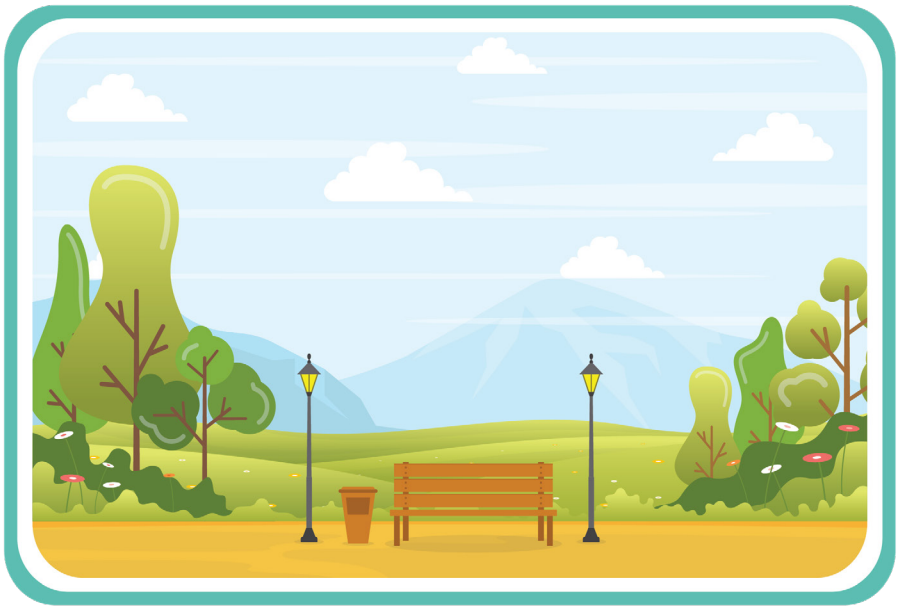
It is recommended to screen people at stage F3 (Fibroscan® score greater than 10 kPa) every six months.

HCC contributes to a general decrease in life expectancy, with a mortality rate between 2-6% per year. For 2022, Canada estimated 3500 new diagnoses of HCC and 1650 associated deaths.[42]

Evolution of the HCV effects



Key populations



Certain communities are at greater risk of exposure to hepatitis C. This is due to practices within these communities, but also to socioeconomic factors, discrimination, stigma and barriers to services (particularly prevention and healthcare).

A study in British Columbia found that new HCV infections are particularly prevalent among people co-infected with HIV and HBV, in socioeconomically marginalised communities, and among people living with mental health and addiction problems.[43]

People who use drugs

PWUD (people who use drugs, both injecting and non-injecting) have the highest prevalence of HCV. Globally, 39.2% of people who have used drugs this year are living with HCV and 8.5% of all people with HCV are people who inject drugs (PWID).[44]

In Canada, PWID account for 80% of people living with HCV. The prevalence rate of HCV among PWID is 70% and 82.4% among PWID living with HIV.

According to simulations, 70-80% of new HCV infections occur among PWID.[45]

Indigenous peoples (First Nations, Inuit et Métis)

Despite data limitations, available data suggest that the prevalence of HCV among indigenous people is five times higher than the rest of the Canadian population.[46]

This overrepresentation is due to multiple factors, including racism, colonialism, intergenerational trauma and systemic abuse, which increase the risk of exposure to HCV for indigenous people. This problem is compounded by other issues of governance and access to health care and harm reduction services.

Gay and bisexual men who have sex with men (GBMSM)

Gay and bisexual men who have sex with men (GBMSM) are an emerging priority because HCV, which is generally not transmitted through sexual contact, is becoming more prevalent in this population. It is estimated that 5% of GBMSM are or have been infected with HCV.

The probable risk factors for transmission are sexual contact and drug use, especially in the context of chemsex.

Since 2000, an increase in the rate of HCV among GBMSM living with HIV has been observed, probably largely due to exposure to infected blood during sexual relations.[47]

It should also be noted that new cases are occurring among GBMSM taking PrEP. The emergence of HIV-prevention strategies such as **PrEP** and **Undetectable = Untransmittable [u=u]** as well as a lack of knowledge and understanding about HCV may contribute to this increase among GBMSM.[48]

GBMSM, particularly those living with HIV, are increasingly experiencing reinfection with HCV after being rid of the virus.[49,50]

People who are/were incarcerated

Incarcerated people are 40 times more at risk of exposure to HCV than the general Canadian population. More than 50% of the Canadian prison population have previously used drugs. Further, more than 75% of PWID in Canada have had previous experiences of incarceration, which puts this population at the highest prevalence for HCV of all detained people.

The lack of access to safe materials for tattooing, piercing or drug injection forces many people to reuse non-sterile material.

Continuing anti-HCV care after liberation from prison is a major problem faced by correctional systems worldwide.[51] In Quebec, for example, incarcerated people lose their drug insurance coverage at the start of their sentence, which can be a major barrier to treatment after incarceration.

Immigrants and newcomers from countries where HCV is endemic

Immigrants and newcomers from countries where HCV is endemic account for about 35% of the total number of cases of current or past hepatitis C infection in Canada.

In countries where HCV is endemic, it is primarily transmitted through unsafe medical or dental practices (transfusions or reuse of non-sterile instruments). HCV screening is not part of the health checkup requirements for Immigration Canada. It is recommended depending on the country of origin, but there is currently no information on the practical application of this recommendation.

Although voluntary screening after arrival in Canada is one of the national recommendations, access to health care services for immigrants and newcomers can be very complicated. Racism, stigmatization, and language or cultural barriers can be major obstacles to accessing to healthcare, and even more so for people whose immigration status is precarious.

A study that examined data from 1990 to 2018 indicates that for immigrants in Quebec, the median time to receive a diagnosis of hepatitis C was 7.1 years after arrival, 12.4 years for a diagnosis of decompensated cirrhosis, and 14.8 years for a diagnosis of hepatocellular carcinoma. After arrival in Canada, the median life expectancy of immigrants who die from a liver-related disease is 17.8 years.[52]

People born between 1945 and 1975

The highest prevalence of HCV affects the cohort of people born between 1945 and 1975. They account for 66-75% of the total number of people living with HCV in Canada. These people living with HCV are five times more likely to develop complications (cirrhosis, cancer, premature death) than the general Canadian population. Many people born between 1945 and 1975 have not been tested for HCV.

98% of liver transplants are performed in people 40 years and older. Most cases of HCV among people in this cohort are associated with medical/hospital procedures prior to 1992 or with past drug use, including injection drug use..[53]

Screening and diagnosis

Screening recommendations

U.S. recommendations

In the United States, HCV screening recommendations were based on risk factors until 2012. Beginning in 2012, a recommendation was implemented that all patients born between 1945 and 1975 should be screened once in their lifetime, regardless of risk factors.

In 2020, the Center for Disease Control (CDC) updated its HCV screening recommendations to include all individuals at least once in their lifetime and all pregnant women once per pregnancy.[54] These decisions followed recent U.S. data including an increase in the number of new hepatitis C cases, particularly among young people.

Canadian recommendations

In Canada, the recommendations of the Canadian Task Force on Preventive Health Care[55] are based solely on risk factors. They don't include screening for people born between 1945 and 1975 contrary to demands from the Canadian Association for the Study of the Liver (CASL)[56] and the Canadian Network on Hepatitis C (CanHepC).[57]

In 2021, British Columbia issued provincial recommendations to test everyone born between 1945 and 1975 once in their lifetime.

Quebec recommendations

In Quebec, hepatitis C screening is only recommended for people with risk factors for HCV:

- Having consumed drugs by injection, even if only once;
- Originating from a country or region where HCV is endemic (Pakistan, Egypt, Syria, Romania, Taiwan, Eastern Europe, Central Asia, Central sub Saharan Africa). Note that HCV screening is not required by Immigration Canada;
- Being a GBMSM living with HIV or who plans on going on PrEP;
- Being a person living with HIV and having contracted lymphogranuloma venereum (LGV) or having possibly contracted the hepatitis B virus through contact with blood;
- Having been exposed to blood or other potentially infected biological fluids (tattooing or piercing in non-sterile environments, or by exposure within a work context or a non-professional context);*
- Having undergone a procedure (surgical or otherwise) with potentially contaminated material or instruments in a region of the world where the HCV prevalence is high (> 2 %);
- Having received a transfusion of blood

or blood products, or a transplant of cell or organ tissue (in Canada, prior to April 1992);
- Being a pregnant person who is associated with HCV risk factors prior to or during the pregnancy;
- Having had experience of incarceration;
- Receiving services in a center for drug addiction;
- Undergoing hemodialysis;
- Infants and children born to a parent who is a carrier of HCV* (RNA or HCV positive).

*Only concerning pregnant people.

In addition to this list, government recommendations add the following clinical conditions:

- Presenting an unexplained increase of the aspartate aminotransferase (AST) or alanine transaminase (ALT) enzymes or both transaminases;
- Having a hepatic disease that may be detected by clinical, biological and/or radiological indicators;
- Presenting extra-hepatic manifestation (EHM) resembling HCV.[58]

In theory, all people who request screening, even in the absence of risk factors, should have access to it, but the application of this recommendation is uneven. We also know that reporting risk factors is suboptimal because there are numerous barriers to revealing them, most notably discrimination and the stigma associated with such risk factors.

The practice of screening pregnant people is not yet recommended in Quebec, though we are currently awaiting the next set of recommendations from the Society of Obstetricians and Gynaecologists of Canada (SOGC). For the time being, the practice is becoming more and more common.

HCV screening

Quebec guide for STBBI screening

Screening for chronic hepatitis C is most often done with a blood test and is completed in two steps:

- First, a screening is done for HCV antibodies in order to determine if a person has been exposed to HCV;
- Next, an RNA HCV test is conducted in order to determine whether the person is a carrier of an active (or viremic) hepatitis C virus.

Following exposure to HCV, a person develops antibodies within six to eight weeks. The window period for HCV screening is 12 weeks. It is important to note that this period may be prolonged in cases of HIV-HBV coinfection.

HCV antibodies are present in all people exposed to the virus, but unlike HBV antibodies, they don't protect against subsequent infection.

A person with no history of anti-HCV serology will be prescribed an HCV antibody test. This test is always done first because it costs much less than the RNA test ($9 versus $60).

- If the test is negative, the screening is complete and the person has not been exposed to HCV.
- If the antibody test is positive, the person has been exposed to HCV. The next step is to determine whether the person is one of the 15-40% of people who will spontaneously clear HCV or is a carrier of the virus.

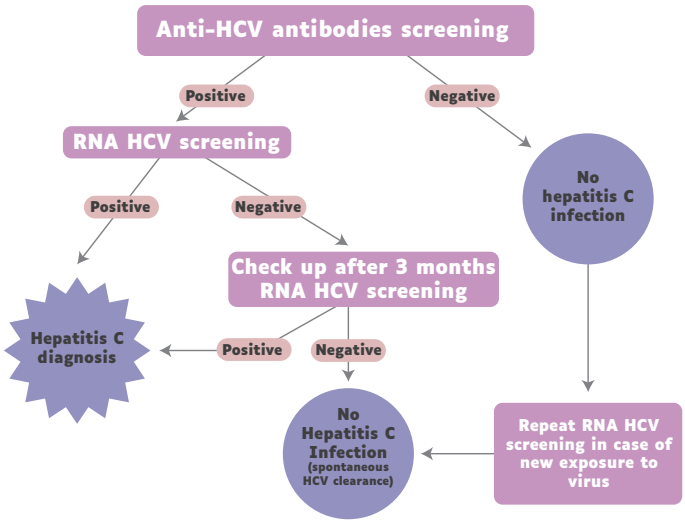
After a positive HCV antibody test, one must undergo an HCV RNA test, which provides an indication of their viral load (the measure of virus per mL of blood). This test indicates both the qualitative RNA and the quantitative viral load. HCV RNA is present in the body after exposure to the virus.

- If the test is positive, the person is viremic and a carrier of chronic hepatitis C.
- If the test is negative, this indicates that the person has undergone spontaneous HCV clearance. However, a three-month observation period is recommended for confirmation of results.

If the person has already received a positive HCV antibody test (for example, for someone whose hepatitis C infection has been treated and cured), it is recommended to proceed directly to HCV RNA testing.

If exposure to HCV is confirmed (for example, after using a syringe shared with someone who is HCV-positive), HCV RNA testing is possible after four weeks.

Hepatitis C is a nationally notifiable disease (NND), which means that the treating physician must notify local public health authorities of each new case.[59]



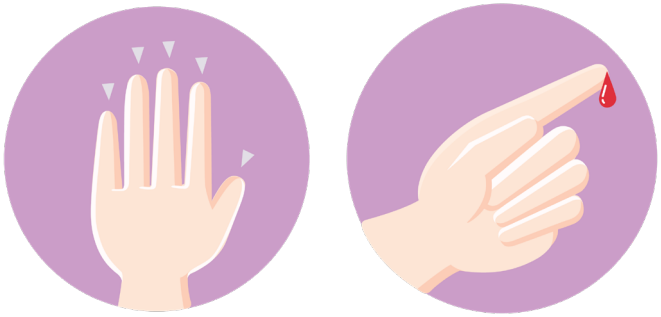
Genotyping prior to treatment is no longer necessary with pangenotypic treatments. It is possible, however, that health care professionals may request genotyping (even if only to delay initiation of treatment) for individuals at higher risk of contracting HCV in order to differentiate treatment failure from future reinfection.

Current methods and technology

HCV screening is frequently conducted via blood test. Other methods and technologies do, however, exist.

Rapid tests

Rapid tests speed up the antibody screening process using a simple capillary puncture or saliva sample. Depending on the test, results can be available in one minute (INSTI® HCV Test) or up to 20-40 minutes (OraQuick® HCV Rapid Antibody Test). Currently, only OraQuick® is approved in Canada and is performed by capillary puncture only. The test has a sensitivity of 95.9% and a specificity of 99%.[60].



Capillary puncture

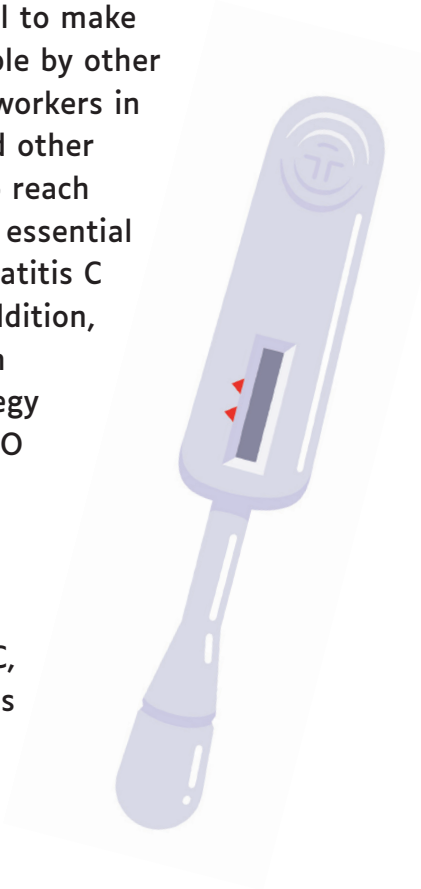
According to a recent study, the waiting time for results can be reduced to as little as five minutes without compromising the quality of identifying viremic patients..[61]

These rapid tests are mainly used in outreach efforts for point-of-care testing: in community organisations, pharmacies, street-based sites, etc. They facilitate access without the need for a blood test, reduce waiting times and allow screening to be carried out in a familiar, non-medical environment.

However, these tests do not provide a diagnosis of hepatitis C. If a rapid test is positive, the person will be referred to the appropriate services for an HCV RNA test.

In Quebec, according to the Act respecting health and social services, screening is a medical act that can only be performed by doctors, nurses and midwives. In other countries, such as the United Kingdom, Australia or France, these rapid tests can be carried out by community workers or trained peers.

In the context of the current nursing shortage and difficulties in access to screening (exacerbated by the COVID-19 pandemic), it would be highly beneficial to make this medical act practicable by other professions. Community workers in the fight against HIV and other STBBIs are well placed to reach key communities and are essential partners in achieving hepatitis C elimination targets. In addition, decentralisation of health care is an essential strategy recommended by the WHO in the fight against viral hepatitis.[62]



This is why the Provincial Committee on Hepatitis C, coordinated by CAPAHC, is committed to advocating for government approval of rapid tests.

Although rapid HIV tests will be available in Canada in November 2020, this is not yet the case for HCV. To move forward, manufacturers would need to apply to Health Canada to license their rapid testing technology.

REFLEX tests

The Reflex test procedure allows HCV RNA testing (following a positive antibody test) to be performed using a single vial of blood, which can be part of the same blood sample used for the antibody test. Reflex testing can also be done using dried blood (see below). This technology reduces the number of diagnostic steps by reducing the number of consultations and blood samples required. This method is already used in eight provinces, including Alberta, British Columbia and New Brunswick, but not in Quebec.[63]

Dried blood spot (DBS) test

The Dried Blood Spot (DBS) test uses a filter paper to collect drops of blood from a capillary puncture for later analysis. This allows screening to be carried out in areas where material is less available. Filter papers can also be sent by mail for testing in laboratories that can perform both HCV antibody and HCV RNA testing.

The HCV DBS antibody test has a sensitivity of 98% and a specificity of 99%.[64] The HCV DBS RNA test has a sensitivity of 98% and a specificity of 98%.[65]

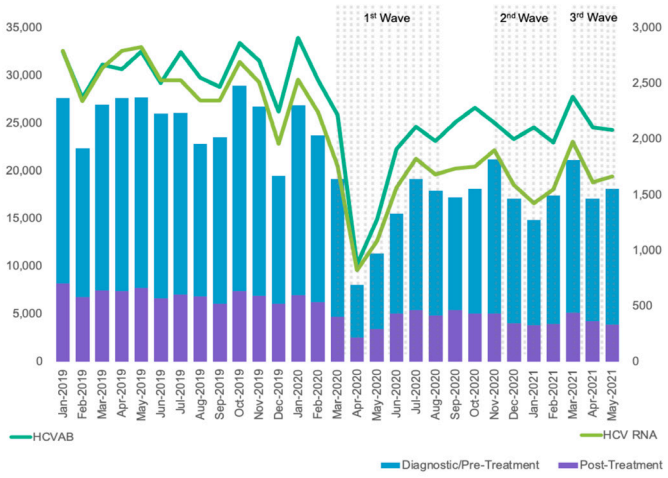
GeneXpert®

GeneXpert® can perform a PCR test in 60-100 minutes and screen for multiple viruses including SARS-CoV2, HPV, HIV and HCV. Currently, Health Canada has not licensed the device for HCV testing, but Action Hepatitis Canada has asked the manufacturer, CepHEID, to prioritise licensing its technology for HCV testing.[66]

Multiple options for HCV screening exist, and yet they remain unavailable in Quebec. It is clear that by increasing the number of options available, more people will be able to access screening.

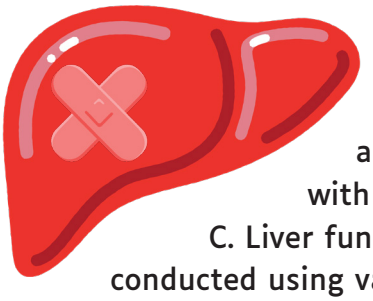
It is important to emphasise that the COVID-19 pandemic has had an impact on access to screening. A recent study in Ontario showed that HCV testing has still not returned to pre-pandemic levels.[67]

Impact of the COVID-19 pandemic on hepatitis C screening in Ontario, Canada



(Mandel, 2022)

Liver function tests



Determining the state of fibrosis in the liver is a major element in the prognosis of a person diagnosed with chronic hepatitis C. Liver function tests can be conducted using various methods--both invasive and non-invasive--and provide a clear evaluation of the degree to which the illness has progressed. It should be noted that an invasive test involves breaking the skin far more than a simple vein puncture. In fact, it typically involves an incision or even introducing a medical instrument inside the body in order to conduct a biopsy.

Non-invasive tests

APRI score and Fib-4

The APRI (AST-to-Platelet Ratio Index) score and the Fib-4 (Fibrosis-4) and first generation tests. They are calculated using simple mathematical formulas and indirect markers of fibrosis observed during a routine check-up. These tests and high availability online.

APRI

This score allows the exclusion of a cirrhosis diagnosis if it gives a result of 1 and a negative predictive value of 91%. An APRI score greater than 1, with a sensitivity of 76% and a specificity of 72%, may provide a diagnosis of cirrhosis. If the score is greater than 2 and aspartate aminotransferase (AST) levels are also greater than alanine transaminase (ALT) levels, there is a high probability of cirrhosis. The performance of this score is suboptimal for diagnosing moderate fibrosis (F2).[68]

Fib-4

With a high degree of certainty, this score can exclude the diagnosis of advanced fibrosis or cirrhosis if it is less than 1.45, with a negative predictive value of 94.7% for F3 or F4. If the Fib-4 score is higher than 3.25, it has a positive predictive value of 65% to 82% for F3 or F4.

However, caution is recommended as the score tends to give false positives in subjects aged 60 and over, and also tends to place around 30% of subjects in the 'grey area' between 1.45 and 3.25.

The combination of these two scores reduces the need for the use of Fibroscan for assessment of liver function:

- If APRI<1 and FIB-4<1,45, no Fibroscan is required
- If APRI>1 and/or FIB-4>1,45, Fibroscan is required for differentiating between a severe fibrosis and a cirrhosis.

According to the guide *"La prise en charge et le traitement des personnes vivant avec*

le virus de l'hépatite C," we can take either the Fib-4 or the APRI score into account in a treatment context.

Other biochemical scores - 2nd generation

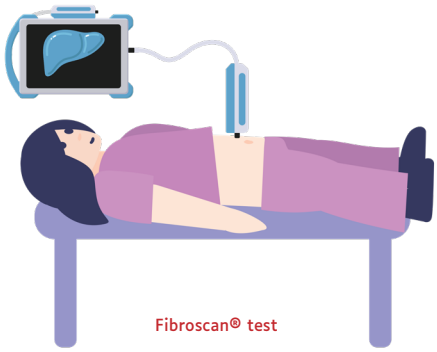
Second generation tests include Fibrotest®, FibroMètre®, ELF® and Hépascore®. They are based on direct fibrosis markers and are more effective (there is no 'grey area'). Unfortunately, however, most tests are patented by private companies and must be purchased. In Quebec, we can find Fibrotest® and Fibromètre® tests, but they are not very common.

Liver stiffness measurement

Measurement of liver stiffness, which directly correlates with the degree of fibrosis in the liver, is another non-invasive method of determining the stage of fibrosis.

Fibroscan®

The best known tool for measuring liver stiffness is Fibroscan®. It is painless, takes five minutes and must be done after at least two hours of fasting. However, it is not recommended for people who are pregnant.



Fibroscan® test

For hepatitis C, the diagnostic thresholds are:

- Significant fibrosis F2 median ≥ 7.1 kPa
- Severe fibrosis F3 median ≥ 10 kPa
- Cirrhosis F4 median ≥ 12.5 - 13 kPa

The Fibroscan® must be administered by a trained professional. Due to the high cost of the device, it is not widely available in Quebec.

It is important to note that after a sustained virological response (SVR), liver stiffness may decrease and even return to normal levels, but this does not mean that the cirrhosis has disappeared.

Following HCV treatment, the Fibroscan® does not provide further information on liver status and screening for hepatocarcinoma is recommended.[69]

Other technologies

Other technologies for measuring liver stiffness include point shear wave elastography (SWE) using acoustic radiation force impulse (ARFI) technology and also magnetic resonance elastography (MRE), which is currently in development.

Invasive tests

Liver biopsy

In certain cases, a liver biopsy may be recommended. This invasive test is done in cases of unexplained inconsistencies between the APRI, Fib-4 and Fibroscan® scores, especially if a result could lead to a change in treatment.

Treatment

Hepatitis C is the first chronic viral illness that can be cured in humans.

History of treatments

Interferon (IFNα) therapy

Interferons are an antiviral therapy and were the first molecule used to treat hepatitis non-A non-B, the original name given to hepatitis C before its discovery. In a primary study, patients were treated with interferon for 12 months and researchers observed a significant reduction in serum transaminases. This began an era of interferon therapy as primary treatment, despite an efficacy rate of only 40%. A patient with a sustained virological response (SVR) 24 weeks after the end of treatment was considered cured.

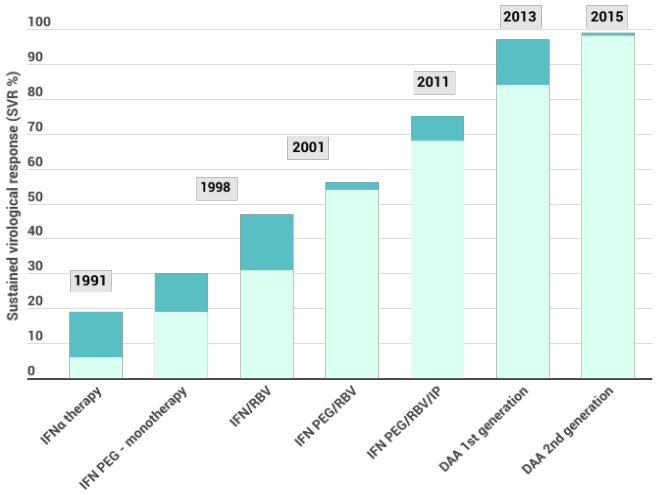
Introduction of ribavirin

In 1998, a second antiviral, ribavirin, was combined with interferons in HCV treatment, which increased its efficacy and resulted in an increased SVR.

Pegylated interferons (2001-2011)

The next advance in HCV treatment was the use of pegylated (longer-lasting) interferons in 2001. More effective and easier to administer (only one dose per week), pegylated interferon therapy allowed better monitoring of patients. This new combination led to SVR in 55% of cases, but the duration of these treatments was long with limited efficacy. They also caused many troublesome side effects. Depending on the genotype, treatment could last from 24 to 48 weeks and SVR could vary from 30 to 55%. Most people who underwent this therapy had to stop working because

Sustained virological response rate according to treatment used



of the adverse and variable effects of the interferons and ribavarin.

Understanding the life cycle of HCV led to the development of a new generation of antiviral treatments: direct-acting antivirals (DAAs) These new molecules directly targeted certain viral proteins necessary for HCV's replication. The first DAAs developed, Boceprevir and Telaprevir, were protease inhibitors. Their function was to prevent the HCV polyprotein from splicing between NS3 and NS4A. In 2011, they were approved as a treatment for HCV. Adding protease inhibitors to the Peg-IFN–RBV combination increased the rate of SVR rate by 30% in treatment-naive patients and shortened the duration of treatment. However, health risks and increased side effects have been observed with this treatment combination. New treatments expected

Interferon-free treatment (2013)

Given the side effects and limitations of interferon-based treatment, it became necessary to develop new interferon-free treatments. The development of NS5A inhibitors has been a major step forward. In 2012, a primary study demonstrated the possibility of treating HCV without interferons (Lok, 2012).

Sofosbuvir was the first interferon-free therapy to be approved. In general, it has few side effects and is well tolerated by most patients. High SVR rates have been documented after only 12 weeks of treatment in treatment-naive patients, a dramatic change.

Simeprevir and daclatasvir have been used for genotypes 1 and 3. In the randomised COSMOS study, patients treated with a combination of simeprevir and daclatasvir achieved SVR rates of 90-92% after 12-24 weeks of treatment. New studies published in 2014 demonstrated the efficacy of DAAs combinations. SVR rates of 95% were reported for genotype 1 carriers.

Pangenotypic treatments

One of the latest advances in the treatment of HCV, velpatasvir, arrived in 2016. A second-generation pan-genotypic NS5A inhibitor, velpatasvir is used in combination with sofosbuvir to treat HCV. In one study, a cohort of patients achieved an SVR of 99% over 12 weeks, regardless of genotype. In patients who had already received some form of treatment (non-treatment-naive), SVR rates were lower (93% among patients with cirrhosis and 89% among those without).

In 2017, the combination of glecaprevir and pibrentasvir was approved. It is well tolerated by patients and achieves similar SVR rates to velpatasvir. Treatment-naive carriers with genotypes 1, 2, 4, 5 or 6 achieved SVR rates of 97-100% in 8 weeks.[70]

Research is currently underway to find ways to reduce the time it takes to treat those previously diagnosed with HCV.[71-72] Most of these studies demonstrate that DAAs lose their efficacy if the treatment period is less than eight weeks.

Treatments available and covered in Quebec[73]

Combination	Dosage	Effectiveness
Elbasvir - Grazoprevir ZepatierTM	1 tablet/day	Genotype 1 and 4
Glecaprevir - Pibrentasvir MaviretTM	3 tablets/day taken while eating	Pangenotypic
Ledipasvir - Sofosbuvir HarvoniTM	1 tablet/day	Genotype 1, 4, 5 and 6
Sofosbuvir - Velpatasvir EpclusaTM	1 tablet/day	Pangenotypic
Sofosbuvir - Velpatasvir - Voxilaprevir VoseviTM	1 tablet/day	Pangenotypic

NS3/4A protease inhibitors
NS5A inhibitors
NS5B polymerase inhibitors

(Hassoun, 2022)

Treatment protocol in QC

Prior to treatment, a healthcare professional will carry out an initial assessment that includes diagnosis, medical history (lifestyle and medication history), clinical examination, biological report and evaluation of the stage of fibrosis.[74] Genotyping is not obligatory at the start of treatment, unless otherwise specified by the health professional. It is important to consider the psychosocial aspects of the patient (RAMQ card, risk of incarceration, income, access to transportation, nutrition...) as well as their physical health (prevention of reinfection, risk of overdose...).
The patient should be given verbal and written information about the medical follow-up, and it is important to note any medication taken in order to avoid drug interactions and to ensure contraception (cf. HCV and pregnancy).

During treatment, a blood test for quantitative RNA is performed at week four (in case of doubt about adherence), but this result does not predict treatment success.

At 12 weeks into treatment, SVR testing takes place involving another blood test (viral load and ALT) to assess treatment response.

The WHO's latest strategy for eliminating viral hepatitis recommends simplifying treatment:

- Offering decentralized services (for example, rapid tests at points of service);
- Eliminating unnecessary appointments (for example, implementation of REFLEX tests);
- Elimination non-obligatory tests (for example, Fibroscan at a score of Fib-4, genotyping...).

Missed doses

Missing a dose of DAA is relatively common. Most of the time, doses are missed for only short periods of time. According to available data, it is estimated that an interruption of treatment of less than seven days does not have a significant chance of impacting SVR level.
However, longer periods can certainly reduce the effectiveness of treatment.

Recommendations have been formulated in cases of non-adherence to the treatment, see *hcvguidelines.org.*

Interactions

The effects of drug interactions are generally undesirable and sometimes harmful. Interactions may include:

- An increase in effect, leading to side effects or toxicity;
- Decrease in effect, making the treatment less effective.

Certain DAAs can interact with other treatments such as acid-reducing agents (which affect their absorption) or amiodarone (a medication that prevents and treats arrhythmia), which can lead to a risk of severe bradycardia when taken with sofosbuvir. Tools are available for evaluating drug interactions, see *hep-druginteractions.org*.[75]

In addition to drug interactions, other serious interactions may occur with natural health products. Certain hepatotoxic plants can damage the liver. Others are falsely claimed to have hepatoprotective effects on the liver or to prevent HCV. It is important to note that no study has yet demonstrated the efficacy of medicinal plants in protecting against or curing HCV. In addition, certain

herbs may interfere with DAAs such as St. John's wort, reducing their concentration.[76]

Health care professionals should be informed about all the medicines and natural products that their patients are taking.

Barriers in access to treatment

Since 2018, access to DAAs in Quebec is universal for people living with hepatitis C, regardless of their fibrosis stage or whether they have health insurance (RAMQ, IFPH or NIHB).

Many barriers remain, however, in terms of access to screening and treatment. For example, stigmatization, racism and institutional or structural discrimination faced by key populations affected by HCV may discourage people from seeking services.

Certain factors, such as judicialization, criminalization, poverty and precarity of communities at risk, create a coercive environment in which people prioritize survival and end up relegating health concerns to a lower level of importance. In addition, the criminalisation of drug consumption undermines efforts to prevent STBBI.

Living in situations of homelessness and having limited means of communication are also factors to be considered in ensuring access to care related to HCV.

Considering the impact of the COVID-19 pandemic on access to care in general, the healthcare system in Quebec itself can be considered a barrier to access to care. The waiting time to see a family doctor is several years, blood tests take weeks... And although the WHO has implemented recommendations to simplify and decentralise care in the fight against STBBIs, screening in Quebec is still only possible by doctors and nurses. As a result, community workers cannot be trained to offer rapid tests at the point of service.

Finally, a lack of knowledge about HCV among many doctors is also an obstacle. The goal of the educational video *"ÉCHO du CHUM hépatite C et problématiques des troubles de l'usage"* is to increase HCV testing, evaluation and treatment rates by informing first- and second-line health professionals about best practices related to HCV, especially in remote regions.

Reinfection

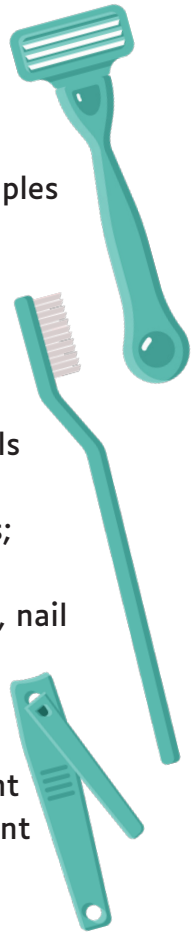
Hepatitis C can be treated and cured, but people do not develop immunity to the virus. This means that reinfection with HCV is possible. The risk of infection is highest among people who consume drugs (especially for recent consumption and consumption via injection) and people living with HIV/HCV coinfection.[77]

Among PWUD, age is the highest risk factor for reinfection (those under 30 are at greater risk), as well as opioid consumption. On the other hand, a reduced risk has been observed among those receiving opioid agonist therapy (OAT), those with access to mental health support and those receiving antipsychotic treatment as indicated.
In order to prevent reinfection, it is important to promote harm reduction services (distribution of sterile equipment for consumption, supervised consumption sites, OAT, safe supply, Naloxone...), provide adapted ways of informing and educating people, and facilitate access to screening for concerned communities.[78]

Prevention strategies

Considering how the virus is transmitted, many strategies can help to prevent the disease, including:

- The use of sterile, single-use equipment for the consumption of drugs (also requiring sufficient distribution and accessibility);
- Monitoring tissue and blood samples (in place in Canada since 1992);
- Ensuring all piercing and tattooing is done using sterile single-use materials, including ink. In Quebec, training for the proper use of single-use materials exists but is not obligatory for piercing and tattoo professionals;
- Never share personal hygiene equipment (razors, toothbrushes, nail clippers, etc.);
- Getting tested simply to know one's own serological status, in order to have access to treatment if HCV is diagnosed and to prevent transmission of the virus.



Raising public awareness is also essential to prevent HCV from getting transmitted.

Other HCV prevention measures to be implemented at the macro level include adequate funding for organisations involved in harm reduction and the prevention of transmission of STBBIs, making screening more accessible and decriminalizing drug possession.

Progress toward a vaccine?

In Canada, Dr. Jordan Feld seeks to begin a study involving a controlled human infection model (CHIM). CHIM studies are conducted with healthy adult volunteers who receive either a vaccine or a placebo and are then exposed to HCV in order to evaluate the vaccine's efficacy. Participants who develop chronic hepatitis C are quickly treated.

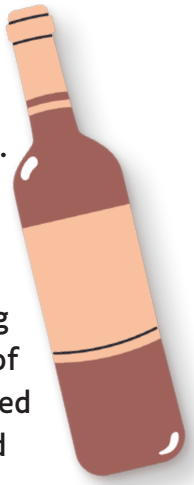
This type of approach has certain advantages such as shortening waiting times and reducing costs. It does, however, raise numerous questions in terms of ethics, science (regarding the strain of HCV used in the vaccine) and safety (can the results be transposed on to key communities?).[79]

The development of a vaccine against HCV is still a long way off. That's why it's important to increase screening efforts, improve access to treatment and implement prevention strategies if we hope to eliminate HCV.[80]

HCV &

HCV and alcohol

Alcohol can be hepatotoxic. Its consumption reduces the rates of spontaneous HCV clearance and can seriously aggravate the evolution of liver disease in people living with HCV.



It is important to note that the efficacy of DAAs is not altered by present or past alcohol consumption. Alcohol consumption should not impede access to treatment.[81]

In people living with HCV, consuming alcohol accelerates the progression of fibrosis, increases the risk of advanced fibrosis/cirrhosis and decompensated cirrhosis, increases the risk of liver cancer (particularly at a younger age and with limited response to treatment) and increases the risk of death.

The severity of the consequences depends on the amount of alcohol absorbed and the frequency of consumption. According to one study, the impact is significant when 14 or more units of alcohol are consumed per week. For people who consume alcohol, the risk of decompensated cirrhosis and death remains even after DAA treatment compared with people who do not.[82]

HCV and drugs

As previously stated, people who use drugs (injected or not) are among those most affected by HCV. Infection modelling suggests that in 'developed' countries, 70-80% of new HCV infections will be people who use drugs via injection.
Current or past drug consumption does not impede the efficacy of DAA treatment. All related studies demonstrate similar efficacy for DAA for people who consume psychoactive substances and the rest of the population. There are no interactions between DAA treatment and opioid agonist therapy (OAT). Cocaine, however, can be hepatotoxic and the consumption of stimulants may affect adherence to treatment.[83]

It should also be emphasised that the stigmatization faced by people who use drugs is a barrier to accessing treatment and other services.

Considering the risks of reinfection for people who inject drugs, the most important measures are prevention, education and increased access to safe injection materials. If reinfection occurs, treatment must be provided without judgment.

HCV and pregnancy

Vertical transmission is the main cause of pediatric hepatitis C (approximately 60% of cases worldwide). According to a meta-analysis, the risk of vertical transmission is estimated to be 5.8%. Breastfeeding is considered safe for people living with HCV, except in cases of nipple cracking and bleeding.

Some studies report that HCV is associated with an increased risk of gestational diabetes, intrahepatic cholestasis of pregnancy (ICP), preterm delivery and low birth weight.

Data is limited about the effects of DAA treatment during pregnancy (accidental or intentional).
Currently, DAA treatment is not recommended during pregnancy or breastfeeding due to the lack of data about its safety.
It is important to consider the implications for pregnant people who are diagnosed with HCV without treatment options before giving birth or stopping breastfeeding.[84]

HCV in children

The prevalence of HCV in children is lower than that in adults, although it is estimated that between 3.5 and 5 million children are living with chronic hepatitis C.[85]
To screen children for hepatitis C, an antibody test is recommended at 18 months (testing before this age carries the risk of detecting antibodies from the parent instead). If an antibody test is positive, the next step is an RNA test at the age of three, as 50% of children experience spontaneous HCV clearance. Since June 2022, the Maviret™ treatment has been authorized by the Public Health Agency of Canada for children aged three years and older. Treatment lasts eight weeks and has an efficiency rate of 98.4%.[86]
The pediatric Maviret™ is dispensed in unit-dose packets of oral pellets to make it easier for children to take.

HCV and HBV

The global prevalence of HBV/HCV coinfection is unknown. HBV/HCV coinfection is associated with higher rates of cirrhosis, increased severity of liver disease and a higher risk of HCC compared with those infected with either HBV or HCV alone.
Treatment for coinfected people is complex due to the interactions between the viruses and the potential reactivation of either virus during antiviral treatment.[87]

The American Association for the Study of Liver Diseases (AASLD) recommends beginning hepatitis B treatment at the same time as, or even before, DAA treatment for people with a coinfection. Regular follow ups are necessary to evaluate whether either of the two viruses will reactivate.
HBV/HCV coinfection does not affect the recovery rate of HCV by DAA treatment.

HCV and HIV

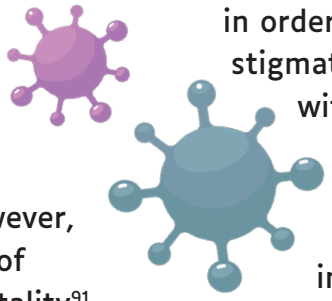
Worldwide, it is estimated that 2.3 million people live with HIV/HCV coinfection, majoritarily affecting PWID and GBMSM populations. The risk of HCV is six times higher for people living with HIV compared to those without. In Canada this coinfection affects 20-30% of people living with HCV and is responsible for a heavy burden of morbidity and mortality.[88]
People living with HIV/HCV coinfection face a risk of accelerated fibrosis progression, a greatly increased risk of hepatocellular carcinoma and a high risk of mortality

compared to people with HCV mono infection, even when taking antiretroviral (ARV) treatment. HCV impacts the progression of HCV, notably facilitating its replication. Recent studies indicate that the SVR for people with HIV/HCV coinfection are comparable to those with HCV monoinfection.[89]

It is recommended to begin with antiretrovirals and to only start DAA treatment once the HIV virus is undetectable.

HCV and COVID

It has been observed that among people infected with COVID-19, those who have had a previous HCV infection are additionally subjected to a higher virulence of SARS CoV-2, independently of base comorbidities, or to hepatic lesions induced by COVID-19.[90]



People living with chronic hepatitis C have a greater risk of hospitalization due to SARS-CoV-2 and the hospitalization rate increases with a FIB-4 score. The presence of HCV does not, however, have a significant impact on rates of admission to intensive care or mortality[91] Patients with cirrhosis of the liver are susceptible to complications or death due to COVID-19.[92]

Beyond increasing severity of illness for people living with HCV, the COVID-19 pandemic has also impacted access to care and hepatitis C services at all levels of the cascade of care, particularly for key communities, including people who use drugs.

The report on the effects of COVID-19 on the provision of screening and treatment for STBBIs in Canada demonstrated that "The reduction and suspicion of services affected the provision of prevention services, screening and treatment for STIs, including support and treatment for people living with HIV and/or hepatitis C."

It should not be overlooked that the curfew put in place in Quebec--as well as the disproportionate criminalization of marginalized communities during the pandemic, particularly in Quebec--impeded access to care and services, notably those related to harm reduction.[93] The pandemic therefore hindered efforts to eliminate HCV.

It has also been observed that the groups most disproportionately affected by HCV were particularly affected by COVID. The pandemic exacerbated existing issues and worsened social inequalities. Efforts should be redoubled in order to address barriers associated with stigmatization, discrimination, poverty and with the overdose and housing crises.[94]

The COVID-19 pandemic created opportunities for healthcare innovation such as the growth of telehealth, which serves as a means of increasing engagement for marginalized communities.[95] It remains to be seen whether governments will seize upon these opportunities.

Strategies for combating hepatitis C

Globally

Recognizing viral hepatitis as a public health issue requires addressing different aspects such as strategies, action plans and allocating sufficient funding to ensure its elimination. It should be noted that since 2010, July 28th has been recognized as World Hepatitis Day. This event is meant to raise awareness and promote the prevention of viral hepatitis as well as access to screening, treatment and care.

Towards Ending Viral Hepatitis - Global Health Sector Strategy on Viral Hepatitis, 2016-2021

In 2016, the WHO launched the first global strategy concerning viral hepatitis T*owards Ending Viral Hepatitis - Global Health Sector Strategy on Viral Hepatitis, 2016-2021*. It addresses the issues associated with hepatitis while also recognizing the global public health burden. Its objective is elimination of hepatitis by 2030 as a public health threat.

This strategies depends on:

- **Universal health coverage:** to allow all individuals to benefit from health services they require with sufficient quality and without being exposed to financial difficulty.
- **The continuum of hepatitis services:** that includes preventing and diagnosing infection, linking people to health services, through to providing treatment and chronic care.
- **A public health approach:** that is concerned with preventing infection and disease, promoting health, and prolonging life among the population as a whole.

This strategy identified 2020 targets for the elimination of viral hepatitis in 2030 and defined the strategic plans with which to proceed.[96]

Global health sector strategies on, respectively, HIV, viral hepatitis and sexually transmitted infections for the period 2022-2030[97]

In 2022, the WHO launched *Global health sector strategies on, respectively, HIV, viral hepatitis and sexually transmitted infections for the period 2022-2030*. These integrated strategies seek to eliminate HIV/AIDS and end hepatitis and STI pandemics by 2030. Concerning viral hepatitis, this new strategy takes into consideration lessons learned from the 2016-2021 plan where targets were not achieved.

Targets to achieve

These new strategies identify targets to achieve by 2025 and 2030 in order to eliminate HIV, viral hepatitis and STIs. Concerning hepatitis C, the targets are as follows:

- Reduce the number of new hepatitis C infections from 1.575 million (in 2020) to 350 000 (in 2030);

- Reduce the annual number of deaths due to hepatitis C from 290 000 (in 2020) to 140 000 (in 2030);
- Increase the diagnosis percentage of people living with hepatitis C from 30% (in 2020) to 90% (in 2030);
- Increase the percentage of people diagnosed and cured of hepatitis C from 30% (in 2020) to 80% (in 2030).

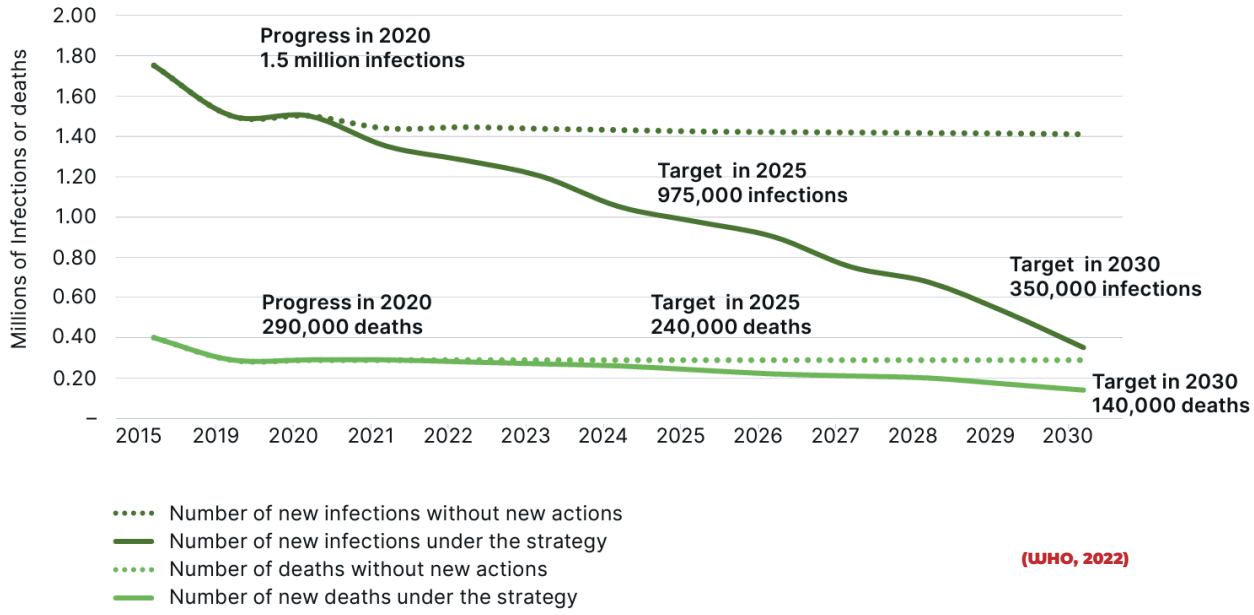
Strategic directions

Concerning viral hepatitis, the main strategic directions are:

- Raising greater public and political awareness, particularly among those responsible for health governance;
- Secure funding;
- Produce data to be used for decision-making and planning;
- Improved access to screening and treatment;
- Promote models of simplified service delivery, such as decentralized screening and treatment for hepatitis B and C;
- Reinforce community participation, notably proposing adapted models of service delivery

In order to guarantee the tracing of indicators and a proper implementation of these strategies, the WHO plans to hold itself and participating countries accountable. A mid-term review is planned for 2026.

Hepatitis C: incidence and mortality trends between 2020 and 2030, with and without the new measures envisaged in the strategies



(WHO, 2022)

Canada

Government level

On June 16, 2016, the federal government of Canada committed to eliminate hepatitis C by 2030, combat viral hepatitis and adopt the WHO's Global Health Sector Strategy on Viral Hepatitis along with 193 other states.[98] Despite this political commitment, the federal government engages with health governance via the following authority:

- Criminal laws intended to protect physical health and public security by controlling possible dangers posed by products and substances such as tobacco or certain medications;
- The power to fund research and promote health and general awareness about health issues.[99]

Federal powers are limited in their ability to combat hepatitis.

In 2018, the government, via the Public Health Agency of Canada (PHAC), published *Reducing the health impact of sexually transmitted and blood-borne infections (STBBIs) in Canada by 2030: A pan-Canadian STBBI framework for action*. This framework promoted an integrated approach to "reduce the impact of STBBI in Canada and to contribute to the global efforts to end AIDS, viral hepatitis, and sexually transmitted infections as major health concerns."[100]

In July, 2019, the PHAC also published the *Accelerating our response: Government of Canada five-year action plan on sexually transmitted and blood-borne infections. This report "sets out the Government of Canada's priorities as we advance the Pan-Canadian Framework for Action," and its objective is to "celerate prevention, diagnosis and treatment to reduce the health impacts of sexually transmitted-and blood-borne infections (STBBI) in Canada by 2030."[101] A revision of this action plan is currently underway in 2023, though its deadlines and objectives remain unchanged.*

The Community Action Fund (CAF) for HIV and Hepatitis C is one of the means by which the government of Canada finances the fight against STBBIs. The yearly funding for the CAF is $26.4 million.[102] This amount has not changed in 15 years. Community organizations working to combat STBBIs denounce the underfunding of the PHAC[103] as well as the complex process that organizations must undergo in order to access this funding.[104]

Scientific level

In Canada, the scientific community is also highly mobilized in the fight against hepatitis C. In May, 2019, the Canadian Network on Hepatitis C published the *Blueprint to inform hepatitis C elimination efforts in Canada*. The goal of this document is to establish the roadmap for a public health response that will meet HCV elimination goals in Canada by 2030.[105]

Community level

On the community level, Action Hepatitis Canada (AHC) has been ensuring the concentration of organizations dedicated to the fight against hepatitis B and C since the 2000s. Its work aims to promote prevention of hepatitis B and C, expand access to care and treatment, increase research and innovation, develop public health awareness, improve skill sets for health professionals, and support community groups and initiatives.

In its 2023 report, *Progress Toward Viral Hepatitis Elimination Canada*, the AHC compiled advances in the fight against hepatitis C and provided tools necessary to ensure accountability of different levels of government. The report shows, for example, that seven of the ten provinces and two of the 3 territories are on track to meet their elimination targets.. Sufficient data is unavailable to evaluate the situation in Canada's three territories. The three provinces not on track to meet elimination targets are Ontario, Manitoba and Quebec[106]. In 2022, AHC, CanHepC, CanHepB, the Canadian Liver Foundation and the Canadian Association for the Study of the Liver were able to convince the Canadian parliament to declare May 11 as the annual Canadian Viral Hepatitis Elimination Day.

Quebec

Government level

Contrary to the federal level, the provincial government has the majority of power and responsibility for health care, which includes:

- Establishing hospital networks and organize their respective administrations;
- Ensuring adequate hygiene and public health for the population;
- Establishing an obligatory health insurance plan, notably regarding costs related to health (hospitalization fees, medical fees and medication).[107]

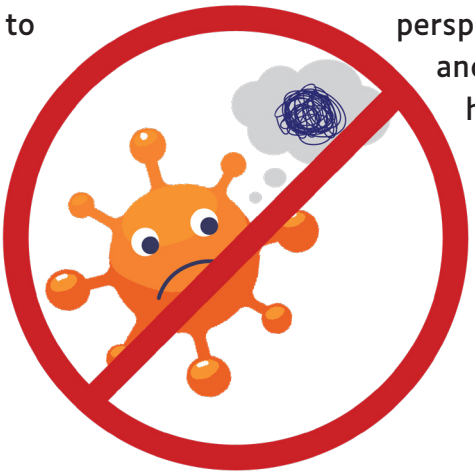
In 2017, the *Ministère de la Santé et des Services Sociaux* (MSSS) of Quebec published the *Programme national de santé publique - Joindre, dépister et détecter, traiter - Intégrer la prévention des ITSS dans les plans d'action régionaux de santé publique*. This document covers the period of 2015-2025 and proposes an "integrated approach, rather than per individual infections, which allows for targeting common factors between them and tackling sexual health and substance consumption."[108] This plan is financed by diverse public health measures, managed by the Directions Régionales de Santé Publique (DRSP). Barring any changes, the current government priority list in Quebec does not include the fight against STBBIs and HCV.

Community level

In Quebec, community organizations work together in combating hepatitis C through the Comité provincial de concertation en hépatite (Provincial Committee for Collaboration on Hepatitis C). This committee aims to ensure that community organizations collaborate in recognizing and following recommendations regarding hepatitis C. The committee also seeks to promote knowledge, harmonize

policies and support its members in their actions. Its philosophy is to focus on the people most at risk or living with hepatitis C within a framework of autonomization and harm reduction. 32 organizations or member groups make up this committee.

It is important to underland that since 2016, April 29th has been designated the *Journée nationale de sensibilisation à l'hépatite C* (National Day for Hepatitis C Awareness) in Quebec. This designation seeks to improve hepatitis C prevention, accelerate diagnosis and expand care for people living with the virus. The efforts of Laurence Mersilian, director of CAPAHC, led to the vote passing unanimously to the National Assembly in 2015.[109]



The roadmap for eliminating hepatitis C in Quebec fits into a pan-Canadian initiative facilitated by the CanHepC research network. Inspired by traces identified in guidelines published in 2019, roadmaps are developed for different regions of the country as well as a national roadmap specific to indigenous communities. As such, adapted strategies will be offered to respond to the varied realities of hepatitis C

Concept of Micro-elimination

In the fight against hepatitis C, the micro-elimination approach is used frequently. It consists of a strategy for meeting national elimination goals via initiatives targeting specific communities such as people who inject drugs, incarcerated populations or immigrants and newcomers. This approach aims to increase prevention, screening, diagnosis, linkage to care and access to treatment.

Micro-elimination is a pragmatic, people-centered approach with realistic goals. This allows for meeting elimination goals within shorter deadlines, adapting different approaches that take into account the perspectives of front-line workers and affected populations. It has been demonstrated that micro-elimination reduces the risk of reinfection in key population segments. Additionally, it provides the opportunity to try and test new models of care and

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