ONTARIO HEALTH TECHNOLOGY ASSESSMENT SERIES

Hepatitis C Screening

A Health Technology Assessment

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Ontario Health

Key Messages

What Is This Health Technology Assessment About?

Infection by the hepatitis C virus (HCV) affects the liver and can result in serious liver damage. HCV spreads through contact with infected blood. Some people with HCV may have mild or no symptoms, and it may take years or decades for symptoms to appear. HCV infection can be treated with medications that are taken orally. Curing the infection decreases the risk of HCV transmission to others and prevents the development of its long-term consequences.

Screening for HCV can identify people with the infection so they can be linked to care and treatment. Currently in Ontario, HCV screening generally requires that risk factors for the infection be identified by a health care provider or disclosed by the person. More general HCV screening approaches that do not require the identification or disclosure of risk factors have been suggested, such as one-time HCV screening for all adults or for people born between 1945 and 1975 in addition to continuing HCV screening according to the presence of risk factors.

This health technology assessment looked at how effective and cost-effective HCV screening is for all adults or for people born between 1945 and 1975 in addition to risk-based screening. It also looked at the budget impact of publicly funding HCV screening for all adults or for people born between 1945 and 1975 and at the experiences, preferences, and values of people who have experienced HCV screening.

What Did This Health Technology Assessment Find?

HCV screening for all adults in addition to risk-based screening may result in more people with HCV being identified and linked to care and treatment compared with risk-based screening alone.

Compared with risk-based screening alone, HCV screening for all adults and for those born between 1945 and 1975 would be less costly and more effective. We estimate that publicly funding HCV screening for all adults and for people born between 1945 and 1975 in Ontario over the next 5 years would cost an additional $111 million and $32 million, respectively.

People with HCV shared how the infection negatively affected their health and social well-being, often highlighting the emotional distress caused by the stigma associated with it. They also highlighted the importance of adopting universal or routine testing strategies to enable earlier diagnosis and intervention.

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Abstract

Background

Hepatitis C virus (HCV) infection causes liver inflammation that, if left untreated, can lead to scarring of the liver (cirrhosis), liver failure, liver cancer (hepatocellular carcinoma [HCC]), and death. For most people, this process usually progresses slowly, over 10 to 20 years or more, during which time the person may remain asymptomatic despite the ongoing process of liver damage. HCV screening aims to identify people with an HCV infection so that they can be linked to care and treatment. We conducted a health technology assessment of (1) one-time HCV screening for all adults in addition to risk-based HCV screening and (2) one-time HCV screening for people born between 1945 and 1975 (1945–1975 birth cohort) in addition to risk-based HCV screening, compared with risk-based HCV screening alone. This included an evaluation of effectiveness, cost-effectiveness, the budget impact of publicly funding one-time HCV screening in those populations, and patient preferences and values.

Methods

We performed a systematic literature search of the clinical evidence. We assessed the risk of bias of each included study using the Risk of Bias in Nonrandomized Studies – of Interventions (ROBINS-I) tool and the quality of the body of evidence according to the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) Working Group criteria. We performed a literature search of the quantitative evidence on the preferences for HCV screening of the adult population and health care providers. We performed a systematic economic literature search and conducted a cost–utility analysis with a lifetime horizon from a public payer perspective to compare (1) one-time HCV screening for all adults plus risk-based HCV screening and (2) one-time HCV screening for the 1945–1975 birth cohort plus risk-based HCV screening, against risk-based HCV screening alone. We also analyzed the budget impact of publicly funding one-time HCV screening for all adults plus risk-based HCV screening and one-time HCV screening for the 1945–1975 birth cohort plus risk-based HCV screening in Ontario. We performed a literature search of the quantitative evidence on the preferences of adults and health care providers for HCV screening. To contextualize the potential value of expanding HCV screening, we spoke with people with HCV.

Results

We included 3 observational studies in the clinical evidence review. The study findings suggest that one-time HCV screening for all adults plus risk-based HCV screening may identify more people with HCV and may result in more people with HCV linked to care compared with risk-based HCV screening alone (GRADE: Very low). No studies were identified for the assessment of one-time HCV screening for the 1945–1975 birth cohort or for the assessment of the quantitative preferences of adults and health care providers for HCV screening. One-time HCV screening for all adults plus risk-based HCV screening and one-time HCV screening for the 1945–1975 birth cohort plus risk-based HCV screening are less costly and more effective than risk-based HCV screening alone. The probability of one-time HCV screening for all adults plus risk-based HCV screening and one-time HCV screening for the 1945–1975 birth cohort plus risk-based HCV screening being cost-effective versus risk-based HCV screening alone is 100% at a willingness-to-pay of $50,000 per quality-adjusted life-year (QALY) gained and 100% at a willingness-to-pay of $100,000 per QALY gained. The annual budget impact of publicly funding one-time HCV screening for all adults plus risk-based HCV screening in Ontario over the next 5 years ranges from an additional

$22 million in year 1 to $14 million in year 5. The annual budget impact of publicly funding one-time HCV screening for the 1945–1975 birth cohort plus risk-based HCV screening in Ontario over the next 5 years ranges from an additional $9 million in year 1 to $1 million in year 5. The people with HCV with whom we spoke reported that HCV negatively affected their health and social well-being, and they highlighted the emotional distress caused by the stigma associated with the infection.

Conclusions

One-time HCV screening for all adults plus risk-based screening may identify more people with HCV and may result in more people with HCV linked to care compared with risk-based HCV screening alone, but the evidence is very uncertain due to concerns with generalizability of the study findings to the Ontario context. One-time HCV screening for all adults plus risk-based screening and one-time HCV screening for the 1945–1975 birth cohort plus risk-based screening are both less costly and more effective than risk-based HCV screening alone. We estimate that publicly funding one-time HCV screening for all adults plus risk-based screening and one-time HCV screening for the 1945–1975 birth cohort plus risk-based screening in Ontario would result in additional costs of $111 million and $32 million, respectively, over the next 5 years. People with HCV emphasized the need to expand HCV screening beyond traditionally defined high-risk groups to enable earlier diagnosis and treatment.

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Objective

This health technology assessment evaluates the comparative effectiveness and cost-effectiveness of (1) one-time hepatitis C virus (HCV) screening for all adults in addition to risk-based HCV screening and (2) one-time HCV screening for people born between 1945 and 1975 (1945–1975 birth cohort) in addition to risk-based HCV screening, compared with risk-based HCV screening alone. It also evaluates the budget impact of publicly funding HCV screening for all adults and for the 1945–1975 birth cohort, as well as the preferences of patients for HCV screening.

Background

Health Condition

The hepatitis C virus (HCV) is a single-stranded ribonucleic acid (RNA) virus[1] that was identified in 1989.[2] It is transmitted when the blood of a person infected with HCV comes in contact with the blood of another person.[3] HCV infection causes liver inflammation that can lead to scarring of the liver (cirrhosis), liver failure, liver cancer (hepatocellular carcinoma [HCC]), and death[2,4] if left untreated.[5] HCV infection leads to more years of life lost than any other infectious disease in Ontario[6] and Canada.[7]

Acute HCV infection refers to the first 6 months after the infection, during which most people are asymptomatic or present with mild, nonspecific, short-lived symptoms (e.g., fatigue, tenderness on the right side of the abdomen, decreased appetite, and jaundice).[3] Symptoms of acute HCV infection are observed in about 15% of cases.[1] It is estimated that approximately 25% of people with acute HCV infection eliminate the virus spontaneously and are considered cured from the infection; the remaining 75% develop chronic disease.[3,8]

People living with chronic HCV infection are also typically asymptomatic, even if cirrhosis develops.[3] If the infection is not treated, the inflammation caused by HCV destroys liver cells over time, leading to the development of scar tissue in a process called fibrosis[3] (assessed according to the METAVIR [Meta-analysis of Histological Data in Viral Hepatitis] scoring system ranging from F0 [no fibrosis] to F4 [cirrhosis][4]; Appendix 1). For most people, this process usually progresses slowly, over 10 to 20 years or more, during which time the person may remain asymptomatic despite the ongoing process of liver damage[3] that can eventually lead to cirrhosis and HCC.[3,8-10] It is estimated that approximately 5% to 25% of people with chronic HCV develop cirrhosis within 10 to 20 years of the infection,[9] resulting in a 1% to 4% annual risk for HCC[9] and a 3% to 6% annual risk of decompensated cirrhosis (impaired liver function due to the extent of fibrosis).[2] If decompensated cirrhosis or HCC develops, liver transplantation may be considered.[3,4] The risk of death 1 year after the development of decompensated cirrhosis is estimated to be 15% to 20%.[2] HCC, the most common form of primary liver cancer,[4,11] is often diagnosed at a late stage and has a poor prognosis.[11] HCV and hepatitis B virus infections are the most common risk factors for HCC.[11] In 2013, in Ontario, it was estimated that 225 new cases of liver cancer (approximately 24% of liver cancer cases) were attributed to HCV infection.[12]

Chronic HCV infection can also be associated with extrahepatic diseases, independent from fibrosis, for example, cryoglobulinemia (when abnormal proteins in the blood [cryoglobulins] thicken and clump

together at cold temperatures), diabetes mellitus, heart disease, chronic renal disease, and non-Hodgkin's lymphoma.[4,8,13]

As HCV can be present in the body for decades before symptoms start to develop,[3] it often remains undiagnosed.[8] An Ontario study estimated that, in 2014, 36% of people with a chronic HCV infection were undiagnosed.[14]

It generally takes 2 weeks to 6 months from the time of exposure for the development of detectable HCV antibodies (window period).[4] HCV antibodies remain in the body after a person is cured from the infection, either through treatment or spontaneous clearance, but do not provide immunity; therefore, a person can be reinfected if exposed to the virus again.[3,8] There is no vaccine to prevent HCV infection.[8]

Two types of tests are used in the diagnosis of an HCV infection. The HCV antibody test is performed first: a reactive (positive) HCV antibody test indicates a current or past infection that may have been cleared either spontaneously or with treatment.[3] The HCV RNA test, which is generally performed for people with a positive HCV antibody test, is used to determine whether a current infection is present.[3] Additional information is provided in the Hepatitis C Virus Testing in Ontario section, below.

The introduction of direct-acting antivirals (DAAs), a safe and highly effective new treatment for HCV with cure rates of approximately 95%, has impacted the field of hepatitis C.[15] Curing hepatitis C prevents HCV transmission to others and prevents the development of its long-term consequences.[15,16]

Hepatitis C Initiatives

In May 2016, the World Health Organization's (WHO's) Global Health Sector Strategy on viral hepatitis set targets to eliminate HCV as a public health threat globally by 2030, aiming to reduce new HCV infections by 80% and related deaths by 65%.[8,17] This requires an increase in testing to diagnose 90% of people with HCV and initiating treatment for 80% of eligible people with HCV.[8] Each country is responsible for defining the specific populations that are most affected by viral hepatitis, and the response should be carried out according to the epidemiological and social context.[17]

Canada has endorsed the WHO's goals.[8,15] The 2019 *Blueprint to Inform Hepatitis C Elimination in Canada* is a guide to achieving the WHO's goals in Canada.[8] It provides recommendations to improve HCV prevention, testing, care, and treatment, including specific recommendations for populations disproportionately affected by HCV.[8] The Blueprint complements[8] the Public Health Agency of Canada's (PHAC's) *Pan-Canadian Framework for Action for Reducing the Health Impact of Sexually Transmitted and Bloodborne Infections in Canada by 2030*.[18]

In Ontario, the *Ontario Hepatitis C Elimination Roadmap*[15] was prepared by a multidisciplinary team of experts to guide the province toward the goal of eliminating HCV as a public health threat.[15] The document provides recommendations on harm reduction, testing, awareness, and linkage to care and treatment, including specific recommendations based on the needs of different groups disproportionally affected by HCV.[15]

Clinical Need and Population of Interest

Activities that have a greater likelihood of exposure to the blood of a person with HCV are more likely to result in HCV transmission.[3] Exposure of mucous membranes to blood and percutaneous exposure can also result in transmission, but with a lower risk.[9,19]

Risk factors for HCV include the following[3,20,21]:

- Use of injection, intranasal, or inhaled drugs with shared equipment
- Exposure to nonsterile medical, dental, or personal services equipment (e.g., hemodialysis, occupational injuries [such as needle stick injuries], unsafe tattooing or body piercing, surgical procedures)
- Receiving invasive medical procedures in countries where infection prevention and control practices are not sufficient
- Sharing of personal care items (e.g., razors, toothbrushes)
- Condomless sex with a person with HCV (particularly if contact with blood occurs)
- Being born to a pregnant person with HCV
- Receipt of blood, blood products, and organs in Canada before 1992
- Being born in, having travelled to, or having lived in a region with a high prevalence of HCV (e.g., Central, East, and South Asia; Eastern Europe; North Africa and the Middle East; Sub-Saharan Africa; Australia and Oceania)

PHAC[21] and the *Blueprint to Inform Hepatitis C Elimination Efforts in Canada*[8] identified 5 priority populations that "experience a disproportionate burden of HCV and/or those with challenges in accessing HCV care and services." These populations are disproportionately affected by HCV due to factors such as poverty, homelessness, and mental health issues, which may increase their risk or make them more vulnerable to the disease; they also experience stigma and other obstacles that make it difficult for them to access health care.[8] These populations are as follows:

- People who inject or use drugs
- Indigenous people (First Nations, Inuit, Métis)
- People with experience in the federal or provincial prison system
- Immigrants and newcomers from countries where HCV is common
- Men who have sex with men

The Canadian Blueprint document also identified people born between 1945 and 1975 (1945–1975 birth cohort) as a group of interest; this age group is estimated to represent 66% to 75% of people with HCV in Canada.[8] HCV infections in this group occurred mostly due to medical procedures performed before the implementation of HCV screening of blood, blood products, and organs or due to prior use of injected drugs; people in this birth cohort may also be part of other priority populations with increased risk of HCV.[8] However, given health care providers' general perception of low risk of infection in this population, testing in this age group tends to be low.[8] People with HCV within this age group are

believed to have been living with the infection for decades and are at risk for HCV-related complications such as cirrhosis and cancer.[8]

On the other hand, new HCV infections in Canada are believed to occur primarily among younger people who inject drugs (estimated to account for 85% of new HCV infections).[8]

Number of Reported Cases and Prevalence of Hepatitis C Virus in Ontario and Canada

Number of Hepatitis C Virus Cases Reported

Hepatitis C is a nationally and provincially notifiable disease[22] monitored by PHAC[23] and by Public Health Ontario (PHO).[24] The number of cases reported in Canada overall and in Ontario in recent years are shown below.

Canada

In 2021, 7,535 HCV cases (19.7 HCV cases per 100,000 population) were reported in Canada.[25] However, this may be an underestimate because disruptions in the demand for and access to services (including testing) in 2020 and 2021 due to the COVID-19 pandemic likely contributed to fewer HCV cases being detected.[25]

Ontario

In 2023, 3,406 HCV cases (21.8 HCV cases per 100,000 population) were reported in Ontario.[26] Approximately 60% of the cases occurred in men, and drug use (injection and noninjection) was the most common risk factor among cases with a risk factor reported.[26] The highest HCV rate was observed among people 30 to 39 years of age.[26]

The authors of the report advise that surveillance data for HCV cases reported between 2020 and 2023 should be interpreted with caution due to changes in the availability of health care, health-seeking behaviour, public health follow-up, and case entry during the COVID-19 pandemic and subsequent recovery period.[26]

Hepatitis C Virus Prevalence

Canada

As case notification patterns are strongly influenced by HCV testing practices, they do not accurately reflect HCV prevalence and incidence.[4] Therefore, modelling methods have been used to estimate HCV prevalence[8,27] using data on HCV-related outcomes such as HCC (back-calculation statistical modelling).[28]

In 2021, PHAC estimated that 0.99% of the population in Canada had HCV antibodies (representing a current or past infection) and that 0.56% of the population had chronic HCV.[29] Table 1 provides the estimated prevalence of HCV antibody positivity in the general population, in priority populations, and among people born between 1945 and 1975.

Table 1: Estimated Prevalence of HCV Antibody Positivity in Canada, 2021

Population group[a]	Estimated number of people (%)
General population	0.99%[b]
1945–1975 birth cohort	270,000 (1.9)
People who have used injection drugs (lifetime history)	137,000 (35.4)
People who have used injection drugs (current, in the past 12 months)	64,400 (64.2)
Immigrant population (from countries where HCV is common[c])	51,500 (4.0)
First Nations Peoples[d]	84,000 (8.0)
Men who have sex with men	20,100 (3.0)
People incarcerated in federal prisons	1,400 (11.1)
People incarcerated in provincial prisons	2,700 (14.2)

Abbreviations: HCV, hepatitis C virus.

[a]These categories are not mutually exclusive.[29]

[b]People with positive HCV antibody status, including people with chronic hepatitis C, those who spontaneously resolved the infection, and those with treatment-related cure.[29]

[c]Country or regional HCV antibody prevalence estimate is 2% or greater.[29]

[d]The data provided in the publication are specific to First Nations Peoples because there was insufficient information to provide national estimates for Inuit and Métis Peoples.[29]

Source: Public Health Agency of Canada.[29]

Ontario

The prevalence of chronic HCV in Ontario in 2014 was 0.91% (95% confidence interval [CI]: 0.83, 1.02) in adults and 1.93% (95% CI: 1.69, 2.25) among people born between 1945 and 1964 as estimated by a modelling study.[14] The study also estimated that 36.0% (95% CI: 31.2, 38.9) of people with chronic HCV in the adult population and 21.1% (95% CI: 17.6, 24.0) of people born between 1945 and 1964 were not aware of their infection.[14]

An Ontario study conducted between 2016 and 2020 evaluated the HCV antibody positivity among 16,672 adults born between 1945 and 1975.[30] HCV antibody tests were performed in different settings (e.g., primary care, emergency department, screening events) (Table 2).[30] The overall prevalence of HCV antibody positivity was 3.2%, but it varied according to the decade of birth (0.9% for 1945–1955 to 4.6% for 1966–1975) and setting (0.5% in primary care to 28.7% in drug treatment centres) (Table 2).[30]

Table 2: Prevalence of HCV Antibody Positivity in Ontario, 2016–2020 (1945–1975 Birth Cohort)

Group	N	Number with positive HCV antibody[a] (%)
Overall	16,672	529 (3.2)
Decade of birth: 1945–1955	4,329	39 (0.9)
Decade of birth: 1956–1965	6,259	210 (3.4)
Decade of birth: 1966–1975	6,084	280 (4.6)
Setting: Primary care[b]	9,034	45 (0.5)
Setting: Emergency department	2,368	47 (2.0)
Setting: Walk-in clinic	963	7 (0.7)
Setting: Screening event[c]	1,818	26 (1.4)
Setting: Community outreach[d]	1,887	265 (14.0)
Setting: Drug treatment centre	471	135 (28.7)
Other[e]	131	4 (3.1)

Abbreviation: HCV, hepatitis C virus.

[a]HCV antibody testing occurred by conventional serologic laboratory testing, rapid antibody test, or dried blood spot. Performance of follow-up HCV RNA testing was left up to each site.[30]

[b]Including family health teams, community health centres, nurse practitioner–led clinics, and family medicine physician practices.

[c]Including health fairs and screening taking place in hospital lobbies.[30]

[d]Screening events for higher-risk populations (e.g., shelters, drop-ins, street outreach).[30]

[e]Including pharmacies, sexual health clinics, and HIV pre-exposure prophylaxis.[30]

Source: Biondi et al.[30]

An Ontario seroprevalence study measured the prevalence of HCV antibody positivity among people born between 1945 and 1974 using residual sera that had been obtained for other laboratory tests at the largest private diagnostic laboratory in Ontario.[31] Among the 10,006 sera included in the study, 155 (1.55%; 95% CI: 1.32, 1.81) had a positive HCV antibody test result.[31] The estimated prevalence of antibody positivity was 2.14% (95% CI: 1.76, 2.58) in men and 0.96% (95% CI: 0.71, 1.27) in women.[31] Table 3 provides the prevalence of HCV antibody positivity according to age.

Table 3: Prevalence of HCV Antibody Positivity According to Birth Year in Ontario, 2014–2015 (1945–1974 Birth Cohort)

Birth year	N	Number with positive HCV antibody (%)
1945–1949	1,666	17 (1.02)
1950–1954	1,667	33 (1.98)
1955–1959	1,668	30 (1.80)
1960–1964	1,668	33 (1.98)
1965–1969	1,669	23 (1.38)
1970–1974	1,668	19 (1.14)
Total	**10,006**	**155 (1.55%)**

Abbreviation: HCV, hepatitis C virus.

Source: Bolotin et al.[31]

Hepatitis C Virus Testing in Ontario

HCV testing is indicated for people who may have been exposed to the virus (e.g., as part of an outbreak investigation, infection control breach, or personal or occupational exposure), people suspected of having chronic or acute viral hepatitis, and people with unexplained elevated liver function tests; HCV testing is also indicated for screening people at high risk of infection.[32]

HCV screening is performed by different health care providers in different settings (e.g., primary care, hospitals, outreach groups).[3] PHAC also recommends HCV screening for people diagnosed with hepatitis B virus or human immunodeficiency virus (HIV) infections.[21] Routine screening is recommended for people with ongoing risks of HCV infection.[3]

HCV screening is also provided by the Ontario Hepatitis C Teams,[33] which are funded by the Ontario Ministry of Health and located in community settings (e.g., AIDS service organizations, shelters, community health centres, hospitals) throughout the province.[15,33,34] The aim is to improve access to HCV prevention and care services, including screening, particularly for populations that experience systemic and social barriers to accessing health care, which includes people who use drugs, Indigenous people, people with experience of incarceration, people who are unhoused or underhoused, and street-involved youth.[15,33,34]

An HCV antibody test is performed first,[3] and, in some cases, a second or supplemental antibody test is done. Some labs, including that of PHO, have established their own internal cutoff above which a supplemental antibody test is not required.[32]

The HCV RNA test is a follow-up test performed in people with a reactive (positive) HCV antibody test or evidence of liver disease to determine whether a current infection is present.[35] It can also be performed if reinfection is suspected and after the end of treatment to determine sustained virologic response (SVR), among other indications.[35] HCV genotyping is done on the first pretreatment specimen submitted for HCV RNA testing or when HCV reinfection is suspected if the specimen meets the minimum viral load requirement.[36]

The HCV RNA test is performed as a reflex test (i.e., automatically performing the RNA test on the same specimen used for the antibody test instead of requiring collection of a new specimen) at PHO under several circumstances: on a first-time reactive HCV antibody test, a previously reactive HCV antibody test without HCV RNA testing available on record, and on a first-time inconclusive HCV antibody test.[35]

Hepatitis C Virus Treatment

The aim of treatment is the elimination of HCV from the body, also referred to as cure or SVR, to prevent the complications of HCV-related liver and extrahepatic diseases and to prevent transmission of the infection.[7,37] Cure or SVR is defined by a negative or undetectable HCV RNA test result 12 weeks or more after the end of treatment.[3,7] Late viral relapse after DAA treatment is considered uncommon.[7]

Before DAAs became available in Canada in 2015,[8] interferon-based regimens were used to treat HCV infections.[7] Interferon regimens lasted up to 48 weeks, required injections, cured less than 60% of cases, and were difficult to tolerate.[20]

DAA treatment has replaced interferon-based regimens.[8,9] DAAs are taken orally once a day for 8 or 12 weeks[3,8] and are better tolerated than interferon regimens.[9] Pangenotypic DAA regimens (i.e.,

regimens that can be used to treat any known HCV genotype) are generally used.[3] The most common first-line DAA regimens in Ontario include Epclusa (sofosbuvir/velpatasvir) and Maviret (glecaprevir/pibrentasvir).[3] Vosevi (sofosbuvir/velpatasvir/voxilaprevir) is used as salvage treatment when initial treatment fails.[3,7]

HCV infection is curable in most cases (> 95%[38]) with DAA treatment.[7,23] Treatment eradicates the virus and prevents further disease progression.[7,8] It improves liver function[37]; reduces the risk of cirrhosis, liver cancer, liver transplantation, type 2 diabetes, stroke, heart attack, and death; and improves insulin resistance and other extrahepatic manifestations.[2,8,39] In people who have already developed advanced fibrosis or cirrhosis, eradication of the virus reduces the risk of HCC and liver-related mortality; however, as the risk is not eliminated, continued surveillance is required.[4]

DAAs were initially restricted to HCV cases with advanced liver fibrosis due to their high cost.[8] With a lowering of the price of DAAs in Canada in 2017, this restriction was removed in 2018, and people with chronic HCV are now eligible for treatment with DAAs in Ontario and in other Canadian provinces.[8,23,30]

Hepatitis C Cascade of Care

The hepatitis C cascade of care describes the HCV care continuum from HCV testing through linkage to care, treatment, and cure, with the goal of tracking the uptake of each step.[27] This helps identify gaps in the stages of care and helps monitor progress toward achieving the WHO targets.[27]

Hepatitis C Cascade of Care in Ontario

A population-based cohort study from Ontario included people who had HCV antibody and RNA tests performed at the PHO laboratory between January 1, 1999, and December 31, 2018.[27] Among 108,428 people in Ontario who were alive and had a positive HCV antibody test between those dates, 95,002 (87.6%) had an HCV RNA test performed, of whom 59,370 (62.5%) had a positive RNA test result and 56,140 (94.6%) were genotyped. Treatment was initiated in 31,656 (53.3%) people who had a positive HCV RNA test result, and 23,950 (75.9%) of those achieved SVR; 242 (1.0%) either had a reinfection or a relapse after treatment completion.

A prospective study reported on HCV screening and diagnosis, with treatment provided by primary care nurse practitioners working within family health teams in Southwestern Ontario.[40] At most sites, patients were identified during primary care visits performed for reasons not related to HCV and during which laboratory tests were performed. The nurse practitioners were encouraged to screen people based on year of birth (1945–1975) and the presence of risk factors according to the 2018 guidelines from the Canadian Association for the Study of the Liver (CASL). Over 1 year, 9 nurse practitioners prospectively screened 1,026 patients, 17 (1.7%) of whom had a positive HCV antibody test. All patients with a positive HCV antibody test received an HCV RNA test, and 13 (76.5%) had a positive RNA result. HCV treatment was completed by all 12 patients with a positive HCV RNA test who were eligible for treatment. Treatment was provided by a nurse practitioner for 11 patients and by a specialist for 1 patient. SVR was confirmed for 10 (83.3%) patients, and 2 (16.7%) did not return to confirm whether they had attained SVR.

A study reporting on HCV screening at the Centre for Addiction and Mental Health (CAMH) psychiatric hospital in Toronto between January 1, 2017, and May 31, 2021, was also identified; HCV screening was performed at the attending health care provider's discretion either at admission or at any time during the patient's stay.[41] Among 1,031 patients admitted to forensic and nonforensic inpatient units during

the study period, 652 (63.3%) were screened for HCV. A total of 32 (4.9%) patients screened had a positive HCV antibody test; 27 (84.4%) had an HCV RNA test done, of whom 15 (55.6%) had a positive result. Seven of the 15 patients with a positive HCV RNA test were treated on site, of whom 6 completed treatment and were considered cured based on SVR. The remaining 8 patients were referred to a specialist, 3 (37.5%) of whom attended the visits and started treatment. All 3 patients completed treatment, but only 1 returned to be tested to confirm SVR.

Hepatitis C Cascade of Testing in Ontario

The cascade of testing for confirmed HCV cases reported in the integrated Public Health Information System (iPHIS) in Ontario showed that, in 2023, 3,035 (89.1%) of 3,406 HCV cases identified had an HCV RNA test. The HCV RNA test was positive in 1,703 (56.1%) cases, and 1,378 (80.9%) had an HCV genotype test performed.[26]

Hepatitis C Virus Screening

HCV screening aims to identify people with an HCV infection who are not aware of their infection[7,9,42] so that they can be linked to care and treatment.[8] HCV screening and treatment may also prevent transmission between individuals.[3,16,42] Given the nature of the disease (it can remain asymptomatic for decades despite the continuous process of liver injury),[3] early diagnosis and treatment are important to prevent liver damage, the development of advanced liver disease,[2,3] and extrahepatic manifestations.[2]

Risk-based screening presupposes that the risk of exposure – which may have happened decades before – is recognized and acknowledged by either the person or the health care provider.[8,15] However, screening relying entirely on risks being disclosed may miss a large number of people with HCV, as many may identify themselves as low risk,[19] and some health care providers may not be aware of the risk factors associated with HCV.[15] Additionally, people may avoid talking about their risk because of stigma and systemic barriers to health care.[15,43]

Therefore, as it is believed that the risk-based approach led to a low HCV screening rate,[8,15] more general approaches that potentially remove stigma have been suggested.[8,15] This includes, for instance, one-time screening of birth cohorts (e.g., people born between 1945 and 1964 or between 1945 and 1975)[8] or screening the general adult population, in addition to risk-based screening.[15]

Barriers to Hepatitis C Virus Screening

According to a scoping review that included studies from various countries, the 3 main categories of barriers for health care providers to offer HCV screening and testing include (1) time constraints to provide counselling, (2) lack of specific knowledge about who to test, and (3) discomfort discussing HCV with their patients.[42] The review also identified barriers to HCV testing among people who do not inject drugs: lack of knowledge about HCV, self-perceived low risk of infection, fear of a positive diagnosis, stigma and discrimination, and limited access to health care services.[42] A cross-sectional survey of people who inject drugs and access a syringe exchange program in the United States found that barriers to HCV testing included lack of access to transportation, time constraints, and lack of knowledge of testing,[44] in addition to the barriers identified by people who do not inject drugs in the aforementioned scoping review.

Harms of Hepatitis C Virus Screening

A systematic review from the United States Centers for Disease Control and Prevention (CDC)[9] evaluated the harms of HCV screening. The CDC review identified 26 studies, none of which compared different screening approaches. Harms reported in these studies included anxiety and stress related to testing, waiting for test results, or receiving positive results; time for screening; cost; and interpersonal problems related to a positive HCV infection status. As these studies were conducted in other countries, not all findings may be applicable to Canada or Ontario.

The authors of the CDC report concluded that the identified or potential harms did not outweigh the benefits of screening.[9] Similarly, in making its HCV screening recommendations, the United States Preventive Services Task Force considered that "there is adequate evidence to bound the overall harms of screening and treatment as small based on the known harms of treatment, the high accuracy of screening, and the low likelihood of harms from a blood draw" (Appendix 2). [45]

Regulatory Information

Screening is not subject to Health Canada approval.

Hepatitis C Virus Screening Recommendations in Canadian and International Jurisdictions

We identified some HCV screening recommendations from Canadian, American, Australian, and European organizations (Appendix 2).[7-9,15,16,45-49]

Most were published after the restrictions on the use of DAAs were removed. Factors generally considered when making the recommendations included the HCV prevalence in some population groups, the burden of liver disease in its advanced stages, and the availability of curative DAA treatment that prevents the development of HCV-related consequences.[7]

Some of these documents also include recommendations on HCV prevention, patient and provider education, linkage to care, and treatment, which are not included in this report.

Canada

The Canadian Task Force on Preventive Health Care[46] recommendations were published in April 2017 (at which time, treatment was restricted to people with advanced liver fibrosis). The document recommends against HCV screening of asymptomatic adults without a risk factor (Table 4). Canadian recommendations published from 2018 to 2023 recommend HCV screening in the 1945–1975 birth cohort or the general adult population, in addition to risk-based screening (Table 4).[7,8,15,47]

Table 4: HCV Screening Recommendations in Canada

Publication title or organization, year	Recommendations
Ontario Hepatitis C Elimination Roadmap, 2023[15]	• Expand HCV testing beyond risk-based screening: develop guidelines for one-time HCV screening and testing as a part of routine primary care for all adults and for people who are pregnant in Ontario • Promote routine screening for all clients in key care settings, including sexual health clinics, hospital emergency rooms, addiction treatment services, and mental health settings The document also provides recommendations specific to the various priority populations
British Columbia Ministry of Health, 2021[47]	• One-time HCV testing for people born between 1945 and 1965 should be considered • One-time HCV testing for people who immigrated from endemic areas is recommended • Annual HCV testing for people with ongoing risks for infection or reinfection is indicated

Blueprint to Inform Hepatitis C Elimination Efforts in Canada, 2019[8]	Suggested activities:
	• Increase diagnosis among the 1945–1975 birth cohort
	  • Implement one-time HCV testing in this population
	  • Improve reach of, access to, and availability of HCV screening and testing services across all medical settings
	• Increase diagnosis among people who are members of the priority populations[a] and/or those who are at ongoing risk, by expanding the reach of and access to testing
	The document also provides policy and service delivery recommendations specific to each priority population and the 1945–1975 birth cohort

Canadian Association for the Study of the Liver, 2018[7]	• To increase the identification of the large proportion of people with undiagnosed HCV, CASL recommends that screening be both risk-based and target the 1945–1975 birth cohort, which currently encompasses most people chronically infected with HCV in Canada • Annual HCV RNA testing to assess for reinfection is suggested in cases where there is continued risk of HCV exposure
Canadian Task Force on Preventive Health Care, 2017[46,50]	• Recommends against screening for HCV in asymptomatic Canadian adults (including baby boomers) who are not at elevated risk of HCV infection • This recommendation does not apply to pregnant women or adults who are at elevated risk for HCV [b]

Abbreviation: CASL, Canadian Association for the Study of the Liver; HCV, hepatitis C virus.

[a]People who inject or use drugs, Indigenous people (First Nations, Inuit, Métis), people with experience in the federal or provincial prison system, immigrants and newcomers from countries where HCV is common, and men who have sex with men.[8]

[b]People with current or a history of injection drug use; individuals who have been incarcerated; individuals who were born, travelled to, or resided in HCV-endemic countries; individuals who have received health care where there is a lack of universal precautions; recipients of blood transfusions, blood products, or organ transplant in Canada before 1992; patients on hemodialysis; individuals who have had needlestick injuries; individuals who have engaged in other risks sometimes associated with HCV exposure, such as high-risk sexual behaviours, homelessness, intranasal and inhalation drug use, tattooing, body piercing, or sharing sharp instruments or personal hygiene materials with someone who is HCV positive; and anyone with clinical clues suspicious for HCV infection (and above risk factors).[46]

Other Countries

The CDC,[9] the United States Preventive Services Task Force,[45] and the American Association for the Study of Liver Diseases (AASLD) in conjunction with the Infectious Diseases Society of America (IDSA)[48] recommend one-time HCV screening of adults in addition to risk-based HCV screening.[45] The CDC and the AASLD/IDSA also recommend prenatal screening during every pregnancy.[9,48]

In Australia, according to a 2022 consensus statement from the Hepatitis C Virus Infection Consensus Statement Working Group, all people with an HCV risk factor should be screened for HCV.[49]

The scientific advice from the European Centre for Disease Prevention and Control's (ECDC's)[16] 2018 public health guidance on HIV, hepatitis B, and hepatitis C testing for the European Union/European Economic Area states that targeted HCV screening should be performed according to risk factors and the presence of suggestive clinical symptoms, in addition to testing people diagnosed with HIV or hepatitis B

virus infection. The document also stated that screening for the general population may also be considered (e.g., universal testing in high-prevalence areas or birth-cohort testing) on a country-specific basis according to epidemiological and financial considerations.[16]

Appendix 2 provides additional information about screening recommendations in other countries.

Equity Context

We use the PROGRESS-Plus framework[51] to help explicitly consider health equity in our health technology assessments. PROGRESS-Plus is a health equity framework used to identify population and individual characteristics across which health inequities may exist. These characteristics include place of residence; race or ethnicity, culture or language; gender or sex; disability; occupation; religion; education; socioeconomic status; social capital; and other key characteristics (e.g., age) that stratify health opportunities and outcomes.

Some populations have been identified as being disproportionately affected by HCV: people who inject or use drugs, Indigenous people (First Nations, Inuit, Métis), people with experience in the federal or provincial prison system, immigrants and newcomers from countries where HCV is common, and men who have sex with men.[8]

In Ontario, health care providers may perform HCV screening for people with certain risk factors and for people disproportionately affected by HCV, as previously described (see the Hepatitis C Virus Testing in Ontario section, above). Additionally, the Ontario Hepatitis C Teams, which are located across the province, aim to improve access to HCV prevention, screening, and care services for populations who face barriers to accessing mainstream health services (i.e., people who use drugs, Indigenous people, people with experience of incarceration, people who are unhoused or underhoused, and street-involved youth).[33]

Our review aims to assess HCV screening for the general adult population and for the 1945–1975 birth cohort to identify individuals who have an HCV infection. HCV screening for the general adult population or for the 1945–1975 birth cohort aims to provide screening without attempting to identify risk factors.[5] Cases in people who are disproportionally affected by HCV may also be identified through screening the general population, but this review does not focus on studies in these specific populations.

Ethical Considerations

The 10 principles that should be used to assess whether screening is appropriate to improve public health according to Wilson and Jungner[52] are listed below:

1) The condition should be an important health problem
2) There should be an accepted treatment for patients with recognized disease
3) Facilities for diagnosis and treatment should be available
4) There should be a recognizable latent or early symptomatic phase
5) There should be a suitable test or examination
6) The test should be acceptable to the population
7) The natural history of the condition, including development from latent to declared disease, should be adequately understood

8) There should be an agreed policy on whom to treat as patients
9) The cost of case-finding (including a diagnosis and treatment of patients diagnosed) should be economically balanced in relation to possible expenditure on medical care as a whole
10) Case-finding should be a continuous process and not a "once and for all" project

A 2021 health technology assessment from the Health Information and Quality Authority (HIQA)[4] in Ireland that evaluated HCV screening for the 1965–1985 birth cohort discussed ethical considerations for HCV screening within the Irish context. The evaluation included the following domains: (1) benefits and harm balance (safety of testing, stigma, timely intervention, overtreatment, prevalence within the birth cohort), (2) acceptability (testing, treatment, autonomy and shared decision-making), (3) justice and equity (factors influencing access, use of resources), and (4) ethical consequences of the health technology assessment (choice of outcomes, timing of the assessment, data sources).[4] The key points of the HIQA report[4] are as follows:

- Benefit–harm balance: birth-cohort screening could result in a large number of people being tested, approximately 1% of whom are expected to benefit directly by HCV infection detection and treatment
  - The harms associated with getting tested are considered low
  - Given the high test accuracy, the risk of false-positive and false-negative results is relatively low
- The economic evaluation concluded that it would be an efficient use of resources
- As stigma is often associated with HCV, birth-cohort screening must be performed in a way that is sensitive to stigma and ensures best uptake and treatment completion
- Birth-cohort screening could, over a relatively short period of time, identify a large number of people infected with HCV compared with risk-based screening, which could lead to issues with providing timely treatment for all patients if there are capacity constraints
- Health service utilization from birth-cohort screening could displace other care, especially in the primary care setting, and increase demand for primary care, which may affect the availability of services
- A number of important ethical considerations, including issues relating to benefit–harm balance, acceptability, and equity of access, could be addressed by requiring any birth-cohort screening to meet WHO criteria for effective screening programs (i.e., requiring mechanisms for systematic invitation and follow-up, a participation rate of over 70%, adequate infrastructure and resourcing to ensure diagnosis and treatment, and a monitoring and evaluation framework)

Expert Consultation

We engaged with experts in the specialty areas of health economics, laboratory medicine, public health, and nursing, as well as clinicians and researchers with expertise in hepatology and primary care, to help inform the development and refinement of the research questions, review methods, and review results, as well as to contextualize the evidence on HCV screening to Ontario.

PROSPERO Registration

This health technology assessment has been registered in PROSPERO, the international prospective register of systematic reviews (CRD42025641633), available at crd.york.ac.uk/PROSPERO.

Clinical Evidence

Our review aimed to assess 2 hepatitis C virus (HCV) screening approaches: (1) one-time screening of all adults plus risk-based screening and (2) one-time screening of people born between 1945 and 1975 (1945–1975 birth cohort) plus risk-based screening. We compared each approach with risk-based screening alone to evaluate their ability to identify people with HCV so that they can be linked to care and treatment.

Research Questions

1) What is the effectiveness of (1) one-time HCV screening for all adults plus risk-based HCV screening and (2) one-time HCV screening for the 1945–1975 birth cohort plus risk-based HCV screening compared with risk-based HCV screening alone to identify people with HCV?
2) What is the effectiveness of one-time HCV screening for all adults plus risk-based HCV screening compared with one-time HCV screening for the 1945–1975 birth cohort plus risk-based HCV screening to identify people with HCV?

Information about risk-based HCV screening in Ontario is provided in the Hepatitis C Virus Testing in Ontario section, above.

Out of Scope

We did not evaluate the diagnostic accuracy of HCV tests (antibody, ribonucleic acid [RNA]), as these are established tests that have been recommended by the World Health Organization (WHO)[5] and are considered accurate.[53] Comparisons between different forms of specimen collection (i.e., venipuncture vs. finger-prick for point-of-care or dried-blood-spot testing) were also not evaluated.

We did not assess strategies aiming to increase screening uptake (e.g., screening location, outreach, education, incentives) as part of this review. We also did not evaluate the harms of HCV screening, as the harms have been assessed and deemed acceptable by other reviews.[9,45]

Methods

Clinical Literature Search

We performed a clinical literature search on December 4, 2024, to retrieve studies published from January 1, 2014, until the search date. We used the Ovid interface in the following databases: MEDLINE, Embase, the Cochrane Central Register of Controlled Trials, the Cochrane Database of Systematic Reviews, the National Health Service Economic Evaluation Database (NHS EED), and the Cumulative Index to Nursing and Allied Health Literature (CINAHL).

A medical librarian developed the search strategies using controlled vocabulary (e.g., Medical Subject Headings) and relevant keywords. The final search strategy was peer-reviewed using the PRESS Checklist.[54]

We created database auto-alerts in MEDLINE, Embase, and CINAHL and monitored them until March 24, 2025. We also performed a targeted grey literature search of the International HTA Database, the websites of health technology assessment organizations and regulatory agencies, and clinical trial and systematic review registries, following a standard list of sites developed internally. See Appendix 3 for our literature search strategies, including all search terms.

Eligibility Criteria

Studies

Inclusion Criteria

- English-language full-text publications
- Studies published since January 1, 2014, as this is approximately when direct-acting antivirals (DAAs) were introduced
- Studies from Canada, the United States, Europe, Australia, and New Zealand
- Randomized controlled trials and comparative observational studies
- Systematic reviews and health technology assessments: we considered leveraging existing work, taking into account factors such as recency, quality, and relevance to the research questions

Exclusion Criteria

- Modelling studies, editorials, commentaries, case reports, conferences abstracts, and letters
- Animal and in vitro studies

Participants

Inclusion Criteria

- Adults (≥ 18 years) who are asymptomatic, who are not suspected of having an HCV infection (based on an absence of clinical signs or symptoms or on laboratory findings), who have not previously been treated for HCV, and who have not previously had a positive HCV test
  - May include adults belonging to a birth cohort (e.g., 1945–1975)
  - May include pregnant people, but studies specific to prenatal testing strategies were excluded
  - Studies on a mixed population were included if results were reported separately or if 80% or more of the population met the eligibility criteria

Exclusion Criteria

- Children and adolescents (< 18 years)
- Studies that focused on people with known risk factors, those suspected of having an HCV infection, or populations disproportionately affected by HCV as previously described
  - Studies that included screening according to risk factors in addition to screening of the adult population or birth cohort as described above were included

Interventions

Inclusion Criteria

- One-time HCV screening for the birth cohort (1945–1975) plus risk-based HCV screening
  - Studies that evaluated screening of a birth cohort that did not match the 1945–1975 birth cohort exactly but encompassed at least part of it were included

Or

- One-time HCV screening for adults (≥ 18 years) plus risk-based HCV screening

Note: Studies could include HCV antibody testing alone or followed by HCV RNA testing if the antibody test was positive. Various methods of testing could be included (e.g., venipuncture, dry blood spot, point of care).

Exclusion Criteria

- Risk-based screening alone
- Studies specific to prenatal HCV screening
- Studies evaluating HCV prevalence
- Studies focused on evaluating testing or implementation strategies aiming to increase screening uptake (e.g., screening location, outreach, education, incentives)
  - Studies that incorporated interventions to improve screening uptake were considered eligible if they matched the population, intervention, and comparator eligibility criteria
- Studies focused on evaluating specific types of HCV tests such as dry-blood-spot or point-of-care testing
- Studies performed before the introduction of DAAs at the study site

Comparators

Inclusion Criteria

- Research question 1: Risk-based HCV testing using criteria similar to those used in Ontario
- Research question 2: One-time HCV screening for adults or one-time HCV screening for the 1945–1975 birth cohort plus risk-based HCV screening, depending on the intervention evaluated
  - Studies that included a birth cohort that did not match the 1945–1975 birth cohort exactly but encompassed at least part of it were included

Outcome Measures

- Identification of people with HCV
- Screening uptake
- Percentage of people with HCV identified who were linked to care and treatment
- Reduced HCV transmission

- Treatment outcomes (cure or sustained virologic response [SVR]) and adverse events
- Clinical outcomes (HCV-related morbidity [e.g., cirrhosis, hepatocellular carcinoma (HCC)], liver transplantation, extrahepatic manifestations, and mortality)

Literature Screening

Two reviewers screened titles and abstracts to assess the eligibility of a sample of 100 citations to validate the inclusion and exclusion criteria. A single reviewer then screened all remaining citations using Covidence[55] and obtained the full texts of studies that appeared eligible for review according to the inclusion criteria. The same reviewer then examined the full-text articles and selected studies eligible for inclusion. The reviewer also examined reference lists and consulted content experts for any additional relevant studies not identified through the search.

Data Extraction

We extracted relevant data on study characteristics and risk-of-bias items using a data form to collect information on the following:

- Source (e.g., citation information, study type)
- Methods (e.g., study design, study duration and years, participant allocation, allocation sequence concealment, blinding, reporting of missing data, reporting of outcomes, whether the study compared 2 or more groups)
- Outcomes (e.g., outcomes measured, number of participants for each outcome, number of participants missing for each outcome, outcome definition and source of information, unit of measurement, upper and lower limits [for scales], time points at which the outcomes were assessed)

We contacted study authors to provide clarification as needed.

Equity Considerations

Our review aimed to assess HCV screening for adults, including those born between 1945 and 1975, to identify people with HCV in the general population, which encompasses the priority populations.

Potential equity issues related to the research questions in the adult population were not evident during scoping. However, we report the available characteristics of participants in the included studies (e.g., PROGRESS-PLUS characteristics, groups belonging to populations disproportionally affected by HCV) where provided in the studies.

Statistical Analysis

We did not perform a meta-analysis due to differences in outcome reporting across studies.

We calculated *P* values using a chi-square test for some outcomes when the information was not provided in the studies.

We were unable to undertake subgroup analyses because the information was not provided in the studies.

Critical Appraisal of Evidence

We assessed risk of bias using the Risk of Bias in Nonrandomized Studies – of Interventions (ROBINS-I) tool[56] (Appendix 4).

We evaluated the quality of the body of evidence for each outcome according to the *Grading of Recommendations Assessment, Development, and Evaluation* (GRADE) *Handbook*.[57] The body of evidence was assessed based on the following considerations: risk of bias, inconsistency, indirectness, imprecision, and publication bias. The overall rating reflects our certainty in the evidence.

Results

Clinical Literature Search

The clinical literature search yielded 3,290 citations, including grey literature results and after removing duplicates, published between January 1, 2014, and December 4, 2024. We did not identify any additional eligible studies from other sources, including database alerts (monitored until March 24, 2025). In total, we identified 3 studies[43,58,59] (all observational) that met our inclusion criteria. See Appendix 5 for a list of selected studies excluded after full-text review. Figure 1 presents the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) flow diagram for the clinical literature search.

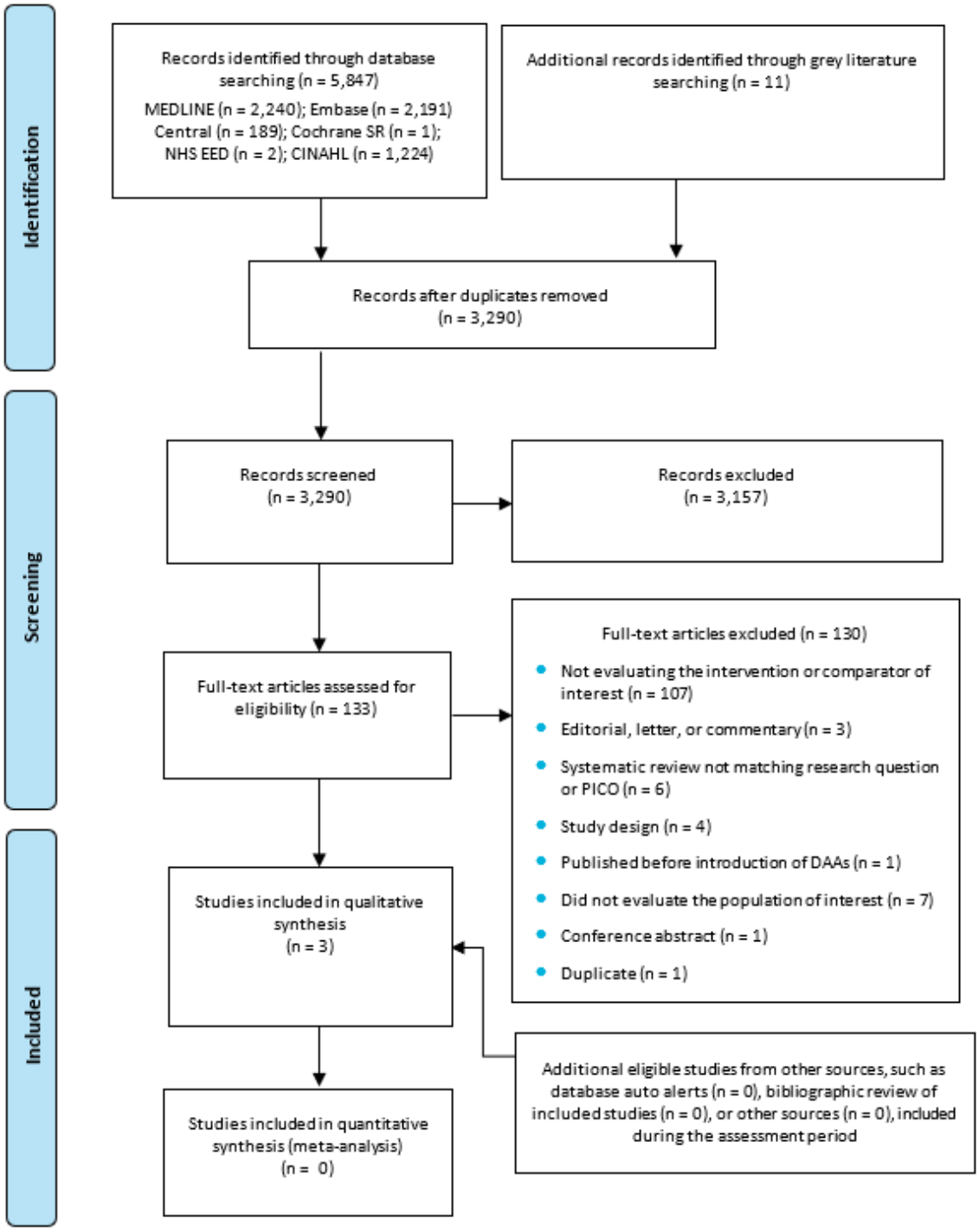

Figure 1: PRISMA Flow Diagram – Clinical Systematic Review

PRISMA flow diagram showing the clinical systematic review. The clinical literature search yielded 3,290 citations, including grey literature results and after removing duplicates, published between January 1, 2014, and December 4, 2024. We screened the abstracts of the 3,290 identified studies and excluded 3,157. We assessed the full text of 133 articles and excluded a further 130. In the end, we included 3 articles in the qualitative synthesis.[43,58,59]

Abbreviations: CINAHL, Cumulative Index to Nursing and Allied Health Literature; Cochrane SR, Cochrane Database of Systematic Reviews; DAAs, direct-acting antivirals; NHS EED, National Health Service Economic Evaluation Database; PICO, population, intervention, comparator, outcomes; PRISMA, Preferred Reporting Items for Systematic Reviews and Meta-analyses.

Source: Adapted from Page et al.[55]

Characteristics of Included Studies

We identified 3 observational studies that addressed part of research question 1 (i.e., comparing HCV screening for adults aged 18 years and older plus risk-based screening versus risk-based screening alone),[43,58,59] but we did not identify any studies that evaluated HCV screening for the 1945–1975 birth cohort or any studies comparing the 2 screening approaches (research question 2).

Two of the 3 studies identified included adults seeking care at an emergency department,[43,58] and 1 study reported on a national HCV screening program for adults performed at primary care centres.[59] The studies were conducted in Spain,[58] Lithuania,[59] and the United States.[43]

Outcomes reported in the studies included the percentage of people screened, percentage of people with positive antibody and RNA tests, percentage of people previously unaware of the infection, liver fibrosis status, and percentage of people linked to care. One study reported on the absolute number of people treated with DAAs, but the information was not provided as a percentage of people screened and diagnosed with an HCV infection.[43,58,59]

In the study by Camelo-Castillo et al,[58] HCV screening was implemented between August 2021 and April 2023 for adults 18 to 69 years old seeking urgent medical care at an emergency department in Spain who required a blood test during the visit and who had not had an HCV test in the previous year in the catchment area where the study was conducted. The study also reported on risk-based screening according to clinical symptoms and medical judgment performed at the same time as the intervention and during the comparator period (December 2019 to July 2021). A total of 22,712 adults were considered eligible for HCV screening, and 267 people were screened through risk-based screening during the comparator period.

In the study by Petkevičienė et al,[59] which included the participation of all primary health care centres in Lithuania, adults born between 1945 and 1994 were invited for one-time HCV screening during routine general practitioner visits; people of any age who presented with risk factors (intravenous drug use or HIV) were invited for screening annually. The study was performed between May 5, 2022, and April 30, 2023. Approximately 1.8 million people in Lithuania were born between 1945 and 1994 and were thus eligible for the study.

The study by Wojcik et al[43] included adults (≥ 18 years old) seeking care at an emergency department in the United States who had not been screened for HCV in the previous year and who required a blood test during their visit. The electronic medical records system was programmed to issue an alert for HCV screening to be performed for those considered eligible during each study period. During the intervention period (June 1, 2018, to October 31, 2018), an alert was issued annually for adults with no risk factors and quarterly if risk factors were present. During the comparator period (January 1, 2018, to May 31, 2018), an alert was issued for adults with risk factors based on the United States Centers for Disease Control and Prevention (CDC) criteria and for people with complaints related to intravenous drug use. People could opt out of screening and health care providers could decline testing if it was considered irrelevant to people's acute care needs or if additional laboratory tests were not requested during the emergency department visit. A total of 31,422 adults were eligible for HCV screening during the study periods.

Appendix 6 provides additional information about the characteristics of the included studies.

Characteristics of Participants in the Included Studies

In the study by Camelo-Castillo et al,[58] among 11,368 adults screened, 5,529 (48.6%) were between 18 and 49 years old, and the remainder were between 50 and 69 years old; 5,797 (51%) were male, and 9,788 (86.1%) were of Spanish nationality.

In the study by Petkevičienė et al,[59] among 790,070 adults screened during the study period, 438,852 (55.5%) were born between 1965 and 1994, and 330,466 (41.8%) were male.

In the study by Wojcik et al,[43] among 444 people with a positive HCV antibody test, the median ages were 40 years in the adult plus risk-based screening group and 39 years in the risk-based screening group. Of the participants, 275 (61.9%) were male. With regard to race and ethnicity, 405 (91.2%) were white, 20 (4.5%) were African American, and 1 (0.2%) was Hispanic; for 19 (4.3%), either more than 1 ethnicity was reported or the information was not reported.

Appendix 7 provides additional information about participant characteristics.

Risk of Bias in the Included Studies

The risk of bias was considered low in the studies identified due to the low risk of selection bias and the completeness of the outcome data (Appendix 4).

Percentage of People Screened

In the study by Camelo-Castillo et al,[58] during the 20-month intervention period (August 9, 2021, to April 8, 2023), out of 22,712 eligible adults (aged 18 to 69 years) seeking care at an emergency department in Spain, 11,368 (50.1%) were screened using HCV antibody testing based on either age or risk-based screening criteria. Reasons for not being screened included patient refusal or problems with sample collection (breakdown not provided). During the 20-month comparator period (December 9, 2019, to August 8, 2021), 267 people received risk-based screening (percentage screened not available because the number of eligible people was not provided).

In the study by Petkevičienė et al,[59] during 1 year (May 2022 to April 2023), out of approximately 1.8 million adults living in Lithuania who were born between 1945 and 1994, 790,070 (44%) were screened using HCV antibody testing, including 783,375 people screened based on the age criterion and 6,695 people of any age who received risk-based screening (percentage screened not available because the number of eligible people was not provided).

In the study by Wojcik et al,[43] during a 5-month period (June 1, 2018, to October 31, 2018), out of 16,454 adults seeking care at an emergency department in the United States, 5,407 (32.9%) were screened using HCV antibody testing in the adult screening plus risk-based screening group. During the 5-month comparator period (January 1, 2018, to May 31, 2018), 3,014 of 14,968 (20.1%) adults were screened due to the presence of risk factors ($P < .001$ [calculated by the authors of this health technology assessment]). Reasons for not screening may have included that a blood test was not always required during the emergency department visit and a lack of consistency in provider compliance when a screening alert was triggered.

Appendix 7 provides additional information about the percentage of people screened.

The GRADE quality of the evidence was considered Very low due to the observational nature of the studies identified and concerns with the generalizability of study results to HCV screening for adults in Ontario (Appendix 4).

Percentage of People With a Positive Hepatitis C Virus Antibody Test

In the study by Camelo-Castillo et al,[58] 199 (1.75%) of 11,368 people screened in the adult plus risk-based screening group had a positive HCV antibody test. Information for the risk-based screening alone group was not provided.

In the study by Petkevičienė et al,[59] a positive HCV antibody test was reported in 11,943 (1.5%) of the 790,070 people screened in the adult plus risk-based screening group and in 2,087 (31.1%) of the 6,695 people screened through risk-based screening alone ($P < 0.00001$ [calculated by the authors of this health technology assessment]).

In the study by Wojcik et al,[43] a positive HCV antibody test was reported in 318 (5.9%) of 5,407 people screened in the adult plus risk-based screening group and in 126 (4.2%) of 3,014 adults screened in the risk-based screening alone group ($P < .001$).

Appendix 7 provides additional information about the percentage of people with a positive HCV antibody test.

The GRADE quality of the evidence was considered Very low due to the observational nature of the studies identified, inconsistency in study results, and concerns with the generalizability of study results to HCV screening for adults in Ontario (Appendix 4).

Percentage of People With a Positive Hepatitis C Virus RNA Test

In the study by Camelo-Castillo et al,[58] a positive HCV RNA test was reported in 43 people in the adult plus risk-based screening group, representing 21.6% of the 199 people with a positive antibody test and 0.38% of the 11,368 people screened. According to the authors, no one was diagnosed with a viral infection in the emergency department in the year prior to the start of the study.

In the study by Wojcik et al,[43] a positive HCV RNA test was reported in 186 adults in the adult plus risk-based screening group, representing 58.5% of the 318 people with a positive HCV antibody test and 3.4% of the 5,407 people screened. Risk-based screening alone identified 76 adults with a positive HCV RNA test, representing 60.3% of the 126 people with a positive HCV antibody test and 2.5% of the 3,014 people screened. The difference between the 2 groups was statistically significant among people screened ($P = .02$ [calculated by the authors of this health technology assessment]) but not among people with a positive HCV antibody test ($P = .72$).

Petkevičienė et al[59] did not report the percentage of people with a positive HCV RNA test.

Appendix 7 provides additional information about the percentage of people with a positive HCV RNA test.

The GRADE quality of the evidence for the percentage of people with a positive RNA test among those screened was considered Very low due to the observational nature of the studies identified and

concerns with the generalizability of the study results to HCV screening for adults in Ontario (Appendix 4).

Percentage of People Previously Unaware of Their Hepatitis C Virus Infection

The study by Camelo-Castillo et al[58] reported that 24 (55.8%) of 43 people with a positive HCV RNA test were previously unaware of their infection (previously undiagnosed), whereas Wojcik et al[43] reported that 229 (72%) of 318 people with a positive HCV antibody test in the adult plus risk-based screening group and 86 (68.3%) of 126 people in the risk-based screening alone group had not been diagnosed previously (*P* = .44 [calculated by the authors of this health technology assessment]). The study by Petkevičienė et al[59] did not report the percentage of people previously unaware of their HCV infection.

Appendix 7 provides additional information about the percentage of people previously unaware of their HCV infection.

The GRADE quality of the evidence was considered Very low due to the observational nature of the studies identified and concerns with the generalizability of the study results to HCV screening for adults in Ontario (Appendix 4).

Liver Fibrosis Status

Only the study by Camelo-Castillo et al[58] assessed the degree of liver fibrosis. In this study, 38 of 43 people had a positive HCV RNA test and had sufficient information for the authors to calculate fibrosis scores using the Aspartate Aminotransferase to Platelet Ratio Index (APRI) and the Fibrosis-4 (FIB-4) Index.[58] Additionally, 18 of 43 people with a positive HCV RNA test underwent transient elastography to assess the degree of liver fibrosis. Among 38 people for whom APRI and FIB-4 scores could be calculated, 9 (23.7%) and 10 (26.3%), respectively, had advanced liver fibrosis or cirrhosis (Table 5).[58] Among 18 people who underwent transient elastography, 7 (38.8%) were found to have advanced liver fibrosis or cirrhosis (Table 5). According to the authors, this indicates that the diagnosis occurred at a late stage of the HCV infection.

Table 5: Liver Fibrosis Status

Author, year	APRI score[a] at diagnosis, n (%)	FIB-4 score[b] at diagnosis, n (%)	Transient elastography, n (%)
Camelo-Castillo et al, 2024[58]	N = 38 < 0.5 (no or moderate liver fibrosis): 16 (42.1) 0.5–1.5 (undetermined): 13 (34.2) 1.5–2.0 (advanced liver fibrosis): 4 (10.5) > 2.0 (cirrhosis): 5 (13.1)	N = 38 < 1.45 (no or moderate liver fibrosis): 11 (28.9) 1.45–3.25 (undetermined): 17 (44.7) > 3.25 (advanced fibrosis): 10 (26.3)	N = 18 F0 (no fibrosis): 5 (27.7) F1 (mild fibrosis): 4 (22.2) F2 (moderate fibrosis): 2 (11.1) F3 (advanced fibrosis): 1 (5.5) F4 (cirrhosis): 6 (33.3)

Abbreviations: APRI, Aspartate Aminotransferase to Platelet Ratio Index; FIB-4, Fibrosis-4.

[a]Calculated using the aspartate aminotransferase value, its laboratory upper limit, and the platelet count.[58]

[b]Calculated using the aspartate aminotransferase and alanine aminotransferase values, the platelet count, and age.[58]

The GRADE quality of the evidence for this outcome was not assessed because a comparison between groups was not provided in the study identified.

Percentage of People Linked to Care

In the study by Camelo-Castillo et al,[58] among 43 people with a positive HCV RNA test in the adult plus risk-based screening group, 37 (86%) were contacted for a medical consultation (6 [14%] could not be contacted due to lack of contact information or death). Four (10.8%) of 37 people contacted were not linked to a medical consultation owing to concomitant conditions or refusal of the proposal for possible treatment. The remaining 33 (76.7%) people contacted were linked to care, of whom 24 had a medical consultation and 9 did not owing to death, failure to attend the scheduled consultations, or incarceration. The outcome was not assessed in the risk-based screening alone group.

In the study by Wojcik et al,[43] 205 (64.5%) of 318 people with a positive HCV antibody test in the adult plus risk-based screening group and 59 (46.8%) of 126 people with a positive HCV antibody test in the risk-based screening alone group were linked to care (*P* = .004 [calculated by the authors of this health technology assessment]), defined as a follow-up contact with a primary care or specialty provider through consultation or medical appointment.

Petkevičienė et al[59] did not report the percentage of people linked to care.

Appendix 7 provides additional information about the percentage of people linked to care.

The GRADE quality of the evidence was considered Very low due to the observational nature of the studies identified and concerns with the generalizability of study results to HCV screening for adults in Ontario (Appendix 4).

Number of People Treated with Direct-Acting Antivirals

Petkevičienė et al[59] reported that 2,581 people received DAA treatment during the 1-year study period (treatment criterion: liver fibrosis stage ≥ F2). The results were not provided as a percentage of the people who had a positive HCV RNA test.

The GRADE quality of the evidence for this outcome was not assessed because no comparison between groups was provided in the study identified.

Discussion

Our systematic review identified 3 observational studies[43,58,59] that evaluated HCV screening for adults plus risk-based screening compared with risk-based screening alone. Screening was performed in one-third to one-half of eligible adults[43,58,59] and, based on 1 study,[43] 20% of adults in the risk-based group. The study findings suggest that more HCV infections were identified through HCV screening for adults plus risk-based screening compared with risk-based HCV screening alone.[43,58,59]

Two studies reported that a large percentage of the HCV infections identified had not been diagnosed previously,[43,58] indicating that a large percentage of people were unaware that they had an HCV infection.[58]

Strengths and Limitations

The 3 studies identified evaluated HCV screening in large populations, but none was conducted in Canada. Additionally, 1 study was performed in primary care practices,[59] and 2 were performed at single

emergency departments[43,58]; although these studies included a general adult population, emergency departments may be overrepresented by a population with risk factors for HCV and poor access to primary care services.[43] These factors may affect the generalizability of the results to HCV screening in a general adult population in Ontario.

The comparative results were based primarily on 1 study.[43]

No studies evaluated screening for the 1945–1975 birth cohort, and none reported on some of the outcomes that we planned to assess (e.g., reduced HCV transmission, treatment and clinical outcomes).

Conclusions

The results of the studies identified suggest that one-time HCV screening for all adults plus risk-based HCV screening may identify more people with HCV and may result in more people with HCV being linked to care compared with risk-based HCV screening alone. However, the evidence is very uncertain due to concerns with the generalizability of the results to HCV screening for adults in Ontario (GRADE: Very low).

We identified no studies evaluating one-time HCV screening for the 1945–1975 birth cohort plus risk-based HCV screening or comparing one-time HCV screening for adults versus the 1945–1975 birth cohort in addition to risk-based HCV screening.

We identified no randomized controlled trials evaluating the effect of HCV screening on the development of long-term consequences of HCV such as decompensated cirrhosis, hepatocellular carcinoma, and HCV-related mortality.

Economic Evidence

Research Question

What is the cost-effectiveness of (1) one-time hepatitis C virus (HCV) screening for all adults plus risk-based HCV screening and (2) one-time HCV screening for people born between 1945 and 1975 (1945–1975 birth cohort) plus risk-based HCV screening, compared with risk-based HCV screening alone?

Methods

Economic Literature Search

We performed an economic literature search on December 9, 2024, to retrieve studies published from January 1, 2014, until the search date. To retrieve relevant studies, we developed a search using the clinical search strategy with an economic and costing filter applied. We used the Ovid interface in the following databases: MEDLINE, Embase, the Cochrane Central Register of Controlled Trials, the Cochrane Database of Systematic Reviews, the National Health Service Economic Evaluation Database (NHS EED), and the Cumulative Index to Nursing and Allied Health Literature (CINAHL).

We created database auto-alerts in MEDLINE, Embase, and CINAHL, and monitored them until July 8, 2025. We also performed a targeted grey literature search following a standard list of websites developed internally, which includes the International HTA Database and the Tufts Cost-Effectiveness Analysis Registry. See Clinical Literature Search, above, for further details on methods used. See Appendix 3 for our literature search strategies, including all search terms.

Eligibility Criteria

Studies

Inclusion Criteria

- English-language full-text publications
- Studies published since January 1, 2014, as this is approximately when direct-acting antivirals (DAAs) were introduced
- Studies from Canada, the United States, Europe, Australia, and New Zealand
- Cost-effectiveness analyses and cost–utility analyses

Exclusion Criteria

- Studies in which the outcomes of interest are not reported or cannot be extracted
- Nonsystematic reviews, editorials, case reports, commentaries, conference abstracts, letters, and unpublished studies
- Noncomparative costing studies and feasibility analyses

Population

Inclusion Criteria

- Adults (≥ 18 years) who are asymptomatic, who are not suspected of having an HCV infection (based on an absence of clinical signs or symptoms or on laboratory findings), who have not previously been treated for HCV, and who have not previously had a positive HCV test
  - May include adults belonging to a birth cohort (e.g., 1945–1975)
  - May include pregnant people, but studies specific to prenatal testing strategies were excluded
  - Studies on a mixed population were included if results were reported separately or if 80% or more of the population met the eligibility criteria

Exclusion Criteria

- Children and adolescents (< 18 years)
- Studies that focused on people with known risk factors, those suspected of having an HCV infection, or populations disproportionately affected by HCV as previously described

Interventions

Inclusion Criteria

- One-time HCV screening for the birth cohort (1945–1975) plus risk-based HCV screening
  - Studies that evaluate screening of a birth cohort that does not match the 1945–1975 birth cohort exactly but encompass at least part of this cohort were included

Or

- One-time HCV screening for adults (≥ 18 years) plus risk-based HCV screening

Note: Studies could include HCV antibody testing alone or followed by HCV ribonucleic acid (RNA) testing if the antibody test was positive. Various methods of testing could be included (e.g., venipuncture, dry blood spot, point of care).

Exclusion Criteria

- Risk-based screening alone
- Studies specific to prenatal HCV screening
- Studies evaluating HCV prevalence
- Studies focused on evaluating testing or implementation strategies aiming to increase screening uptake (e.g., screening location, outreach, education, incentives)
  - Studies that matched the population, intervention, and comparator eligibility criteria but also incorporated interventions to improve screening uptake were considered eligible
- Studies focused on evaluating specific types of HCV tests such as dry-blood-spot or point-of-care testing

- Studies performed before the introduction of DAAs at the study site

Comparator

- Risk-based HCV screening alone

Outcome Measures

- Costs
- Health outcomes (e.g., quality-adjusted life-years [QALYs])
- Incremental costs
- Incremental effectiveness
- Incremental cost-effectiveness ratios (ICERs)

Literature Screening

A single reviewer conducted an initial screening of titles and abstracts using Covidence[55] and then obtained the full texts of studies that appeared eligible for review according to the inclusion criteria. The same reviewer then examined the full-text articles and selected studies eligible for inclusion. The reviewer also examined reference lists and consulted content experts for any additional relevant studies not identified through the search.

Data Extraction

We extracted relevant data on study characteristics and outcomes to collect information about the following:

- Source (e.g., citation information, study type)
- Methods (e.g., study design, analytic technique, perspective, time horizon, population, intervention[s], comparator[s])
- Outcomes (e.g., health outcomes, costs, ICERs)

Study Applicability and Limitations

We determined the usefulness of each identified study for decision-making by applying a modified quality appraisal checklist for economic evaluations originally developed by the National Institute for Health and Care Excellence (NICE) in the United Kingdom.[60] The NICE checklist has 2 sections: the first is for assessing study applicability, and the second is for assessing study limitations. We modified the wording of the questions of the first section to make it specific to Ontario. Using this checklist, we assessed the applicability of each study to the research question (directly, partially, or not applicable). Next, we assessed the limitations (minor, potentially serious, or very serious) of the studies that we found to be applicable.

Results

Economic Literature Search

The economic literature search yielded 849 citations, including grey literature results and after removing duplicates, published between January 1, 2014, and December 9, 2024. In total, we identified 16 cost-effectiveness studies that met our inclusion criteria. Figure 2 presents the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) flow diagram for the economic literature search.

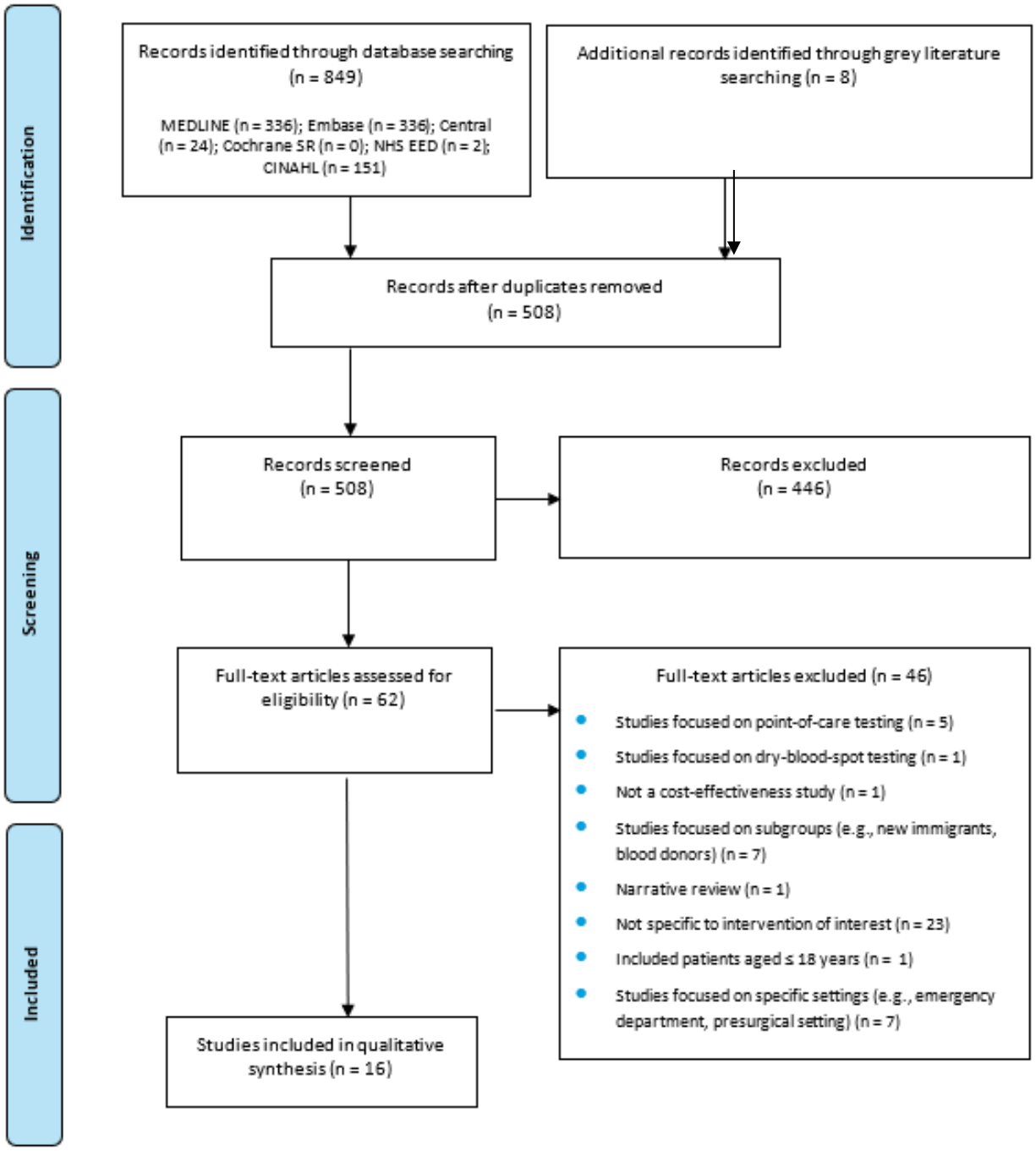

Figure 2: PRISMA Flow Diagram – Economic Systematic Review

PRISMA flow diagram showing the economic systematic review. The economic literature search yielded 508 citations, including grey literature results and after removing duplicates, published between January 1, 2014, and December 9, 2024. We screened the abstracts of the 508 identified studies and excluded 446. We assessed the full text of 62 articles and excluded a further 46. In the end, we included 16 articles in the qualitative synthesis.

Abbreviations: CINAHL, Cumulative Index to Nursing and Allied Health Literature; Cochrane SR, Cochrane Database of Systematic Reviews; NHS EED, National Health Service Economic Evaluation Database; PRISMA, Preferred Reporting Items for Systematic Reviews and Meta-analyses.

Source: Adapted from Page et al.[55]

Overview of Included Economic Studies

We identified 16 published cost-effectiveness studies that met our inclusion criteria, which were conducted in different parts of the world.[61-75] Table 6 presents the distribution of these studies by world region.

Table 6: Included Studies by World Region

World region	Country	Number of studies
Europe	Italy	1[75]
Europe	Spain	1[63]
Europe	Ireland, United Kingdom	2[64,71]
Europe	Ireland	1[64]
Europe	France	1[65]
North America	United States	3[62,66,70]
North America	Canada	4[68,72-74]
Asia	Pakistan	1[67]
Asia	South Korea	1[69]
Asia	China	1[76]
Asia	Iraq	1[61]
Total		**16**

All studies assessed the impact of either universal screening or birth-cohort screening compared with risk-based screening or no screening. In a study conducted in Italy,[75] the authors concluded that universal screening of adults and screening of different birth cohorts were more cost-effective than risk-based screening. In a Spanish study,[63] the authors concluded that HCV screening and treatment of the general adult population is cost-effective compared with screening of high-risk groups or the population with the highest anti-HCV prevalence plus high-risk groups. Similar results were observed in a study conducted in Ireland.[64] In this Irish study, the authors concluded that birth-cohort screening was more cost-effective than risk-based screening.[64] The study's findings showed that despite the substantial upfront costs, birth-cohort screening would be the optimal strategy in Ireland.[64] We observed similar conclusions from the studies conducted in the United States.[62,66,70] In a US study conducted by Barocas et al,[62] the authors concluded that one-time HCV screening of all adults plus risk-based screening would be cost-effective compared with risk-based screening alone and would lead to improved clinical outcomes. The authors also found that one-time HCV screening of all adults plus risk-based screening identified more people with HCV than the current birth-cohort screening in the United States.[62] In another US study conducted by Eckman et al,[66] the authors estimated the cost-effectiveness of one-time universal screening for all adults living in the United States compared with the current one-time birth-cohort screening and no screening, and determined the prevalence of HCV antibody above which HCV testing was cost-effective. The study found that universal one-time screening of all adults with a prevalence of HCV antibody greater than 0.07% cost less than $50,000 USD per QALY compared with no screening.[66] Compared with one-time birth-cohort screening, universal one-time screening and treatment cost $11,378 USD per QALY gained.[66] Universal screening was cost-effective compared with birth-cohort screening when the prevalence of HCV antibody positivity was greater than 0.07% among adults not in the 1945–1965 birth cohort.[66]

The cost-effectiveness studies conducted in Asia showed that the approaches of universal screening of all adults and of birth-cohort screening were more cost-effective than risk-based screening alone.[61,67,69]

Overall, both universal screening and birth-cohort screening were found to be cost-effective compared with risk-based screening alone. When compared with no screening, the cost-effectiveness of universal screening for HCV depended on the prevalence of HCV antibody in the general population.[66,70]

Given that this health technology assessment focuses on evaluating the cost-effectiveness of different HCV screening strategies in Ontario, the 4 Canadian cost-effectiveness studies were most relevant to our research question.[68,72-74] These studies examined universal screening and birth-cohort screening in addition to risk-based screening, using Canadian-specific data on HCV epidemiology, treatment costs, and utility values. We therefore chose to summarize the findings of these 4 Canadian economic studies (Table 7).

Wong et al (2015)[74] developed a Canadian policy model – commissioned by the Public Health Agency of Canada – to compare 4 screening strategies among Canadians aged 25 to 64 years and those aged 45 to 64 years: (1) no screening, (2) screen and treat with pegylated interferon plus ribavirin, (3) screen and treat with pegylated interferon plus ribavirin–based DAAs, and (4) screen and treat with interferon-free DAAs. A cohort-based state-transition model was used to simulate the natural history of chronic HCV from acute infection to end-stage liver disease. The results showed that a selective one-time HCV screening program would prevent at least 9 HCV-related deaths per 10,000 people over the lifetime of the cohort and is likely to be cost-effective compared with no screening (ICER: $34,359–$44,034/QALY gained).

To support the Canadian Task Force on Preventive Health Care in making up-to-date recommendations, Wong et al (2017)[72] updated the previously developed and validated Canadian policy model with new parameters and additional scenarios. The analysis compared no screening with a screen-and-treat strategy across 4 populations of interest (scenarios): (1) asymptomatic people not at high risk for HCV infection, (2) immigrant populations with a high prevalence of HCV, (3) a birth cohort of people aged 25 to 64 years, and (4) a birth cohort of people aged 45 to 64 years. The model showed that screening would prevent 49.7%, 57.4%, 64.1%, and 49.6% of HCV-related deaths over the lifetime of the cohort in scenarios 1 through 4, respectively. The authors concluded that compared with no screening, HCV screening would be cost-effective (ICER ranged from $31,468/QALY to $50,490/QALY, depending on the population of interest).

Given newly available evidence on HCV prevalence, costs, health state utilities, and DAA treatment, Wong et al (2023)[73] further updated the Canadian policy model to incorporate the most current data. The analysis compared the cost-effectiveness of risk-based HCV screening (status quo) with one-time HCV screening of 3 birth cohorts across Canada's provinces and territories: (1) individuals born before 1945, (2) individuals born between 1945 and 1964, and (3) individuals born after 1965. The results of this study showed that one-time HCV screening of individuals born before 1945 was not cost-effective compared with risk-based HCV screening. However, one-time HCV screening of individuals born after 1945 was cost-effective compared with risk-based HCV screening.

Recognizing gaps in the HCV cascade of care (described in the Background section), Sahakyan et al[68] assessed the level of service scale-up required to meet the World Health Organization's (WHO's) mortality target – specifically, a 65% reduction in liver-related mortality by 2030 compared with 2015 – by updating parameters in the existing Canadian policy model developed by Wong et al (2015).[74]

Sahakyan et al[68] increased both RNA testing and treatment rates to 98%, followed by increasing antibody testing uptake until the WHO's liver-related mortality target was achieved. The study results showed that without any scale-up, the projected QALYs and costs per person by 2030 were 9.156 and $48,996, respectively. Increasing RNA testing and treatment rates from the current levels (88% and 53%, respectively) to 98% reduced liver-related deaths to 3.3 per 100,000 people – a 57% reduction from 2015. Further doubling the antibody testing rate could help achieve the WHO's mortality target by 2035, though not by 2030. Compared with the status quo, such a program would be considered cost-effective at a willingness-to-pay value of $50,000 per QALY gained if annual implementation costs stayed under $2.3 million per 100,000 people. Although achieving the WHO's goals by 2030 is unfeasible, the combined scale-up strategy (i.e., doubling antibody testing rates and increasing RNA testing and treatment rates) showed promise in reaching the WHO's goals by 2035.

Table 7: Characteristics of the 4 Canadian Studies Included in the Economic Literature Review

Author, year	Type of analysis, study design, perspective, time horizon, discount rate	Population	Intervention(s) and comparator(s)	Results		
				Health outcomes , QALYs	Costs, $	Cost-effectiveness
Wong et al,[74] 2015	Type of analysis: cost–utility Study design: Markov state transition model Perspective: health care payer Time horizon: lifetime Discount rate: 1.5%	1. People aged 23–64 y 2. People aged 45–64 y	Interventions **Strategy 1:** screen and treat with pegylated interferon plus ribavarin **Strategy 2:** screen and treat with pegylated interferon plus ribavarin–based DAAs **Strategy 3:** screen and treat with interferon-free DAAs Comparator **Strategy 4:** no screening	**25–64 years of age** Interventions **Strategy 1:** 13.7685 **Strategy 2:** 13.7729 **Strategy 3:** 13.7716 Comparator **Strategy 4:** 13.7653 **45–64 years of age** Interventions **Strategy 1:** 12.1068 **Strategy 2:** 12.1104 **Strategy 3:** 12.1122 Comparator **Strategy 4:** 12.1027	**25–64 years of age** Interventions **Strategy 1:** 71,450 **Strategy 2:** 71,593 **Strategy 3:** 71,593 Comparator **Strategy 4:** 71,327 **45–64 years of age** Interventions **Strategy 1:** 83,476 **Strategy 2:** 83,672 **Strategy 3:** 83,673 Comparator **Strategy 4:** 83,335	**25–64 years of age** **Strategy 1** vs. no screening: $38,117/QALY **Strategy 2** vs. no screening: $34,783/QALY **Strategy 3** was dominated by strategy 2 **45–64 years of age** **Strategy 1** vs. no screening: $34,359/QALY **Strategy 2** vs. no screening: $55,151/QALY **Strategy 3** vs. no screening: $36,471/QALY **PSA:** **Strategies 1, 2, and 3** have a 56%, 51%, and 60% chance of being cost-effective, respectively, compared with no screening
Wong et al,[72] 2017	Type of analysis: cost–utility Study design: Markov state transition model Perspective: health care payer Time horizon: lifetime Discount rate: 1.5%	1. Asymptomatic people not at high risk for HCV infection (**Scenario 1**) 2. Immigrant populations with high prevalence of HCV (**Scenario 2**) 3. Birth cohort of people aged 25–64 years (**Scenario 3**) 4. Birth cohort of people aged 45–64 years (**Scenario 4**)	Intervention Screen and treat with DAAs Comparator No screening	Intervention **Scenario 1**: 14.0644 **Scenario 2**: 13.7478 **Scenario 3**: 14.2615 **Scenario 4**: 12.8067 Comparator **Scenario 1**: 14.0644 **Scenario 2**: 13.7281 **Scenario 3**: 14.2536 **Scenario 4**: 12.7979	Intervention **Scenario 1**: 69,871–69,877 **Scenario 2**: 73,384–73,446 **Scenario 3**: 72,767–72,789 **Scenario 4**: 84,914–84,938 Comparator **Scenario 1**: 69,769 **Scenario 2**: 72,765 **Scenario 3**: 72,506 **Scenario 4**: 84,610	**ICERs:** **Scenario 1:** $50,490–$53,938/QALY **Scenario 2:** $31,468–$34,600/QALY **Scenario 3:** $32,712–$35,619/QALY **Scenario 4:** $34,614–$37,167/QALY **PSA:** **Scenaries 1, 2, 3, and 4** have a 39.5%, 63.2%, 58.4%, and 58.1% chance of being cost-effective at a WTP of $50,000/QALY, respectively

Author, year	Type of analysis, study design, perspective, time horizon, discount rate	Population	Intervention(s) and comparator(s)	Results		
				Health outcomes , QALYs	Costs, $	Cost-effectiveness
Wong et al,[73] 2023	Type of analysis: cost–utility Study design: Markov state transition model Perspective: health care payer Time horizon: lifetime Discount rate: 1.5%	1. People born before 1945 2. People born between 1945 and 1964 3. People born after 1964	Intervention One-time screening of people born (1) before 1945, (2) between 1945 and 1964, and (3) after 1964 Comparator Risk-based screening (status quo)	Intervention **People born before 1945:** 6.1771–6.1786 **People born between 1945 and 1964:** 15.6430–15.6525 **People born after 1964:** 25.3468–25.3530 Comparator **People born before 1945:** 6.1768–6.1785 **People born between 1945 and 1964:** 15.6417–15.6513 **People born after 1964:** 25.3448–25.3518	Intervention **People born before 1945:** 188,211–346,217 **People born between 1945 and 1964:** 216,665–347,082 **People born after 1964:** 210,842–321,085 Comparator **People born before 1945:** 188,203–346,199 **People born between 1945 and 1964:** 216,628–347,020 **People born after 1964:** 210,790–321,031	**ICERs:** **People born before 1945:** $27,422–$42,191/QALY **People born between 1945 and 1964:** $35,217–$48,197/QALY **People born after 1964:** $142,182–$178,195/QALY **PSA:** HCV screening of people born before 1945, between 1945 and 1964, and after 1964 has a 90%, 80%, and 100% chance of being cost-effective at a WTP of $50,000/QALY, respectively, across all provinces and territories
Sahakyan et al,[68] 2023	Type of analysis: cost–utility Study design: Markov state transition model Perspective: health care payer Time horizon: until 2030 and until 2035 Discount rate: 1.5%	People aged ≥ 18 y	Interventions **Strategy 1:** improved linkage to care (98% HCV RNA and 98% treatment) **Strategy 2:** reaching the undiagnosed population by doubling antibody testing in the status quo strategy in addition to strategy 1 measures Comparator Risk-based screening (status quo)	**As of December 2030** Interventions **Strategy 1:** 9.157 **Strategy 2:** 9.157 Comparator **Status quo:** 9.155 **As of December 2035** Interventions **Strategy 1:** 12.242 **Strategy 2:** 12.243 Comparator **Status quo:** 12.239	**As of December 2030** Interventions **Strategy 1:** 56,793 **Strategy 2:** 56,812 Comparator **Status quo:** 56,791 **As of December 2035** Interventions **Strategy 1:** 79,517 **Strategy 2:** 79,509 Comparator **Status quo:** 79,635	**As of December 2030** Strategy 1 vs. status quo: $1,018/QALY Strategy 2 vs. status quo: $52,505/QALY **As of December 2035** Cost savings for both strategies 1 and 2 **PSA:** This target was attained in 52% of simulations, with a mean rate of 2.41 (95% CI: 2.15–2.69)/100,000

Abbreviations: CI, confidence interval; DAAs, direct-acting antivirals; HCV, hepatitis C virus; ICER, incremental cost-effectiveness ratio; PSA, probabilistic sensitivity analysis; QALY, quality-adjusted life-year; RNA, ribonucleic acid; WTP, willingness-to-pay.

Applicability and Limitations of the Included Studies

Appendix 8, Table A7, provides the results of the quality appraisal checklist for economic evaluations applied to the included studies. We appraised only the 4 Canadian economic studies since they are the studies most relevant to our research question.[68,72-74] Of these, 2 studies[72,74] were deemed not applicable because the comparator was no screening, whereas the other 2 studies[68,73] were considered partially applicable. Concerns regarding applicability arise primarily from the following:

- Different birth cohort of interest: No studies specifically included individuals born between 1945 and 1975
- Time horizon: 1 study used a shorter time horizon (projecting outcomes only until 2030 or 2035)[68]

Discussion

We identified 4 studies conducted in Canada that met our inclusion criteria.[68,72-74] These studies evaluated the cost-effectiveness of various HCV screening strategies for various populations, including multiple birth cohorts and people aged 18 years and older.

Based on the findings of these studies, HCV screening was deemed cost-effective for people aged 23 to 64 years and 45 to 64 years, as well as for immigrants from regions with high HCV prevalence, compared with no screening.[72,74] One-time birth-cohort screening of people born before 1945 was found not to be cost-effective compared with current risk-based screening in Canada.[73] However, one-time birth-cohort screening of people born between 1945 and 1964 and of those born after 1964 was found to be cost-effective compared with current risk-based screening.[73]

One study focused on assessing the cost-effectiveness of scaling up the HCV cascade of care in Ontario to achieve the WHO's goal of reducing liver-related mortality by 65% by 2030. Although current HCV screening strategies have been shown to reduce the number of cases of decompensated cirrhosis, hepatocellular carcinoma (HCC), liver transplant, and liver-related death compared with no screening or risk-based screening, findings from Sahakyan et al[68] revealed that these measures alone would be insufficient for Canada to achieve the WHO's goal by 2030. Adopting strategies that improve linkage to care are crucial. Sahakyan et al[68] showed that improving linkage to care – by increasing both HCV RNA testing and treatment rates to 98% – would reduce liver deaths by 51% by 2030. Further, doubling the HCV antibody testing rate, in combination with improving linkage to care, would reduce liver-related deaths by 57% by 2030, which is still below the WHO's goal.[68] However, if the time horizon were extended to 2035, Ontario might be able to meet the WHO's goal of reducing liver-related mortality.

Across all studies, key factors influencing cost-effectiveness included the price of DAAs and the uptake rates of HCV antibody testing, RNA testing, and treatment for chronic HCV.

All 4 studies were based on the HCV policy model originally developed by Wong et al (2015),[74] which has been widely recognized and applied in Canada. One of the structural differences of the model developed by Sahakyan et al[68] was that people with decompensated cirrhosis and HCC received treatment with DAAs. The model was updated in each study to incorporate newer clinical data, different treatment regimens, and updated DAA costs and to evaluate different populations of interest.

Conclusions

The results of these studies indicate that HCV screening in Canada for all adults is likely to be a cost-effective strategy compared with no screening or risk-based screening (status quo). We identified no studies that evaluated the cost-effectiveness of HCV screening of people born between 1945 and 1975.

Primary Economic Evaluation

We identified 4 published Canadian economic evaluations that assessed the cost-effectiveness of various hepatitis C virus (HCV) screening strategies implemented for various populations in Canada.[68,72-74] While these studies generally found HCV screening to be cost-effective across various populations (risk-based populations and different birth cohorts such as people born before 1945, those born between 1945 and 1965, and those born after 1965), none evaluated the cost-effectiveness of HCV screening in our population of interest: people born between 1945 and 1975.

Given the evolving epidemiology of HCV, recent changes in Canada's screening recommendations for the 1945–1975 birth cohort, the availability of reflex testing, the availability of more recent data on Ontario's HCV cascade of care, and updated testing costs, we chose to adapt the Canadian HCV screening model developed by Sahakyan et al[68] (Table 8). This model builds on the previously published chronic hepatitis C (CHC) policy model developed by Wong et al (2015, 2017)[72,74] and Erman et al.[72,74,77] Our adaptation involved updating several model parameters to reflect current evidence, ensuring both robustness and comparability with existing research.

Table 8: Adaptations to the Cost-Effectiveness Model

Model parameter	Cost-effectiveness model by Sahakyan et al[68]	Our model adaptation
Population of interest	- All adults - 3 birth cohorts (people born before 1945, between 1945 and 1965, and after 1965)	- All adults - People born between 1945 and 1975
Costing year	2023 Canadian dollars	2025 Canadian dollars
Cost of HCV testing	Test cost included: - Cost of HCV antibody test and personnel: $56 - Cost of HCV RNA test: $133 The cost of HCV genotyping was not included	Updated cost of HCV testing using data provided by PHO: - Cost of HCV antibody test and personnel: $8.50 - Cost of supplemental HCV test and personnel: $10.33 - Cost of HCV RNA test and personnel: $42.25 - Cost of HCV genotyping and personnel: $98.04
Starting age of each birth cohort	The average starting age in adults born before 1945, between 1945 and 1965, and after 1945 was 39, 58, and 78 years, respectively. The analysis was conducted for the periods of January 1, 2019, to December 31, 2030, and January 1, 2019, to December 31, 2035.	We modified the starting age parameter by adding 6 years to the starting age of each birth cohort to reflect the age increase.
Percentage of population in each birth cohort	The results for the overall adult population were calculated as a weighted average of the 3 birth cohorts. The proportions of the 3 birth cohorts were calculated using 2019 population data.	The proportions of the 3 birth cohorts were updated using 2025 projected population data from the Ontario Ministry of Finance[78]
Reference case – comparator	The probabilities of: - HCV antibody testing: derived using back-calculation modelling - HCV RNA testing = 88% (based on a population-based study in Ontario)[79] - Treatment = 53% (based on a population-based study in Ontario)[79]	The probabilities of: - HCV antibody testing: calculated using the most recent data from PHO - HCV RNA testing = 89.1% (updated based on a recent PHO report)[80] - Treatment = 53% (assumed the same as current level)[79]

Model parameter	Cost-effectiveness model by Sahakyan et al[68]	Our model adaptation
Reference case – intervention	For the strategy of "improving linkage to care," the probabilities of: - HCV antibody testing: same as the comparator - HCV RNA = 98% (assumption) - Treatment = 98% (assumption) For the strategy of "reaching the undiagnosed population," the probabilities of: - HCV antibody testing: assumed to be 2 times higher than that of the comparator - HCV RNA = 98% (assumption) - Treatment = 98% (assumption)	The probabilities of: - HCV antibody testing: assumed to be 49% higher than that of the comparator[81] - HCV RNA = 89.1%[80] - Treatment = 53%[79]
Time horizon	12 years (2019–2030) and 17 years (2019–2035)	Lifetime

Abbreviations: HCV, hepatitis C virus; PHO, Public Health Ontario; RNA, ribonucleic acid.

Research Question

From the perspective of the Ontario Ministry of Health, what is the cost-effectiveness of one-time HCV screening plus risk-based HCV screening compared with risk-based HCV screening alone for all adults and for people born between 1945 and 1975 (1945–1975 birth cohort)?

Methods

The information presented in this report follows the reporting standards set out by the Consolidated Health Economic Evaluation Reporting Standards (CHEERS) statement.[82] The content of this report is based on a previously developed economic project plan.

Type of Analysis

We conducted a cost–utility analysis because it is the recommended reference case approach in the Canada's Drug Agency (CDA) guidelines for economic evaluation.[83] Quality-adjusted life-years (QALYs) gained was used as the effectiveness outcome. QALYs consider both a person's survival and their quality of life (e.g., 1 QALY represents 1 year of perfect health). A generic outcome measure such as the QALY allows decision-makers to make comparisons across various conditions and interventions.

We also estimated clinically relevant outcomes, including the following:

- Life-years
- HCV-related deaths
- Number of cases of decompensated cirrhosis
- Number of cases of hepatocellular carcinoma (HCC)
- Number of liver transplants

Population of Interest

Our population of interest was adults (≥ 18 years) who are asymptomatic, who are not suspected of having an HCV infection (based on an absence of clinical signs or symptoms or of laboratory findings), who have not previously been treated for HCV, and who have not previously had a positive HCV test. The population may include adults belonging to a birth cohort (e.g., 1945–1975).

Using the 2025 projected population data from the Ontario Ministry of Finance,[78] we calculated the size of our population of interest and the proportion of each birth cohort of interest (Table 9).

Table 9: 2025 Projected Population in Ontario by Birth Cohort

Birth cohort	Projected population in 2025	Proportion of population (%)
Born before 1945	672,407	5%
Born between 1945 and 1965	3,442,384	25%
Born between 1966 and 1975	1,925,080	14%
Born after 1975 and before 2007[a]	7,486,944	55%
Total population born between 1945 and 1975	**5,367,464**	**39%**
Total population	**13,526,815**	**100%**

[a]People aged 18 years and older by 2025 must have been born in 2007 or earlier.

Perspective

We conducted this analysis from the perspective of the Ontario Ministry of Health.

Interventions and Comparators

We evaluated the following HCV screening strategies (interventions):

- One-time HCV screening for all adults plus risk-based HCV screening
- One-time HCV screening for the 1945–1975 birth cohort plus risk-based HCV screening

Our comparator was risk-based HCV screening as currently performed in Ontario (status quo).

As noted in the Clinical Evidence section, HCV screening in Ontario is performed as currently recommended in Canada for individuals who disclose risk factors (past or present) for HCV.[42] Health care providers may perform HCV screening for those who belong to a population disproportionately affected by HCV or for those who request it. Routine screening is recommended for people with ongoing risks of HCV infection,[3] but the frequency of testing is not defined.

We estimated the annual probability of receiving an HCV antibody test using the most recent data available from Public Health Ontario (PHO).[80] For the interventions, we assumed that with more structure in one-time HCV screening for all adults and for the 1945–1975 birth cohort plus risk-based HCV screening, the annual probability of receiving an HCV antibody test would increase by 49% over the probability reported by a US study.[62] In that study, of those with a positive HCV antibody test, 89.1% received the confirmatory ribonucleic acid (RNA) test, and, of those with a positive HCV RNA test, 53%

received an antiviral treatment. In the PHO report, individuals who did not receive an RNA test (10.9%) and those who did not initiate treatment (47%) were assumed to be lost to care.[80]

Table 10 summarizes the values used for the comparator and interventions in the economic model.

Table 10: Comparator and Interventions Evaluated in the Primary Economic Model

Cascade of care[a]	Comparator	Intervention
Uptake of HCV antibody testing	Calculated using the most recent data from PHO	Assumed to be 49% higher than that of the comparator[81]
Uptake of HCV RNA testing if HCV antibody test is positive	89.1%[80]	89.1%[80]
Uptake of treatment if HCV RNA test is positive	53%[79]	53%[79]

Abbreviations: HCV, hepatitis C virus; PHO, Public Health Ontario; RNA, ribonucleic acid.
[a]These data apply to the screening of both people aged 18 years and older and the 1945–1975 birth cohort.

Time Horizon and Discounting

We used a lifetime horizon in our reference case analysis. In accordance with the CDA guidelines,[83] we applied an annual discount rate of 1.5% to both costs and QALYs incurred after the first year.

Model Structure

We adapted the state-transition model developed by Sahakyan et al[68] to project the health and economic outcomes associated with improving the HCV cascade of care in Ontario. This model aligned with our research question by allowing us to do the following:

- Assess the cost-effectiveness of HCV screening for various populations, such as all adults and the 1945–1975 birth cohort
- Evaluate the impact of improving linkage to care by (1) increasing the uptake of HCV RNA testing through the use of HCV reflex testing, in which the same blood sample is used for both HCV antibody and HCV RNA testing when a person has a positive antibody test, and (2) increasing the uptake of HCV treatment for individuals who test positive with HCV RNA testing through improved collaboration among health care providers
- Examine strategies to reach the undiagnosed population through more structured screening by increasing the uptake of HCV antibody testing
- Explore the combined effect of these measures on the cost-effectiveness of HCV screening for the population of interest

We based the model on previously published CHC policy models,[72,74,77] which consist of the following components:

- Natural history of CHC, including fibrosis stages (F0–F4), decompensated cirrhosis, HCC, liver transplant, post-liver transplant, liver-related mortality, and reinfection
- HCV infection status (i.e., uninfected, spontaneous clearance, and CHC)
- HCV cascade of care (i.e., undiagnosed infection, antibody tested, RNA tested, genotype tested, treatment initiated, and sustained virologic response [SVR] achieved)
- Disengagement from care (e.g., not receiving confirmatory testing, not initiating treatment, discontinuing HCV treatment, or being a nonresponder)

Sahakyan et al[68] provides further details of the model. Figure 3 presents the model schematic.

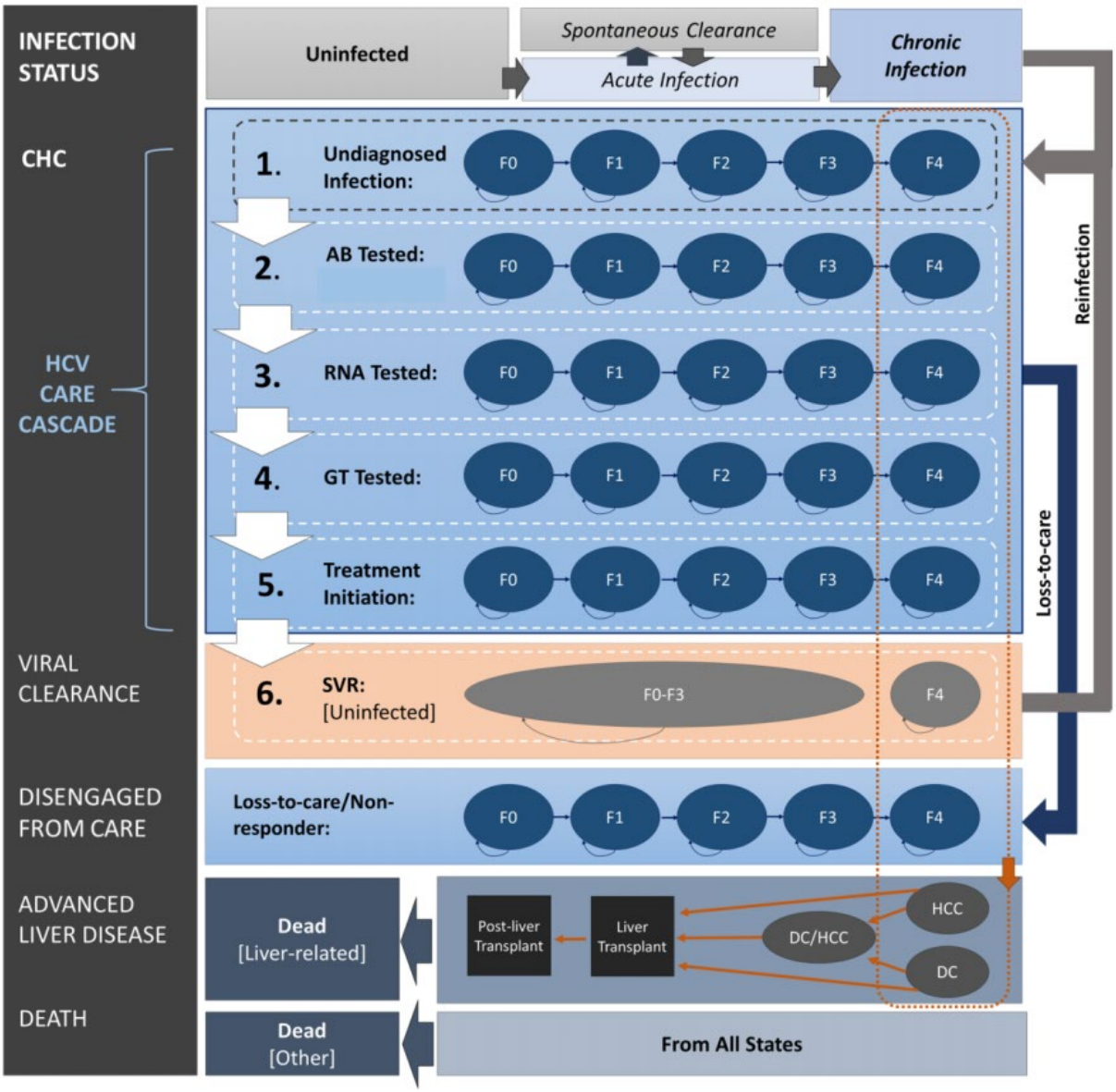

Figure 3: HCV Disease Progression

Figure 3 shows (1) HCV infection status (uninfected or infected with acute or chronic infection), (2) HCV cascade of care (undiagnosed, antibody tested, RNA tested, genotype tested, treated, or SVR attained), (3) disengagement from care, and (4) natural progression of CHC (fibrosis stages F0–F4, decompensated cirrhosis, HCC, liver transplantation, and death). Arrows indicate the transitions allowed between health states. Transitions to treatment initiation and SVR status for individuals with HCC or decompensated cirrhosis are not shown.
Abbreviations: AB, antibody; CHC, chronic hepatitis C; DC, decompensated cirrhosis; F0–F4, fibrosis stages, where F0 is no fibrosis and F4 is cirrhosis; GT, genotype; HCC, hepatocellular carcinoma; HCV, hepatitis C virus; RNA, ribonucleic acid; SVR, sustained virologic response.
Source: © Sahakyan et al,[68] Figure 1. The image is unmodified and used under a CC BY license.

Main Assumptions

Since we adapted the model developed by Sahakyan et al,[68] we retained the core model assumptions. The model's main assumptions were as follows:

- Uninfected individuals under the age of 50 years are at risk of acquiring an HCV infection or remain uninfected (i.e., individuals < 50 years old are at risk of infection; individuals > 50 years old are not)
- All individuals with new infections could either spontaneously clear the virus or progress through the stages of CHC, starting with nonadvanced liver disease (F0–F3) and potentially progressing to advanced liver disease (F4: compensated cirrhosis, decompensated cirrhosis, or HCC)
- Individuals at an advanced stage of liver disease (HCC or decompensated cirrhosis) could receive a liver transplant and then transition to the post-transplant state
- Individuals who develop decompensated cirrhosis are at risk of developing HCC or having both decompensated cirrhosis and HCC. All patients with decompensated cirrhosis and HCC are at risk of liver-related mortality and might receive a liver transplant, after which they remain in the post-transplant state and are at risk of liver-related mortality

We modified some model parameters to better align with our research question, and we made several additional assumptions:

- Individuals with a negative HCV antibody test could be retested in the future
- Following a positive HCV antibody test, individuals would receive either reflex HCV RNA testing or HCV RNA testing as a follow-up test
- In a scenario analysis, we assumed that all individuals with a positive HCV antibody test would receive an HCV reflex test, which would increase the HCV RNA testing uptake rate to 98%, compared with 89.1% in the reference case
- All tests would be conducted in PHO laboratories
- The cost of HCV RNA testing would be the same regardless of whether it was performed as a reflex test or a standalone follow-up test
- The cost of implementation (e.g., costs related to training, coordination, overhead, etc.) was excluded from the reference case analysis

Clinical Outcomes and Utility Parameters

We applied model parameters similar to those reported by Sahakyan et al[68] with a few modifications. Since our model focused on the 1945–1975 birth cohort, we divided this birth cohort into 2 subcohorts: 1945–1965 and 1966–1975. Based on population data, we estimated that 64% of people in the 1945–1975 birth cohort were born between 1945 and 1965 and that 36% were born between 1966 and 1975. We also estimated the mean age for the 1966–1975 birth cohort. Table 11 lists all model parameters.

We used several types of input parameters to populate the model:

- Epidemiological parameters
  - Incidence of HCV
  - Prevalence of HCV
  - Natural history of CHC
  - Population proportions across 3 birth cohorts: those born before 1945, those born between 1945 and 1965, and those born after 1965
  - Liver-related mortality
  - Proportion of people with diagnosed and undiagnosed CHC
- HCV testing parameters
  - Uptake of HCV testing (both antibody and RNA)
  - Sensitivity and specificity of HCV antibody and RNA tests
- Treatment parameters
  - Uptake of HCV treatment following a positive RNA test
  - Treatment effectiveness of drugs
- Utility parameters
  - Health state utilities (i.e., quality-of-life weights for various health states)

Probability of People Receiving Hepatitis C Virus Antibody Testing in the Status Quo Strategy (Risk-Based Screening Alone)

We estimated the probability of receiving HCV antibody testing for people with and without HCV using multiple data sources. We obtained the number of HCV antibody tests conducted from PHO (PHO, email communication, March 29, 2025; of note, these numbers did not consider the proportion of HCV antibody tests performed at PHO compared with other laboratories); the projected number of people aged 18 years and older from the Ontario Ministry of Finance[78]; estimates of the proportion of undiagnosed and diagnosed CHC from Forouzannia et al[84]; data on acute HCV from Wong et al[73] and Forouzannia et al[73,84]; and our calculation methods from Wong et al[73] (see Table 11 for details).

Mortality and Life Expectancy

We used Canadian life tables to estimate mortality by age and sex.[85] Since we adapted the model developed by Sahakyan et al,[68] we applied the following age-related assumptions for simplicity:

- For people aged 18 years and older, we kept the original starting ages assigned to each birth cohort (i.e., born before 1945, born between 1945 and 1965, and born after 1965). We added 6 years to each age parameter to reflect the passage of time since the model's development in 2019.
- We divided the 1945–1975 birth cohort into 2 subcohorts: 1945–1965 and 1966–1975. For the 1945–1965 subcohort, we applied the same mean age as reported in Sahakyan et al.[68] People in the 1966–1975 birth subcohort were between 44 and 53 years old in 2019. We thus estimated the mean age of this cohort to be 47 years. Again, to reflect the cohort's mean age in 2025, we added 6 years in the age parameter of the model.

Table 11: Input Parameters

Model parameter	Value (95% CI)	Reference
Baseline characteristics of cohort		
Uninfected people, %		
People born before 1945	99.08	Wong et al[73]; Forouzannia et al[84]
People born between 1945 and 1965	97.62	Wong et al[73]; Forouzannia et al[84]
People born after 1965	99.26	Wong et al[73]; Forouzannia et al[84]
Acute HCV, %		
People born before 1945	0.16	Wong et al[73]; Forouzannia et al[84]
People born between 1945 and 1965	0.64	Wong et al[73]; Forouzannia et al[84]
People born after 1965	0.11	Wong et al[73]; Forouzannia et al[84]
Chronic HCV, %		
People born before 1945	0.76	Forouzannia et al[84]
People born between 1945 and 1965	1.74	Forouzannia et al[84]
People born after 1965	0.63	Forouzannia et al[84]
Proportion of undiagnosed CHC, %		
People born before 1945	19.71	Forouzannia et al[84]
People born between 1945 and 1965	15.72	Forouzannia et al[84]
People born after 1965	42.39	Forouzannia et al[84]
Proportion of undiagnosed CHC – no cirrhosis, %		
People born before 1945	50.2	Wong et al[73]
People born between 1945 and 1965	50.2	Wong et al[73]
People born after 1965	80.9	Wong et al[73]
HCV cascade of care – reference case		
Annual probability of receiving HCV antibody test for people without disease born before 1945	0.01191	Calculated from data provided by PHO (email communication, March 29, 2025)
Annual probability of receiving HCV antibody test for people with undiagnosed disease born before 1945	0.04516	Calculated from data provided by PHO (email communication, March 29, 2025)
Annual probability of receiving HCV antibody test for people without disease born between 1945 and 1975	0.01265	Calculated from data provided by PHO (email communication, March 29, 2025)
Annual probability of receiving HCV antibody test for people with undiagnosed disease born between 1945 and 1975	0.07274	Calculated from data provided by PHO (email communication, March 29, 2025)
Annual probability of receiving HCV antibody test for people without disease born after 1975	0.02688	Calculated from data provided by PHO (email communication, March 29, 2025)
Annual probability of receiving HCV antibody test for people with undiagnosed disease born after 1975	0.07946	Calculated from data provided by PHO (email communication, March 29, 2025)
Uptake of HCV RNA testing if HCV antibody test is positive	89.1%	PHO[80]
Uptake of CHC treatment if HCV RNA test is positive	53%	Erman et al[79]
CHC progression		
Annual probability of progressing from F0 to F1	0.107 (0.097–0.118)	Erman et al[27]

Model parameter	Value (95% CI)	Reference
Annual probability of progressing from F1 to F2	0.082 (0.074–0.091)	Erman et al[27]
Annual probability of progressing from F2 to F3	0.117 (0.107–0.129)	Erman et al[27]
Annual probability of progressing from F3 to F4	0.116 (0.104–0.131)	Erman et al[27]
Annual probability of progressing from F4 to DC (non-SVR)	0.036 (0.027–0.043)	Van de Meer[86]
Annual probability of progressing from F4 to HCC (non-SVR)	0.024 (0.018–0.03)	Van de Meer[86]
Annual probability of progressing from DC to HCC	0.06 (0.011–0.08)	Planas et al[87]
Annual probability of liver transplant	0.033 (0.026–0.038)	Van de Meer[86]
Hazard ratio for risk of progression from F4 to HCC (SVR)	0.31 (0.27–0.37)	Sahakyan et al[88]
Hazard ratio for risk of progression from F4 to DC (SVR)	0.11 (0.05–0.24)	Sahakyan et al[88]
Annual probability of death from DC	0.216 (0.162–0.27)	D'Amico et al[89]
Annual probability of death from HCC	0.38 (0.31–0.51)	Giannini et al[90]
Hazard ratio for risk of progression from DC or HCC to death (SVR)	0.25 (0.22–0.3)	Sahakyan et al[88]
Annual probability of death from liver transplant (first year)	0.142 (0.124–0.159)	Charlton et al[91]
Annual probability of death from liver transplant (after first year)	0.034 (0.024–0.043)	Charlton et al[91]
HCV testing		
Sensitivity of antibody test	0.98 (0.95–1)	Tang et al[92]
Specificity of antibody test	1 (0.95–1)	Tang et al[92]

Abbreviations: CHC, chronic hepatitis C; CI, confidence interval; DC, decompensated cirrhosis; F0–F4, fibrosis stages, where F0 is no fibrosis and F4 is cirrhosis; HCC, hepatocellular carcinoma; HCV, hepatitis C virus; RNA, ribonucleic acid; SVR, sustained virologic response.

Health State Utilities

As we adopted the model developed by Sahakyan et al,[68] all health states remained the same. Therefore, we applied the same utility values for CHC health states as those reported in the study[68] (Tables 12a and 12b).

Table 12a: Utilities Used in the Economic Model – Age Groups

General population age group, y	Mean utility value	Standard error	Source
18–24	0.879	0.102	Yan et al[93]
25–34	0.881	0.122	Yan et al[93]
35–44	0.878	0.094	Yan et al[93]
45–54	0.855	0.13	Yan et al[93]
55–64	0.839	0.14	Yan et al[93]
65–74	0.867	0.113	Yan et al[93]
> 74	0.861	0.109	Yan et al[93]

Table 12b: Utilities Used in the Economic Model – CHC Health States

CHC health state	Mean utility value	95% confidence interval	Source
No cirrhosis	0.806	0.767–0.845	Saeed et al[94]
Compensated cirrhosis	0.726	0.680–0.772	Saeed et al[94]
Decompensated cirrhosis	0.657	0.602–0.711	Saeed et al[94]
HCC	0.717	0.647–0.788	Saeed et al[94]
Post-transplant	0.712	0.657–0.767	Saeed et al[94]
SVR post-treatment	0.841	0.801–0.880	Saeed et al[94]
Disutility of being on DAA therapy	−0.019	0.006–0.031	Saeed et al[94]

Abbreviations: CHC, chronic hepatitis C; DAA, direct-acting antiviral; HCC, hepatocellular carcinoma; SE, standard error; SVR, sustained virologic response.

Cost Parameters

We updated the following cost parameters:

- Cost of hepatitis C testing (e.g., cost of an HCV antibody test, cost of an HCV RNA test, cost of HCV genotyping)
- Cost of CHC treatment
- Cost of direct-acting antiviral (DAA) treatment, considering either 100% or 88% public coverage

Costs of Screening and Diagnostic Tests

As indicated in the Clinical Evidence section, the diagnosis of an HCV infection involves 2 sequential tests: (1) an HCV antibody test and (2) an HCV RNA test (either as a separate test or as part of reflex testing).

Based on data provided by PHO (email communication, January 24, 2025), the cost of an HCV antibody test (including reagent, labour, and overhead costs) is $8.50, and the cost of an HCV RNA or HCV reflex test (including reagent, labour, and overhead costs) is $42.25. These costs are those incurred by PHO; costs at other laboratories may vary.

For the reference case analysis, we did not include the cost of implementation.

Cost of Direct-Acting Antiviral Treatment

As indicated in the Clinical Evidence section, because of their high cost, DAAs were initially limited in Canada to cases of HCV with advanced liver fibrosis.[8] However, following a substantial price reduction in 2017, this restriction was removed in 2018, and people with CHC have since become eligible for treatment with DAAs in Ontario and throughout Canada. The most common first-line DAA regimens in Ontario include Epclusa (sofosbuvir/velpatasvir) and Maviret (glecaprevir/pibrentasvir).[3] Vosevi (sofosbuvir/velpatasvir/voxilaprevir) is used as salvage treatment when initial treatment fails.[3,7]

Following consultation with a clinical expert (J. Feld, MD, virtual communication, August 2024), we assumed that Epclusa is most commonly used for first-line treatment and that Vosevi is most commonly used for second-line treatment. The cost per day for both Epclusa and Vosevi is $714.29.[95] Therefore, a

12-week treatment course using Epclusa or Vosevi would be $60,000 per patient ($714.29/day × 7 days/week × 12 weeks). In our model, if a patient was diagnosed at stage F0, they would start to receive DAA treatment.

In the reference case analysis, we used the published prices of Epclusa and Vosevi in the Ontario Drug Benefit Formulary and assumed that 100% of people would be publicly funded. In a scenario analysis, we considered partial public coverage, assuming that 88% of DAA treatment costs are covered publicly and 12% are paid through private insurance or out of pocket.[96]

Since the negotiated prices of DAAs are not publicly available, we ran a scenario analysis assuming a lower price of DAAs (reduced by 50%).

Costs Associated With Health States

We applied the same health state costs as reported by Sahakyan et al.[68] These costs were derived from a population-based retrospective cohort study using administrative health data from Ontario.[97] The model included costs for 9 mutually exclusive health states: no cirrhosis, no cirrhosis (RNA negative) (i.e., cured HCV infection), compensated cirrhosis, decompensated cirrhosis, HCC, both decompensated cirrhosis and HCC, liver transplantation, terminal (liver-related), and terminal (non-liver-related). We adjusted the medical costs to reflect 2025 Canadian dollars using the Consumer Price Index and incorporated these costs into our decision analytic model.[98]

Cost of Care for General Population

We applied the same cost of care for the general population by age group as reported by Sahakyan et al.[68] This cost is also applied for people diagnosed with CHC, and we inflated it to reflect 2025 Canadian dollars.[98]

Table 13 presents all costs used in the economic model.

Table 13: Costs Used in the Economic Model

Parameter	Mean, $	95% Confidence interval	Reference
Cost of HCV screening			
Cost per HCV antibody test	8.50	N/A	Expert consultation
Cost per HCV RNA test or reflex testing	42.25	N/A	Expert consultation
Cost of HCV genotyping	98.04	N/A	Calculated from data provided by PHO (email communication, January 25, 2025)
Cost of DAAs			
12-week treatment with Epclusa or Vosevi	60,000	45,000–75,000	Ontario Drug Benefit Formulary[95]
Cost of CHC health states per month			
No cirrhosis (F0–F3)	1,825	1,244–1,966	Wong et al[97]
Compensated cirrhosis (F4)	4,491	3,067–4,816	Wong et al[97]
Decompensated cirrhosis	10,743	8,522–12,891	Wong et al[97]
HCC	5,202	4,279–7,485	Wong et al[97]
Decompensated cirrhosis and HCC	10,251	8,105–12,396	Wong et al[97]
Liver transplantation	8,244	5,844–10,589	Wong et al[97]
SVR	927	872–985	Wong et al[97]
Liver-related death (the last 6 months of life)	13,749	12,308–14,047	Wong et al[97]
Non-liver-related (the last 6 months of life)	10,802	9,046–10,573	Wong et al[97]
Annual cost of care for uninfected individuals, by age			
15–25 years	2,083	2,021–2,146	Krajden et al[99]; Mendlowitz et al[100]
26–35 years	2,043	2,002–2,083	Krajden et al[99]; Mendlowitz et al[100]
36–45 years	2,268	2,223–2,315	Krajden et al[99]; Mendlowitz et al[100]
46–55 years	2,955	2,926–2,986	Krajden et al[99]; Mendlowitz et al[100]
56–65 years	4,911	4,766–5,059	Krajden et al[99]; Mendlowitz et al[100]
66–75 years	7,609	7,459–7,764	Krajden et al[99]; Mendlowitz et al[100]
> 76 years	9,310	8,943–9,688	Krajden et al[99]; Mendlowitz et al[100]

Abbreviations: CHC, chronic hepatitis C; DAA, direct-acting antiviral; F0–F4, fibrosis stages, where F0 is no fibrosis and F4 is cirrhosis; HCC, hepatocellular carcinoma; HCV, hepatitis C virus; N/A, not applicable; PHO, Public Health Ontario; RNA, ribonucleic acid; SVR, sustained virologic response.

Internal Validation

The secondary health economist conducted formal internal validation. This process included testing the mathematical logic of the model, checking for errors, and ensuring the accuracy of parameter inputs and equations.

Equity Considerations

Economic evaluations inherently focus on horizontal equity (i.e., people with similar characteristics are treated in a similar way). Where possible, we conduct subgroup or scenario analyses to best address vertical equity (which allows for people with different characteristics to be treated differently according to their needs).

In our economic evaluation, the use of QALYs reflects horizontal equity because equal social value is assigned to each unit of health effect, regardless of the characteristics of the people who receive those effects or the condition being treated.

Analysis

Our reference case and sensitivity analyses adhered to CDA guidelines[83] where appropriate. The reference case represents the analysis with the most likely set of input parameters and model assumptions.

Owing to the complexity of the model and computational intensity, we calculated the reference case of this analysis by running 1,000 simulations (probabilistic analysis) that simultaneously captured the uncertainty in all parameters that were expected to vary. We set distributions for variables within the model (gamma distribution for cost, beta distribution for utilities, log normal and beta distributions for clinical parameters). We calculated mean costs and mean QALYs with credible intervals for each intervention assessed. We also calculated the mean incremental costs and incremental QALYs with credible intervals. Further, we calculated incremental cost-effectiveness ratios (ICERs) for one-time HCV screening of all adults aged 18 years and older plus risk-based HCV screening and for one-time HCV screening of the 1945–1975 birth cohort plus risk-based HCV screening, both versus risk-based HCV screening alone.

We present the results of the probabilistic analysis in a cost-effectiveness acceptability curve. Although not used as definitive willingness-to-pay (WTP) thresholds, including graphical indications of the location of the results relative to guideposts of $50,000 per QALY and $100,000 per QALY facilitates interpretation of the findings and comparison with historical decisions.

Scenario Analyses

Table 14 presents the variables varied in the scenario analyses.

Table 14: Variables Varied in Scenario Analyses

Parameter	Reference case	Scenario analysis
Scenario 1: Including the cost of HCV genotyping	Cost of HCV genotyping not included	Cost of HCV genotyping included
Scenario 2: Reaching undiagnosed population by varying the uptake of HCV antibody testing only	49% higher than current uptake	100% higher than current uptake
Scenario 3: Improving linkage to care by increasing the uptake of HCV RNA testing and CHC treatment	Uptake of HCV RNA testing: 89.1% Uptake of CHC treatment: 53%	Uptake of HCV RNA testing: 98% Uptake of CHC treatment: 98%

Abbreviations: CHC, chronic hepatitis C; HCV, hepatitis C virus; RNA, ribonucleic acid.

Sensitivity Analysis

We conducted a sensitivity analysis to explore the impact of the uptake of HCV antibody testing on the cost-effectiveness results by varying the value of this model parameter from as low as a 1.1-times increase in uptake.

Results

Reference Case Analysis

Hepatitis C Virus Screening of All Adults Plus Risk-Based Screening

In the reference case analysis, when the uptake of HCV antibody testing under the "HCV screening of all adults plus risk-based screening" strategy was 49% higher than in risk-based screening alone, the former was a dominant strategy (less costly and more effective) (Table 15). Under the "HCV screening of all adults plus risk-based screening" strategy, there were fewer cases of decompensated cirrhosis, HCC, liver transplant, and liver-related death than under the "risk-based HCV screening alone" strategy (Table 16).

Table 15: Reference Case Analysis Results – Comparing HCV Screening Strategies in All Adults (Results per Person)

Strategy	Average total cost, $ (95% CrI)	Incremental cost, $[a,b,c] (95% CrI)	Average total QALYs (95% CrI)	Incremental QALYs[c,d] (95% CrI)	ICER[c]	Life-years[f]
Risk-based HCV screening alone	289,701.76 (244,933.21–313,267.32)	—	22.8245 (4.9459–27.0470)	—	—	36.9537
HCV screening of all adults plus risk-based screening	289,646.45 (244,934.23–313,256.67)	−55.30 (−89.80 to 1.25)	22.8253 (4.9459–27.0480)	0.0008 (0.00001–0.0014)	Dominant[e]	36.9547

Abbreviations: CrI, credible interval; HCV, hepatitis C virus; ICER, incremental cost-effectiveness ratio; QALY, quality-adjusted life-year.
[a]Incremental cost = average cost (HCV screening of all adults plus risk-based screening) − average cost (risk-based HCV screening alone).
[b]Negative costs indicate savings.
[c]Results may appear inexact due to rounding.
[d]Incremental effect = average effect (HCV screening of all adults plus risk-based screening) − average effect (risk-based HCV screening alone).
[e]HCV screening of people aged 18 years and older plus risk-based screening was less costly and more effective than risk-based screening alone.
[f]Life-years were not discounted.

Table 16: Reference Case Analysis Results – Cascade-of-Care Cases Categorized by HCV Strategy in All Adults (Results per 100,000 People)

	Cascade-of care-outcomes (total cases per 100,000 people)			
Strategy	Decompensated cirrhosis	Hepatocellular carcinoma	Liver transplant	Liver-related death
Risk-based HCV screening alone	229	151	4.0	325
HCV screening of all adults plus risk-based screening	224	148	3.8	319

Abbreviation: HCV, hepatitis C virus.

Cost-Effectiveness Acceptability Curve for All Adults

Figure 4 shows the cost-effectiveness acceptability curves representing the uncertainty in the estimated ICERs generated in the probabilistic sensitivity analyses for risk-based HCV screening alone and for HCV screening of all adults plus risk-based screening. HCV screening of all adults plus risk-based screening was dominant (less costly and more effective than risk-based screening alone) at all WTP values assessed.

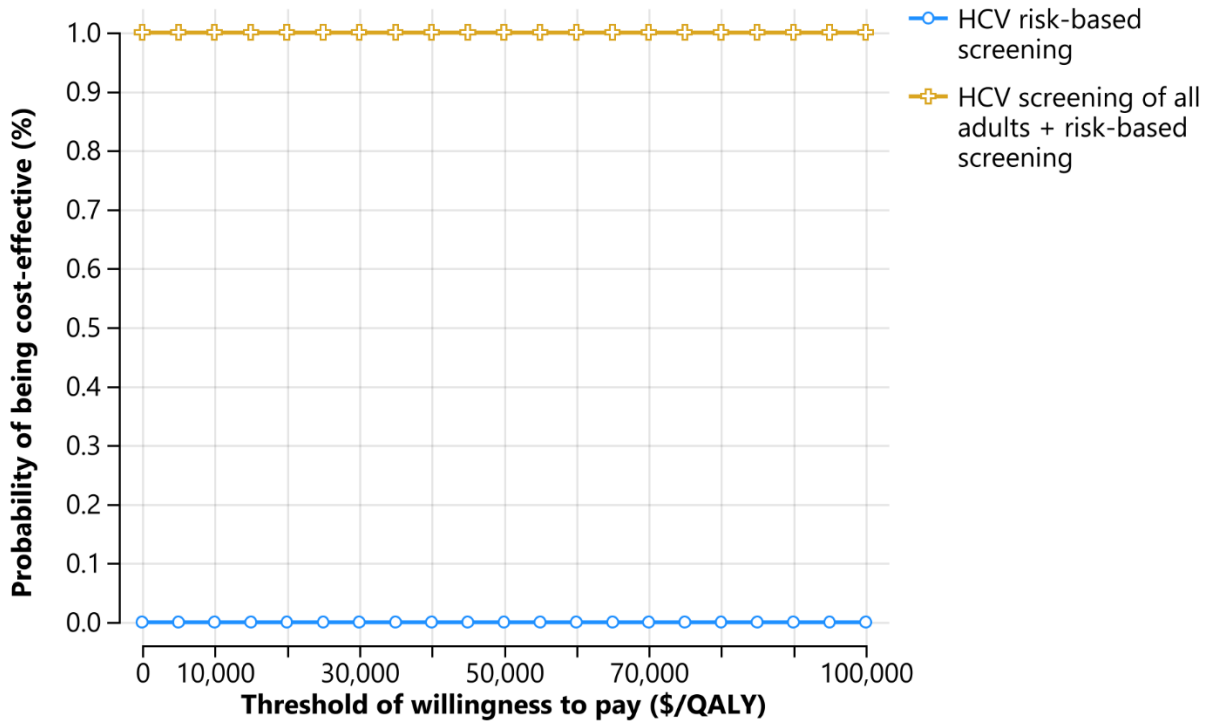

Figure 4: Cost-Effectiveness Acceptability Curve – All Adults

Hepatitis C Virus Screening of the 1945–1975 Birth Cohort Plus Risk-Based Screening

In the reference case analysis, when the uptake of HCV antibody testing under the "HCV screening of the 1945–1975 birth cohort plus risk-based screening" strategy was 49% higher than under "risk-based HCV screening alone" strategy, the former was a dominant strategy (less costly and more effective) (Table 17). Under the "HCV screening of the 1945–1975 birth cohort plus risk-based screening" strategy, there were fewer cases of decompensated cirrhosis, HCC, liver transplant, and liver-related death (Table 18) than under the "risk-based HCV screening alone" strategy.

Table 17: Reference Case Analysis Results – Comparing HCV Screening Strategies in the 1945–1975 Birth Cohort (Results per Person)

Strategy	Average total cost, $ (95% CrI)	Incremental cost, $[a,b,c] (95% CrI)	Average total QALYs (95% CrI)	Incremental QALYs[c,d] (95% CrI)	ICER[c]	Life-years[f]
Risk-based HCV screening alone	308,996.75 (303,442.01–313,969.34)	—	16.6774 (14.5938–20.1437)	—	—	24.7684
HCV screening of the 1945–1975 birth cohort plus risk-based screening	308,980.37 (303,420.71–313,958.86)	−15.38 (−25.33 to −8.70)	16.6777 (14.5940–20.1441)	0.0003 (0.0002–0.0004)	Dominant[e]	24.7688

Abbreviations: CrI, credible interval; HCV, hepatitis C virus; ICER, incremental cost-effectiveness ratio; QALY, quality-adjusted life-year.

[a]Incremental cost = average cost (HCV screening of the 1945–1975 birth cohort plus risk-based screening) − average cost (risk-based HCV screening alone).

[b]Negative costs indicate savings.

[c]Results may appear inexact due to rounding.

[d]Incremental effect = average effect (HCV screening of the 1945–1975 birth cohort plus risk-based screening) − average effect (risk-based HCV screening alone).

[e]HCV screening of the 1945–1975 birth cohort plus risk-based screening was less costly and more effective than risk-based screening alone.

[f]Life-years were not discounted.

Table 18: Reference Case Analysis Results – Cascade-of-Care Cases Categorized by HCV Strategy in the 1945–1975 Birth Cohort (Results per 100,000 People)

	Cascade-of-care outcomes (total cases per 100,000 people)			
Strategy	Decompensated cirrhosis	Hepatocellular carcinoma	Liver transplant	Liver-related death
Risk-based HCV screening alone	227	147	4.06	308
HCV screening of the 1945–1975 birth cohort plus risk-based screening	224	145	3.98	305

Abbreviation: HCV, hepatitis C virus.

Cost-Effectiveness Acceptability Curve for the 1945–1975 Birth Cohort

Figure 5 shows the cost-effectiveness acceptability curves representing the uncertainty in the estimated ICERs generated in the probabilistic sensitivity analyses for risk-based HCV screening alone and for HCV screening of the 1945–1975 birth cohort plus risk-based screening. HCV screening of the 1945–1975 birth cohort plus risk-based screening was dominant (less costly and more effective than risk-based screening alone) at all WTP values assessed.

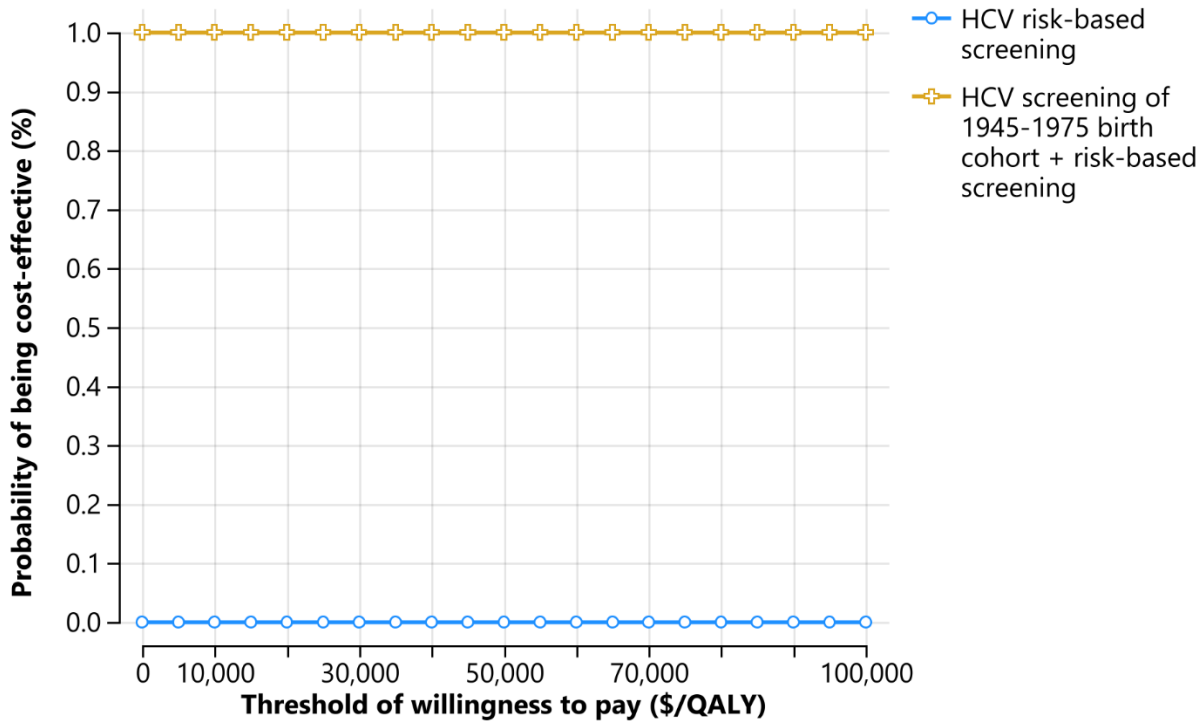

Figure 5: Cost-Effectiveness Acceptability Curve – 1945–1975 Birth Cohort

Scenario Analysis

Hepatitis C Virus Screening of All Adults Plus Risk-Based Screening

Results from all scenario analyses showed that HCV screening of all adults plus risk-based screening was dominant (less costly and more effective than risk-based screening alone) (Table 19).

Table 19: Scenario Analysis Results – Comparing HCV Screening Strategies in All Adults (Results per Person)

Strategy	Average total cost, $	Incremental cost, $[a,b,c]	Average total effects	Incremental effect[c,d]	ICER[c]
Scenario 1: Including the cost of HCV genotyping					
Risk-based HCV screening alone	289,702.05	—	22.8245	—	—
HCV screening of all adults plus risk-based screening	289,646.74	−55.31	22.8253	0.0008	Dominant[e]
Scenario 2: HCV antibody testing uptake = 2 × status quo HCV antibody testing uptake					
Risk-based HCV screening alone	289,701.76	—	22.8245	—	—
HCV screening of all adults plus risk-based screening	289,614.19	−87.56	22.8258	0.0013	Dominant[e]
Scenario 3: HCV antibody testing uptake = 1.49 × status quo HCV antibody testing uptake, HCV RNA = 98%, treatment = 98%					
Risk-based HCV screening alone	289,701.76	—	22.8245	—	—
HCV screening of all adults plus risk-based screening	288,629.75	−1,072.01	22.8441	0.0196	Dominant[e]

Abbreviations: HCV, hepatitis C virus; ICER, incremental cost-effectiveness ratio; RNA, ribonucleic acid.
[a]Incremental cost = average cost (HCV screening of all adults plus risk-based screening) − average cost (risk-based HCV screening alone).
[b]Negative costs indicate savings.
[c]Results may appear inexact due to rounding.
[d]Incremental effect = average effect (HCV screening of all adults plus risk-based screening) − average effect (risk-based HCV screening alone).
[e]HCV screening of people aged 18 years and older plus risk-based screening was less costly and more effective than risk-based screening alone.

Hepatitis C Virus Screening of the 1945–1975 Birth Cohort Plus Risk-Based Screening

Results from all scenario analyses showed that HCV screening of the 1945–1975 birth cohort plus risk-based screening was dominant (less costly and more effective than risk-based screening alone) (Table 20).

Table 20: Scenario Analysis Results – Comparing HCV Screening Strategies in the 1945–1975 Birth Cohort (Results per Person)

Strategy	Average total cost, $	Incremental cost, $[a,b,c]	Average total effects	Incremental effect[c,d]	ICER[c]
Scenario 1: Including the cost of HCV genotyping					
Risk-based HCV screening alone	308,995.99	—	14.5966	—	—
HCV screening of the 1945–1975 birth cohort plus risk-based screening	308,980.62	−15.37	14.5969	0.00028	Dominant[e]
Scenario 2: HCV antibody testing uptake = 2 × status quo HCV antibody testing uptake					
Risk-based HCV screening alone	308,996.75	—	16.6774	—	—
HCV screening of the 1945–1975 birth cohort plus risk-based screening	308,969.10	−26.65	16.6779	0.0005	Dominant[e]
Scenario 3: HCV antibody testing uptake = 1.49 × status quo HCV antibody testing uptake, HCV RNA = 98%, treatment = 98%					
Risk-based HCV screening alone	308,996.75	—	16.6774	—	—
HCV screening of the 1945–1975 birth cohort plus risk-based screening	308,603.23	−393.52	16.6886	0.0112	Dominant[e]

Abbreviations: HCV, hepatitis C virus; ICER, incremental cost-effectiveness ratio; RNA, ribonucleic acid.

[a]Incremental cost = average cost (HCV screening of the 1945–1975 birth cohort plus risk-based screening) − average cost (risk-based HCV screening alone).

[b]Negative costs indicate savings.

[c]Results may appear inexact due to rounding.

[d]Incremental effect = average effect (HCV screening of the 1945–1975 birth cohort plus risk-based screening) − average effect (risk-based HCV screening alone).

[e]HCV screening of the 1945–1975 birth cohort plus risk-based screening was less costly and more effective than risk-based screening alone.

Sensitivity Analysis

We varied the uptake of HCV antibody testing from as low as a 10% increase in HCV screening of all adults and of the 1945–1975 birth cohort compared with risk-based HCV screening. The results showed that HCV screening of all adults and of the 1945–1975 birth cohort remained the dominant strategies (less costly and more effective).

Table 21: Scenario Analysis Results – Comparing HCV Screening Strategies in All Adults and in the 1945–1975 Birth Cohort (Results per Person)

Uptake of HCV antibody testing	Strategy	Average total cost, $	Incremental cost, $[a,b,c]	Average total QALYs	Incremental QALY[c,d]	ICER[c]
All adults						
1.1 times increase in intervention	Risk-based HCV screening	289,701.76	—	22.8245	—	—
	HCV screening of all adults plus risk-based screening	289.695.25	−6.51	22.8247	0.0002	Dominant[e]
1945–1975 birth cohort						
1.1 times increase in intervention	Risk-based HCV screening	308,996.75	—	16.6774	—	—
	HCV screening of the 1945–1975 birth cohort plus risk-based screening	308,994.11	−1.64	16.6774	0.0001	Dominant[e]

Abbreviation: HCV, hepatitis C virus; ICER, incremental cost-effectiveness ratio; QALY, quality-adjusted life-year.

[a]Incremental cost = average cost (strategy B) − average cost (strategy A).

[b]Negative costs indicate savings.

[c]Results may appear inexact due to rounding.

[d]Incremental effect = average effect (strategy B) − average effect (strategy A).

[e]HCV screening of all adults plus risk-based screening and HCV screening of the 1945–1975 birth cohort plus risk-based screening were both less costly and more effective than risk-based screening alone.

Discussion

Building on the cost-effectiveness model developed by Sahakyan et al,[68] we conducted analyses to evaluate the cost-effectiveness of 2 HCV screening strategies in Ontario compared with risk-based screening alone: (1) screening all adults aged 18 years and older plus risk-based screening and (2) screening the 1945–1975 birth cohort plus risk-based screening.

In the reference case analysis, we found that when the uptake of HCV antibody testing in the "HCV screening of all adults" and "1945–1975 birth cohort" strategies was 49% higher than with risk-based HCV screening alone, both strategies would be cost-saving. These screening strategies led to fewer cases of decompensated cirrhosis, HCC, liver transplant, and liver-related death. We also found that HCV screening of all adults plus risk-based HCV screening dominated HCV screening of the 1945–1975 birth cohort plus risk-based screening.

The results remained the same in all scenario and sensitivity analyses. Importantly, even with a 10% increase in the uptake of HCV antibody testing, both screening strategies were dominant over the status quo.

Our findings align with results from previously published cost-effectiveness studies in Canada.[68,73] Wong et al[73] concluded that 2 birth cohort screening strategies (1945–1964 and after 1965) were cost-effective compared with the current risk-based screening in Ontario. Sahakyan et al[68] found that HCV screening of people aged 18 years and older would be cost-effective or even cost-saving compared with risk-based screening alone in Ontario.

Strengths and Limitations

Our analysis had several strengths. First, we used the most up-to-date costs of HCV antibody testing, HCV RNA testing, and HCV genotyping, provided by PHO (email communication, January 28, 2025). Second, based on the most recent volumes of HCV antibody tests provided by PHO, we recalculated the annual probability of receiving HCV antibody testing among those with and without HCV. Third, we updated the model parameters with the most recent data available on the cascade of care in Ontario, such as the uptake of HCV RNA testing after a positive antibody test. Fourth, we included the cost of HCV genotyping in the analysis.[80]

However, our analysis also had several limitations. First, as we adopted the model from Sahakyan et al,[68] all limitations from the original model remained. Specifically, our analysis was conducted on a static cohort; thus, it did not account for immigration patterns in Canada and may have underestimated the number of projected individuals with CHC due to migration from regions with a higher prevalence of HCV. However, the objective of our analysis was to evaluate costs and health outcomes of HCV screening of all adults and of people in the 1945–1975 birth cohort rather than to target subgroups of the population with a higher prevalence of CHC. In the absence of a real uptake rate for HCV antibody testing among all adults and among those born between 1945 and 1975 in Canada, we opted to use an uptake rate published in the United States for our reference case.[81] To overcome this limitation, we ran a sensitivity analysis in which we varied this uptake parameter from a 1.1-times increase to a 2-times increase. The result of the one-way sensitivity analysis showed that even when the uptake of HCV antibody testing was increased as little as 1.1 times, HCV screening of all adults and of people born between 1945 and 1975 would still dominate risk-based screening alone. Finally, our analysis did not include all possible costs associated with the health care system, such as the costs of phlebotomy and transporting samples and the cost of implementation.

Conclusions

In the reference case analysis, when the uptake of HCV antibody testing in the strategies of HCV screening of all adults and of people born between 1945 and 1975 was 49% higher than in the strategy of risk-based HCV screening alone, those strategies were both less costly and more effective. HCV screening for all adults plus risk-based screening was less costly and more effective than HCV screening of the 1945–1975 birth cohort plus risk-based screening. Expanding HCV screening to birth-cohort screening or population-based screening reduced cases of decompensated cirrhosis, HCC, liver transplant, and liver-related death.

Budget Impact Analysis

Research Question

What is the potential 5-year budget impact for the Ontario Ministry of Health of publicly funding one-time hepatitis C virus (HCV) screening for all adults and for people born between 1945 and 1975 (1945–1975 birth cohort) plus risk-based HCV screening, compared with risk-based HCV screening alone?

Methods

Analytic Framework

We estimated the budget impact of publicly funding (1) one-time HCV screening for all adults plus risk-based HCV screening and (2) one-time HCV screening for the 1945–1975 birth cohort plus risk-based HCV screening. This was done by running the cost-effectiveness model at a population level over a 5-year period, without discounting. Figure 6 presents the model schematic. (The budget impact is calculated as the cost of HCV screening for [1] all adults plus risk-based HCV screening or [2] the 1945–1975 birth cohort plus risk-based screening, minus the cost of risk-based HCV screening [status quo].)

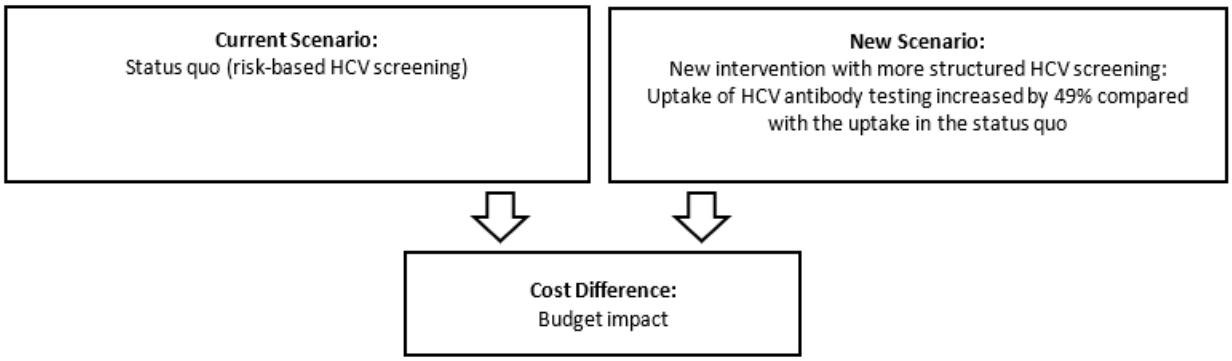

Figure 6: Schematic Model of Budget Impact

Flow chart describing the model for the budget impact analysis. The current scenario would explore resource use and total costs for risk-based HCV screening alone. The new scenario would explore resource use and total costs with public funding for (1) one-time HCV screening for all adults plus risk-based HCV screening and (2) one-time HCV screening for the 1945–1975 birth cohort plus risk-based HCV screening. The budget impact would represent the difference in costs between the 2 scenarios.

Key Assumptions

- As we strictly estimated the impact of HCV screening on the population in 2025, we did not account for individuals entering the cohort after 2025 (i.e., those turning 18 years old between 2026 and 2029). We considered that the effect of such a population change would be minimal.
- We considered the impacts of HCV screening only on individuals without HCV and those with HCV but unaware of their infection. People diagnosed with HCV were considered ineligible for screening.

- We did not consider the cost of genotyping in the reference case analysis.
- The same assumptions were applied for all adults and for the 1945–1975 birth cohort.

Population of Interest

We had 2 populations of interest: (1) all adults and (2) people born between 1945 and 1975. Both groups included people without HCV and people with HCV but unaware of their infection. We excluded people with a diagnosis of HCV.

Calculating the Number of Adults Without Hepatitis C or With Undiagnosed Hepatitis C in 2025

By 2025, there were 13,467,258 people living in Ontario aged 18 years and older,[78] of which 672,407 were born in 1945; 3,442,384 were born between 1945 and 1965; and 9,412,024 were born after 1965. Applying the undiagnosed proportions (19.71%, 15.72%, and 42.39%, respectively)[73] and the prevalence of chronic hepatitis C (CHC) (0.76%, 1.74%, and 0.63%, respectively)[84] corresponding to the 3 birth cohorts, there would be 668,304, 3,391,902, and 9,377,864 people in these respective cohorts in 2025.

Calculating the Number of People in the 1945–1975 Birth Cohort Without Hepatitis C or With Undiagnosed Hepatitis C in 2025

By 2025, there were 5,367,464 people living in Ontario born between 1945 and 1975,[78] of which 3,442,384 were born between 1945 and 1965 (1945–1965 birth cohort) and 1,925,080 were born between 1965 and 1975 (1965–1975 birth cohort). Applying the undiagnosed proportions (15.72% and 42.39%, respectively)[73] and the CHC prevalence (1.74% and 0.63%, respectively)[84] corresponding to the 2 birth cohorts, there would be 3,432,968 and 1,919,939 people in these respective cohorts in 2025.

Current Intervention Mix

In the current scenario, the uptake of HCV screening (both HCV antibody and HCV ribonucleic acid [RNA] tests) and the percentage of people who received HCV treatment following positive RNA testing were same as in the status quo (see Table 11).

Uptake of the New Intervention and New Intervention Mix

In the new scenario, we assumed that by screening all adults or the 1945–1975 birth cohort plus risk-based screening, the annual uptake of HCV antibody testing would increase by 49% compared with the uptake of HCV antibody testing in the current scenario (status quo). This means that we expect HCV antibody testing volume to increase by 49%. We assumed that the uptakes of HCV RNA testing and CHC treatment were the same as in the current scenario.

Resources and Costs

We took the annual costs incurred from each HCV screening strategy for all adults and for those in the 1945–1975 birth cohort for the next 5 years from the cost-effectiveness models described in the Primary Economic Evaluation section. In this budget impact analysis, we excluded the cost incurred by the general population. Therefore, we categorized the average total cost per person by the costs of HCV antibody testing, HCV RNA testing, HCV genotyping, direct-acting antivirals (DAAs), and treating CHC complications (Tables 22 and 23).

Table 22: Costs Incurred per Person by HCV Screening Strategy

	Average cost incurred per strategy per person, $				
Cost	**Year 1**	**Year 2**	**Year 3**	**Year 4**	**Year 5**
Risk-based HCV screening					
HCV antibody testing	0.195	0.194	0.193	0.192	0.192
HCV RNA testing	0.007	0.007	0.007	0.008	0.008
HCV genotyping	0.007	0.008	0.008	0.008	0.008
DAAs	3.601	6.300	6.524	6.577	6.582
Treating CHC complications	408.668	439.547	466.447	492.805	518.374
Total	**412.471**	**446.049**	**473.172**	**499.582**	**525.155**
HCV screening for all adults plus risk-based screening					
HCV antibody testing	0.292	0.291	0.290	0.288	0.287
HCV RNA testing	0.0104	0.0104	0.0103	0.0101	0.0100
HCV genotyping	0.011	0.011	0.011	0.011	0.011
DAAs	5.153	8.622	8.589	8.412	8.216
Treating CHC complications	408.657	439.406	466.127	492.302	517.688
Total	**414.113**	**448.329**	**475.015**	**501.013**	**526.200**

Abbreviations: CHC, chronic hepatitis C; DAA, direct-acting antiviral; HCV, hepatitis C virus; RNA, ribonucleic acid.

Table 23: Costs Incurred per Person in the 1945–1975 Birth Cohort by HCV Screening Strategy

	Cost incurred per strategy per person, $				
Cost	**Year 1**	**Year 2**	**Year 3**	**Year 4**	**Year 5**
Risk-based HCV screening					
HCV antibody testing	0.109	0.108	0.107	0.106	0.105
HCV RNA testing	0.007	0.007	0.006	0.005	0.005
HCV genotyping	0.008	0.007	0.006	0.006	0.005
DAAs	4.083	6.760	6.426	5.882	5.314
Treating CHC complications	444.058	475.430	504.044	533.997	565.657
Total	**448.265**	**482.312**	**510.590**	**539.996**	**571.086**
HCV screening for the 1945–1975 birth cohort plus risk-based screening					
HCV antibody testing	0.163	0.162	0.160	0.159	0.157
HCV RNA testing	0.011	0.010	0.008	0.007	0.006
HCV genotyping	0.011	0.010	0.009	0.007	0.006
DAAs	5.731	8.968	8.081	7.071	6.121
Treating CHC complications	443.978	475.191	503.670	533.508	565.070
Total	**449.895**	**484.340**	**511.928**	**540.752**	**571.360**

Abbreviations: CHC, chronic hepatitis C; DAA, direct-acting antiviral; HCV, hepatitis C virus; RNA, ribonucleic acid.

Internal Validation

The secondary health economist conducted formal internal validation. This process included checking for errors and ensuring the accuracy of parameter inputs and equations in the budget impact analysis.

Analysis

We conducted a reference case analysis and scenario analyses. Our reference case analysis represents the analysis with the most likely set of input parameters and model assumptions. Our scenario analyses explored how the results are affected by varying input parameters and model assumptions. We conducted the following scenarios for HCV screening of all adults and of the 1945–1975 birth cohort.

Scenario Analyses

Table 24 presents the variables varied in the scenario analyses.

Table 24: Variables Varied in Scenario Analyses

Parameter	Reference case	Scenario analysis
Scenario 1: Cost of HCV genotyping and proportion of funding of DAAs	Cost of HCV genotyping not included; DAAs 100% publicly funded	Included cost of HCV genotyping; DAAs 88% publicly funded
Scenario 2: Proportion of public funding of DAAs	DAAs 100% publicly funded	DAAs 88% publicly funded
Scenario 3: Cost of DAAs and proportion of public funding of DAAs	Published price of DAAs	Cost of DAAs discounted by 50%; DAAs 88% publicly funded
Scenario 4: Varying uptake of HCV RNA testing and treatment	Uptake of HCV RNA testing = 89.1% Uptake of treatment = 53% *(excludes people previously diagnosed with HCV)*	Uptake of HCV RNA testing = 98% Uptake of treatment = 98% *(includes people previously diagnosed with CHC)*
Scenario 5: Varying the cost of HCV antibody testing	Cost of HCV antibody testing = $8.50	Cost of HCV antibody testing = $15.00

Abbreviations: CHC, chronic hepatitis C; DAA, direct-acting antiviral; HCV, hepatitis C virus; RNA, ribonucleic acid.

Results

Reference Case

Hepatitis C Virus Screening of All Adults Plus Risk-Based Screening

In the reference case analysis, the results showed that screening 13,438,070 adults without HCV or with HCV but unaware of their infection would require an additional $22 million in year 1 to $14 million in year 5, for a total amount of $111 million over the next 5 years.

The additional costs of HCV antibody testing and HCV RNA testing would be $6.47 million and $0.2 million, respectively, in the next 5 years (Table 25). This budget does not include the costs of screening implementation and the HCV genotyping test.

Table 25: Budget Impact Analysis Results for All Adults – Reference Case

Cost	Budget impact, $ million[a]					
	Year 1	Year 2	Year 3	Year 4	Year 5	5-year total
Risk-based HCV screening alone						
HCV antibody testing	2.62	2.61	2.60	2.59	2.57	12.99
HCV RNA testing	0.09	0.10	0.10	0.10	0.10	0.49
DAAs	48.39	84.66	87.67	88.39	88.45	397.55
Treating CHC complications	5,492	5,907	6,268	6,622	6,966	31,255
Total	**5,543**	**5,994**	**6,359**	**6,713**	**7,057**	**31,666**
HCV screening of all adults plus risk-based screening						
HCV antibody testing	3.93	3.91	3.89	3.87	3.85	19.46
HCV RNA testing	0.14	0.14	0.14	0.14	0.13	0.69
DAAs	69.25	115.86	115.42	113.04	110.40	523.97
Treating CHC complications	5,492	5,905	6,264	6,616	6,957	31,232
Total	**5,565**	**6,025**	**6,383**	**6,733**	**7,071**	**32,235**
Budget impact[b,c]						
HCV antibody testing	1.31	1.30	1.29	1.29	1.28	6.47
HCV RNA testing	0.05	0.04	0.04	0.04	0.03	0.2
DAAs	21	31	28	25	22	126
Treating CHC complications	−0.15	−1.89	−4.31	−6.76	−9.22	−22
Total budget impact	**22**	**31**	**25**	**19**	**14**	**111**

Abbreviations: CHC, chronic hepatitis C; DAA, direct-acting antiviral; HCV, hepatitis C virus; RNA, ribonucleic acid.

[a]In 2025 Canadian dollars.

[b]Negative costs indicate savings.

[c]Results may appear inexact due to rounding.

We also explored when HCV screening of all adults plus risk-based screening would be come cost-saving compared with risk-based HCV screening alone. Figure 7 shows that the yearly budget impact starts to show savings in year 9 and that these savings would increase over time. As a result, from year 16 onward – when the cumulative budget impact becomes negative – HCV screening of all adults plus risk-based screening would become a cost-saving strategy.

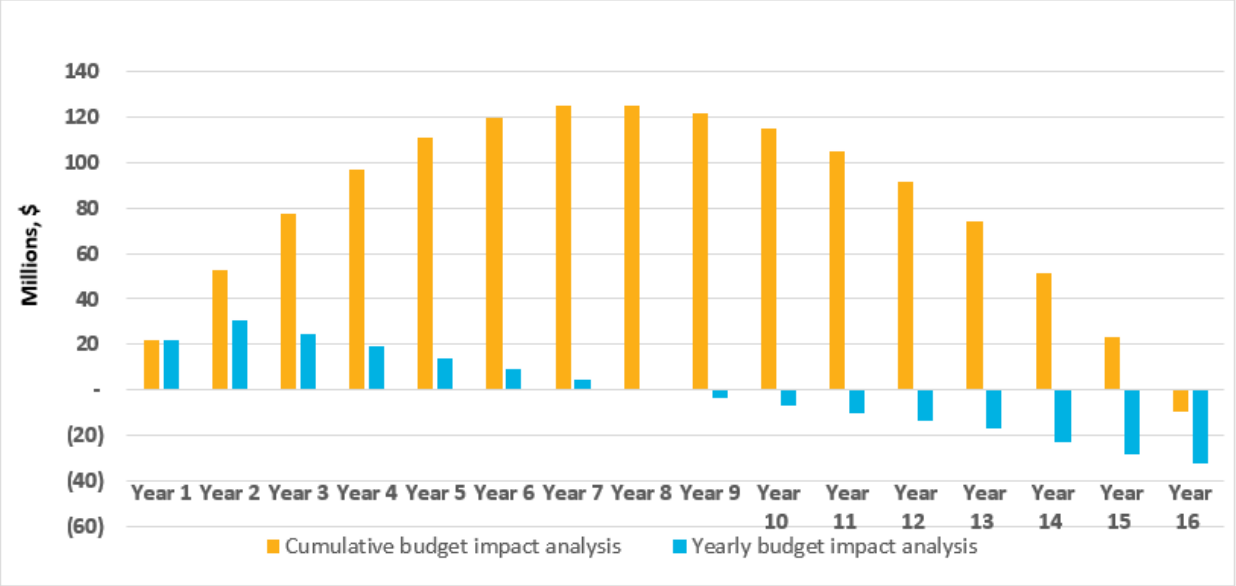

Figure 7: Cumulative and Yearly Budget Impacts – HCV Screening of All Adults Plus Risk-Based Screening

Hepatitis C Virus Screening of the 1945–1975 Birth Cohort Plus Risk-Based Screening

The results showed that screening 5,367,464 people in the 1945–1975 birth cohort (i.e., those without HCV and those with HCV but unaware of their infection) would require an additional $9 million in year 1 to $1 million in year 5, for a total of $32 million over the next 5 years.

The additional costs of HCV antibody testing and HCV RNA testing would be $1.42 million and $0.06 million, respectively, over the next 5 years (Table 26). This budget does not include the costs of screening implementation and the HCV genotyping test.

Table 26: Budget Impact Analysis Results for the 1945–1975 Birth Cohort – Reference Case

	Budget impact, $ million[a]					
Cost	**Year 1**	**Year 2**	**Year 3**	**Year 4**	**Year 5**	**5-year total**
Risk-based HCV screening alone						
HCV antibody testing	0.59	0.58	0.58	0.57	0.56	2.88
HCV RNA testing	0.04	0.04	0.03	0.03	0.03	0.16
DAAs	22	36	34	32	29	153
Treating CHC complications	2,383	2,552	2,705	2,866	3,036	13,543
Total	**2,406**	**2,589**	**2,741**	**2,898**	**3,065**	**13,699**
HCV screening of the 1945–1975 birth cohort plus risk-based screening						
HCV antibody testing	0.88	0.87	0.86	0.85	0.84	4.30
HCV RNA testing	0.06	0.05	0.04	0.04	0.03	0.22
DAAs	31	48	43	38	33	193
Treating CHC complications	2,383	2,551	2,703	2,864	3,033	13,534
Total	**2,415**	**2,600**	**2,748**	**2,902**	**3,067**	**13,731**
Budget impact[b,c]						
HCV antibody testing	0.29	0.29	0.28	0.28	0.28	1.42
HCV RNA testing	0.02	0.02	0.01	0.01	0.01	0.06
DAAs	8.85	11.85	8.88	6.38	4.33	40.30
Treating CHC complications	−0.43	−1.28	−2.01	−2.62	−3.15	−9.50
Total budget impact	**9**	**11**	**7**	**4**	**1**	**32**

Abbreviations: CHC, chronic hepatitis C; DAA, direct-acting antiviral; HCV, hepatitis C virus; RNA, ribonucleic acid.

[a]In 2025 Canadian dollars.

[b]Results may appear inexact due to rounding.

[c]Negative costs indicate savings.

We also explored when HCV screening of the 1945–1975 birth cohort plus risk-based screening would be come cost-saving compared with risk-based HCV screening alone. Figure 8 shows that the yearly budget impact starts to show savings in year 6 and that these savings would increase over time. As a result, starting from year 13 onward – when the cumulative budget impact becomes negative – HCV screening of the 1945–1975 birth cohort plus risk-based screening would become a cost-saving strategy.

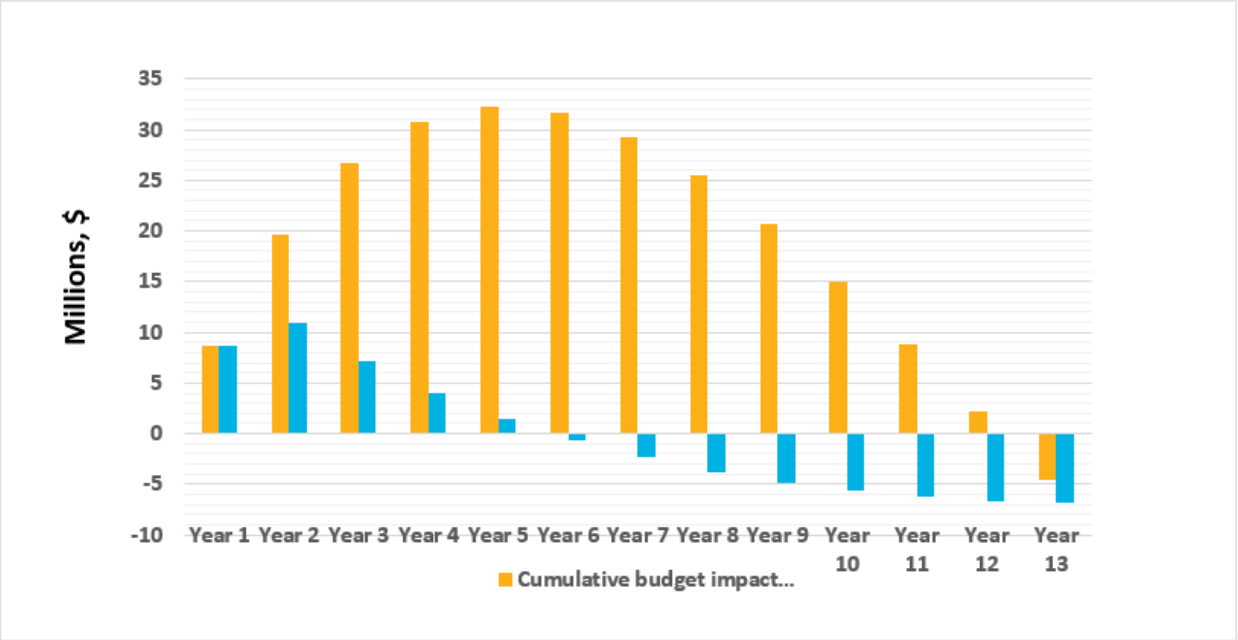

Figure 8: Cumulative and Yearly Budget Impacts – HCV Screening of the 1945–1975 Birth Cohort Plus Risk-Based Screening

Scenario Analysis

Hepatitis C Virus Screening of All Adults Plus Risk-Based Screening

Table 27 presents various scenario analyses of HCV screening of all adults plus risk-based screening compared with risk-based HCV screening alone. The budget impact was sensitive to the cost of DAAs (scenario 3). When the cost of DAAs was reduced by 50%, the 5-year budget impact would be $40 million as opposed to $111 million in the reference case. We also explored an ideal scenario in which the uptake of follow-up HCV RNA testing and timely access to HCV treatment were increased to 98% (scenario 4). In this scenario, we also included people with HCV to capture the impact of timely treatment. The yearly budget impact becomes negative in year 2, meaning that the strategy of HCV screening of all adults plus risk-based screening would become cost-saving at that point. These savings come from a reduction in the cost of CHC treatment. Scenario analyses showed that the cost of HCV genotyping has minimal impact on the budget impact analysis.

We also considered that much HCV antibody testing is done outside Public Health Ontario (PHO) laboratories. When positive antibody results from another laboratory are referred to PHO, the samples are retested, which means that the cost of HCV antibody testing is higher. Therefore, we explored a scenario in which the cost of HCV antibody testing was increased to $15. We did this to assess the impact of a change in testing cost on the budget impact (scenario 5). In this scenario, the 5-year budget impact would be $116 million as opposed to $111 million in the reference case.

Table 27: Budget Impact Analysis Results for All Adults – Scenario Analysis

Cost	Budget impact, $ million[a]					
	Year 1	Year 2	Year 3	Year 4	Year 5	5-year total
Scenario 1: Including the cost of HCV genotyping; 88% public funding for DAAs						
Risk-based HCV screening alone	5,537	5,984	6,348	6,703	7,047	31,619
HCV screening of all adults plus risk-based screening	5,557	6,011	6,369	6,719	7,058	31,174
Budget impact[b,c]						
HCV antibody testing	1.31	1.30	1.29	1.29	1.28	6.47
HCV RNA testing	0.05	0.04	0.04	0.04	0.03	0.19
HCV genotyping	0.05	0.04	0.04	0.04	0.03	0.20
DAAs	18.35	27.45	24.42	21.70	19.32	111
Treating CHC complications	−0.15	−1.89	−4.31	−6.76	−9.22	−22.32
Total budget impact	**20**	**27**	**21**	**16**	**11**	**96**
Scenario 2: Not including the cost of HCV genotyping; 88% public funding for DAAs						
Risk-based HCV screening alone	5,537	5,984	6,348	6,703	7,046	31,619
HCV screening of all adults plus risk-based screening	5,557	6,011	6,369	6,719	7,058	31,713
Budget impact[b,c]						
HCV antibody testing	1.31	1.30	1.29	1.29	1.28	6.47
HCV RNA testing	0.05	0.04	0.04	0.04	0.03	0.19
DAAs	18.35	27.45	24.42	21.70	19.32	111
Treating CHC complications	−0.15	−1.89	−4.31	−6.76	−9.22	−22.32
Total budget impact	**20**	**27**	**21**	**16**	**11**	**96**
Scenario 3: 50% discount to the cost of DAAs; 88% public funding for DAAs						
Risk-based HCV screening alone	5,516	5,947	6,310	6,664	7,008	31,444
HCV screening of all adults plus risk-based screening	5,526	5,960	6,319	6,669	7,009	31,484
Budget impact[b,c]						
HCV antibody testing	1.31	1.30	1.29	1.29	1.28	6.47
HCV RNA testing	0.05	0.04	0.04	0.04	0.03	0.19

Cost	Budget impact, $ million[a]					
	Year 1	Year 2	Year 3	Year 4	Year 5	5-year total
DAAs	9.18	13.73	12.21	10.85	9.66	55.62
Treating CHC complications	−0.15	−1.89	−4.31	−6.76	−9.22	−22.32
Total budget impact	**10**	**13**	**9**	**5**	**2**	**40**
Scenario 4: HCV RNA testing = 98%; treatment = 98%						
Risk-based HCV screening alone	10,070	8,000	8,301	8,611	8,919	43,910
HCV screening of all adults plus risk-based screening	12,177	7,960	8,228	8,501	8,774	45,639
Budget impact[b,c]						
HCV antibody testing	1.31	1.30	1.29	1.29	1.28	6.47
HCV RNA testing	0.06	0.06	0.06	0.06	0.05	0.29
DAAs	2,183.19	142.90	142.35	138.20	134.58	2,741
Treating CHC complications	−77.58	−184.03	−216.80	−249.53	−281.50	−1,009
Total budget impact	**2,106.98**	**−39.76**	**−73.09**	**−109.98**	**−145.58**	**1,739**
Scenario 5: Cost of HCV antibody testing = $15						
Risk-based HCV screening alone	5,545	5,996	6,361	6,715	7,059	31,676
HCV screening of all adults plus risk-based screening	5,568	6,028	6,386	6,736	7,074	31,791
Budget impact[b,c]						
HCV antibody testing	2.31	2.30	2.28	2.27	2.26	11.42
HCV RNA testing	0.05	0.04	0.04	0.04	0.03	0.2
DAAs	21	31	28	25	22	126
Treating CHC complications	−0.15	−1.89	−4.31	−6.76	−9.22	−22
Total budget impact	**23**	**32**	**26**	**20**	**15**	**116**

Abbreviations: CHC, chronic hepatitis C; DAA, direct-acting antiviral; HCV, hepatitis C virus; RNA, ribonucleic acid.

[a]In 2025 Canadian dollars.

[b]Negative costs indicate savings.

[c]Results may appear inexact due to rounding.

Hepatitis C Virus Screening of the 1945–1975 Birth Cohort Plus Risk-Based Screening

Table 28 presents various scenario analyses of HCV screening of the 1945–1975 birth cohort plus risk-based screening compared with risk-based screening alone. The budget impact was sensitive to the cost of DAAs (scenario 3). When the cost of DAAs was reduced by 50%, the 5-year budget impact would be $11 million as opposed to $32 million in the reference case.

We also explored an ideal scenario in which the uptake of follow-up HCV RNA testing and timely access to HCV treatment were increased to 98% (scenario 4). In this scenario, we also included people with HCV to capture the impact of timely treatment. The yearly budget impact becomes negative in year 2, meaning that the strategy of HCV screening of the 1945–1975 birth cohort plus risk-based screening would become cost-saving at that point. These savings come from a reduction in the cost of CHC treatment. Scenario analyses showed that the cost of HCV genotyping has minimal impact on the budget impact analysis.

In a scenario in which the cost of HCV antibody testing was increased to $15 (scenario 5), the 5-year budget impact increased to $35 million as opposed to $32 million in the reference case.

Table 28: Budget Impact Analysis Results for the 1945–1975 Birth Cohort – Scenario Analysis

Cost	Budget impact, $ million[a]					
	Year 1	Year 2	Year 3	Year 4	Year 5	5-year total
Scenario 1: Including the cost of HCV genotyping; 88% public funding for DAAs						
Risk-based HCV screening alone	2,422	2,644	2,841	3,050	3,274	14,230
HCV screening of the 1945–1975 birth cohort plus risk-based screening	2,430	2,654	2,847	3,053	3,275	14,259
Budget impact[b,c]						
HCV antibody testing	0.29	0.29	0.28	0.28	0.28	1.42
HCV RNA testing	0.02	0.02	0.01	0.01	0.01	0.06
HCV genotyping	0.02	0.02	0.01	0.01	0.01	0.07
DAAs	7.79	10.43	7.82	5.62	3.81	35.46
Treating CHC complications	−0.06	−0.75	−1.62	−2.42	−3.16	−8.01
Total budget impact	**8.05**	**10.00**	**6.51**	**3.50**	**0.95**	**29.00**
Scenario 2: Not including the cost of HCV genotyping; 88% public funding for DAAs						
Risk-based HCV screening alone	2,422	2,644	2,841	3,050	3,274	14,230
HCV screening of the 1945–1975 birth cohort plus risk-based screening	2,430	2,654	2,847	3,053	3,275	14,259
Budget impact[b,c]						
HCV antibody testing	0.29	0.29	0.28	0.28	0.28	1.42
HCV RNA testing	0.02	0.02	0.01	0.01	0.01	0.06
DAAs	7.79	10.43	7.82	5.62	3.81	35.46
Treating CHC complications	−0.06	−0.75	−1.62	−2.42	−3.16	−8.01
Total budget impact	**8.03**	**9.98**	**6.49**	**3.49**	**0.94**	**28.94**
Scenario 3: 50% discount to the cost of DAAs; 88% public funding for DAAs						
Risk-based HCV screening alone	2,413	2,628	2,826	3,036	3,261	14,163
HCV screening of the 1945–1975 birth cohort plus risk-based screening	2,417	2,632	2,828	3,036	3,260	14,174
Budget impact[b,c]						
HCV antibody testing	0.29	0.29	0.28	0.28	0.28	1 .42
HCV RNA testing	0.02	0.02	0.01	0.01	0.01	0.06

Cost	Budget impact, $ million[a]					
	Year 1	Year 2	Year 3	Year 4	Year 5	5-year total
DAAs	3.89	5.22	3.91	2.81	1.91	18
Treating CHC complications	−0.06[c]	−0.75[c]	−1.62[c]	−2.42[c]	−3.16[c]	−8.01[c]
Total budget impact	**4**	**5**	**3**	**1**	**−1[c]**	**11**
Scenario 4: HCV RNA testing = 98%; treatment = 98%						
Risk-based HCV screening alone	5,192	3,945	4,088	4,256	4,445	21,926
HCV screening of the 1945–1975 birth cohort plus risk-based screening	6,346	3,895	4,015	4,159	4,328	22,743
Budget impact[b,c]						
HCV antibody testing	0.29	0.29	0.28	0.28	0.28	1.42
HCV RNA testing	0.03	0.02	0.02	0.01	0.01	0.09
DAAs	1,192.92	49.48	43.05	35.56	29.19	1,350
Treating CHC complications	−39	−100	−117	−132	−147	−535
Total budget impact	**1,153.91**	**−50.27**	**−73.32**	**−96.46**	**−117.13**	**817**
Scenario 5: Cost of HCV antibody testing = $15						
Risk-based HCV screening alone	2,425	2,648	2,845	3,054	3,278	14,250
HCV screening of the 1945–1975 birth cohort plus risk-based screening	2,435	2,660	2,853	3,059	3,280	14,285
Budget impact[b,c]						
HCV antibody testing	0.52	0.5	0.5	0.49	0.49	2.5
HCV RNA testing	0.02	0.02	0.01	0.01	0.01	0.06
DAAs	8.85	11.85	8.88	6.38	4.33	40.30
Treating CHC complications	−0.06	−0.75	−1.62	−2.42	−3.16	−8.01
Total budget impact	**10**	**12**	**8**	**5**	**1**	**35**

Abbreviations: CHC, chronic hepatitis C; DAA, direct-acting antivirals; HCV, hepatitis C virus; RNA, ribonucleic acid.

[a]In 2025 Canadian dollars.

[b]Negative costs indicate savings.

[c]Results may appear inexact due to rounding.

Discussion

In the reference case analysis, publicly funding HCV screening for all adults plus risk-based screening and for the 1945–1975 birth cohort plus risk-based screening would require an estimated $111 million and $32 million, respectively, over the next 5 years in Ontario.

Scenario analyses showed that both models were sensitive to the cost of DAAs. When the cost of DAAs was reduced by 50%, the 5-year budget impact was reduced substantially, demonstrating the considerable impact of DAA pricing on the budget impact.

We also explored a scenario in which the linkage to care was optimized – that is, nearly everyone who tested positive with HCV antibody testing would receive follow-up HCV RNA testing, and nearly everyone who was diagnosed would be promptly connected to treatment. In this scenario, HCV screening of all adults and of the 1945–1975 birth cohort would start to show benefits from year 2. Here, the savings derive the substantial reduction in the cost of treating CHC complications because of there being only a 2% loss to follow-up. However, we acknowledge that this scenario might not be feasible to implement in the short term because it would take time to achieve the target of connecting 98% of people diagnosed with HCV to liver specialists or other health care providers for timely treatment. That said, the results showed the importance of improving the linkage to care in making HCV screening effective in the long term. Indeed, the findings of Sahakyan et al[68] show that meeting the World Health Organization's goal of eliminating HCV by 2035 would require an effective screening strategy and timely treatment initiation.[68]

We also considered a scenario in which HCV antibody testing was done outside PHO laboratories by increasing the cost of an HCV antibody test from $8.50 (the value used in the reference case) to $15 to cover the cost of supplemental testing. In this scenario, the 5-year budget impact for screening all adults would be $116 million as opposed to $111 million in the reference case. The 5-year budget impact for screening the 1945–1975 birth cohort would be $35 million as opposed to $32 million in the reference case.

Our reference case analysis did not include the cost related to implementation. For the new screening strategy to be successful, additional investment would be needed – both to raise awareness of screening benefits and to support health care professionals and educators in delivering care.

Our analyses confirmed that reaching the undiagnosed population and improving linkage to care both play an important role in effective HCV screening. Reaching the undiagnosed population means increasing the uptake of HCV antibody testing. Improving linkage to care means improving coordination between testing and treatment, as well as ensuring that people with a reactive (positive) HCV antibody test receive follow-up HCV RNA testing and, if confirmed to have CHC, are promptly connected to a specialist for treatment initiation. Importantly, reducing the cost of DAAs would play a substantial role in minimizing budget impact. Lower DAA prices would allow cost savings to accrue faster, enhancing the financial viability of large-scale screening programs.

Strengths and Limitations

Our analyses have several strengths. First, we calculated the 5-year budget impact analysis for both all adults and the 1945–1975 birth cohort, providing valuable insights into different populations of interest. We derived the costs used in the budget impact analysis from our cost-effectiveness models, allowing

for detailed itemization of cost components. This detailed itemization could be useful for budget planning related to test procurement. Second, cost inputs were based on recent data from Ontario, enhancing the relevance and applicability of the findings. Third, our budget impact focused on people without HCV and those with HCV but unaware of their infection, thereby avoiding overestimating costs by excluding costs related to those already diagnosed or undergoing treatment.

Our analysis also has several limitations. First, we used a closed-cohort model, meaning we did not account for people entering or exiting the cohort over time. But given the slow progression of CHC, we assumed that over the short time frame of 5 years, the impact of such population change would be minimal.[80] Additionally, we estimated the total yearly budget impact by using the average yearly costs per patient and the size of population that received the intervention in each year. According to Xie et al,[101] this approach does not require the analyst to calculate survival probabilities over time, the number of patients who received the intervention in previous years and who survived to the current year, or the average yearly per-patient costs for those who survived because the yearly costs per patient from the model results reflect the average costs for the entire cohort, which account for both survivors and those who have died. Second, due to a lack of data on the uptake of HCV antibody testing among all adults and the 1945–1975 birth cohort, we relied on estimates from a study based in the United States.[81] Third, we derived the uptake of treating CHC complications from a study that followed a cohort of CHC patients in 2018, which might not reflect current access to treatment.[27]

To overcome these limitations and explore the impact of improved treatment access and enhanced linkage to care, we conducted scenario analyses. The results of these showed that the strategies of HCV screening of all adults plus risk-based screening and of HCV screening of the 1945–1975 birth cohort plus risk-based screening would become cost-saving if linkage to care were substantially improved.

Conclusions

Over the next 5 years, publicly funding HCV screening of all adults plus risk-based screening would require $111 million, and publicly funding HCV screening of the 1945–1975 birth cohort plus risk-based screening would require $32 million. The cost of DAAs, the uptake of HCV RNA testing, and the uptake of HCV treatment were the model parameters that most influenced the budget impact results.

Preferences and Values Evidence

Objective

The objective of this analysis was to explore the underlying values, needs, and priorities of those who have lived experience of hepatitis C virus (HCV) screening, as well as the preferences and perceptions of both patients and providers of HCV screening tests.

Background

Exploring patient preferences and values provides a unique source of information about people's experiences of a health condition and the health technologies or interventions used to manage or treat that health condition. It includes the impact of the condition and its treatment on the person with the health condition, their family and other care partners, and the person's personal environment. Engagement also provides insights into how a health condition is managed by the province's health care system.

Information shared from lived experience can also identify gaps or limitations in published research (e.g., outcomes important to those with lived experience that are not reflected in the literature).[102-104] Additionally, lived experience can provide information and perspectives on the ethical and social values implications of health technologies or interventions.

Because the needs, preferences, priorities, and values of those with lived experience in Ontario are important to consider to understand the impact of a technology or intervention in people's lives, we may speak directly with people who live with a given health condition, including those with experience of the technology or intervention we are exploring.

For this analysis, we examined the preferences and values of people who received or may receive HCV screening in 2 ways:

- A review by Ontario Health of the quantitative evidence on preferences of individuals and providers
- Direct engagement by Ontario Health with people with HCV through interviews

Quantitative Evidence

Research Questions

- What is the relative preference of patients and providers for one-time HCV screening for all adults or for a birth cohort (e.g., 1945–1975) plus risk-based HCV screening compared with risk-based HCV screening alone?
- How does one-time HCV screening for all adults or for a birth cohort (e.g., 1945–1975) plus risk-based HCV screening impact patients' psychological well-being and quality of life compared with risk-based HCV screening alone?
- How satisfied are patients and providers with one-time HCV screening for all adults or for a birth cohort (e.g., 1945–1975) plus risk-based HCV screening compared with risk-based HCV screening alone?

Methods

Literature Search

We performed a literature search for quantitative evidence of preferences and values on December 11, 2024, to retrieve studies published from January 1, 2014, until the search date. We used the Ovid interface to search MEDLINE and the Cumulative Index to Nursing and Allied Health Literature (CINAHL).

The search was based on the population and intervention of the clinical search strategy with a methodological filter applied to limit retrieval to quantitative evidence of preferences and values (modified from Selva et al[105]). The final search strategy was peer-reviewed using the PRESS Checklist.[54]

We created database auto-alerts in MEDLINE and CINAHL and monitored them until March 24, 2025. We also performed a targeted grey literature search following a standard list of websites developed internally, which includes the International HTA Database and the Tufts Cost-Effectiveness Analysis Registry. See Clinical Literature Search for further details on methods used. See Appendix 3 for our literature search strategies, including all search terms.

Eligibility Criteria

Studies

Inclusion Criteria

- English-language full-text publications
- Studies published since January 1, 2014, as this is approximately when direct-acting antivirals (DAAs) were introduced
- Key study designs (e.g., surveys, discrete choice experiments, quality-of-life studies) that examined:
  - Patients' or providers' preferences for one-time HCV screening for all adults or for a birth cohort (e.g., 1945–1975) or its impact on patients' psychological well-being and quality of life compared with risk-based HCV screening; and

- Utility measures: direct techniques (standard gamble, time trade-off, rating scales) or conjoint analysis (discrete choice experiment, contingent valuation and willingness-to-pay, probability trade-off); or
- Nonutility quantitative measures: direct-choice techniques, decision aids, surveys, questionnaires

Exclusion Criteria

- Editorials, commentaries, case reports, conferences abstracts, and letters
- Animal and in vitro studies

Participants

Inclusion Criteria

- Adults (≥ 18 years) who are asymptomatic, who are not suspected of having an HCV infection (based on an absence of clinical signs or symptoms or on laboratory findings), who have not previously been treated for HCV, and who have not previously had a positive HCV test
  - May include adults belonging to a birth cohort (e.g., 1945–1975)
  - May include pregnant people, but studies specific to prenatal testing strategies were excluded
  - Studies on a mixed population were included if results were reported separately or if 80% or more of the population met the eligibility criteria
- Health care providers of the patients described above

Exclusion Criteria

- Children and adolescents (< 18 years)
- Studies that focused on people with known risk factors, those suspected of having an HCV infection, or populations disproportionately affected by HCV as previously described

Interventions

Inclusion Criteria

- One-time HCV screening for the birth cohort (1945–1975) plus risk-based HCV screening
  - Studies that evaluate screening of a birth cohort that does not match the 1945–1975 birth cohort exactly but encompass at least part of this cohort were included

Or

- One-time HCV screening for adults (≥ 18 years) plus risk-based HCV screening

Note: Studies could include HCV antibody testing alone or followed by HCV ribonucleic acid (RNA) testing if the antibody test was positive. Various methods of testing could be included (e.g., venipuncture, dry blood spot, point of care).

Exclusion Criteria

- Risk-based screening alone
- Studies specific to prenatal HCV screening
- Studies evaluating HCV prevalence
- Studies focused on evaluating testing or implementation strategies aiming to increase screening uptake (e.g., screening location, outreach, education, incentives)
    - Studies that matched the population, intervention, and comparator eligibility criteria but also incorporated interventions to improve screening uptake were considered eligible
- Studies focused on evaluating specific types of HCV tests such as dry-blood-spot or point-of-care testing
- Studies performed before the introduction of DAAs at the study site

Comparator

- Risk-based HCV screening alone

Outcome Measures

- Health utilities
- Contingent valuation
- Willingness-to-pay
- Probability trade-off

Literature Screening

A single reviewer conducted an initial screening of titles and abstracts using Covidence.[55] No studies appeared eligible for review according to the inclusion criteria; therefore, no full-text studies were obtained for review.

Data Extraction

Data extraction was not performed as no eligible studies were identified to evaluate the quantitative preferences of patients and health care providers regarding HCV screening.

Statistical Analysis

Statistical analysis was not performed as no eligible studies were identified to evaluate the quantitative preferences of patients and health care providers regarding HCV screening.

Critical Appraisal of Evidence

Critical appraisal of evidence was not performed as no eligible studies were identified to evaluate the quantitative preferences of patients and health care providers regarding to HCV screening.

Results

Literature Search

The literature search of the quantitative evidence of preferences and values yielded 369 citations, including grey literature results and after removing duplicates, published between January 1, 2014, and December 11, 2024. We did not identify any additional studies from other sources, including database alerts (monitored until March 24, 2025). We did not identify any studies that met our inclusion criteria. Figure 9 presents the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) flow diagram for the literature search for quantitative evidence of preferences and values.

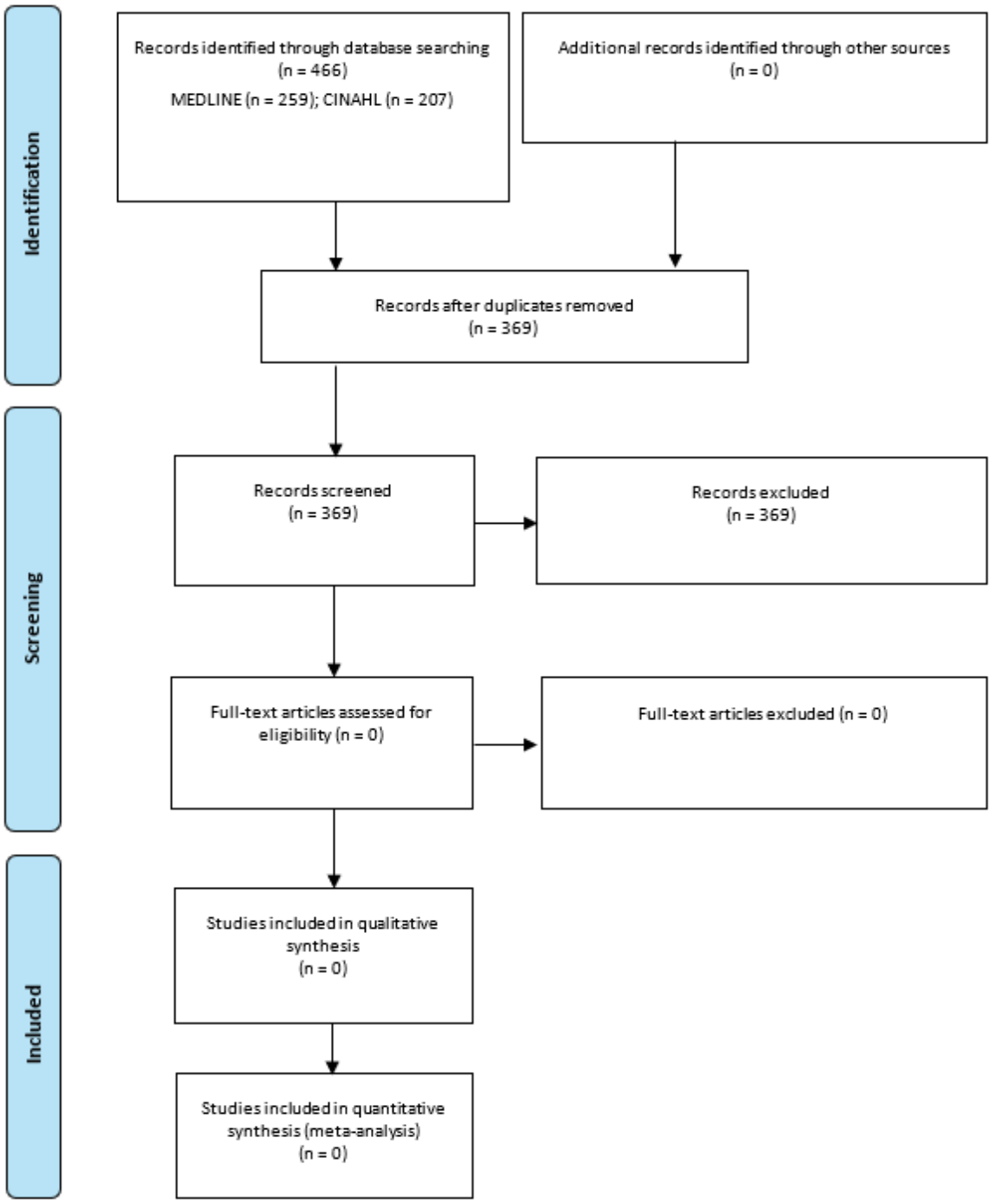

Figure 9: PRISMA Flow Diagram – Quantitative Evidence of Preferences and Values Review

PRISMA flow diagram showing the quantitative evidence of preferences and values review. The literature search for quantitative evidence of preferences and values yielded 369 citations, including grey literature results and after removing duplicates, published between January 1, 2014, and December 11, 2024. We screened the abstracts of the 369 identified studies and excluded all 369. We did not assess the full text of any articles. In the end, we included no articles in the qualitative synthesis.

Abbreviations: CINAHL, Cumulative Index to Nursing and Allied Health Literature; N/A, not applicable; PRISMA, Preferred Reporting Items for Systematic Reviews and Meta-analyses.

Source: Adapted from Page et al.[55]

Discussion

No eligible studies were identified to evaluate the quantitative preferences of patients and health care providers regarding HCV screening.

Conclusions

No eligible studies were identified to evaluate the quantitative preferences of patients and health care providers regarding HCV screening.

Direct Patient Engagement

Methods

Partnership Plan

The partnership plan for this health technology assessment focused on consultation to examine the experiences of people with HCV and those of their families or care partners. We engaged people via telephone interviews.

We used a qualitative interview, as this method of engagement allowed us to explore the meaning of central themes in the experiences of people with HCV, their journey to diagnosis, and the experiences of their families or care partners.[106] The sensitive nature of exploring people's experiences of a health condition and their quality of life further supported our choice of an interview methodology.

In addition, we drew on prior patient engagement work:

- *Patient Preferences in Considering Hepatitis C Screening and Treatment Outcomes: Phase Two* from the Canadian Task Force on Preventive Health Care[107]
- *Hepatitis C Screening in Alberta: A Health Technology Assessment* from the University of Calgary[108]
- Public consultation on the draft *Health Technology Assessment of Birth Cohort Testing for Hepatitis C* from the Health Information and Quality Authority in Ireland[4]

Participant Outreach

We used an approach called purposive sampling,[109-112] which involves actively reaching out to people with direct experience of the health condition and health technology or intervention being reviewed. We approached clinical experts to assist in identifying and connecting with individuals diagnosed with HCV. Our interview recruitment poster was shared with HCV clinics and support organizations throughout Ontario. To encourage participation and recognize their contribution, we also provided an honorarium to participants.

Inclusion Criteria

We sought to speak with adults with lived experience of HCV and their family or care partners.

Exclusion Criteria

We did not set exclusion criteria for participants who otherwise met the inclusion criteria.

Participants

For this project, we spoke to 10 people, of whom 9 had been diagnosed with HCV and 1 was a family member of a person with HCV.

Approach

At the beginning of the interview, we explained the role of our organization, the purpose of this health technology assessment, the risks of participation, and how participants' personal health information would be protected. We gave this information to participants both verbally and in a letter of information (Appendix 9) if requested. We then obtained participants' verbal consent before starting the interview. With participants' consent, we audio-recorded and then transcribed the interviews.

Interviews lasted approximately 30 to 60 minutes. The interview was semistructured and consisted of a series of open-ended questions. Questions were based on a list developed by the Health Technology Assessment International Interest Group on Patient and Citizen Involvement in Health Technology Assessment.[113] Questions focused on the impact of HCV, the journey to diagnosis, and perceptions regarding the expansion of HCV screening. See Appendix 10 for our interview guide.

Data Extraction and Analysis

We used a modified version of a grounded-theory methodology to analyze interview transcripts. This approach allowed us to organize and compare information on experiences across participants. This method consists of a repetitive process of obtaining, documenting, and analyzing responses while simultaneously collecting, analyzing, and comparing information.[114,115] We used the qualitative data analysis software program NVivo[116] to identify and interpret patterns in the data. The patterns we identified allowed us to highlight the impact of hepatitis C on the patients and family members we interviewed.

Results

Attitudes Toward Expanded HCV Screening

Participants expressed support for expanding hepatitis C screening beyond high-risk groups, noting that while individuals experiencing poverty, homelessness, or substance use are targeted for screening, many others remain undiagnosed. Participants were in favour of making screening more universal, such as by incorporating it into standard medical care or routine blood work for broader populations. They believed that more widespread screening could uncover many undetected cases, especially among those who may be unaware of their status or hesitant to seek testing. They viewed early detection as not only beneficial for individual health but also more cost-effective for the health care system, helping prevent serious complications and allowing timely access to effective treatment.

> *The testing [for HCV] should be more universal, just like in places that service people living in poverty, or people who are homeless, or people that are drug users. The doctors are all aware and test them all the time.*
>
> *Early detection I think would be in the best interest of the health care system. I believe it is much more cost-effective [to catch cases early] than having this disease progress without any manifestation or without any symptoms and produce very serious liver complications for individuals.*

I think that's a good idea [to expand screening] because there's a lot of people who don't know they have it [HCV] or that are too scared to find out. And if it was mandatory to find out, I think you'd find there's a lot more people with hep C than we know.

It is infinitely better and wiser to invest the money in early detection and early administering of the medication. And now that we seem to have medications that can manage hep C – if not eliminate it very well – I think from my own selfish point of view, I would be a very big proponent of mandatory screening.

He never found out he had hepatitis C or knew hepatitis C existed until he was dying of it.

Everybody from a certain age group should be tested for hepatitis C on their routine blood work.

Diagnosis and Testing

Participants described a variety of paths to their hepatitis C diagnosis. Many recalled having no symptoms and learning of their infection only by chance – often during hospital visits for unrelated issues where routine blood work uncovered the virus. In some cases, primary care providers recommended testing after spotting abnormal liver enzyme levels.

I was pretty much asymptomatic throughout the process. The only reason that I actually went to the doctor was for a routine annual medical, and my GP [general practitioner] identified some anomalies in my liver enzymes and felt that it would be appropriate to get tested [for HCV].

It was almost an accidental diagnosis a number of years ago, and it happened through testing procedures for surgeries that he needed for the health issues.

Others decided to get tested after noticing symptoms such as fatigue, loss of appetite, and low energy. A few participants sought testing after becoming aware of the risks associated with sharing needles during periods of drug use.

We didn't have a clue that he had hepatitis C. He was feeling generalized symptoms – loss of appetite, lethargy, and anxiety – and the family doctor did a full panel of blood work. When that blood work report came back, the doctor told him that he had hepatitis C.

I was using needles, and I was sharing them just with 1 person, but because I was told to be careful when you share them, I went and did a full blood test, and I found out that I had hep C.

Participants described their experiences with hepatitis C testing. Some initiated the process themselves, often by requesting blood work through support services, while others were tested following their doctor's recommendation during routine health assessments. In most cases, testing was perceived as a straightforward, one-time procedure involving a blood draw.

I went in twice to do the STI [sexually transmitted infection] testing, and then the blood work testing was a different appointment. But it was just 1 blood work appointment for that day for hepatitis C.

I requested the blood work through my provider, and I tested positive, and they linked me to the hepatitis C clinic.

The doctor wanted to do blood tests to make sure that I wasn't sick or anything. And it came back that I had hepatitis C.

Importance of Proactive Screening

Participants emphasized the importance of proactive HCV screening, sharing that accidental or late diagnoses had a major impact on their lives. One spoke about the relief of finding a treatable condition after fearing they would not live long, while another discovered the infection only when very ill.

His diagnosis may have been by accident and yet it had a tremendous impact on his life going forward, so across-the-board testing and diagnosing seems important to me. Discovering something like that by accident is not a proactive way.

I never thought I'd live this long because I had hepatitis. So, when I found out that I had hep C and that it was treatable, I was quite happy and relieved.

Impact on Health Outcomes

Participants shared that living with undiagnosed HCV for many years had serious consequences for their health. Because the infection often had no noticeable symptoms, some found out only after substantial liver damage had already occurred, leading to conditions like cirrhosis. One care partner recounted that their loved one died from liver disease, with hepatitis C being a contributing factor.

Unfortunately, the damage done to my liver as a result of 25 years plus of having hepatitis C has left me with a cirrhotic liver.

He died of liver disease, and hepatitis C played a part in that.

The Stigma Surrounding Hepatitis C and Its Emotional Impact

Participants shared that the stigma surrounding HCV had a significant impact on their lives, both socially and in the health care system. Many chose not to disclose their diagnosis beyond their care providers due to fear of judgment and common misconceptions, such as the belief that HCV is transmitted only sexually or through needle sharing.

I don't think I've really told anybody about it [HCV diagnosis] other than the care providers that knew about it that were treating me. As far as being a former injection drug user, there is definitely stigma in health care that still presents itself today.

> *People think it [HCV] is only sexually transmitted, and I think that's the stigma around it. People feel like it's like getting AIDS or herpes. It's just gotten a negative stigma attached to it.*

> *Mentally, I was affected because in the back of my mind, the stereotype of people who get hep C is [that they got it] because they shared needles. I never shared a needle with anybody.*

Some likened the stigma to that surrounding HIV, noting how it affected their mental health and self-perception. Participants with a history of drug use or methadone treatment also reported feeling judged in health care settings, which at times led them to avoid care altogether. These experiences left many feeling anxious, ashamed, and isolated – not only because of the illness itself but also because of how they were perceived by others.

> *Back in the day when he was diagnosed, there was quite a stigma around that kind of a diagnosis. In their mind, I feel like they [people diagnosed with HCV] felt like they [had] contracted AIDS. This really played a part on their mental health.*

> *I avoided interaction with health care when I was using, and I still do because there's so much stigma from even having a history of being on methadone.*

Impact on Social Life and Relationships

Participants shared that their social lives were negatively affected after being diagnosed with HCV. Many expressed fears – often based on limited information – about potentially transmitting the virus to others, which led them to withdraw from social situations and relationships. Some avoided close contact or stopped participating in everyday activities out of caution. Others spoke about the emotional difficulty of disclosing their diagnosis, especially in the context of sexual relationships, where they felt a responsibility to be open despite the stigma.

> *They [people diagnosed with HCV] also probably stop being as social. I think they thought in their mind, somehow, [that] they could give it to one of their friends, even though they couldn't.*

> *There wasn't as much knowledge about transmission [when the person was diagnosed]. So, I would say that he was very concerned that he [would] not transmit it to someone else through bodily fluids, so that impacted his ability to have relationships.*

> *It changed more in the fact that I had to be more open with people. If I was in a sexual relationship with somebody, I would definitely have to make sure that I let them know that I was hepatitis C positive.*

The care partner we spoke with shared that they had to invest a significant amount of time and money to support their family member in managing their liver disease, particularly in terms of providing transportation to medical appointments.

> *In the latter stages of his liver disease, he didn't have a driver's licence at that point. So, I was the person who incurred that. And I was retired at the time, so*

for me, there was a pretty significant investment of time and money to get him to his various appointments.

Treatment

Participants reflected on their treatment experiences, noting that the standard regimen typically involved taking medication – often 3 pills a day – for about 2 months. After completing the treatment, they were retested to assess changes in their viral load. While many responded well to the initial treatment and achieved sustained virologic response [i.e., cure], some faced ongoing challenges.

> *After my diagnosis, I got a prescription, and I followed my prescription. It took 8 weeks for the pills to work. And I waited for few weeks to get tested again to make sure that it is working.*
>
> *It was 2 months, and it was just 3 pills a day.*

One participant did not respond to standard therapies and had to undergo multiple experimental drug trials over extended periods, sometimes spanning years, without sustained success. In other cases, difficulty with medication adherence was noted as contributing to a poor treatment outcome.

> *I was involved in 4 or 5 – I can't recall now – different trials over a period of approximately 20 years. And each time, I was not a responder… What invariably happened was within 2 to 3 months after completing taking the medication, my viral load would rise again.*
>
> *He had difficulty following through on medications, so he may have inadvertently caused himself more troubles because of that.*

Participants described receiving comprehensive support from their health care teams during treatment. This included clear education on medication options and program details, access to counselling, and regular follow-ups. In addition, practical supports such as bus passes, meal vouchers, and small financial incentives were provided to help reduce barriers to accessing treatment.

> *All of the information given to me beforehand was extremely well done. The health care team did a wonderful job of explaining to me which medications I could choose, which duration of time I could choose, what programs they have… If I had any questions, I had 3 different phone numbers of people I could call.*
>
> *They provided me with bus passes so I can get down here and get home and get back again following treatment.*
>
> *There was education on different things, including the resources available for many things in the community. And they gave us a meal every time we came and $10 and 2 bus tickets.*

Barriers to Accessing Care

Lack of Awareness

Participants emphasized a significant lack of awareness about HCV, particularly regarding how it is transmitted and who may be at risk. Many were unaware that even limited or past needle use could result in infection. Misconceptions about the virus, such as the belief that it affects only certain stigmatized groups, further contributed to missed diagnoses.

> *I didn't know that you can get hepatitis C from your own needles. So, lack of knowledge is why I ended up getting hepatitis C.*
>
> *He had absolutely no knowledge about hep C or hep C screening or what's available.*
>
> *They were shocked because they thought hep C was for people that were maybe sexually promiscuous or something like that. And that wasn't the case.*

Participants called for health care providers to take a more proactive approach in initiating conversations and recommending screening. They also stressed the importance of expanding outreach beyond individuals who currently use drugs because those with past drug use may not realize they are still at risk. Suggestions included increasing public health messaging through media and offering screening information at locations like needle exchange programs, where individuals may be more likely to engage with health care–related services.

> *The most important thing to me is that there is outreach done beyond people who currently use drugs. Because if they have used drugs in the past, a lot of people don't even know they were at risk of it.*
>
> *Doctors should be asking people, but there should also be more commercials on TV, online, [and] in magazines to get checked – even if you only ever use the needle once, get checked just in case.*
>
> *I wish I had somebody talk to me about it [HCV screening] at the needle exchange place where I would go get supplies… That's the only interaction I was really having with anybody that would be health care related.*

Health Care System Barriers

Participants identified several systemic barriers that contributed to delayed HCV diagnosis and treatment. Long wait times to secure a family doctor and limited access to primary care led to missed opportunities for earlier detection. Even when care was accessed, assumptions made by health care providers, such as judging a person's risk based on appearance or not asking about drug use, contributed to delays in diagnosis. Some participants also expressed hesitation to disclose risk behaviours due to concerns about stigma or potential consequences, such as impacts on insurance eligibility.

> *He had to wait almost 2 years to find a family doctor for himself. And then, once he was able to find a family doctor, they did a full panel for him of blood work, and when the reports came back, the doctor told him that he had hepatitis C.*

> *My doctor never asked me if I use drugs, but I don't know if I would have told him because I was worried about getting life insurance. I guess they [doctors] assume when you present a certain way, you don't use drugs, but they were wrong.*
>
> *I could go to a family doctor with blood work that showed my liver enzymes were out of whack, and they automatically assume that I didn't use drugs. I think something like this is a barrier, doctors thinking they know it all.*

A participant with refugee status also encountered delays in receiving treatment, often due to prolonged insurance approval processes and limited access to necessary health care services.

> *He is currently on a refugee status in Canada, and it's been more than 6 weeks since he's been waiting for his medication. The last provider has sent his prescription to his pharmacy, but they need approval from [insurance company], and he's been waiting for over 6 weeks now.*

Geographic Barriers

Participants living in rural areas described significant challenges in accessing medical care due to limited availability of specialists nearby. For some, the only option was to travel long distances to urban centres, which often required a full day and resulted in additional burdens such as transportation costs, including gas and parking fees.

> *We only have 1 person who practises that kind of internal medicine, and so it was either that doctor or lengthier travel times [to an urban health centre].*
>
> *He was living in a rural area, and it would have been quite lengthy travel times to Toronto, which would be a full-day activity.*
>
> *There [were] travel expenses, including gas and parking.*

Preferences and Values Evidence Discussion

We identified no eligible studies to evaluate the quantitative preferences of patients and health care providers regarding HCV screening.

Nine of our interview participants had personal experience with HCV, and one was a family member of a person with HCV. Participants expressed strong support for expanding HCV screening beyond traditionally defined high-risk groups. Participants emphasized that the infection can remain asymptomatic for long periods and may go undetected without proactive screening, which underscores the importance of expanding access to screening. This finding aligns with that of the Canadian Task Force on Preventive Health Care, who found that participants wanted be screened for HCV but faced barriers like cost.[107]

Participants shared how HCV negatively affected both their health and social well-being, often highlighting the emotional distress caused by the stigma associated with the disease, an observation consistent with findings from the systematic review presented in the *Hepatitis C Screening in Alberta* health technology assessment.[108] While most participants described their treatment experiences as

generally positive, some noted ongoing challenges in managing their viral load, which required adjustments to their medication regimens over extended periods.

One limitation of our study is the absence of participants from Northern Ontario. However, we did include perspectives from both rural and urban settings. Another limitation is that our study focuses exclusively on individuals with lived or close experience with HCV and thus does not capture the views of those without HCV who may still be affected by changes to screening recommendations. We included only individuals diagnosed with HCV because their perspectives are grounded in lived experience, offering meaningful insights into the limitations of existing screening practices and the potential benefits of broader access to screening.

Preferences and Values Evidence Conclusions

We identified no eligible studies to evaluate the quantitative preferences of patients and health care providers regarding HCV screening.

Participants' experiences underscored the significant challenges faced in managing HCV. While many expressed relief upon receiving a diagnosis and beginning treatment, others reported barriers, including delays in both diagnosis and access to care. Limited awareness of HCV testing and transmission, along with geographic obstacles, further hindered timely diagnosis and treatment. Participants emphasized the need to expand access to HCV screening, highlighting early detection as a critical step toward effective care and improved outcomes.

Conclusions of the Health Technology Assessment

One-time HCV screening for all adults plus risk-based HCV screening may identify more people with HCV and may result in more people with HCV being linked to care compared with risk-based HCV screening alone; however, the evidence is very uncertain due to concerns with the generalizability of study results to the context of HCV screening for adults in Ontario.

Compared with risk-based screening alone, HCV screening for all adults and for those born between 1945 and 1975 would be less costly and more effective. We estimate that publicly funding HCV screening for all adults and for people born between 1945 and 1975 in Ontario over the next 5 years would cost an additional $111 million and $32 million, respectively.

Patients' experiences reveal the challenges of managing HCV and highlight the need for broader screening. Participants emphasized that the infection can remain asymptomatic for years, often going undetected without proactive screening. Patient perspectives supported universal or routine screening to enable earlier diagnosis and treatment.

Abbreviations

CanHepC: Canadian Network on Hepatitis C

CDA: Canada's Drug Agency

CDC: United States Centers for Disease Control and Prevention

CHC: chronic hepatitis C

CI: confidence interval

DAA: direct-acting antiviral

GRADE: Grading of Recommendations Assessment, Development, and Evaluation

HCC: hepatocellular carcinoma

HCV: hepatitis C virus

HIV: human immunodeficiency virus

ICER: incremental cost-effectiveness ratio

PHAC: Public Health Agency of Canada

PHO: Public Health Ontario

QALY: quality-adjusted life-year

RNA: ribonucleic acid

SVR: sustained virologic response

WHO: World Health Organization

WTP: willingness-to-pay

Glossary

Budget impact analysis: A budget impact analysis estimates the financial impact of adopting a new health care intervention on the current budget (i.e., the affordability of the new intervention). It is based on predictions of how changes in the intervention mix will impact the level of health care spending for a specific population. Budget impact analyses are typically conducted for a short-term period (e.g., 5 years). The budget impact, sometimes referred to as the net budget impact, is the estimated cost difference between the current scenario (i.e., the anticipated amount of spending for a specific population without using the new intervention) and the new scenario (i.e., the anticipated amount of spending for a specific population following the introduction of the new intervention).

Cost-effective: A health care intervention is considered cost-effective when it provides additional benefits, compared with relevant alternatives, at an additional cost that is acceptable to a decision-maker based on the maximum willingness-to-pay value.

Cost-effectiveness acceptability curve: In economic evaluations, a cost-effectiveness acceptability curve is a graphical representation of the results of a probabilistic analysis. It illustrates the probability of health care interventions being cost-effective over a range of willingness-to-pay values. Willingness-to-pay values are plotted on the horizontal axis of the graph, and the probability of the intervention of interest and its comparator(s) being cost-effective at corresponding willingness-to-pay values is plotted on the vertical axis.

Cost–utility analysis: A cost–utility analysis is a type of economic evaluation used to compare the benefits of 2 or more health care interventions with their costs. The benefits are measured using quality-adjusted life-years, which capture both the quality and quantity of life. In a cost–utility analysis, the main outcome measure is the incremental cost per quality-adjusted life-year gained.

Discounting: Discounting is a method used in economic evaluations to adjust for the differential timing of the costs incurred and the benefits generated by a health care intervention over time. Discounting reflects the concept of positive time preference, whereby future costs and benefits are reduced to reflect their present value. The health technology assessments conducted by Ontario Health use an annual discount rate of 1.5% for both future costs and future benefits.

Disutility: A disutility is a decrease in utility (i.e., a decrease in preference for a particular health outcome) typically resulting from a particular health condition (e.g., experiencing a symptom or complication).

Dominant: A health care intervention is considered dominant when it is more effective and less costly than its comparator(s).

Equity: Unlike the notion of equality, equity is not about treating everyone the same way.[117] It denotes fairness and justice in process and in results. Equitable outcomes often require differential treatment and resource redistribution to achieve a level playing field among all individuals and communities. This requires recognizing and addressing barriers to opportunities for all to thrive in our society.

Health state: A health state is a particular status of health (e.g., sick, well, dead). A health state is associated with some amount of benefit and may be associated with specific costs. Benefit is captured

through individual or societal preferences for the time spent in each health state and is expressed in quality-adjusted weights called utility values. In a Markov model, a finite number of mutually exclusive health states are used to represent discrete states of health.

Horizontal equity: Horizontal equity requires that people with like characteristics (of ethical relevance) be treated the same.

Incremental cost: The incremental cost is the additional cost, typically per person, of a health care intervention versus a comparator.

Incremental cost-effectiveness ratio (ICER): The incremental cost-effectiveness ratio (ICER) is a summary measure that indicates, for a given health care intervention, how much more a health care consumer must pay to get an additional unit of benefit relative to an alternative intervention. It is obtained by dividing the incremental cost by the incremental effectiveness. Incremental cost-effectiveness ratios are typically presented as the cost per life-year gained or the cost per quality-adjusted life-year gained.

Markov model: A Markov model is a type of decision-analytic model used in economic evaluations to estimate the costs and health outcomes (e.g., quality-adjusted life-years gained) associated with using a particular health care intervention. Markov models are useful for clinical problems that involve events of interest that may recur over time (e.g., stroke). A Markov model consists of mutually exclusive, exhaustive health states. Patients remain in a given health state for a certain period of time before moving to another health state based on transition probabilities. The health states and events modelled may be associated with specific costs and health outcomes.

Ministry of Health perspective: The perspective adopted in economic evaluations determines the types of costs and health benefits to include. Ontario Health develops health technology assessment reports from the perspective of the Ontario Ministry of Health. This perspective includes all costs and health benefits attributable to the Ministry of Health, such as treatment costs (e.g., drugs, administration, monitoring, hospital stays) and costs associated with managing adverse events caused by treatments. This perspective does not include out-of-pocket costs incurred by patients related to obtaining care (e.g., transportation) or loss of productivity (e.g., absenteeism).

Natural history of a disease: The natural history of a disease is the progression of a disease over time in the absence of any health care intervention.

One-way sensitivity analysis: A one-way sensitivity analysis is used to explore uncertainty in the results of an economic evaluation. It is done by varying one model input (i.e., a parameter) at a time between its minimum and maximum values to observe the potential impact on the cost-effectiveness of the health care intervention of interest.

Probabilistic analysis: A probabilistic analysis (also known as a probabilistic sensitivity analysis) is used in economic models to explore uncertainty in several parameters simultaneously and is done using Monte Carlo simulation. Model inputs are defined as a distribution of possible values. In each iteration, model inputs are obtained by randomly sampling from each distribution, and a single estimate of cost and effectiveness is generated. This process is repeated many times (e.g., 10,000 times) to estimate the number of times (i.e., the probability) that the health care intervention of interest is cost-effective.

Quality-adjusted life-year (QALY): The quality-adjusted life-year (QALY) is a generic health outcome measure commonly used in cost–utility analyses to reflect the quantity and quality of life-years lived. The life-years lived are adjusted for quality of life using individual or societal preferences (i.e., utility values) for being in a particular health state. One year of perfect health is represented by one quality-adjusted life-year.

Reference case: The reference case is a preferred set of methods and principles that provide the guidelines for economic evaluations. Its purpose is to standardize the approach of conducting and reporting economic evaluations, so that results can be compared across studies.

Scenario analysis: A scenario analysis is used to explore uncertainty in the results of an economic evaluation. It is done by observing the potential impact of different scenarios on the cost-effectiveness of a health care intervention. Scenario analyses involve varying structural assumptions from the reference case.

Sensitivity analysis: Every economic evaluation contains some degree of uncertainty, and results can vary depending on the values taken by key parameters and the assumptions made. Sensitivity analysis allows these factors to be varied and shows the impact of these variations on the results of the evaluation. There are various types of sensitivity analysis, including deterministic, probabilistic, and scenario.

Time horizon: In economic evaluations, the time horizon is the time frame over which costs and benefits are examined and calculated. The relevant time horizon is chosen based on the nature of the disease and health care intervention being assessed, as well as the purpose of the analysis. For instance, a lifetime horizon would be chosen to capture the long-term health and cost consequences over a patient's lifetime.

Uptake rate: In instances where 2 technologies are being compared, the uptake rate is the rate at which a new technology is adopted. When a new technology is adopted, it may be used in addition to an existing technology, or it may replace an existing technology.

Utility: A utility is a value that represents a person's preference for various health states. Typically, utility values are anchored at 0 (death) and 1 (perfect health). In some scoring systems, a negative utility value indicates a state of health valued as being worse than death. Utility values can be aggregated over time to derive quality-adjusted life-years, a common outcome measure in economic evaluations.

Vertical equity: Vertical equity allows for people with different characteristics (of ethical relevance) to be treated differently.

Willingness-to-pay value: A willingness-to-pay value is the monetary value a health care consumer is willing to pay for added health benefits. When conducting a cost–utility analysis, the willingness-to-pay value represents the cost a consumer is willing to pay for an additional quality-adjusted life-year. If the incremental cost-effectiveness ratio is less than the willingness-to-pay value, the health care intervention of interest is considered cost-effective. If the incremental cost-effectiveness ratio is more than the willingness-to-pay value, the intervention is considered not to be cost-effective.

Appendices

Appendix 1: Liver Fibrosis Assessment

The stage of liver fibrosis can be assessed using the METAVIR (Meta-analysis of Histological Data in Viral Hepatitis) scoring system, which ranges from F0 to F4[4]:

- F0: No fibrosis
- F1: Periportal fibrotic expansion
- F2: Periportal septae (> 1 septum)
- F3: Portal-central septae (septal fibrosis)
- F4: Cirrhosis

Stages F0 and F1 can be interpreted as no or mild fibrosis; F2 represents moderate fibrosis; F3 represents advanced fibrosis; and F4 represents cirrhosis.[4]

Appendix 2: Hepatitis C Screening Recommendations From Other Countries

Table A1: HCV Screening Recommendations

Organization, year	Recommendations
United States	
Centers for Disease Control and Prevention, 2020[9]	• HCV screening at least once for all adults and for all pregnant women during each pregnancy except in settings where the prevalence of HCV RNA positivity is < 0.1% • One-time HCV testing for people with recognized risk factors or exposures regardless of age or setting prevalence • Routine HCV screening of people with continued risk factors, while risk factors persist • Any person who requests HCV testing should receive it, regardless of disclosure of risk, because many people might be reluctant to disclose stigmatizing risks
United States Preventive Services Task Force, 2020[45]	• HCV screening for asymptomatic adults 18 to 79 years old without known liver disease (one-time testing in most cases) • Also suggests that clinicians consider screening people younger than 18 years and older than 79 years who are at high risk for infection (e.g., those with past or current injection drug use) • Screening pregnant people < 18 years for HCV should be considered • People who are at a continued risk for HCV infection should be screened periodically
American Association for the Study of Liver Diseases and the Infectious Diseases Society of America, 2023[48]	• One-time HCV testing is recommended for all adults ≥ 18 years old • One-time HCV testing should be performed for all people < 18 years old with activities, exposures, or conditions or circumstances associated with an increased risk of HCV infection • Prenatal HCV testing as part of routine prenatal care is recommended with each pregnancy • Periodic repeat HCV testing should be offered to all people with activities, exposures, or conditions or circumstances associated with an increased risk of HCV exposure • Annual HCV testing is recommended for all people who inject drugs, for HIV-infected men who have unprotected sex with men, and men who have sex with men taking pre-exposure prophylaxis
Australia	
Hepatitis C Virus Infection Consensus Statement Working Group, 2022[49]	• All individuals with a risk factor for HCV infection should be tested Transmission of HCV infection is associated with identifiable risk factors, and most diagnoses result from screening of at-risk populations
Europe	

European Centre for Disease Prevention and Control, 2018[16]	<u>Public health guidance on HIV, HBV, and HCV testing – scientific advice to countries in the EU/EEA region</u>
	• Targeted testing according to risk factors, presence of suggestive clinical symptoms, patients diagnosed with HBV, HCV, or HIV infection
	• Testing in the general population may also be considered and should be country-specific based on epidemiological and financial considerations:
	  ○ Universal testing in high-prevalence areas
	  ○ Birth-cohort testing

Abbreviations: EU/EEA, European Union/European Economic Area; HBV, hepatitis B virus; HCV, hepatitis C virus; HIV, human immunodeficiency virus; RNA, ribonucleic acid.

Appendix 3: Literature Search Strategies

Clinical Evidence Search

Database:
EBM Reviews - Cochrane Central Register of Controlled Trials <November 2024>
EBM Reviews - Cochrane Database of Systematic Reviews <2005 to December 4, 2024>
EBM Reviews - NHS Economic Evaluation Database <1st Quarter 2016>
Embase <1980 to 2024 Week 48>
Ovid MEDLINE(R) ALL <1946 to December 04, 2024>

#	Query	Results from 5 Dec 2024
1	exp Hepatitis C/	216,870
2	Hepacivirus/	43,000
3	(hepatitis C or hep C or hcv or hepacivirus*).ti,ab,kf.	279,106
4	or/1-3	318,983
5	Mass Screening/	186,879
6	(("non targeted" or mass or population or asymptomatic or universal or "opt out" or general or widespread or unrestricted or risk based or antibod*) adj3 (screen* or test*)).ti,ab,kf.	276,328
7	((opportunistic or sentinel or group or sub?group) adj3 (screen* or test*)).ti,ab,kf.	142,085
8	((cohort* or age or generation* or "birth year" or baby boom*) adj3 (screen* or test*)).ti,ab,kf.	105,973
9	or/5-8	660,439
10	4 and 9	13,767
11	Case Reports/ or Comment.pt. or Editorial.pt. or (Letter not (Letter and Randomized Controlled Trial)).pt. or Congress.pt.	6,829,122
12	10 not 11	13,266
13	exp Animals/ not Humans/	16,657,825
14	12 not 13	11,375
15	limit 14 to english language [Limit not valid in CDSR; records were retained]	10,369
16	15 use medall,cctr,coch,cleed	4,964
17	exp hepatitis C/	216,870
18	Hepatitis C virus/	112,882
19	(hepatitis C or hep C or hcv or hepacivirus).tw,kw,kf,dv.	279,621
20	or/17-19	326,203
21	mass screening/	186,879
22	(("non targeted" or mass or population or asymptomatic or universal or "opt out" or general or widespread or unrestricted or risk based or antibod*) adj3 (screen* or test*)).tw,kw,kf.	280,510
23	((opportunistic or sentinel or group or sub?group) adj3 (screen* or test*)).tw,kw,kf.	144,865
24	((cohort* or age or generation* or "birth year" or baby boom*) adj3 (screen* or test*)).tw,kw,kf.	108,742
25	or/21-24	667,821
26	20 and 25	13,983
27	Case Report/ or Comment/ or Editorial/ or (letter.pt. not (letter.pt. and randomized controlled trial/)) or conference abstract.pt. or conference review.pt.	12,035,610
28	26 not 27	10,628

29	(exp animal/ or nonhuman/) not exp human/	12,339,673
30	28 not 29	10,577
31	limit 30 to english language [Limit not valid in CDSR; records were retained]	9,509
32	31 use emez	4,348
33	16 or 32	9,312
34	limit 33 to yr="2014 -Current"	4,623
35	34 use medall	2,240
36	34 use emez	2,191
37	34 use cctr	189
38	34 use coch	1
39	34 use cleed	2
40	remove duplicates from 34	2,854

CINAHL

Thu, December 5, 2024 4:49:40 p.m.

#	Query	Results
S1	(MH "Hepatitis C+")	16,821
S2	TI(hepatitis C or hep C or hcv or hepacivirus)	13,457
S3	AB(hepatitis C or hep C or hcv or hepacivirus)	12,950
S4	S1 OR S2 OR S3	22,042
S5	(MH "Health Screening")	58,163
S6	TI(("non targeted" or mass or population or asymptomatic or universal or "opt out" or general or widespread or unrestricted or risk based or antibod*) N3 (screen* or test*))	5,592
S7	AB(("non targeted" or mass or population or asymptomatic or universal or "opt out" or general or widespread or unrestricted or risk based or antibod*) N3 (screen* or test*))	25,714
S8	TI((opportunistic or sentinel or group or sub?group) N3 (screen* or test*))	922
S9	AB((opportunistic or sentinel or group or sub?group) N3 (screen* or test*))	26,918
S10	TI((cohort* or age or generation* or "birth year" or baby boom*) N3 (screen* or test*))	1,576
S11	AB((cohort* or age or generation* or "birth year" or baby boom*) N3 (screen* or test*))	14,956
S12	S5 OR S6 OR S7 OR S8 OR S9 OR S10 OR S11	120,218
S13	S4 AND S12	2,006
S14	S4 AND S12	1,252
S15	S4 AND S12	1,252
S16	(MH "Animals+") not (MH "Animals+" and MH "Human")	37,248
S17	S15 not S16	1,250
S18	PT Proceedings	77,071
S19	S17 not S18	1,224

Economic Evidence Search

Database: EBM Reviews - Cochrane Central Register of Controlled Trials <November 2024>, EBM Reviews - Cochrane Database of Systematic Reviews <2005 to December 4, 2024>, EBM Reviews - NHS Economic Evaluation Database <1st Quarter 2016>, Embase <1980 to 2024 Week 49>, Ovid MEDLINE(R) ALL <1946 to December 09, 2024>
Search Strategy:
---

1 exp Hepatitis C/ (217076)
2 Hepacivirus/ (43002)
3 (hepatitis C or hep C or hcv or hepacivirus*).ti,ab,kf. (279345)
4 or/1-3 (319257)
5 Mass Screening/ (186978)
6 (("non targeted" or mass or population or asymptomatic or universal or "opt out" or general or widespread or unrestricted or risk based or antibod*) adj3 (screen* or test*)).ti,ab,kf. (276757)
7 ((opportunistic or sentinel or group or sub?group) adj3 (screen* or test*)).ti,ab,kf. (142286)
8 ((cohort* or age or generation* or "birth year" or baby boom*) adj3 (screen* or test*)).ti,ab,kf. (106212)
9 or/5-8 (661365)
10 4 and 9 (13782)
11 economics/ (267083)
12 economics, medical/ or economics, pharmaceutical/ or exp economics, hospital/ or economics, nursing/ or economics, dental/ (1131645)
13 economics.fs. (479509)
14 (econom* or price or prices or pricing or priced or discount* or expenditure* or budget* or pharmacoeconomic* or pharmaco-economic*).ti,ab,kf. (1417869)
15 exp "costs and cost analysis"/ (726555)
16 (cost or costs or costing or costly).ti. (357058)
17 cost effective*.ti,ab,kf. (507705)
18 (cost* adj2 (util* or efficacy* or benefit* or minimi* or analy* or saving* or estimate* or allocation or control or sharing or instrument* or technolog* or increment*)).ab,kf. (339198)
19 models, economic/ (16978)
20 markov chains/ or monte carlo method/ (116430)
21 (decision adj1 (tree* or analy* or model*)).ti,ab,kf. (77334)
22 (markov or markow or monte carlo).ti,ab,kf. (195491)
23 quality-adjusted life years/ (61686)
24 (QOLY or QOLYs or HRQOL or HRQOLs or QALY or QALYs or QALE or QALEs).ti,ab,kf. (125761)
25 ((adjusted adj1 (quality or life)) or (willing* adj2 pay) or sensitivity analys*s).ti,ab,kf. (229114)
26 or/11-25 (3692404)
27 10 and 26 (1775)
28 exp Animals/ not Humans/ (16665273)
29 27 not 28 (1505)
30 Case Reports/ or Comment.pt. or Editorial.pt. or (Letter not (Letter and Randomized Controlled Trial)).pt. or Congress.pt. (6832952)
31 29 not 30 (1452)
32 limit 31 to english language [Limit not valid in CDSR; records were retained] (1376)
33 32 use medall,coch,cctr,cleed (609)
34 exp hepatitis C/ (217076)

35 Hepatitis C virus/ (112961)
36 (hepatitis C or hep C or hcv or hepacivirus).tw,kw,kf,dv. (279860)
37 or/34-36 (326491)
38 mass screening/ (186978)
39 (("non targeted" or mass or population or asymptomatic or universal or "opt out" or general or widespread or unrestricted or risk based or antibod*) adj3 (screen* or test*)).tw,kw,kf. (280940)
40 ((opportunistic or sentinel or group or sub?group) adj3 (screen* or test*)).tw,kw,kf. (145066)
41 ((cohort* or age or generation* or "birth year" or baby boom*) adj3 (screen* or test*)).tw,kw,kf. (108981)
42 or/38-41 (668748)
43 37 and 42 (13998)
44 Economics/ (267083)
45 Health Economics/ or Pharmacoeconomics/ or Drug Cost/ or Drug Formulary/ (158426)
46 Economic Aspect/ or exp Economic Evaluation/ (588059)
47 (econom* or price or prices or pricing or priced or discount* or expenditure* or budget* or pharmacoeconomic* or pharmaco-economic*).tw,kw,kf. (1438599)
48 exp "Cost"/ (726555)
49 (cost or costs or costing or costly).ti. (357058)
50 cost effective*.tw,kw,kf. (516730)
51 (cost* adj2 (util* or efficac* or benefit* or minimi* or analy* or saving* or estimate* or allocation or control or sharing or instrument* or technolog* or increment*)).ab,kw,kf. (349811)
52 Monte Carlo Method/ (89886)
53 (decision adj1 (tree* or analy* or model*)).tw,kw,kf. (80788)
54 (markov or markow or monte carlo).tw,kw,kf. (198987)
55 Quality-Adjusted Life Years/ (61686)
56 (QOLY or QOLYs or HRQOL or HRQOLs or QALY or QALYs or QALE or QALEs).tw,kw,kf. (129136)
57 ((adjusted adj1 (quality or life)) or (willing* adj2 pay) or sensitivity analys*s).tw,kw,kf. (250269)
58 or/44-57 (3183092)
59 43 and 58 (1588)
60 (exp animal/ or nonhuman/) not exp human/ (12351490)
61 59 not 60 (1575)
62 Case Report/ or Comment/ or Editorial/ or (letter.pt. not (letter.pt. and randomized controlled trial/)) or conference abstract.pt. or conference review.pt. (12067760)
63 61 not 62 (1248)
64 limit 63 to english language [Limit not valid in CDSR; records were retained] (1169)
65 64 use emez (500)
66 33 or 65 (1109)
67 limit 66 to yr="2014 -Current" (698)
68 67 use medall (336)
69 67 use emez (336)
70 67 use cctr (24)
71 67 use coch (0)
72 67 use cleed (2)
73 remove duplicates from 67 (446)

CINAHL

#	Query	Results
S1	(MH "Hepatitis C+")	16,857

S2 TI(hepatitis C or hep C or hcv or hepacivirus) 13,602
S3 AB(hepatitis C or hep C or hcv or hepacivirus) 13,128
S4 S1 OR S2 OR S3 22,219
S5 (MH "Health Screening") 58,443
S6 TI(("non targeted" or mass or population or asymptomatic or universal or "opt out" or general or widespread or unrestricted or risk based or antibod*) N3 (screen* or test*)) 5,720
S7 AB(("non targeted" or mass or population or asymptomatic or universal or "opt out" or general or widespread or unrestricted or risk based or antibod*) N3 (screen* or test*)) 26,076
S8 TI((opportunistic or sentinel or group or sub?group) N3 (screen* or test*)) 932
S9 AB((opportunistic or sentinel or group or sub?group) N3 (screen* or test*)) 26,937
S10 TI((cohort* or age or generation* or "birth year" or baby boom*) N3 (screen* or test*)) 1,588
S11 AB((cohort* or age or generation* or "birth year" or baby boom*) N3 (screen* or test*)) 15,015
S12 S5 OR S6 OR S7 OR S8 OR S9 OR S10 OR S11 120,906
S13 S4 AND S12 2,040
S14 (MH "Economics") 13,990
S15 (MH "Economic Aspects of Illness") 11,275
S16 (MH "Economic Value of Life") 654
S17 MH "Economics, Dental" 154
S18 MH "Economics, Pharmaceutical" 2,461
S19 MW "ec" 194,280
S20 (econom* or price or prices or pricing or priced or discount* or expenditure* or budget* or pharmacoeconomic* or pharmaco-economic*) 337,145
S21 (MH "Costs and Cost Analysis+")139,678
S22 TI cost* 65,805
S23 (cost effective*) 53,011
S24 AB (cost* N2 (util* or efficacy* or benefit* or minimi* or analy* or saving* or estimate* or allocation or control or sharing or instrument* or technolog*)) 40,315
S25 (decision N1 (tree* or analy* or model*)) 12,441
S26 (markov or markow or monte carlo) 7,982
S27 (MH "Quality-Adjusted Life Years") 6,130
S28 (QOLY or QOLYs or HRQOL or HRQOLs or QALY or QALYs or QALE or QALEs) 15,920
S29 ((adjusted N1 (quality or life)) or (willing* N2 pay) or sensitivity analysis or sensitivity analyses) 26,980
S30 S14 OR S15 OR S16 OR S17 OR S18 OR S19 OR S20 OR S21 OR S22 OR S23 OR S24 OR S25 OR S26 OR S27 OR S28 OR S29 477,298
S31 S13 AND S30 241
S32 PT (Case Study or Commentary or Editorial or Letter or Proceedings) 1,298,823
S33 S31 NOT S32 222
S34 S31 NOT S32 (Limiters -2014-current) 151
S35 S31 NOT S32 (Limiters - English Language Only) 151

Quantitative Evidence of Preferences and Values Search

Database: Ovid MEDLINE(R) ALL <1946 to December 11, 2024>
Search Strategy:
---

1 exp Hepatitis C/ (72471)
2 Hepacivirus/ (38769)
3 (hepatitis C or hep C or hcv or hepacivirus*).ti,ab,kf. (101436)
4 or/1-3 (111035)
5 Mass Screening/ (120077)
6 (("non targeted" or mass or population or asymptomatic or universal or "opt out" or general or widespread or unrestricted or risk based or antibod*) adj3 (screen* or test*)).ti,ab,kf. (115211)
7 ((opportunistic or sentinel or group or sub?group) adj3 (screen* or test*)).ti,ab,kf. (49820)
8 ((cohort* or age or generation* or "birth year" or baby boom*) adj3 (screen* or test*)).ti,ab,kf. (39426)
9 or/5-8 (298669)
10 4 and 9 (5485)
11 Attitude to Health/ (85537)
12 Health Knowledge, Attitudes, Practice/ (133305)
13 Patient Participation/ (30623)
14 Patient Preference/ (11548)
15 Attitude of Health Personnel/ (136336)
16 *Professional-Patient Relations/ (12582)
17 *Physician-Patient Relations/ (37849)
18 Choice Behavior/ (35980)
19 (choice or choices or value* or valuation* or knowledg*).ti. (348782)
20 (preference* or expectation* or attitude* or acceptab* or point of view).ti,ab,kf. (815213)
21 ((clinician* or doctor* or (health* adj2 worker*) or patient*1 or personal or physician* or practitioner* or professional*1 or provider* or user*1 or women or men) adj2 (participation or perspective* or perception* or misperception* or perceiv* or view* or understand* or misunderstand* or value*1 or knowledg*)).ti,ab,kf. (207197)
22 health perception*.ti,ab,kf. (3645)
23 *Decision Making/ (48009)
24 (clinician* or doctor* or (health* adj2 worker*) or patient*1 or personal or physician* or practitioner* or professional*1 or provider* or user*1 or women or men).ti. (3203917)
25 23 and 24 (8753)
26 (decision* and mak*).ti. (42071)
27 (decision mak* or decisions mak*).ti,ab,kf. (247156)
28 26 or 27 (248890)
29 (clinician* or doctor* or (health* adj2 worker*) or patient*1 or personal or physician* or practitioner* or professional*1 or provider* or user*1 or women or men).ti,ab,kf. (10711276)
30 28 and 29 (157025)
31 (discrete choice* or decision board* or decision analy* or decision-support or decision tool* or decision aid* or latent class* or decision* conflict* or decision* regret*).ti,ab,kf. (59405)
32 Decision Support Techniques/ (23177)
33 (health and utilit*).ti. (2165)

34 (gamble* or prospect theory or health utilit* or utility value* or utility score* or utility estimate* or health state or feeling thermometer* or best-worst scaling or time trade-off or TTO or probability trade-off).ti,ab,kf. (18745)
35 (preference based or preference score* or preference elicitation or multiattribute or multi attribute).ti,ab,kf. (4338)
36 or/11-22,25,30-35 (1723933)
37 10 and 36 (426)
38 Case Reports/ or Comment.pt. or Editorial.pt. or (Letter not (Letter and Randomized Controlled Trial)).pt. or Congress.pt. (4576612)
39 37 not 38 (414)
40 exp Animals/ not Humans/ (5288192)
41 39 not 40 (414)
42 limit 41 to english language (388)
43 limit 42 to yr="2014 -Current" (259)

CINAHL

#	Query	Results
S1	(MH "Hepatitis C+")	16,857
S2	TI(hepatitis C or hep C or hcv or hepacivirus)	13,602
S3	AB(hepatitis C or hep C or hcv or hepacivirus)	13,128
S4	S1 OR S2 OR S3	22,219
S5	(MH "Health Screening")	58,443
S6	TI(("non targeted" or mass or population or asymptomatic or universal or "opt out" or general or widespread or unrestricted or risk based or antibod*) N3 (screen* or test*))	5,720
S7	AB(("non targeted" or mass or population or asymptomatic or universal or "opt out" or general or widespread or unrestricted or risk based or antibod*) N3 (screen* or test*))	26,076
S8	TI((opportunistic or sentinel or group or sub?group) N3 (screen* or test*))	932
S9	AB((opportunistic or sentinel or group or sub?group) N3 (screen* or test*))	26,937
S10	TI((cohort* or age or generation* or "birth year" or baby boom*) N3 (screen* or test*))	1,588
S11	AB((cohort* or age or generation* or "birth year" or baby boom*) N3 (screen* or test*))	15,015
S12	S5 OR S6 OR S7 OR S8 OR S9 OR S10 OR S11	120,906
S13	S4 AND S12	2,040
S14	(MH "Attitude to Health")	50,049
S15	(MH "Health Knowledge")	41,995
S16	(MH "Consumer Participation")	24,861
S17	(MH "Patient Preference")	3,699
S18	(MH "Attitude of Health Personnel")	58,676
S19	(MM "Professional-Patient Relations")	15,017
S20	(MM "Physician-Patient Relations")	17,845
S21	(MM "Nurse-Patient Relations")	15,117
S22	TI (choice or choices or value* or valuation* or knowledg*)	126,061
S23	(preference* or expectation* or attitude* or acceptab* or point of view)	580,537
S24	((clinician* or doctor* or (health* N2 worker*) or nurse or nurses or patient or patients or personal or physician* or practitioner* or professional or professionals or provider* or user or users or women or men) N2 (knowledg* or misperception* or misunderstand* or participation or perceiv* or perception* or perspective* or understand* or value or values or view*))	190,905
S25	health perception*	5,634
S26	(MH "Decision Making, Shared")	4,679

S27 (MH "Decision Making, Patient") 15,966
S28 (MH "Decision Making, Family") 4,323
S29 (MM "Decision Making") 26,786
S30 TI (clinician* or doctor* or (health* N2 worker*) or nurse or nurses or patient or patients or personal or physician* or practitioner* or professional or professionals or provider* or user or users or women or men)1,498,933
S31 S29 AND S30 5,728
S32 TI (decision* and mak*) 23,264
S33 (decision mak* or decisions mak*) 190,748
S34 S32 OR S33 190,991
S35 (clinician* or doctor* or (health* N2 worker*) or nurse or nurses or patient or patients or personal or physician* or practitioner* or professional or professionals or provider* or user or users or women or men)3,928,955
S36 S34 AND S35 134,595
S37 (discrete choice* or decision board* or decision analy* or decision support or decision tool* or decision aid* or latent class* or decision* conflict* or decision* regret*) 39,349
S38 (MH "Decision Support Techniques") 7,892
S39 TI (health and utilit*) 1,279
S40 (gamble* or prospect theory or health utilit* or utility value* or utility score* or utility estimate* or health state or feeling thermometer* or best worst scaling or time trade off or TTO or probability trade off) 19,595
S41 (preference based or preference score* or preference elicitation or multiattribute or multi attribute) 1,915
S42 S14 OR S15 OR S16 OR S17 OR S18 OR S19 OR S20 OR S21 OR S22 OR S23 OR S24 OR S25 OR S26 OR S27 OR S28 OR S31 OR S36 OR S37 OR S38 OR S39 OR S40 OR S41 966,582
S43 S13 AND S42 262
S44 PT (Case Study or Commentary or Editorial or Letter or Proceedings) 552,685
S45 S43 NOT S44 253
S46 S43 NOT S44 - Limiters - Publication Date: 20140101-2024123 209
S47 S43 NOT S44 - Narrow by Language: - english 207

Grey Literature Search

Performed: December 12–18, 2024

Websites searched: Alberta Health Evidence Reviews, BC Health Technology Assessments, Canadian Agency for Drugs and Technologies in Health (CADTH), Institut national d'excellence en santé et en services sociaux (INESSS), Institute of Health Economics (IHE), University Of Calgary Health Technology Assessment Unit, Ontario Health Technology Assessment Committee (OHTAC), McGill University Health Centre Health Technology Assessment Unit, Centre Hospitalier de l'Universite de Quebec-Universite Laval, Contextualized Health Research Synthesis Program of Newfoundland (CHRSP), Health Canada Medical Device Database, International HTA Database (INAHTA), Agency for Healthcare Research and Quality (AHRQ) Evidence-based Practice Centers, Centers for Medicare & Medicaid Services Technology Assessments, Veterans Affairs Health Services Research and Development, Institute for Clinical and Economic Review, Oregon Health Authority Health Evidence Review Commission, Washington State Health Care Authority Health Technology Reviews, National Institute for Health and Care Excellence (NICE), National Health Service England (NHS), Healthcare Improvement Scotland, Health Technology Wales, Ireland Health Information and Quality Authority Health Technology Assessments, Adelaide

Health Technology Assessment, Australian Government Medical Services Advisory Committee, Monash Health Centre for Clinical Effectiveness, The Sax Institute, Australian Government Department of Health and Aged Care, Australian Safety and Efficacy Register of New Interventional Procedures - Surgical (ASERNIP-S), Pharmac, Italian National Agency for Regional Health Services (Aegnas), Belgian Health Care Knowledge Centre, Ludwig Boltzmann Institute for Health Technology Assessment (Austria), The Regional Health Technology Assessment Centre (HTA-centrum), Swedish Agency for Health Technology Assessment and Assessment of Social Services, Norwegian Institute of Public Health - Health Technology Assessments, The Danish Health Technology Council, Ministry of Health Malaysia - Health Technology Assessment Section, Tuft's Cost-Effectiveness Analysis Registry, Sick Kids PEDE Database, PROSPERO, EUnetHTA, clinicaltrials.gov

Keywords: Hepatitis C; Hep C; Hepacivrus, HCV; hepatitis c screening; screen*; test*; cohort*; age; generation*; "birth year"; baby boom*; opportunistic; sentinel; group; sub?group; "non targeted"; mass; population; asymptomatic; universal; "opt out"; general; widespread; unrestricted; risk based; antibod; "Mass Screening"; l'hépatite c; hépatite c; HCV

Appendix 4: Critical Appraisal of Clinical Evidence

Table A2: Risk of Bias[a] Among Nonrandomized Trials (ROBINS-I Tool)

	Pre-intervention		At intervention	Post-intervention			
Author, year	Confounding	Study participation selection	Classification of interventions	Deviations from intended intervention	Missing data	Measurement of outcomes	Selection of reported results
Camelo-Castillo et al, 2024[58]	Low	Low	Low	Low	Low	Low	Low
Petkevičienė et al, 2024[59]	Low	Low	Low	Low	Low	Low	Low
Wojcik et al, 2020[43]	Low	Low	Low	Low	Low	Low	Low

Abbreviation: ROBINS-I, Risk of Bias in Nonrandomized Studies – of Interventions.

[a]Possible risk-of-bias levels: low, moderate, serious, critical, no information.

Table A3: GRADE Evidence Profile for the Comparison of General Adult HCV Screening Plus Risk-Based Screening and Risk-Based HCV Screening Alone

Number of studies (design)	Risk of bias	Inconsistency	Indirectness	Imprecision	Publication bias	Upgrade considerations	Quality
Percentage of people screened (HCV antibody test) among people eligible for screening							
3 (observational)[43,58,59]	No serious limitations	No serious limitations	Serious limitations (−1)[a]	No serious limitations[b]	Undetected	Not applicable	⨁ Very low
Percentage of people with a positive HCV antibody test among people screened							
3 (observational)[43,58,59]	No serious limitations	Serious limitations (−1)[c]	Serious limitations (−1)[a]	No serious limitations	Undetected	Not applicable	⨁ Very low
Percentage of people with a positive HCV RNA test among people screened							
2 (observational)[43,58]	No serious limitations	No serious limitations	Serious limitations (−1)[a]	No serious limitations[b]	Undetected	Not applicable	⨁ Very low
Percentage of people previously unaware of their HCV infection							
2 (observational)[43,58]	No serious limitations	No serious limitations	Serious limitations (−1)[a]	No serious limitations[b]	Undetected	Not applicable	⨁ Very low
Linkage to care							
2 (observational)[43,58]	No serious limitations	No serious limitations	Serious limitations (−1)[a]	No serious limitations[b]	Undetected	Not applicable	⨁ Very low

Abbreviations: GRADE, Grading of Recommendations Assessment, Development, and Evaluation; HCV, hepatitis C virus; RNA, ribonucleic acid.

[a]We decided to downgrade the evidence for indirectness because no studies were conducted in Canada and because 2 of 3 studies were conducted in emergency departments, which may have an overrepresentation of people at higher risk of infection who have poor access to primary care services.

[b]Based on 1 study[43] that reported a statistical comparison between the 2 groups.

[c]The results of 2 studies that provided results for the intervention and comparator groups were inconsistent.

Appendix 5: Selected Excluded Studies – Clinical Evidence

For transparency, we provide a list of studies that readers might have expected to see but that did not meet the inclusion criteria, along with the primary reason for exclusion.

Citation	Primary reason for exclusion
Systematic reviews and health technology assessments	
Chou R, Dana T, Fu R, Zakher B, Wagner J, Ramirez S, et al. Screening for hepatitis C virus infection in adolescents and adults: a systematic review update for the U.S. Preventive Services Task Force. Evidence Synthesis No. 188. AHRQ Publication No. 19-05256-EF-1. Rockville, MD: Agency for Healthcare Research and Quality; 2020. Available from: https://www.ncbi.nlm.nih.gov/books/NBK554896/pdf/Bookshelf_NBK554896.pdf	Different population (restricted to studies from the United States)
Goller J, Munari S, Caddy C, Ludwick T, Coombe J, Temple-Smith M, et al. General practice engagement: STI, HIV and viral hepatitis care: an evidence check rapid review brokered by the Sax Institute (www.saxinstitute.org.au) for the NSW Ministry of Health, 2023. Available from: https://www.saxinstitute.org.au/evidence-check/general-practice-engagement-sti-hiv-and-viral-hepatitis-care-an-evidence-check-rapid-review/	Different intervention and comparator
Health Information and Quality Authority. Health technology assessment of birth cohort testing for hepatitis C. 2021. Available from: https://www.hiqa.ie/sites/default/files/2021-07/HTA-of-birth-cohort-testing.pdf	Different research question and/or PICO
Health Technology Assessment Unit, University of Calgary. Hepatitis C screening in Alberta: a health technology assessment. 2016. Available from: https://open.alberta.ca/dataset/94508e51-c9ae-4777-971f-3484860f7ede/resource/cbb2a13f-2a0f-428d-b3e2-5af1c6d514d1/download/ahtdp-hepatitisc-screening-hta-report-2016.pdf	Different research question and/or PICO
Mason LMK, Veldhuijzen IK, Duffell E, van Ahee A, Bunge EM, Amato-Gauci AJ, et al. Hepatitis B and C testing strategies in healthcare and community settings in the EU/EEA: a systematic review. J Viral Hepat. 2019;26(12):1431-53.	Different research question and PICO
Méndez AL, Linde JMM, Hidalgo CC, Peláez SM. Clinical effectiveness, safety, and economic assessment of mass screening for hepatitis C: systematic review. Sevilla: AETSA, Evaluación de Tecnologías Sanitarias de Andalucía, Madrid: Ministerio de Sanidad 2022. Available from: https://www.aetsa.org/download/AETSA_Cribado_VHC_DEF_WEB.pdf	Different intervention and comparator
Schillie S, Wester C, Osborne M, Wesolowski L, Ryerson AB. CDC recommendations for hepatitis C screening among adults - United States. MMWR Recomm Rep. 2020; 69(2):1-17	Different population (restricted to studies from the United States)
Observational studies	
Bätz O, Petroff D, Jedrysiak K, Wolffram I, Berg T, Kramer J, Wiegand J. Successful hepatitis B and C screening in the health check-up in the German primary care setting. JHEP Rep. 2024 24;6(9):101122.	Different intervention
Chastain CA, Jenkins CA, Rose M, Moore D, Parker D, Cave B et al. H. Non-targeted hepatitis C virus screening in acute care healthcare settings in the Southern Appalachian region. J Am Coll Emerg Physicians Open. 2022 Sep 12;3(5):e12819	Noncomparative
Galbraith JW, Anderson ES, Hsieh YH, Franco RA, Donnelly JP, Rodgers JB, Schechter-Perkins EM, Thompson WW, Nelson NP, Rothman RE, White DAE. High prevalence of hepatitis C infection among adult patients at four urban emergency departments - Birmingham, Oakland, Baltimore, and Boston, 2015-2017. MMWR Morb Mortal Wkly Rep. 2020 ;69(19):569-74.	Different comparator
Southern WN, Norton B, Steinman M, DeLuca J, Drainoni ML, Smith BD, Litwin AH. A birth-cohort testing intervention identified hepatitis c virus infection among patients with few identified risks: a cross-sectional study. BMC Infect Dis. 2015 Dec 1;15:553	Different population, intervention, and outcomes

Abbreviation: PICO, population, intervention, comparator, outcomes.

Appendix 6: Study Characteristics – Clinical Evidence

Table A4: Characteristics of Studies Included in the Clinical Literature Review

Author, year Country N Funding	Study design and methods	Participants	Intervention	Comparator	Outcomes
Camelo-Castillo et al, 2024[58] Spain 22,712 (11,368 screened) Gilead Sciences FOCUS program[a]	Prospective data from screening at ED (intervention) Retrospective (comparator) In case of a positive HCV RNA test, the project hepatologist was informed; appointment was made as soon as possible for assessment and treatment to start HCV tests: HCV antibody (LIAISON X-Diasorin assay) + reflex HCV RNA (Roche Cobas 6800 system)	Adults (18–69 y) seeking urgent medical care in the ED, requiring blood test for any reason in their care, with no HCV tests in previous year in the area served by the hospital Hospital is the area's main health care provider	HCV screening for adults (18–69 y) in ED Risk-based: see comparator Period: August 9, 2021, to April 8, 2023	HCV screening in ED based solely on clinical symptoms or medical judgment Period: December 9, 2019, to August 8, 2021	% screened % HCV antibody positive % HCV RNA positive (primary outcome) % previously unaware of HCV infection Liver function assessment % linked to care (phone contact by the project hepatologist and consultation scheduling)
Petkevičienė et al, 2024[59] Lithuania ~1,800,000 (790,070 screened) No external funding	Prospective data received from the National Health Insurance Fund database People with positive HCV antibody test results referred to specialist for HCV RNA test; if positive, transient elastography done; if fibrosis stage ≥ F2 and age 15–74 y, DAAs prescribed All primary health care centres in the country participated Bonus given to GPs to promote and conduct HCV antibody tests HCV tests: HCV antibody, HCV RNA	Adults born between 1945 and 1994 (general adult screening) People of any age (risk-based screening)	One-time HCV screening for adults (1945–1994 birth cohort) + annual risk-based screening (see comparator) Individuals invited for screening during routine primary care visits Period: May 2022 to April 2023	Annual risk-based HCV screening (PWID or living with HIV, any age) Individuals invited for screening during routine primary care visits Period: May 2022 to April 2023	% screened % HCV antibody positive Number of people treated with DAAs

Author, year Country N Funding	Study design and methods	Participants	Intervention	Comparator	Outcomes
Wojcik et al, 2020[43] United States 8,421 Gilead Sciences FOCUS program (EMR programming[b])	Prospective HCV screening based on EMR alert Retrospective EMR chart review for people with positive antibody test If HCV antibody or HCV RNA test positive, infectious disease referral initiated	Adults (≥ 18 y) presenting to the ED who required a blood sample to be drawn and who had not been screened in the previous year EMR alert issued to identify patients for general adult screening and risk-based screening HCV screening provided at no cost to patients	Annual HCV screening for adults (≥ 18 y) Testing every 3 months if risk factors identified Triggered by screening alert Period: June 1, 2018, to October 31, 2018	Risk-based HCV screening of adults ≥ 18 y (CDC-listed risk factor or triage complaint related to intravenous drug use) Triggered by screening alert Period: January 1, 2018, to May 31, 2018	% screened % HCV antibody positive % HCV RNA positive % previously unaware of HCV infection % linked to care (follow-up contact with a primary care provider or specialist through consultation or medical appointment)

Abbreviations: CDC, Centers for Disease Control and Prevention; DAA, direct-acting antiviral; ED, emergency department; EMR, electronic medical record; F0–F4, fibrosis stages, where F0 is no fibrosis and F4 is cirrhosis; GP, general practitioner; HCV, hepatitis C virus; HIV, human immunodeficiency virus; PWID, people who inject drugs; RNA, ribonucleic acid.

[a]Assists in the implementation and establishment of routine infectious disease–related screenings, such as for HCV and HIV, and linkage to care.[58]

[b]Assists in the implementation and establishment of routine infectious disease–related screenings, such as for HCV and HIV. For this study, EMR programming was provided to identify patients for general adult screening and risk-based screening (an HCV screening alert was issued for ED health care providers). HCV screening was provided at no cost to patients.[43]

Appendix 7: Patient Characteristics and Study Results – Clinical Evidence

Table A5: Characteristics of Study Participants

Author, year Country N screened	n by age	Male, n (%)	Ethnicity, n (%)
Camelo-Castillo et al, 2024[58] Spain 11,368	Among people screened (N = 11,368) 18–29 y: 1,453 (12.8%) 30–39 y: 1,818 (16.0%) 40–49 y: 2,258 (19.8%) 50–59 y: 2,463 (21.6%) 60–69 y: 3,376 (29.7%) Among people with positive HCV antibody test (N = 199) 18–29 y: 1 (0.5%) 30–39 y: 7 (3.5%) 40–49 y: 22 (11.0%) 50–59 y: 103 (51.7%) 60–69 y: 66 (33.1%) Among people with positive HCV RNA test (N = 43) 18–29 y: 0 (0.0%) 30–39 y: 0 (0.0%) 40–49 y: 4 (9.3%) 50–59 y: 27 (62.7%) 60–69 y: 12 (27.9%)	Among people screened 5,797 (51) Among people with positive HCV antibody test 151 (75.9) Among people with positive HCV RNA test 34 (79.1)	Among people screened Spanish nationality: 9,788 (86.1) Other: 1,580 (13.9) Among people with positive HCV antibody test[a] Spanish nationality: 67 (88.2) Other: 9 (11.8) Among people with positive HCV RNA test Spanish nationality: 38 (88.3) Other: 5 (11.6)
Petkevičienė et al, 2024[59] Lithuania 790,070	Birth year 1985–1994: 107,940 (13.7%) Birth year 1975–1984: 136,952 (17.3%) Birth year 1965–1974: 193,960 (24.5%) Birth year 1955–1964: 213,397 (27.0%) Birth year 1945–1954: 137,628 (17.4%)	330,466 (41.8)	Not reported
Wojcik et al, 2020[43] United States General adult + risk-based screening: N = 318 with HCV antibody positive result Risk-based screening: N = 126 with positive HCV antibody result	Median age for general adult + risk-based screening: 40 y (range: 19–81 y) Median age for risk-based screening: 39 y (range: 21–73 y)	General adult + risk-based screening: 200 (62.9) Risk-based screening: 75 (59.5)	White General adult + risk-based screening: 292 (91.8) Risk-based screening: 113 (89.7) African-American General adult + risk-based screening: 15 (4.7) Risk-based screening: 5 (4.0) > 1 or unknown ethnicity General adult + risk-based screening: 11 (3.5) Risk-based screening: 8 (6.3) Hispanic General adult + risk-based screening: 0 Risk-based screening: 1 (0.8)

Abbreviations: HCV, hepatitis C virus; RNA, ribonucleic acid.

[a]Information as per the numbers provided in the publication; numbers do not add to 199 (number of people with a positive antibody test).

Table A6: Study Results

Author, year Country N	Antibody testing, n (%)	Positive HCV antibody test, n (%)	Positive HCV RNA test, n (%)	Previously unaware of infection or previously undiagnosed, n (%)	Linkage to care, n (%)
Camelo-Castillo et al, 2024[58] Spain 22,712	General adult + risk-based screening: 11,368 (50.1)[a] Risk-based screening: 267 (NR)	General adult + risk-based screening: 199 (1.75) Risk-based screening: NR	General adult + risk-based screening: 43 (0.38 of screened, 21.6 of antibody positive) Risk-based screening: 0 (1 y before general adult screening started) <u>Risk factors among 21 (48.8%) people with a documented risk factor</u> Use of injected or inhaled drugs: 18 (41.9%) From countries with a medium or high HCV prevalence: 4 (9.3%) History of incarceration: 3 (7%) HIV or HBV coinfection: 1 (2.3%)	General adult + risk-based screening: 24 (55.8) Risk-based screening: NR	<u>General adult + risk-based screening</u> *Linked:* 33 (76.7) Seen in consultation: 24 Not seen (because of death, failure to attend scheduled consultations, or incarceration): 9 *Not linked:* 10 (23.3) No consultation (because of concomitant diseases or refusal of possible treatment): 4 Could not be contacted (because of lack of contact information or death): 6 <u>Risk-based screening</u> NR
Petkevičienė et al, 2024[59] Lithuania ~1,800,000	General adult + risk-based screening: 790,070 (44) Risk-based screening: 6,695 (NR)	General adult + risk-based screening: 11,943 (1.5) (male: 6,306 [1.9%]; female: 5,637 [1.2%]) Risk-based screening: 2,087 (31.1) (male: 1,083 [32.3%]; female: 1,004 [29.9%])	NR	NR	NR

Author, year Country N	Antibody testing, n (%)	Positive HCV antibody test, n (%)	Positive HCV RNA test, n (%)	Previously unaware of infection or previously undiagnosed, n (%)	Linkage to care, n (%)
Wojcik et al, 2020[43] United States 31,422	General adult + risk-based screening: 5,407 (32.9) Risk-based screening: 3,014 (20.1) *P* < 0.00001[b]	General adult + risk-based screening: 318 (5.9) Risk-based screening: 126 (4.2) *P* < .001 <u>Risk factors among people with a documented risk factor</u> *IDU (most common)* General adult + risk-based screening: 166 (58.7) Risk-based screening: 73 (73.0) *P* = .21 *1945–1965 birth cohort* General adult + risk-based screening: 80 (28.3%) Risk-based screening: 59 (59.0) Note: 11 people in the risk-based screening group had both risk factors	General adult + risk-based screening: 186 (3.4 of screened, 58.5 of antibody positive) Risk-based screening: 76 (2.5 of screened, 60.3 of antibody positive) *P* = .72 for people with a positive antibody test *P* = .02[b] for people screened	<u>Newly identified infection</u> General adult + risk-based screening: 229 (72.0) Risk-based screening: 86 (68.3) *P* = .44[b]	General adult + risk-based screening: 205 (64.5) Risk-based screening: 59 (46.8) *P* = .0007[b]

Abbreviations: HBV, hepatitis B virus; HCV, hepatitis C virus; HIV, human immunodeficiency virus; IDU, intravenous drug use; NR, not reported; RNA, ribonucleic acid.

[a]Either 11,344 refused the test or there were problems with sample collection.[58]

[b]Calculated by the authors of this report using the chi-square test.

Appendix 8: Results of Applicability Checklists for Studies Included in the Economic Literature Review

Table A7: Assessment of the Applicability of Studies Evaluating the Cost-Effectiveness of HCV Screening

Author, year, country	Is the study population appropriate for the review question?	Are the interventions appropriate for the review question?	Is the system in which the study was conducted sufficiently like the current Ontario context?	Is the perspective of the costs appropriate for the review question (e.g., Canadian public payer)?	Is the perspective of the outcomes appropriate for the review question?	Are all future costs and outcomes discounted appropriately (as per current CDA guidelines)?	Are QALYs derived using CDA's preferred methods, or is an appropriate social care–related equivalent used as an outcome? (If not, describe rationale and outcomes used in line with the analytical perspective taken)	Overall judgment[a]
Wong et al, 2015,[74] Canada	Partially	Yes, partially	Yes	Yes	Yes	Yes	Yes	Partially applicable
Wong et al, 2017,[72] Canada	Partially	Yes, partially	Yes	Yes	Yes	Yes	Yes	Partially applicable
Wong et al, 2023,[73] Canada	Partially	Yes, partially	Yes	Yes	Yes	Yes	Yes	Partially applicable
Sahakyan et al, 2023,[68] Canada	Partially	Yes, partially	Yes	Yes	Yes	Yes	Yes	Partially applicable

Note: Response options for all items were "yes," "partially," "no," "unclear," and "NA" (not applicable).

Abbreviations: CDA, Canada's Drug Agency; QALY, quality-adjusted life-year.

[a]Overall judgment may be "directly applicable," "partially applicable," or "not applicable."

Appendix 9: Letter of Information

LETTER OF INFORMATION

Ontario Health

Ontario Health is conducting a review of **hepatitis C screening.** The purpose is to better understand the feasibility of expanding screening to all adults in Ontario.

An important part of this review involves gathering perspectives of patients who have been diagnosed or tested for hepatitis C.

WHAT DO YOU NEED FROM ME

- ✓ Willingness to share your story
- ✓ 30-40 minutes of your time for a phone interview
- ✓ Permission to audio- (not video-) record the interview

WHAT YOUR PARTICIPATION INVOLVES

If you agree to share your experiences, you will be asked to have an interview with Ontario Health (OH) staff. OH staff will contact interested participants by collecting contact information (i.e., email address and/or phone number) to set up an interview. The interview will last about 30-40 minutes. It will be held over the telephone. With your permission, the interview will be audio-taped. The interviewer will ask you questions about your or your loved one's condition and your perspectives about your diagnosis and treatment options in Ontario. Participation is voluntary. You may refuse to participate, refuse to answer any questions or withdraw before or at any point during your interview. Withdrawal will in no way affect the care you receive.

CONFIDENTIALITY

All information you share will be kept confidential and your privacy will be protected except as required by law. The results of this review will be published, however no identifying information will be released or published. Any records containing information from your interview will be stored securely until project completion. After completion of the project, the records will be destroyed. If you are sending us personal information by email, please be aware that electronic communication is not always secure and can be vulnerable to interception.

Ontario Health is designated an "institution" by the *Freedom of Information and Protection of Privacy Act* (FIPPA) and is collecting your personal information pursuant to FIPPA and the *Connecting Care Act, 2019* to support the Health Technology Assessment Program. If you have any questions regarding Ontario Health's collection and use of personal information for the purposes of this program, please contact Team Lead, Jigna Mistry noted below.

RISKS TO PARTICIPATION

There are no known physical risks to participating. Some participants may experience discomfort or anxiety after speaking about their experience.

IF YOU ARE INTERESTED, PLEASE CONTACT US:

Appendix 10: Interview Guide

Diagnosis and Burden of Disease

- Can you describe your diagnosis journey with HCV?
- What was the impact of HCV on your day-to-day life, social life, work, relationships, and quality of life?
- What was the impact of diagnosis? Peace of mind after diagnosis?
- Did you experience any stigma or discrimination due to this disease?

Screening

- How did you become aware about HCV screening or testing?
- Where did you get screened for HCV? (probe: family doctor, walk-in clinic, hepatitis C program, community HCV testing event, emergency department, etc.)
- What HCV test did you get? (i.e., antibody, RNA)
- How was the test conducted? Was there a follow up?
  - HCV antibody screening → blood draw or point-of-care or finger-prick test
  - HCV RNA test to assess for active infection → blood draw, dried blood spot, or point of care or finger prick (for HCV RNA testing, point of care is unlikely but maybe in the context of research)
- What was your overall experience with HCV screening or testing? (probe: was it quick, did you have to make multiple visits, over how long, was there support, pre- and post-test counselling, etc.)
- Did you have to pay, any miscellaneous cost associated with screening? (probe: inconvenience, loss of income, loss to follow-up leading to potential risk of disease progression for the individual and potential transmission to others, etc.)
- Did you receive a gift (e.g., money, gift card) for get screened or tested for HCV?
- Were there any barriers to access screening or testing for HCV? (probe: barriers to access care and treatment)

If Diagnosed With HCV

- How did you seek treatment? What treatment was offered? How long did it take?
- What do you think could have made it easier for you to get screened, tested, and treated?
- What is your opinion/preference regarding expanding HCV screening beyond risk-based groups?

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About Us

We are an agency created by the Government of Ontario to connect, coordinate, and modernize our province's health care system. We work with partners, providers, and patients to make the health system more efficient so everyone in Ontario has an opportunity for better health and well-being.

Equity, Inclusion, Diversity and Anti-Racism

Ontario Health is committed to advancing equity, inclusion and diversity and addressing racism in the health care system. As part of this work, Ontario Health has developed an Equity, Inclusion, Diversity and Anti-Racism Framework, which builds on existing legislated commitments and relationships and recognizes the need for an intersectional approach.

Unlike the notion of equality, equity is not about sameness of treatment. It denotes fairness and justice in process and in results. Equitable outcomes often require differential treatment and resource redistribution to achieve a level playing field among all individuals and communities. This requires recognizing and addressing barriers to opportunities for all to thrive in our society.

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