# HEPATITIS C SELF-TESTING AND SELF-COLLECTION AMONG PEOPLE WITH EXPERIENCE IN THE CANADIAN CARCERAL SYSTEM: A QUALITATIVE STUDY

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## Abstract

### Background

The World Health Organization (WHO) has identified hepatitis C virus (HCV) self-testing as a priority to achieve global HCV elimination goals. However, uptake remains limited, especially among individuals with incarceration experience. This study explored their perspectives, preferences, and needs regarding HCV self-testing delivery in Canada.

### Methods

Fifteen individuals with lived experience of the Canadian carceral system participated in semi-structured interviews between August and October 2023. Interviews explored preferences for HCV self-testing and self-collection. Data were analyzed using interpretive description.

### Result(s)

Four themes emerged: 1) authentic representation as "words carry power"; 2) altruism triumphs in the face of stigma and uncertainty; 3) distrust of society, systems and self, shaping preferences for privacy, autonomy and control; and 4) low-barrier and accessible options described as "easy, easy, easy." Most participants preferred access to test kits immediately after release. Promotional materials should authentically reflect the population. Distrust of systems led to flexible options for receiving results, including phone, text, in-person, or email.

### Conclusion(s)

Findings provide guidance for designing accessible and acceptable HCV self-testing programs that reflect the preferences and needs of people with incarceration experience.

*Keywords: hepatitis C virus; self-testing; carceral settings; perspectives; interpretative description*

## Summary for Lay Audience

Hepatitis C virus (HCV) is a viral infection that is passed through blood-to-blood contact and if left untreated can cause severe liver damage and liver cancer. HCV affects about 50 million people worldwide. Each year, around 1 million people become newly infected and approximately 242,000 people die from hepatitis C-related illnesses. HCV continues to be a major public health issue around the world and in Canada. It is estimated that about 387,000 Canadians have been infected with the virus leading to serious health problems and increased use of healthcare services. In the past, treatment for HCV required 24 to 48 weeks of interferon-based injections. This treatment had serious side effects, low cure rates and was not suitable for people with advanced liver disease or people who had certain mental health concerns. Since 2018, most Canadians have had access to well-tolerated oral medications that can cure HCV in 8 to 12 weeks, but many people remain untreated. As a result of improvements in diagnostic testing and curative treatment, in 2016 the World Health Organization (WHO) has set a goal to eliminate HCV as a public health threat by 2030, and Canada has signed on to this goal.

HCV can be easily passed from person to person through sharing injection drug equipment, and people who inject drugs are one of the populations most affected by HCV. Rates of HCV are also high among people who have experience being incarcerated. This is partly because people who are or have been incarcerated are more likely to have a history of injection drug use and may face barrier to accessing HCV prevention, testing, and treatment, but also because of a complete lack of access to harm reduction supplies in facilities for safer sex, tattooing, snorting, and injecting. Frequent movement between correctional facilities and the community increases the importance of providing access to screening, care, and curative treatment in both settings.

Correctional facilities are recognized by the WHO as important locations for HCV testing, treatment, and prevention efforts to support the elimination of HCV.

HCV diagnosis in many parts of Canada involves a multistep process that can create barriers to timely diagnosis and treatment. Initial HCV screening is performed using an HCV antibody test, which identifies whether a person has ever been exposed to the virus. However, a positive antibody result cannot determine whether the person is infected, and a second test called an HCV RNA test is required to detect the presence of the virus in the blood. In many large urban centres, laboratories use reflex testing. This means an HCV RNA test is automatically performed on the same blood sample following a positive antibody result. However, reflex testing is not available in all settings/regions, and patients may need to return for additional blood draws, clinic visits, or follow-up appointments. These additional steps combined with barriers such as stigma and systemic racism in healthcare in addition to transportation challenges, childcare needs, unstable housing, language barriers, mental health challenges, and substance use related barriers; delay diagnosis and increase the risk of individuals being lost to follow-up before they are linked to HCV care and treatment.

In 2017, Health Canada approved the first HCV point-of-care (POC) test allowing screening with a simple fingerprick blood sample. A POC test can be performed in non-clinical settings and can help to reach people who might not otherwise be tested. However, a positive HCV antibody test must be followed by confirmatory testing to determine whether an individual has an active infection requiring treatment. One approach is the use of dried blood spot (DBS) testing, which involves collecting a few drops of blood from a fingerprick onto a paper card that is sent to a laboratory for analysis. DBS testing is less invasive than a traditional blood draw and can

improve access to HCV testing, particularly for people with a current or history of injection drug use who may experience challenges with blood draws.

HCV POC tests have made HCV screening more accessible and has helped decentralize HCV diagnosis by moving testing outside of traditional laboratory environments. This shift has contributed to the development of more autonomous approaches such as self-testing. Building on this progress, the WHO recommends HCV self-testing as a strategy to further improve testing uptake and early diagnosis. The WHO's recommendation is largely informed by evidence from HIV self-testing, which has been shown to be accurate, acceptable, and effective at increasing testing rates across diverse populations, particularly when linked to appropriate confirmatory testing and care pathways. Self-testing allows individuals to collect their own sample, perform a rapid test, and interpret results privately, which can reduce concerns related to stigma, confidentiality, and healthcare engagement. HCV self-testing is not currently Health Canada approved, however, in theory an individual could perform a rapid HCV antibody POC test and, if the result is positive, self-collect a DBS sample for confirmatory testing.

Building on the evidence from HIV self-testing and the limited HCV specific data available, this study explored the views on HCV self-testing of people who have spent time in Canadian correctional facilities. HCV self-testing allows individuals to collect their own sample, perform an HCV antibody test themselves, and receive their results privately and conveniently outside of a healthcare setting. Researchers interviewed 15 individuals and found that participants generally supported self-testing, especially if it was easy to access, offered privacy, and gave them control over how they received their results. Many preferred to receive self-test kits immediately after release from custody. Participants emphasized the importance of using respectful, authentic

language and images that reflect the experiences of people with incarceration histories. Despite concerns about stigma and distrust of healthcare and other systems, many were motivated by a desire to help themselves and others access testing and care. The study findings provide important guidance for designing HCV self-testing programs that are accessible, trustworthy, and responsive to the needs of people with experience of incarceration. Future research on HCV self-testing should focus on evaluating implementation strategies that integrate self-testing for key populations while ensuring programs are equity based, accessible and provide linkage to care across diverse and underserved populations.

## Honouring the Land and Territory

I wanted to recognize the lands upon which I live in Victoria, British Columbia, Canada which is the traditional and unceded territories of the Lək̓ʷəŋən (Songhees and Xwsepsum/Esquimalt) and W̱SÁNEĆ Peoples.

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## Co-Authorship Statement

Tamara Barnett completed the work for this thesis under the supervision of Dr. Mia J. Biondi and Dr. Karen A. Campbell, who will be co-authors of all publications and presentations developing from this work.

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## Table of Contents


Abstract ..... ii

Summary for Lay Audience ..... iv

Honouring the Land and Territory ..... viii

Co-Authorship Statement ..... ix

Canadian Network on Hepatitis C (CanHepC) Acknowledgement ..... x

Acknowledgements ..... xi

Table of Contents ..... xiv

List of Abbreviations ..... xvii

CHAPTER ONE ..... 1

INTRODUCTION ..... 1

Hepatitis C Virus and Clinical Manifestations ..... 2

Direct-Acting Antiviral Therapy ..... 3

HCV Related Healthcare Costs and Co-Occurring Structural Barriers ..... 5

Traditional Diagnostic Pathways Versus POC Testing ..... 6

Simplified Service Delivery Through Decentralization, Task-Shifting and Task-Sharing ..... 7

Nurse-led Models of Care ..... 9

The Role of Peers in HCV Care ..... 10

Self-Testing and Self-Collection ..... 11

Injection Drug Use, Incarceration, and HCV ..... 15

Rationale for Study ..... 17

Statement of Study Purpose ..... 18

HCV Self-Testing Operationally Defined ..... 18

Positionality ..... 18

Overview of the Thesis ..... 21

CHAPTER TWO ..... 23

A QUALITATIVE STUDY: HEPATITIS C SELF-TESTING AND SELF-COLLECTION AMONG PEOPLE WITH EXPERIENCE IN THE CANADIAN CARCERAL SYSTEM ..... 23

Background ..... 23

Methods ..... 26
Results ..... 30
Table 1. Summary of themes, responses, and quotes. ..... 31
Authentic Representation Because “Words Carry Power” ..... 32
Figure 1. HCV self-testing sample poster shown to study participant to get their feedback on future HCV self-testing flyers. ..... 33
Table 2. Participants’ suggestions for HCV self-testing advertising and awareness campaigns. ..... 35
Altruism Triumphs Even in the Face of Stigma & Uncertainty ..... 36
Distrust of Society, System, & Self ..... 37
Low-barrier and Accessible Means “Easy, Easy, Easy…” ..... 38
Discussion ..... 40
Conclusion ..... 44
CHAPTER THREE ..... 47
SUMMARY OF KEY FINDINGS, CLINICAL IMPLICATIONS, RECOMMENDATIONS FOR FUTURE RESEARCH AND KNOWLEDGE DISSEMINATION ..... 47
Summary of Key Findings ..... 47
Strengths and Limitations ..... 48
Clinical Implications ..... 49
Recommendations for Future Research ..... 51
Integrated Knowledge Translation and Dissemination ..... 53
Conclusion ..... 54
References ..... 55
APPENDICES ..... i
APPENDIX A ..... i
Ethics Approval from York University ..... i
APPENDIX B ..... ii
Qualitative Interview Guide ..... ii
APPENDIX C ..... v
Study Protocol ..... v
1.0 BACKGROUND & RATIONALE ..... vi

2.0 STUDY OBJECTIVES, HYPOTHESIS & ENDPOINTS ..... viii
3.0 STUDY DESIGN ..... ix
4.0 DATA ANALYSIS ..... x
5.0 QUALITY ASSURANCE & QUALITY CONTROL ..... xi
6.0 DATA HANDLING AND RECORD KEEPING ..... xi
7.0 FUNDING ..... xi
8.0 REFERENCES ..... xi
APPENDIX D ..... xiv
Informed Consent Form for Participation in Research Study ..... xiv

## List of Abbreviations

CanHepC: Canadian Network on Hepatitis C

CATIE: Canada's Source for HIV and Hepatitis C Information

CDDW-CLM: Canadian Digestive Disease Week-Canadian Liver Meeting

COVID-19: coronavirus disease 2019

DAA: direct acting antiviral

DBS: dried blood spot

FMP: Family Medicine Physician

gbMSM: gay, bisexual, men who have sex with men

HIV: human immunodeficiency virus

HCV: hepatitis C virus

HPV: human papilloma virus

ID: interpretive description

INHSU: Internation Network on Health and Hepatitis in Substance Users

MSM: men who have sex with men

NP: Nurse Practitioner

OAT: opioid agonist therapy

PASAN: Prisoners HIV/AIDS Support Action Network

POC: point-of-care

PWID: people who inject drugs

PWLLE: people with lived and living experience

QR: quick response

RN: Registered Nurse

RN(c): Registered Nurse with certified practice

RNA: ribonucleic Acid

STBBI: sexually transmitted and blood-borne infection

SVR: sustained virological response

WHO: World Health Organization

# CHAPTER ONE

## INTRODUCTION

Hepatitis C virus (HCV) infection affects 50 million people worldwide, with 1 million new infections occurring each year, and approximately 242,000 HCV related deaths occurring annually (World Health Organization, 2022b). Globally, HCV remains a significant public health concern and an important public health problem within Canada as there are an estimated 387,000 Canadians affected by the virus, resulting in considerable morbidity and healthcare utilization (Popovic et al., 2022). Initially, HCV was categorized as non-A, non-B, hepatitis and believed to have originated 500 to 2000 years ago (Stroffolini & Stroffolini, 2024). It remained unidentified until the virus was successfully isolated and cloned in 1989, with the scientists responsible being awarded a Nobel Prize in 2020 (Stroffolini & Stroffolini, 2024). HCV is a ribonucleic acid (RNA) virus and classified as a *Hepacivirus* with in the *Flaviviridae* family (Stroffolini & Stroffolini, 2024). HCV is transmitted through exposure to HCV infected blood or bodily fluids, including unsafe medical and dental procedures, unscreened blood and blood product transfusions, sexual practices involving exposure to blood, vertical transmission and sharing of drug use equipment (Stroffolini & Stroffolini, 2024; World Health Organization, 2022b). In high-income countries the risk of contracting HCV through blood transfusion and iatrogenic exposure has been minimized through blood product screening, infection control practices, and the implementation of safer medical and dental procedures. The use of non-sterilized glass syringes and unscreened blood transfusion continue to play major role in HCV transmission in low and middle income countries (Cameroon, Central Africa Republic, Egypt) (Stroffolini & Stroffolini, 2024). At present in Canada, HCV is commonly transmitted through sharing drug use equipment for injecting and snorting.

Epidemiologic data in Canada demonstrates that people who inject drugs continue to bear a disproportionate burden of HCV, accounting for many new and existing HCV cases (Lourenço et al., 2021; The Canadian Network on Hepatitis C, 2019). At the same time transmission among underserved and equity deserving populations such as Indigenous Peoples, men who have sex with men (MSM), people with experience in carceral settings and those born to someone with HCV (vertical transmission) remains a significant public health challenge (Dunn, 2024; Lourenço et al., 2021; The Canadian Network on Hepatitis C, 2019).

## Hepatitis C Virus and Clinical Manifestations

Following HCV exposure, the immune system can take up to 12 weeks for antibodies to develop and these antibodies can be detected through HCV antibody screening to determine whether an individual has ever been exposed to the virus, while active infection is confirmed through nucleic acid testing for HCV RNA (Liu & Kao, 2023). Most acute HCV infections (approximately 80%) are asymptomatic (Liu & Kao, 2023), and 25-50% of individuals spontaneously clear the virus within six months of acquisition. The hepatitis C virus is often asymptomatic particularly in the early stages of the disease. When symptoms do occur, they develop six to seven weeks after infection with symptoms including fever, fatigue, loss of appetite, nausea, vomiting, abdominal pain, dark urine and jaundice (British Columbia Centre for Disease Control, 2026; World Health Organization, 2022b). Those with chronic infection will continue to have a detectable HCV RNA after six months and will be unlikely to spontaneously clear on their own (Bulteel et al., 2016; Grebely et al., 2010; Rzymski et al., 2024). Factors associated with spontaneous clearance include younger age, female sex, lower viral load, frequent injection drug use, and hepatitis B co-infection (Bulteel et al., 2016; Grebely et al., 2010; Rzymski et al., 2024). Chronic HCV infections is often associated with persistent fatigue and reduced energy levels and

these non-specific symptoms can be difficult to diagnosis as they are common to many other health conditions (British Columbia Centre for Disease Control, 2026). Overtime, chronic HCV has many serious long term health implications such as liver fibrosis, liver cirrhosis, hepatocellular carcinoma and death (Liu & Kao, 2023). Chronic HCV has also been shown to have negative effect on well-being and to have profound social consequences, including isolation, anxiety related to stigma and fear of transmission, worsening mood, perceived discrimination, and low self-esteem (Harris et al., 2021; Miller et al., 2012).

Currently, there is no vaccine available to prevent HCV infection, although recent efforts are focusing on innovative models to expedite vaccine testing (Feld et al., 2023). Prior to 2015, and the introduction of direct acting antiviral (DAA) medications the standard HCV treatment included specialist-led (hepatology, gastroenterology, infectious disease) use of interferon-based treatment regimens (pegylated interferon plus ribavirin over 24-48 weeks) which had poor tolerance, challenging side effects (flu-like symptoms, fatigue, cognitive changes, exacerbation of psychiatric conditions, thrombocytopenia, hemolytic anemia), with only 50% of individuals achieving HCV cure (sustained virological response (SVR)) (Kohli et al., 2014). Due to the serious side effects and long treatment duration, the use of interferon-based treatments was limited to selected patient populations while excluding individuals with decompensated cirrhosis and people with psychiatric conditions (Dietz & Maasoumy, 2022; Kohli et al., 2014; Maasoumy et al., 2013).

## Direct-Acting Antiviral Therapy

The introduction of DAA therapies in 2015 revolutionized HCV treatment (Dietz & Maasoumy, 2022). DAAs are antiviral medications that specifically target viral proteins (one non-structured protein (NS5A) and two HCV enzymes (NS3/4A, NS5B)) and stop viral replication in the body (Li & De Clercq, 2017). Formerly used interferon in combination with ribavirin worked

by creating a broad non-specific immune response throughout the body that inhibited viral replication, disrupts RNA synthesis, and promoted viral mutagenesis (Feld & Hoofnagle, 2005). DAAs are well tolerated when compared to interferon-based regimes because they target specific viral proteins involved in HCV replication rather than triggering a non-specific systemic immune response. DAAs are highly effective leading to a cure in over 95% of individuals, safe, with minimal on treatment monitoring, and well tolerated with only mild side effects such as fatigue, nausea and headache, curing most infections within 8 or 12 weeks (Dietz & Maasoumy, 2022). Clinically, HCV cure after treatment with DAAs is defined as SVR, which refers to the absence of detectable HCV RNA in the blood following treatment. SVR is typically assessed 12 weeks after therapy ends (SVR12) and recently SVR4 (SVR at 4 weeks post treatment completion) has been suggested to reduce lost to follow up for confirmatory cure bloodwork (McDonell et al., 2026). The high efficacy and favourable tolerability profile of DAAs expanded treatment eligibility to populations that had previously been excluded from HCV therapy because of contraindications associated with earlier treatment regimens. As a result, many individuals who were once considered unsuitable candidates for treatment could now be successfully treated and cured of HCV infection. This led the WHO in 2016 to release a global strategy to eliminate HCV by 2030 as a global public health problem (World Health Organization, 2016a, 2016b). The WHO released global HCV elimination targets of a 90% reduction in HCV incidence, and a 65% reduction in morbidity by 2030 (World Health Organization, 2016a, 2016b). Canada developed its own National guiding document and in 2019, the *Blueprint to Inform Hepatitis C Elimination Efforts in Canada* was developed by the Canadian Network on Hepatitis C (CanHepC) to guide Canada's response to meet the WHO's HCV elimination targets (The Canadian Network on Hepatitis C, 2019). The Blueprint recognizes five priority populations that are disproportionally affected by

HCV which includes people who inject drugs, Indigenous peoples (First Nations, Métis, Inuit), people who have experienced incarceration, newcomers and immigrants, those born between 1945-1975 (birth cohort), and gay, bisexual, and men who have sex with men (gbMSM) (The Canadian Network on Hepatitis C, 2019). Initially, there was reluctance in some settings to treat people who were actively using substances. However, findings from a landmark international multicentre open-label phase 4 trial and a pragmatic randomized trial in the United States showed that individuals who are actively injecting drugs can achieve high cure rates, thus active drug use should not be considered a barrier to successful HCV treatment (Conway et al., 2024; Cunningham et al., 2018; Heo et al., 2024). Importantly, SVR rates of a least 90% can be obtained even with missed doses and ongoing substance use (Heo et al., 2024).

## HCV Related Healthcare Costs and Co-Occurring Structural Barriers

Annual HCV related costs in Canada, are estimated at $160 million per year and are projected to increase to $260 million per year by 2032 (Myers et al., 2014). Thus, HCV 'treatment as prevention' is a key public health strategy that focuses on identifying and treating individuals living with HCV to achieve a cure and prevent onward transmission (Grebely & Dore, 2017; Hajarizadeh et al., 2021; Hickman et al., 2015). Improving access to testing and treatment is essential for priority populations that experience intersectionality, where factors such as race, gender, immigration status, Indigenous identity, poverty, housing instability, substance use, current or former involvement with the justice system that overlap and intersect. People facing intersectionality may be less likely to receive HCV testing, diagnosis and linkage to care. Structural barriers to healthcare access, including stigma, discrimination, social marginalization, and socioeconomic inequities can also further hinder access to HCV care (Passos-Castilho et al., 2024). The burden of HCV is particularly pronounced among populations disproportionately affected by

HCV, intersectionality, and structural barriers to healthcare including people who inject drugs (85% of new HCV infections; 46% prevalence) and individuals in carceral settings prison (8–40% HCV prevalence) (Bartlett et al., 2021; Popovic et al., 2022). Although the introduction of DAAs has made HCV highly curable, achieving HCV elimination requires more than effective treatment alone. It requires reaching populations that are underserved by traditional healthcare systems. In Canada, approximately 0.54% of Canadians are living with HCV with nearly one-quarter remaining undiagnosed due to the asymptomatic nature of the infection (Popovic et al., 2022).

## Traditional Diagnostic Pathways Versus POC Testing

Another major barrier to HCV elimination is the multistep diagnostic pathway, which requires multiple healthcare visits and can result in delays and loss to follow-up (Feld, 2024). Specifically, the traditional screening and diagnosis of HCV requires an HCV antibody test to determine exposure. Of individuals exposed to HCV, approximately 25-50% will clear the infection on their own (Grebely et al., 2010; Kimble, Javanbakht, et al., 2019; Newsum et al., 2017), and be antibody positive, but not actively infected (HCV RNA negative). To determine if an individual has an active infection, an HCV RNA test must be completed. Unfortunately, this two-step process leads to loss to follow-up rates of 30% (Spradling et al., 2014) in places where the test is not reflexed (HCV positive antibody test automatically sent for HCV RNA testing) (Mandel et al., 2023). Thus, many individuals never find out if they are actively infected and therefore are never engaged in HCV treatment pathways. Additionally, many other barriers contribute to the difficulty in HCV case-finding. People who have a current or history of using injection drugs may have difficult venous access; are re-traumatized during phlebotomy; or might never return for results. Each individual step from antibody positivity to HCV cure, leads to opportunities for loss to follow-up.

Fortunately, in 2017, Health Canada approved the first POC HCV antibody test. This test utilizes lateral flow technology, to give a visual result of HCV seropositivity and has a sensitivity of 98% and specificity of 100% (Cha et al., 2013). Approved POC antibody tests for HCV include the OraQuick, with an on-label result in 20 minutes. However, the read time of this test can be shortened to 5 minutes which will identify viremic patients with 100% sensitivity (95% CI, 98.4%–100%)) (Smookler et al., 2021). The HCV INSTI is more recently approved by Health Canada, and provides results in one minute (bioLytical, 2025). POC HCV antibody testing has had tremendous utility, helping to reach individuals who would not have been screened through conventional methods, with only a single drop of blood from a fingerprick (Smookler et al., 2021). Despite the utility of POC antibody testing, confirmation of active infection is required. One way to avoid venipuncture is to use dried blood spots (DBS) to collect a blood sample for HCV RNA testing. This method uses a fingerprick to collect drops of blood onto filter paper, which is then sent to a laboratory, cut out, eluted, and processed. DBS has a sensitivity and specificity of 97% and 100% making DBS testing reliable at identifying HCV RNA with extremely low likelihood of producing false positive results (Catlett et al., 2022). POC antibody testing with subsequent DBS allows for HCV diagnosis without requiring venipuncture or a visit to a laboratory, reducing barriers associated with traditional diagnostic pathways, may decrease loss to follow-up, and allows for self-collection (Stevens et al., 2025). Unfortunately, this test is not available in all provinces (Mandel et al., 2023). HCV POC antibody and DBS testing may also support ongoing HCV screening for individuals with persistent risk factors for reinfection.

**Simplified Service Delivery Through Decentralization, Task-Shifting and Task-Sharing**

According to the WHO, “achieving the 2030 90% testing, and 80% treatment coverage targets for HCV elimination, will require a radical simplification of care pathways to overcome

barriers in access to HCV testing and treatment" (World Health Organization, 2022c, p. 1). Recent advances in HCV care, including DAA and POC testing has made HCV testing and treatment easier to deliver across diverse healthcare settings and allowed for simplified pathways. Decentralization of HCV care has shifted testing, treatment, and follow-up services from specialized hospital settings to primary care and community-based locations, improving access to care for people who may otherwise face barriers (World Health Organization, 2022b). Task-shifting refers to the delivery of HCV testing, treatment and care by trained non-specialist healthcare providers such as Family Medicine Physicians (FMPs), Nurse Practitioners (NPs), and Registered Nurses (RN); rather than specialist clinicians such as infectious disease and hepatologists (Oru et al., 2021; World Health Organization, 2022c). Traditional specialist-led model of HCV care creates many barriers to accessing HCV care among populations disproportionately impacted by HCV. This includes barriers such as long wait times due to limited availability of specialist services, travel distance to clinics, the need to be seen in person, and difficulties maintaining follow-up appointments which can delay and prevent diagnosis and treatment (Biondi & Feld, 2020). Task-sharing, as recommended by the WHO, is defined as the "redistribution of tasks among healthcare workforce teams", where responsibilities are "shared and delegated from highly trained healthcare workers to those with shorter training or fewer qualifications", such as peers (people with lived and living experience of HCV) (World Health Organization, 2022c, p. 1). The combination of POC testing, decentralization, task-shifting, and task-sharing is recommended to improve the reach and accessibility of HCV care. Expanding HCV testing and treatment services can be achieved by integrating care into existing healthcare and community-based settings where individuals who may be at risk of HCV are already accessing support. This includes providing HCV testing and treatment at primary care clinics, opioid agonist

therapy (OAT) clinics, drug and alcohol treatment facilities, harm reduction programs (needle and syringe programs, overdose prevention units), mobile health outreach vans, outreach healthcare programs, and correctional facilities. These approaches are very effective in reaching underserved populations, including people who inject drugs and other groups who often face barriers to healthcare access and are at higher risk of being lost to follow-up (The Canadian Network on Hepatitis C, 2019). The WHO's *Updated Recommendation on Simplified Service Delivery and Diagnostics for Hepatitis C Infection Policy Brief* found that fully decentralized and integrated HCV testing and treatment had the greatest impact among people who inject drugs and incarcerated population (World Health Organization, 2022c). Additionally, end-users surveys found that delivery of HCV testing and treatment by staff at harm reduction facilities was associated with less stigma and as a result promoted engagement in care (World Health Organization, 2022d).

## Nurse-led Models of Care

As HCV elimination efforts increasingly rely on decentralized care and task-shifting and task-sharing, nurse-led models have become essential for expanding access to services. As a frequent point of contact within the healthcare system, particularly for underserved populations, nurses are well positioned to reduce barriers to care and improve access to HCV services (Dale, Smith, & Biondi, 2022; Richmond et al., 2020; Selfridge et al., 2022). Although there is no universally accepted definition of a nurse-led model of care, these models typically involve nurses with specialized expertise serving as the primary coordinators and providers of care within multidisciplinary teams or in solo environments (Clarke et al., 2025; Richmond et al., 2020; Schmüdderich et al., 2023). In this role, nurses hold primary responsibility and accountability for the planning, delivery, and quality of care provided to individuals and communities (Clarke et al., 2025). These models emphasize person-centred, holistic care and address both clinical needs and

social determinants of health, making them well suited to serving populations that face barriers to healthcare access (Barnett, Guarasci, et al., 2026; Richmond et al., 2020; Selfridge et al., 2022; Selfridge et al., 2025). Nurse-led HCV care has been associated with high treatment uptake and cure rates, and cost-effectiveness across a range of settings, including correctional facilities, mental health services, harm reduction programs, and supportive housing sites (Dawe et al., 2023; Harney et al., 2021; Palmer et al., 2021; Papaluca et al., 2019; Selfridge et al., 2022; Selfridge et al., 2025).

## The Role of Peers in HCV Care

Peers are people with lived or living experience (PWLLE) of HCV who are frequently engaged from priority populations in HCV elimination efforts to support outreach, engagement, and linkage to care for people with limited engagement in healthcare (Barnett et al., 2023). Evidence to support the role of peers in HCV care is based on other healthcare contexts, including HIV treatment, harm reduction service for people who use drugs, chronic disease management such as diabetes and cancer care (Andreae et al., 2020; Parkes et al., 2022; Pijl et al., 2021). In these settings, peers support has consistently been shown to foster trust, which can improve individuals' willingness and readiness to engage in care. People who use drugs are often underserved in HCV testing and treatment due to the criminalisation of drug use, stigma and discrimination; which can lead to marginalization, distrust of healthcare services, and reluctance to disclose health or substance use information. People who are incarcerated face many barriers when transitioning back to community including negative and stigmatizing beliefs from healthcare professionals (Palis et al., 2024). Evidence is increasingly demonstrating that peer-led services play an important role in supporting community reintegration, particularly by helping individuals address the complex social, structural, and personal barriers that arise during this period of transition (Palis et al., 2024). Peer support workers can better understand the challenges faced by

people living with HCV, they are often able to build trust, improve communication, and reduce perceived judgement within healthcare interactions (Jugnarain et al., 2022). They also help translate medical information into accessible language, supporting informed decision-making and may compliment clinical services by addressing emotional, social, and practical needs related to HCV care (Seaman et al., 2025). Nurses, nurse-led programs, and peers often work together in HCV care to improve engagement and access. In these models, nurses provide clinical assessment, treatment, and care coordination; while peers support outreach, trust-building, and retention in care, addressing both clinical and social barriers across the HCV care cascade (Barnett, Guarasci, et al., 2026; Barnett et al., 2023; Richmond et al., 2020).

The role of peers in the design of HCV models of care has often emerged through co-designed approaches arising from participatory research methodologies that involve collaboration between researchers and end users, based on trust, respect and shared decision-making in the design of interventions (Zogas et al., 2024). PWLLE are essential in co-designing and developing innovation, effective research, tools, services and clinical pathways (Vargas et al., 2025). In our study, this approach recognizes that PWLLE of incarceration and HCV are in the best position to identify barriers to HCV testing, treatment and engagement in care and to suggest practical and feasible solutions. Furthermore, co-design ensures that patient-facing interventions are relevant, acceptable, and accessible to the lived realities of people who have been incarcerated.

## Self-Testing and Self-Collection

Linkage to care remains a challenge even in decentralized and non-specialist models (Crespi et al., 2024). Despite advances in HCV and service delivery models, challenges remain in identifying, engaging, and retaining individuals in care, resulting in ongoing gaps across the HCV care cascade. Given the large proportion of undiagnosed infections, expanding HCV screening is

critical to elimination efforts, and self-testing has been endorsed by the WHO in 2021 as a strategy to enhance patient autonomy, increase testing uptake and case finding (World Health Organization, 2021, 2023, 2024b). The WHO's HCV self-testing recommendation is based largely on evidence from HIV and COVID-19 self-testing rather than HCV specific data (World Health Organization, 2021). HIV and COVID-19 self-testing have been shown to be accurate, feasible, and acceptable across diverse populations and settings, increasing testing access, uptake, and earlier linkage to care, which are outcomes that are equally critical for HCV elimination efforts (Walker, 2021; World Health Organization, 2021).

Self-testing refers to a process where an individual collects their own specimen, preforms the test and interprets the results independently or with varying levels of support (World Health Organization, 2024b). Specifically, HCV antibody self-testing involves preforming a fingerprick to obtain a capillary blood sample for use in a lateral flow test to detect the presence of antibodies while giving a visual result to interpret (Cha et al., 2013). Self-tests typically include written or visual instructions to guide users through the process and result interpretation independently (World Health Organization, 2024b). Evidence from HIV self-testing programs demonstrates a range of models that include real-time support such as hotlines, peer navigators and healthcare provider assistance during testing (World Health Organization, 2024b). Virtual and digital platforms for HIV self-testing include mobile apps, text messaging, and video guidance (Beecroft et al., 2025; McGuire et al., 2021). These supports are designed to help individuals correctly complete and interpret tests and to facilitate linkage to confirmatory testing and care if needed (Beecroft et al., 2025). However, the level and type of support provided varies across programs and settings, ranging from fully unassisted self-testing to assisted and digitally supported models (World Health Organization, 2021).

HCV self-testing, as part of decentralization and task-sharing to the patient allows individuals to collect their own specimens, perform rapid diagnostic testing, and interpret their own results privately addressing concerns with healthcare engagement, confidentiality and promoting greater autonomy in the testing process (World Health Organization, 2021). A recent study was conducted in Johannesburg, South Africa evaluating HCV antibody self-testing using both oral fluid and blood among people who inject drugs and attended a mobile harm reduction site or a central clinic (Msolomba et al., 2026). Reactive HCV antibody tests were followed with on-site phlebotomy for confirmatory RNA testing, with referral for DAA treatment delivered through a centralized facility (Msolomba et al., 2026). Although participants reported high acceptability of self-testing, progression through the HCV care cascade was limited. Among 854 individuals who were RNA positive, only 147 (17.2%) were prioritized for treatment with only three participants achieving SVR (Msolomba et al., 2026). Thematic analysis revealed key barriers to initiating HCV treatment including fear of needles, poor venous access, and structural barriers such as centralized treatment delivery (Msolomba et al., 2026).

An observational cross-sectional study evaluating secondary distribution of HCV self-test in Tbilisi, Georgia recruited women attending cancer screening centers who reported a male family member aged 30 to 59 years old whom had not previously been tested for HCV (Stvilia et al., 2026). Eligible participants were provided oral fluid HCV self-test kits to distribute to the men, who were instructed to perform the test, upload their results online, complete demographic questions and report factors associated with HCV antibody positivity (Stvilia et al., 2026). Between June 2022 and March 2023, a total of 2,744 kits were distributed by 1,859 women who were enrolled in the study (Stvilia et al., 2026). A total of 852 men uploaded test results, of whom 88 (10.3%) reported prior HCV testing with 16 (1.9%) reporting reactive antibody results (Stvilia

et al., 2026). Reactive results were significantly associated with a history of incarceration ($p<0.01$) and injection drug use ($p<0.02$). Seven men were found to be RNA positive and initiated treatment (Stvilia et al., 2026). Finally, in Malaysia, a randomized control trial evaluating HCV self-testing using oral fluid and blood based kits, delivered by mail after online ordering, found high testing uptake in the intervention group compared to the control group (Asgharzadeh et al., 2023).

Self-collection involves individuals collecting their own biological sample for diagnostic testing with the sample being sent to a laboratory for analysis. Common examples of self-collection in some regions of Canada include vaginal swabs for human papillomavirus (HPV) screening, and rectal swabs for chlamydia and gonorrhea testing, all of which are increasingly used in routine practice and have been shown to increase screening uptake (Colonetti et al., 2024; Liao et al., 2020; Lunny et al., 2015). If an HCV POC self-test result is antibody positive, confirmation of an active infection is required. DBS testing provides a practical way of completing confirmatory HCV RNA testing through self-collection. Access to DBS testing allows individuals to self-collect a capillary blood sample using a fingerpick with the blood transferred to filter paper for HCV RNA analysis at a laboratory (Stevens et al., 2025). Furthermore, once the blood has dried on the filter paper, DBS samples are easy to store and can be shipped in the mail to a laboratory at room temperature making the test user friendly.

A home-based DBS feasibility study conducted in the Netherlands concluded that DBS self-collection is a feasible and reliable approach for HCV RNA detection, with the potential to expand access to confirmatory testing (Prinsenberg et al., 2020). Research conducted in Toronto, Canada, evaluated the concordance between self-collected DBS samples and conventional phlebotomy-based testing for HCV, hepatitis B virus, and COVID-19 (Tran et al., 2024). The study found high concordance with conventional testing methods, along with strong participant

acceptability that suggests that self-collected DBS is a viable approach for expanding testing access among populations facing barriers to care (Tran et al., 2024). Christensen et al. (2026) evaluated a web-based sexually transmitted and blood-borne infection (STBBI) testing program in Calgary, Canada, where participants ordered self-collection kits online, collected samples at home (including DBS), and mailed them to the laboratory for analysis. The web-based STBBI program found high acceptability, with participants reporting satisfaction with the convenience, privacy, and ease of home-based testing, suggesting that self-collection may reduce barriers to clinic-based testing (Christensen et al., 2026). These findings support HCV self-testing models and programs in which individuals preform an initial HCV antibody self-test followed by a self-collected DBS for confirmatory HCV RNA testing (if needed), enabling a decentralized diagnostic pathway and supporting the potential implementation of scalable HCV self-testing programs.

## Injection Drug Use, Incarceration, and HCV

At present, sub-optimal rates of HCV diagnosis persist, reflecting systemic barriers in reaching those with limited healthcare access, people who inject drugs, and individuals who are currently or formerly incarcerated (Rockstroh et al., 2023). The WHO has called for a focus on carceral settings to achieve global HCV elimination and has released guidelines recommending increased harm reduction, HCV testing, and simplified treatment while calling for a move towards a ‘one-stop-shop’ for prison settings (World Heatlh Organization, 2019). Throughout this document carceral and correctional experience and/or facilities as well as the word prisons is used to reflect a similar environment in Canada, as different jurisdictions and sectors refer to these setting in various ways. People who are currently or formerly incarcerated are recognized by the WHO as a priority population for HCV elimination efforts (World Health Organization, 2023) due to the high prevalence of HCV in correctional settings and the intersection between incarceration

and the criminalization of drug use (Stone et al., 2018). The priority populations affected by HCV are not mutually exclusive and often experience overlapping experiences. Indigenous Peoples, racialized individuals, and newcomers are disproportionately represented within correctional settings, and among people who use drugs (Bergen & Abji, 2019; Hawk et al., 2020). Individuals in carceral settings remain underdiagnosed and undertreated, presenting a significant global public health challenge (Akiyama et al., 2021). In Canada, those incarcerated in federal facilities typically have access to HCV testing, care, and treatment as federal sentences are typically two years or longer, providing sufficient time to completed HCV screening, treatment and follow-up to confirm cure. However, the provincial/regional landscape is quite different. HCV prevalence in provincial correctional facilities is not well understood and varies by study. A report released from the Public Health Agency of Canada in 2025, described a prevalence of 11% in federal correctional facilities and 14% in provincial facilities (Public Health Agency of Canada, 2023). In provincial carceral settings in Canada, fewer than half of facilitates provide HCV screening and 46% of provincial prisons have never provided DAA treatment (Kronfli et al., 2021). Furthermore, most facilities do not have programmatic approaches to testing, and even when someone is aware of their status, they may wait months for care and treatment. Key barriers to treatment uptake and engagement in carceral settings include poor awareness of advancements in HCV treatment options, lack of training among healthcare staff, inadequate screening strategies and protocols, limited resources and staffing challenges (Akiyama et al., 2021; Kronfli et al., 2021). Efforts to overcome this barrier in Ontario including new virtual training modules and collaborative models for on-site staff are aimed at expanding access to HCV screening, treatment and care in carceral settings (Biondi & Feld, 2024; Dale et al., 2025).

Another challenge in provincial carceral settings is the transient nature of incarceration, characterized by rapid intakes and releases, with an average length of stay 28 days across Canada, making it difficult to identify individuals with active HCV infections and complete treatment during incarceration (Bartlett et al., 2021). Furthermore, there is concern about HCV treatment continuity of care and individuals becoming lost to follow up upon release (Kronfli et al., 2019; Kronfli et al., 2025). In response to this challenge, innovative models such as a nurse-led community health centre and correctional partnerships for HCV testing and treatment in Victoria, British Columbia have demonstrated successful HCV treatment initiation within correctional setting and linkage to care post release (Selfridge et al., 2025). However, timely diagnosis and treatment initiation within the short duration of incarceration remains a challenge. Therefore, expanding and scaling up testing strategies such as POC and self-testing is essential to bridge the diagnostic gap in carceral settings by enabling faster diagnosis, treatment initiation and effective prevention (Kronfli et al., 2019).

## Rationale for Study

Although DAAs have transformed HCV into the first ever chronic curable viral infection, HCV elimination efforts are dependent on increasing diagnosis among populations disproportionately affected by HCV including people with incarceration experience. HCV self-testing has been identified by the WHO as a promising strategy to improve autonomy, testing uptake and linkage to care, however, little is known about how self-testing should be designed and delivered for individuals with a history of incarceration. Given the unique barriers faced by this population, including stigma, distrust of healthcare systems, and limited access to care, understanding preferences and needs is essential for developing effective HCV self-testing programs.

## Statement of Study Purpose

The purpose of this study was to explore the perspectives, preferences, and concerns of individuals with Canadian incarceration experience regarding HCV self-testing. Specifically, the study aimed to generate clinically relevant insights to inform the design and implementation of HCV self-testing programs, including preferences for kit distribution, promotional materials, result reporting, confirmatory testing, follow-up care, and potential barriers to self-testing.

## HCV Self-Testing Operationally Defined

Self-testing for infectious pathogens has primary been used for HIV in Canada and became further normalized during the COVID-19 pandemic. Self-testing is the act of being able to receive/obtain a testing kit, follow the included instructions, collect a sample, complete the test and interpret the result. For this study, we operationally defined HCV self-testing as a testing approach in which individuals with incarceration experience would: (1) receive an HCV test kit either while in custody, at the point of release, or post-release in the community; (2) collect their own specimen (e.g. fingerprick capillary blood) using a simplified, pre-packaged kit; (3) perform a rapid antibody test themselves; and (4) interpret the result privately. Self-collection is the ability to collect one's sample using instructions, with results not necessarily available at the POC. As collection of HCV RNA through DBS is commonly used in Ontario, this study explored the option of subsequent self-collection of a confirmatory DBS HCV RNA test and linkage to care through health or community services (World Health Organization, 2024b).

## Positionality

Qualitative inquiry requires reflexivity where researchers critically examine how their background, beliefs, assumptions, experiences, and positionality may influence the research process and findings (Saldana & Omasta, 2021). The purpose of outlining my professional

background and experiences in the following paragraph is to provide context for the motivations and aims of this research. Acknowledging my positionality is essential to reflexivity, and supports transparency regarding how my personal experiences, background, assumptions and biases may shape the research process (Shaw, 2020). Qualitative health research and intersectional epistemology involve methodological attention to reflexivity and interpretation, which is closely linked to how findings can be applied to advance health equity (Abrams et al., 2020). To enhance rigor, I have engaged in ongoing peer debriefing, sought feedback from supervisors and colleagues, presented abstracts and shared findings from this research at conferences where I received feedback through audience questions and comments. By explicitly acknowledging my positionality, I aim to strengthen the rigor, trustworthiness and integrity of our work.

I have worked as a Registered Nurse with certified practice (RN(c)) for 18 years across a range of acute and community-based settings, including acute hemodialysis, peritoneal dialysis, acute medical units, sexual health clinics, women's health services, and as a forensic sexual assault nurse examiner. For the last 14 years, I have worked as a street nurse with a focus on primary care, complex mental health and substance use including injection drug use, infectious diseases, sexual health, harm reduction, team-based care, integration of healthcare with social supports, social justice and nurse-led programs. For over 10 years, I have worked as a primary care nurse at an inner-city community health center. I have been involved in the care of people living with HCV since interferon-based treatment regimens, and have witnessed firsthand the poor tolerance, challenging side effects, and low HCV cure rates. Over time, I have seen the profound transformation in HCV treatment, as the introduction of DAAs has brought shorter, well-tolerated, and highly effective curative therapies, changing both outcomes and the lived experience of HCV

treatment for both patients and clinicians. This shift has not only improved clinical outcomes but has also fundamentally changed the way care is delivered to patient populations.

As the HCV treatment coordinator and lead of an internationally recognized, award-winning nurse-led HCV treatment program, I have seen that when nurses are empowered and given autonomy, they can adapt, pivot and respond to the changing needs of the patient population. Our HCV micro-elimination approach in supportive housing site, shelters, and encampments while incorporating POC testing, a peer program, and prison-based initiatives serves as a practical example of decentralization and task-shifting in action. In my clinical practice, I have witnessed people be cured of HCV and observed the significant improvements this brings to their health, wellbeing, and sense of hope for the future. I have also observed that not every strategy to engage people in HCV testing and treatment are effective for everyone, and that self-testing may play an important role in reaching individuals who may not ever engage with traditional healthcare services. By offering privacy, convenience, and greater control over the testing process, self-testing may help reduce common barriers such as stigma, mistrust of healthcare systems, and logistical challenges, thereby improving uptake among underserved populations. This research is motivated by my passion to make things easier for patients and remove barriers that prohibit patients from seeking care.

I am a white, middle-class Canadian-born female (she/her) with an undergraduate degree in nursing and multiple post-graduate nursing certifications. I recognize that I am in a position of privilege and this includes the opportunity to pursue and complete a Master of Science in Nursing degree. My privilege has shaped my access to education, professional opportunities, and perspectives within this research. I also want to acknowledge that I currently do not understand

what it would feel like to receive an HCV diagnosis, access care related to HCV or go through HCV treatment. As an HCV provider preceptor, I have firsthand experience using HIV and HCV rapid POC tests on myself both to familiarize myself with using the tests and to teach other providers how to use the tests. This experience provided insight into the testing process, although I recognize that it does not reflect the emotional or clinical realities of testing for individuals who may be at risk of infection. I have also led an HCV testing and treatment program within a provincial correctional facility working closely with healthcare and correctional staff within the jail. This role involved providing care in the health centre, and on the units, in the outside recreational area, and within individual cells. Through these experiences, I have gained insight into the delivery of healthcare in carceral settings, the role of officers, the impact of lockdowns, and aspects of daily life while incarcerated. However, I recognize that my perspective is limited by my position as a healthcare provider. While I have spent considerable time within this environment, I was always able to leave, and therefore I cannot fully understand the lived experience of incarceration.

## Overview of the Thesis

This thesis is comprised of three chapters. Chapter One provides an overview of the HCV virus and clinical manifestations, related costs and co-occurring structural barriers, traditional diagnostic pathways versus POC testing, simplified services delivery though decentralization and task-shifting, nurse-led models of care, the role of peers, self-testing and self-collection, and the intersection of injection drug use and incarceration. Chapter One also includes the rationale for the study, the study purpose, the research question, the operational definition of HCV self-testing and the author's positionality. Chapter Two includes the main thesis, which is a published manuscript. It includes the background, study methodology, participant recruitment, data collection, study

findings and discussion. Chapter Three includes recommendations for clinical practice, areas for future research, and knowledge translation and mobilization. Additionally, Chapter Three discusses future directions which could be considered in the context of this work.

# CHAPTER TWO

## A QUALITATIVE STUDY: HEPATITIS C SELF-TESTING AND SELF-COLLECTION AMONG PEOPLE WITH EXPERIENCE IN THE CANADIAN CARCERAL SYSTEM

Chapter Two has been published in BMC Infectious Disease peer-reviewed journal on April 1, 2026, with the following refence:

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### Background

The World Health Organization (WHO) has called for the elimination of hepatitis C virus (HCV) as a public health threat by 2030 (World Health Organization, 2024a). Historically, HCV care was complex with treatment provided by specialists only; however significant advances such as the availability of point-of-care (POC) testing, decentralization of care, and task-shifting, has greatly improved access to testing and diagnosis (World Health Organization, 2022d). Despite this progress, lower than ideal diagnosis rates persist, reflecting systemic barriers in reaching those with limited healthcare access, people who inject drugs (PWID), and individuals who are currently or formerly incarcerated (Rockstroh et al., 2023). People who are currently or formerly incarcerated are recognized by the WHO as a priority population for HCV elimination efforts (World Health Organization, 2023), due to the high prevalence of HCV in correctional settings and the intersection between incarceration and the criminalization of drug use (Stone et al., 2018). Individuals in carceral settings remain underdiagnosed and undertreated, presenting a significant global public health challenge (Akiyama et al., 2021). In Canada, those incarcerated in federal

facilities typically have access to HCV care and treatment. However, the provincial/regional landscape is quite different. Prevalence is not well understood and varies depending on the study, but a report released from the Public Health Agency of Canada in 2025, described a prevalence of 11% in federal correctional facilities and 14% in provincial facilities (Popovic et al., 2025). Furthermore, most facilities do not have programmatic approaches to testing, and even when someone is aware of their status, they may wait months for care and treatment. Expanding and scaling up testing strategies such as POC and self-testing is essential to bridge the diagnostic gap by enabling faster diagnosis, treatment initiation and effective prevention (Kronfli et al., 2019).

The WHO's *Global Health Sector Strategy On, Respectively, HIV, Viral Hepatitis and Sexually Transmitted Infections for the Period of 2022-2030* (World Health Organization, 2022b) provides a framework to guide elimination efforts. It emphasizes decentralizing healthcare services (shifting healthcare delivery from central facilities to community-based settings), improving equity, and enhancing patient autonomy through differentiated testing approaches such as POC testing and community-led models (The Canadian Network on Hepatitis C, 2019; World Health Organization, 2016b, 2021, 2022d). Building on experience from other infections, the WHO issued a recommendation in 2021 identifying HCV self-testing as a priority to achieve global HCV elimination goals, basing this largely on evidence from HIV and COVID-19 self-testing rather than HCV-specific data (World Health Organization, 2021). HIV and COVID-19 self-testing have been shown to be accurate, feasible, and acceptable across diverse populations and settings, increasing testing access, uptake, and earlier linkage to care, which are outcomes that are equally critical for HCV elimination efforts (Walker, 2021; World Health Organization, 2021). HCV self-testing, as part of decentralization and task-shifting to the patient, allows individuals to collect their own specimens, perform rapid diagnostic testing, and interpret their own results privately, addressing

concerns with confidentiality and promoting greater autonomy in the testing process (World Health Organization, 2021). However, there is very limited empirical evidence on the use, acceptability, and implementation of HCV self-testing among people with incarceration experience, either in correctional settings or post-release (Cunningham et al., 2025; Cunningham et al., 2022).

Multiple lower-barrier technologies are used to support decentralization. In 2017, Health Canada approved the first HCV antibody POC test, which uses lateral flow technology to provide a visual result for HCV seropositivity and has demonstrated high sensitivity (98%) and specificity (100%) (Cha et al., 2013). POC HCV antibody testing has had tremendous utility, helping to reach individuals who would not have been screened through conventional methods, with only a single drop of blood from a fingerprick (Smookler et al., 2021). However, a second test is required to differentiate exposure from infection. Dried blood spot (DBS) testing enables detection of HCV RNA to confirm active infection through collection of a small amount of capillary blood done by fingerprick onto filter paper (Carrington et al., 2024; Cunningham et al., 2022). While the result is not given in real-time, it does avoid phlebotomy. DBS has been well received particularly among individuals with poor venous access and has been shown to be a low barrier, accessible option for HCV testing (Harris & Rhodes, 2013) with a sensitivity and specificity for HCV RNA detection at 97% and 100% (Catlett et al., 2022). Although these assays are typically delivered as provider- or peer-administered POC tests rather than self-tests or self-collected specimens, they demonstrate the technical feasibility of simplified, minimally invasive testing platforms that could underpin HCV self-testing strategies in the future.

While HCV antibody self-testing with follow-up DBS self-collection has the potential to reach priority populations and increase testing rates, there is limited understanding and knowledge gap about optimal implementation strategies, needs, and preferences of priority populations

including people with a history of incarceration (Fontaine et al., 2025). At present, most studies evaluating POC HCV self-testing were using saliva (Fajardo et al., 2022; Paing et al., 2024), but these saliva-based tests are not currently approved in Canada and many other countries, and there has been limited investigation on self-testing among those who have experience being incarcerated. This study aimed to explore the perspectives, preferences and needs of individuals with experience in the Canadian correctional system in the context of HCV self-testing delivery.

## Methods

Study decisions were guided by Interpretive Description (ID) qualitative research design (Thorne, 2025). ID was chosen for this study because it aims to develop knowledge that can directly inform clinical practice. ID is the most appropriate methodology in the context of this study because it is used for applied health and the evolving nursing discipline as the methodology aims to generate clinical meaningful understandings of participants' experiences while also recognizing the diversity and contextual differences within participants' experiences (Thorne, 2025; Thorne, Kirkham, & O'Flynn-Magee, 2004). Where, phenomenology seeks to describe the essence of lived experience, or where grounded theory which aims to develop a formal explanatory theory of a social process; ID is a pragmatic design and aims to generate interpretive finding that can directly inform practice (Campbell et al., 2021; Thorne, 2020). Through reflective, critical examination, ID seeks to advance thinking within the discipline of nursing and "assumes nurse investigators are rarely satisfied with description alone and are always exploring meanings and explanations that may yield application implications" (Thorne, Kirkham, & O'Flynn-Magee, 2004, p. 3) in practice. For example, ID studies identify patterns across participants' experiences while also identifying differences, contradictions, and contextual factors that may be important for nursing practice and decision-making (Thorne, 2025; Thorne, Kirkham, & O'Flynn-Magee, 2004).

Researchers' disciplinary knowledge is a critical component of the ID approach (Thorne, 2025). ID recognizes that nurses, nurse researchers, and nurse scientists bring professional knowledge and experiences that shapes how they engage and interpret the data. Therefore, in this study and thesis, my disciplinary knowledge and experience as a registered nurse with certified practice **(see Positionality Statement)** informed what was found to be clinically meaningful aspects of the participants' experience and supported interpretation of the findings.

Within ID methodology the researcher is seen to be an active participant in the analytical process and the interpretation of the data is therefore shaped by the researcher's bias (perspectives, assumptions, and prior experiences) (Thorne, 2025; Thorne, Kirkham, & O'Flynn-Magee, 2004). Researcher bias may influence how the study participants' interviews are understood and interpreted. However, ID does not seek to eliminate bias or subjectivity (Thorne, 2025). Rather, ID recognizes and supports the use of the researcher's interpretive lens informed by disciplinarily logic to generate nuanced and clinically relevant knowledge and insights (Thorne, 2025). While research bias is typically seen as a limitation in qualitative research within ID methodology the researcher's disciplinary knowledge is seen as a strength. To mitigate potential bias in this study reflexivity was used as a critical component to the research process. Reflexivity can be understood as the researchers continual self-awareness in critiquing, appraising, and evaluating how their subjectivity, assumptions and context may influence the research process (Olmos-Vega et al., 2022). In this study, reflexivity was used throughout the research process to critically examine how my assumptions, perspectives, and disciplinary experiences could influence data collection, analysis and interpretations (Olmos-Vega et al., 2022; Thorne, 2025). Through the practice of reflexivity, my disciplinary expertise and experience can be leveraged to inform the interpretation of the qualitative data, while remaining aware of how my perspectives may shape the analysis

(Thorne, 2025). Reflexivity in this study included documenting decisions, discussing interpretations with the larger research team while also considering alternative decisions and interpretations. Reflexivity supported transparency in the research process and ensured that my nursing disciplinary knowledge informed but did not predetermine the interpterion of the qualitative data (Olmos-Vega et al., 2022; Thorne, 2025).

This qualitative study included a collaborative community consultation with Prisoners HIV/AIDS Support Action Network (PASAN), a community-based harm reduction, HIV, and HCV organization that provides support, education and advocacy for individuals who are currently or formerly incarcerated in Ontario, Canada. PASAN also works with organizations to reduce barriers that incarcerated, and formerly incarcerated people encounter when accessing housing, social services, and healthcare. The community consultation with PASAN involved collaborating on participant recruitment and providing ongoing input throughout the research process. Participants were recruited by PASAN team members prior to participants engaging with the study team. This could have occurred through any of PASAN's in-person in-reach or outreach- based programing. PASAN recruited participants with the following inclusion criteria: 1) Incarcerated in a Canadian prison/jail (provincial or federal); 2) Speak English; 3) Over the age of 16; 4) Currently reside in Ontario. The exclusion criteria included: 1) Incarcerated in prison or jail outside of Canada; 2) Currently on HCV treatment. Participants received a $50 honorarium for their participation, and the interview occurred in a confidential office setting at PASAN. This study was conducted in accordance with the ethical principles outlined in the Declaration of Helsinki and approved by York University Institutional Review Board (certificate e2023-222). Informed consent was obtained from all participants prior to their involvement in the study.

Given that the purpose of this research is to inform HCV self-testing rollout programs for people who have been incarcerated, it was essential to generate clinically relevant insights for implementation purposes. Interview guides (**Appendix B**) were developed to explore participants' perspectives on HCV self-testing with questions relating to the following key ideas: preferences for receiving kits and timing, views on promotional materials and ordering platforms, feelings about reporting results and confirmatory testing, preferred follow-up contact, concerns about self-testing, and overall thoughts on self-testing for their population.

For this study, we operationally defined HCV self-testing as a testing approach in which individuals with incarceration experience would: (1) receive an HCV test kit either while in custody, at the point of release, or post-release in the community; (2) collect their own specimen (e.g. fingerprick capillary blood) using a simplified, pre-packaged kit; (3) perform a rapid antibody test themselves; and (4) interpret the result privately, with the option of subsequent self-collection of a confirmatory DBS HCV RNA test and linkage to care through health or community services (World Health Organization, 2024b).

Data was collected at PASAN through semi-structured interviews, which were audio-recorded and transcribed verbatim. When discussing the tests or platforms as noted in the guides, images or extensive description was used to describe the format. In alignment with ID methodology, data analysis involved finding the knowable, moving beyond the evident, engaging in interpretation, and making meaning of the data that informs practice (Thorne, 2025). The specific steps that guided this process included: 1) multiple readings of the transcripts, 2) creating narrative summaries of the transcripts, 3) noting insights through memos and diagrams, and 4) constantly comparing the concepts and data (Maietta et al., 2021). Analysis was conducted by researchers (TB, KM) who have qualitative research training and using Microsoft 365 applications.

Findings were discussed and corroborated with the larger research team, which included clinicians and methodologists with respective expertise. This process conforms to the 'thoughtful clinician' test in ID that seeks to determine if findings resonate with clinicians and to interpret them to produce practical insights that inform clinical practice or policy (Thorne, 2025).

## Results

Between August and October of 2023, a total of 15 participants were enrolled in the study (11 men, 4 women). Interviews ranged from ~5-20 minutes, but most were between 10 and 20 minutes. Four key themes were developed from the data (**Table 1**), each reflecting complexity of HCV self-testing for people who have experienced incarceration in Ontario, Canada. These themes included: 1) Authentic representation because "words carry power," which emphasizes the importance of being seen and how language shapes identity and influences perception; 2) Altruism triumphs even in the face of stigma and uncertainty which explores the tension between caring for others and navigating societal judgment; 3) Distrust of society, system and self, which focuses on deep skepticism toward institutions and internalized doubt; and, 4) Low-barrier and accessible means "Easy, easy, easy…," which reflects the desire for simplicity amid persistent challenges and systemic barriers.

**Table 1. Summary of themes, responses, and quotes.**

| Themes | Responses | Quotes |
|---|---|---|
| **Authentic representation because "Words carry power"** | Participants felt that to engage people with experience being incarcerated, the images needed to be authentic pictures of real people who had been incarcerated or pictures of prison art.<br><br>Participants wanted HCV self-testing flyers and website to feel real and relatable and stressed the importance of the proper use of words. | *"That way I'll know the advertisement is for me."*<br><br>*"When you're dealing with addicts, ex-cons, all of this stuff, you got to keep in mind there's a stigma there, and there's a barrier there. Words carry power. Whatever is said, whatever is being mentioned has to bring reality back to the effectiveness. So that is the big thing. It's the common thing with this, right?"* |
| **Altruism triumphs even in the face of stigma and uncertainty** | Participants saw HCV self-testing as a way to protect loved ones, not just themselves.<br><br>Participants felt torn—they valued the privacy of self-testing but also wanted support. They wanted to know their results but feared being anxious about them. Participants shared experiences of stigma, shame, fear of judgment and isolation. | *"Get tested, man. It's for your own good, for the people you're living with."*<br><br>*"A lot of people don't really want to know the f**king answer to that test. I've had hep C for like, back then, I think it was like 15 years and because of the stigma and that, I went to a few places the way I got treated. So, I just said, f**k it! You know what I mean? You're asking people to go through that."*<br><br>*"A lot of people who have hep C, they have lost a lot of self-esteem."* |
| **Distrust of society, system and self** | Deep distrust in systems, others, and even self led to concerns about result accuracy, data misuse, and anxiety about correctly using self-test kits. | *"So, if you don't trust the system. Look here I don't trust the system and if you've been living with hep C… you don't care or you think you are… you want to test yourself because you can't trust people."*<br><br>*"That's just too sketchy for me. People crack up, people crack emails. You have to make sure the results are correct and that they are yours! You've got to actually see your file."*<br><br>*"Because there's many things that could go wrong. I mean, I'm sure I would get directions, and they would be as clear as they could possibly be but the way I might read it might be different from the way it's explained. I would probably be reading it over and over and over again and probably get nervous to do it the more I read it, right? Because…things of this importance are very delicate. You know, so…I think I'd probably want to go to my physician."* |

| | | |
|---|---|---|
| **"Low-barrier and accessible means "Easy, easy, easy…"** | Easy access is key. Participants stressed that self-testing must be low-barrier, accessible, simple, timely, and available in familiar, convenient places during moments of readiness. | *"Yeah, I mean we do it for COVID it just makes sense… self-testing."*<br><br>*"No, I think it actually simplifies it for folks because… a lot of folks' veins are hard."*<br><br>*"Make it easy so we can execute it, I don't have to jump through rings and hoops to get it done, right? Especially if I want to get it done. So, you need to break it down as simple as possible."* |

**Authentic Representation Because "Words Carry Power"**

In response to viewing HCV self-testing promotion material, including a sample flyer (**Figure 1**) and navigating a national comprehensive HIV self-testing website (readytoknow.ca), participants provided feedback on the content, design, and wording for advertising HCV self-testing kits within the community. All study participants felt that to engage and better reflect people who have been incarcerated the images on the flyer and website needed to be "hip and cool" and include authentic pictures of real people who had been incarcerated or pictures of prison art done by people with experience in corrections. Participants made comments, such as *"that way I'll know the advertisement is for me,"* reflecting that participants need to be represented authentically. Generic or stock images were viewed as inauthentic and disconnected, and participants emphasized the need for poster advertisements to have relatable images that reflected their realities.

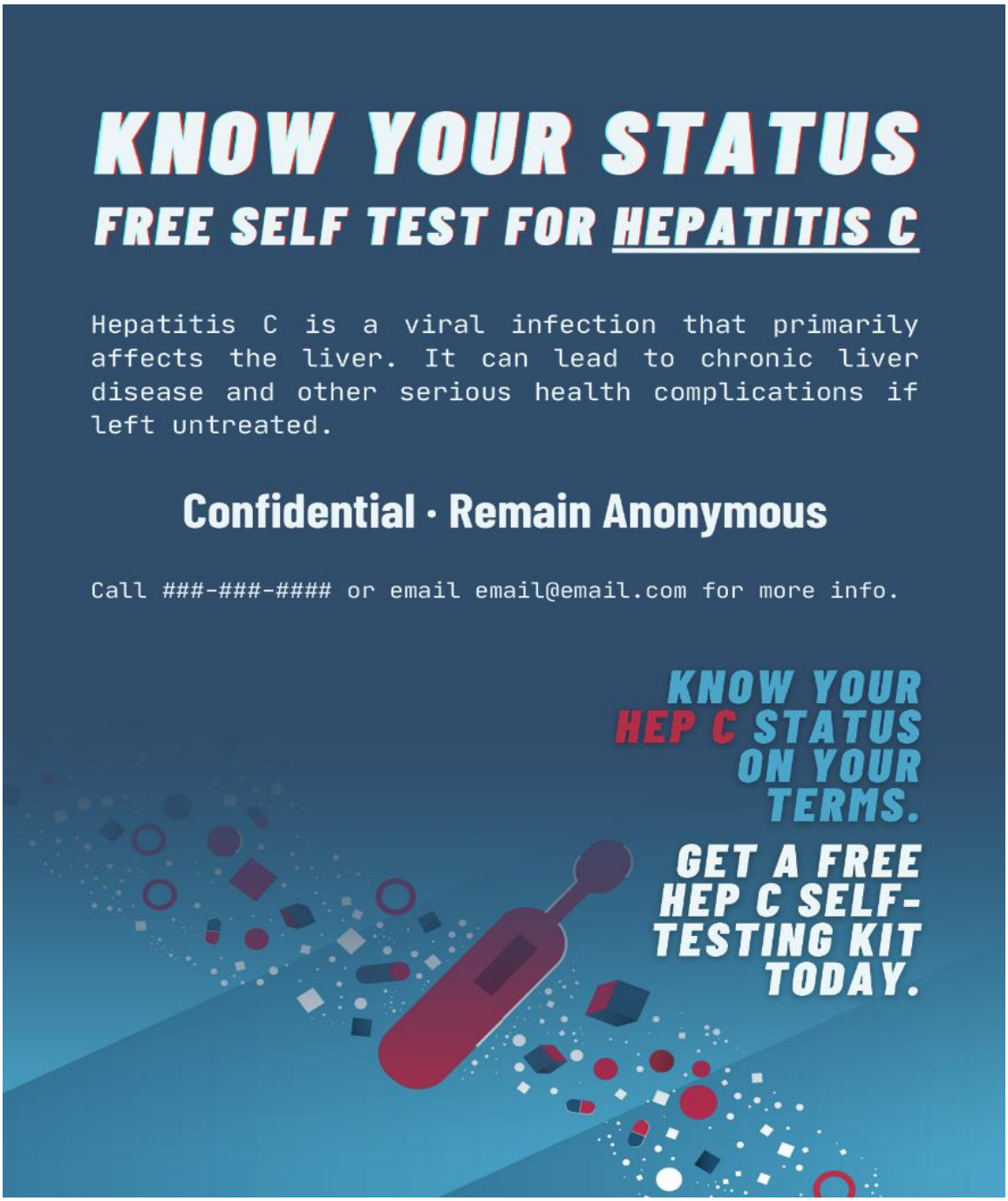


**Figure 1. HCV self-testing sample poster shown to study participant to get their feedback on future HCV self-testing flyers.**

Participants noted that HCV self-testing advertisements should have just enough information without overwhelming the reader. Participants provided important insights into promotion materials including positive messaging to combat HCV stigma, a few statistics about HCV, and information about HCV transmission. The importance of the word, "free," was emphasized by participants who encouraged including the cost of the test on materials as well as adding a quick response (QR) code for quick and easy access to additional information online. Participants thought the website should include information about HCV, such as the accuracy of the self-test kit, a list of resources, and treatment options. Treatment options need to include clinicians who provide healthcare for people with HCV who have been incarcerated. This is reflected when a participant speaks about HCV treatment: *"A lot of folks know but they don't know where to get treated, especially without being stigmatized. I think that's an important thing."* This illustrates how access to stigma-free, supportive healthcare is essential for people with HCV who have been incarcerated.

Innovative suggestions for promoting HCV self-testing materials were offered from people who experienced incarceration. These suggestions included offering a multipack available through the website that contained fentanyl test strips, naloxone kits, and both HIV and HCV self-testing kits. In addition, participants suggested that people with lived and living experiences of HCV and incarceration are included in designing HCV self-testing websites. Slogans were suggested by participants to advertise HCV self-testing kits though flyers and websites (**Table 2**).

**Table 2. Participants' suggestions for HCV self-testing advertising and awareness campaigns.**

| |
|---|
| *Know your hep C status on your terms, get a free test kit.* |
| *You've gotten free from jail, you want to get free from this as well, it's easy now.* |
| *Do you or do you not have hep C? Get tested now!* |
| *Don't be shy to get tested. It's for your own good. It's for your own good and the people who are living around you.* |
| *Get tested, man. It's for your own good and for the people you're living with!* |

The language used for HCV self-testing flyers and websites deeply mattered for participants, particularly as people who have been incarcerated and who may also have experience with addictions, shame, and systemic- and self-stigma. The notion of words carry power was introduced by one participant while explaining the importance of messages that are truthful, trustful, and effective:

> *"When you're dealing with addicts, ex-cons, all of this stuff, you got to keep in mind that there's [two] things that are extremely important. Your words. So, words carry power. Whatever's said, whatever is being transmitted has to be, really has to be effective.*
>
> *The second thing is that talk is cheap. It's the common thing with us, right?"*

Thus, messaging and advertising must come across as empowering with recognition that words are relational and are not just for information exchange. HCV self-testing advertisements must ensure that the words used do not unintentionally reinforce stigma but instead foster dignity, engagement, and be relevant to the lived experience of people with a history of incarceration. Participants suggested that promotional materials be posted in high visibility public spaces that people with a history of incarceration frequent such as on buses and subways, at community service

agencies that work with people that have a history of incarceration, and in newsletters/magazines that people with experience in correction read.

### Altruism Triumphs Even in the Face of Stigma & Uncertainty

Participants were not only motivated to self-test for their own health, but they also felt a sense of responsibility and desire to protect their families, partners, friends, and the community around them from unknowingly transmitting HCV. Many participants made comments, such as, *"Don't be shy to get tested. It's for your own good. It's for your own good and the people who are living around you"* or *"It makes sense to get tested and [ensure you do] not give it to others."* Altruism led to a strong preference for receiving HCV self-testing kits immediately upon release from correctional facilities, so that people who have been incarcerated could have the option to self-testing prior to going back into their communities.

Concern for the health of others despite the potential personal risk or discomfort also emerged in the qualitative data as many participants expressed conflicting emotion of wanting the autonomy to test for HCV independently but also desiring support or guidance from others. Despite this internal conflict and experiences of stigma, fear, judgement and uncertainty surrounding HCV testing, disclosure and treatment, altruistic motivation persisted guiding participants' decisions to protect both themselves and those around them. One participant described the profound impact of stigma and negative healthcare experiences:

> *"A lot of people don't really want to know the f**king answer to that test. I've had hep C for like, back then, I think it was like 15 years and because of the stigma and that, I went to a few places [and saw] the way I got treated. So, I just said, f**k it! You know what I mean? You're asking people to go through that."*

This reflects the profound impact of stigma and negative healthcare experiences on willingness to keep engaging in a healthcare system after being treated poorly. It illustrates how past healthcare experiences and judgement can cause individuals to avoid accessing healthcare all together despite living with HCV for a long time. *"You're asking people to go through that,"* also speaks to anticipated stigma and this further reinforces the need for non-judgmental and trauma informed approaches to HCV self-testing initiatives and *"A lot of people who have hep C, they have lost a lot of self-esteem,"* emphasising how stigma and feelings of shame can erode confidence and hinder engagement in care.

**Distrust of Society, System, & Self**

Distrust was prevalent in society, systems, and self. Beyond the stigma participants experienced from society, they also distrusted systems, such as healthcare organizations and even new technologies. Data reflected a justified distrust in the healthcare system due to negative experiences which motivated participants to want HCV self-testing.

> *"So, if you don't trust the system. Look we don't trust the system and if you have been living with hep C… You're not sure or you think you are… you want to test yourself because you can't trust people."*

Even though participants distrusted healthcare organizations, they also struggled to trust themselves. One participant stated:

> *"Because there's many things that could go wrong. I mean, I'm sure I would get directions, and they would be as clear as they could possibly be but the way I might read it might be different from the way it's explained. I would probably be reading it over and over and over again and probably get nervous to do it the more I read it, right? Because…things of this*

*importance are very delicate. You know, so…I think I'd probably want to go to my physician."*

Overwhelmingly, participants expressed concerns about privacy and technology used in systems. For example, they were wary to submit a DBS for HCV RNA testing to confirm an active infection if HCV self-testing showed a positive antibody result. System distrust, likely stemming from their experiences with the carceral system, was a significant barrier:

*"They'll do a DNA sample on you especially in a prison system and they say, well, it gets deleted after so much time. Did it really get deleted? You know what they're saying. And they can get a court order if they want to. You can fight it, but you're going to lose, I think, in the end."*

Distrust was not only about the technology, but also about the system and their potential of misusing blood samples in an unauthorized manner. The suspicion around data security and the accuracy of results further complicated this issue: *"That's just too sketchy for me. People crack up, people crack emails. You have to make sure the results are correct and that they are yours! You've got to actually see your file."* Participants expressed significant concerns about privacy, trust, and security of results related to HCV self-testing and follow up procedures involving DBS testing. Having autonomy in choosing their method of receiving results was one way to combat system distrust.

**Low-barrier and Accessible Means "Easy, Easy, Easy…"**

Recognizing the stigma and barriers faced when accessing healthcare in traditional settings, data suggested the importance of offering accessible and non-stigmatizing testing options. Participants recognized the ease of self-testing and related this to their experiences of COVID-19 self-testing, *"Yeah, I mean we do it for COVID it just makes sense…self-testing."* When asked

about performing a fingerprick and collecting a drop of blood to complete the self-test, participants expressed confidence and willingness to engage in the process: *"No, I think it actually simplifies it for folks because… a lot of folks' veins are hard."* Participants further agreed that the HCV self-testing process must be low-barrier and accessible when speaking about challenges people have with phlebotomy making self-testing and DBS collection practical and easy. One participant stated:

> *"Make it easy so we can execute it. [So that] I don't have to jump through rings and hoops to get it done, right? Especially if I want to get it done. So, you need to break it down as simple as possible."*

There was a strong preference to receive kits in low-barrier, accessible and easy places that participants frequented the most and felt comfortable. Established relationships such as community organization, harm reduction sites, supervised consumption sites, health centres, and pharmacies that provided support to people who have been incarcerated were also important. Another participant stated, *"Let me say my pharmacist is a very nice guy. So, you know, so it would be easier with the pharmacist…"* Probation offices could be another option for distributing HCV self-testing kits. Frequent interactions and an established relationship create an ideal opportunity for kit distribution:

> *"If probation officers can hand it out because they've got to see them every week anyways or every other week. That might be useful. Someone we see all the time …some person we see or like somewhere we have to go to…"*

Participants suggested embedding HCV self-testing kits within existing support systems to increase accessibility and uptake, specifically for individuals who are navigating the justice system and disengaging with traditional healthcare. In addition, making HCV self-testing kits available in settings where access feels easy and routine.

The timing of receiving a self-test kit was highly individualized amongst participants. Most participants agreed that there is a window immediately after release when they may be more motivated to self-test, and providing an HCV self-test on release was viewed as a low-barrier and accessible option that is easy. For example, one participant stated:

> *"If I walk out with this test kit, I might walk out and test myself right now because I'm out here right now... But if we walk out and think about testing it in two months down the road, I'm probably involved with a whole bunch of other stuff. So, you really want to utilize that window, that very little window."*

Using this window of opportunity, one participant suggested HCV self-test kits be included upon release:

> *"So, in that release bag - it should come with an HIV test kit, a hep C test kit, condoms, tampons, pads, underwear, whatever. Those are the essentials. Those are the essential things that you want because you want to make sure that you're safe as an individual."*

This suggestion reflects a harm reduction approach where low-barrier and accessible means easy access to testing which can help reduce risk and promote autonomy. The entire process from obtaining an HCV self-testing kit to completing the test, reporting the result, collecting and submitting a DBS sample if the test is positive, and receiving the confirmatory result must be simple, efficient, and easy to navigate.

## Discussion

Our study findings describe the perspectives, preferences, and needs in the context of HCV antibody self-testing HCV RNA DBS self-collection. We highlight several critical themes that span the self-testing and self-collection cascade of engagement, act of testing, obtaining results and reporting, and linkage to care. Overall participants were open to receiving self-testing kits through

various mechanisms, with a key mechanism as receiving upon release. Clear self-testing instructions during self-testing was highlighted as a way to increase confidence. Distrust of systems led to the desire for flexible options for receiving results, including phone, text, in-person, or email.

In terms of advertising and engagement in self-testing, our findings suggest that HCV self-testing messaging, imagery, and rollout strategies must be tailored to people with incarceration experience, a priority population that has often been overlooked in self-testing research and program design. Promotional materials should incorporate prison-related imagery, depicting people with correctional experience, HCV statistics, and QR codes to link to more information. The WHO recommends using digital platforms to support ordering self-testing kits, voluntary reporting of results, and for facilitating linkage to care (World Health Organization, 2024b), 2024b), which is consistent with our study findings. However, this study revealed the importance of attention to accessible and non-stigmatizing language for people who have experienced incarceration. Furthermore, our findings suggest that the ideal time to self-test is when individuals feel ready, with kit distribution prioritized at the point of release from correctional facilities. Taken together, these findings suggest that HCV self-testing could be integrated into "release planning" and community re-entry supports as a concrete micro-elimination strategy, aligning with WHO calls for differentiated, people-centred models of HCV testing and care for justice-involved populations (Selfridge et al., 2025).

Altruistic motivation has also been found among people who inject drugs in other studies when exploring barriers and facilitators to HCV testing with participants reporting they tested out of concern for their significant others and the broader community (Barocas et al., 2014). Similar findings were found in Seattle where individuals living with HCV who were actively injecting

drugs expressed a desire to test to protect their relatives and the wider injecting community from HCV transmission (Tsui et al., 2021). Altruistic values may be leveraged to encourage HCV self-testing and could be embedded in self-testing promotion material and program roll out, appealing to the value of protecting friends, partners, families, and the overall community. Messaging that frames self-testing as an act of care for loved ones, rather than solely an individual responsibility, may be particularly resonant for people with incarceration experience who often occupy multiple caregiving roles despite structural marginalization.

While not explored extensively in this study, peer support is effective in engaging underserved populations including people who use drugs and those with incarceration histories by reducing stigma and building trust (Henderson, Madden, & Kelsall, 2017). Peers are often seen as credible sources of information and studies have shown that peer support and involvement increases linkage to care and can accelerate treatment initiation (Papaluca et al., 2022). Within carceral and post-release contexts, peers with lived and living experience of incarceration and HCV may be uniquely positioned to "bridge" distrust in health systems and support interpretation of self-test results, facilitate self-collected DBS for HCV RNA, and navigation to treatment. Embedding self-testing within peer-supported models of care, rather than relying solely on anonymous digital platforms, may therefore be critical for ensuring both acceptability and effective linkage to care among people with incarceration experience. However, peer-supported models and digital care are not mutually exclusive, and our study findings suggest voluntary reporting of self-testing results must be via a secure, confidential, web-based portal. Digital reporting is both feasible and acceptable for people with a history of incarceration if care to address concerns is forefront in practices and policies.

This study highlights the importance of distributing self-testing kits through low-barrier, easily accessible locations such as pharmacies, probation offices, health centres, harm reduction sites, supervised consumption sites, and organizations supporting formerly incarcerated individuals. Trust, familiarity, and repeated contact in specific locations may increase HCV self-testing uptake. HCV self-testing kit distribution was also reported in a study in Vietnam with PWID and gay, bisexual, and other men who have sex with men (gbMSM), describing privacy, convenience, and flexibility as key benefits of receiving a kit through community-based organizations (Nguyen et al., 2021).

Our findings demonstrate that almost all participants reported a strong willingness to perform a fingerprick while reporting no concerns with respect to pricking their own finger for both HCV self-testing and DBS self-collection following a positive self-test, highlighting acceptability and a clear preference for less invasive testing methods. Similarly, in a randomized trial, acceptance of the OraQuick fingerprick HCV antibody test was higher than that of traditional venipuncture, which was accepted by only 87% of participants (Kronfli et al., 2020). Our study suggests that for HCV self-testing to be acceptable; the testing process needs to be "easy." Acceptability of self-testing is further reinforced by the importance of a simple, easy, and user-friendly testing process. This is in line with studies using oral-based HCV self-tests which were found to be acceptable among people who use drugs although concerns exist about practical usability and linkage to care (Fajardo et al., 2022; Guise et al., 2018).

Participants in our study described that when HCV antibody positive, performing a self-collected DBS was possible. However, autonomy and flexibility in returning DBS tests and receiving DBS test results are critical and could include phone calls, text messages, or be in-person. In Denmark, mail-based DBS HCV self-collection was shown to be feasible among PWID through

an online harm reduction program that provides supplies to PWID in the mail, with participant receiving their results by peers via telephone calls (Demant et al., 2025). However, self-testing and self-collection with positive results needs to be followed by linkage to appropriate post-test services.

A limitation of this study is that participants did not handle testing materials or navigate proposed online platforms. Future studies should utilize an end-user framework to validate both self-testing/self-collection and to better understand real-world acceptability. In addition, in this form of inquiry is that we cannot capture all possible experiences across a broad range of participants, and that those who chose to participate are a subset of the total population of people who may require HCV self-testing within the context of experience with the correctional system. While participants with experience being incarcerated were the focus of this study, it would be crucial for future studies to engage policy stakeholders who would be instrumental to implement and scale-up HCV self-testing and self-collection. Finally, we did not demographic information from participants. Therefore, transferability to other contexts may limited.

## Conclusion

This study offers important insights into the perspectives, preferences and needs of HCV self-testing among individuals with lived experience in the Canadian carceral system, a priority population for HCV elimination efforts that is often underserved in traditional healthcare models. Findings indicate that HCV self-testing is well received and highlight key considerations for the design, implementation, and roll out of tailored self-testing programs. Iterations of self-testing rollout should consider incorporating such findings. Ultimately, this study contributes to the growing evidence base supporting HCV self-testing as a strategy to increase autonomy, improve testing uptake, and linkage to care among priority populations.

## Declarations

### Ethics Approval and Consent to Participate

This study was conducted in accordance with the ethical principles outlined in the Declaration of Helsinki and approved by York University Institutional Review Board (certificate e2023-222). Informed consent was obtained from all participants prior to their involvement in the study.

### Consent for Publication

All authors consent for this article to be published.

### Availability of Data and Materials

The data that support the findings of this study are not openly available due to reasons of sensitivity and are available from the corresponding author upon reasonable request.

### Competing Interests

TB declares speaking and consulting fees from AbbVie and Gilead. MJB declares receiving research funding from AbbVie, Gilead, and Cepheid, and speaking and consulting fees from AbbVie and Gilead. No other authors declared a competing interest.

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### Author Contributions

Conceptualization: KM, OG., KC, MJB; Investigation and Methodology: TB, KM, OG, CC, GF, KC, MJB; Data Curation: KM, OG; Formal analysis: TB, KC, MJB; Project

Administration, Resources and Supervision: KC, MJB; Writing – Original Draft: TB, KC, MJB; Writing – Review and Editing: KM, OG, CC, ABM, GF, KC, MJB.

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# CHAPTER THREE

# SUMMARY OF KEY FINDINGS, CLINICAL IMPLICATIONS, RECOMMENDATIONS FOR FUTURE RESEARCH AND KNOWLEDGE DISSEMINATION

## Summary of Key Findings

Self-testing has been shown to be accurate, acceptable, feasible and safe among key populations including people who may not otherwise test across settings in various regions; however, the evidence supporting the WHO recommendation for HCV self-testing is based entirely on HIV self-testing literature (World Health Organization, 2021, 2022a, 2022c, 2022d, 2023, 2024a, 2024b). Furthermore, most studies of HCV self-testing have focused on saliva-based tests (Fajardo et al., 2022; Paing et al., 2024), which are not currently approved in Canada, and have lower sensitivity (Kimble, Stafylis, et al., 2019). This study addresses a key gap by exploring perspectives on fingerprick HCV self-testing, a more available testing method among individuals with experience of incarceration. Using ID methodology and rapid thematic analysis this thesis sought to generate relevant clinical practice knowledge from the perspectives, preferences, and concerns of individuals with experience in carceral settings. The key findings of *Hepatitis C Self-Testing and Self-Collection Among People with Experience in the Canadian Carceral System* indicated that people with lived experience of incarceration were receptive to HCV self-testing and self-collection (Barnett, Muncaster, et al., 2026). Participants emphasizing that successful implementation would depend on approaches that were trustworthy, accessible, low-barrier, and tailored to the unique need and circumstances of people who had been incarcerated (Barnett, Muncaster, et al., 2026).

The findings indicate that HCV self-testing promotional material and advertisements must be authentic and use non-stigmatizing messaging while reflecting the realities of people with carceral experience. Participants suggested education materials and advertisements be developed

in collaboration with people with lived and living experience of carceral settings to ensure they are relevant. Most participants identified the period immediately after release from carceral settings as a critical window period to offer HCV self-testing. Participants reported that providing self-testing kits at the time of release may leverage a period when motivation to test for HCV is highest as participants expressed a desire to protect their partners, families and communities. This suggests that altruistic motivations may outweigh concerns about stigma and testing at time of release. Distrust of healthcare and institutional settings along with experiences of stigma, discrimination and surveillance led participants to value privacy, autonomy and the control offered by HCV self-testing. Due to ongoing concerns about confidentiality, privacy, and data security, participants reported the need for multiple ways of accessing DBS HCV RNA results such as phone, text, email and in person. Simplicity and accessibility were repeatedly emphasized as the entire testing process should be "easy, easy, easy" with kits easily available through familiar and trusted community settings such as pharmacies, harm reduction services, and organizations the support formerly incarcerated people. However, successful implementation will require low-barrier, stigma-free, and flexible approaches that prioritize authentic representation, autonomy, privacy and access to testing at key transition points such as release from carceral institutions (Barnett, Muncaster, et al., 2026), and this could be the focus of additional research in the future.

## Strengths and Limitations

This study explored HCV self-testing using a fingerprick sample, among people with experience of incarceration. A strength of ID methodology is its ability to generate practice relevant knowledge that can inform healthcare delivery and policy. However, its reliance on researcher interpretation may introduce bias, making reflexivity, transparency, and methodological rigor essential throughout the research process. This sample size of 15 participants may be considered a

limitation in terms of the range of experiences represented. However, within ID methodology, sample size is not determined by a predetermined number or by achieving saturation, but by the relevance and richness of the data in relation to the research questions (Thorne, 2020, 2025; Thorne, Kirkham, & O'Flynn-Magee, 2004). Saturation traditionally refers to the point at which a researcher determines that sufficient data has been collected and that perusing additional data collection is redundant. ID does not use saturation to determine when data collection should end, as Thorne (2020) cautions, saturation is often used routinely to justify a predetermined sample size rather than demonstrating the meaningful depth and richness of qualitative data. In this study, the 15 participants provided detailed qualitative data to identify meaningful patterns and variations across experiences as seen in this thesis manuscript. Therefore, this sample is considered sufficient to support the interpretations developed in this study. A limitation of this study is that participants did not handle HCV self-testing materials or navigate proposed online platforms. In addition, this form of inquiry cannot capture all possible experiences across a broad range of participants, and those who choose to participate represent a subset of the total population of people who may require HCV self-testing within the context of carceral system involvement. Finally, demographic information was not collected from participants. Therefore, transferability to other contexts or provinces may be limited.

## Clinical Implications

The findings of this study offer important clinical implications and valuable insights for the development and implementation of accessible and equitable HCV testing approaches; especially for populations who are underserved in the current HCV testing and treatment pathways due stigma and discrimination. The high HCV prevalence in Canadian provincial prisons is driven by the criminalization of injection drug use resulting in the over-representation of people who

inject drugs and a lack of harm reduction which leads to the sharing of drug use equipment (Kronfli et al., 2021). Given these gaps and ongoing transmission risks, HCV self-testing may improve access to diagnosis by reducing reliance on clinic-based services in both correctional facilities and community settings. Self-testing may be particularly helpful during post-release periods when competing priorities and structural barriers limit healthcare engagement. HCV self-testing rollout programs should therefore consider providing self-test kits at the point of release to maximize testing uptake during this critical transition period as well as providing kits in locations that people with histories of incarceration frequent.

Most studies on HCV self-testing have focused on oral saliva-based tests (World Health Organization, 2021)**,** which are not currently approved in Canada. This study addresses a key gap by exploring perspectives on fringerprick POC self-testing and DBS self-collection a more invasive but available testing method. Findings suggest that preforming a fingerprick is a reasonable approach to both HCV antibody and DBS RNA testing which support future HCV self-testing programs using fingerprick testing modalities. Currently, there is no approved HCV self-test available for distribution in Canada, however, the findings from this study suggest that if given the option, many people with lived experience of incarceration would be willing to engage in HCV self-testing.

For HCV self-testing to be effective, it should be implemented using a tailored approach, as a 'once size fits all' model is unlikely to meet the needs of diverse priority populations. Future HCV self-testing program development should consider the unique and specific needs of key populations as the effectiveness of self-testing programs will depends on tailored interventions that reflect priority populations specific contexts and preferences. Co-developing future HCV self-testing programs in partnership with key populations is essential to ensure that interventions are

acceptable, accessible, and responsive to community needs. Engaging individuals with lived and living experience throughout the design and implementation process could improve the relevance, uptake, and effectiveness of self-testing programs while helping to address barriers related to trust, stigma, and healthcare access. Clinicians and public health practitioners should ideally consider the potential role of self-testing as a complementary screening strategy for reaching populations that may be less likely to engage with conventional testing services. Ultimately, the utility of HCV self-testing devices in Canada will depend on the willingness of diagnostic companies to pursue and obtain Health Canada approval.

## Recommendations for Future Research

While this thesis did not evaluate the usability or acceptance of HCV self-testing, it does provide important evidence regarding the perceived feasibility of self-testing among people with lived experience of incarceration in Ontario. Future research should build on these findings by including other priority and key populations for HCV elimination efforts such as Indigenous peoples (First Nations, Métis, and Inuit; competed and currently in preparation), newcomers and immigrants, and gay, bisexual, gbMSM; and perhaps even the general population in line with newer all adult screening recommendations (United States Centres for Disease Control and Prevention (CDC), 2025). Expanding research across these groups will help determine whether acceptability and perceived feasibility are consistent across diverse populations and will inform the development of equitable, tailored, and effective HCV self-testing strategies. Repeating the study across diverse settings such as rural and remote locations and different provinces across Canada would help determine whether the acceptability and perceived feasibility of HCV self-testing are consistent across settings and populations. This could provide a more comprehensive understanding of population-specific needs, barriers, and preferences, thereby informing the

development of tailored, equitable, and targeted self-testing programs based on each priority populations unique needs and contexts. Of note, a manuscript is currently pending publication titled *"Hepatitis C Self-Testing: Perspectives on Relevance, Awareness, and Next Steps Accessing Care"*, which examines Indigenous community members' perspectives on HCV self-testing, including its relevance, awareness, and pathways to accessing care. These findings compliment the results of the present study in people with lived experience of incarceration as both highlight the importance of acceptability, trust, and clear linkage to care in the implementation of HCV self-testing. Together, this evidence suggests that while self-testing is viewed as a promising approach across equity deserving groups the success will depend on ensuring culturally and contextually appropriate delivery models that address specific barriers to healthcare access.

This thesis supports the need for future clinical and implementation science research in this area. Future research should focus on evaluating the usability of HCV self-tests in people with experience in carceral settings, while assessing whether individuals can correctly perform the test, interpret the results, and follow instructions. This includes utilizing end-user frameworks to validate both self-testing and self-collection and to better understand real-world acceptability. There is also a role for implementation science research focused on evaluating how HCV self-testing can be integrated into existing healthcare systems including linkage to confirmatory testing, treatment, and follow-up care for individuals who receive an HCV diagnosis. While participants with experience being incarcerated were the focus of this study, it would be crucial for future implementation studies to engage policy makers and other provincial stakeholders who would be instrumental to implement and scale-up HCV self-testing and self-collection in the provinces across Canada.

## Integrated Knowledge Translation and Dissemination

Integrated knowledge translation and dissemination was used throughout the design and facilitation of the study. The interview guides were co-designed. As a first step a community gathering held at PASAN invited those with lived experience to provide feedback on the idea of self-testing and this study. The interview guides were then co-designed with PASAN staff, who led recruitment and facilitated the creation of a safe space for the interviews to occur. The preliminary findings were shared with PASAN following data analysis to invite feedback. Sharing the results with PASAN also supported reciprocal knowledge exchange by returning the findings to the organization that supported the research and created opportunities for the findings to inform future programming and service delivery. Knowledge dissemination and mobilization for this study also included an oral presentation at the Canadian Digestive Disease Week-Canadian Liver Meeting (CDDW-CLM) (Barnett et al., 2025); a poster presentation at the International Network on Health and Hepatitis in Substance Users (INHSU) conference (Muncaster et al., 2024); publication in the peer-reviewed journal BMC Infectious Disease (Barnett, Muncaster, et al., 2026); and a feature of the research in a blog article written by Canada's Source for HIV and Hepatitis C Information (CATIE) (2026). Importantly, CATIE is a national, non-profit knowledge dissemination and mobilization organization focused on HIV and HCV prevention, testing, treatment and care. The organization is primarily funded through the Public Health Agency of Canada. CATIE's main audience is healthcare professionals, public health practitioners, program planners, harm reduction workers, peer support workers, community-based organizations working in HIV/HCV services, people with lived and living experience of HIV and/or HCV, researcher and policy makers working in infectious disease and health equity (Canada's Source for HIV and Hepatitis C Information, 2025). CATIE designs resources by translating evidence into practical

and accessible information for underserved communities disproportionately affected by HIV and HCV (Canada's Source for HIV and Hepatitis C Information, 2025). The presentations, publication, and featured blog post brought awareness of the potential of HCV self-testing for people with histories of incarcerations and reached community leaders, government agencies, policy makers, researchers, and clinicians in Canada and globally.

## Conclusion

This thesis provided valuable insight into the views and needs of people with histories of incarceration. This research can be used to help inform future HCV self-testing programs as a viable option for HCV testing. Participants valued the privacy, autonomy and convenience that self-testing offered and viewed the test as a low-barrier strategy that could help overcome challenges associated with testing through traditional healthcare pathways. There was a preference for receiving self-testing kits immediately following release from carceral settings along with flexible options for DBS result delivery and follow-up care. These preferences demonstrate the importance of person-centered and accessible HCV self-testing program design and development. Furthermore, participants identified important concerns related to stigma, trust in healthcare systems, privacy and data security. The findings suggest the need for trauma- and violence-informed, non-judgmental, and culturally relevant implementation strategies that incorporate authentic representation, clear instructions, multiple support options, and meaningful involvement of people with lived experience of incarceration in program development. Overall, HCV self-testing has the potential to increase testing uptake, through an anonymous testing option, facilitate earlier diagnosis, and improve linkage to care to low-barrier models among individuals with carceral experience while supporting broader HCV elimination efforts in Canada.

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# APPENDICES

## APPENDIX A

## Ethics Approval from York University

YORK
UNIVERSITÉ
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| | |
|---|---|
| **Certificate #:** | **e2023-222** |
| **Initial Approval:** | **07/13/23-07/13/24** |
| **Amendments:** | **Amendment approved: 11/24/23; 2nd Amendment approved: 11/29/24** |
| **Renewals:** | **07/08/24-07/08/25**<br>**07/09/25-07/09/26** |
| **Current Approval Period:** | **07/09/25-07/09/26** |

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# ETHICS RENEWAL

**To:** **Professor Mia Biondi**
Department of Nursing
Faculty of Health
kmuncas@uwo.ca; mbiondi@yorku.ca

**From:** Alison M. Collins-Mrakas, Director, Research Ethics
*(on behalf of Gillian Parekh, Chair, Human Participants Review Committee)*

**Date:** Wednesday, July 9, 2025

**Title:** **Community perspectives on hepatitis C virus point-of-care self-testing**

**Risk Level:** ☒ Minimal Risk ☐ More than Minimal Risk

**Level of Review:** ☒ Delegated Review ☐ Full Committee Review

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I am writing to inform you that this research project, **"Community perspectives on hepatitis C virus point-of-care self-testing"** has received ethics review and renewal by the Human Participants Review Sub-Committee, York University's Ethics Review Board and conforms to the standards of the Canadian Tri-Council Research Ethics guidelines.

Note that renewal is granted for one year. Ongoing research – research that extends beyond one year – must be renewed prior to the expiry date.

Any changes to the approved protocol must be reviewed and approved through the amendment process by submission of an amendment application to the HPRC prior to its implementation.

Any adverse or unanticipated events in the research should be reported to the Office of Research ethics (ore@yorku.ca) as soon as possible.

For further information on researcher responsibilities as it pertains to this approved research ethics protocol, please refer to the attached document, **"RESEARCH ETHICS: PROCEDURES to ENSURE ONGOING COMPLIANCE".**

Should you have any questions, please feel free to contact me at: ore@yorku.ca

Yours sincerely,

Alison M. Collins-Mrakas M.Sc., LLM
Director, Office of Research Ethics

## APPENDIX B

## Qualitative Interview Guide

**Before starting:**

First, thank you for taking the time to talk to me. I am one of the researchers, and my role has been…. [personalize]

Second, I have a gift card to thank you for your time and willingness to do this interview.

**Provide card to participant. This is their card regardless of how much of the interview they complete.*

Since already consented, reaffirm consent with audio recording.

If I ask any questions that you don't want to answer, just say "pass." You can stop the interview or take a break at any time. The interview should take around an hour. Do you have any questions before we begin?

> **If "yes", follow up to address any questions or concerns before proceeding.*
>
> **If "no", proceed with interview.*

**Section 1 Preamble:**

As you know, we are interested in learning about what your preferences would be for the roll-out of a self-test for a virus called hepatitis C. The current test, called a point-of-care test, requires a single drop of blood. Right now, in Canada, it must be administered by someone trained, meaning you would need to seek out a tester, or be in a location where there is testing. With self-testing, someone could obtain a kit with instructions and test themselves in whatever location they wish. This is like COVID-19 self-testing, expect instead of a nasal swab, it a single drop of blood that you would obtain with a device that would prick your finger. You would collect the blood and then put the blood into a liquid and the test into the liquid. It would be something like this (interviewer uses the POC kit and pretends to complete a self-test).

1. If you were going to test yourself for HCV, how would you want to receive the self-testing kit?

> Probes: Some options might be to order it online, pick it up at a community organization, or pick it up and be supported by a staff member to take the test. Would you like to pick it up at a methadone clinic or a pharmacy? Would you be comfortable if it were to be delivered to your home? Would you want to pick it up at a health centre? A community organization?

2. When is a good time to receive this kit considering life's competing priorities?

> Probes (priority population specific):
>
> ***Experience in the jail system:*** Would it be better to receive the self-testing kit on release the jail system? Or would it be better to have some time to settle and receive it in a few months? Would you remember to reach out for it? Would you want a reminder?

3. I'm going to show you some examples of flyers that we might use to inform people about HCV self-testing. Please tell me your thoughts about these?

Probes: What do you like about the appearance? Does it draw you in? The wording? Are any of the images or words offensive? Are the directions clear and understandable? What would you like to see changed?

4. Websites has been designed for ordering HIV self-tests. I'd like to walk you through this website and get some of your thoughts on how we could make this better for people considering HCV self-testing.

Probes:

Landing page:

Is this visually appealing?

Allow the participant to navigate:

Is it clear on how to order and what to do?

What do you think about the feature to connect with a peer?

What do you like most about the website?

What do you like least?

5. How would you feel about reporting your results of your HCV POC self-test?

Probes: Would you be open to inputting results onto a secured and confidential website using a code and not your name?

**Section 2 Preamble**: The next few questions refer to what to do after the self-test. The HCV self-test tells us whether or not someone has HCV antibodies. This means that someone was exposed to HCV. But in order to determine if someone actually has hepatitis C, we need to do an RNA test. This would require taking another small blood sample for your finger. What would be the best way to facilitate the second test? This test is not a test where you get the answer right away, but it could be a sample that you take for yourself. It would be something like this (interviewer uses the DBS kit and pretends to complete a self-collection onto dried blood spot).

Probes:

Repeat: If the result of your self-test was positive, how would you like to move forward to the next step of HCV testing?

Would you want to take a second blood sample from your finger? If yes, how could the sample get returned? Would you want to drop it off somewhere? Would you want to mail it?

If you would not want to collect a second sample, what would you want to do to find out it you have active infection? Would you want to put your POC test results into a website and someone would call you? If no, would having support from a worker change your opinion on this? Would you make an appointment with a healthcare provider on your own?

7. If you choose to collect your sample and drop it off or mail it in, what would be the best way to reach you if you have a HCV positive result, meaning you were actively infected.

Probes: Would you like to receive a text, email, phone call, etc.? Would you prefer to have the responsibility to coming back to check-in to find out your results?

8. I mentioned that the HCV test requires a finger prick and collecting your blood). Thinking of this type of test, are there any parts of this test that would make you nervous or less likely to want to do the test?

9. Is there anything else you think we should know as we plan for providing self-test kits for hepatitis C among (priority population)?

**APPENDIX C**

**Study Protocol**

# Community perspectives on hepatitis C virus point-of-care self-testing

**Short Title:** hepatitis C point-of-care self-testing

**Principal Investigator:**
Mia Biondi, PhD, NP-PHC

**Co-Investigators:** Karen Campbell, Kody Muncaster

**Institutions:** School of Nursing, York University
Health, Nursing and Environmental Studies, 104 Scholars Walk, Toronto, ON, M3J 1P3

**Sponsor:** Mia Biondi, PhD, NP-PHC
**Funder:**

**Protocol Version No.:** 1.0

**Protocol Version Date:** May 25, 2023

# PROTOCOL SUMMARY

**Full Title:** Community perspectives on hepatitis C virus point-of-care self-testing

**Short Title:** hepatitis C point-of-care self-testing

**Study Population:**
10-20 people who have ever been incarcerated in a Canadian prison/jail, 10-20 gay or bisexual men, and 10-20 people who were born in 1945-1975

**Study Design:** Semi-structured interview

**Study Duration:** 12 months

**Primary Objective:** To assess the feasibility of hepatitis C self-testing in at-risk populations.

## 1.0 BACKGROUND & RATIONALE

Hepatitis C virus (HCV) infection remains an important public health problem for Canadians, causing more years of life lost than any other infectious disease[1]. The introduction of highly effective direct acting antiviral (DAA) regimens has revolutionized the treatment of HCV infection with cure rates >95%. As a result, the World Health Organization (WHO) released a global strategy for eliminating viral hepatitis by 2030, and Canada has committed to reaching these targets[2]. However, to achieve global elimination, a change in the way testing and care is delivered will be required. Many marginalized groups never seek testing because of structural and geographic barriers[3], including experiencing stigma in healthcare settings[3] as well as concerns about confidentiality and public health reporting[4].

The *Blueprint to Inform Hepatitis C Elimination Efforts in Canada* was developed by the CIHR-funded Canadian Network on Hepatitis C (CanHepC) and released in 2019[5]. At that time, six groups disproportionately affected by HCV were identified as a priority focus for elimination efforts. These include people who use drugs, newcomers and immigrants, Indigenous Peoples (First Nations, Metis, Inuit), gay and bisexual men who have sex with men (gbMSM), those who are criminalized and/or incarcerated, and those born between 1945-1975 (the "birth cohort"). As the *Blueprint* is a national document, but as healthcare is delivered provincially, CanHepC has developed a process to implement the *Blueprint* recommendations across the country, and in Ontario, a core group of members with cross-disciplinary and community experience established the *Roadmap to Hepatitis C Elimination in Ontario* in 2020 (https://on.endhepc.ca). **A key recommendation is increasing screening for HCV, and self-testing specifically has been recognized as a priority by the WHO to drive elimination efforts.** We plan to explore self-testing. We will use semi-structured interviews to engage in community-based dialogue and consultations on how to best offer HCV self-testing and self-sampling.

**Objectives:** To complete a population-informed pilot end-user study for HCV self-testing using point-of-care antibody testing.

**Aim: Develop a framework and workflow to pilot HCV self-testing and self-sampling.**

**Epidemiology and Impact of HCV –** It has been estimated that globally, 58 million people are living with chronic HCV and 290,000 deaths occurred globally in 2019 as a result of liver failure and liver cancer[6]. In 2019, the rate of HCV infection in Canada was 30.4 cases per 100,000 people, with a slightly higher rate of 33.2 per 100,000 in Ontario[7]. The asymptomatic nature of HCV infection means that the virus often remains undiagnosed and thus, untreated for years or even decades after infection[8]. Due to the lack of symptoms, HCV can cause slow but progressive liver disease, remaining clinically silent until complications from cirrhosis, liver failure or hepatocellular carcinoma (HCC) develop. Indeed 33% of Ontarians who developed liver failure or liver cancer from HCV were diagnosed within 6 months of that complication, many of whom come from marginalized populations with barriers to testing[9].

**HCV Screening and Diagnosis –** The traditional pathway for screening and diagnosis begins with HCV antibody testing to determine exposure. Of those exposed, ~25-50% will clear the infection[10-12], and be antibody positive, but not actively infected. To determine if an individual has active infection an HCV RNA or HCV core antigen test must be completed. Unfortunately, this two-step process leads to loss to follow-up rates of 30%[13] in places where the test is not reflexed; and at present, Ontario and Quebec are the only two provinces in Canada that do not reflex[14]. Thus, many individuals never find out if they are actively infected and therefore are never engaged in treatment. Additionally, many other barriers contribute to the difficulty in HCV case-finding. People who have a current or history of using injection drugs may have difficult venous access or are re-traumatized during blood draws or might never return for results. Each individual step from antibody positivity to cure, leads to opportunities for loss to follow-up. ***Fortunately, in 2017, Health Canada approved the first point-of-care (POC) HCV antibody test.*** This test utilizes lateral flow technology, to give a visual result of HCV seropositivity and has a sensitivity of 98% and specificity of 100%[15]. POC HCV antibody testing has had tremendous utility, helping to reach individuals who would not have been screened through conventional methods, with only a single drop of blood from a fingerpick[16]. Despite the utility of POC antibody testing, confirmation of active infection is required. One way to avoid venipuncture is to use dried blood spots (DBS) to collect a blood sample for RNA testing (**Appendix Figure 2**). This method uses a finger prick to collect drops of blood onto filter paper, which is then cut out, eluted, and processed. At present, Ontario is the only province where DBS RNA is available through the provincial laboratory[17]. POC with subsequent DBS allows for diagnosis without ever having to have a blood draw or go to a laboratory.

**Opportunities for Engagement, Linkage to Care, Cure, and Cancer Prevention –** To achieve viral elimination, a change in the way care is delivered will be required. This is complicated, as engaging and linking marginalized individuals to care remains a challenge, even when care is provided by non-specialists[18,19]. However, despite treatment uptake in primary care, 36% of Ontarians with HCV remain unaware of their infection[20]. Although many of these individuals may face barriers such as pervasive stigma[3] in healthcare or competing life or health priorities, many may just have never been identified as someone with past or current risk factors. This is especially true of persons who have very remote risk factors and are living with undiagnosed advanced liver disease due to HCV. In fact, despite availability of curative therapy, very late diagnosis, within 6 months of liver failure or liver cancer, occurs in over 30% of those who develop complications and disappointingly, this rate has not gone down over time[9]. Unfortunately, rural and remote communities throughout Canada face inequities when it comes to hepatology care. However, if

individuals are screened and treated for HCV prior to the development of cirrhosis, the risk of developing advanced liver disease or its complications, particularly liver cancer, drops dramatically. Strategies to enable early HCV detection, particularly in areas with limited healthcare resources or barriers to healthcare access, should be prioritized for innovative **cancer prevention tools**.

**Current Policy Initiatives –** As a part of Canada's commitment to the WHO strategy, in 2019, the *Blueprint to Inform Hepatitis C Elimination Efforts in Canada* was created by the Canadian Network on Hepatitis C (CanHepC) outlining steps necessary for Canada to achieve the WHO targets[5], which complements the Public Health Agency of Canada Action Plan on sexually transmitted and bloodborne infections[21]. Both call for HCV-relevant data to understand the impact of infection on at-risk populations. Importantly, as of 2018, all provinces removed fibrosis restrictions to accessing HCV treatment, **however no province is fully leveraging all possible diagnostic tools, provider scope, or minimizing paperwork prior to treatment initiation[14].** As healthcare is delivered provincially, implementation of the *Blueprint* recommendations requires a regional approach. CanHepC has developed 7 regional groups to develop provincial/regional *Roadmaps* for HCV elimination. In Ontario a core group of members with cross-disciplinary and community experience established the *Roadmap to Hepatitis C Elimination in Ontario* in 2020. From 2020 to present, the non-profit organization CATIE (Canada's source for HIV and hepatitis C information) led consultations with providers across sectors, as well as numerous group and one-on-one consultations among organizations that represent priority populations, and people with lived and living experience. The recommendations, entire consultation process and stakeholder identities is available at https://on.endhepc.ca. **One strong recommendation that has emerged is the need to increase screening, including mechanisms that promote autonomy.** Unfortunately, Ontario has been greatly affected by the primary care shortage, make up 61% of the Canadian population[22], and both Quebec and Ontario are the only provinces which do not have reflex testing[14], making self-testing with POC antibody and DBS RNA even more relevant and useful.

**Knowledge Gaps and Opportunities** – Although existing research has alluded to self-testing as a feasible and acceptable HCV case-finding mechanism[23], there is minimal evidence on the uptake or impact of HCV self-testing programs. In 2021, the WHO released recommendations and guidance on HCV self-testing, encouraging country programmes to consider self-testing as **a means to engage priority groups in case-finding and regions that exhibit gaps in testing coverage[24]. However, strikingly, this recommendation was based exclusively on evidence from HIV self-testing programs highlighting the association between self-testing with increased usability and feasibility, increased equity to testing services and promoting autonomy[24]. Complimenting the recommendation, a systematic review of HCV self-testing performed by the WHO acknowledged no direct evidence of the benefits or harms of HCV self-testing clearly highlighting this major data gap[24].** Microbiological self-testing has become widespread during the COVID-19 pandemic. HIV self-testing is now Health Canada approved[25], an initiative that was advocated for by members of affected communities. HCV self-testing has the potential to reach individuals who cannot access healthcare because of geographic barriers such as urban transportation or rural/remote settings; structural barriers, such as stigma or fear of public health reporting; or due to a lack of access to providers in the context of the ongoing primary care crisis.

## 2.0 STUDY OBJECTIVES, HYPOTHESIS & ENDPOINTS

### 2.1 Study Purpose and Objectives

The purpose of this study is to determine the best ways to roll-out HCV self-testing in at-risk populations. This study focuses three of the six priority populations for HCV: on gay and bisexual men who have sex with men (gbMSM), those who are criminalized and/or incarcerated, and those born between 1945-1975 (the "birth cohort"). These three populations have been chosen due to the expertise of the research team with these communities. 10-20 semi-structured interviews will be conducted with each of the three populations, for a total of 60. Specific themes of the interviews will include: 1) preferred means of receiving self-testing kits, 2) when in one's life would be the best time to receive a kit, 3) perspectives on what should go into flyers advertising kits, 4) perspectives on potential websites for ordering kits, 5) feelings about potentially reporting test results, 6) feelings about performing confirmatory dried blood spot self-sample collection, 7) best means of contact if results are positive, 8) any apprehensions around self-testing, and 9) general thoughts on self-testing for the participant's priority population.

### 2.2 Study Hypothesis

We hypothesize that participants will have high interest in HCV self-testing due to its removing barriers and due to familiarity with HIV and covid-19 self-testing. We also hypothesize that participants will have a great deal of feedback on topics such as preferred mechanism of receiving kits, design of instructions as well as the other themes asked in the interviews.

## 3.0 STUDY DESIGN

### 3.1 Population/Inclusion Criteria

1) Have ever been incarcerated in a Canadian prison/jail OR are a gay or bisexual man who has sex with men (cisgender or transgender) OR were born between 1945-1975;
2) Speak English;
3) Are over the age of 16;
4) Reside in Ontario.

### 3.2 Population/Exclusion Criteria

1) Incarcerated in a prison or jail outside of Canada
2) Currently on HCV treatment

### 3.3 Potential Risks to Participants

There are minimal risks associated with this study. By taking part in this study, the participant be discussing perspectives on HCV self-testing and disclosing belonging to one of the three priority populations studied. While the information collected will be used for

research purposes only and will not be used to identify the participant, this information can be personal and sensitive, and the participant may feel some discomfort disclosing it.

### 3.4 Potential Benefits to Participants

There are no direct benefits for participating in this study. However, if the participant was previously unaware of HCV testing, they may learn about it during the interview.

### 3.6 Participant Consent

Study recruitment will happen across sites in Ontario, using professional networks to identify agency staff who are aware of study inclusion and exclusion criteria. Potential participants will be identified by agency staff. When a prospective participant is identified by the staff, they will be asked their permission to be approached for the study. Should they consent, research team member will review the signed written consent form. Should they consent, they will be interviewed by study staff. Participants will have the option to complete interviews in-person or on zoom. In-person interviews will use paper consent forms that will be immediately digitized on a secure server. Zoom interviews will use the same consent form but on Qualtrics. The primary organizations involved are: 1) Prisoners with HIV/AIDS Support Action Network (PASAN) is a community-based organization with large networks providing support for those in and out of the jail system. PASAN in Ontario will assist in the recruitment of approximately 10-20 participants with lived experience in the criminal justice system. 2) The Ontario Gay Men's Sexual Health Alliance (GMSH) is a network of HIV and HCV prevention workers across the province with a mandate to work with the gay male community. GMSH has a significant social media presence with wide reach and has been involved in recruiting many large studies in this community. PrEPrx Clinics is a HIV pre-exposure prophylaxis clinic that has primarily gay male clients. GMSH and PrEPrx will support recruitment of approximately 10-20 participants. 3) 10-20 participants from the birth cohort will be recruited. The NPA Biondi is a part of large primary care nursing network that will support dissemination of recruitment materials. Strategies include engagement with social media, snowball sampling, groups, and promotion through organizations where participants may attend (including community and clinic). For each of the populations, email blasts with the ethics approved poster may be sent to relevant organizations for recruitment.

### 3.7 Interview Guides

The study will involve semi-structed interviews with interview guides found in Appendix A.

### 3.8 Participant Honorarium

Participants in the will receive a $50 money card for agreeing to participate.

## 4.0 DATA ANALYSIS

The study will use NVivo software to conduct thematic analysis of participant responses, categorizing commonalities across the data set.

## 5.0 QUALITY ASSURANCE & QUALITY CONTROL

Steps to be taken to ensure the accuracy and reliability of data include the review of protocol procedures with the investigator and study-site personnel before the study. Instructions will be provided for the collection and handling of records. The investigator will examine logs for accuracy and completeness during periodic reviews; any discrepancies will be resolved with the investigator or designee, as appropriate. Data will be verified for accuracy and consistency with the data sources.

## 6.0 DATA HANDLING AND RECORD KEEPING

The Principal Investigator will monitor and manage all de-identified data collected as part of this study. These data include questionnaire results. Any research derived from collected data will be anonymous.

All paper records and documents pertaining to this study will be retained in a secure and confidential prior to being digitized, but will be digitized as soon as possible, and then stored for 10 years.

## 7.0 FUNDING

The study will be funded by the PI, Dr. Mia Biondi's generic funding.

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## APPENDIX D

## Informed Consent Form for Participation in Research Study

**CONSENT FORM TO PARTICIPATE IN A RESEARCH STUDY**

**Study Title:** Community perspectives on hepatitis C virus point-of-care self-testing

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**Sponsor:** Mia Biondi, PhD, NP-PHC

### Introduction

You are being asked to take part in a research study. Please read the information about the study presented in this form. The form includes details on the study's risks and benefits that you should know before you decide if you would like to take part. You should take as much time as you need to make your decision. You should ask study staff to explain anything that you do not understand and make sure that all of your questions have been answered before signing this consent form.

Before you make your decision, feel free to talk about this study with anyone you wish including your friends, family, and health care provider. Participation in this study is voluntary.

**Background/Purpose**

Hepatitis C virus (HCV) infection remains an important public health problem for Canadians, causing more years of life lost than any other infectious disease. The introduction of highly effective direct acting antiviral (DAA) regimens has revolutionized the treatment of HCV infection with cure rates >95%. As a result, the World Health Organization (WHO) released a global strategy for eliminating viral hepatitis by 2030, and Canada has committed to reaching these targets. However, to achieve global elimination, a change in the way testing and care is delivered will be required. Many marginalized groups never seek testing because of structural and geographic barriers, including experiencing stigma in healthcare settings as well as concerns about confidentiality and public health reporting.

The Blueprint to Inform Hepatitis C Elimination Efforts in Canada was developed by the CIHR-funded Canadian Network on Hepatitis C (CanHepC) and released in 2019. At that time, six groups disproportionately affected by HCV were identified as a priority focus for elimination efforts. These include people who use drugs, newcomers and immigrants, Indigenous Peoples (First Nations, Metis, Inuit), gay and bisexual men who have sex with men (gbMSM), those who are criminalized and/or incarcerated, and those born between 1945-1975 (the "birth cohort"). The Blueprint is a national document, but as healthcare is delivered provincially, CanHepC has developed a process to implement the Blueprint recommendations across the country, and in Ontario, a core group of members with cross-disciplinary and community experience established the Roadmap to Hepatitis C Elimination in Ontario in 2020 (https://on.endhepc.ca). A key recommendation is increasing screening for HCV, and self-testing specifically has been recognized as a priority by the WHO to drive elimination efforts. This project involves interviewing participants from these priority populations on how to best offer HCV self-testing and self-sampling.

**The purpose of this study is to understand the best ways to develop HCV self-testing from the perspectives of gbMSM, people who have experienced incarceration in Canada, and people in the birth cohort.**

**Study Visits and Procedures**

If you agree to participate, you will complete an interview either via Zoom or in-person, whichever is your preference. The purpose of the interview is to share your perspectives on the most effective ways to roll out HCV self-testing. The interview will take approximately 30-60 minutes to complete.

***The interview currently includes the following themes:***

1) preferred means of receiving self-testing kits,

2) when in one's life would be the best time to receive a kit,

3) perspectives on what should go into flyers advertising kits,

4) perspectives on potential websites for ordering kits,

5) feelings about potentially reporting test results,

6) feelings about performing confirmatory dried blood spot self-sample collection,

7) best means of contact if results are positive,

8) any apprehensions around self-testing, and

9) general thoughts on self-testing for the participant's priority population.

**Risks and Discomforts**

There are minimal risks associated with this study. By taking part in this study, you will be discussing your perspectives on HCV self-testing and disclosing that you belong to one of the three priority populations studied. While the information collected will be used for research purposes only and will not be used to identify you, this information can be personal and sensitive and you may feel some discomfort disclosing it.

**Benefits of the Research and Benefits to You**

There are no direct benefits to you for completing the questionnaire in this study. However, if you were previously unaware of HCV testing, you will learn about it during the interview. The findings of the study may shape clinical recommendations for the development of future initiatives for HCV self-testing.

**Compensation**

If you decide to participate in this study, you will receive a $50 money card in appreciation for your time. Please note that you will still be eligible to receive this compensation even if you complete a portion, rather than the entirety of the interview.

**Voluntary Participation**

Your participation in the study is completely voluntary and you may choose to stop participating at any time up until you have completed the interview. Your decision not to participate will not influence any health care you may be receiving from researchers or study staff, or the nature of your relationship with York University either now, or in the future.

**Withdrawal from the Study**

You can choose to end your participation in this research (called withdrawal) without providing a reason up until the time you finish the interview. If you choose to withdraw from the study, please stop the interview and inform the site investigator that you are withdrawing. The site investigator

who will ensure that it any recordings of the interview will be destroyed appropriately. Your decision to stop participating, or to refuse to answer questions, will not affect your relationship with the researchers, York University, or any other group associated with this project. You will still be eligible to receive the $50 money card if you choose to withdraw or do not complete the interview.

**Confidentiality**

All information you supply during the research will be de-identified, held in confidence, and used only for the purposes of the study. Your name will not appear in any report or publication of the research. Only the researchers and study staff will have access to your information. Paper-based consent forms will be converted to electronic copies and then the paper versions will be destroyed. Your data will be safely stored on a secure server and only research staff/research team members will have access to this information. All copies of the research data will be destroyed in line with the York University guidelines from the Research Quality Integration department in January 2033, approximately 10 years after the study is completed. Confidentiality will be provided to you to the fullest extent possible by law.

**Rights as a Participant**

By signing this form, you do not give up any of your legal rights against the investigators or institution for compensation, nor does this form relieve the investigators, or institution of their legal and professional responsibilities.

**Conflict of Interest**

The researchers and sponsors have an interest in completing this study. Their interests should not influence your decision to participate in this study.

**Questions About the Research?**

If you have questions about the research in general or about your role in the study, please feel free to contact Dr. Biondi either by telephone at 647-628-6461 or by e-mail (mbiondi@yorku.ca). This research has received ethics review and approval by the Human Participants Review Sub-Committee, York University's Ethics Review Board and conforms to the standards of the Canadian Tri-Council Research Ethics guidelines. If you have any questions about this process, or about your rights as a participant in the study, please contact the Sr. Manager & Policy Advisor for the Office of Research Ethics, 5th Floor, Kaneff Tower, York University (telephone 416-736-5914 or e-mail ore@yorku.ca).

**CONSENT**

I have read this Study Information Form (or had it read to me) for the study named **"Community perspectives on hepatitis C virus point-of-care self-testing"**. I know that I may leave the study

at any time. I agree to the use of my information as described in this form. I agree to take part in this study. My questions, if any, have been answered to my satisfaction and by signing, I do not waive any of my rights.

By signing this consent form, I am agreeing to complete the measures involved in this study as described to me by research staff.

☐ I agree to audio recording of the interview so that the research team can keep an accurate record of what is said.

| | | |
|---|---|---|
| Print Study Participant's Name | Signature | Date |

My signature means that I have explained the study to the participant named above. I have answered all questions.

| | | |
|---|---|---|
| Print Name of Person Obtaining Consent | Signature | Date |

*(Continue, if applicable)*

**Was the participant assisted during the consent process? ☐ YES ☐ NO**

If **YES**, please check the relevant box and complete the signature space below:

☐ The **consent form was read to the participant**. The person signing below attests that the study as set out in this form was accurately explained to and has had any questions answered.

| | | |
|---|---|---|
| Print Name of Witness | | Signature |
| | Date | |

Relationship to Participant