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Rapid point-of-care testing for hepatitis C – assessment of feasibility, knowledge of participants and outcomes

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ABSTRACT

Aim: We assessed the feasibility of point-of-care testing to gain insights into participants' knowledge, experience and its effect on hepatitis C management.

Background: In New Zealand, only 50% of people infected with hepatitis C (HCV) are currently diagnosed. HCV infection is the most common diagnosis leading to liver transplantation in New Zealand. A point-of-care test can streamline HCV management.

Methods: The OraQuick HCV test (mouth swab or finger-prick) was offered to participants aged 45 to 65 and anyone with a risk factor for hepatitis C. Data collected included demographics, risk factors, and participant experience with testing.

Results: A total of 218 participants were recruited. The median age was 29 years (IQR 22 to 46). All the tests via the finger-prick method were negative. Fourteen positive mouth-swab tests were negative on ELISA testing. One person was detected to have HCV infection and treated. Knowledge regarding HCV was low. There were no statistically significant differences in knowledge between participants with different education levels, F (4213=0.857, P=0.491 and different ethnicities, F (4,213)0.857, P=0.491. The majority of study participants preferred the point-of-care test.

Conclusion: Point-of-care testing for HCV is feasible and preferred. Knowledge regarding HCV was low. This study has also provided valuable insights into the viability and experience of offering point-of-care testing.

Keywords: Hepatology, Hepatitis C, Point-of-care testing, Care cascade, Liver disease

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Introduction

In the global health landscape, chronic hepatitis C infection presents a significant challenge, affecting over 70 million individuals worldwide (1). The recent advancements in diagnostic and therapeutic strategies have marked a turning point in managing hepatitis C virus (HCV) infection. In this context, the World Health Organization (WHO) has ambitiously set a target to eliminate HCV as a major public health threat by 2030 (1). One of the insidious characteristics of HCV infection is its asymptomatic nature, often remaining undetected for decades. This poses a substantial barrier to early diagnosis and effective intervention. The primary mode of HCV transmission is parenteral, highlighting the need for enhanced preventative measures in healthcare settings and among populations at risk (2). In the absence of timely and appropriate treatment, the progression of HCV infection presents a grim picture. Epidemiological data indicates that approximately 50% to 80% of those infected will go on to develop chronic hepatitis C (3). This chronic infection sets the stage for more severe complications; approximately half of these individuals will develop liver cirrhosis, and up to 5% are at risk of developing hepatocellular carcinoma over 20-30 years. This underscores the urgent need for widespread access to effective testing and treatment modalities to reduce the global burden of HCV infection and achieve the WHO's elimination goals.

In the context of global HCV epidemiology, New Zealand presents a significant case study. Current

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estimates suggest that over 50,000 individuals in the country are living with chronic hepatitis C infection (4). In addition, there are approximately 1000 new hepatitis C infections in New Zealand each year (5). Notably, only about half of the estimated number of New Zealanders with chronic hepatitis C have been formally diagnosed, indicating a considerable gap in the detection and management of this condition. Demographic analysis reveals that the prevalence of HCV in New Zealand is particularly high among the middle-aged population. In the age bracket of 45 to 65, the prevalence rate is estimated at around 3.0% in females and 4.5% in males (6). These figures underscore the need for targeted public health strategies and enhanced screening efforts within this demographic cohort.

The 2017 report by Pharmac, New Zealand's pharmaceutical management agency, indicates that 2,000 individuals had been treated with the newer Direct-Acting Antivirals (DAAs) (7). However, to align with the World Health Organization's (WHO) objective of eliminating HCV as a major public health threat by 2030, it is imperative for New Zealand to ramp up its efforts significantly. The WHO's targets stipulate that 90% of HCV patients should be diagnosed, and 80% should receive treatment by 2030 (8). Currently, the HCV care cascade in New Zealand involves several stages before initiating treatment (5). This multi-step process potentially contributes to a higher likelihood of interruptions in patient management and an increased risk of patients being lost to follow-up (9). Addressing these challenges is crucial to improving the continuity of care for individuals with HCV and achieving the ambitious goals set by the WHO. This calls for a comprehensive approach that includes expanding diagnostic capabilities, streamlining treatment pathways, and implementing effective strategies to retain patients within the care continuum.

A point-of-care test is a swift testing method that allows individuals to be tested and informed of the results during the same visit (10). A point-of-care test for hepatitis C can significantly streamline the diagnostic process and make the care cascade more efficient (11). The sensitivity of the OraQuick ® (oral liquid) test is 95.9 to 98% and the specificity of 99% in a meta-analysis (12). It may also improve access for populations who may not have equitable access to health care (13).

The objectives of the study were to:

a) Assess the feasibility of point-of-care HCV testing in a general practice setting in New Zealand.

b) Gain insights into the participants' experience with the test and different testing modalities.

c) Assess the participants' knowledge regarding the prevalence, transmission, and treatment of hepatitis C.

d) Assess patient uptake of further investigations after a positive point-of-care HCV test.

Methods

Recruitment methodology

Information about the study was given to prospective participants attending three general practice settings and one sexual health clinic in Dunedin, New Zealand. Institutional peer review was done, and ethical approval was obtained from the University of Otago Ethics Committee (HE18/009). Written informed consent was obtained from all participants following the Declaration of Helsinki. Recruitment was done over twelve months, from November 2018 to October 2019. Convenience sampling was used in this study.

Inclusion and exclusion criteria

Inclusion criteria for participants were as follows:

1. All individuals aged 45 to 65 (inclusive), regardless of risk factors.
2. All adults who report any of the following risk factor(s):
   a. Any history of intravenous drug use.
   b. Born to an HCV-positive mother.
   c. Have human immunodeficiency virus (HIV) infection.
   d. Have received blood products or organ(s) before 1993.
   e. Have you ever been on hemodialysis.
   f. Have received blood products or organs overseas (excluding Canada, United States, Western Europe, and Australia).
   g. Have any surgical or dental procedures overseas (excluding Canada, the United States, Western Europe, and Australia).
   h. Have you ever been incarcerated.
   i. Have you ever had any tattoo, piercing, or used piercing equipment that may have been unsterilized (as perceived by the study participant depending on observed practices).

j. Have you ever visited a barber, beauty therapist/nail salon in unsterile conditions.

k. Have a sexual partner with known hepatitis C.

The exclusion criteria for participants were as follows:

1. Aged under 18 years old.
2. Previous diagnosis of hepatitis C infection or previous positive test for HCV.
3. Unwilling or unable to give informed consent.

Testing for hepatitis C

This study's participants underwent rapid point-of-care testing for the hepatitis C virus (HCV) antibody. The testing protocol employed the OraQuick ® test, a Food and Drug Administration-approved product of OraSure Technologies (14). The study was structured in two phases concerning the sample collection method. Initially, HCV testing was conducted using an oral fluid sample collected via a mouth swab. Subsequently, the study incorporated finger-prick blood sampling, utilizing the identical test kit, to obtain results and evaluate the comparative experiences of participants with these testing methods. The detailed workflow of this methodology is depicted in Figure 1 of the study.

A validity check was periodically conducted to ensure the reliability of the testing kits used in the study. During these intervals, the study included five volunteers known to have hepatitis C infection. These individuals were subjected to both the mouth swab and finger-prick point-of-care testing methods. This exercise aimed to validate the accuracy of the test kits in use. Consistently, all tests from these volunteers yielded positive results, as anticipated. However, it is important to note that these results were excluded from the main analysis of the study. This approach was

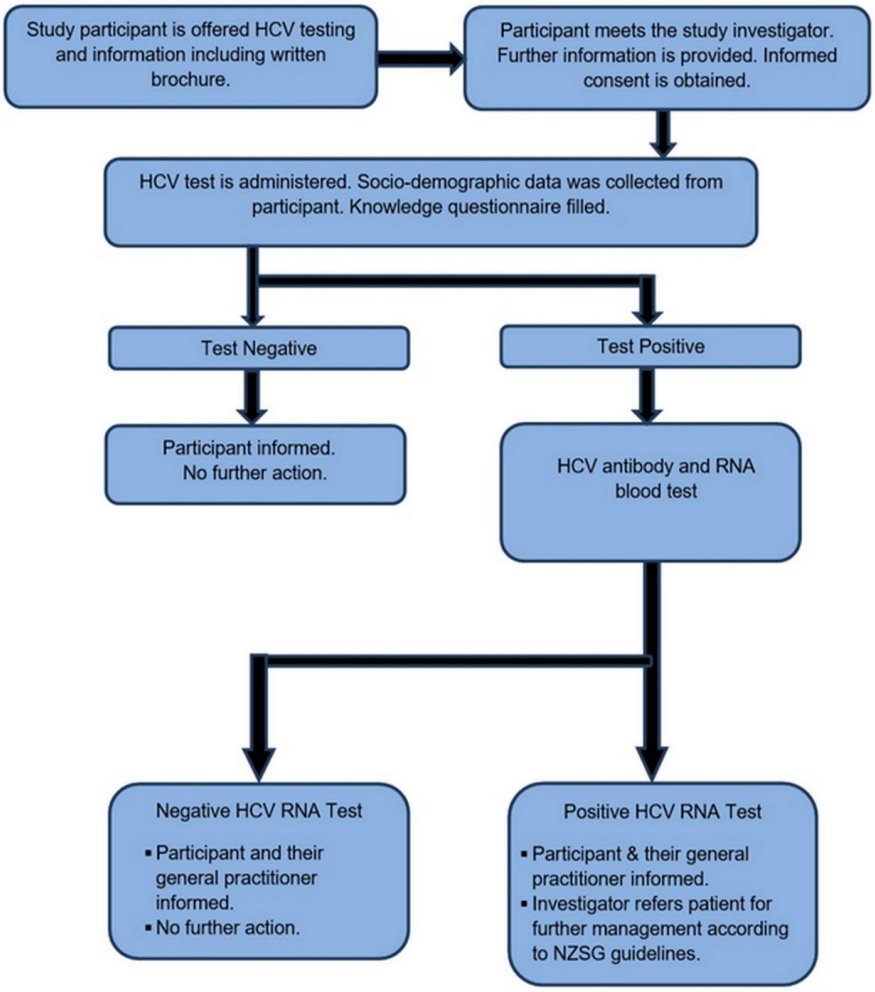

Figure 1. Summary of study methodology before and after administration of point-of-care test for hepatitis C.

essential in maintaining the integrity of the study's findings, focusing solely on assessing test experiences and results among the general participant group.

Data collection and analysis

Data for this study was gathered through a de-identified questionnaire, as seen in Supplementary Material 1. The analysis encompassed clinical and socio-demographic variables, employing chi-square and t-tests when deemed appropriate. Statistical significance was established at a p-value threshold of less than 0.05. A chi-square test of independence was utilized to investigate potential correlations between participants' levels of tested knowledge, educational background, ethnicity, and identified risk factors.

Further, the chi-square and t-test methodologies were applied in the data analysis phase to explore associations. Additionally, a one-way ANOVA, complemented by a Tukey HSD post hoc test specifically for the education level variable, was employed to assess the relationship between various demographic factors and the scores obtained in the knowledge questionnaire. This comprehensive statistical approach was key in understanding how demographic factors might influence knowledge levels about HCV infection.

Results

Participants' demographic data

A total of 218 participants were recruited for the study. Demographic characteristics of participants are given in Table 1.

Results of HCV point-of-care test

In this study, 107 participants underwent HCV point-of-care testing using the finger-prick method, with all results returning negative. One hundred and eleven participants had the mouth swab test, and 15 tested positive. Subsequently, these individuals were subjected to more comprehensive testing, including venepuncture for enzyme-linked immunosorbent assay (ELISA) antibody testing and HCV RNA polymerase chain reaction (PCR) analysis. Of the 15 participants who tested positive via the mouth swab, only one was confirmed to have an active HCV infection through the subsequent ELISA and PCR tests. The 14 patients who tested positive with the point-of-care test but had a negative ELISA antibody test did not report any known previous infection with hepatitis C. The sole male participant who tested positive - through the mouth swab, serum antibody tests, and detectable HCV RNA - was treated following the New Zealand Society of Gastroenterology (NZSG) guidelines, leading to a sustained virologic response (SVR). The effect of point-of-care testing on linkage to care could not be assessed as only one participant was detected to have an active HCV infection.

Risk factors of hepatitis C among study participants

The most common risk factor reported was a history of getting service at a nail salon or barber, which the participants deemed unhygienic or unsterile. Table 2 details the prevalence of risk factors for hepatitis C infection according to the age categories of the participants. Most risk factors were higher in those under 45 years old. A total of 5% participants reported a previous history of intravenous drug use.

Table 1. Demographic characteristics of participants.

Characteristics of Participants	% (n)
Sex, male	44% (n = 96)
Mean age in years (IQR)	35.2 (22 – 46)
Ethnicity	
New Zealand European	69.3% (n = 151)
Maori	10.6% (n = 23)
Other European	16.1% (n = 35)
Asian	3.2% (n = 7)
Other	0.9% (n = 2)
Education	
Secondary	12.8% (n = 28)
Tertiary	33.5% (n = 73)
Undergraduate	43.5% (n = 94)
Graduate	10.6% (n = 23)

Knowledge of study participants regarding hepatitis B and C

The median percentage of correct answers in the knowledge-based questions was 58.3%, with an interquartile range of 50 to 75. The number of participants who provided correct answers to knowledge-based questions is given in Table 3. Unless otherwise stated, data are mean (M) ± standard deviation (SD). There was no statistically significant difference in the percentage of correct answers between males and females, M = 2.35, 95% CI [-2.52 to 7.22], t (216) = 0.951, P = 0.343.

A one-way ANOVA was conducted to determine if the percentage of correct answers was different for participants of different ethnicities. Variances were homogeneous, as assessed by Levene's test for equality of variances (P = 0.470). There were no statistically significant differences in the percentage of correct answers for knowledge-based questions between participants of different ethnicities, F (4, 213) = 0.857, P = 0.491. Similarly, there were no statistically significant differences in the percentage of correct answers for knowledge-based questions between participants with different levels of education, F (4, 213) = 0.857, P =0.491.

Experience of participants with rapid point-of-care test

One hundred and eleven (50.9%) of the participants

Table 2. Risk factors for hepatitis C infection according to the age categories of the participants.

	Less than 45 years. % (n = 162)	45 to 65 years. % (n = 41)	More than 65 years. % (n = 15)	Total % (n = 218)
IV drug use	5.6 % (9)	4.9% (2)	0 % (0)	5% (11)
HCV antibody positive mother	0.6 % (1)	0 % (0)	0 % (0)	0.5% (1)
HIV Infection	0.6 % (1)	0 % (0)	0 % (0)	0.5% (1)
Blood/organ recipient before 1990	1.9 % (3)	4.9 % (2)	20 % (3)	3.7% (8)
Haemodialysis	0.6 % (1)	0 % (0)	0 % (0)	0.5% (1)
Blood/organ recipient overseas*	0.6 % (1)	2.4 % (1)	0 % (0)	0.9% (2)
Procedure overseas*	11.1 % (18)	17.1% (7)	6.7 % (1)	11.9% (26)
Ever been in prison	8% (13)	2.4 % (1)	0 % (0)	6.4% (14)
Tattoo/piercing with possible unsterilized equipment	41.3 % (67)	16.7 % (7)	33.3 % (5)	36.2% (79)
Barber/nail salon	55.6 % (90)	26.8 % (11)	40 % (6)	49.1% (107)
Needle stick injury	6.8 % (11)	24.4 % (10)	6.7 % (1)	10.1% (22)
Administered first aid to an unknown bleeding person	17.9 % (29)	34.1 % (14)	6.7 % (1)	20.2% (44)

*****Blood/organ recipient and procedures done overseas excluding Canada, United States, Western Europe and Australia.

Table 3. Study participants who provided correct answers to knowledge-based questions.

Question	Percent correct answers
How are hepatitis B & C spread?	
-sharing a toothbrush or razor	61.9% (n = 135)
-sharing IV drug utensils (needles/spoons)	95.4% (n = 208)
-through sexual intercourse	68.8% (n = 150)
-from mother to baby at birth	71.6% (n = 156)
-unsterile medical/dental/cosmetic procedures (tattoos, piercings)	91.3% (n = 199)
-occupational hazards (blood exposure in workplace)	83.5% (n = 182)
Can hepatitis be treated?	
-hepatitis B	41.7% (n = 91)
-hepatitis C	59.2% (n = 129)
Can you be vaccinated against hepatitis B? (yes)	55% (n = 120)
Can you be vaccinated against hepatitis C? (no)	21.6% (n = 47)
Is treatment for hepatitis funded in New Zealand?	46.8% (n = 102)
How common is viral hepatitis in New Zealand?	11% (n = 24)*

*Options of 5%, 10%, 20% and 50% were selected by 24%, 27.8%, 23.6% and 13.4% participants respectively.

had the mouth swab test, and 107 (49.1%) had the finger prick point-of-care test. Most participants (n = 131, 60.1%) reported choosing the rapid point-of-care test because they prefer fast results. Two hundred and eleven (96.8%) participants reported that they would recommend the rapid point-of-care test to their friend or family member. Most study participants (93.6%) preferred to get their results on the same day. Most participants (74.8%) reported that the rapid point-of-care test caused less anxiety.

Discussion

Current estimates suggest that about 1% of the global population, equating to upwards of 70 million individuals, are living with chronic HCV infection. (1) This significant health concern has far-reaching consequences, particularly concerning mortality and morbidity. In the year 2015, the world witnessed over 500,000 fatalities directly linked to chronic HCV and its resultant complications. (15) In New Zealand, the impact of chronic HCV infection is particularly notable in the field of organ transplantation. Chronic HCV infection and its complications are the predominant reasons for liver transplants in the country, highlighting the severe end-stage liver disease and hepatocellular carcinoma that can arise from prolonged HCV infection. (16) This trend underscores the critical need for effective public health strategies to address HCV, from early diagnosis to advanced treatment options.

The prevalence of chronic hepatitis C and its progression to life-threatening liver diseases not only poses a challenge to individual health but also places a significant strain on healthcare systems, especially in areas like liver transplantation services. Addressing this global health challenge requires a multifaceted approach, including heightened awareness, improved screening and diagnostic measures, access to effective medical treatments, and comprehensive care strategies. Such efforts are essential for reducing the incidence and severity of HCV-related health complications, thereby decreasing the demand for complex medical procedures like liver transplants. This situation underscores the pressing need for global collaboration and resource allocation to combat the widespread impact of chronic hepatitis C.

The advent of direct-acting antivirals in treating hepatitis C has led to a notable decrease in the necessity for liver transplants due to hepatitis C and its related complications within Australia and New Zealand (17). It's crucial to not only detect hepatitis C infections but also to optimize the treatment process for affected patients. The diagnostic and treatment care cascade for chronic HCV infection must be streamlined and easily accessible. Understanding patients' acceptance, views, and attitudes towards diagnostic modalities and treatment algorithms is crucial. Most of the participants in the study preferred the rapid point-of-care test over the usual blood test via venepuncture. A previous study has noted that rapid testing for hepatitis C was preferred by 82.9% of participants over venepuncture in their cohort of high-risk participants comprising people who inject drugs (PWID) (18). One of the main reasons for preference for point-of-care tests in this cohort at high risk of hepatitis C is venous access difficulties with venepuncture tests (19). Consistent with findings reported in prior research, participants in this study preferred these rapid testing methods over more traditional testing approaches (20). It is important to note that within the scope of this study, a direct comparative analysis between the mouth swab and finger-prick testing modalities was not conducted on the same set of participants. Nevertheless, observations show a preference for rapid testing over conventional blood testing conducted through venepuncture. Those getting the finger-prick rapid POC test still preferred it over the usual blood test via venepuncture. This general preference for rapid tests could be attributed to various factors inherent to the nature of point-of-care testing, such as the convenience, speed, and perceived lower invasiveness of these methods compared to traditional venepuncture. These findings are significant as they suggest a potential shift in patient preferences towards more modern, less invasive testing techniques. Such trends are vital for medical practitioners to consider, as they can influence patient compliance and satisfaction with diagnostic procedures, ultimately impacting the overall effectiveness of disease screening and management strategies.

In this study, a notable 36.2% of participants disclosed having received tattoos or body piercings in settings that potentially lacked sterile conditions. This revelation underscores the persisting risk of HCV outbreaks linked to such practices, highlighting an area of public health concern (21). a significant portion of

the study group, accounting for 49.1%, reported utilizing services at barbers or nail salons where hygienic and sterile practices may not have been adequately maintained. Further emphasizing the public health implications, a regional health survey conducted in 2018 in the Wellington region of New Zealand revealed some probable concerning practices in nail salons (22). It was found that 60% of these establishments would proceed with treatments even in the presence of bleeding, a factor that significantly increases the risk of transmitting infections like HCV. Parallel to these findings, the study noted a generally low level of awareness and knowledge about chronic viral hepatitis among participants. However, it was noted that there was a desire for development and further improvement. This observation aligns with results from a previous study conducted 2015 among middle-aged adults in Dunedin, New Zealand, where similar knowledge gaps were identified (23). Having risk factors for hepatitis C infection has been associated with a lack of knowledge regarding the condition (24). These findings underscore the necessity for enhanced educational initiatives and awareness campaigns focused on hepatitis C. Such efforts are crucial in understanding transmission risks associated with everyday activities, such as visiting nail salons or getting tattoos, and ensuring sterile conditions. Increased public awareness is a pivotal step in enhancing care coordination and reducing the spread of HCV, contributing to better public health outcomes and improving care coordination (25).

In the present study, a striking finding was that 14 out of the 15 positive results via the mouth swab method were not confirmed by ELISA antibody testing. Notably, all these instances were associated with using the mouth swab method. Prior research examining the OraQuick HCV point-of-care test, when conducted via mouth swab, has consistently reported a high specificity, typically ranging from 99 to 100% (26). However, our study's unexpectedly high incidence of false positives presents a discrepancy that warrants further investigation. All standard procedural steps for the mouth swab test were diligently followed in this study. These steps included adhering to the recommended waiting period after taking food, beverages, and oral care products before administering the test. Despite these precautions, the rate of false positives observed was notably higher than those reported in previous studies. This discrepancy highlights a potential concern regarding the optimal use of the mouth swab modality of this test in practical settings. It underscores the need for further investigation and possibly re-evaluating the test's application to ensure accurate and reliable HCV screening in diverse real-world scenarios.

The reported prevalence of chronic hepatitis C in New Zealand is believed to be 1.28% (8). The prevalence of hepatitis C antibody positivity has been reported to be 0.3% in a prevalence study done in Christchurch using an electoral role (27). The prevalence of hepatitis C antibodies in those aged forty to fifty-nine years is 4.01% among people living in Dunedin (23). Our study had a relatively small number of participants. Still, we expected more positive tests due to the inclusion criteria and the proportion of participants reporting risk factors. The limited locality and number of participants may have resulted in an underestimation of the prevalence. There may be a selection bias for the participants as they were engaged with health care services. It is known that groups at high risk of hepatitis C can have difficulties in engaging with health care services (28). One must also consider that there may be an overestimation of HCV prevalence in the New Zealand population.

The current methodology for diagnosing and initiating treatment for chronic hepatitis C is characterized by a multi-step process, as depicted in Figure 2. A significant challenge in this approach lies in the fact that most patients with chronic hepatitis C are asymptomatic. This lack of symptoms can reduce these individuals' motivation to engage in the extensive diagnostic and treatment initiation processes actively. This trend of diminished patient engagement due to asymptomatic conditions has been similarly observed in asymptomatic patients with HIV (29). An effective strategy to address this issue involves integrating POC diagnostic tests into the existing care cascade. This integration can significantly alleviate the burden on patients by streamlining the process and reducing the need for multiple healthcare visits and appointments. Such a consolidation of the management pathway not only enhances patient convenience but also has the potential to improve adherence to treatment protocols and overall health outcomes. Healthcare systems must consider these nuances to ensure effective

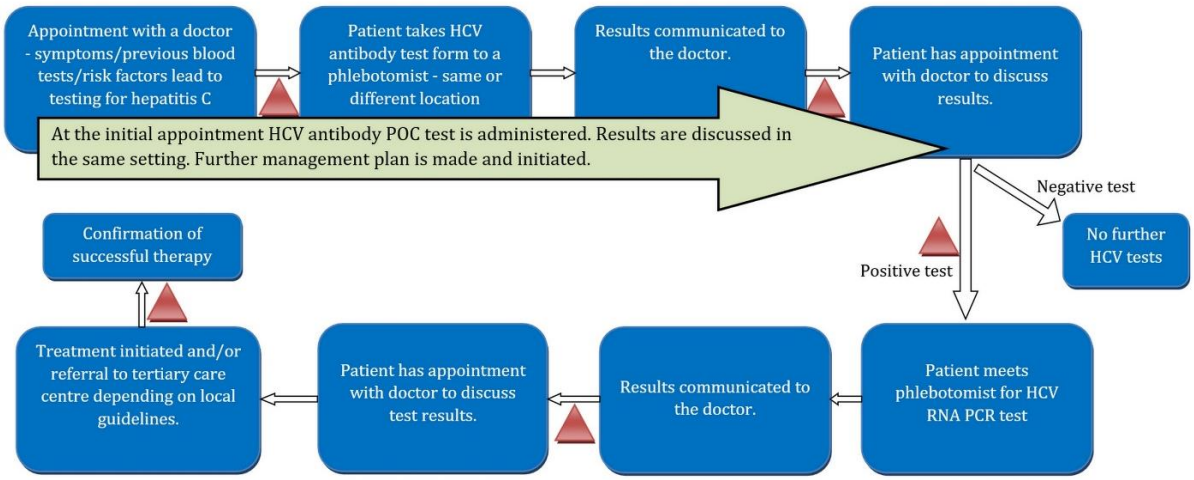

Figure 2. HCV care cascade and steps leading to treatment using HCV antibody point-of-care test. Points of potential loss to follow-up due to patient factors are indicated by red triangles. HCV: Hepatitis C. PCR: Polymerase chain reaction. RNA: ribonucleic acid.

management and care for patients with chronic hepatitis C, particularly given the asymptomatic nature of many cases.

The "Wai 2575 Māori Health Trends Report," published by the New Zealand Ministry of Health, presents changes in health in Indigenous peoples in New Zealand (Māori). The health outcomes among Māori are less favorable compared to other demographics (30). This disparity is further compounded by a higher prevalence of certain health conditions in this population that contribute to liver fibrosis and neoplastic transformation. Notably, type 2 diabetes and various elements of metabolic syndrome are more prevalent in this population, which could potentially escalate the risk of complications in those with hepatitis C infection. This should be part of broader public health initiatives aimed at reducing the incidence of hepatitis C and improving overall health outcomes within this group. Effective communication strategies, culturally sensitive educational programs, and community engagement are vital in addressing this health issue.

This study marks a significant first in investigating hepatitis C point-of-care testing within the general population of New Zealand. Our findings reveal that point-of-care testing is well received and preferred by participants. Despite this acceptance, the study highlighted a notable issue with the mouth swab testing method, which produced many false positives. This outcome raises critical questions about the accuracy of this specific methodology when used with this assay, underscoring the need for a thorough understanding of the real-world performance of any testing strategy implemented.

A key observation from this study was the generally low level of knowledge about hepatitis C among participants. This finding indicates a valuable opportunity for public health improvement through educational initiatives. Effectively disseminating knowledge about hepatitis C, particularly to those populations at higher risk, should be an integral part of any public health initiative aimed at disease prevention. Empowering individuals with information can play a pivotal role in reducing disease incidence.

Looking ahead, it will likely be more advantageous to focus POC testing for hepatitis C in settings where there is a higher prevalence of the disease. One of the persistent challenges in the management of hepatitis C is the identification and subsequent care linkage of individuals with undiagnosed, asymptomatic chronic infections. In this context, along with enhancing public awareness, the strategic use of point-of-care testing can significantly improve disease identification. By facilitating earlier detection and streamlined access to care, POC testing can be a valuable tool in addressing the ongoing challenges posed by hepatitis C, ultimately leading to better health outcomes and a reduction in disease burden, bringing us closer to achieving WHO targets.

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Conflict of interests

The authors declare that they have no competing interests.

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