

# Nurse practitioners as primary care site champions for the screening and treatment of hepatitis C virus

Cheryl H. Dale, MScN, NP-Adult (Provider Solutions Manager - Hepatology)<sup>1</sup>, Elizabeth Smith, MN, NP-PHC (Primary Care Nurse Practitioner and Nurse Practitioner Clinical Lead)<sup>1,2</sup>, & Mia J. Biondi, PhD, NP-PHC (NP-Researcher)<sup>1,3</sup>

## ABSTRACT

**Background:** Primary care providers are often the first point of contact for hepatitis C virus (HCV) care, yet treatment initiation in primary care continues to be low. Nurse practitioners (NPs) are autonomous providers who, in Ontario, currently prescribe HCV therapy; however, methods to engage primary care NPs in HCV care have not occurred.

**Purpose:** To assess the feasibility of a systematic approach to train and support NPs in HCV testing, care, and treatment.

**Methodology:** Nurse practitioners from Canada's largest family health team (FHT) were recruited. Nurse practitioners received six hours of training and develop approaches to screen and treat at FHT sites. Treatment algorithms were given, and the number and types of inquiries from NPs were recorded.

**Results:** Over 1 year, 9 NPs screened 1,026 patients; 87.4% were screened based on the identification of a risk factor. A mail-out approach for birth cohort screening occurred at a single site, resulting in rapid uptake in screening. Antibody prevalence was 1.66%, with 76.5% RNA positivity. All RNA-positive treatment-eligible individuals were treated by an NP and completed treatment. Thirty-eight consults occurred over 1 year, the majority related to HCV or liver disease staging.

**Conclusions:** Formalized initiatives to engage and educate NPs lead to innovative strategies to test for HCV. Nurse practitioners can safely and effectively treat HCV in primary care with minimal support.

**Implications:** This work could be extrapolated to NPs in other primary care settings. Implementing formalized strategies has the potential to create NP leaders in the treatment and elimination of HCV in Ontario, Canada, and globally.

**Keywords:** Hepatitis C virus; models of care; nurse practitioners; primary care; treatment.

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## Background

The World Health Organization has called for the elimination of hepatitis C virus (HCV) by 2030 (World Health Organization, 2016). Canada signed on to this agreement; however, achieving this goal requires innovative approaches from all health sectors, to reach the 40–70% who are unaware of their infection, as well as those who are more difficult to reach (Rotermann et al., 2013;

Trubnikov et al., 2014). Historically, HCV treatment has been complex, lengthy, with extensive side effects, and with cure rates often of only ~40–50% (Fried et al., 2002; Manns et al., 2001). Initiating patients on therapy was labor intensive and required multidisciplinary teams with specialist oversight (reviewed by (Biondi & Feld, 2019)). Newer all-oral direct-acting antivirals (DAAs) have cure rates of 95–99%, with minimal side effects and are 8–12 weeks in duration (Fierer & Wyles, 2020). These incredible advances in treatment options have simplified treatment for patients and providers. However, to achieve elimination, engaging community providers in HCV screening, linkage to care, and HCV treatment is required (Binka et al., 2020; Canadian Network on Hepatitis C, 2019).

The 2018 Canadian HCV Guidelines recommend a one-time birth cohort screening for those born between 1945 and 1975 (Shah et al., 2018). As many as 75% of HCV infections in Canada are in this age cohort (Shah et al., 2013). In addition,

<sup>1</sup>Arthur Labatt Family School of Nursing, Western University, London, Ontario, Canada, <sup>2</sup>Thames Valley Family Health Team, London, Ontario, Canada, <sup>3</sup>Viral Hepatitis Care Network (VIRCAN) Study Group, Toronto Centre for Liver Disease, Toronto, Ontario, Canada

**Correspondence:** Mia J. Biondi, PhD, NP-PHC, Toronto Centre for Liver Disease, Toronto General Hospital, University Health Network, 200 Elizabeth Street 9EB 240, Toronto, ON M5G 2C4; E-mail: mia.biondi@mail.mcgill.ca

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Canada has identified five priority populations who are disproportionately affected by HCV (Canadian Network on Hepatitis C, 2019). Engaging both birth cohort and at-risk populations continues to be a challenge, with the need to see a specialist for HCV treatment an ongoing barrier in progressing from diagnosis to cure. In the United States, only 17% of individuals confirmed to have HCV have been linked to specialty care, and as such reaching the undiagnosed or unengaged requires moving care away from specialty settings and into the community (Reau et al., 2018). Primary care providers are well situated to screen, manage, and treat patients in their practice (Kapadia & Marks, 2018). The *ASCEND* trial (A Phase IV Pilot Study to Assess Community-Based Treatment Efficacy in Chronic Hepatitis C in the District of Columbia) evaluated the ability of generalists (i.e., not infectious disease or hepatology practitioners), including nurse practitioners (NPs), to treat HCV in comparison with infectious disease physicians and hepatologists. This trial demonstrated that NPs, physician assistants, and family medicine physicians achieved the same cure rates as specialists, including among cirrhotic individuals. Nurse practitioners had the highest appointment adherence among all practitioners (Kattakuzhy et al., 2017). Engaging primary care has not been simple, and despite implementation of such models of care, a large US study demonstrated that treatment uptake is still as low as 4% in primary care, suggesting more work is required to develop sustainable HCV care models in primary care settings (Reau et al., 2018).

In Ontario, Canada, NPs are autonomous practitioners who do not have restrictions on ordering laboratory investigations or prescribing. Nurse practitioners are more likely to work with populations who may be at higher risk for HCV and often are able to spend more time with patients than their family physician colleagues (Dahrouge et al., 2014). Despite the demonstrated ability of NPs to treat HCV, methods to engage NPs specifically are lacking. The aim of this study was to assess the feasibility of a systematic approach to engage NPs within an Ontario-based Family Health Team (FHT) to become HCV clinical site champions as a formalized model of care.

## Materials and methods

### NP recruitment

An introductory 1-hour presentation was given to the NP team from one of the largest FHTs in Canada serving ~158,000 patients in both urban and rural settings. Nurse practitioners work across 19 FHT locations in three counties in southwestern Ontario. Within each team, NPs work with 3–8 family physicians, serving patients across rosters. Following the session, 9 of 26 NPs agreed to participate.

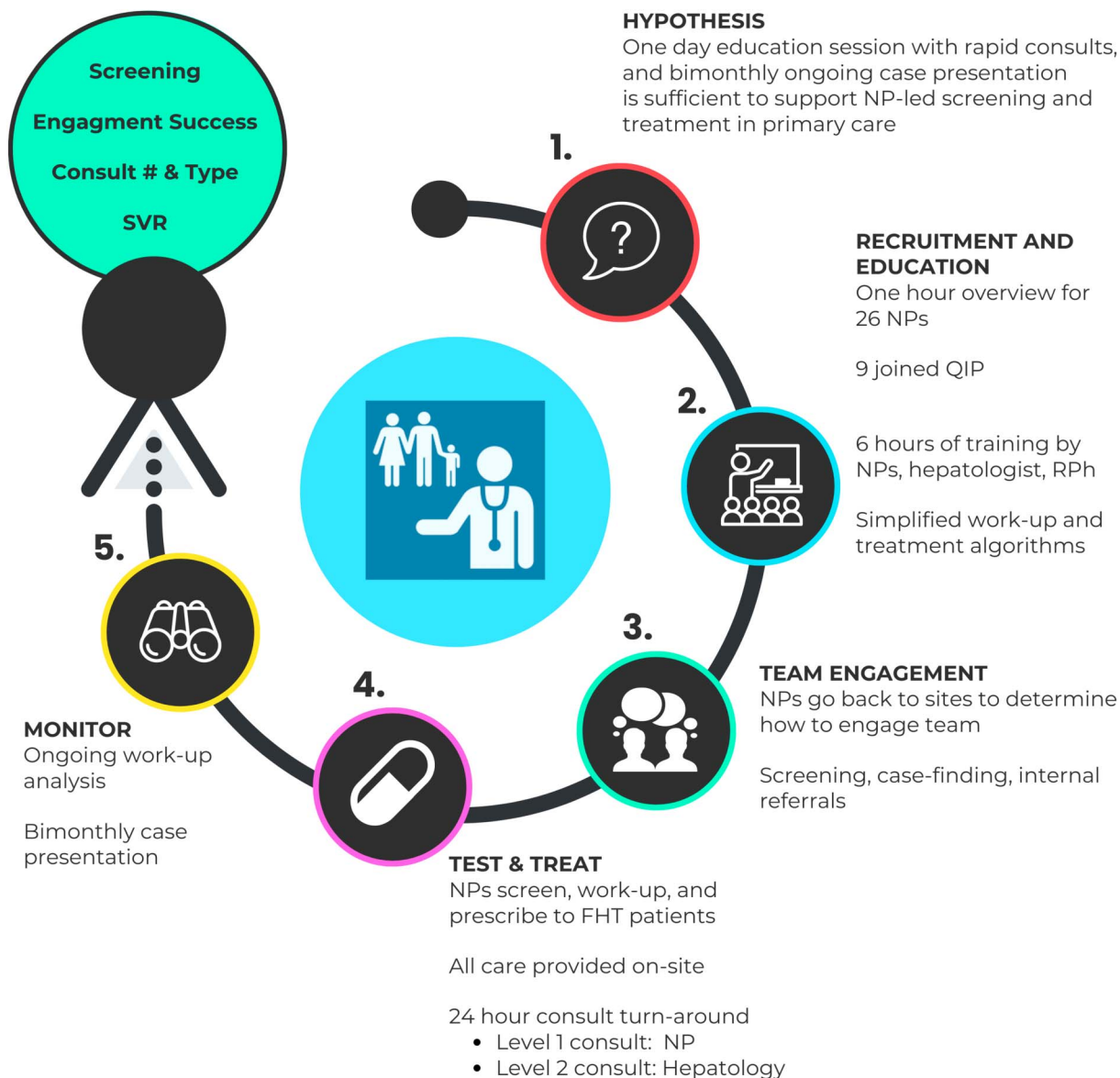
### Training and mentorship

In the Fall of 2018, a 6-hr education session was developed for primary care NPs. Nurse practitioners

received an honorarium for attending. The session was co-facilitated by a multidisciplinary team, including two NPs, a hepatologist, and a pharmacist, all with expertise in the treatment of HCV. Content included simplified workup and treatment algorithms in line with Canadian guidelines (Shah et al., 2018). No NP trained who attended the training had previously prescribed DAAs, and no NP felt comfortable in identifying which treatment regimen should be used. In addition, no family physicians or NPs at these primary care sites were treating HCV. Nurse practitioners received an honorarium to compensate for 1 year of data collection regarding screening, treatment, and follow-up because not all electronic medical records (EMRs) allowed for rapid data extraction. An intake, workup, treatment decision-making, on-treatment monitoring, and posttreatment guidance document was created, and NPs were encouraged to use these forms to guide their practice. After training, NPs had rapid access to consultation (response within 24 hr) for questions through informal mechanisms such as email or phone without providing patient identifiers. An escalated approach was used to address questions, whereby experienced NP treaters were first consulted, and questions were escalated to hepatologists if required. Questions and resolutions were recorded. Nurse practitioners could also send workups and treatment decision-making forms completed to be reviewed before prescribing. Case presentations or updates from relevant conferences occurred bimonthly for 1 year. This process is summarized in **Figure 1**.

### Screening, linkage, and treatment

Primary care NPs were encouraged to screen based on the 2018 Canadian guidelines, which includes both risk-based and birth cohort screening (Shah et al., 2018). Screening by NPs was facilitated by identifying patients over a 1-year period by birth year or risk factors during an unrelated primary care visit and screening laboratory investigations were ordered. A single rural clinic site facilitated a mail-out for birth cohort screening. The contents of the mail-out contained a letter to describe why testing was being recommended as well as a laboratory requisition. In certain sites with higher prevalence, patients who were known antibody or RNA positive were referred to the primary care NP. Patients were worked up according to guideline recommendations, and if a FibroScan was needed, it was made available within 1–2 weeks. Pharmacist support was provided to NPs, especially where reimbursement was more challenging to navigate, such as with private payers. Patients were treated by the NP or referred depending on the complexity of the patient. The collection of these data has received a Research Ethics Board Waiver from University Health Network (17-0136).



**Figure 1.** Systematic approach to train, mentor, and support NPs as HCV site champions in primary care.

**Results**

**Screening and case-finding**

Over a 1-year period, 9 NPs screened 1,026 patients and found 12 known antibody-positive patients through chart review from a single site. Of the 1,026 patients, the reason for screening was identified in all but 78. All screening was done through serum (as opposed to point-of-care testing) in a community laboratory as opposed to on-site venipuncture, which was not possible due to the busy nature of the primary care sites. Follow-up RNA testing was also exclusively done by serum, with the exception of a single dried blood spot card for collection. This was done in-office because difficult venous access was a barrier to treatment for this patient, even when attempted by experienced phlebotomists.

**Demographics**

Age was captured in all but 23 entries, and sex was captured in all but 12 entries. Of those with gender identified, 591 were female (57.6%) and 435 were male (42.4%) (Table 1). By age, 34 who were screened were ages 16–29 (3.3%) years, 57 were ages 30–44 (5.6%) years, 410 were ages 45–59 (40.4%) years, 504 were ages 60–74 (49.7%) years, and 10 were ages ≥75 (1.0%) years (Table 1).

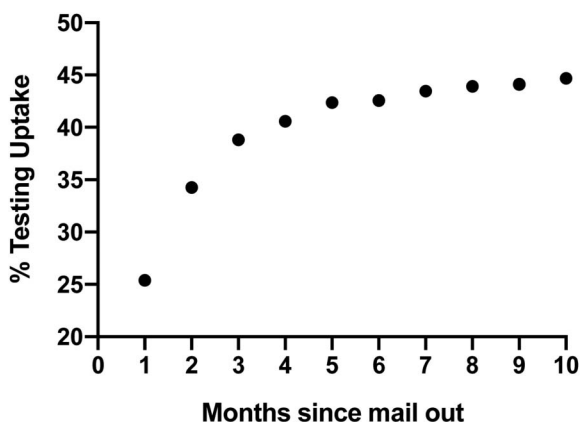
**Reason for screening**

Screening was subclassified as birth cohort; risk factor/possible exposure; and as a part of a workup for medical procedures, another liver disease, or symptoms. Birth cohort screening was the reason for the majority of testing, largely due to the ease of identification and not

**Table 1. Patient demographics**

Baseline Variable	
Sex (1,026)	
Female	591 (57.6%)
Male	435 (42.4%)
Age bands (1,015) (years)	
16–29	34 (3.3%)
30–44	57 (5.6%)
45–59	410 (40.4%)
60–74	504 (49.7%)
≥75	10 (1.0%)
Reason for testing (948)	
Birth cohort	897 (87.4%)
Risk factor or exposure	48 (4.7%)
Symptoms, unrelated medical workup, another liver disease	15 (1.5%)
2+ indications	11 (1.1%)

requiring additional pretest discussion. Of the 1,026 tests with a reason identified, 897 were based on age (87.4%), 48 were tested for risk factor/possible exposure (4.7%), and 15 were for an unrelated workup, screening related to the presence of another liver disease, or symptoms (1.5%). There were only 11 individuals who were tested for both age and another reason (1.1%); however, it should be noted that risk factor–based screening did not occur for those tested based on birth year, but rather the risk/exposure/comorbidity was identified, and age was the secondary reason (Table 1).



**Figure 2.** A total of 902 letters and requisitions were mailed out to patients in the birth cohort. Testing uptake was greatest in the first and second months, plateauing at 4 months. Final testing uptake over 10 months was 403 tests, and uptake of 44.7%.

### Mail-out as an effective testing strategy

Two family physicians were interested in a birth cohort mail-out to their rostered patients. In the first roster mail-out, 902 birth cohort patients were identified. In the week following the mail-out, 112 tests were completed, demonstrating the efficiency of sending an introductory awareness letter describing birth cohort screening accompanied by a requisition. By 1 month, 25.4% of all tests were completed. By 10 months, few additional tests were being completed month to month, with a total of 403 over the time frame, an overall uptake of 44.7% (Figure 2). For the second mail-out, it was decided that the letters would be sent out in four batches over 2 months to manage the influx of results. Immediate uptake was 13.1% uptake in the first week, very similar to the 12.4% uptake in the initial mail-out of 902.

### Antibody and RNA positivity

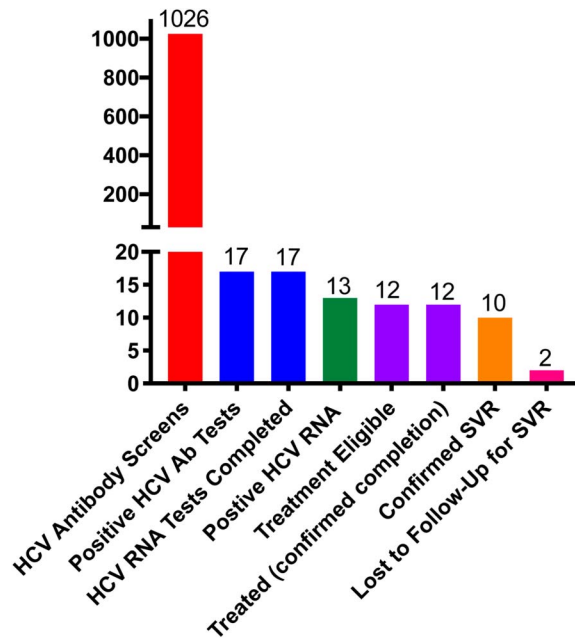
Overall antibody prevalence among those prospectively screened was 1.66%, and 35.3% of positives (6/17) were in the birth cohort, as opposed to being screened for risk alone. Among those both prospectively screened and antibody positive, all were tested for RNA and 13 (76.5%) were RNA positive. It is important to note that, in Ontario, a second sample must be submitted for HCV RNA because reflex testing is not available.

### Linkage to care and treatment

Of the 12 RNA-positive patients found by a retrospective chart review by one trained NP, three were treated. Although multiple attempts were made to establish contact with patients to reengage them in the care cascade, nine were unable to be contacted. Only one of three was treated by the NP site champion, one had been treated in specialty care, and one was treated while in corrections. Although the initial reason for testing was not evaluated, this may demonstrate the low yield of EMRs to case-find in a difficult-to-reach population. Of the 13 RNA-positive patients found prospectively, all 12 who were eligible completed treatment (demonstrated chronicity), 11 by a primary care NP and one in specialty. Two individuals were lost to follow-up for sustained virologic response (SVR), and all others were confirmed SVR (Figure 3).

### Rapid consults to support NP Treeters

NPs were encouraged to consult when needed at any point in the cascade of care. Consult type was classified as one of the following: health promotion, HCV-related, liver disease staging, hepatitis B virus (HBV), treatment in special populations, treatment decision making, reimbursement, and reinfection. Questions that were HCV related or which were regarding liver disease staging were the most common, leading to 26.3% of all questions (Table 2). Themes for HCV-related questions included determining acute vs chronic, ordering



**Figure 3.** Cascade of care among patients prospectively tested. Antibody prevalence was 1.66%, with an RNA positivity rate of 76.5% among those tested. All 12 eligible patients were treated, 11 by a primary care NP. Twenty percent of those treated were lost to follow-up for confirmation of SVR.

laboratory investigations including SVR and resistance testing. Liver disease staging questions were common regarding determining whether a FibroScan was needed, interpretation of these results, or interpretation of isolated abnormal laboratory values. Questions regarding HBV represented 13.2% of total questions, all related to HBsAg<sup>-</sup>/HBcAb<sup>+</sup> patients. Of the 38 questions, only 3 (7.9%) required input from hepatology (**Table 2**), providing evidence that expert NPs can manage the majority questions coming from novice HCV treaters, but not all.

## Discussion

In many primary care teams, expertise for various clinical areas is developed, which facilitates internal referral, decreases wait times for care, and lost to follow-up (Lee et al., 2017). In the descriptive study presented here, the utilization of primary care NPs facilitated novel approaches to increase screening, internal referrals from family physicians, and case-finding in practices with high prevalence. Nurse practitioners received a 6-hr training and ongoing support and mentorship. Lost to follow-up was low among the currently engaged patients (those with a recent HCV diagnosis or being seen for other reasons in primary care), and confirmed treatment completion was 100%.

In Ontario, there are 3,252 NPs trained in primary care (College of Nurses of Ontario, 2021). Primary care practice settings include NP-led clinics, FHTs, Family Health Organizations, Community Health Centres, and private practices (Mattison & Wilson, 2018). Nurse practitioners also have increasing presence in specialty practice, including addictions and recovery medicine, mental health, and corrections. In a recently published study in the United States, NPs were more interested in continued learning in HCV care than their family physician colleagues (Doshi et al., 2020). Thus, the NP model of care is well aligned with comprehensive, low-barrier access for HCV screening and treatment. It is important that, although only 9 of 26 NPs participated after the introductory session, the NPs trained worked in different clinical sites, and thus, nearly half of the sites within this FHT now have trained NP HCV treaters, with supports in place for consultation.

Increasing the utilization of NPs to screen and treat HCV will lead to a cure in many patients who otherwise would not have been screened or who would not have transitioned through the cascade of care. Initial screening was aimed at screening during episodic-based clinic

**Table 2. Types and level of consult required to support NP treaters**

Consult Type	Nurse Practitioner	Hepatology	Total
Health promotion	4	0	4
HCV-related	10	0	10
Liver disease staging	8	2	10
HBV	5	0	5
Safety in special populations	1	1	2
Treatment decision making	3	0	3
Reimbursement (private payers)	3	0	3
Reinfection	1	0	1
Total	35	3	38

visits and EMR searches for patients who have previously tested anti-HCV positive. One participating NP and associated physicians elected to do birth cohort screening of the patient roster through mail-out as a means of screening as many people as possible. The mail-out included a laboratory requisition, accompanied by a letter of explanation from the NP and primary care physician, which addressed what HCV was, the importance of screening, and that the NP would contact them directly if follow-up was warranted. This initial mail-out resulted in a return rate of 12.4% in the first week after mail-out, and overall rate of 45% at 10 months. Due to the success of the first mail-out, a second physician also participated. In our study, the two mail-outs occurred in a highly rural population, potentially reaching a patient population who do not traditionally seek preventive health care. Although mailing both point-of-care screening kits (Carvalho-Gomes et al., 2020) and dried blood spot cards (Prinsenberget al., 2020) has been evaluated, our study demonstrated high uptake as an approach to universally offering one-time birth cohort screening.

Internal referrals from family physicians to NP led to high treatment uptake. We suspect this is likely due to the co-localization of care in primary care, as well as the opportunity for a soft handover. Retrospective chart review in a practice which serves high-risk individuals was less successful. Of the 12 HCV RNA-positive individuals identified, only three went on to be treated, one by the NP site champion. The lack of the ability to reengage a known antibody-positive individual continues to be an ongoing challenge, and multiple strategies have been proposed (Stagg et al., 2019).

The HCV provider training was set up as a 6-hr session and ongoing monthly check-ins, with consults on demand. The initial 6-hr training session included an overview of HCV and liver disease, approach to treatment, treatment choices, pharmacologic considerations, reimbursement issues, and how to access support. Nurse practitioners were asked to complete templates that had been developed and inserted into the EMRs. Once the NP had made a treatment decision, the templates were de-identified and sent to the study lead for review. At any stage, NPs were encouraged to consult an expert HCV NP to address any identified issues or questions. If the expert NPs could not answer the question, it was escalated to a hepatologist. The majority of questions were either HCV related (26.3%) or liver disease staging related (26.3%). Additionally, questions pertaining to HBV, particularly regarding of the interpretation of serology, were also common (13.2%). Over the course of the project, of 38 consults, only three were escalated to a hepatologist, two were related to fibrosis staging, and one to the treatment of a patient within a special population. This suggests that expert HCV NP providers can support the majority of questions from primary care NPs but also that access to

specialty should be built into future NP trainer models. Future education of NPs should specifically aim to address common gaps in knowledge (Table 2).

A recent article suggested that not only are obstacles remaining in place in meeting elimination goals, but that treatment uptake would need to remain stable from 2020 to 2030 in order for Canada to achieve elimination (Binka et al., 2020). These estimates were based on pre-COVID pandemic rates and do not account for decreases in screening (Mandel et al., 2021) and treatment initiation in Ontario (data not shown) for over 1 year. The COVID-19 pandemic has also led to increased high-risk drug use (The Ontario Drug Policy Research Network, 2020), leading to likely more new infections among vulnerable populations. Considering the increased presence of NPs in mental health, drug-use locations (supervised injection/overdose prevention/safe supply), and addictions treatment settings, it is prudent to provide similar training for NPs in these practice settings in addition to primary care settings.

### Limitations

This study was an evaluation of a small number of NPs as treatment site champions in a FHT model of primary care in Ontario. Although it should be noted that NPs were given a small honorarium, and this may not be feasible in all practice settings, it was provided to incentivize the time spent to collect the data on the patients screened. This was to evaluate the process but is not required for routine clinical HCV care, so may not be relevant when implementing in other settings. Nurse practitioners in other practice settings may be even more likely to see at-risk or positive patients in primary care models where the mandate is to serve vulnerable populations such as Community Health Centres or NP-Led Clinics. The FHT for which NPs were engaged serves ~158,000 individuals. However, the practices which engaged in this work still represent a small geographical region in Ontario. Of interest, approaches to case-find occurred organically based on the types of populations served. However, due to the differences in EMR types and functions, well-characterized approaches such as EMR reminders (Jones et al., 2019; Kasting et al., 2019; Konerman et al., 2017; Mulhem et al., 2020) were considered, but ultimately not used and were deemed more appropriate for a future direction by the clinical teams. Finally, it is possible that consult requests decreased over time; however, this was difficult to specifically evaluate because consults were also driven by new diagnosis or the reengagement of a patient in the cascade of care.

### Conclusion

This study demonstrates that NPs are well situated to act as primary care site champions toward the elimination of HCV. Novel screening initiatives beyond traditional care

was initiated by two practices, and linkage to care was high among positive patients, with high treatment completion and SVR rates. Training and support required by novice HCV treaters was facilitated through utilization of expert peers (HCV NP treaters) and hepatologists. Expansion of this model of care should be considered across primary care settings where NPs practice. Treating patients in their home community settings has clear benefits (Castro et al., 2020; Radley et al., 2019), including a preexisting patient-provider relationship that may facilitate preventative health care. Future studies should also evaluate patient satisfaction with such models.

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**Authors' contributions:** C. H. Dale, E. Smith, and M. J. Biondi conceived and designed the study. C. H. Dale and M. J. Biondi were in clinical roles for consultation. C. H. Dale, E. Smith, and M. J. Biondi collaborated on site-specific mechanisms to implement testing, linkage to care, and treatment, retrieved and analyzed the data. Initial and final manuscript preparation was completed by C. H. Dale, E. Smith, and M. J. Biondi, and all have approved the final version to be published and agreed to be accountable for all aspects of the work.

**Competing interests:** CD reports serving as a speaker, consultant, and advisory board member for Gilead and AbbVie. MJB reports receiving research support and consulting fees from AbbVie, Gilead, and Specialty Rx Solutions. Honorarium for NPs was provided by Specialty Rx Solutions. No other competing interests were declared.

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