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Research

Family medicine–directed hepatitis C care and barriers to treatment: a mixed-methods study

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Abstract

Background: Antivirals for the treatment of hepatitis C virus (HCV) infection are effective, but many patients remain untreated and treatment is not yet routine in primary care. We evaluated the characteristics of patients who engaged in HCV treatment, and clinician perspectives on the barriers and facilitators to treatment.

Methods: Our mixed-method, parallel-design study was conducted at a multisite primary care centre in downtown Toronto. In a retrospective chart review, we searched records from 2011 to 2017 to collect quantitative data, including HCV infection status and HCV treatment status. To contextualize the data, we conducted in-depth interviews with select physicians between Aug. 1 and Nov. 1, 2017, and analyzed the transcripts using content analysis.

Results: Of the 40 381 charts reviewed, 727 patients (1.8%, 95% confidence interval [CI] 1.7%–1.9%) were infected with HCV, and 542 (74.6%) had HCV infection requiring treatment. Of those, 255 patients (47.0%) had engaged in treatment. Patients who had engaged in treatment were more likely to be male (odds ratio [OR] 1.63, 95% CI 1.10–2.42), older (OR 1.04 per year increase in age, 95% CI 1.02–1.05) and housed (OR 2.2, 95% CI 1.36–3.75), and they were more likely not to have engaged in injection drug use (OR 1.87, 95% CI 1.33–2.63). Based on interviews with 8 physicians, treatment barriers included a lack of knowledge about HCV treatment, concerns that patients would not adhere to medications and challenges related to medication access. Facilitators of treatment included access to specialist consultation, pharmacist support and primary care treatment guidelines. Common themes that emerged in both quantitative and qualitative components were the roles of unstable housing and intravenous drug use as barriers to engaging in and completing treatment.

Interpretation: Our study captured provider-identified barriers to HCV care and the key factors related to retention in HCV care, including gender, age, housing status and experience with drug use. Successful primary-care-led HCV treatment programs may incorporate specialist and pharmacy support and focus on younger, female, underhoused populations and people who use drugs.

In Canada, the prevalence of hepatitis C virus infection (hereafter HCV) is estimated at 0.64% to 1.55%.[1–4] In Ontario, HCV has the greatest impact on public health of all reportable infectious diseases because of its progression to cirrhosis and related complications.[5] The prevalence of HCV-related liver disease, including cirrhosis and hepatocellular carcinoma, is projected to increase substantially over time.[6]

In 2012, the first generation of direct-acting antivirals (DAAs) was introduced in Canada. These drugs were effective, but uptake was limited by adverse effects. In 2014, a second generation of DAAs became available that produced cure rates exceeding 95%, with improved tolerability profiles relative to first-generation DAAs.[7] Data from the period shortly following the availability of second-generation DAAs demonstrated a rapid uptake of these drugs in Canada, and a decrease in liver and HCV-related hospitalizations in 2016.[7] Since 2018, all jurisdictions in Canada provide publicly funded therapy to infected people, regardless of the state or severity of infection (e.g., level of fibrosis). Internationally, the World Health Organization has called on all member countries to work toward the elimination of HCV by 2030.[8]

Despite these advances, many people living with chronic HCV remain untreated. For example, in a well-characterized population-based cohort in British Columbia in 2018, only 28.5% of people with HCV received treatment.[9] In Canada, it is estimated that 44% of people living with chronic hepatitis C are unaware of their diagnosis.[1] Without a renewed focus on identifying infected persons and treating them, Canadians

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will continue to bear the burden of HCV and we will not achieve World Health Organization elimination targets.

Given the number of untreated patients living with HCV in Canada and the challenges in accessing specialist care, primary care is integral to efforts to eliminate HCV and provide HCV treatment efficiently and effectively. Primary care is characterized by longitudinal clinical relationships and often serves vulnerable patients who may be hesitant to engage with other parts of the health care system. Furthermore, primary care is increasingly team-based and interdisciplinary, and it takes a holistic approach to addressing biological, psychological and social factors.[10–12] Only 8% of Canadian family physicians currently provide HCV treatment to their patients.[13] Several successful family-medicine-directed HCV treatment programs exist in Canada, the United States and the United Kingdom.[14–16] Various models of care have been successful, ranging from solo family physician care to team-based care, often including specialist consultation as needed.[17]

In this study, we examined the epidemiology of HCV in a large, multisite academic primary care organization, and identified the perceived barriers and facilitators to HCV treatment.

Methods

Study setting

The St. Michael's Hospital Academic Family Health Team is a group of 6 inner-city primary care clinics in downtown Toronto. Human resources include 74 family physicians and a team of 56 allied health providers (nurses, pharmacists, social workers, dietitians and physiotherapists).

Study design

Our mixed-methods parallel-design study had 2 parts: a quantitative component and qualitative component. Data for both components were collected and analyzed concurrently. For the quantitative component, we performed a retrospective chart review using the electronic medical record (EMR) from 2011 to 2017. Because family physicians did not typically provide antiviral treatment for patients with HCV before the availability of DAAs, we supplemented our quantitative study by conducting in-depth interviews with family physicians to understand current HCV treatment practices, perceived barriers to care and ideas related to improving care.

Quantitative study

All patients who had at least 1 visit to the family medicine clinic between Mar. 1, 2015, and Mar. 1, 2017, were considered eligible. To identify patients with HCV, we searched for "hepatitis C" and related terms (e.g., "hep C") in the problem list and past medical history; generic and brand names for HCV antiviral agents in the medications list; relevant billing codes (K027A, K026A); HCV-RNA-positive results; and HCV-antibody-positive results. Demographic and clinical data were also extracted, including birth date and diabetes status (Appendix 1 available at www.cmajopen.ca/content/9/1/E201/suppl/DC1). Information was extracted from the EMR by our trained institutional EMR specialist.

Additional demographic data were captured by manual review, including housing status (based on "no fixed address" or free-text documentation of homelessness), HIV status (based on previous validated institutional tagging) and history of intravenous drug use (defined as any recorded history of intravenous drug use in the "Habits" section or free text in the chart).

To ascertain treatment status, a trained study team member (A.C.-N.) reviewed the full patient record, examining specialist consult notes, viral load results and the continuous patient profile. We defined a hepatitis C case as a patient with a positive hepatitis C antibody test, because this was the most widely used HCV screening test in primary care.[18–20] Patients were categorized as treated successfully; being treated currently; failed treatment; did not complete treatment; completed treatment, success unknown; treatment-naive; HCV cleared; and HCV-negative. A manual that defined hepatitis C categories and a data collection form were created by the study team. The definitions of each hepatitis C category were based on the medical literature[18,19] and confirmed by an expert physician (i.e., our hepatologist coinvestigator). To calculate "HCV requiring treatment" in a conservative manner, we removed the "HCV cleared" and "HCV status unknown" categories from the total sum of patients with HCV needing treatment. Full categorization details are provided in Appendix 2 (available at www.cmajopen.ca/content/9/1/E201/suppl/DC1).

Categorization was verified by the principal investigator (Z.vA.) to ensure accuracy. Approximately 1% of hepatitis C charts were audited (Z.vA.). Discrepancies were discussed and consensus was reached (A.C.-N., Z.vA.). Next, we compared the demographic and clinical characteristics of the "HCV ever-treated" group (defined as those who were treated successfully, were currently being treated, had failed treatment, did not complete treatment, or had completed treatment with unknown success) with the "HCV treatment-naive" group using descriptive statistics (C.M.).

Qualitative study

We purposively recruited physicians with 10 or more HCV-positive patients in their practice. We chose 10 as the threshold for expertise based on the review of our department's practice data (number of HCV patients per provider) and our collective clinical experience. We approached these physicians via email (July 10, 2017, to Aug. 1, 2017) and asked them to take part in an in-depth interview. The interview was conducted by a trained research assistant who had no prior relationship with the participants. The interview was composed of scripted open-ended questions that focused on physicians' perception of the challenges and successes of HCV monitoring and treatment in family medicine (Appendix 3 available at www.cmajopen.ca/content/9/1/E201/suppl/DC1). The interview questions were informed by HCV research literature[21–23] and consultation with clinician coinvestigators.

Data analysis

Quantitative study data analysis

Descriptive statistics were computed for the entire sample ("HCV treatment-naive," "HCV ever-treated," "HCV cleared" and "HCV status unknown") and the subset of the sample who were "HCV treatment-naive" versus "HCV ever-treated". We described the distribution of categorical variables using counts and percentages, and continuous variables using medians and interquartile ranges.

We investigated the association between demographic or clinical variables and our dichotomous outcome (i.e., "HCV treatment-naive" and "HCV ever-treated") using bivariate and multivariable logistic regression models. We estimated odds ratios (associated with "ever-treated" v. "treatment-naive") and 95% confidence intervals (CIs). We used $\alpha < 0.05$ to declare statistical significance. All statistical analyses were conducted using R version 3.6.2.[3,24]

Qualitative study data analysis

We used conventional content analysis to analyze the transcripts of the interviews,[25,26] and themes were derived inductively. As such, themes and subthemes were driven by qualitative data content, not pre-established frameworks nor constructs. Two members of the study team (A.C.-N., Z. vA.) independently reviewed the transcripts to develop a coding framework of recurrent themes. The reviewers compared these themes and when discrepancies arrived, they referred to protocol objectives and came to mutual consensus through discussion (A.C.-N., Z.vA.). A preliminary transcript was reviewed using this coding framework, and no discrepancies occurred. The remaining transcripts were divided between the 2 reviewers and analyzed using the developed framework. Microsoft Word and Excel were used for the data analysis.

Data integration

When quantitative and qualitative data analysis was complete, we assessed and integrated the information. The authors met in person to review aggregate data, identify common themes and determine the optimal means for presentation of key findings. Discussion occurred and mutual consensus was reached.

Ethics approval

This study was approved by the St. Michael's Hospital Research Ethics Board (REB 16-298).

Results

Quantitative results

From 40 381 chart reviews, 1408 (3.5%) charts had an indication of HCV testing (collected from our automated search) and 727 (1.8%, 95% CI 1.7%–1.9%) were diagnosed as having HCV infection. The mean age of the infected population was 52.6 (median 54) years, and most were male (71%). The prevalence of HIV was 19%, and 44% had a history of injection drug use (Table 1). Overall, 124 patients (17%) had spontaneously cleared HCV, 255 (35%) had received treatment at some point, 287 (39%) were treatment-naive, and 61 (8%) had an unknown status. Of those who had been treated, 188 (74%) had been treated successfully, 20 (8%) had failed treatment, 3 (< 1%) did not complete treatment, 17 (7%) completed treatment with unknown success and 27 (11%) were currently being treated (Table 1).

Compared with those who were treatment-naive, patients who had ever received treatment ("HCV ever-treated") were significantly more likely to be male (OR 1.63, 95% CI 1.10–2.42), older (OR 1.04 per year increase in age, 95% CI 1.02–1.05) and housed (OR 2.23, 95% CI 1.36–3.75), and they were more likely not to have engaged in intravenous drug use (OR 1.87, 95% CI 1.33–2.63; Table 2). Diabetes and HIV status were not significantly associated with the likelihood of ever being treated for HCV. Inferences from bivariate logistic regression model fits were consistent with those obtained from adjusted and multivariable logistic regression models.

Qualitative results

Nine family physicians had substantial hepatitis C experience and were invited for the interview. Eight physicians responded to this invitation and completed the interview at their workplace within approximately 30 to 60 minutes between Aug. 1, 2017, and Oct. 1, 2017. Most physician participants were male (75%) and, as a whole, the group had an average of 13.25 years of medical experience. After analyzing the transcripts from these interviews, we identified consistent themes and deemed further interviews unnecessary.

We identified 3 themes related to treatment barriers: patient readiness to commit to treatment (i.e., anticipated medication adherence), physicians' lack of up-to-date treatment knowledge, and limitations in access to medications. Physicians further elaborated that substance use, unstable housing and chronic illnesses made medication adherence and engagement with monitoring quite challenging. Treatment facilitators included access to specialist consultation, pharmacist support and the need for a primary care HCV treatment guideline (Table 3).

Synthesis of quantitative and qualitative results

When we considered the quantitative and qualitative study components in unison, stable housing and intravenous drug use stood out as common themes. Our quantitative results highlighted the fact that those able to engage in treatment tended to have stable housing and no history of intravenous drug use. Participants in the qualitative interviews echoed that finding, noting that unstable housing and intravenous drug use made it difficult to retain patients in HCV treatment, and many suggested that strong social work and addictions programs could ameliorate the situation.

Interpretation

In this study of a large inner-city family medicine practice, we found that 1.8% of patients had HCV and almost 40%

Table 1: Demographic and clinical characteristics of patients diagnosed with HCV

Characteristic	No. (%) of patients*			
	Overall *n* = 727	HCV ever-treated and treatment-naïve subgroups *n* = 542	HCV ever-treated *n* = 255	HCV treatment-naive *n* = 287
HCV treatment status				
Treated successfully	188 (25.9)	188 (34.6)	188 (73.7)	0 (0)
Being treated currently	27 (3.7)	27 (5.0)	27 (10.6)	0 (0)
Failed treatment	20 (2.8)	20 (3.7)	20 (7.8)	0 (0)
Did not complete treatment	3 (0.4)	3 (0.6)	3 (1.2)	0 (0)
Completed treatment, success unknown	17 (2.3)	17 (3.1)	17 (6.7)	0 (0)
Treatment-naïve	287 (39.4)	287 (53.0)	0 (0)	287 (100)
HCV cleared without treatment	124 (17.1)	–	–	–
Unknown	61 (8.4)	–	–	–
Male	515 (70.8)	403 (74.4)	202 (79.3)	201 (70.0)
Age (continuous), median (IQR)	54 (46–61)	55 (47–61)	56 (50–62)	53 (45–60)
Age (categorical), yr				
≤ 45	177 (24.3)	116 (21.4)	40 (15.7)	76 (26.5)
46–65	465 (64.0)	364 (67.2)	176 (69.1)	188 (65.5)
> 65	85 (11.7)	62 (11.4)	39 (15.2)	23 (8.0)
HIV	139 (19.1)	108 (19.9)	55 (21.6)	53 (18.5)
Diabetes type 2	69 (9.5)	57 (10.5)	29 (11.4)	28 (9.8)
History of intravenous drug use	317 (43.6)	259 (47.8)	101 (39.6)	158 (55.1)
Ever homeless or shelter or underhoused	98 (13.5)	81 (14.9)	25 (9.8)	56 (19.5)

Note: HCV = hepatitis C virus, IQR = interquartile range.
*Unless otherwise specified.

remained treatment-naive. The facilitators of, and barriers to, HCV treatment that we identified are all pragmatic and applicable. Hence, there is a great deal of potential to scale up HCV treatment in primary care. The strength of this study was its focus on family medicine patients and their providers. The richness of our family medicine data allowed us to capture some of the key characteristics associated with engagement with HCV care (Table 2). The unique longitudinal perspectives of our clinicians allowed us to identify novel solutions, such as pharmacist integration in care and the need for family medicine HCV guidelines (Table 3).

Some common barriers to HCV care have been identified by previous research. For example, the idea of treatment "compliance" is a frequently discussed barrier, with terms ranging from "adherence" to those touching upon broader concepts of "superseding social issues" as an impedance to HCV care.[27,28] Another predominant theme highlighted by our participants was physician knowledge of new HCV treatment regimens (Table 3). These same "knowledge" concerns were highlighted by recent work with Canadian infectious disease physicians[29] and Canadian family physicians.[13] Complementing this "knowledge" topic was discussion from our participants about access to specialist consultation. This idea was highlighted and brought successfully into practice by a family medicine group in New York City, who used "telementoring" to liaise regularly with HCV experts.[30] Although these topics have been well examined by prior studies, our findings related to pharmacist inclusion in HCV care and the development of family-medicine-focused HCV guidelines (Table 3) appear to stand alone and represent a potentially creative approach to HCV care planning in family medicine.

Our results fit with other research on the epidemiology of HCV in North America, but they also build on it by providing a more comprehensive account of the population because of the rich detail contained in family medicine documentation. The relatively high HCV prevalence in our sample was likely a result of the population's inner-city location. With respect to demographic profile, our population's age and sex characteristics were in keeping with a recent Philadelphia-based community HCV treatment cohort[31] and a Vancouver-based family medicine HCV treatment program. The prevalence of injection drug use in our cohort (44%) was lower than that of Vancouver (75%).[16] Our results support current

Table 2: Bivariate and multivariate logistic regression assessing the impact of clinical and demographic factors on the likelihood of being "ever-treated" versus being "treatment-naïve" (*n* = 542)

Characteristic	OR (95% CI)	
	Bivariate logistic regression	Multivariate logistic regression
Sex		
Female	Reference	Reference
Male	1.63 (1.10–2.42)	1.69 (1.12–2.58)
Age (continuous), per year increase	1.04 (1.02–1.05)	–
Age (categorical), yr		
≤ 45	Reference	Reference
46–65	1.78 (1.16–2.77)	1.74 (1.10–2.79)
> 65	3.22 (1.71–6.20)	3.04 (1.55–6.07)
HIV		
No	Reference	Reference
Yes	1.21 (0.80–1.85)	1.52 (0.96–2.42)
Diabetes type 2		
No	Reference	Reference
Yes	1.19 (0.68–2.06)	1.03 (0.58–1.82)
History of intravenous drug use		
Yes	Reference	Reference
No	1.87 (1.33–2.63)	1.85 (1.29–2.67)
Ever homeless or shelter or underhoused		
Yes	Reference	Reference
No	2.23 (1.36–3.75)	1.86 (1.10–3.20)

Note: CI = confidence interval; OR = odds ratio.

Canadian recommendations, which recommend screening of those with a history of injection drug use.[32]

When comparing the characteristics of our "ever-treated" patients to those of previous studies, older age appears to be a common predictor of treatment engagement.[12] This trend may be due to historical, policy-directed efforts to target costly therapy at those with advanced liver disease, and also because the natural history of liver symptoms typically present later in life (resulting in delayed engagement in HCV care).[12] Aside from the Vancouver study described above,[16] few recent studies have assessed the indicators of treatment engagement in a Canadian family medicine context.

Limitations

One major limitation to this analysis was the single-centre, urban, academic setting. The lack of involvement of geographically diverse, unattached populations limits the transferability of results to a national family medicine level. Another limitation was the variability in clinicians' documentation. This limitation likely affected the assessment of key factors such as homeless status and history of drug use. It also meant that general HCV status was documented in an irregular manner in the charts, and other terms (i.e., medication prescriptions) were recorded in a more standardized fashion, potentially leading to a bias in capturing treated patients (i.e., because various medications were part of search criteria). Furthermore, our inability to access a precise diagnosis date meant that we could not adjust for variable follow-up periods, likely affecting captured treatment outcomes. Another limitation was that our data did not include an overlay of "outside" administrative changes, such as the introduction of second-generation DAAs and public drug coverage (and the disease stage requirements for such public coverage), or specialist involvement. Therefore, the barriers to treatment were likely even more diverse and time- and location-dependent than we have presented. Also, our initial EMR search method was not validated. With respect to the qualitative component, the interviews had a relatively small sample size and included only physicians, missing out on the perspectives of patients and the allied health care team.

Conclusion

This study highlighted various provider-identified barriers to HCV care, including gaps in medical knowledge, concerns regarding patient compliance, and difficulty accessing medication. It also identified key factors related to retention in HCV care, including sex, age, housing status and experience with drug use.

Table 3: Content analysis of physician interviews investigating barriers and facilitators to patient, physician and system-level access to HCV care

Group	Common themes	Interview samples
Barriers		
Patient	• Readiness to start treatment • Medication adherence • Adverse effects of the medication • Reinfection concerns	A big challenge is … gauging whether or not a patient is ready to start treatment … and can they commit to taking the medications consistently … For my patients who are dealing with some of these issues, homelessness, ongoing substance abuse disorder, can they consistently take their hep C medications … over the next 8 to 12 weeks? (Participant 8) [An]other major issue is actually re-infection … I know that he's likely going to get … the treatment covered, but they probably won't approve more than once for this one individual. So, I have to have a conversation with him saying … "Are you ready? Are you really ready? And if you relapse and you start using again and you get infected again, that can mean that's it, you don't have another shot at this." (Participant 8)
Physician	• Lack of up-to-date knowledge about the standard of treatment • Uncertainty about to how to monitor patients • Easy access to specialists and other supports (no urgency to expand HCV knowledge) • Lack of exposure to HCV complications (therefore lack of perceived urgency to treat) • Lack of awareness of eligibility criteria • Lack of confidence in treating • Drug interactions	It would be hard to … keep up with … standards of treatment when it comes to hep C. The more the science and standards of treatments change around something, the less confident you feel around dealing with it yourself. (Participant 3) We see less of … the longer-term complications of hep C. The urgency of dealing with it is not as prominent because you're not seeing the consequences of not dealing with it in the same way (Participant 3) The only issue is … drug interactions with the medications, but what I tend to do is verify with our really experienced pharmacist. (Participant 8)
System	• Lack of resources (solo-practice practitioners) • Limitations to access to medications (coverage or eligibility) • Trillium copayment* • ODB dispensing rules (patients need to visit the pharmacy frequently) • Cost of medications • Many tools focusing only on HCV and not taking social context into account	ODB, sort of, dispensing rules...I think the maximum that you can dispense at one time through ODB, in terms of … overall cost of medications, is, I think it's $10 000 … In some cases, what it's meant is that patients of mine need to go to the pharmacy every week to pick up the next 7 pills of their regimen ...You can't take any holidays. You can't go out of town … because they're having to come back to the pharmacy regularly. (Participant 2) There are people who, perhaps, may want to go on treatment but they're not eligible according to the … treatment criteria for coverage. (Participant 6)
Facilitators		
	• Consultative support (i.e., e-consult) • Greater involvement of pharmacists • Awareness around medication availability and family physicians' management potential • Clear and structured process to follow • Improved provider confidence • Education sessions for physicians • Advocacy for patients • Frequent follow-up visits (if the patient is on multiple medications) • Follow-up phone calls (to assess adverse effects and adherence) • Involvement of case workers, addiction counsellors • Patient support groups • Daily dispensing from the pharmacy • Primary care guidelines • Stamp in the EMR (i.e., eligibility criteria for treatment) • Algorithmic tool • Care flow sheet • Reminder tools via email • Apps • Product monographs for common medications	You need to bring up provider's confidence, so you'd need to have education sessions to get people ready for that type of move. And, then ideally, some sort of consultative support, in the background …. It doesn't have to be specialists, but people who have specialized knowledge, they can help with any issues that come up, quickly. (Participant 3) Support within the team for follow up. If patients are started on medications and they're having problems with compliance …. Nurses, or addictions workers, or whoever, could help to chase these patients down to, support them in being compliant. (Participant 7) I think through engaging patients and other organizations to help support them … the goal would be to eliminate hep C. (Participant 8) Sometimes get the pharmacist to take a look, do a consult, or, just monitor them a little more closely, a little more frequently. (Participant 5) I think a really powerful thing has been actually just talking with colleagues who are also treating people with hep C, and just what has been their experience. (Participant 8) We actually don't have a lot of guidelines on treatment … and, particularly … primary care guidelines. (Participant 2) I find there's stuff out there but … it's not primary-care-focused …. I don't have the time to go and read 30 papers on it. (Participant 7)

Note: EMR = electronic medical record, HCV = hepatitis C virus, ODB = Ontario Drug Benefit program.
*The Trillium Drug Program provides drug coverage for eligible individuals, subject to an annual deductible based on total household net income.

Based on these findings, future successful primary care–led HCV treatment programs may incorporate specialist and pharmacy personnel support, as well as creative continuing medical education training programs for providers. They should also focus on attracting and retaining younger, female, underhoused populations and people who use drugs. It can be further surmised that aiming to treat the mental health issues that often underlie substance use, as well as ameliorating housing insecurity, would allow for greater stability and engagement in HCV care.

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