ORIGINAL RESEARCH

Increasing Treatment Rates for Hepatitis C in Primary Care

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Background: **Despite antiviral agents that can cure the disease, many individuals with Hepatitis C Virus (HCV) remain untreated. Primary care clinicians can play an important role in HCV treatment but often feel they do not have the requisite skills.**

Methods: **We implemented a population-based improvement intervention over 10 months to support treatment of HCV in a primary care setting. The intervention included a decision-support tool, education for clinicians, enhanced interprofessional team supports, mentorship, and proactive patient outreach. We used process and outcome measures to understand the impact on the proportion of patients who initiated treatment and achieved Sustained Virologic Response (SVR). We used physician focus groups and pharmacist interviews to understand the context and mechanisms influencing the impact of the intervention.**

Results: **Between December 2018 and June 2020, the percentage of HCV RNA positive patients who started treatment rose from 66.0% (354/536) to 75.5% (401/531) with 92.5% (371/401) of those starting treatment achieving SVR. Qualitative findings highlighted that the intervention helped raise awareness and confidence among physicians for treating HCV in primary care. A collaborative team environment, education, mentorship, and a decision-support tool integrated into the electronic record were all enablers of success although patient psychosocial complexity remained a barrier to engagement in treatment.**

Conclusion: **A multifaceted primary care improvement initiative increased clinician confidence and was associated with an increase in the proportion of HCV RNA positive patients who initiated curative treatment. (J Am Board Fam Med 2023;36:591–602.)**

Keywords: **Family Medicine, Focus Groups, Hepatitis C, HCV Antibodies, Pharmacists, Primary Health Care, Physicians, Quality Improvement, Sustained Virologic Response**

Introduction

Hepatitis C Virus (HCV) affects 58 million people worldwide.[1] Chronic infection leads to liver complications, including cirrhosis and carcinoma, and can reduce life span by as much as 15 years.[1] In 2019, HCV resulted in approximately 1.1 million deaths globally.[1] Even in high-income countries, HCV has resulted in more years of life lost than other infectious diseases including HIV, influenza, and pneumococcal disease. These deaths

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are particularly distressing because they are avoidable.[2]

Hepatitis C can be cured. Curative interferon-based treatment agents became available in 1998, but had significant side effects. Direct-acting antiviral (DAA) agents have been available since 2014. A simple, 2 or 3-month treatment regimen with these oral agents cures 95% of patients with minimal side effects.[3] But, despite the availability of these new drugs, according to World Health Organization data approximately 6 out of 10 people with HCV remain untreated worldwide[1]. Reasons for being untreated are multifactorial but include financial barriers, lack of awareness, fear of side effects, difficulty with adherence and comorbid conditions, including substance use.[4]

HCV treatment has historically been the purview of internists specializing in hepatology or infectious disease. However, DAAs are relatively straightforward to prescribe and use, opening the door to more community-based treatment—a particularly relevant approach given that many individuals who remain untreated in high-income countries struggle with social issues including incarceration and substance use.[5,6] Family Medicine specialists are uniquely situated to treat HCV because of their longstanding relationships with patients, and ability to connect with hard-to-reach populations. However, many do not feel they have the knowledge and skills to initiate HCV treatment.[7]

We designed a quality improvement initiative to empower and support Family Medicine specialists to cure Hepatitis C using a data-driven, planned, proactive approach for their practice population. We tracked process and outcome measures to understand the implementation and impact of the initiative and used qualitative methods to understand the context and mechanisms that influenced project outcomes.

Methods

Setting and Context

The St. Michael's Hospital Academic Family Health Team (SMHAFHT) serves approximately 49,000 patients at 6 primary care clinics in the inner city of Toronto, Canada. The team cares for many historically marginalized populations including people with HIV, mental health conditions and addictions, and those living in poverty. The team comprises approximately 80 staff physicians and more than 60 other health professionals including nurses, nurse practitioners, pharmacists, and social workers.

The vast majority of our patients are permanent residents of Ontario and primary care services are free at the point-of-care via the Ontario Health Insurance Plan (OHIP) but medication coverage is varied. DAA therapy can range in cost from CAD $45,000 to CAD$100,000. Some patients have coverage via private insurance and others via Ontario Drug Benefits (eg, if they are on social assistance, age 65 and older, or meet low-income criteria). Those without prescription drug coverage can access drug company special access funds. DAAs for HCV became fully covered for recipients of Ontario Drug Benefits in 2018. Data drawn from our practice electronic medical record (EMR) in 2017 found only 47% of those who were HCV RNA positive were engaged in treatment.[7]

Intervention

We conducted a multi-faceted, population-based quality improvement intervention between March 2019 and December 2020 to increase HCV treatment rates. First, we supported our clinical team to develop the knowledge, skills, and processes to treat HCV within the Family Medicine setting. We worked with a clinical working group to develop an internal treatment pathway that summarized workup and treatment of HCV, team roles, and other supports (Online Appendix 1). One pharmacist with HCV expertise trained the 3 general pharmacists on our team so that all had expertise in HCV medication management. One pharmacist (DC) continually updated the medication algorithm available in the decision-support tool form based on evolving guidelines. We identified 4 physician peer mentors with experience treating HCV who could be available for support. We also worked closely with 2 hepatologists who reviewed our pathway and tools and who were available to be consulted for complex cases. In collaboration with our EMR specialist, we built an interactive HCV decision support tool for the EMR to guide workup, treatment, and consultation with peer mentors, pharmacists, and specialist (Online Appendix 2). Between March

the Canadian Institutes of Health Research and Health Quality Ontario as an Embedded Clinician Researcher.

Dr. Gordon Arbess has received honoraria for presentations from Gilead Sciences Canada and Merck. He sits on the Advisory Board for Gilead Sciences Canada, Merck, and Viiv Healthcare. The other authors have no conflicts of interest to declare.

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and June 2019, we delivered group education sessions to clinic staff at departmental rounds and a lunch-and-learn session at each of the 6 clinics. The EMR tool was proactively entered on the charts of patients with designated HCV positive.

Second, we conducted proactive outreach for all registered practice patients known to be HCV RNA positive or whose HCV treatment status was unknown. We identified patients who were HCV antibody positive using an automated search of our electronic medical record (EMR) and manual chart review by a trained research coordinator (ACN) as done with a previous chart audit.[7] Between May and August 2019, research staff met individually with physicians with at least 1 patient known to be HCV RNA positive for more than 6 months to provide education on the treatment pathway and the decision support tool and to confirm their list of active untreated patients. Physicians confirmed HCV status and determined whether a patient should be contacted on their behalf. A clerical staff member called these patients (Online Appendix 3). If we were unable to reach them after 2 attempts, we sent a letter and/or e-mail. Initial outreach was done for all patients between May and September; a second round was done between November and December 2019.

The intervention was refined iteratively based on feedback from a clinical working group and a patient advisory group as well as review of process and outcome measures by the study team.

Evaluation Approach

We conducted a mixed method evaluation excluding patients who died or left our practice during the study period. First, we tracked outcome measures for all registered practice patients who were HCV antibody positive (% who started treatment; % with sustained virologic response [SVR]) and process measures for those patients eligible for proactive outreach (% with an informed discussion, % with some pretreatment work-up). Data were collected by ACN using manual chart audit every 4 to 8 months.

A second team member reviewed twenty of the charts to ensure HCV treatment status and outcome measures were correctly classified. There were no discrepancies between the 2 reviewers. We did not do serial reviews of the charts of patients who were successfully treated or who had spontaneously cleared the virus at baseline.

Second, we compared characteristics of HCV RNA positive patients who were, and were not, treated at the end of study using Chi square and Mann-Whitney tests. Data on patient demographics, comorbidities, and visit history were collected using an automated search of our EMR. Age, sex, and postal code were collected from registration information. Postal code was used to derive neighborhood income quintile using 2007 census data from Statistics Canada. We noted whether patients had HIV, diabetes, or serious mental illness based on ICD codes validated by the most responsible clinician; we used diagnostic and service codes from physician billing to note whether patients had any mental health condition or addiction. We used billing data from EMR to determine the number of visits in the last year. These analyses were done using R Version 4.0.0.

Finally, we explored physicians' and pharmacists' perceptions of the strengths, limitations, contextual contributors, and perceived outcomes of the intervention. We conducted 3 focus groups with staff physicians, targeting those who had patients eligible for proactive outreach (n = 65), and individual interviews with pharmacists (n = 4). Invitations and reminders were sent by e-mail. Focus groups and interviews were held in person or online, were conducted by an experienced qualitative researcher, and were audio recorded and transcribed verbatim; they were 30 to 60 minutes in length and followed a semistructured guide developed by the research team (Online Appendix 4).

We analyzed the qualitative data after interpretive description,[8] which involved reading the transcripts, describing the main patterns related to the research questions, and interpreting the results with the full team (including clinicians and methodologists). After best practices in program evaluation[9] and implementation science,[10,11] we focused on aspects of both the intervention and the context that may have influenced outcomes. KH inductively coded the data to explore participants' general impressions of the initiative and then grouped the codes into program strengths or limitations, contextual facilitators or challenges, and perceived outcomes. KH was not involved in the design or implementation of the QI initiative, enabling an openness to the data during inductive coding. KH iteratively discussed the codes and categories with CJP, AS, and TK, who provided methodological, clinical, and content expertise in the later stages of analysis.

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We also explored patients' perspectives on receiving HCV treatment, but report on those separately.

Clinician and Patient Involvement

A clinical working group helped inform the intervention, engage clinicians, and interpret results. In addition, an advisory group of patients with lived experience of HCV gave advice on the intervention, particularly our approach to patient outreach, and the interpretation of the results. As an example, based on advice from patient advisors, we increased health promotion efforts about HCV treatment through social media and posters in community pharmacies and clinics using material from a reputable national organization (https://orders.catie.ca/publications/treatment/).

Ethics

Institutional authorities at Unity Health Toronto formally reviewed a protocol for the quantitative component and deemed it to neither require Research Ethics Board approval nor written informed consent from participants. The qualitative study protocol was reviewed and approved by the Unity Health Toronto Research Ethics Board.

Results

We identified 701 patients who were HCV antibody positive in December 2018, 536 of whom were HCV RNA positive and 165 that had spontaneously cleared the virus (Figure 1). Of those who were HCV RNA positive, 299 were fully treated successfully, and 55 were actively engaged in treatment at the start of our initiative. We identified 182 patients who were HCV RNA positive and potentially still needed HCV treatment (ie, treatment naïve, had unknown treatment status, or previous treatment failure).

Patient Characteristics

The average age of patients needing HCV treatment was 52.4 years; 64.3% (n = 117) were male, 20.7% (n = 18) lived in a neighborhood in the

Figure 1. Cohort of patient identified as being Hepatitis C Virus (HCV) RNA positive as of December 2018 and needing treatment.

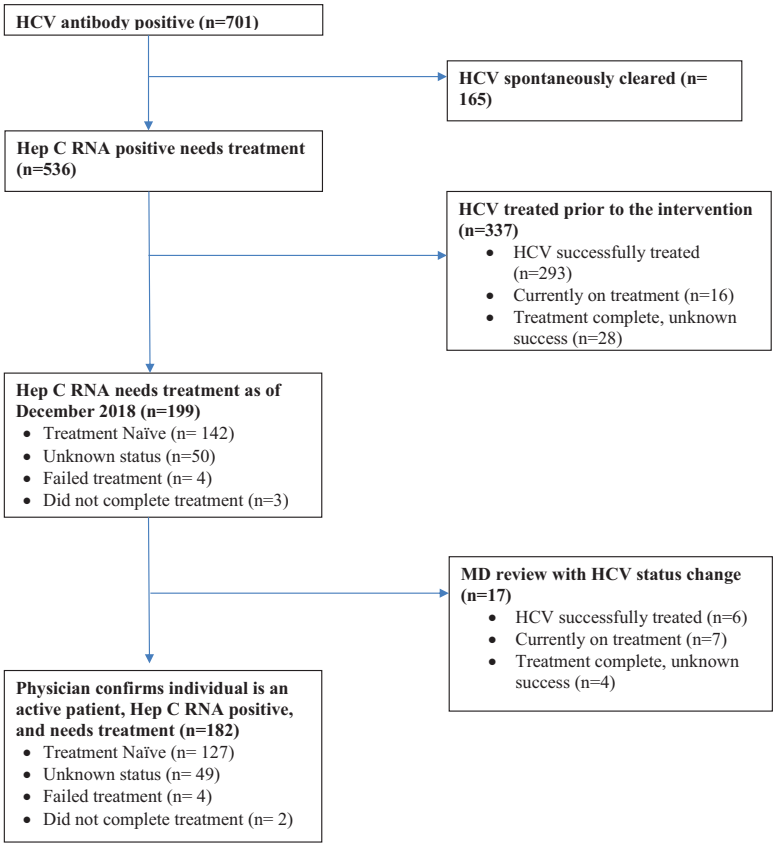

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Table 1. Characteristics of Patients Included in the Intervention Who Were Hepatitis C Virus (HCV) RNA Positive for More Than 6 Months and Untreated[1] as of December 2018 (*n* = 182)

Demographic Characteristic	Patients Needing treatment[1] as of Dec 2018
Age, Mean (S.D.)	52.4 (12.3)
Age, N (%)	
<40	28 (15.4%)
40 to 64	126 (69.2%)
65+	28 (15.4%)
Sex, N (%)	
Female	65 (35.7%)
Male	117 (64.3%)
Neighborhood income quintile, N (%)	
No fixed address or homeless	13 (14.9%)
1 (Lowest)	18 (20.7%)
2 to 5	56 (64.4%)
Chronic conditions, N (%)	
Diabetes	10 (5.5%)
HIV	30 (16.5%)
Mental health and addictions, N (%)	
Any mental health or addictions[2]	129 (70.9%)
Addiction	36 (19.8%)
Schizophrenia or bipolar	28 (15.4%)
Visit with any physician at the FHT within the past 2 years (December 2016-December 2018)	
Mean (S.D.)	12.9 (14.5)
Visit with any physician at the FHT within the past 2 years (December 2016-December 2018), N (%)	
0	25 (13.7%)
1 to 2	17 (9.3%)
3 to 5	23 (12.6%)
6 to 10	39 (21.4%)
11 to 19	42 (23.1%)
20+	36 (19.8%)

[1]Patients who are treatment naive, have unknown treatment status, did not complete treatment or where treatment failed to clear the virus.
[2]Per billing codes for depression, anxiety, addictions, schizophrenia, or bipolar disorder.
Abbreviations: HCV, Hepatitis C Virus; FHT, Family health team; SD, Standard deviation.

lowest income quintile, 14.9% (n = 13) were homeless, 70.9% (n = 129) faced challenges with mental health or substance use, 16.5% (n = 30) had HIV. The mean number of physician visits for these patients was 12.9 over a 1-year period (Table 1).

Patient Outreach

Of the 182 patients eligible for outreach, 119 were contacted by phone, e-mail or letter (Figure 2a). 74 of the patients who were contacted did not respond to calls, had no e-mail consent on record, and/or their address was no longer current. We reached 45 patients, of whom 37 were booked with their physician, 25 attended their appointment, and 6 ultimately began treatment.

Physicians declined patient outreach for 63 patients of the 182 eligible for outreach, citing a variety of reasons including prior engagement in treatment work-up, being followed elsewhere, had previously declined treatment or were already seeing the MD regularly. By the end of the intervention, 26 of these 63 patients had been seen by a hospital-based internist, hepatologist or infectious disease specialist to discuss HCV treatment. Another 32 of the 63 were seen in our family practice for other reasons, and of these, 24 had an informed discussion with their Family Medicine specialist about HCV treatment (Figure 2b).

Outcome Measures

Between December 2018 and June 2020, the percentage of HCV RNA positive patients who started treatment rose from 66.0% (354/536) to 75.5%

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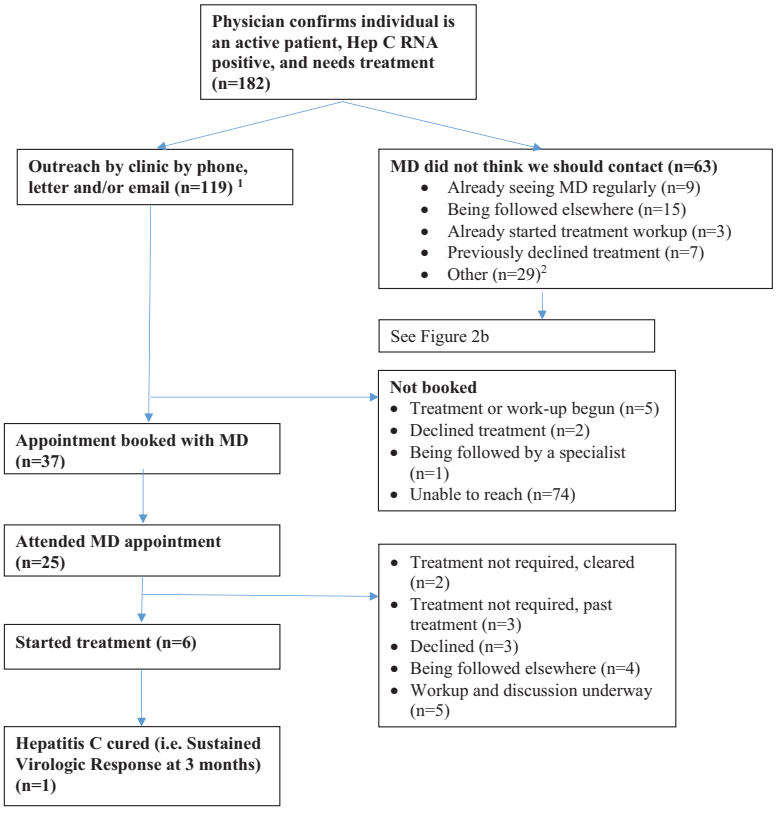
Figure 2a. Individuals who were Hepatitis C Virus (HCV) RNA positive and untreated in December 2018 and received study outreach. Sixty-three were called twice; 54 letters and 3 emails were sent. Other reasons include mental health issues, complicated or difficult patients, pregnancy, cancer, incarceration, not engaged in care or unknown.



(401/531). Similarly, the percentage of HCV RNA positive patients who achieved SVR rose from 55.8% (299/536) to 69.9% (371/531). As of June 2020, 92.5% (371/401) of patients who started treatment achieved SVR (Figure 3).

Process Measures

Of the 182 HCV RNA positive patients untreated in December 2018, 60.4% (110) had an informed discussion with their doctor regarding HCV treatment. 25.3% (46) had some pretreatment investigations including repeat HCV RNA level or an ultrasound ordered by their family doctor. 9.9% (18) declined treatment at various stages in the process, 9 declined before an appointment was booked with their clinician and 9 declined after having an informed discussion with their clinician. The EMR decision support tool was used by 29 unique physicians on 45 patients.

Characteristics of Individuals Who Have and Have Not Been Treated

At study end, there were 130 HCV RNA positive individuals who still required treatment (Table 2). Compared with those who were treated, individuals who were untreated were younger (51 vs 57, $P<.001$), a greater proportion were women (35.4% vs 25.4%, $P<.05$), lived in the lowest neighborhood income quintile (24.2% vs 4.1%, $P<.001$), and had a comorbid diagnosis of mental health or addiction (73.9% vs 62.8%, $P<.05$). Mean visits were lower among those who were untreated (8.1 vs 10.8, $P<.001$); specifically, a higher proportion of those untreated had zero visits to a physician during the study period (33.1% vs 10.6%, $P<.001$).

Qualitative Findings

Between February 2020 and June 2021, we held 3 focus groups with a total of 14 physicians and 3 individual interviews with pharmacists, representing clinicians across 4 of 6 clinical sites. Findings are summarized below and summarized in Figure 4.

Program Strengths and Contextual Facilitators

Participants highlighted key strengths of the initiative, including the EMR-embedded decision

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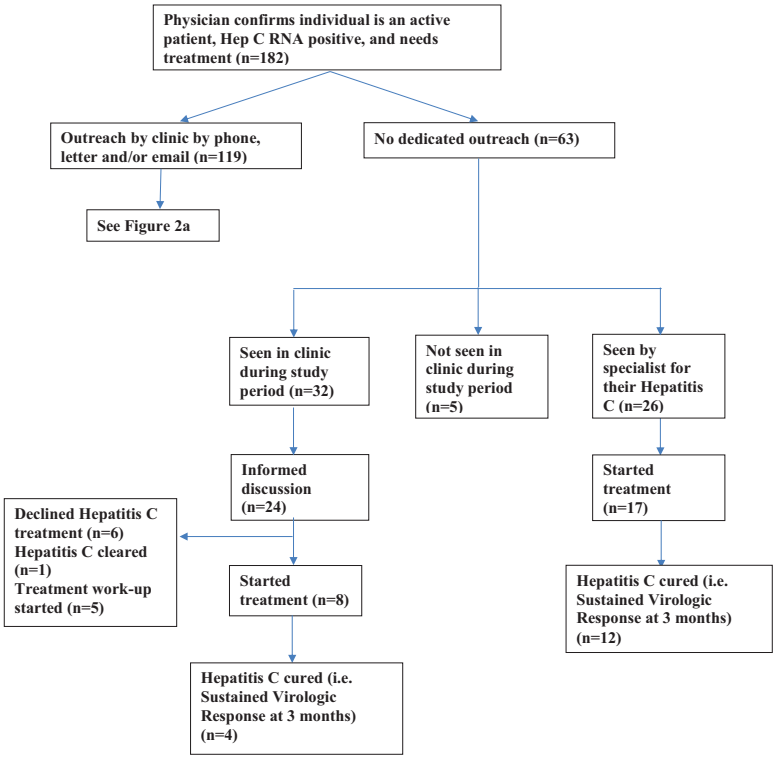
Figure 2b. Individuals who were Hepatitis C Virus (HCV) RNA positive and untreated in December 2018 but did NOT receive study outreach.



support tool, team-based approach, mentorship, and the multi-pronged educational support. Collectively, these supports reportedly increased physicians' confidence in HCV treatment and alleviated their need to research pharmacological aspects of treatment, which they indicated was previously a barrier. Many noted that the decision support tool was critical to the program's success and sufficient as a stand-alone support, but that the education and mentorship helped to build comfort in using the tool initially.

Figure 3. Change in the number of Hepatitis C Virus (HCV) RNA positive patients who started treatment and achieved cure (Sustained Virologic Response, SVR) between December 2018 and June 2020.

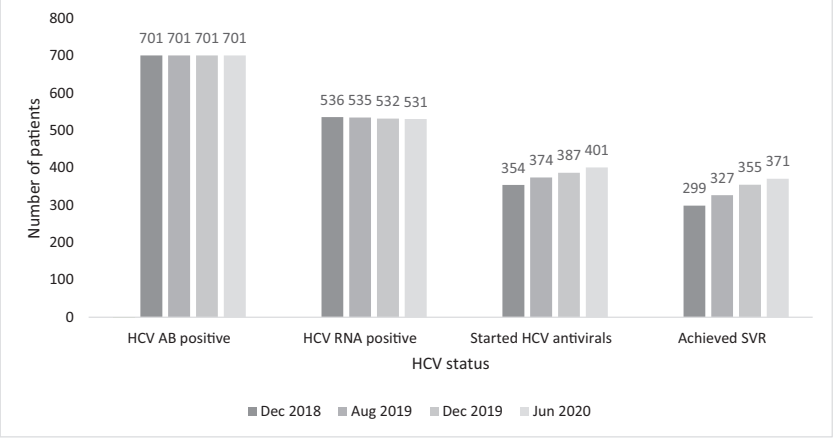


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Table 2. Characteristics of Patients Who Were Hepatitis C Virus (HCV) RNA Positive for >6 Months, by Whether or Not They Were Treated at the End of the Intervention

Demographic Characteristic	Patients needing treatment[1] as of June 2020 (*n* = 130)	All patients treated[2] as of June 2020 (*n* = 406)	*P*-value
Age, Mean (S.D.)	51.1 (12.8)	57.2 (10.4)	<0.001
Age, N (%)			
<40	25 (19.2%)	26 (6.4%)	<0.001
40 to 64	89 (68.5%)	273 (67.2%)	
65+	16 (12.3%)	107 (26.4%)	
Sex, N (%)			
Female	46 (35.4%)	103 (25.4%)	<0.05
Male	84 (64.6%)	303 (74.6%)	
Income quintile, N (%)			
No fixed address or homeless	6 (9.7%)	70 (35.9%)	<0.001
1 (Lowest)	15 (24.2%)	8 (4.1%)	
2 to 5	41 (66.1%)	117 (60.0%)	
Chronic conditions, N (%)			
Diabetes	7 (5.4%)	52 (12.8%)	<0.05
HIV	22 (16.9%)	94 (23.2%)	0.17
Mental health and addictions, N (%)			
Any mental health or addictions	96 (73.9%)	255 (62.8%)	<0.05
Addiction	22 (16.9%)	60 (14.8%)	0.65
Schizophrenia or bipolar	20 (15.4%)	50 (12.3%)	0.45
Visit with any physician during the study period (December 2018-June 2020)			
Mean (S.D.)	8.1 (12.6)	10.8 (11.9)	<0.001
Visit with any physician at the FHT within the past 2 years (December 2016-December 2018), N (%)			
0	43 (33.1%)	43 (10.6%)	<0.001
1 to 2	16 (12.3%)	56 (13.8%)	
3 to 5	21 (16.2%)	71 (17.5%)	
6 to 10	17 (13.1%)	82 (20.2%)	
11 to 19	20 (15.4%)	94 (23.2%)	
20+	13 (10.0%)	60 (14.8%)	

[1]Patients who are treatment naïve, have unknown treatment status, or where treatment failed to clear the virus.
[2]Patients being treated successfully, being treated currently, or having completed treatment without a final confirmatory RNA. Five patients who cleared the infection spontaneously during the intervention are also included.
Abbreviations: HCV, Hepatitis C Virus; FHT, Family health team; SD, Standard deviation.

Participants conveyed that the collaborative culture of the practice and the accessibility of the mentors were key facilitators, often enabling just-in-time patient care. Participants spoke highly of the pharmacist-physician collaboration:

> Because the pharmacist was profiled or highlighted in multiple parts of the work… I think [it]… gave clinicians the understanding that the pharmacist was there as a support for them. (Pharmacist 3)

> I feel like why [the initiative] worked well here was because of the really easy access to [the HCV] team. We're lucky because we have the pharmacist in house, so even if it wasn't an instant message through EMR, it was a tap on the shoulder when they're walking by. And sometimes that makes all the difference, actually, because if a patient who's there, who may not follow up. … Sometimes it has to happen at that moment. (Physician 2)

In addition, the established patient-clinician relationships and the relative ease of the current HCV treatment regimen appeared to facilitate patients' acceptance and uptake of the treatment.

Program Limitations and Contextual Barriers

Physicians spoke about challenges with patient adherence and concerns related to potential

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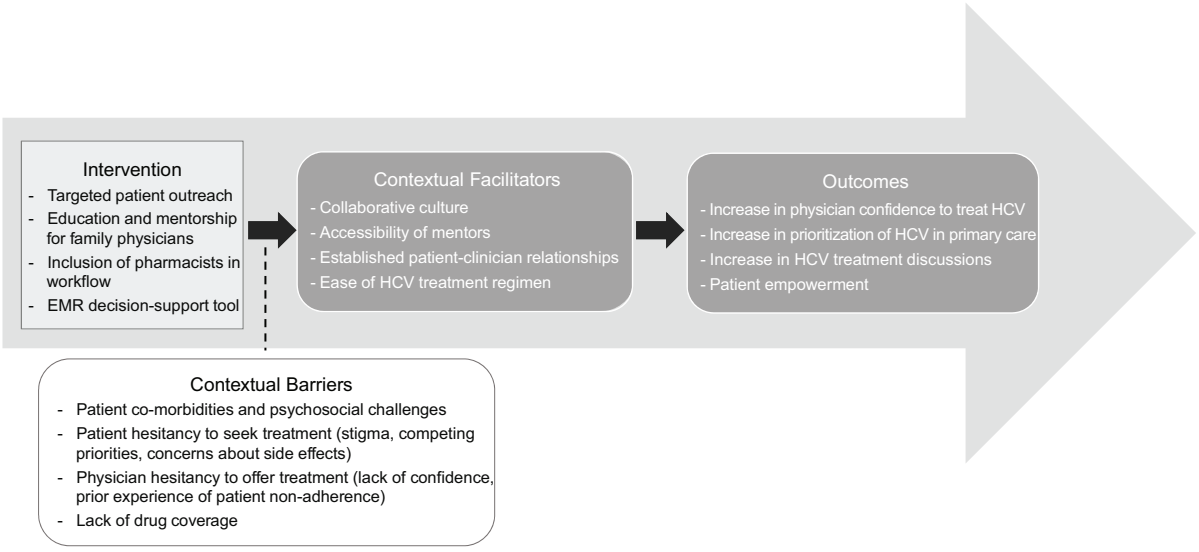
Figure 4. Facilitators and barriers influencing outcomes after the intervention, summary of qualitative findings from physician focus groups and pharmacist interviews. Abbreviation: HCV, Hepatitis C Virus.



reinfection. Despite social work supports, clinicians described psychosocial complexities as a barrier to treatment including mental health and addictions comorbidities and housing instability:

> We're still trying to figure out how exactly to increase the continuity with these patients. Most of my patients have a drop-in policy, so they just come in, they'll see me right away. But even that, I don't think, is enough to ensure that they'll be compliant with the entire course of medication. . . . That's probably where maybe some advice from our clinical champions to figure out how to actually work with this patient population. (Physician 5)

> They're a hard to reach bunch sometimes because there's often concomitant illnesses, mental illness or addiction. (Physician 6)

Some clinicians spoke of specific instances in which they tried to initiate treatment, but patients did not follow through, whereas others noted cases where they assumed adherence would be an issue so did not offer treatment. Notably, a few physicians described forgoing treatment conversations with patients because of worries about adherence:

> There are some patients that I personally didn't think would succeed in treatment, and they did, and they may have failed at other times. I think I just had this pre-conceived notion of other patients in the past that maybe I shouldn't offer it. . . that it's possible that we that might be our own filter. And sometimes we get in the way of our own opinion of whether people really could, or at least minimally should be offered and given a chance to [accept treatment]. (Physician 2)

Some emphasized the importance of offering treatment multiple times because some patients accept after previously refusing. Patients' concerns about potential side effects and lack of drug coverage were additional barriers to treatment which clinicians felt was out of their control.

Our interviews with patients [data not presented] corroborated the views of clinicians, with patients noting that competing health priorities and life circumstances, as well as concerns about side effects, prevented them from initiating treatment.

Program Outcomes

Physicians found that the initiative raised their awareness of HCV, and prioritized it, enabling some to overcome their hesitancy to treat:

> I had become practiced in probably not addressing [HCV] as assertively as I should have because I presumed I knew the answer in a couple of cases. . . I think it brings to light the idea that, at some point, these patients probably will change their minds and we just need to be opportunistic in terms of grabbing them at the right stage of their life. (Physician 4)

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Participants indicated that the program increased physicians' confidence in treating HCV and empowered them to view treatment as within their scope of practice:

> The message that this initiative gave is that [treating HCV] is something within your competency. You can do this safely as a family doctor. Sometimes we kind of question ourselves like, "Should I be sending this person out to a specialist? Am I going to be able to do a good enough job?" And so the fact that the message was clear: Yes, this is something you can do; here's how you do it. I think it was an enabler for us. (Physician 14)

Participants also noted that treating HCV may have helped their patients feel empowered by enabling them to gain control of their condition:

> I've had two patients who … were actually quite emotional about being treated and feeling a sense of autonomy or being able to take charge of something with regard to their health… this was, I think, really empowering for them. (Physician 1)

> I think the patient and myself were both so excited getting that final negative RNA. It was like the best thing in the world. (Physician 11)

Discussion

Our multifaceted quality improvement initiative resulted in an overall increase in patients initiating HCV treatment from 66% to 76% with 93% of those initiating treatment achieving a SVR by the end of the 18-month study period. Further, nearly 2/3 of patients who were untreated at the start of the study had informed discussions about HCV treatment with their clinicians by study end. Compared with those who were treated, a higher proportion of patients who were untreated were younger, female, had comorbid mental health and addictions, and had zero physician visits during the study. Qualitative findings highlighted that the intervention helped raise awareness and confidence among physicians for treating Hepatitis C in primary care. A collaborative team environment, education, mentorship, and a decision-support tool integrated into the electronic record were all enablers of success although patient psychosocial complexity remained a barrier to engagement in treatment.

Our initiative focused on patients of our large primary care organization. Even so, we were unable to reach almost 2/3 of untreated patients who we attempted to proactively contact by phone, letter, and/or e-mail. For some patients, the contact information was not up to date, whereas others may not have had a working phone or stable housing—a reflection of the challenging social circumstances facing many people with Hepatitis C and the opportunity for primary care organizations to take more creative steps to retain them in care. Indeed, we found higher treatment rates among those HIV in our practice likely reflecting their greater engagement in ongoing care. The vast majority of untreated patients who did not receive active outreach from our team were engaged in care during the study period either with an HCV specialist or with their Family Medicine specialist.

That untreated patients were more likely to have mental health and addictions may speak to these patients having different care priorities for themselves, but our qualitative results suggest it may also relate to physicians making a judgment that a patient will be unable to successfully engage in treatment. Studies have shown, however, that SVR is achievable, even in this patient population.[4,5,12–14] Specifically, people who use drugs can be effectively treated for HCV with supports such as telephone reminders,[13] coverage of transportation costs,[15] engagement with community workers and patient navigators,[16,17] and help with applications for drug coverage.[17,18] Other strategies for supporting adherence among patients with psychosocial complexity include medication delivery, connection to opioid use disorder treatment,[19] enhanced pharmacist care[13,16,20] or incentives such as grocery cards.[21] Many of these supports were available to our patients but we hypothesize that they were not used systematically and that clinicians would benefit from additional education on strategies to support more marginalized populations. Notably, there was a relatively high prevalence of schizophrenia and bipolar disorder among our patients with HCV—a finding in keeping with the literature.[22]

Our results are in keeping with studies that have shown family medicine teams can effectively treat HCV infection using direct acting antiviral therapy in settings as diverse as rural Australia,[16] Alaska,[23] and the US inner city.[4,5] Indeed, studies have shown very similar cure rates[13,23–25] between hospital and family medicine settings. Empowering primary care to treat HCV is particularly relevant given the importance of positive patient relationships and trust in supporting marginalized populations.[15] Our initiative integrated many strategies

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shown to be effective for spreading HCV to primary care settings including coordinated care with other health care disciplines such as case managers, nurse practitioners, and pharmacists, patient outreach, designating leaders or champions within the team[4,16,23,25,26]—strategies that could be spread to other primary care teams.

Our study has both strengths and limitations. We implemented a population-based multifaceted improvement initiative to increase HCV treatment rates largely using existing practice resources—the only such initiative to our knowledge in Canada. We conducted a mixed method evaluation that demonstrated practice-level improvement in our primary outcome and included qualitative interviews that provided insights into the context and mechanisms influencing outcomes, including ones that are hard to measure. However, our study was conducted at a single primary care organization in an urban area that serves a relatively high number of patients with HCV and includes government funding for different health professionals including pharmacists, nurses, and social workers—factors that limit its generalizability. Further, our study began just after direct-acting antivirals became covered by the provincial drug formulary and it is difficult to speculate how many people would have been treated in the absence of our intervention. However, our qualitative findings support that our intervention positively influenced clinician behavior.

Conclusion

A multifaceted quality improvement initiative implemented in a primary care setting over 10 months using existing team resources was associated with an increase in the proportion of patients with RNA positive HCV who had initiated curative treatment. Clinicians described improved awareness and confidence in treating HCV after the intervention with key enablers being the collaborative culture, team supports, mentorship, education, and a decision-support tool. The working relationship between team pharmacists and physicians was a key strength. Potential next steps include spreading this intervention to other family practices although doing so may require funding for team resources, particularly pharmacists. Future iterations of the intervention will also need to include strategies to directly address the psychosocial complexity of patients—a real and perceived barrier to treatment. Our study adds to the growing literature demonstrating that with the right supports, Family Medicine specialists can play an important role in the global pursuit of HCV elimination.

We are grateful to Aine Workentin who assisted with physician education; Erin McAllister, who completed the patient outreach; Lisa Miller, who helped develop the decision-support tool embedded in the electronic medical record; and Mo Al-Haj, who conducted much of the data extraction using automated searches of our electronic medical record. Thank you to our team pharmacists Jon Hunchcuk, Brenda Chang, and Doret Cheng as well as their hospital colleague Mark Naccarato and liver specialists Dr. Hemant Shah and Dr. David Wong, who assisted with the development of the study materials and provided guidance to the family doctors treating their patients with Hepatitis C. Thanks also to Tiffany Jenkins of the Applied Health Research Centre (AHRC) and Tony Antoniou for their support and contribution to the qualitative research component. Finally, thank you to clinical working group members not already mentioned, including Michael Adia, Yosra Al Makadma, Daniel Bois, Ashna Bowry, Monica Gad, and Zoe Von Aesch, who provided overall guidance on the project. Much appreciation goes to our patient advisory group including Neil Davis, Walter Tupholme, Jay Wagner, Helen Posno, and Andrew Cumming, who provided input on the study including improving patient outreach and our patient interview guide.

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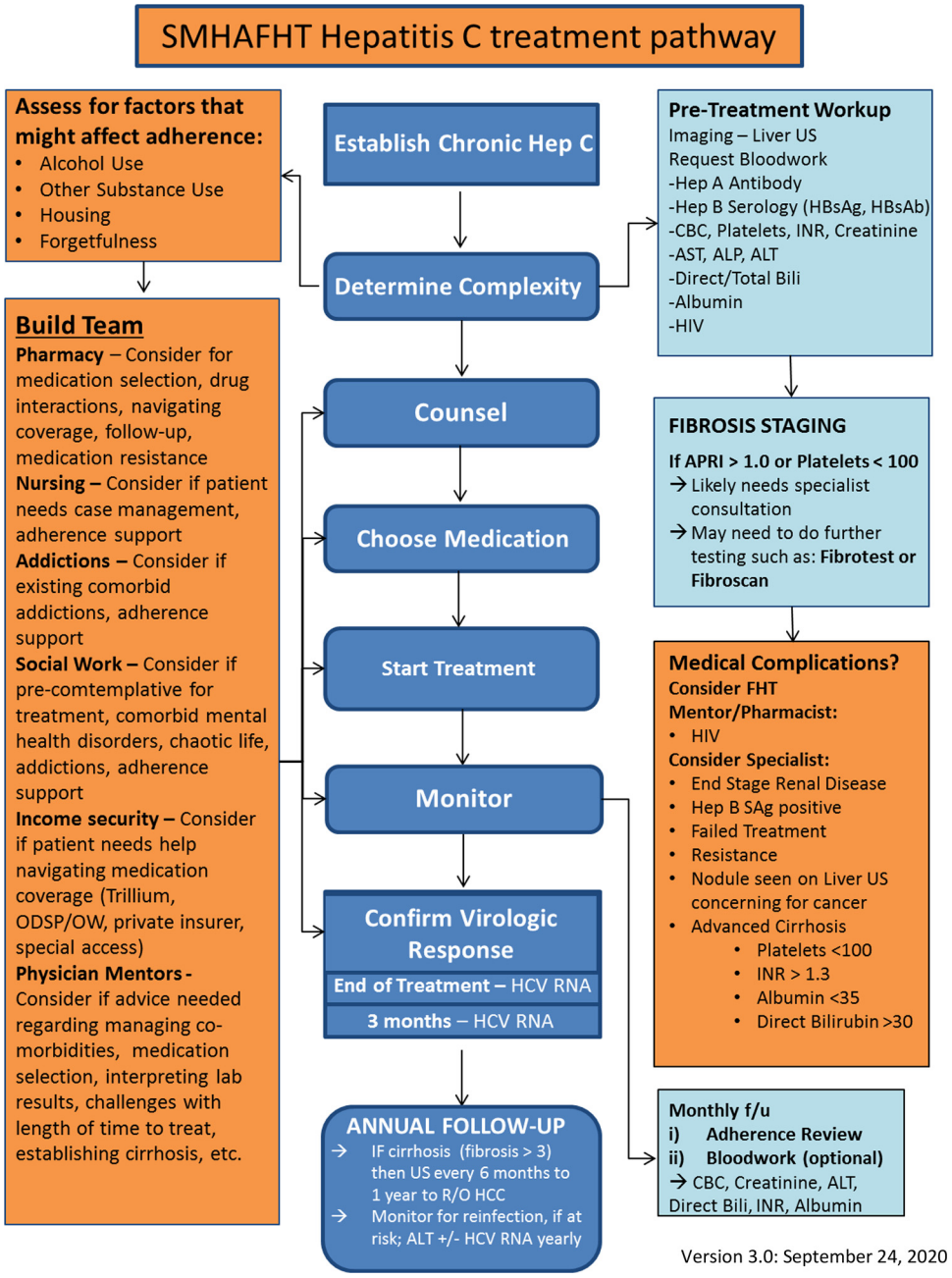
Appendix 1.



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Treating Hepatitis C

A physician's guide to treating and curing Hep C

Things to remember!

! Chronic Hep C is established when the patient receives two RNA+ results 6 or more months apart

! **Key Question to ask to determine adherence:** "How many doses of your medication have you missed in the last few weeks?"

ENGAGE WITH YOUR PHARMACIST EARLY ON!

TIP:
If patients do not have positive serology for Hep A & Hep B antibody, consider vaccination

MEDICATION INFO

Treatment Naïve + Non-Cirrhotic

- **HCV genotype 1a + HCV PCR < 6 million IU/mL**
  → Sofosbuvir 400mg + Ledipasvir 90 mg (Harvoni) – 8 wks
- **HCV genotype 1b**
  → Elbasvir 50 mg + Grazoprevir 100 mg (Zepatier) – 8 wks
- **HCV genotype 1-6 + treatment naïve + non-cirrhotic**
  → Glecaprevir 300mg + Pibrentasvir 120mg (Maviret) – 8 wks

Treatment Naïve + Compensated Cirrhosis

- **HCV genotype 1, 2, 4, 5, 6, genotype 3 (BW otherwise normal, platelets >100)**
  → Glecaprevir 300mg + Pibrentasvir 120mg (Maviret) – 8 wks
- **HCV genotype 3 (if BW abnormal, consider involving specialist)**
  → Sofosbuvir 400mg + Velpatasvir 100mg (Epclusa) – 12 wks
  → Glecaprevir 300mg + Pibrentasvir 120mg (Maviret) – 12 wks

Treatment Experienced* + Non-Cirrhotic

- **HCV genotype 1, 2, 4, 5, 6,**
  → Glecaprevir 300mg + Pibrentasvir 120mg (Maviret) – 8 wks
- **HCV genotype 3 (if BW abnormal, consider involving specialist)**
  → Sofosbuvir 400mg + Velpatasvir 100mg (Epclusa) – 12 wks

Treatment Experienced* + Compensated Cirrhosis

- **HCV genotype 1, 4**
  → Elbasvir 50 mg + Grazoprevir 100 mg (Zepatier) – 12 wks
- **HCV genotype 2, 5, 6**
  → Glecaprevir 300mg + Pibrentasvir 120mg (Maviret) – 12 wks
  → Sofosbuvir 400mg + Velpatasvir 100mg (Epclusa) – 12 wks
- **HCV genotype 3**
  → Glecaprevir 300mg + Pibrentasvir 120mg (Maviret) – 16 wks
  → Sofosbuvir 400mg + Velpatasvir 100mg (Epclusa) – 12 wks

! **At the end of treatment:**

- **Test Hep C Viral Load**
- **For patients with greater than stage 3 fibrosis, order an US every 6 months**
- **Patients remain at risk! Consider retesting for Hepatitis C every 12 months**

$$\text{APRI} = \frac{\dfrac{\text{Patient AST Level (IU/L)}}{\text{AST (Upper limit of normal) (IU/L)}}}{\text{Platelet Count } (10^9/\text{L})} \times 100$$

APRI Score > 1.0 = suggests fibrosis

*if exposed to a prior DAA that is not interferon or ribavirin, should have resistance testing done to guide treatment

Hep C treatment guidance is evolving and this tip sheet has been developed based on expert advice obtained in spring 2019. We suggest consulting your team pharmacist for the most up-to-date medication recommendations.

Feedback or questions? Email ann.stewart@unityhealth.to or tara.kiran@utoronto.ca

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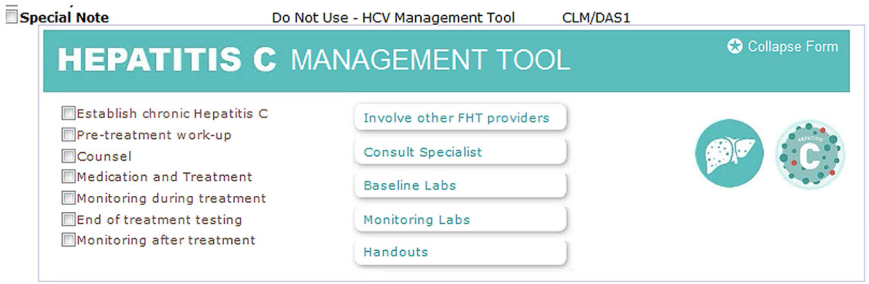
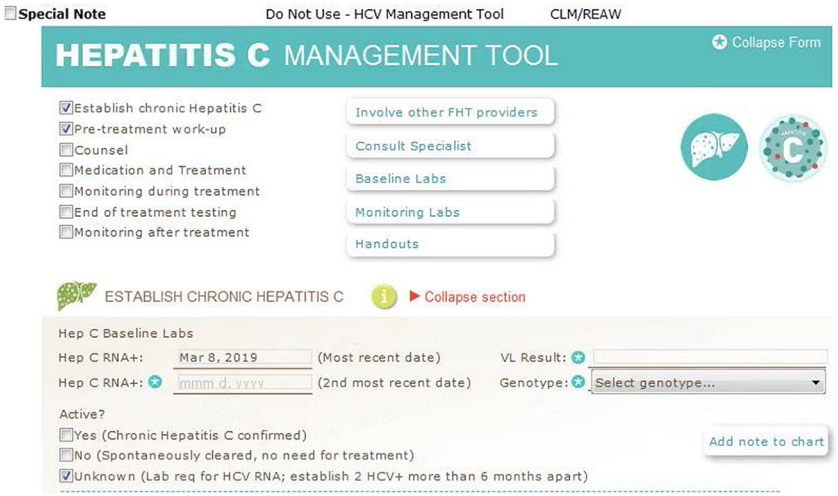
Appendix 2.

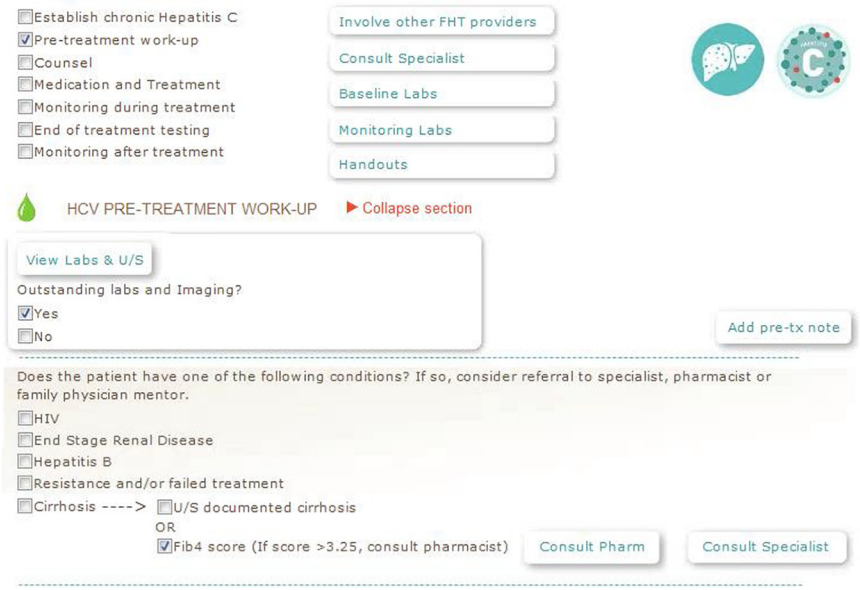
EMR Hepatitis C management tool



Confirm Chronic Hep C



Pre-Treatment Work-Up



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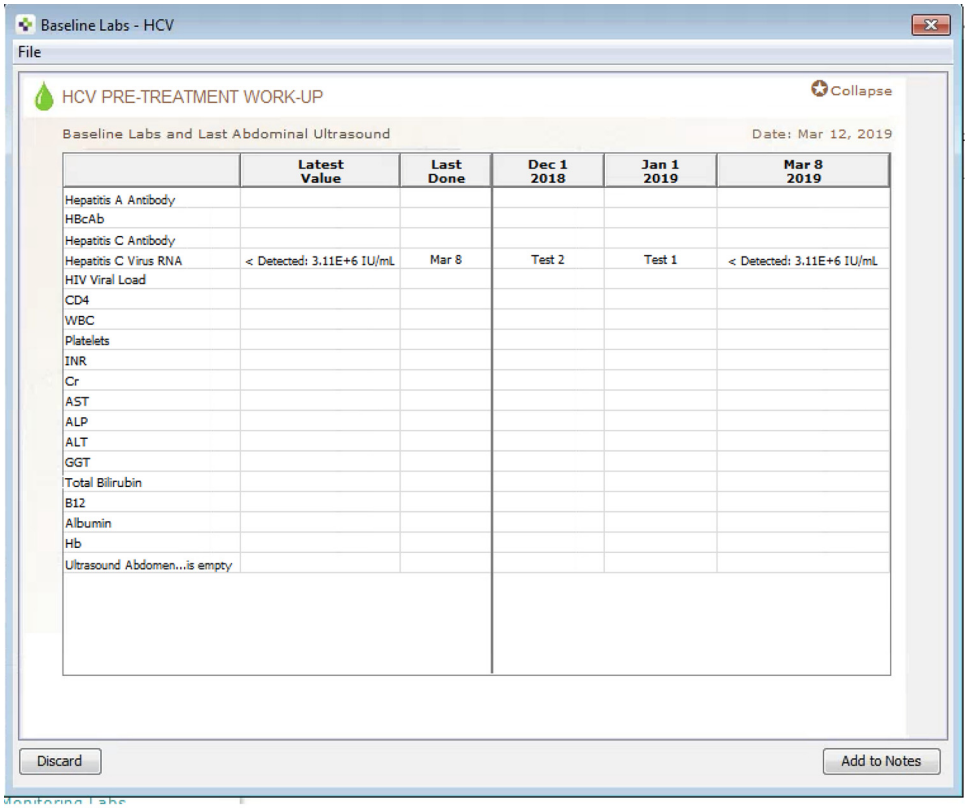
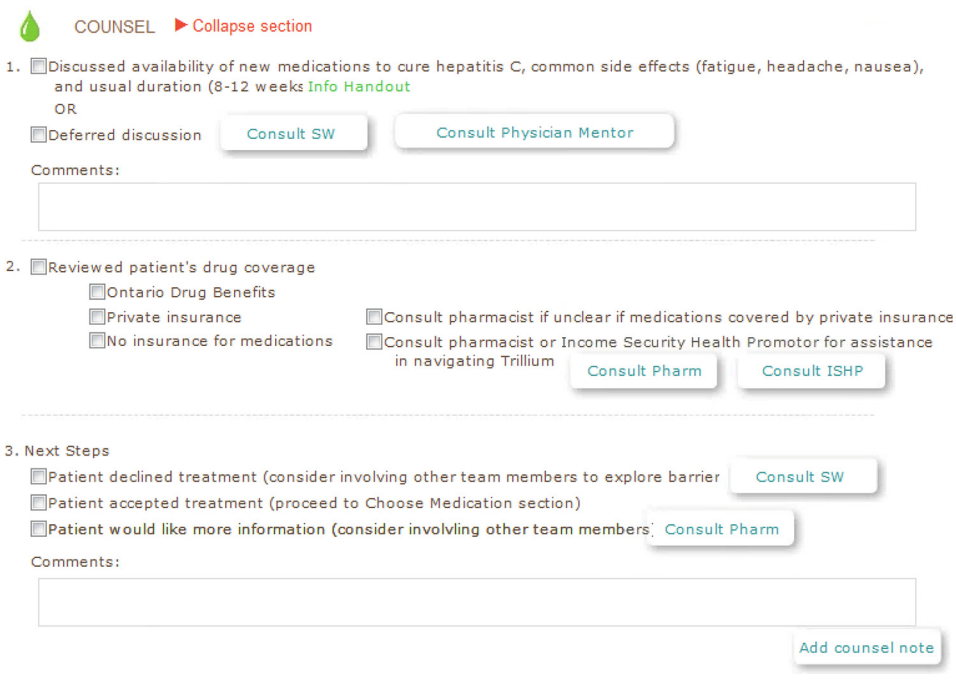


COUNSEL



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Appendix 3.

CURING HEPATITIS C – PATIENT OUTREACH PHONE CALL PROCEDURE

PATIENT OUTREACH – PHONE CALL SCRIPT

Phone call script

1. **Leave a message for the patient**

This is a message for _____. My name is _____ and I'm calling on behalf of Dr._____'s office. We have an opportunity that you might want to take advantage of, so can you please return my call at XXX-XXX-XXXX. Again my name is _____ and my number is XXX-XXX-XXXX. Thank you.

2. **Initial call to the patient**

Good morning/afternoon, may I please speak with _____? My name is _____ and I am calling on behalf of Dr._____'s office. I am calling because there is a treatment for hepatitis that Dr._____ would like to talk to you about. Just so you are aware we are not worried about you. We are calling every patient who could benefit from the hepatitis treatment. Are you available to book an appointment right now? What's most important is that you come in so let's work around your schedule.

3. **No symptoms**

Example: "I feel fine, I don't think I need to come in"

Sample response: "Sometimes people with hepatitis can feel fine but we know the virus can still do damage to your liver. Luckily we now have a treatment to cure hepatitis. Can I book you in to discuss things further with Dr. _____?"

4. **No knowledge/memory of hepatitis**

Example: "I don't really remember my doctor talking to me about hepatitis"

Sample response: "Hepatitis C is a virus that affects your liver. When people first get hepatitis C, often they have few symptoms. But after some time, hepatitis C can damage your liver and make you sick. The good news is that now there is a treatment to help cure you from the virus.

4. Confusion about the call

Example: I don't understand why you are calling me

Sample responses: Your doctor has asked for my help to call patients who are overdue

5. **Language barrier**

Example: Patient does not speak English or other language of the clinic staff

Sample approach:

- First option: Ask patient if they agree to use the language line. If they agree, follow the procedure for using the language line and use the regular initial call script.

-Second option: If at all possible, try to get someone on the phone who speaks English. Most households recognize the words English and doctor. If unable to obtain a family member or friend, offer to call back at a later time.

DO NOT SAY WHAT THE APPOINTMENT IS FOR; JUST BOOK AN APPOINTMENT WITH THE CLINICIAN.

6. **Lack of Commitment**

Examples: Can I think about it?

Sample approach: Yes, when would be a good time for me to call you back?

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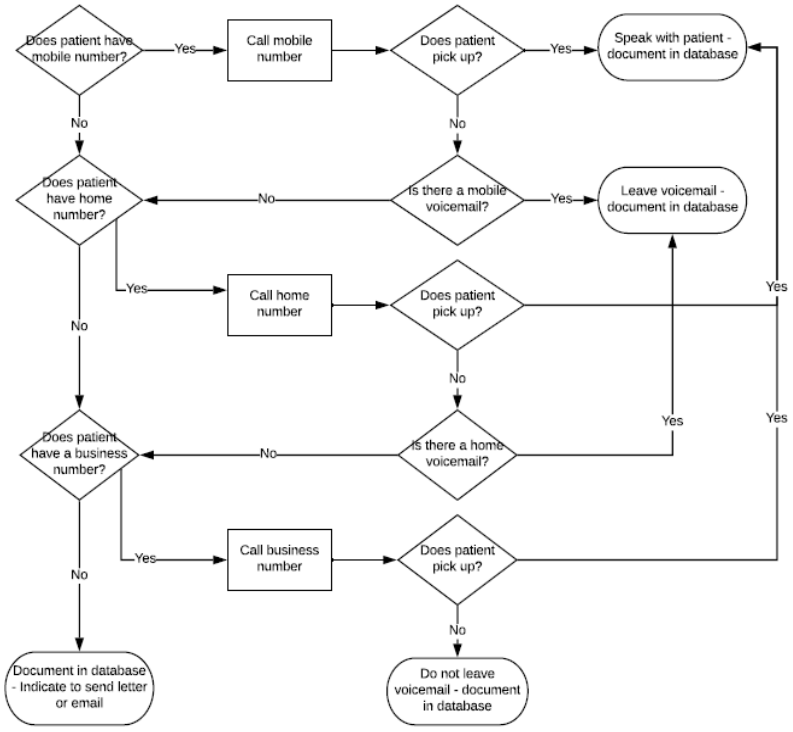
CURING HEPATITIS C – PATIENT OUTREACH PHONE CALL PROCEDURE



OTHER GUIDELINES

Voicemails:

- Never mention any personal health information when leaving voicemails
- For automated voicemail boxes or the voicemail box of a caseworker: leave generic voicemail (from script) ensuring you provide a private extension for the patient to call back

→Language Barriers: Use the language line if possible

Circumstances when you would speak to family members:

1) Language barrier (if unable to use language line)
2) Disability

→If speaking to a case manager/worker: Leave a message for patient to call back or, if necessary, book appointment for patient without any mention of PHI

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Appendix 4.

1. Individual Interview Guide

Thank you for participating in this individual interview. I am a researcher from the Applied Health Research Centre of the Li Ka Shing Knowledge Institute at St. Michael's Hospital in Toronto and am part of a team who is trying to learn about pharmacists' experiences with the "Hepatitis C" initiative happening at the SMH Family Health Team.

During the interview today, I will pose questions about the initiative, your involvement and the supports you provided you physicians and patients to treat Hepatitis C. The questions serve as a guide only. If there are other topics you think are important, please feel free to raise these.

This interview is a voluntary activity. You may stop the interview at any time. If any question I ask makes you uncomfortable, tell me and we can skip it. If any question does not make sense, let me know and I can rephrase it. We will audio record the interview so that we do not lose any details of the discussion, however, only members of the study team will hear the recordings. The PIs (Dr. Tara Kiran and Dr. Ann Stewart) will not hear or see the raw data and will only review the transcripts once they are de-identified. No identifiable information will be present in any reports or publications generated from this study. Your real name will not appear anywhere in written transcripts, or reports concerning this research. Please be assured that we will keep the information you provide confidential. Confidentiality is a key concern and we ask that you respect each other's confidentiality with the information you share today.

Do you have any questions before we begin?

*get signed consent or record verbal consent

Questions

1. Over the last year, there has been an initiative in our department to cure Hep C. Please tell us about your involvement with this initiative.

2. What support did you provide to physicians as part of this Hep C initiative? Please describe.
    a. Was there an increase in consults? How did these go?
    b. Can you describe one or two cases where your provided support to a physician?

3. What support and/or counselling did you provide to patients? Please describe (specific cases).

4. As part of this initiative, physicians received different support related to Curing Hep C (Grand rounds presentation, a series of lunch and learns, a new EMR tool, links to allied health professionals and physician mentors, one-on-one physician meetings and patient outreach). Do you feel that physicians changed in their knowledge or attitude about treating patients for Hep C due to this initiative?
    a. Do you feel that physicians changed their approach in consulting or working with you as a pharmacist?

5. How well did you feel prepared for the role in supporting physicians and patients in Hep C treatment? [preparation included education and training; ongoing support from other pharmacists/physicians/specialists in or outside the FHT]

6. How do you think this initiative has affected you personally? (i.e. pressures on time, stress levels, greater knowledge, changes in your role, increased confidence treating patients for Hep C – [mention prompts only if they have not been covered previously])

7. Did you experience any surprises in implementing this initiative? Please describe.

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8. What are your thoughts about this initiative for the future?
    a. Would you like to continue providing this pharmacist support?
    b. How could the initiative be improved from your perspective?
    c. Where there specific challenges that we need to address?
    d. Do you have experiences from other similar initiatives that would help provide feedback for the Cure Hep C initiative
    e. What do you think would be useful to keep in mind if this initiative is scaled up to other sites or contexts?

        [*Probe* if helpful: How could you see this initiative being spread to other sites?]

9. Has this initiative affected your practice in some way outside of caring for patients with Hep C? (i.e. improved teamwork at FHT, perception of role of pharmacists, use of EMR etc.)

10. That concludes the questions we had prepared for today. Is there anything else you would like to share about the Hep C initiative?

Thank you.

2. Focus Group Guide

Thank you for coming to the focus group today. I am a researcher from the Applied Health Research Centre of the Li Ka Shing Knowledge Institute at St. Michael's Hospital in Toronto and am part of a team who is trying to learn about physicians' experiences with the "Hepatitis C" initiative happening at the SMH Family Health Team.

During the focus group today, we will pose questions about challenges and supports you experienced in treating patients with Hepatitis C. The questions serve as a guide only. If there are other topics you think are important, please feel free to raise these. It is OK if you all do not agree; feel free to speak your mind and talk about what is relevant to you. Not everyone is likely to have the same experiences and we want to know how yours is similar or different from the other people in this room.

We will audio record or video record the focus group so that we do not lose any details of the discussion, however, only members of the study team will hear the recordings. Please refrain from identifying yourself or others during this conversation to protect the privacy of one another. Any remaining identifiable information with be de-identified during the transcription of the audio-recordings. The PIs (Dr. Tara Kiran and Dr. Ann Stewart) will not hear or see the raw data and will only review the transcripts once they are de-identified. No identifiable information will be present in any reports or publications generated from this study. Your real name will not appear anywhere in written transcripts, or reports concerning this research. Please be assured that we will keep the information you provide confidential. Confidentiality is a key concern and we ask that you keep this discussion confidential and respect each other's confidentiality with the information you share today.

Are there any questions before we begin?

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Questions

1. Over the last year, there has been an initiative in our department to cure Hep C. Can you describe what you know about this initiative and what supports you have observed or used?
    a. Prompts: Grand rounds presentation, a series of lunch and learns, a new EMR tool, links to allied health professionals and physician mentors, one-on-one physician meetings and patient outreach [mention ones that were not brought up].
    b. [put up list of components] Prompt: Did you find any of these particularly helpful or unhelpful? Why?

2. Please think about Hep C patients that are part of your practice. Please tell us about your experience trying to managing them in the last year.
    a. Is there a particular case that was difficult or smooth? Please tell us about this.
    b. Is there a situation where you debated whether to treat or not? Why?

3. How well do you think this initiative has worked for you and your patients toward the goal of curing Hepatitis C?
    a. Have you experienced changes in your confidence or abilities in treating patients with Hep C? Please describe.
    b. Have the barriers you initially faced with treating patients for Hep C changed? How?

4. What specific aspects of the Hep C initiative did you find to be the most helpful?
    a. Did you use the pharmacist support? How did you find that?
    b. Did you use the MD mentor support? How did you find that?
    c. What interactions, if any, have you had with specialists? Please describe.

5. What challenges persisted for you despite the supports?
    a. We know that many of these patients face other health and social challenges, how did this influence how you were able to manage their Hep C?
    b. We noticed in the one-on-one meetings that there were many patients that physicians didn't think we should contact on their behalf. What do you think are some of the reasons for this?
    c. How should we as a team manage cases where patients have already declined treatment once? What about the situation where a clinician isn't sure the patient can follow through reliably with the medications?

6. How could we further support you to effectively manage your patients with Hep C?
    a. Do you have experiences from other similar initiatives that could inform what we could do here at the FHT?
    b. We didn't have a patient peer support component, do you think this would be helpful for your patients?
    c. What do you think would be useful to keep in mind if this initiative is scaled up to other sites or contexts?
        [*Probe* if helpful: How could you see this initiative being spread to other sites?]
7. Did you experience any surprising results in engaging in this initiative? Please describe.

8. Has this initiative affected your practice in some way outside of caring for patients with Hep C?
    a. Probes: impact on teamwork at FHT, perception of role of pharmacists, use of EMR etc.

NOTE: with 10 minutes left, skip to 7/8

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