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QUALITATIVE STUDY OF A PRIMARY CARE-BASED HEPATITIS C TREATMENT PROGRAM AT A SAFETY-NET HOSPITAL

by

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QUALITATIVE STUDY OF A PRIMARY CARE-BASED HEPATITIS C TREATMENT PROGRAM AT A SAFETY-NET HOSPITAL

MAGDALENA BUCZEK

ABSTRACT

Introduction: Mortality associated with hepatitis C virus (HCV) infection is increasing, yet only a small percentage of HCV-infected individuals are aware of their infections, complete treatment, and achieve a cure, defined as a sustained virologic response. In March 2015, the Section of General Internal Medicine at Boston Medical Center (BMC), New England's largest safety-net hospital, implemented the Adult Primary Care HCV Treatment and Triage Program to increase access to treatment. We are unaware of prior studies that have explored a pharmacist-centered primary care-based HCV treatment model in the era of newer direct-acting antiviral (DAA) medications.

Objectives: To gain a deeper understanding of the roles of each program staff member, as well as an understanding of how primary care providers (PCPs) who refer patients to the program perceive and interact with the program. Such an understanding will help promote implementation and dissemination of the program.

Methods: We conducted in-depth semi-structured interviews with six staff members and with five PCPs in the Section of General Internal Medicine at BMC who refer patients to the program. We asked staff members about their roles and their perception of the program's impact on patient linkage to HCV treatment.

We probed PCPs about their experiences with HCV screening, referral, and follow-up processes, and differences in accessing HCV treatment for their patients prior to and following the implementation of the program. We audiotaped and transcribed interviews, and identified major themes through qualitative analysis.

Results: We identified five major themes that characterize how the HCV treatment program delivers care: 1) efficiency ("So here I feel like…they get evaluated…they get treated. Boom, it's done"); 2) clear and open communication ("…one of the strengths of our program is that we have…a lot of direct contact with patients…"); 3) personalized medicine ("…I've set up the pill box for them [patients]…we tailor it to whatever they need"); 4) high patient engagement ("So if I get a referral for a patient…I call the patient three times. If I haven't heard from the patient…I send them a letter and I tell the PCP"); 5) patient empowerment through education ("I think patient education is the best thing…if the patient is involved then… they'll do what they need to do"). Additionally, the public health social worker and the pharmacist play key roles in the program. The social worker supports patients throughout treatment and addresses psychosocial barriers to treatment engagement ("I had a patient…who stopped taking his medication because his apartment was infested with bed bugs…[Social worker] got the patient furniture for free and got an exterminator…"). The pharmacist provides medication management during face-

to-face patient visits ("…I go over everything imaginable...proper adherence…adverse effects, interactions…").

Conclusions: The HCV treatment program at BMC is a promising model to deliver HCV treatment to urban, underserved patient populations. Our findings suggest that public health social workers and pharmacists may be one approach to increasing access to HCV treatment in primary care settings in the era of DAA medications. Further study of the program's efficacy in improving HCV outcomes is warranted.

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LIST OF ABBREVIATIONS

BMC……..Boston Medical Center

CCM……..Chronic Care Model

CM……..Case Manager

DAA……Direct-Acting Antiviral

ECHO……Extension for Community Healthcare Outcomes

ED……Emergency Department

EHR……..Electronic Health Record

FDA……..Food and Drug Administration

FQHC……Federally-Qualified Health Center

HAV…….Hepatitis A Virus

HBV…….Hepatitis B Virus

HCV…….Hepatitis C Virus

HIV……Human Immunodeficiency Virus

IDU……..Injection Drug User

IFN……...Interferon

IV……..Intravenous

MA……Medical Assistant

OBOT……Office Based Opioid Treatment with Buprenorphine

PA……...Prior Authorization

PCP……...Primary Care Provider

Peg-IFN……Pegylated Interferon

PPMI……....Pharmacy Practice Model Initiative

PTSD…….Post-Traumatic Stress Disorder

RBV……..Ribavirin

RN……Registered Nurse

RNA……...Ribonucleic Acid

SEP……..Syringe Exchange Program

SVR……Sustained Virologic Response

INTRODUCTION

Hepatitis C Virus (HCV) Infection – A Growing Problem

HCV is a primarily blood borne pathogen that infects the liver. The single-stranded ribonucleic acid (RNA) virus is prone to error during viral replication,[1] and thus there exist six major genotypes and multiple subtypes within each genotype.[2] Genotype 1 is the most prevalent genotype, accounting for 83.4 million cases (46.2%) globally.[3] In the United States, genotype 1 is the most common, accounting for 75.52% of cases, and genotypes 2 and 3 account for 12.46% and 10.36% of cases respectively. Genotypes 4-6 each account for <1.1% of cases.[3]

HCV is primarily transmitted through percutaneous methods. Common parenteral means of HCV transmission include the sharing of injection equipment by injection drug users (IDUs), the inadequate sterilization of medical equipment, and needle injuries in health care settings.[4] About 15-25% of individuals with HCV infection clear the virus without treatment. The remaining 75-85% of HCV-infected individuals develop chronic infections.[5] Acute HCV infection is mostly asymptomatic, and thus infections are rarely treated during this stage. Chronic HCV infection is also usually asymptomatic until symptoms appear as a result of liver decompensation.[6] Cirrhosis, the irreversible loss of liver cells and subsequent liver scarring, can lead to end-stage liver disease, hepatocellular carcinoma, and death if left untreated.[4] HCV-related end-stage liver disease is

the leading indication for liver transplantation among adults in the United States, accounting for more than 30% of liver transplant cases.[7]

An estimated 4.6 million people in the United States are HCV antibody-positive, indicating they have a past or current HCV infection. Of these, an estimated 3.5 million people are HCV RNA-positive, indicating they have a chronic HCV infection.[8] Furthermore, mortality rates associated with HCV infection are growing. Between 1999-2007, while deaths associated with human immunodeficiency virus (HIV) infection saw an age-adjusted annual decrease of .21 deaths per 100,000 people, deaths associated with HCV infection saw an age-adjusted annual increase of .18 deaths per 100,000 people.[9] Another report noted an age-adjusted annual increase in HCV-related deaths of .14 deaths per 100,000 people from 2003 to 2013.[10] Meanwhile, the rate decreased by .34 deaths per 100,000 people for a conglomerate of 60 infectious diseases over the same time period.[10]

HCV infection rates are not consistent across subgroups of the United States population. For example, the HCV antibody prevalence in adults born between 1945-1965 is 3.25%, which is five times higher than among adults born in any other year.[11] Three-fourths of all chronic HCV infections are among adults in this birth cohort.[11] Thus, a 2012 recommendation from the Centers for Disease Control and Prevention states that patients in the 1945-1965 birth cohort with no previous assessment of HCV risk should receive one-time HCV testing.[12] Additionally, previous HCV infection rate estimates may have been an

underestimate due to the omission of several vulnerable populations in sampling. Underrepresented groups that are at increased risk of HCV infection include individuals who are incarcerated, experiencing homelessness, and hospitalized, among others.[8] The weighted average HCV seroprevalence rates across several studies for these three groups were 23.1%, 32.1%, and 15.6% respectively,[8] compared to the 1.0% rate in the general population.[13] It is imperative to target high-risk populations for HCV screening and treatment to yield high cure rates.

Today there exists a HCV treatment cascade of care in which a small percentage of HCV-infected individuals complete treatment and achieve sustained virologic response (SVR). SVR is defined as the absence of detectable levels of viral RNA in the blood either 12 or 24 weeks after treatment completion.[14,15,16] For example, a retrospective cohort study at BMC found that 17% of patients with detectable viremia initiated HCV treatment between 2005-2011.[17] Additionally, only 1% of patients who engaged in HCV care in the same time period completed all five HCV quality indicators of care defined by the Centers for Medicare and Medicaid Services.[17] Between 2014-2015, only 21.3% of individuals in the 1945-1965 birth cohort were screened for HCV at urban and suburban internal medicine clinics in the Henry Ford Health System based in Detroit, Michigan.[18] Of the patients who tested positive, only 30% completed treatment.[18] Other analyses have described similar drop-offs between the proportion of patients who are diagnosed with HCV infection and those who complete treatment and achieve SVR.[19,20]

HCV Treatment in the Interferon Era

The history of HCV treatment and the strides made by the pharmaceutical and medical communities over the past few decades give context for low HCV linkage to care rates. Interferon (IFN)-based treatments were the standard of care for HCV genotype 1 from 1991 – 2013.[21] The original standard IFN treatment regimen was administered as an injection three times per week for six months, and resulted in SVR rates of 6% for HCV genotype 1.[21,22] In 1998, the United States Food and Drug Administration (FDA) approved an IFN and ribavirin (RBV)[23] combination and SVR rates for HCV genotype 1 increased to 32%.[21] Between 2001-2002, the FDA approved two pegylated interferon (peg-IFN) therapies,[24,25] and when combined with RBV, SVR rates for HCV genotype 1 increased to 43%.[21]

IFN-based therapies were suboptimal on several counts. First, SVR rates after therapy completion were low. Second, side effects were frequent and harsh, making treatment completion difficult. Common side effects of peg-IFN with RBV include fatigue, mild fevers, nausea, and coughing.[26] The treatment regimen can potentially exacerbate or initiate depression and other psychiatric symptoms.[26] IFN can induce neutropenia, a low count of a type of white blood cell called a neutrophil.[22] Neutropenia in some patients can increase risk of bacterial infections. RBV can also cause hemolytic anemia.[23] Third, medication administration was complex, lengthy, and uncomfortable. Peg-IFN came as a pen injection system or as a prefilled syringe for subcutaneous injection once

weekly.[26] Medication injection was intimidating for patients and a potential trigger for IDUs in recovery. Additionally, treatment duration was lengthy, with the regimen lasting 48 weeks for genotype 1 and 24 weeks for genotypes 2 and 3.[26] Due to serious side effects, low medication efficacy, and inconvenient methods of medication administration, patients were not motivated to begin treatment, and providers were not eager to refer patients for treatment.

Advent of Direct-Acting Antivirals (DAAs)

In 2011, the FDA approved the first direct-acting antivirals (DAAs) in combination with peg-IFN and RBV for treatment of HCV genotype 1. DAAs act directly on the viral life cycle and inhibit viral production.[14] For example, telaprevir (Incivek)[27] and boceprevir (Victrelis)[28] are both NS3/4A protease inhibitors; they inhibit the enzyme NS3/4A protease that is involved in post-translational processing of proteins.[14] In contrast, IFN acts on the immune system.[14] Telaprevir and boceprevir, in combination with peg-IFN and RBV, increased SVR rates to 70% for HCV genotype 1.[21] In 2013, the FDA approved two other DAAs, also in combination with peg-IFN and RBV. Simeprevir (Olysio)[29] and sofosbuvir (Sovaldi)[30] increased SVR rates for HCV genotype 1 treatment–naïve patients (those who had never previously undergone HCV treatment) to 80% and 90%, respectively.[21] DAAs presented new side effects in addition to those associated with peg-IFN and RBV, namely skin reactions and dysgeusia, a distortion in the sense of taste.[21]

Starting in 2014, the FDA began approving IFN-free HCV DAA therapies. Side effects drastically diminished without the IFN, and the number of treatment options for all genotypes increased. These medications include ledipasvir/sofosbuvir (Harvoni)[31] and ombitasvir/paritaprevir/ritonavir + dasabuvir (Viekira Pak)[32] approved in 2014, daclatasvir (Daklinza)[33] + sofosbuvir approved in 2015, and elbasvir/grazoprevir (Zepatier)[34] approved in 2016. Additionally, sofosbuvir/velpatasvir (Epclusa)[35] is the first regimen indicated to treat HCV genotypes 1-6, and SVR rates reach 95-100% across the six genotypes.[21] Treatment adherence is eased since IFN-free DAA therapies are taken orally instead of as injections, and treatment duration is eight or twelve weeks as opposed to the 24 or 48 weeks for IFN-based therapies. One exception is that treatment-experienced patients (those who have previously undergone HCV treatment) with cirrhosis may have to take the oral agents for 24 weeks.[36] Although barriers to treatment access associated with DAA medications exist, such as the high costs of the medications and the changing insurance requirements for prior authorizations (approvals from health plans to cover an ordered prescription), the improvements in the treatment process itself are substantial.

The advent of oral, DAA medications has improved adherence to HCV treatment by easing side effects, improving medication administration methods, and decreasing treatment duration. HCV treatment is also a cost-effective decision for the United States health care system.[37,38] With such treatment

enhancements, it is critical that DAA medications be accessible to HCV-infected patients.

Primary Care's Role in Increasing HCV Treatment Accessibility

Although oral IFN-free DAA therapies have improved medication adherence and treatment efficacy, the HCV treatment process continues to be complex and lengthy. Daily adherence and regular lab monitoring are needed, and substance use should be limited. Drug-drug interactions need to be monitored, especially given a high prevalence of chronic diseases[39] and increasing polypharmacy in the United States.[40] Additionally, many barriers to accessing HCV treatment still exist at the patient, provider, and system levels. Patient-level barriers include substance use,[41,42,43] unstable housing,[44] inadequate social support,[45,46] poor treatment literacy,[41,44,46,47,48] stigma,[41,43] transportation logistics to distant medical facilities,[41] low patient motivation,[44] and physical and psychological comorbidities.[42,44] Providers may also not have time to address or assess HCV infection.[46] A system-level barrier includes long appointment wait times at specialty clinics.[42,46] There is a need to support patients through the complex treatment schedule and to address barriers to care. One approach is to treat HCV infection in primary care as opposed to in specialty clinics.

Why might HCV treatment in primary care provide support for patients and reduce barriers to care? First, there is an insufficient supply of clinicians to treat HCV infection, and long appointment wait times to see such clinicians are

associated with high no-show rates.[42,49,50] HCV treatment provided by primary care providers (PCPs) increases the number of providers who deliver care and thus may reduce appointment wait times. Second, treatment in a new specialty clinic where patients are unfamiliar with staff and clinic procedures may be a deterrent to seeking care. On the other hand, the familiarity of a primary care clinic may facilitate patient education, counseling, and general support. Oftentimes patients with HCV have co-morbidities such as diabetes, and health behaviors such as tobacco and other substance use that can be more effectively monitored and treated at the same location as their HCV treatment. Third, many patients with HCV infection do not have a consistent home address, phone number, or mode of transportation. The lack of dependable communication and transportation makes it difficult to establish contact between a patient and a new clinic. The primary care setting may enable face-to-face engagement about HCV treatment in a location that is familiar to patients.

In March 2017, we conducted a literature search to identify studies that assessed HCV treatment in primary care. We aimed to better understand the models through which primary care settings deliver HCV treatment. We only included studies that incorporated HCV treatment into a primary care setting; studies that solely integrated HCV screening or linkage-to-care efforts were excluded. We found twelve studies published between 2006-2017 that met our criteria. One-third (4/12) of programs were geared specifically towards increasing HCV treatment access among IDUs.[51,52,53,54] Two studies had primary

outcomes other than increasing HCV treatment access in primary care: one focused on increasing HCV screening and linkage-to-care rates,[55] and a second focused on the implementation of a weekly HCV treatment support group.[51] Nonetheless, both studies incorporated HCV treatment into a primary care setting and were thus included in our review. Finally, one study incorporated HCV treatment into four federally-qualified health centers (FQHCs), as well as six syringe exchange programs (SEPs) and two collocated FQHCs and SEPs.[55] The health care settings in all twelve studies served high-risk and underserved populations.

We found no published studies of treatment programs that were implemented solely in the era of newer oral agents. All twelve studies utilized at least some IFN-based treatment. Ten studies utilized peg-IFN and RBV exclusively. One study utilized triple therapy exclusively (telaprevir or boceprevir in combination with peg-IFN and RBV),[56] and another study utilized triple therapy in 26.4% of patients and peg-IFN and RBV regimens in the remaining cases.[57] Eight programs were implemented in urban settings, two in rural settings,[57,58] and two in mixed (urban, suburban, and/or rural) settings.[59,60] Two of the studies in urban settings occurred at the same site,[56,61] and the two programs utilized in rural areas both incorporated Project Extension for Community Healthcare Outcomes (ECHO) clinics.[57,58] The Project ECHO model utilizes videoconferencing technology for specialists to train PCPs in HCV treatment, and

it has been widely accepted as a successful model for HCV treatment expansion into primary care.[58]

Two-thirds (8/12) of studies utilized patient navigation. Patient navigation connects and integrates healthcare systems so that patients move swiftly through a complex continuum of care.[62] Patient navigation tasks may include, but are not limited to: communicating with patients, referring patients to social and addiction support programs, and organizing referrals, insurance logistics, transportation, and appointment escorts.[62] Patient navigation is a useful method for ensuring treatment adherence in a vulnerable patient population facing significant barriers to care. Although a majority of programs utilized patient navigation in their models, its implementation looked different from program to program. For example, three programs assigned patient navigation tasks to clinical staff, such as registered nurses (RNs)[52,58,60] and medical assistants (MAs).[58] Another study utilized a counselor to provide practical and therapeutic support to patients.[54] Four other studies used HCV patient navigators,[55,56,57,61] but none specified a public health social worker in the role of a patient navigator. Finally, one-third (4/12) of studies did not mention a patient navigator role.[51,53,59,63]

HCV-specific education or training for patient navigation was only specified in one of the eight studies, and it consisted of a five day training in a HCV-focused navigation curriculum (e.g. navigation protocols, data collection, expectations, data reporting, and caseload management).[55] Interestingly, the three studies that implemented Project ECHO clinic sessions varied in their

patient navigation (one relied on the local health department or a HCV patient navigator in higher volume clinics depending on the state and need,[57] one used a RN coordinator,[60] and one used either a RN or MA coordinator[58]).

One-third (4/12) of studies utilized a pharmacist as part of a multidisciplinary specialist team[57,58] or a primary care HCV treatment team.[60,63] Multidisciplinary specialist teams served as resources and supports for PCPs implementing HCV treatment, such as those that provided guidance with videoconferencing technology in the Project ECHO clinics. Multidisciplinary primary care HCV treatment teams determined treatment plans and delivered HCV care. In one program, a pharmacist was part of the health center that implemented HCV treatment, but the paper did not specify a direct role for the pharmacist in the HCV treatment process.[52] None of the studies ascribed a leading or managerial role in HCV treatment to the pharmacist. Seven studies did not mention a pharmacist role.

Pharmacist-provided treatment programs have effectively managed patients and their medications in chronic diseases such as diabetes,[64] hypertension,[65,66,67] and high cholesterol.[68] A few health systems have implemented pharmacist-provided medication management models for HCV treatment, but none as far as we know have been in primary care settings or have exclusively utilized IFN-free, DAA treatment regimens. Rather, health systems implemented these models in specialty clinics and during the IFN era.[69,70,71]

The treatment models in the twelve studies reviewed here demonstrate that primary care centers are well positioned to play a major role in increasing access to HCV treatment, especially in more vulnerable populations. As of March 2017, we are unaware of primary care-based HCV treatment programs that follow the model implemented at Boston Medical Center (BMC), namely that of a pharmacist-provided medication management program utilizing a public health social worker as a patient navigator in the era of DAA therapies. The following section describes the HCV treatment program at BMC in more depth.

Primary Care HCV Treatment Program at Boston Medical Center (BMC)

The Adult Primary Care HCV Treatment and Triage Program was implemented in March 2015 in the Section of General Internal Medicine at BMC. The program was established in anticipation of a greater volume of patients expressing interest in HCV treatment following the advent of new, IFN-free, DAA medications. The program is based on the Chronic Care Model (CCM), a multidimensional approach to improving chronic disease care in primary care.[72] Revenue generated from the 340B drug discount program supported the employment of a multidisciplinary HCV treatment delivery team and implementation of the program. Under the 340B drug discount program, safety-net providers purchase drugs from manufacturers at lower prices than the insurance reimbursements they receive, thus generating revenue when patients fill their prescriptions at safety-net setting pharmacies.[73]

Lasser et al. describe the structure of the primary care HCV treatment program at BMC.[74] Briefly, the program utilizes the following staff members: a public health social worker (hereon called "case manager"); a pharmacist; a pharmacy technician; and general internists trained to treat HCV (hereon called "PCP treaters"). As part of training, PCP treaters complete American Association for the Study of Liver Diseases online training modules and shadow a specialist physician who treats HCV-infected patients for one four-hour clinic session.[75] PCPs may consult specialist physicians for clinical backup by phone and electronic messaging.

The program receives referrals from several sources. General internal medicine PCPs who are not trained to treat HCV (hereon called "referring PCPs") refer patients to the program. To aid referring PCPs in screening for HCV infection, the program implemented a "best practice alert" in the electronic health record (EHR) at BMC in April 2016. This alert notifies providers to complete a one-time HCV test of patients in the 1945-1965 birth cohort. The program also receives notifications of all positive HCV antibody results from the BMC laboratory and of HCV-infected patients who are not engaged in care from the BMC EHR. Lastly, the program accepts peer referrals from community programs and referrals from the BMC Emergency Department (ED).

The case manager reviews charts of referred patients and reaches the following patients by phone call to schedule an initial appointment with a PCP treater: those who have active viremia, who are not connected to treatment, and

who do not have co-morbidities that would require specialty care. Patients co-infected with HIV are referred to infectious disease; patients with hepatitis B virus (HBV) infection, decompensated cirrhosis, or other significant comorbidities are referred to gastroenterology. Throughout a patient's participation in the program, the case manager delivers patient education, appointment reminders, and transportation assistance. Additionally, the case manager maintains a log of patient interactions, outreach, and updates to help with patient management.

At the initial visit, the PCP treater assesses a patient's HCV infection and gathers treatment and substance use history to gauge the risk of non-adherence to treatment and reinfection. The PCP treater encourages avoidance of alcohol use and orders tests, including HCV genotype testing, complete blood count and INR, a complete metabolic panel, and hepatitis A virus (HAV), HBV, and HIV serology. Additionally, the PCP treater places orders for the patient to obtain a FibroSure, FibroScan, and abdominal ultrasound.

Whenever possible, the PCP treater pages the case manager at the end of the appointment to do a warm handoff, a referral practice where a provider introduces a patient to another provider in-person. The case manager's office is located within the Adult Primary Care Clinic, and this proximity eases the patient's transition to the program. The case manager completes an intake assessment of the patient's income, housing, mental health, substance use, and other social determinants of health. The case manager follows up on any patient

needs through referrals to appropriate resources, such as job training, counseling, substance use treatment, and housing resources.

At the second visit with the PCP treater, the PCP treater and patient review the results of labs and other tests. If patient readiness and motivation with regards to psychosocial factors and medication adherence are once again affirmed, the PCP treater prescribes the appropriate medication. The patient also receives HAV and HBV vaccines as needed.

When the order for the HCV medication reaches the pharmacy, the pharmacy technician obtains the prior authorization (PA) for the treatment through the patient's insurance company. If the request for the PA is denied, the pharmacy technician in collaboration with the pharmacist collects relevant records to build a case for an appeal. If the appeal is also denied, the case manager notifies the patient that they must wait one year before requesting a re-evaluation.

Patients for whom treatment is approved meet with the pharmacist before initiating treatment. The pharmacist teaches patients how to administer the medication, and about adverse effects and the importance of adherence. The pharmacist contacts patients two weeks into their treatment course to check about adverse effects and to remind patients to pick up their medication refills. The pharmacist also meets with patients four weeks into the treatment course and at its completion. At both of these visits, the pharmacist orders lab tests and assesses adherence and adverse effects.

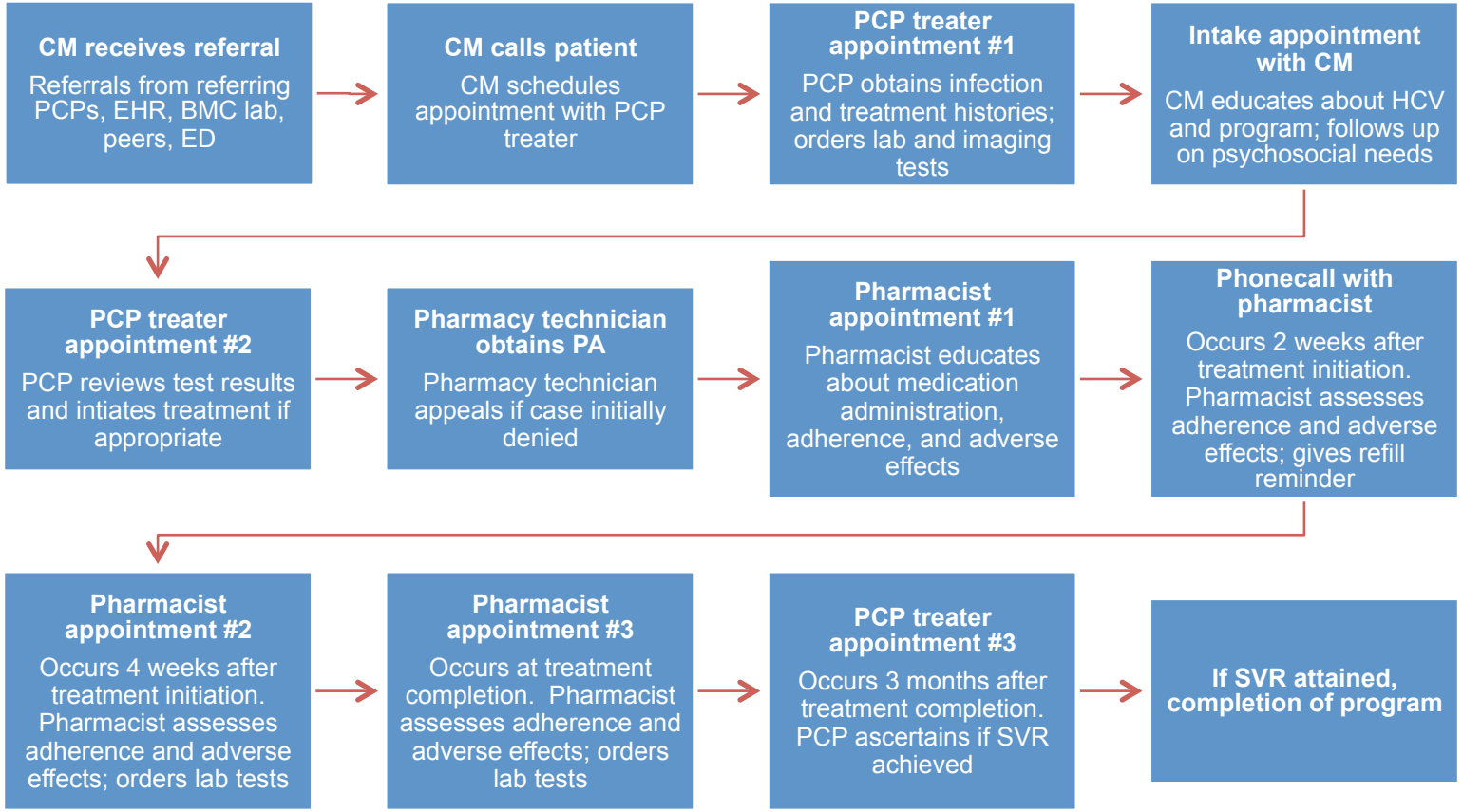
Lastly, patients attend their final appointment with the PCP treater three months after their treatment completion. At this visit, the PCP treater checks the HCV RNA to determine whether SVR is attained.[74] Table 1 outlines the tasks of each of the program staff. Figure 1 shows the flow of treatment in the program. Since the program implementation in March 2015, 46 patients attended the last appointment with the PCP treater and all achieved SVR.

Table 1: Descriptions of staff roles in the primary care hepatitis C virus (HCV) treatment program at Boston Medical Center (BMC)

Program staff role	Role Description
Case Manager	• Educates patients about HCV and the HCV treatment program • Schedules appointments with PCP treaters • Provides appointment reminder phone calls and addresses various psychosocial needs • Maintains patient log with communication and treatment details, from referral to discharge
PCP Treater	• Visit #1: obtains infection, treatment, and substance use histories; orders lab and imaging tests • Visit #2: reviews test results, assesses motivation and readiness for treatment, prescribes indicated agent • Visit #3: checks HCV RNA to assess SVR attainment
Pharmacist	• Educates patients about medication administration, adverse effects, and importance of adherence • Assesses adverse effects and reminds patients about medication refills by phone call • Meets with patients during and at the end of treatment for lab testing and assessment of adherence and adverse effects
Pharmacy Technician	• Prepares PA paperwork • Appeals if PA is denied

Abbreviations: Case Manager – public health social worker; PA – prior authorization; PCP – primary care provider; PCP treater – general internal medicine PCP trained to treat HCV; RNA – ribonucleic acid; SVR – sustained virologic response

Figure 1: Flow chart of the primary care hepatitis C virus (HCV) treatment program at Boston Medical Center (BMC)



Abbreviations: CM – case manager (public health social worker); ED – Emergency Department; EHR – electronic health record; PA – prior authorization; PCP – primary care provider; PCP treater – general internal medicine PCP trained to treat HCV; referring PCP – general internal medicine PCP who refers patients to the program; SVR – sustained virologic response

SPECIFIC AIMS AND OBJECTIVES

The aims of this research are twofold. The first objective is to gain a deeper understanding of the roles and activities of each program staff member in the primary care HCV treatment program in the Section of General Internal Medicine at BMC. A greater knowledge of the team members' tasks and the ways in which the team members collaborate will help facilitate the dissemination and implementation of the program in other primary care settings.

The second objective is to gain an understanding of how PCPs who refer patients to the program perceive and interact with the program – its components and delivery of care. Knowledge of referring PCPs' experience of the program will also help facilitate the dissemination and implementation of the program in other primary care settings.

METHODS

Setting

The Adult Primary Care Practice is an accredited patient-centered medical home situated at BMC, New England's largest safety-net hospital. BMC serves a predominantly multicultural and low-income population. Thirty-one percent of patients at BMC do not speak English as their primary language, and fifty-nine percent of patients are from under-served populations.[76]

Participants

Between March – June 2016, a research assistant (EAJ) invited staff members of the primary care HCV treatment program to participate in an open-ended, semi-structured interview lasting 30-60 minutes. Appendix A contains the study recruitment email used to reach staff members. The research assistant conducted face-to-face, audio-recorded interviews in a confidential space with staff members who were willing to participate. Six program staff members participated: the medical director, case manager, pharmacy technician, pharmacist, practice manager, and a PCP treater. The medical director was also a PCP treater, and the other PCP treater interviewed was a suboxone prescriber in BMC's Office Based Opioid Treatment with Buprenorphine (OBOT) Program.

We also aimed to conduct semi-structured interviews with patients, in order to hear their perspective on engagement with the HCV treatment program. We particularly wished to hear from patients who were not engaging with the program: patients who we were unable to contact, who were missing their initial

visit with the PCP treater, or who were not following through on the steps towards treatment initiation. We suspect that due to substance use and other chaotic life factors, it was difficult to reach these patients for an interview. We amended the initial study protocol to conduct interviews with referring PCPs instead. We believed that referring PCPs would have important insights on their encounters with the HCV treatment program that would help us more fully understand the program's mechanisms.

Between October – November 2016, the Principal Investigator (KEL) invited PCPs in the Section of General Internal Medicine at BMC to participate in a 30-minute open-ended, semi-structured interview. Inclusion criteria required that PCPs had referred at least one patient to the primary care HCV treatment program and that their employment at BMC preceded the program implementation in March 2015. Our goal was to interview referring PCPs who could compare their experiences in accessing HCV treatment for their patients before and after program implementation. Previously, the vast majority of PCPs referred their patients to a specialty clinic for HCV treatment, either gastroenterology or infectious disease. One referring PCP was trained to treat HCV in primary care in the IFN era, but treated few patients. Appendix B contains the email used to recruit referring PCPs. A research assistant (MMB) administered the in-person, audio-recorded interview in a confidential space with those referring PCPs who wished to participate. Five referring PCPs participated in the study out of nine who were emailed.

The Boston Medical Center/Boston University School of Medicine Institutional Review Board approved this protocol. Written consent was obtained from all participating program staff members and referring PCPs.

Data Collection

Our aim with the staff member interviews was to explore staff perspectives on the effectiveness of the program and its various components, as well as barriers to its success. Specifically, we were interested in how staff members perceive the program's impact on patient linkage to HCV treatment, staff member roles, and resource utilization. Our objective with the referring PCP interviews was to ascertain their experiences with HCV screening in their patient population, and with referral and follow-up processes of patients seeking HCV treatment. Additionally, we were seeking their perspective on differences in access to care for their patients from before the program implementation, when specialty clinic referrals were the norm, to after.

The research team developed the program staff interview instrument, which is available in Appendix C. In the first part of the interview, we asked participants to describe their role in the primary care HCV treatment program, their professional background, and any specialized training they may have received in HCV treatment. We further probed about their roles by asking participants how they played a part in providing HCV treatment for a recent patient. In the second part of the interview, we probed participants about any changes they have seen in processes, demand levels, and time frames

associated with access to care since the program implementation. We also asked participants to describe changes in costs associated with program and patient management. We utilized information gained from these probes in a budget impact analysis of the program, a separate project that also utilized information gleaned from the interview transcripts. Towards the end of the interview, we asked participants to describe facilitators and barriers to the success of the program, and their viewpoints on strategies for promoting HCV care in primary care.

The research team designed the referring PCP interview instrument by building on several themes identified in the staff interviews, such as procedural changes in accessing HCV treatment since the program implementation, barriers to care, and program staff roles. The research team also sought insight from a medical sociologist with expertise in qualitative research (JAC). Appendix D displays the referring PCP interview instrument. During the in-person interview, we used probes as they fit most naturally to the flow of the conversation. Initial questions asked referring PCPs to specify their role in and perception of the screening and referral processes prior to the program implementation. We also probed participants about any barriers to care they were aware of prior to the program onset, specifically barriers at the patient, provider, and system levels. At the patient level, we were interested in barriers associated with medication side effects, substance use, and various social determinants of health, such as social and economic environments and transportation. At the provider level, we

probed participants about remembering to screen patients for HCV, having the time to address HCV infection, and abstinence requirements for treatment. At the system level, we probed participants about the logistics of making referrals to and scheduling appointments with specialty clinics, and about appointment wait times.

The second part of the referring PCP interview instrument focused on HCV treatment access following the implementation of the primary care program. We asked referring PCPs about any changes in the screening and referral processes that they have experienced. We also probed participants about their awareness of how different team members of the program (e.g. case manager, PCP treater, pharmacy technician, and pharmacist) support them and their patients. We wanted to know how referring PCPs view the primary care program's effectiveness in addressing the barriers they had named in the first half of the interview. We also probed about any changes in their level of satisfaction with the accessibility and quality of treatment since the program implementation, and changes in the time frame from when they make a referral to when a patient begins treatment. Finally, we probed participants about current barriers to patient engagement in treatment, and about a patient whom they had recently referred to the program.

We concluded both the program staff interviews and the referring PCP interviews by asking demographic questions. We maintained participants' confidentiality with an anonymous numbering system for the audio recordings,

interview guides, and interview transcripts. We offered program staff and referring PCPs a $25 gift card at the completion of the interview.

Data Analysis

Two research assistants (VT and MMB) transcribed audio-recordings verbatim. One research assistant (MMB) imported interview transcripts into NVivo Software 10 for data management, coding, and analysis.[77] Interviews and data analysis occurred concurrently, allowing for modifications to the interview guide and the order in which we delivered probes. In accordance with grounded theory practice, a research assistant (MMB) initiated the coding process by identifying major categories of information within the raw text of the interview transcripts.[78] We utilized the major categories of information to organize the data and to build coding frameworks. We created some concrete codes to describe the HCV program components and processes. We also applied thematic codes, like the perspectives of program staff and referring PCPs towards patient education, medications, and the role of the HCV program. The research assistant (MMB) subsequently created subcategories around themes emerging from the data.[78] Afterwards, we built narratives and relationships across the major themes around a core category.[78] A research team read through the transcripts and met to discuss emerging codes and themes, allowing for an iterative approach to analysis of the interview data.

RESULTS

Themes associated with treatment access in the primary care HCV treatment program

Staff members of the primary care HCV treatment program and referring PCPs identified several themes associated with the program's HCV treatment delivery to an urban, underserved population. Themes include efficiency, clear and open communication, personalized medicine, high patient engagement, and patient empowerment through education. Table 2 contains representative quotes from interview transcripts corresponding to each theme.

Efficiency

Efficiency in the HCV treatment program is identified as a faster treatment process and a smoother referral process. The faster treatment process is due to a few factors: the case manager proactively engages the patient to schedule an initial appointment with the PCP treater; the pharmacy technician works diligently with insurance companies to obtain the PA for the prescribed agent; and PCP treaters increase the number of providers available to deliver HCV treatment. These factors may accelerate the linkage-to-care and treatment initiation processes. Additionally, the referral logistics are smoother for patients and providers because they occur within the same clinic. The case manager's office is near the Adult Primary Care Clinic, and thus referring PCPs may engage in organic interactions with the case manager, such as paging her to do a warm handoff or knocking on her door to discuss a patient case. Patients may also be

familiar with the location and processes of the primary care setting, which may further ease the transition.

Clear and open communication

Program staff and referring PCPs described clear and open communication at multiple levels within the program. First, the staff communicate with referring PCPs through the EHR system about treatment updates and other medical issues. One referring PCP mentioned how the case manager "sends me notes: 'I was talking to so and so about their HCV and, by the way, they mentioned they need this, that, and the other thing.'" The case manager connects back with referring PCPs to notify them of patients' needs.

Second, the program staff complete comprehensive documentation of outreach efforts and treatment updates. The thorough notes allow referring PCPs to stay informed about a patient's HCV treatment status. Third, staff members communicate extensively with each other. As a multidisciplinary treatment team, the staff support one another in contacting patients, working on PAs and appeals, providing medication management, and addressing other psychosocial needs. One staff member explains that HCV treatment is challenging for one provider to deliver on his or her own, especially when each medication has a unique PA requirement and medication management is extensive. The collaborative nature of the program helps because, "just having each individual that can assist, it just makes it go smoothly".

Lastly, the program communicates frequently with patients, which allows the staff to provide support and to keep patients involved in their care. Specifically, the case manager and pharmacist play central roles. The case manager engages in patient navigation, and the pharmacist facilitates detailed and consistent follow-up and teaching appointments with patients. One referring PCP mentioned the following when she saw documentation of program staff placing phone calls to patients about medication refill reminders: "[the communication is] like all the things we wish would happen for every single other medication. It seems like there's that extra level of detail".

Personalized medicine

The program personalizes HCV treatment delivery in at least four ways. First, program staff ensure that treatment is conducive to a patient's physical, social, and emotional environments. For example, the pharmacist dispenses a week's worth of medication to patients living in shelters if patients are uncomfortable holding on to all the medication. In another instance, the pharmacy technician may have vulnerable patients sign a document that authorizes the pharmacy technician to be the designated representative for handling appeals with insurance companies on behalf of the patient. A staff member explains the circumstances around such a decision:

> However, with Hepatitis C, we found that with managed care plans, they add an extra step…it requires the patient to consent with the insurance and there is also not usually a very direct phone number, a direct way of contacting the insurance to authorize this appeal. And because, you know, a lot of times there's language barriers or cultural barriers, or even just like, homelessness, no access to telephones. It's hard for patients to know how and when to authorize an appeal.

> So to bypass this we've had patients sign forms from the drug company [sic] that authorizes the liaison [pharmacy technician] or the provider as a designated representative to handle the appeal on behalf of the patient.

In another example, the program accommodates HCV treatment delivery to alleviate patients' discomfort and anxiety. Program staff and referring PCPs perceived that patients are nervous about navigating the various steps in the HCV treatment process, such as finding the pharmacy to pick up their medications. Getting stuck by a needle for lab tests may be a potential trigger for patients who are in recovery from intravenous (IV) drug use, and it may bring them discomfort. Patients who are simultaneously receiving treatment for their opioid dependency in the OBOT program may experience apprehension associated with their recovery process. In response, the pharmacy technician has the flexibility to show patients the way to the pharmacy or blood-draw station. This may seem like a small gesture, but it helps patients to progress from one step in the treatment process to the next. The pharmacist and case manager may also provide added outreach and support for patients in substance use treatment.

Second, the pharmacist sets up individualized reminders for patients to take medication daily, such as cell phone alarms or signs for a patient's refrigerator. Third, the pharmacist utilizes comprehensive teaching methods, such as pillboxes and teach-back methods, which are geared to each patient's learning style and other health-related issues. Health care providers use teach-back methods to ensure that patients understand the communicated information

whereby they ask patients to “teach-back” the information. Lastly, the case manager personalizes her communication to whichever format works best for patients, including text messaging, phone calls, and letters.

High patient engagement

Program staff exert a high level of patient engagement through proactivity in connecting a patient to care, warm handoffs, and time investment when meeting with patients. The case manager calls a patient three times and sends a letter in an attempt to schedule an intake appointment. The warm handoff between the referring PCP or PCP treater and the case manager may alleviate patients’ apprehension about engaging unfamiliar health professionals and begin the trust-building process between the patient and the program. The program staff also devote a significant amount of time when meeting with patients, which may provide patients with comfort and a safe space to acknowledge concerns about their HCV diagnosis. Additionally, program staff and referring PCPs discussed how patients go through a cognitive journey of acceptance of their HCV diagnosis. One referring PCP describes the cognitive process in this way: “…maybe it’s that model of acceptance, right, and they kind of go through denial and bargaining and all of the like, the seven stages before they get to acceptance and that may be what we’re seeing here.“ The time that program staff take to accompany patients as they accept their diagnosis may help patients initiate and follow through on treatment.

Patient empowerment through education

Patients may associate HCV treatment with the arduous and painful side effects of IFN-based medications and their low success rates in clearing the virus. Some patients have watched friends or family members, or have themselves gone through the IFN-based treatments. They have unpleasant and stress-inducing associations with the idea of HCV treatment. Patients may be unaware of the fewer side effects, shorter treatment course, and higher SVR rates of the IFN-free, DAA therapies. Staff members emphasize education about the responsibilities, timeline, and nature of HCV treatment during meetings with patients, including the difference between IFN-based treatments and DAA therapies. One referring PCP describes the circumstance surrounding the education she provides to patients:

> …so the older, the people I would say who are in their fifties, sixties, seventies who have it, all know people who suffered or they themselves suffered through the treatment, so I've definitely, when I bring it up, they like jump to the ceiling and I have to talk them off the ceiling. I mean, they really have post-traumatic stress disorder (PTSD) from these treatments.

Knowledge about the program and treatment options alleviates patients' stress and allows patients to make informed decisions regarding treatment.

Table 2: Themes associated with hepatitis C virus (HCV) treatment access in the primary care HCV treatment program at Boston Medical Center (BMC)

Program Theme	Description	Example from interview transcript
Efficiency	Faster treatment process	P4: "So here I feel like it's (clap, clap), they get evaluated, boom, boom (clap, clap), [Case Manager] sets them up, they get treated. Boom, it's done."
	Smoother referral process due to proximity of program to primary care clinic	P1: "Well, again, it just seems like it's much smoother and it seems like, I mean, part of it is right there, so it is a lot easier for me to know what's going on. And I've talked to [Case Manager] and asked her questions and if I have a question, I literally go knock on her door."
Clear and open communication	Communication with referring PCPs via EHR system	P2: "But she's very good about sending messages in Epic [EHR] to say like, 'this patient didn't show up, or this patient showed up and we're going to begin treatment', or whatever. So I find that communication really helpful."
	Thorough documentation of outreach efforts and treatment updates by staff	P1: "…they've also done a good job of making it clear, which is just important from the perspective of the PCP in the chart, like this is the FibroScan, this is the genotype, you know, he has active HCV, he doesn't qualify for treatment, we're going to check this in 6 months, and then go from there, so it's like really clear."
	Communication between staff members	S4: "I now have a lot of support with our pharmacy team, so [pharmacist] and then [pharmacy technician]. And they are super helpful and definitely a very important part of our team in terms of doing the other legs of what we do…we are constantly in communication, the three of us about what's going on with patients and where they are… and we loop in the treater [PCP treater] as well so that we're all kind of on the same page. There's a lot of communication back and forth…"
	Communication with patients	S4: "…I do think one of the strengths of our program is that we have the opportunity to have a lot of direct contact with patients, whether that's in reminder calls or me spending a long time with patients, you know, after their provider visit, talking about HCV and explaining and kind of learning more about the patient and what their life is like and you know, I think a lot of that is really valuable…"

Abbreviations: Case manager – public health social worker; EHR – electronic health record; PCP – primary care provider; PCP treater – general internal medicine PCP trained to treat HCV; referring PCP – general internal medicine PCP who refers patients to the program

(Table 2 Continued)

Personalized medicine	Accommodation of treatment access to patient's physical, social, and emotional environments	S2: "If they're living in a shelter and they don't feel comfortable with giving a full month of Harvoni to someone in the shelter then, you know, I can make a plan with the patient like, 'Hey, I'm going to bill the insurance for an entire month of drug but, you know, I'm going to count out seven, put it in a bottle, and we're going to keep the stock in the pharmacy. You have seven. Come back every week to see me and I'll give you.'"
	Individualized reminders for patient to take medication daily	S5: "Even we have patients with psych issues that I've sat down with them, I've set up the pill box for them and I've set an alarm on their cell phone for them so that they can like have so many different reminders. Like we tailor it to whatever they need. So like I've typed up a letter, I mean like a reminder sign in big letters that I've had patients put on their fridge or on their door. I don't usually have a lot that miss."
	Comprehensive teaching methods utilized to educate patient about the medication regimen and treatment process	S5: "When we do the teaching, I sit down with them, I go over everything imaginable, like I go over how to take it, their proper adherence, you know what could happen if you don't adhere to the medication, resistance, you know, avoiding alcohol and drugs…we talk about adverse effects. Interactions. I go over their med list and make sure things are up to date because I always do an interaction check before I see them…and then we go over the timeline, when they're going to start, when they're going to finish, when we're going to see them, what the blood work means, everything."
	Individualized communication with patient – texts, calls, letters	S5: "[Case manager] plays a big part in that, calling and following up with them if they don't show up, calling them twice, sending them a letter, text messaging them with the SMS phone from here."
High patient engagement	Proactive effort to keep patient connected to care	S4: "So if I get a referral for a patient from a PCP, I call the patient three times. If I haven't heard from the patient after the third phone call, I send them a letter and I tell the PCP. If the patient books an appointment during one of those first three phone calls, and no shows it, they get three calls following up to try and get them back in. If they don't answer, they get a letter. If they no show that first appointment and they get those three calls, and they set up a new appointment and no show the second one, I send them a letter. So there's a lot of effort that goes in to trying to, you know, engage the patients."

Abbreviations: Case manager – public health social worker; PCP – primary care provider; SMS – short message service

(Table 2 Continued)

High patient engagement continued	Warm handoff	P1: "I think a lot of times if somebody is interested, at least that initial engagement, and I'm using that word in purpose, because I think there's something about saying, 'Hey, you're interested in being treated for HCV?', and like you, if [Case Manager] is usually there and has enough flexibility where I can walk the person down the hall, and if the patient has enough time, she'll talk to them and…then you're matching a name, I mean a face, with this new program, and so."
	Time investment when meeting with patient	S4: "So I spent a long time meeting with him. I talked with his [referring] PCP and I talked with…the doctor who treated him just to make sure that everybody was kind of on the same page. We talked about outpatient addiction resources…he came and met with me twice and that was like two weeks after his overdose…I wanted to make sure he had the resources that he needed. And so I think that was kind of a major role that I play with patients, is just trying to stay involved in their lives and make sure they know that I am here if they need resources."
Patient empowerment through education	Education about the responsibilities, timeline, and nature of the treatment process	S2: "I think patient education is the best thing. I think, you know, if patients want the treatment they'll get the treatment…I think educating the patients on the seriousness and how important even just the, how expensive…the treatment is…I think if the patient is involved then they'll show up for every appointment and they'll do what they need to do."
	Education about DAAs in contrast to IFN-based therapies	P4: "And I've convinced a number of patients to go for treatment who, you know, were drug addicts for many years and who saw their young, you know, who are like in their sixties, fifties, sixties, seventies, who saw their peers die of HCV, you know, 10-15 years ago. Or see them have horrible experiences with the [IFN-based] treatment, so they're really prejudiced against it."

Abbreviations: Case manager – public health social worker; DAA – direct-acting antiviral; IFN – interferon; PCP – primary care provider; referring PCP – general internal medicine PCP who refers patients to the program

Primary care HCV treatment program staff roles

The four main staff members – the case manager, PCP treater, pharmacist, and pharmacy technician – undertake unique roles in the program. Perceptions of these roles provided by the staff and referring PCPs elucidate how staff members work together and what makes each role valuable. Table 3 summarizes these viewpoints and includes representative quotes from the interview transcripts.

Case manager

The case manager plays a central role in connecting program staff with each other, program staff with patients, and the program to the primary care clinic of which it is a part. The case manager is well informed about a patient's needs and involved at every step of the treatment process. The case manager is thus the central contact person for patients and other staff members, who are involved at different points of the treatment process. She ensures that the patient keeps moving forward toward treatment completion. The case manager describes her role in the following manner:

> [I am] the person who follows them [patients] through that whole process. I have a lot of support from other team members, but I think I'm kind of the person that they can connect with through the whole thing because the other team members will come in at different places.

Other staff members rely on the case manager as an extra resource, possibly due to the case manager's broad involvement at every step of the HCV treatment process. For example, they depend on the case manager to follow up with patients who miss an appointment or to inform patients of HCV treatment

logistics. Referring PCPs also appreciate the case manager's notifications about patients' progress through treatment. Referring PCPs are reassured that the case manager is following up with patients and relaying relevant information back to them. The case manager's role in facilitating communication between the staff and the referring PCPs may smooth the referral process and effectively embed the HCV treatment program in the primary care clinic.

PCP treater

The program staff perceive the PCP treater to experience satisfaction in treating a disease that previously was not directly under a PCP's purview. Because PCP treaters focus solely on the HCV infection during the appointment, the office visit seems less complicated than a regular PCP appointment where multiple chronic and acute issues are addressed simultaneously. One PCP treater described delivering HCV treatment in the following manner: "…in a way, it has made my life as a PCP easier because a HCV visit is by definition easier than an average primary care visit because you're only focusing on one issue…you'll find that people treating HCV, they enjoy it, it's satisfying for them." Additionally, referring PCPs also appreciate the updates they receive from PCP treaters, who may serve as another link between the program and the primary care clinic in which it is housed.

Pharmacist

Both staff members and referring PCPs recognize that the pharmacist delivers the time-consuming and labor-intensive components of HCV treatment

management, such as medication administration and follow up regarding adverse effects, medication adherence, and lab tests. One PCP treater describes her perspective on the pharmacist's role in the program:

> I think in general pharmacists do a lot more than is like kind of visible to us as physicians. And, because it makes sense that she does the counseling for it, adherence counseling, the way to take the medication, and then contacts you by phone and then also has them [patients] come in, I think every 4 weeks or something like that.

The pharmacist's role is significant for the implementation of the numerous treatment steps.

Pharmacy technician

The pharmacy technician plays a critical role for treatment accessibility by obtaining the PA, without which patients cannot obtain their medications. Additionally, the pharmacy technician takes some workload off of referring PCPs and PCP treaters, who in other settings and for other tests/medications may need to be involved in the PA process. Additionally, the partnership between the pharmacist and pharmacy technician is essential for the effectiveness of both roles. The pharmacy technician relies on the pharmacist for guidance with more complex appeals. The pharmacist relies on the pharmacy technician to handle communication with insurance companies, appointment scheduling, and follow-up with patients about additional matters. This working relationship ensures that medication regimens are not interrupted mid-treatment due to insurance or logistics issues and that the greatest number of patients can obtain PAs and begin treatment.

Table 3: Perspectives on program staff roles in the primary care hepatitis C virus (HCV) treatment program at Boston Medical Center (BMC)

Program staff role	Staff view of role	Example from interview transcript	Referring PCP view of role	Example from interview transcript
Case Manager	CM is an extra resource to rely on	S5: "[CM] is always available to me as an extra resource, so if I needed her to reach out to that patient if I didn't have the time or the resources to reach out to that patient, for additional adherence issues, she would certainly do so."	Communication from the CM is helpful	P4: "[CM] is great, she'll flag me if there's other concerns that have come up in the HCV treatment, which are other medical or primary care concerns."
PCP treater	An appointment with a PCP treater is more straightforward than one with a PCP non-treater because only focused on one issue	S3: "…it's actually very easy for them because it's only one problem that they are addressing in the visit as opposed to trying to do diabetes, hypertension, and many, many other things that patients come up [with]. In their primary care visit, they just target HCV, which is a good thing for them because it's a very focused visit. It's kind of like being a specialist in a way."	Appreciation for updates from PCP treaters	P5: "…they've been very good about writing me notes. They'll give me a brief note with an update."
Pharmacist	Pharmacists deliver most of the time-consuming and labor-intensive parts of HCV treatment	S5: "I call them at two weeks to check up on them to see if they're having any side effects. That's usually, usually about 10-15 minute follow-up…I remind them... 'seven days from now, don't forget to call in your refill, to request it'…Then I see them at 4 weeks, where we do blood work, we go over adherence, adverse effects, then they go down to the lab."	Appreciation for the support that the pharmacist provides patients	P1: "…also it looks like there are phone calls being made to make sure that the refills are picked up in a timely fashion, like all the things we wish would happen for every single other medication. It seems like there's that extra level of detail."

Abbreviations: CM – case manager (public health social worker); PCP – primary care provider; PCP treater – general internal medicine PCP trained to treat HCV; referring PCP – general internal medicine PCP who refers patients to the program

(Table 3 Continued)

Pharmacy Technician	Pharmacy technician role is critical for medication access	S5: "I have [pharmacy technician]. I have a patient midway through treatment. Their insurance changed completely. We had to do two different prior authorizations to get it approved for the remainder of treatment and we caught it right before…[pharmacy technician] called the insurance, found out the new insurance. Patient didn't know any of this. Probably would have run out of treatment before the PA was approved in any other place. But here, we have this team of all these people…"	Pharmacy technician takes workload off of referring PCPs and PCP treaters by obtaining PA	P5: "A prior authorization, which is huge. And I have very little clue of how many hours that may take. I know it happens, and I know it has to happen, and I know that that's a central piece of the program."

Abbreviations: PA – prior authorization; PCP treater – general internal medicine PCP trained to treat HCV; referring PCP – general internal medicine PCP who refers patients to the program

Barriers to HCV treatment access

Program staff and referring PCPs identified barriers that patients face in accessing HCV treatment. The most frequently cited patient-associated barriers were substance use, unstable and chaotic life factors, medication side effects, lack of motivation, poor HCV treatment literacy, and insurance access and type. Forgetting or not having enough time to address screening and/or treatment was the most recurring provider-level barrier. Additionally, the most commonly identified barriers associated with the broader health care system were long appointment wait times and changes in insurance requirements for treatment approval. Referring PCPs and program staff described how the program addresses and alleviates the most frequently cited barriers to HCV treatment access (Table 4).

Substance use

The case manager and PCP treater may provide referrals to treatment programs and community resources for patients who wish to treat their substance use before initiating HCV treatment. Some patients who are struggling with substance use are not ready to engage in HCV treatment, and these patients may miss appointments. There are patients whose substance use does not preclude completing HCV treatment; the pharmacist and case manager may provide added support to ensure treatment adherence.

Unstable, chaotic lives

Instability and chaos enter our patients' lives through many avenues. Patients express feeling overwhelmed due to stressors such as low incomes, lack of housing and social support, mental illness, and custody battles. The case manager may support patients in a variety of psychosocial aspects, including helping patients access housing resources, transitional assistance, job training, and mental health services. On one occasion, the case manager assisted a patient in handling bed bugs in his apartment. The pharmacist describes the role that she and the case manager played in handling this issue and encouraging the patient to adhere to his Harvoni medication regimen:

> I had a patient who I called who stopped taking his medication because his apartment was infested with bed bugs, and he had to throw out all of his furniture. Because he had to throw out all of his furniture, he was sitting on his bed, which was the only piece of furniture he had. He had previous lumbar injury, so he had severe back pain. He was in pain. He didn't care about anything. He didn't want to take his Harvoni anymore. So that's where social work comes into play. I don't have a lot of background in getting somebody furniture or getting an exterminator. I can help you to tell you, "no, no, no, don't stop taking the medication." And I can give you as much emotional support as possible but that part I don't have the resource. So then I reach out to her [case manager] and she can then contact whomever. She got the patient furniture for free and got an exterminator coming out, and talked him [the patient] down.

As portrayed in this example, the program staff work to ameliorate unstable situations that place a patient's medication adherence in jeopardy.

Medication side effects

Program staff and referring PCPs named medication side effects as a barrier to HCV treatment access in reference to IFN-based therapies, which were the norm before the new oral medication regimens became available.

Nonetheless, the pharmacist is proactive in communicating with patients about adverse effects of the oral, DAA medications. She may schedule an appointment with the PCP treater for patients who are experiencing side effects.

Patient lack of motivation

The program motivates patients to initiate and complete HCV treatment by frequently reaching out to and engaging patients, providing them with the education to take an active part in treatment decisions, and adapting outreach efforts to each patient's life circumstances. One staff member describes how the case manager increases patient motivation with education and engagement: "…the case manager, she does a lot of outreach, sort of, you know, makes sure people kind of stay on the evaluation pathway and keeps them contacted, does some education, so you know, increasing the wills in some ways."

Poor HCV treatment literacy

The case manager, PCP treater, and pharmacist educate patients about HCV infection and the various components of HCV treatment, including medication adherence, adverse effects, and the program structure. Greater knowledge may increase patients' awareness of the need to be treated and of their own desire to do so. One staff member explains how HCV education influences patients' decisions to get treated: "I think without the education of like looking into like, 'oh, this is what can happen.' If you don't have the education to kind of understand like, 'this is what HCV is,' I don't think that…I think it takes a while maybe before it kicks in that like, 'I want and I need to get treated.'"

Insurance access, type, and requirements for treatment approval

The case manager troubleshoots lapses in insurance coverage and other insurance complications. The issue of insurance requirements for treatment approval is a systemic barrier and beyond the control of the program staff. Nonetheless, it is a program asset to have a pharmacy technician who stays updated on PA requirement changes for different insurances and ensures timely processing of PAs.

Providers forgetting or not having enough time to address screening or treatment

Providers stated that although the "best practice alert" in the EHR at BMC increases screening rates, most patients who screen positive already have known risk factors, such as a history of IV drug use. Several providers mentioned how they plant seeds about HCV treatment for patients who may not be ready to begin treatment. One provider mentioned that she forgot to circle back with the patient until a few months later. Nonetheless, the patient did eventually complete treatment and achieve SVR.

Long appointment wait times

A shortage of specialists who treat HCV is one reason for long appointment wait times in specialty clinics such as gastroenterology or infectious disease. PCP treaters increase the number of providers that can deliver the HCV care normally received in a specialty clinic. Thus, referring PCPs believed that overall wait times for a patient to be assessed for HCV treatment were shorter in primary care than in specialty clinics. Additionally, the proactive case

manager may also decrease appointment wait times by reaching out to patients to schedule the intake appointment in a timely manner.

Lastly, throughout the Results section we have described a few patient emotions related to HCV treatment that program staff and referring PCPs identified as types of barriers to treatment. Table 5 summarizes the patient emotions and identifies aspects of the HCV treatment program that support patients in each emotional state; representative quotes from interview transcripts are also included.

Table 4: The primary care hepatitis C virus (HCV) treatment program at Boston Medical Center (BMC) addresses barriers to HCV treatment

Barriers to HCV treatment access most frequently cited by program staff and referring PCPs	Program component or theme that addresses the barrier
PATIENT BARRIERS	
Substance use (n=8)	• Case manager role: assesses and addresses psychosocial needs, including prior and current substance use; provides additional support during HCV treatment process • PCP treater role: assesses prior and current substance use and may make treatment recommendations • Pharmacist role: provides additional support to ensure medication adherence • Program theme: *personalized medicine*
Unstable, chaotic lives (n=7)	• Case manager role: assesses and addresses psychosocial needs • Pharmacist role: tailors medication adherence strategies to patients' specific needs • Program theme: *personalized medicine* • Program theme: *high patient engagement* • Program theme: *patient empowerment through education*
Medication side effects (n=4)	• This barrier was cited in regards to IFN-based therapies, not DAA medications. • Pharmacist role: regularly assesses medication adverse effects
Patient lack of motivation (n=3)	• Program theme: *personalized medicine* • Program theme: *high patient engagement* • Program theme: *patient empowerment through education*

Abbreviations: Case manager – public health social worker; DAA – direct-acting antivirals; IFN – interferon; PCP – primary care provider; PCP treater – general internal medicine PCP trained to treat HCV

(Table 4 Continued)

Poor HCV treatment literacy (n=3)	• Case manager role: educates patient about HCV and the HCV treatment program • Pharmacist role: educates patient about medication regimen • Program theme: *personalized medicine* • Program theme: *patient empowerment through education* • Program theme: *high patient engagement*
Insurance – access and type (n=3)	• Case manager role: troubleshoots insurance coverage issues
PROVIDER BARRIERS	
Forgetting or not having enough time to address screening or treatment (n=3)	• Program component: "best practice alert" in EHR
SYSTEM BARRIERS	
Long appointment wait time (n=6)	• PCP treater role: increases number of health professionals who treat HCV and thus makes treatment more readily available • Program theme: *efficiency*
Insurance requirements and changes in requirements for treatment approval (n=4)	• Pharmacy technician role: obtains PA and appeals if request denied

Abbreviations: Case manager – public health social worker; EHR – electronic health record; PA – prior authorization; PCP – primary care provider; PCP treater: general internal medicine PCP trained to treat HCV

Table 5: The primary care hepatitis C virus (HCV) treatment program at Boston Medical Center (BMC) responds to patient emotions associated with the HCV treatment process

Patient emotion	Example from interview transcript	Program theme that responds to patient emotion	Example from interview transcript
Discomfort and anxiety about HCV treatment process	S2: "There's been other cases where, you know, patients who have abused IV drugs in the past, you know, we have to get labs or blood drawn at 4 weeks and at the end of treatment to make sure medication's working. And I think a lot, some patients will feel uncomfortable with getting stuck by a needle and having their labs drawn again..."	*Personalized medicine*: Accommodation of treatment access to patient's physical, social, and emotional environments	S2: "…just like making sure the patient goes to the pharmacy and picks up their medicine, or making sure they go to the lab and get their labs drawn. I don't want to say handholding, but I think just kind of walking them through the process of these steps. Or you know, even like they get nervous about knowing where the pharmacy is, walking them directly to the pharmacy. Or they might have a refill on something else at the same time and getting everything together. Just kind of making the process smooth and facilitate it."
Apprehension about engaging with new health professionals	S2: "…he just felt uncomfortable meeting providers and people he's never met before."	*High patient engagement*: Warm handoff	P3: "Well the flow is easier because it's just down the hall. So it's essentially, it's a hand-off more than it is a referral and they'll get to you when they get to you in X number of months."
		Efficiency: Smoother referral process due to proximity of program to primary care	P4: "I think for the patients it's better to do it in primary care if possible, because it's just another barrier to go to a new place where they may not know people."

Abbreviations: IV – intravenous

(Table 5 Continued)

Feeling overwhelmed at prospect of HCV treatment due to other psychosocial factors	P1: "…sometimes I see patients through times when their lives are like, even for chaotic lives, like especially difficult. Like you know, if I see a patient and he says, 'last week I woke up and my girlfriend was dead of an overdose on the bed beside me', like I'm thinking of, I'm not going to say 'Let's refer you for HCV treatment.'"	*Personalized medicine*: Accommodation of treatment access to patient's physical, social, and emotional environments	S3: "…she has a lot of other social things going on. She has her son, for instance, is right now actively using and she's very concerned about that. She has two other kids that are in school. They're doing great but she has some depression and some other stressors that need to be addressed and we want to make sure that we have a holistic approach to care so that she can successfully complete HCV [treatment] so she continues to be healthy."
Worry	P1: "…it is true in a lot of people, even if they aren't necessarily bringing it up, that if you really ask them, they will be very worried about HCV."	*High patient engagement*: Time investment when meeting with patients	S3: "She was very appreciative of like, the social worker, because she was comfortable talking with her, she understood it and that she was going to be an added support throughout this journey."
Stress about HCV treatment with IFN-based therapies and their severe side effects	P4: "Yea, so the older, the people I would say who are in their fifties, sixties, seventies who have it, all know people who suffered or they themselves suffered through the treatment, so I've definitely, when I bring it up, they like jump to the ceiling and I have to talk them off the ceiling. I mean, they really have PTSD from these treatments."	*Patient empowerment through education:* Education about DAAs in contrast to IFN-based therapies	P4: "So I definitely have to do that [educate patients]. For people who are really knowledgeable and have peers, but actually aren't knowledgeable about the new treatments, and they're like converting now. Like now, you know, people are, you know, they've seen the light, they're converted."

Abbreviations: DAA – direct-acting antiviral; IFN – interferon; PTSD – post-traumatic stress disorder

DISCUSSION

In this study, we gained a deeper understanding of the workings of a primary care HCV treatment program in an urban, safety-net hospital. We found that two roles in particular are critical for the success of the program: the case manager, who is a public health social worker, and the pharmacist. The public health social worker plays an integral role in linking patients to care and facilitating their progression through the complex HCV treatment process with its multiple appointments, imaging and lab tests, and trips to the pharmacy. Additionally, the social worker eases the burden of HCV treatment by addressing psychosocial factors. The pharmacist also plays a crucial role by ensuring treatment adherence through medication administration teaching, medication refill reminders, and follow-up appointments for lab tests.

The pharmacist and pharmacy technician work together to obtain PAs for prescribed agents and to address lapses in insurance coverage of medications. Staff members in the HCV treatment program work at the "top of their license," meaning they complete the most complex tasks that their licenses allow. As a result, work is off-loaded from clinicians and allows clinicians to focus on direct patient care. We also identified several themes from interviews with staff and referring PCPs that describe HCV treatment delivery in the program: efficiency, clear and open communication, personalized medicine, high patient engagement, and patient empowerment through education.

Although DAA therapies have increased HCV treatment efficacy, hurdles to attaining HCV eradication remain.[79] Overall, program staff and referring PCPs identified barriers to HCV treatment access that are similar to barriers present since the late 1990s, when IFN-based HCV treatment first became available. However, the types of barriers at the forefront in the DAA era may differ from the most common barriers in the IFN era. For example, HCV treatment programs analyzed in the IFN era noted medication side effects as a major barrier to treatment access. Although medication side effects are still a concern with DAA therapies, they are not as significant. The most frequently identified patient-associated barriers to treatment in our study were substance use and unstable and chaotic life factors.

Additionally, inadequate patient literacy in HCV treatment options and processes may be a more significant barrier with the advent of DAA medications. As our study identified, patients do not always know the difference in treatment processes between IFN-based and DAA regimens. Patients may perceive treatment prospects negatively if they associate the process with IFN side effects. As a result, they may be less likely to take advantage of the improved DAA medications. Greater knowledge about HCV and treatment processes has been shown to encourage treatment considerations.[47] Thus, poor literacy in HCV treatment may be a crucial barrier to address in the DAA era.

High costs of DAA medications have pushed the barriers of insurance coverage and PA attainment to the forefront.[79] One of the assets of the HCV

treatment program at BMC is that the pharmacy technician is able to stay current in insurance coverage requirement changes and PA processes. Health care settings that deliver HCV treatment in the DAA era may need to adjust their processes to address insurance coverage barriers.

Program staff and referring PCPs also identified patient emotions associated with the HCV treatment process that have been previously studied, such as discomfort and anxiety at the prospect of treatment and general worry about a HCV diagnosis.[80,81,82] Support during the treatment process, either from family, friends, or health care providers, is beneficial for treatment adherence, and other studies have also described its importance.[80,81,82] The staff in the HCV treatment program address patients' emotions by filling a niche of support, which may be especially pertinent for our vulnerable patient population with limited sources of assistance and encouragement. Some factors affecting patients' emotions towards treatment may be specific to the patient population at BMC, such as past IV drug use or overwhelming chaotic life factors. Nonetheless, we believe patients' emotions may be generalizable to patient populations at other safety-net hospital settings.

Social workers and pharmacists may be uniquely positioned to address barriers that are at the forefront of HCV treatment access in the era of DAA medications and to provide emotional support. Also, patients who previously would not be considered good candidates for treatment are now eligible with simpler treatment regimens. For example, we can treat through some

substance use, although at the risk of non-adherence and reinfection. The social worker and pharmacist in the HCV treatment program at BMC provide extra support that makes it more feasible to treat high-risk patients.

The HCV treatment program public health social worker brings expertise in population management and community resources to the position. One study conducted qualitative in-depth interviews with participants who had undergone HCV treatment in the United Kingdom and found multiple opportunities for social work involvement.[45] First, social workers are well positioned to increase HCV diagnosis rates due to their wide range of client groups, including high-risk clients who may be incarcerated, homeless, or current or former IDUs. Social workers may begin discussions about HCV testing and treatment with clients who disclose certain risk factors.[45] Second, strong relationships between social workers and medical staff may efficiently link clients to HCV care. Third, social workers may support patients by providing information about HCV and assisting with various psychosocial needs, such as substance use treatment, treatment literacy, and insurance enrollment. Social workers' training in providing holistic social and emotional support, as well as in addressing inequalities and navigating systems, lends itself well to increasing HCV treatment access.[45] Thus, an advantage of receiving care in the HCV treatment program at BMC is that it automatically provides patients with a public health social worker.

Collaboration between social workers and pharmacists in the context of primary care, as seen in the HCV treatment program, is also advantageous for

the quality and delivery of HCV treatment.[83] The collaboration brings together pharmacists' expertise in medication use and social workers' training in psychological, social, and environmental evaluations.[83] Pharmacists and social workers have complementary strengths that, when applied to medication management, can improve health outcomes such as medication adherence. Social workers rely on pharmacists when handling medicine-related issues with patients, and pharmacists can depend on social workers when they identify psychosocial issues.[83]

The expansion of the pharmacist's role into primary care and HCV treatment is especially relevant as the United States is projected to face a shortfall of 14,900-35,600 PCPs by 2025.[84] Simultaneously, chronic diseases are prevalent in the United States population,[39] and medications are playing a more significant role in the prevention and management of chronic diseases within primary care.[85] Additionally, shorter hospital stays and more outpatient surgeries result in patients relying on primary care for more intensive medication therapy.[85] The increasingly complex medication treatment regimens require more oversight of adverse effects.

Pharmacists may be able to fill much-needed roles in primary care and on multidisciplinary teams. The role of the pharmacist is essential to the primary care HCV treatment program at BMC, especially in the guidance that the pharmacist provides patients in adhering to the HCV treatment medication regimen. The pharmacist's role is in accordance with the American Society of

Health-System Pharmacists' Pharmacy Practice Model Initiative (PPMI). The PPMI's goal is to expand the health-system pharmacy practice and transition to a patient-centered care model in order to increase quality and continuity of care.[86] Specifically, pharmacists are moving away from filling prescriptions and preparing products for distribution and towards medication therapy management.[87] The pharmacist administers patient visits that otherwise PCP treaters may conduct in other clinical settings. The pharmacist thus increases access to HCV treatment services and provides needed medication management support for patients.

The change in the role of the pharmacist, namely increased direct patient care, relies on an expansion of the pharmacy technician role.[86,87] Pharmacy technicians became critical resources in the early 2000s during a pharmacist shortage, and their roles have continued to broaden. Pharmacy technicians are responsible for entering medication orders, dispensing prescriptions, and managing medication inventories.[88] Pharmacy technicians are increasingly taking on medication safety and quality assurance and compiling medication lists, among other tasks.[88] Despite the variation in pharmacy technician responsibilities and training across the United States,[89] most pharmacy technicians today also communicate with insurance companies for medication approvals and complete necessary paperwork.[90]

The pharmacy technician completes tasks in the HCV treatment program that may otherwise be completed by PCPs or pharmacists, and thus frees up

PCP treaters' and the pharmacist's time for direct patient care. For example, the time-consuming and labor-intensive process of obtaining prior authorizations requires the pharmacy technician to submit necessary forms, medical records, and test results for approval to the patient's insurance company.[91] In other care models, the pharmacist or PCP may be responsible for this process, but in the HCV treatment program they are able to focus on patient care while the pharmacy technician obtains the PA.

Limitations

Our study has several limitations. First, we assessed patient viewpoints through the lens of third parties such as program staff and referring PCPs.

Second, the PCPs who agreed to participate in the study may not be representative of all PCPs; they may be more likely to have an interest in HCV. They may be more informed about HCV infection and care protocols, have a greater awareness of the program and its functions, and thus engage with the program in more depth. Indeed, several of the referring PCPs who were interviewed have a strong background in substance use and addiction medicine. This background may have skewed their viewpoints and experiences in favor of the program.

A third limitation of our study includes bias in the staff interviews since the staff were describing their own work. They may have been less likely to criticize their efforts in implementing the program. Additionally, interview coding may be subjective. Qualitative methods limit our ability to estimate the frequency of each

identified barrier to HCV treatment access, or the relative importance of each defined program theme. Lastly, this program addresses the needs of an urban, safety-net hospital and its diverse, primarily low-income patient population. Although program aspects may be generalizable to other safety-net hospitals, they may not be generalizable to other clinical settings and patient populations.

Implications

This study shows that the HCV treatment program at BMC has promise to deliver HCV treatment to an urban, underserved patient population. Barriers to treatment accessibility in the DAA era may be more centered on poor patient treatment literacy, psychosocial factors, and insurance coverage as opposed to medication side effects like during the IFN era. Public health social workers and pharmacists may be particularly valuable resources in supporting patients through the treatment process and providing medication management in the era of DAA medications. Further study of the program's efficacy in improving HCV outcomes is warranted.

CONCLUSIONS

In summary, we described a pharmacist-managed primary care-based HCV treatment program at an urban, safety-net hospital patient-centered medical home in the era of DAA medications. We conducted semi-structured interviews with program staff members and general internal medicine PCPs who refer patients to the program, and identified themes from interview transcripts through qualitative analysis. Five themes characterize the program's successful HCV treatment delivery: efficiency, clear and open communication, personalized medicine, high patient engagement, and patient empowerment through education. The pharmacist and public health social worker have key roles in supporting patients in medication management and psychosocial factors respectively. The pharmacy and social work fields may be uniquely positioned to increase HCV treatment access in the DAA era, especially when specialist and primary care fields are overburdened by high demand.

We are unaware of other pharmacist-managed, primary care-based HCV treatment models in which DAA medications have been the exclusive prescribing agents and a public health social worker provides patient navigation. Further study of the program's efficacy in improving HCV outcomes is warranted.

APPENDIX A: Program Staff Study Recruitment Email

Dear [Subject],

My name is [Research Assistant]. I am a [degree] student at the [school] working with [Principal Investigator]. We are conducting interviews as part of a research study designed to increase our understanding of the budgetary impact of the Hepatitis C treatment program in General Internal Medicine at Boston Medical Center. As a member of the treatment program staff you are uniquely positioned to offer valuable information about the program. Your responses will allow our research staff to gauge the fiscal impact of the program as well as barriers and facilitators to its overall success. Information gained from our research will both help to improve the program at BMC and disseminate it elsewhere.

The interview process will be informal and should take about 30-60 minutes of your time. Your responses will be kept confidential and be de-identified in order to ensure anonymity throughout the data collection and analysis process. As a thank you, we will compensate you with a $25 gift card for your participation.

We hope that you will be willing to participate in our study. If so, please suggest some days and times I could meet with you. Thank you for your consideration,

Best regards,

[Research Assistant]

APPENDIX B: PCP Study Recruitment Email

Dear [Subject],

My name is [Principal Investigator] and I am reaching out because my team and I are conducting interviews as part of a research study to increase our understanding of the processes involved in Hepatitis C (HCV) treatment here at BMC. As a primary care provider, you are uniquely positioned to offer insights about the screening, referral, and follow-up processes for HCV treatment within your department, as well as to offer a perspective about factors that either assist or prevent patients from accessing care. Information gained from our research will help us understand best practices for screening and treating patients with HCV in primary care settings.

I would like to invite you to participate in a short (30 minute) interview with our research assistant, [name]. Your responses will be kept confidential and will be de-identified to ensure anonymity. You will receive a $25 gift card for your participation.

We hope that you will be able to participate in our study. Your knowledge and insights are invaluable. If you are able to participate, please suggest some days and times when you could participate in the interview. Thank you in advance for your consideration.

Sincerely,

[Principal Investigator]

APPENDIX C: Program Staff Interview Guide

Hepatitis C (HCV) Treatment Program Budget Impact Analysis (BIA) Interview Guide - Practice Staff

Research Question - Interview questions are designed to engage with and probe subjects (project staff and patients) for perceived impacts of the HCV treatment program. Specifically, we would like to assess barriers and facilitators to program implementation, direct costs of program components, as well as changes in staffing and utilization of resources, which result from program implementation.

Practice Staff Interview – (medical director, HCV provider, case manager, pharmacy technician, pharmacist, practice manager)

Framing prompt:
I am going to ask you some questions about your experiences with the BMC Hepatitis C program. We are interested in hearing your thoughts about the program, its effectiveness, and particularly your opinions of various program components. There are no right or wrong answers and your responses will be anonymous and kept in strict confidentiality. However, because you are the only (medical director, care manager, pharmacy technician, pharmacist) in the program it is possible that some things you say could be associated with you. With that in mind, please let me know if there are any questions you would prefer not to answer.

1. Can you tell me a bit about your professional background, and your role in the hepatitis C treatment program?

2. Where did you complete your (staff specific) training? Prior to the initiation of the program did you have any specialized training in treating HCV patients? What was the timing / duration of this training? Who paid for you to do the training?

3. I would like you to think back to the most recent patient (case) you can recall treating (interacting with) in the HCV program. Can you tell me a bit about this experience and how your role in the program fit into the overall patient treatment process?

4. Can you describe any changes in access to Hepatitis C treatment for patients you have noticed during your time in the program?

5. Were you a part of the care team before the program was implemented, and if so in what ways have care processes changed since the program began?

6. What changes have you noticed in levels of demand for care?

7. What changes have you noticed in the time necessary to treat patients receiving the care intervention?

8. I would like you to think back to before the program was initiated at BMC up to now (or since the program started, if interviewee indicated s/he did not work at BMC before that). In your experience, what if any have been the greatest changes in cost(s) associated with treatment or patient management that you have seen since your time in the program?

******Probes - These cost changes could relate to: Key points from answers to preceding questions will guide probes to cost questions. For example, if staffing changes what are the implications for costs? If any changes in care process, what are the implications for cost? Additionally, we are interested in:***

- Changes in staffing such as hiring additional personnel and / or shift changes
- Increased or decreased utilization of technology
- Costs associated with additional patient appointments or length of patient visits

9. Thinking about your time in the program, what do you think are the best strategies to promote HCV treatment in primary care?

10. What challenges to care delivery have you observed? How did you or others address these?

11. What do you feel have been the greatest barriers to the success of the program?

12. What have been the greatest facilitators of program success?

13. Is there anything else you would like to share about the program?

Demographic Questions
***Note interviewee gender
14. What is your D.O.B?

15. Which racial or ethnic group do you identify with?

16. Do you speak any non-English languages without the use of an interpreter?

17. How many years have you been practicing, working, etc.?

18. In order to complete the BIA we need to have an estimate (within 5-10k / yr.) of your yearly salary. Would you mind providing me with that information?

APPENDIX D: PCP Interview Guide

Framing Prompt: Thank you for taking the time to talk with me. I have several questions for you about the process of treating patients with HCV in your department. I wanted to talk to you because you have been at BMC for a number of years, and could describe to me how HCV treatment has changed over the past few years. There are no right or wrong answers and your responses will be anonymous and kept in strict confidentiality. If there are any questions that you prefer not to answer, please tell me and we can move on to the next question.

1) First, can you take me through the step by step process of how your patients accessed HCV treatment **before** the implementation of the HCV treatment program in primary care, starting when you first became aware of the diagnosis?
   Probes:
   - What prompted you to screen your patients for HCV?
   - Can you describe the referral process that was in place then? (Which patients? To which specialists?)
   - What barriers to HCV treatment were present at that time?
     - *Patient factors* – Social, economic, and physical environments? Logistics of transportation and housing? Medication side effects? Substance use as related to HCV treatment? What substance use treatment programs were available to your patients? Missed appointments?
     - *Provider factors* – Difficulty remembering to screen or having time to screen? Did you have time to assess/address HCV infection? Did the specialist require patient abstinence for HCV treatment?
     - *Systems factors* – Referral was placed but appointment not scheduled? Wait time to get specialty appointment?
   - Can you estimate the time frame from when the referral was made to when treatment was begun?
   - Were you satisfied with your patients' ability to access treatment and the quality of treatment received?

2) Since the HCV treatment program was implemented in primary care, how has the screening and referral process for HCV treatment changed?
   Probes:
   - Has the "best practice alert" changed how many patients you refer for treatment?
   - How do the different team members (case manager, pharmacy technician, and pharmacist) support you/the care of your HCV infected patients?

3) How has the primary care HCV program helped to address patient, provider, and system barriers?
   Probes:
   - Do you rely on other staff members to help you follow up with patients?
   - Has the time frame from when the referral is made to when treatment is begun changed?
   - Are you satisfied with your patients' ability to access treatment and its quality?

4) What are some barriers that remain to having patients engage in treatment?
   Probes:
   - Substance use as related to HCV treatment? Missed appointments?

5) Can you give me an example of a recent patient that you referred to the HCV treatment program? Can you tell me a little bit about this experience, from learning of the patient's HCV diagnosis to going through the referral process?

6) Is there anything else you would like to share about your experience in getting your patients HCV treatment?

Demographic Questions:

7) How many years have you been practicing medicine, including residency?

8) Which best describes your race?
   - White
   - Black or African American
   - American Indian or Alaska Native
   - Asian
   - Native Hawaiian or Other Pacific Islander
   - Other Race:

9) Do you speak any non-English languages without the use of an interpreter?

LIST OF JOURNAL ABBREVIATIONS

Addict Behav…….Addictive Behaviors

AIDS Patient Care STDS……..……AIDS Patient Care and STDs

Aliment Pharmacol Ther……...Alimentary Pharmacology and Therapeutics

Am J Gastroenterol…….The American Journal of Gastroenterology

Am J Health-Syst Pharm...……..American Journal of Health-System Pharmacy

Am J Pharm Educ.……...American Journal of Pharmaceutical Education

Ann Fam Med……...Annals of Family Medicine

Am Fam Physician…….…….American Family Physician

Ann Internal Med…… Annals of Internal Medicine

Ann Pharmacother…….The Annals of Pharmacotherapy

Aust N Z J Public Health…..Australian and New Zealand Journal of Public Health

BMC Infect Dis……BMC Infectious Diseases

Br J Soc Work…….British Journal of Social Work

Can J Gastroenterol……..…Canadian Journal of Gastroenterology

Cancer Epidemiol Biomarkers Prev…….Cancer Epidemiology, Biomarkers and Prevention

Clin Infect Dis……..……..……..Clinical Infectious Diseases

Clin Ther……..Clinical Therapeutics

Clin Tranl Gastroenterol……Clinical and Translational Gastroenterology

Drug Alcohol Rev……...Drug and Alcohol Review

Eur J Gastroenterol Hepatol.....European Journal of Gastroenterology and Hepatology

Gastroenterol Hepatol……Gastroenterology and Hepatology

Gen Hosp Psychiatry……General Hospital Psychiatry

Health Aff……..…Health Affairs

Int J Drug Policy……...The International Journal on Drug Policy

JAMA……..Journal of the American Medical Association

JAMA Intern Med……..JAMA Internal Medicine

J Addict Med……....Journal of Addiction Medicine

J Am Pharm Assoc……..Journal of the American Pharmacists Association

J Clin Gastroenterol…….Journal of Clinical Gastroenterology

J Clin Hypertens……..Journal of Clinical Hypertension

J Clin Nurs……....Journal of Clinical Nursing

J Clin Pharmacol……...Journal of Clinical Pharmacology

J Gen Intern Med……....Journal of General Internal Medicine

J Gen Virol……..……The Journal of General Virology

J Health Care Poor Underserved.....Journal of Health Care for the Poor and Underserved

J Manag Care Spec Pharm.…Journal of Managed Care and Specialty Pharmacy

J Natl Med Assoc……Journal of the National Medical Association

J Viral Hepat…….Journal of Viral Hepatitis

MMWR Morb Mortal Wkly Rep……..…..Morbidity and Mortality Weekly Report

N Engl J Med……..…..The New England Journal of Medicine

Prev Chronic Dis……...Preventing Chronic Disease

Res Social Adm Pharm.....Research in Social and Administrative Pharmacy

Semin Liver Dis……....Seminars in Liver Disease

Soc Work Health Care……...Social Work in Health Care

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