



Successful Implementation of a Shared Medical Appointment Model for Hepatitis C Treatment at a Community Health Center

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Abstract

Highly efficacious direct acting antiviral (DAA) therapy for treatment of Hepatitis C Virus (HCV) infection is largely inaccessible to communities facing a shortage of available specialist providers. Though less demanding than previous interferon regimens, DAA therapy requires patients to adhere to 8–12 weeks of daily treatment, which can be challenging for some patient populations. Duffy Health Center, located on Cape Cod, Massachusetts, provides integrated medical, mental health and case management services to people who are homeless or at risk for homelessness. The goal of this manuscript is to evaluate the outcomes of treatment of HCV infection with a shared medical appointment (SMA) model. The primary outcome was sustained virologic response (SVR-12), or HCV RNA ≤ 15 IU/mL at 12 weeks post-treatment. There were 102 patients recruited, with a total of 104 treatments administered. Over three-fourths of patients who attended one SMA visit (78 of 102) continued in SMA for the duration of treatment. Of these patients opting for SMA, 99% (77 of 78) completed the full treatment course, and 91% (71 of 78) of SMA patients achieved SVR-12. DAA therapy provided by non-specialist providers using the SMA model yielded comparable response rates to those achieved by specialist providers, and has the potential to substantially increase access to HCV treatment for patient populations within high-risk communities.

Keywords Shared medical appointment · Hepatitis C · Task shifting · Peer support · Direct acting antiviral therapy

Background

Hepatitis C virus (HCV) is the most common blood borne infection in the United States [1]. With the advent of highly effective direct acting antiviral (DAA) therapy, task shifting of HCV treatment to community-based providers has demonstrated clinical outcomes comparable to care provided by specialists [2, 3]. Despite evidence that the shared medical appointment (SMA) model improves patient self-care and treatment adherence when applied in the treatment of other chronic diseases [4], application of the SMA model for HCV treatment is scarce in the literature. Duffy Health Center, located in Hyannis, Massachusetts, is a federally qualified

community health center serving a vulnerable population on Cape Cod with high rates of substance use disorder, housing instability, and mental illness.

Objective

To evaluate the feasibility and efficacy of a SMA model for treatment of HCV infection provided by non-specialist practitioners at a community health center.

Methods

Duffy Health Center was awarded a HRSA grant to develop and implement a SMA model of HCV treatment. We have no conflicts of interest to disclose. This study was reviewed by the IRB and determined not to be research involving human subjects as defined by DHHS and FDA regulations, and was granted quality improvement exemption status. Pre-implementation meetings incorporated feedback from clinic staff (nurses, physicians, medical assistants, behavioral health

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workers, administrators, and case managers). Providers were trained on HCV treatment through online tutorials and consultation with an ID specialist. Administrators were trained on the process of requesting prior authorization for HCV medications. Patients were referred by providers within the health center in a non-randomized fashion, and completed five group visits at 4-week intervals. At each visit, patients were seen in a group setting by a multidisciplinary team for counseling and education (topics included harm reduction, nutrition, re-infection), with one-on-one care provided by a clinician during the meetings. Patients could opt for individual treatment rather than SMA at any time [5]. The primary outcome was sustained virologic response (SVR-12) defined as HCV RNA \leq 15 IU/mL at 12 weeks post-treatment. We compared frequency of treatment completion and sustained virologic response in people who completed treatment in the SMA model and people who completed treatment as an individual.

Results

The first SMA group started in March 2016, and here we report on the outcomes of the treatment of 102 patients who attended at least one SMA visit over the first seven cycles completed, with 104 treatments administered in total. Participant baseline characteristics are shown in Table 1. 76% of patients who attended one SMA visit continued in SMA for the duration of treatment. 99% of patients opting for SMA (77 of 78) completed the full treatment course, and 91% of SMA patients (71 of 78) achieved SVR-12 (Table 1). 26 patients opted for individual treatment, including 2 patients who were retreated individually after treatment failure (1 patient) or adverse reaction (rash, 1 patient) during their SMA course. 23 patients (88%) who were treated individually completed treatment and 69% (18 of 26) of individually treated patients achieved SVR-12. People who opted for the SMA treatment model trended towards more likely completion of treatment [OR 10, (95% CI 0.99–101)] and were more likely to achieve SVR-12 [OR 6.33 (95% CI 2.09–19.2)].

Discussion

Diversification of providers overseeing HCV treatment is necessary to end the HCV epidemic [6]. HCV-infected adults undergoing community-based treatment through a shared appointment model showed excellent clinical response consistent with contemporary efforts in a similar patient population [7, 8]. Being in the SMA program was associated with a 6-times increased odds ratio of achieving SVR-12. The SMA model addresses the stigmatized nature of HCV diagnosis by

Table 1 Baseline sociodemographic characteristics and treatment results for a cohort of 102 HCV-infected adults treated with DAA therapy

Demographics and disease-related characteristics	N = 102
Age	45 (sd 14)
Male	65 (64%)
Race	
Non-Hispanic White	85 (83%)
Hispanic/Latino	4 (4%)
Black/African American	6 (6%)
Other/unspecified	7 (7%)
Mental illness (mood, anxiety or psychotic disorder)	65 (64%)
Enrolled in medication-assisted treatment (MAT)	41 (40%)
Fibrosis stage	
F0	41 (40%)
F1	15 (15%)
F2	18 (18%)
F3	12 (12%)
F4	16 (16%)
Genotype	
1	68 (67%)
2	14 (14%)
3	16 (16%)
4	1 (1%)
Mixed	1 (1%)
Unreported	2 (2%)
HCV medication regimen	
LDV/SOF	63 (62%)
SOF/VEL	28 (27%)
ELB/GRAZ	7 (7%)
SOF or LDV/SOF + ribavirin	4 (4%)
Treatment results	
All visits as part of shared medical appointment model	78
Completed treatment course	77
SVR-12	71
Treatment failure	3
Post-treatment lost to follow up	3
Lost to follow up: did not complete treatment course	1
Opted for individual treatment after first SMA	26
Completed treatment course	23
SVR-12	16
SVR-12 with retreatment	2
Treatment failure	1
Post-treatment lost to follow up	4
Did not complete treatment course	3
Lost to follow up	2
Deceased	1

employing peer support, as group sessions allow for patients to discuss shared barriers and personal experiences. Care provided by non-specialist practitioners embedded within

the community allowed for care that was both accessible and context-driven. Co-located management of substance use disorder and HCV was possible and likely contributed to high SVR-12 rates.

The importance of training administrators to work with clinicians on prior authorizations for the HCV medications cannot be understated. Insurance restrictions are consistently listed as one of the major barriers to HCV treatment [9]. As of August 2016, the Medicaid program in Massachusetts (MassHealth) authorized HCV treatment for all people with HCV infection, regardless of a patient's level of liver damage, sobriety, previous treatment history, or prescriber specialty. Prior authorizations were still required and were quite time consuming [10, 11]. Replication of our SMA efforts needs to incorporate similar prior authorization training and expertise.

Limitations of this project should be noted. The patients referred to the SMA models may represent a “cherry-picked” population, and further studies are needed to address harder-to-reach populations including homeless populations and rural populations with limited access to transportation. Patients opting for individualized treatment may have feared pressure to share sensitive personal information in a group setting, indicating appropriate education about SMA programs during recruitment is necessary, and that ultimately the SMA model may not be for everyone.

Currently, there is a clinical trial underway [12] comparing group versus self-administered individual treatment, and the outcomes of this clinical trial can shape international practice and guidelines. Dissemination of the shared medical appointment model for HCV treatment will require buy-in from various stakeholders including clinicians, clinic administrators, insurers and patients. Broad implementation of innovative methods of HCV care delivery is one way to address the burgeoning HCV epidemic and provide quality, curative treatment for all.

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