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BRIEF REPORT

Hepatitis C Treatment Outcomes for People Who Inject Drugs Treated in an Accessible Care Program Located at a Syringe Service Program

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Hepatitis C virus (HCV) is a significant public health problem that disproportionately afflicts people who inject drugs. We describe outcomes of HCV treatment co-located within a syringe services program (SSP). Fifty-three participants started therapy, and 91% achieved sustained virologic response. SSPs provide an effective venue for HCV treatment.

Keywords. hepatitis C; people who inject drugs, syringe service program.

Chronic hepatitis C virus (HCV) is a major public health problem globally that leads to significant morbidity and mortality [1]. People who inject drugs (PWID) constitute the majority of cases of HCV infection in most developed countries [2]. New direct acting agents (DAA) have revolutionized the treatment of HCV, which has led to a discussion about HCV elimination.

If HCV elimination is going to be achieved, it will require treatment of large numbers of PWID, who are at high risk of onward transmission of HCV. Mathematical modeling has suggested that modest increases in the percentage of PWID who are cured of HCV could also reduce onward transmission and achieve a substantial reduction in the prevalence of HCV infection [3]. These reductions in HCV prevalence can be maximized by combining treatment of PWID with HCV-preventive services (behavioral interventions, syringe services programs [SSPs], and opioid agonist therapy [OAT]) [4]. However, PWID face numerous barriers to accessing care in traditional settings, and relatively few PWID receive treatment for HCV [5].

Compared with interferon-based therapies, treatment with DAAs is simpler, more effective, better tolerated, and requires less monitoring. This presents a unique opportunity to develop new models of service delivery that might better serve the needs of PWID. In particular, co-location of care at sites where PWID already receive services presents a promising model of HCV care. SSPs, which often provide multidisciplinary services specifically designed for PWID, represent 1 such setting.

Here we describe a new model of care, an Accessible Care Program (ACP), in which HCV testing, medical evaluation, phlebotomy services, medication distribution, treatment adherence support, and other services are co-located within a syringe service program.

METHODS

The Washington Heights Corner Project (WHCP) is a community-based harm reduction facility and New York State–licensed SSP serving upper Manhattan. Beginning in June 2014, the ACP, a collaboration between the SSP and 2 tertiary medical centers, offered co-located HCV treatment on site at WHCP. Data from participants enrolled through December 2016 are presented here.

SSP participants with confirmed HCV antibody positivity were eligible for enrollment. Recruitment was initially limited to those who had injected in the past 30 days, but starting in the spring of 2016, all interested WHCP participants were enrolled. Participants with clinical evidence of decompensated cirrhosis or deemed to have a life expectancy of less than 1 year were excluded from the co-located treatment program and referred to existing clinic-based services.

ACP participants received medical evaluation, follow-up, and phlebotomy for laboratory testing, and care coordination at the WHCP drop-in site. Flexible appointments and drop-ins were welcome and encouraged. Prior authorization for DAA medications was requested from insurance carriers for participants who desired treatment, and, if approved, medication was delivered to the WHCP where participants decided upon an individualized medication dispensing schedule (eg, daily, weekly, or monthly); care coordinators provided ongoing education and logistical, social, and adherence support. Participants received $20 for each of 1–3 screening or research interview visits but no incentives for taking medication.

The primary outcome was a sustained virologic response (SVR), defined as an undetectable plasma HCV RNA level 12 weeks after treatment completion. Plasma HCV RNA was measured with the COBAS Taqman HCV/HPS v2.0 assay (Roche, Molecular Diagnostics, Pleasanton, CA; limit of detection 15

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IU/mL). All analyses were performed using STATA software (v 13.1; StataCorp, College Station, TX).

This study was approved by the Weill Cornell Medical Center, National Development and Research Institutes, and Columbia University Medical Center Institutional Review Boards.

RESULTS

Eighty HCV-infected SSP participants were seen at least once by ACP providers within the study period, with 53 (66%) participants initiating treatment. Of the 27 participants not started on treatment; 2 have been subsequently started on treatment, 2 were excluded from on-site treatment due to advanced disease, 2 chose to be treated elsewhere, 11 declined treatment at the present time, 3 were incarcerated, 6 were lost to follow-up, and 1 was not treated due to insurance denial.

Of the 53 participants started on therapy, the average age (interquartile range [IQR]) was 47.2 (41–55) years, 83% were men, 41.5% were homeless, all had a history of injection drug use, 45 (85%) had injected illicit drugs in the last 30 days, and 45.3% were concurrently on OAT (all methadone). Most participants (83%) were treatment naïve (Table 1). None were co-infected with HIV. The most common genotype was genotype 1 (66%), with 22.6% having F3 fibrosis or cirrhosis.

Of 53 participants who started on DAA therapy, 48 participants had a confirmed undetectable HCV RNA 12 weeks after completion of therapy (SVR, 91%). One additional participant achieved an end of treatment response but was lost to follow-up before 12-week post-treatment HCV RNA testing.

Of the 53 participants, 3 did not complete the prescribed treatment course. Two participants stopped their therapy early for nonmedical reasons (incarceration, insurance lapse), with 1 achieving SVR and 1 with return of virus. One discontinued therapy because of severe nausea and vomiting 4 weeks into therapy with ombitasvir/paritaprevir/ritonavir/dasabuvir plus ribavirin and did not achieve viral suppression.

Of the 50 participants who completed their prescribed treatment course, 2 did not achieve SVR. Each completed 12 weeks of therapy for genotype 1a infection (1 with sofobuvir-ledipasvir and 1 with sofosbuvir + simeprevir) and achieved an undetectable viral load within 4 weeks of starting treatment that remained undetectable at treatment completion, but failed to achieve SVR. Both participants had viremia within 4 weeks of treatment completion with a previously undetected HCV genotype (both 3a). Both participants reported active injection drug use during therapy, but neither reported sharing of needles, syringes, cookers, or cottons, and testing of each participant's immediate injection network (purchased drug together or injected in the same space in the prior 3 months) failed to demonstrate any genotype 3a infection.

DISCUSSION

To our knowledge, this is the first study examining the effectiveness of a new model of care known as an Accessible Care Program, in which HCV treatment is co-located within an SSP and provides individualized education and support to meet participants' needs. These data provide further evidence that PWID can achieve similar cure rates to those seen in clinical trials [6, 7]. Despite a limited sample size, high rates of SVR were seen across subgroups irrespective of sex, homelessness, active injection drug use, or the presence of advanced fibrosis.

This ACP model offers several potential benefits compared with standard practice. First, integrating medical services within an SSP facility might mitigate any stigma that these individuals face when interfacing with the health care system. Second, regular, often daily, visits to an SSP are already part of the daily routine for many PWID; incorporating HCV treatment into this routine might improve adherence. The presence of preexisting case management, social work, and peer services might also help mitigate barriers to adherence. Finally, co-location with SSP, where PWID can access sterile paraphernalia and receive ongoing harm reduction education, might help reduce the risk of re-infection.

Two participants who failed to achieve SVR developed viremia with genotype 3 HCV soon after treatment for genotype 1 HCV, representing either re-infection or unmasking of a viral strain with a minority genotype. With repeated virus exposure, mixed infection is more common in active PWID [8], and commercial genotype tests may miss minority genotypes [9]. Treatment with DAA specific to a predominant genotype might unmask a minority genotype [10]; pan-genotypic regimens might prevent this outcome.

This study has several limitations. First, it was conducted at a single site with a modest sample size. We may have selectively recruited a more motivated and organized participant pool. Our findings cannot be extrapolated to all PWID. Second, we did not randomize patients or study a control group. However, successful recruitment and treatment of people with ongoing injection drug use in conventional medical settings has rarely been reported. Third, New York State's progressive Medicaid standards approved DAAs for nearly all patients. Many state Medicaid programs require advanced fibrosis or cirrhosis and discriminate against people with past or current substance use [11]. These policies must change before this program can be reproduced nationwide.

Marginalized patient groups who have difficulty accessing care in conventional medical settings can readily be reached in locations that they comfortably frequent. Existing data support the treatment of PWID at OAT clinics [12, 13], while our study adds data to support treatment at SSPs and provides a novel model for doing so. Unfortunately, a significant proportion of PWID around the country are not engaged in, or lack access to, either type of harm reduction modality. Both need to be scaled up, taking into account local community needs and conditions.

Finally, future research should follow PWID cured of HCV to determine rates of re-infection and effective strategies to prevent, detect, and treat re-infection. HCV elimination, or even control of ongoing transmission, will be impossible without treating

Table 1. SVR Rates Among PWID Treated for HCV Co-located Within SSP (n = 53)

				No. (%)
Total				53 (100)
Observed SVR				48[a] (91)
Lost to follow-up prior to SVR[b]				1 (2)
No SVR after treatment discontinuation for nonmedical reasons[c]				1 (2)
Treatment failure				3 (6)
Virologic breakthrough				0 (0)
Treatment discontinuation for side effects				1 (2)
Relapse or reinfection[d]				2 (4)
		No. or Mean	% or Range	SVR12
Total		53		48/53 (91)
Age, y		47.2	(27–71)	
Sex	Male	44	83.0	39/44 (89)
	Female	9	17.0	9/9 (100)
Ethnicity	White (non-Hispanic)	25	47.2	23/25 (92)
	Black (non-Hispanic)	6	11.3	5/6 (83)
	Black Hispanic	3	5.7	3/3 (100)
	White Hispanic	18	34.0	16/18 (89)
	Other	1	1.9	1/1 (100)
Homeless	Yes	22	41.5	20/22 (91)
	No	31	58.5	28/31 (90)
Insurance	Medicaid	50	94.3	45/50 (90)
	Medicare	3	5.7	3/3 (100)
	Private Insurance	0	0.0	
	Uninsured	0	0.0	
Years injecting drugs (n = 34)[e]		26.2	(1–41)	
Active injection drug use (any injection in last 30 d)	Yes	45	84.9	41/45 (91)
	Heroin	42	79.2	38/42 (90)
	Cocaine	9	17.0	7/9 (78)
	Methamphetamine	1	1.9	1/1 (100)
	No	8	15.1	7/8 (88)
Injections in last 30 d (n = 34)[e]		50.4	(4–360)	
Currently on opioid agonist	Yes	24	45.3	21/24 (88)
	No	29	54.7	27/29 (93)
Years since diagnosis (n = 33)[e]		6.8	(0–19)	
Treatment-naïve		44	83.0	39/44 (89)
Previously treated		9	17.0	9/9 (100)
HIV co-infected		0	0.0	-
HCV genotype	1	35	66.0	31/35 (86)
	2	5	9.4	5/5 (100)
	3	11	20.8	10/11 (91)
	4	2	3.8	2/2 (100)
Fibrosis score[f]	≥3	12	22.6	11/12 (92)
	<3	41	77.4	37/41 (90)
Treatment regimen	Sofosbuvir/ledipasvir	22	41.5	20/22 (91)
	Sofosbuvir + simeprevir	3	5.7	2/3 (67)
	Sofosbuvir + ribavirin	5	9.4	5/5 (100)
	Sofobuvir + velpatasvir	4	7.5	4/4 (100)
	Sofosbuvir + daclatasvir	9	17.0	8/9 (89)
	Ombitasvir/paritaprevir/ ritonavir/dasabuvir + ribavirin	1	1.9	0/1 (0)
	Elbasvir/grazopravir	9	17.0	9/9 (100)

Abbreviations: HCV, hepatitis C virus; PWID, people who inject drugs; SSP, syringe service program; SVR, sustained virologic response 12 weeks after treatment completion.

[a]Includes 1 patient who discontinued treatment after 6 weeks because he was incarcerated but achieved SVR12.

[b]Undetectable viral load at end of treatment before being lost to follow-up.

[c]Insurance lapse after 4 weeks of treatment.

[d]Two patients were HCV RNA-negative at the end of treatment but at 4 and 6 weeks, respectively, were HCV RNA-positive with genotype 3 after receiving treatment for genotype 1. This could have been due to either reinfection or the unmasking of a minority genotype not detected at baseline. Both patients achieved SVR after subsequent treatment for genotype 3.

[e]Question asked of only subset of population.

[f]Assessed by FibroSURE.

large numbers of PWID, and more studies of this Accessible Care Program and other novel methods of reaching PWID are needed.

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