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Challenges and Opportunities for Treating Hepatitis C Amongst People Who Use Drugs: Experience of an Integrated Mobile Clinic in Baltimore City

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Abstract

Progress in treating chronic hepatitis C virus (HCV) infection has been slow amongst people who use drugs (PWUD). This study describes the HCV treatment cascade amongst people accessing a mobile clinic offering integrated low-threshold buprenorphine and infectious disease services in Baltimore City. From May 1, 2021, to December 31, 2022, 560 people had a rapid HCV antibody test, of whom 201 (36%) had a positive result and amongst those, 117 (58%) had an HCV RNA test performed, 81 (40%) had a documented positive RNA, 45 (22%) were prescribed medication, 42 (21%) started medication, 32 (16%) completed medication, 22 (11%) had blood work to assess for sustained virologic response and 20 (10%) had a documented cure. Challenges including housing instability, insurance barriers and lack of venous access limit progress in this cascade. Providing integrated care models to meet the needs of PWUD in the community is necessary but not sufficient to make progress in improving HCV treatment. Removal of insurance restrictions, availability of point-of-care HCV RNA testing, development of rapid HCV treatment guidelines and development of long-acting injectable HCV treatment are needed to move towards a same-day, one-time test and treat model of care.

Keywords

hepatitis C treatment; homeless; mobile clinic; people who use drugs

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Conflicts of Interest

The authors declare no conflicts of interest.

1 | Introduction

Despite an ambitious goal for more than 80% of persons with hepatitis C infection to achieve hepatitis C virus (HCV) clearance by 2023, the Centers for Disease Control and Prevention have reported that HCV clearance is only 34% amongst those who have been diagnosed for the first time [1], and the incidence of HCV amongst people who inject drugs increased steadily until 2020 [2]. HCV treatment co-located with treatment for substance use disorder and harm reduction services has been shown to increase HCV treatment and cure rates amongst people who use drugs (PWUD) [3, 4]. Despite these promising models, PWUD and people experiencing homelessness face significant barriers to successful HCV treatment [5, 6]. As of 2016, it was estimated that more than 6200 people who inject drugs in Maryland were HCV RNA positive and in need of treatment [7].

This study examines the HCV treatment cascade for people accessing care at Healthcare on the Spot ('the Spot'), a mobile clinic in Baltimore City that offers integrated low-threshold buprenorphine and infectious disease services. We discuss challenges at each step of the cascade and potential solutions to reduce barriers to treatment.

2 | Methods

2.1 | The Spot Mobile Clinic Model

The Spot is a van-based mobile clinic in Baltimore City providing integrated services for PWUD including low-threshold buprenorphine treatment for opioid use disorder; testing and treatment for HCV, HIV and sexually transmitted infections; PrEP for HIV prevention; screening and treatment for depression; wound care; naloxone distribution; vaccinations including Covid, influenza and hepatitis A and B; and case management, including enrollment in housing services [8]. During the study period, the Spot visited nine sites across the city on a regular schedule, including co-located sites with partner organisations offering harm reduction or drug treatment services. Approximately 75% of patients engage in care for buprenorphine, and all services are offered as the standard of care.

HCV testing and evaluation on the Spot is streamlined to minimise steps and time to treatment. At the first visit, rapid point-of-care HIV and HCV antibody testing is conducted, HCV RNA and treatment evaluation labs are immediately drawn when the HCV antibody is positive, and the provider conducts a treatment evaluation visit on the same day. If phlebotomy is unsuccessful, the patient can go to an external commercial lab and/or to reattempt phlebotomy at a future visit. When the patient is eligible for the simplified HCV treatment algorithm [9], medication is prescribed as soon as lab work has resulted. Once prior authorization is approved, the medication is delivered to the Spot team and brought to the patient, who is then followed for refill delivery and sustained virologic response (SVR) assessment.

2.2 | Study Design

All patients receiving care on the Spot from May 1, 2021, to December 31, 2022, were included in this retrospective cohort analysis, and patient outcomes were assessed through

October 31, 2023. Johns Hopkins Institutional Review Board determined this study to be quality improvement and exempt from human subjects research.

2.3 | Data Management and Statistical Analysis

Data were collected for routine clinical care and managed in REDCap [10]. Patients with a positive HCV antibody test were included in the HCV care cascade, and descriptive statistics were reported.

3 | Results

A total of 739 patients received any service on the Spot from May 1, 2021, to December 31, 2022. Patients were primarily male ($n = 469$, 63%), Black ($n = 534$, 72%) and non-Hispanic ($n = 698$, 94%). Of the 739, 560 (76%) had an HCV antibody test performed and 201 (34%) of those tested had a positive result (Figure 1). Patients with a positive HCV antibody were primarily male ($n = 133$, 66%), half were Black ($n = 100$, 50%), 74 (37%) reported active injection drug use and 133 (66%) received buprenorphine treatment for opioid use disorder in the Spot program. Forty-nine (24%) people reported unstable housing (living in a shelter or with friends or family), 44 (22%) reported being unsheltered (sleeping outside or in abandoned houses), 78 (39%) reported stable housing and 30 (15%) have unknown housing status.

Of the 201 with a positive HCV antibody, 151 (75%) were previously diagnosed, of whom 39 (19%) reported prior cure and three (1%) were engaged in HCV treatment elsewhere. One hundred and seventeen (58%) patients had an HCV RNA test performed, 35 (18%) declined blood work and 49 (25%) were unable to provide a blood specimen due to difficult venous access. Of the 39 reporting prior HCV cure, 21 had an RNA test performed and eight had a positive HCV RNA. Of the 117 who had an HCV RNA test performed, 81 (69%) had a positive RNA. Forty-five people (22% of antibody positive) were prescribed HCV medication, 42 (21% of antibody positive) started medication, 32 (16% of antibody positive) completed treatment, 22 (11% of antibody positive) had labs drawn to assess for sustained virologic response (SVR) at least 12 weeks after treatment completion, and 20 (10% of antibody positive) had a documented SVR.

Three of 45 prescriptions were denied by insurance and required appeal, and all were eventually approved. The median time from initial prescription to medication delivery was 28 days (range 7–143 days). The median time from the HCV antibody test to medication start was 84 days (range 28–532). Of those who were prescribed medication, five were given 1 month of medication before being lost to follow-up, and four decided not to take the medication. Two patients had a detectable viral load after treatment, and one patient who achieved SVR was subsequently reinfected in 2023. SVR rates were 17% for stably housed (13/78), 8% for unstably housed (4/49) and 7% for unsheltered (3/44). Eleven patients (6%) were deceased over the course of the study period, eight of whom (73%) were unsheltered or unstably housed.

4 | Discussion

We present real-world HCV treatment cascade data from a mobile clinic offering integrated low-threshold buprenorphine treatment with infectious disease services in Baltimore City. Prevalence of HCV antibody positivity amongst Spot patients is high at 34%, but despite this model of care reducing barriers, only 58% of those with a positive rapid HCV Ab were tested for viremia and only 25% of patients with known HCV viremia ultimately had a documented cure. Several improvements in HCV care delivery could improve this treatment cascade for PWUD.

First, an FDA-approved point-of-care (POC) HCV viral load testing is needed. Rapid HCV RNA testing through a finger stick sample and dried blood spot testing have been shown to be highly reliable and acceptable and improve engagement in HCV treatment [11–13]. In addition to FDA approval of a POC RNA test, guidelines for ‘rapid start’ HCV treatment with minimal necessary lab work that can be conducted through POC finger stick testing should be developed.

Next, insurance barriers to HCV medications should be removed. Maryland Medicaid still requires prior authorization (PA) and recently received a ‘C’ on the Hepatitis C State of Medicaid Access Report Cards [14]. Despite all prescriptions eventually being approved for our patients, the median time from initial prescription to delivery of medication was 28 days. Many states have made progress in removing restrictions around requirements for advanced fibrosis or for sobriety, and 22 states have removed PA for most patients. National advocacy is needed for continued removal of restrictions and technical assistance for states to pursue innovative financing models such as the ‘Netflix model’ [15], where the state pays a flat fee for drug access, reducing costs and bureaucratic hurdles.

Additionally, progress towards development and approval of a long-acting injectable HCV treatment is urgently needed. Thomas et al. describe the feasibility and pathway towards development, and make the case that one-time injectable treatment would significantly shift the paradigm for tens of millions of people worldwide [16]. Programs such as ours are ideal for same-day test and treatment for high prevalence populations, and this would be broadly applicable in correctional facilities, substance use disorder treatment programs, harm reduction centres, overdose prevention sites and during inpatient hospitalizations.

Finally, and importantly, the patients at the Spot often have immediate and urgent needs related to their substance use disorder and face numerous challenges, such as housing, food, safety and employment instability. Understandably, in this context, treatment for HCV, which is generally asymptomatic, is not prioritised by patients. Patients in our cohort who experienced homelessness had less than half the rate of SVR compared to stably housed patients. In addition, 11 patients died from non-HCV related causes. Homelessness has been estimated to contribute to 20% of HIV and HCV infections amongst PWID [17]. To make substantial and transformative progress in the HCV elimination, it is critical to address structural barriers to care and establish patient-centered service delivery models with integrated medical, behavioural and social services.

Our study has limitations. We present real-world data collected for clinical service delivery and some data are missing.

5 | Conclusion

Progress towards HCV elimination amongst people who use drugs and people experiencing homelessness will continue to be slow unless significant advances are made in medication access, POC evaluation and development of long-acting injectable medication facilitate a same-day, one-time test and treat model of care. The HCV treatment paradigm should shift to lessons learned from HIV care with ‘rapid start’ and ‘treatment as prevention’ being at the forefront of strategy development.

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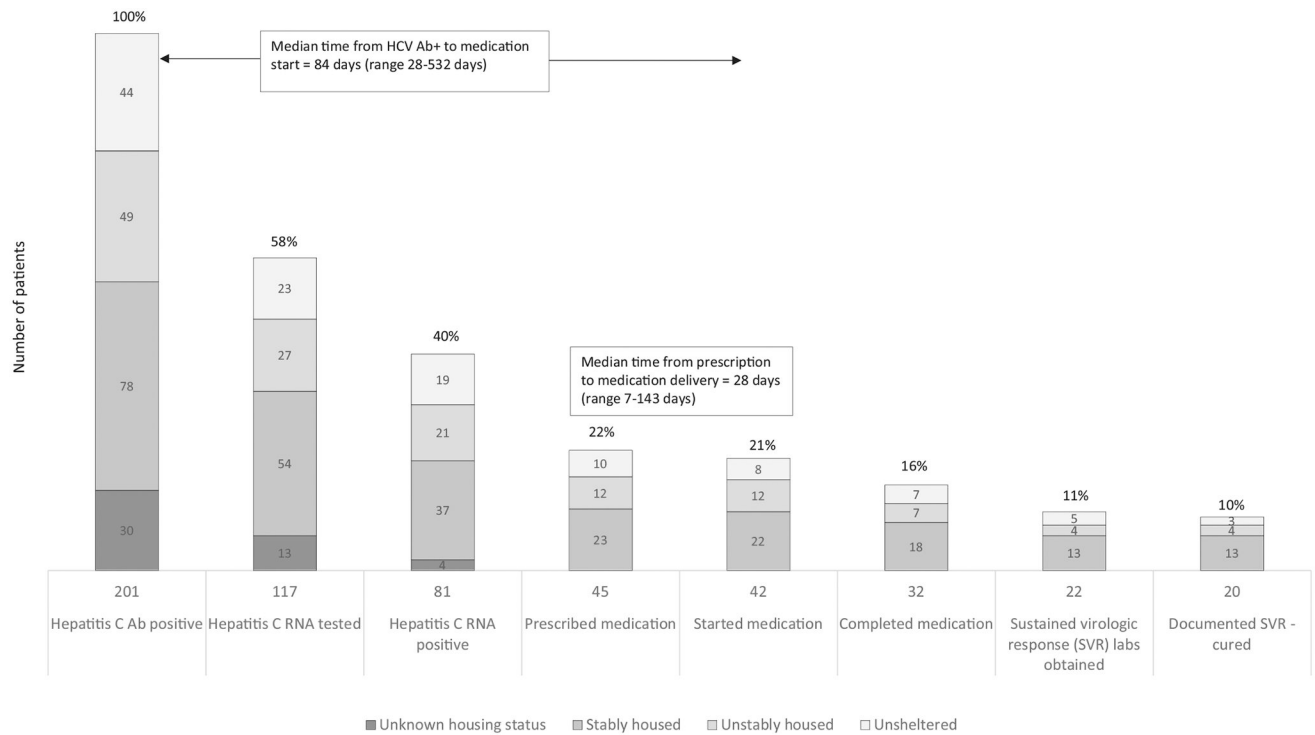
Data Availability Statement

The data that support the findings of this study are available from Baltimore City Health Department. Restrictions apply to the availability of these data, which were used under license for this study. Data are available from the author(s) with the permission of Baltimore City Health Department.

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**FIGURE 1 |.**

Hepatitis C testing and treatment cascade for the Spot mobile clinic for patients with a positive hepatitis C antibody test between May 2, 2021 and December 31, 2022, by housing status. Of 201 HCV antibody positive, 35 declined to have blood drawn and 49 were unable to obtain blood specimens for RNA testing, 3 were in care elsewhere, 34 were lost before treatment and 11 were deceased during the study period. Amongst the 45 who were prescribed medication, 3 were initially denied and all were eventually approved, 5 took 1 month of medication before being lost to follow up, 4 chose to stop medication due to housing instability or other priorities and 10 completed medication but did not return for SVR labs. Of the 22 who had SVR labs drawn, 2 failed treatment. One patient who achieved SVR was reinfected.