Journal of Student-Run Clinics
Original Study

Hepatitis C Treatment for Patients Without Insurance in a Student-Run Free Clinic: Analysis of Demographics, Cost, and Outcomes

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Published: October 23, 2023

Abstract

Background: Hepatitis C virus (HCV) predominantly affects marginalized patients, who have been reported to lack access to effective treatment. A high overlap exists between those at risk for HCV and those cared for by student-run free clinics. The purpose of this study is to present how one student-run free clinic provides accessible HCV care to patients as a model for other free clinics to offer similar services.
Methods: Data was reviewed from the electronic medical record and MedData Services, a software for management of patient assistance program (PAP) applications. Data collected included information regarding HCV diagnosis, treatment, and medication access process.
Results: At our clinic, there were 23 patients with a documented diagnosis or prior history of HCV infection. Treatment was initiated in 83% (n = 19) of patients, and 89% (n = 17) of these patients completed treatment. Most patients (84%, n = 16) received HCV medications directly through Shade Tree Clinic. All but three patients were treated with Harvoni®. All patients with available laboratory data (n = 13) at >12 weeks status-post treatment had achieved sustained viral response. PAP applications were successfully approved for 89% (n = 17) of submitted applications (n = 19), representing the primary avenue for our clinic to access HCV treatments.
Conclusions: Our experience with HCV demonstrates that effective HCV treatment is feasible in a student-run free clinic setting.

Background

Hepatitis C virus (HCV) is the most common bloodborne infection in the United States.[1] Despite a cure rate approaching 90%, an estimated 5.2 million people live with the disease nationally.[2,3] Untreated HCV increases the risk of chronic liver disease, cirrhosis, and hepatocellular carcinoma.[4] Consequently, the United States Preventive Services Task Force recommends universal HCV screening in all adults.[5] However, a discrepancy remains between infection and treatment, with access to care being a major barrier. Patients with HCV are more likely to be uninsured than those without the virus as evidenced by the finding that only 54% of patients with HCV had any type of insurance.[6] Affordability of the treatment is particularly challenging, especially without insurance. The cost of a twelve-week treatment plan is often higher than $80,000.[7] This cost, and the prevalence of HCV infection in uninsured populations, highlights a major challenge in meeting the needs of those with infection and without insurance.[6]

Many socioeconomic factors contribute to HCV's epidemiology. Poverty, fewer than 12 years of education, and former incarceration are all independently associated with the disease.[1,8] Patients with low income (0-49% of the national average) had a 1.64-fold increased risk of HCV infection.[9] People either unemployed or on disability pension also had a 2.24-fold or 2.71-fold risk of HCV infection, respectively.[9] One metanalysis identified that incarceration within the last two years is associated with a 62% increase in HCV acquisition risk.[10] Past incarceration had a smaller, yet still augmented, effect by increasing acquisition risk by 21%.[10] Despite evidence that underserved populations are significantly more affected by HCV, many barriers to treatment remain, including, but not limited to, cost, geographic access, housing instability, and stigma.[11] Finding solutions to these barriers is more relevant than ever, as the 2024 White House Budget proposal included a goal to eliminate HCV within the next five years.[12]

One solution to increase accessibility and affordability of brand-name medications is patient assistance programs (PAPs) provided by pharmaceutical companies.[13] PAPs provide medications at free or significantly reduced prices for patients without insurance. For example, for HCV treatments, Gilead Sciences provides a PAP for sofosbuvir (Sovaldi®), ledipasvir/sofosbuvir (Harvoni®), sofosbuvir/velpatasvir (Epclusa®), and sofosbuvir/velpatasvir/voxilaprevir (Vosevi®).[14] However, PAPs often have varying insurance, income, and/or immigration status criteria, and patients who may qualify are not consistently aware of their availability.[15] Furthermore, qualifying patients may not have consistent access to healthcare to obtain prescriptions and provider-completed documents needed to complete PAP applications. Student-run free clinics have implemented workflows to better utilize PAPs to provide prescription medication access for their patients.[16,17]

Student-run free clinics frequently provide care to uninsured or underinsured community members. A large overlap exists between the demographics of those at greatest risk for HCV and those cared for by student-run free clinics. Access to HCV treatment therefore is paramount to the comprehensive care of these patients. The purpose of this study is to present how one student-run free clinic provides HCV care to its patients and to outline its experience accessing treatment for its patients.

Methods

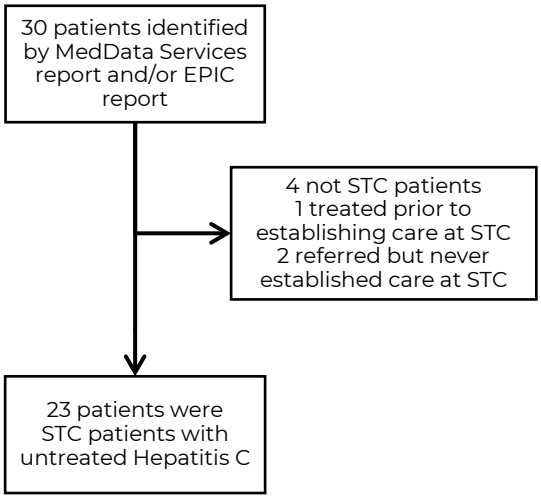
Setting

Shade Tree Clinic (STC) is a student-run free clinic affiliated with Vanderbilt University Medical Center (VUMC) in Nashville, Tennessee (TN). The clinic has a population of nearly 300 uninsured/underinsured patients, to which they provide primary care, and thirteen specialty care services such as rheumatology, orthopedics, plastic surgery, dermatology, and gynecology. The clinic's patient population is generated from a combination of self-referrals, referrals from within VUMC, and referrals from community organizations such as reentry programs or other clinics. Over 50% of the clinic's patients do not speak English or have limited English proficiency. Patients commonly face housing instability, former incarceration, transportation barriers, illiteracy, lack of social security number, and food insecurity. Shade Tree Clinic is located in Davidson County, which is one of the 61 counties (64% of TN counties) that do not offer HCV treatment through the health department.[18] TN has one of the highest rates of acute HCV cases nationally, and Davidson County had an estimated 1,021 newly reported chronic cases of HCV.[19] This study was approved by the local institutional review board (IRB #230016)

Patient Identification

Patients were identified through a PAP software and the electronic health record (EHR). MedData Services (2023, MedData Services, Grapevine, Texas), a software used by STC to manage PAP applications, was used to compile a list of patients who filed applications for the HCV treatments Epclusa® or Harvoni® under a STC provider. A report in Epic (Feb 2023, Epic Systems Corp., Verona, Wisconsin), the EHR used by STC, was concurrently generated for any patients with an encounter in the STC between 2017 to 2022 and who had a diagnosis or history of HCV. Chart review was completed to confirm that the patients on one or both lists were, 1) former or

Figure 1. Patient identification flow diagram



STC: Shade Tree Clinic

current STC patients, 2) had active HCV at some point during their time under the care of STC, and 3) were seen by a STC provider. This process is outlined in Figure 1.

Data Collection

Chart review from the EHR was completed for additional demographic and clinical data collection. Demographic data included age, gender, race, language, patient status, incarceration status prior to HCV diagnosis, and Area Deprivation Index (ADI) state deciles and national percentiles. Patient status (noted as current or past [transitioned, lost to follow up, or deceased]) was determined by chart review and is an indication of whether the patient is still under the care of STC. Incarceration status was determined by searching the EHR for the terms "Incar," "Prison" (which concept maps to include "Jail"), and "Dismas", a local organization which refers formerly incarcerated patients to STC. ADI is a measure for neighborhood disadvantage derived from 17 education, employment, housing-quality, and poverty measures in Census and American Community Survey data, with state ADI reported in deciles and national ADI reported in percentiles.[20] For both, the higher the score, the more disadvantaged the neighborhood.[20] Date and reason for initial establishment of care at STC was determined by review of the EHR. Clinical notes, serologies, and imaging studies were reviewed to collect the date of HCV diagnosis, HCV genotype (the specific viral strain), fibrosis score (a noninvasive measure of hepatic scarring) if available, medication used to treat HCV, dates of treatment initiation and completion, and viral load following completion of treatment. MedData Services patient profiles were reviewed to identify whether medication was obtained through PAPs, the application submission and approval dates, if applicable. A second reviewer doublechecked the MedData and EHR information for accuracy.

Costs were estimated for Harvoni® (ledipasvir 90mg/sofosbuvir 400mg) and Epclusa® (sofosbuvir 100mg/velpatasvir 100mg). These first line medications were the preferred treatments at STC due to accessibility, provider familiarity, and genotype coverage.[21] Costs were estimated according to gross prices at the retail level in the United States and according to the GoodRx average retail price for generic versions.[22,23]

Data were analyzed using Microsoft Excel (Version 2308, Microsoft, Redmond, Washington). Results were reported as percentages or medians with interquartile ranges.

Results

Of all patients with at least one encounter at STC documented in the EHR, 23 patients had a documented diagnosis of or a prior history of HCV infection. Demographics of these patients are described in Table 1. Among the individuals with active HCV infection seen at STC, patients were more likely to be male (65%), English-speaking (87%), and identify as white (87%). Median area deprivation index at the state level was at the 4th decile (interquartile range [IQR], 2.5–6.5) and at the national level was at the 57th percentile (IQR, 40–76), reflecting that these individuals were more disadvantaged than 30% of the state and 57% of individuals across the country, respectively.

Among the patient cohort, six patients (26%) had a known diagnosis of HCV at the time of presentation to STC. In addition, ten patients were formerly incarcerated (44%). Following diagnosis of active HCV infection, patients

Table 1. Demographics of patients with hepatitis C at Shade Tree Clinic

Demographic	Median (IQR)	n (%)
Age	62 (55.5-66.5)	-
Area Deprivation Index: State Decile	4 (2.5-6.5)	-
Area Deprivation Index: National Percentile	57 (40-76)	-
Male	-	15 (65)
English Speaking	-	20 (87)
White	-	13 (87)
History of incarceration prior to establishing care	-	10 (44)
Tennessee resident	-	22 (96)

IQR: interquartile range

Table 2. Hepatitis C diagnosis and treatment characteristics

Treatment characteristic	n (%)
Initiated treatment	
Yes	19 (83)
No	4(17)
Location of treatment (n=19)	
Shade Tree Clinic	16 (84)
Referred within medical center	3 (16)
Medication used for treatment	
Harvoni®	16 (84)
Epclusa®	2 (11)
Ribavirin/Pegasys®/Sofosbuvir®	1 (5)
Completed treatment (n=19)	
Yes	17 (89)
No	2 (11)
Viral load at treatment completion (n=17)	
Undetectable	17 (100)

underwent genotyping and fibrosis scoring. These characteristics are available in Online Appendix A. Most patients (n = 19, 83%) initiated treatment for HCV, and of these 19 patients, 17 (89%) went on to complete treatment (Table 2). Two patients did not begin treatment as they either declined treatment or were lost to follow-up, and one patient's viral load became undetectable during the process of acquiring medication. The fourth patient who has not initiated treatment is pending acquisition of the medication and intends to complete treatment.

Most patients received medications directly through STC (84%). In three cases (16%), patients were referred through STC to the VUMC Hepatology and Infectious Disease clinics for treatment as the clinic had not yet established a process for applying to PAPs. Harvoni® was the most common medication used among STC patients for the treatment of HCV (84%). Epclusa® was prescribed to two patients (11%), and 1 patient (5%) received a regimen of Ribavirin, Pegasys®, and Sofosbuvir®. Of patients who initiated treatment, nearly all (n = 17, 89%) went on to complete treatment. All patients with available laboratory data (n = 13) at >12 weeks status-post treatment achieved sustained viral response. Data were not available for patients who were tested before 12 weeks or who were lost to follow-up. At the time of analysis, 7 (30%) patients were currently patients of STC, 6 (26%) had received insurance and transitioned to new primary care providers, 9 (39%) had been lost to follow-up, and 2 (9%) had passed away.

PAPs were frequently utilized to obtain HCV treatments such as Epclusa® or Harvoni®. Our clinic has submitted 19 applications to PAPs for HCV treatment. 17 (89%) applications were approved. Patients were denied PAP approval for: 1) having Medicaid insurance in another state or, 2) submitting an incomplete application and then becoming lost to follow-up. Of the seventeen patients who had an approved PAP application, two did not initiate treatment for which they were approved (12%). In one case, the patient's HCV viral load became undetectable during the process of obtaining approval, so treatment was no longer indicated. In the second case, the patient declined treatment. Among patients for whom a PAP application was submitted, the median time between a PAP application being created and treatment initiation was 63 days (IQR, 45.5–94.5, n = 15). The times for each step within the PAP application are shown in Table 3. Online Appendix B enumerates the PAP application process for each patient. Available data is presented but some records did not clearly document all timepoints, so sample sizes vary for variables.

The value of HCV treatments (Harvoni®, Epclusa®) obtained for STC patients was estimated as described above. For 18 patients who received Harvoni® (n = 16) or Epclusa® (n = 2), the

Table 3. Time between patient assistance program application steps or PAP characteristics

Variable	n	Median days (IQR)
Time between PAP enrollment and faxing application	16	10.5 (0-23.5)
Time between faxing application and approval	14	6.5 (5.3-20.8)
Time between approval and treatment initiation	12	15.5 (10.8-31.5)
Applied for PAP through Shade Tree Clinic (n=23), n (%)		
Yes	19 (83)	-
No	3 (13)	-
Not yet applied	1 (4)	-
Approved for PAP (n=19)		
Yes	17 (89)	-
Denied	2 (11)	-

IQR: interquartile range; PAP: Patient Assistance Program

estimated gross retail value of treatments was $1,667,173 (Harvoni®: $1,499,065; Epclusa®: $168,108).[21] The estimated average retail price of these generic treatments on GoodRx is listed as $14,288.20 for a 28-day supply of generic Harvoni® and $10,922.07 for a 28-day supply of generic Epclusa®.[22] Medication supplies lasting 84 days would cost patients approximately $42,864.60 for generic Harvoni® and $32,766.21 for generic Epclusa®.[22] The total cost per GoodRx pricing amounts to $737,077.82 (generic Harvoni®: $671,545.40; generic Epclusa®: $65,532.42).[22]

Conclusions

This study highlights one clinic's experience to demonstrate that accessing HCV treatment via PAP programs is feasible and accessible for free clinics and can serve as a vital tool for providing care to underserved populations. Despite the significant costs of HCV medications, receipt of medications by means of PAPs meant that there was no financial expenditure from the clinic to acquire HCV treatment. The demographics of patients in this study reflect the broader literature's assertion that HCV disproportionately affects underserved communities. A significant portion of our study cohort had a history of incarceration and were, on average, more disadvantaged at a national level based on their ADI. Relative to state measurements, our patients were not as proportionately disadvantaged; however, poverty levels in TN are generally higher compared to other states, and the Nashville metropolitan area is also less impoverished compared to other areas of TN.[24] In our experience, all patients who completed their prescribed course of treatment and were tested for viral load >12 weeks after treatment had achieved sustained viral response, highlighting the effectiveness of HCV modern treatments and the potential to reduce the health burden of HCV and its consequences on patients and the healthcare system.

Any successful HCV treatment program must include longitudinal follow-up with patients for diagnosis, monitoring, medication dispensing, and confirmation of viral remission. Clinics must be able to diagnose HCV. Viral genotype is not required to applying for PAP medications, but it can be helpful in guiding treatment decisions despite contributing to cost. The HCV PAP applications do, however, request a fibrosis score, obtained through serum biomarkers or elastography via ultrasound imaging.[25] Beyond simply having access to care for patients, these barriers at the clinic level can impede securing HCV treatment. At the patient level, individuals may decline treatment or be lost to follow-up during treatment, as was the case for some STC patients. Therefore, coordination is required among patients, clinics, and PAP processes to treat HCV among uninsured patients and minimize barriers that delay or prevent completion of treatment, such as lapsing insurance or lack of follow-up.

The establishment of an internal PAP department at STC has afforded patients with

substantially increased medication access without any financial costs to patients or the clinic. Despite the benefits of PAPs, to our knowledge, there are only three published mentions of student-run free clinics utilizing PAPs.[16,26,27] Further integration of PAPs into free clinics is crucial to expand the reach of HCV care. For example, Duke hepatologists approached patients individually in Durham, North Carolina, offering treatment either through PAP or clinical trials.[28] Some patients, however, were unwilling or unable to travel to academic centers.[28] Partnerships with smaller, local clinics will therefore be paramount in reaching these patients.[28] Free clinics, confident in navigating the PAP process, can expand this reach by forming an internal department to support patients completing PAPs, as our clinic has done, and offer care that otherwise would be inaccessible to patients in need.

This study had a few notable limitations. First, the study occurred at a single, urban student-run free clinic. Therefore, the data may not be generalizable to patients at other clinics, particularly in states that have better health-department-led HCV treatment access. Additionally, while STC's patient cohort expands beyond metropolitan Nashville and includes many rural patients, the data may not reflect student-run free clinics that are not near a major city or are exclusively rural in their patient population. Second, the list of HCV-treated patients was compiled from VUMC and STC's MedData Services and EHR records; therefore, the identification of patients was reliant on the quality and consistency of documentation within these data sources. Our records may neglect any patients treated at other institutions, such as a health department or outside hospital system, if not properly documented in the EHR. However, considering the lack of HCV-treatment infrastructure in TN and the very limited healthcare options of our patients, we are confident that we captured most, if not all, STC patients who received HCV treatment since the initiation of the clinic's HCV PAP workflow in 2016.

HCV is a disease that disproportionately affects underserved populations. Therefore, treatment solutions must be designed with these patients in mind. However, high medication costs, limited geographic distribution, lack of transportation, among other social barriers prevent patients from receiving care. Free clinics, including student-run free clinics, nationally work to overcome these barriers, and they can lessen these barriers by offering PAP-provided treatments at clinics closer to patients. STC demonstrates improved access to HCV treatment, with our experience demonstrating the feasibility and success of treatment of HCV in a student-run free clinic setting aided by PAPs to obtain HCV treatments for free. We hope that our experience demonstrating successful resolution of HCV in all patients who completed treatment with medication primarily obtained at no cost from PAPs will serve as a model for similar clinics and institutions. Although the retail cost of HCV treatment is insurmountable for student-run free clinics on a limited budget, PAPs offer an accessible avenue that we have consistently utilized to provide HCV care. Together, we can take a major step towards overcoming the disparity between HCV infection and treatment.

Acknowledgements

We would like to acknowledge Vanderbilt University Medical Center and Vanderbilt University School of Medicine leadership for their support in the treatment of uninsured patients. We would also like to acknowledge Julie Lee, Sharon Kam, MD, and Daniel Sack, PhD, for their previous leadership in coordinating Shade Tree Clinic's use of patient assistance programs. Finally, we would like to thank the Shade Tree Clinic patients for allowing us to be part of their care.

Disclosures

The authors have no conflicts of interest to disclose.

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