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The Hepatitis C Virus treatment cascade at an urban post-incarceration transitions clinic

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Introduction

Chronic Hepatitis C Virus (HCV) infection is a growing public health crisis in the United States. In 2007, HCV-related deaths surpassed those from HIV [1], and over the next 10 years, the burden of HCV-related disease is predicted to triple [2]. Incarcerated individuals are a critical target for HCV treatment; however, population-based epidemiologic studies that collect data on HCV, such as the National Health and Nutrition Examination Survey, typically exclude this population. Although data is limited, HCV prevalence among prisoners is estimated to be 23 times greater than that of the general population [3]. Approximately two-thirds of incarcerated individuals meet criteria for a substance use disorder [4], which is an important risk factor for HCV. Two-thirds of injection drug users with a history of incarceration have been exposed to HCV [5,6]. Adequately addressing the HCV crisis will require the engagement of individuals with criminal justice involvement.

Improvements in HCV treatment with directly acting antivirals (DAAs) have made HCV cure a possibility for the majority of chronically infected individuals. Compared to interferon-based treatment regimens, new all-oral regimens require shorter duration of treatment, are associated with minimal side effects, and have cure rates of greater than 90% [7,8]. In the era of interferon-based regimens, fewer than 20% of all HCV-infected individuals ever initiated treatment [9]. Though some correctional facilities have offered treatment for HCV, the proportion of HCV patients with criminal justice involvement who have been treated is unknown.

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Conflict of Interest

The authors declare that no conflicts of interest are present.

Increasing rates of HCV treatment will require knowledge of where lapses in HCV care occur. The HIV cascade of care was developed to better elucidate these lapses and identify targets to intervene and increase identification and treatment of HIV infection [10]. Similarly, the HCV cascade highlights lapses in the continuum of care of HCV. The steps of the cascade pertain to individuals with chronic HCV infection, including screening, awareness of HCV infection, HCV RNA testing to confirm the chronicity of infection, referral to specialists for staging of disease, prescription and completion of HCV treatment, and achievement of a sustained virologic response (SVR) [11]. In the general population, there are significant lapses at each step of the cascade [9]. Inconsistent screening methods, low referral to specialty providers, missed appointments, and failure to initiate treatment contribute to these lapses in the general population [12]. However, there has been little attention to lapses in the HCV cascade for individuals with criminal justice involvement.

Following release from incarceration, there are opportunities to engage HCV-infected individuals in medical care and initiate HCV treatment; however barriers such as lack of insurance coverage or provider availability prevent individuals with criminal justice involvement from accessing medical care [13]. Post-incarceration transitions clinics have emerged as a model of care to address these specific barriers by facilitating timely linkage to care that is culturally appropriate for formerly incarcerated individuals [14]. Since 2009, we have cared for more than 400 patients with criminal justice involvement at the Bronx Transitions Clinic (BTC) [15]. In this study, we describe the HCV cascade for a cohort of transitions clinic patients with chronic HCV infection in order to identify lapses in HCV care. We also sought to identify specific reasons for lapses in HCV care. This data can inform interventions seeking to improve HCV care for individuals with criminal justice involvement.

Materials and methods

We conducted a retrospective cohort study, reviewing electronic health records for formerly incarcerated individuals who presented for medical care at the BTC between July 2009 and September 2014. The study was deemed exempt by the institutional review board of the Albert Einstein College of Medicine.

Setting

The BTC is located within a federally qualified health center (FQHC) that is affiliated with an academic medical center in New York City. The BTC is a collaboration between the FQHC and the Osborne Association (OA), a community-based organization that provides services to individuals with criminal justice involvement, including discharge planning for individuals with chronic health conditions who are being released from New York state prisons. The BTC offers expedited appointments for comprehensive medical care within two weeks of release. Medical providers have included more than twenty medical residents and five attending generalist physicians. Providers rotate seeing patients during two half-day clinic sessions per week, providing primary care, HIV care, and referrals to specialty services. A community health worker, who was formerly incarcerated and had training in health education and patient navigation, assisted patients with engagement, registration and

accessing specialty care. The BTC has been described in detail elsewhere [15]. Both the BTC and the OA are located in low-income communities with high incarceration rates and serve a predominately racial/ethnic minority population.

The BTC has no standard protocol for HCV assessment and treatment. Providers screen patients for HCV based on known risk factors. Before 2011, patients with chronic HCV were referred to an off-site Hepatology clinic for HCV-specific evaluation and treatment. This clinic is located on the academic medical center's main campus approximately 5 miles from the BTC and is accessible by public transportation. Beginning in 2011, the FQHC housing the BTC began to offer onsite HCV care with a primary care physician trained in providing HCV treatment, including interferon-based regimens. After implementation of onsite HCV care, patients with chronic HCV still required internal referral to this HCV provider, but they received such care onsite at the FQHC.

Participants

All BTC adult patients age 18 or greater who initially presented between July 2009 and September 2014 were included in the study. The BTC keeps a registry of all patients and prior evaluation has demonstrated that most are male, racial/ethnic minorities, have Medicaid, and have at least one chronic health condition [16].

Data Collection

We reviewed electronic health records of all BTC patients using a standardized data collection tool. First, we determined if screening for HCV was performed and identified patients who had screened positive for HCV antibodies (anti-HCV positive). Next, for anti-HCV positive patients, we extracted detailed clinical and sociodemographic data through chart review. We recorded HCV care received at any time following initial presentation and recorded how many months of follow-up each patient underwent. Steps of the HCV treatment cascade were based on previously published data and were adapted for primary care by replacing the step of "liver biopsy" with "referral for specialty HCV care" [9]. As part of our assessment for reasons for lapses in HCV care, we conducted additional review of electronic health records to search for documented reasons. We also used an online New York State Department of Corrections database to determine whether participants were re-incarcerated in a New York State prison during the study period. All data was extracted by one author (LH) and confirmed for accuracy by a second author (ADF).

Measures

The HCV Cascade—Electronic health records were used to assess steps of the HCV treatment cascade, defined as: 1) detection of anti-HCV; 2) confirmation of chronic HCV infection (HCV RNA > 75 IU/mL); 3) referral for specialty HCV care (documentation of referral by the primary care provider or presence of a referral form); 4) received specialist evaluation (per visit note, patient attended at least one on-site or off-site specialist appointment); 5) initiation of HCV treatment (at least one prescription for HCV medications); 6) completion of treatment (completion of a 3-, 6-, or 12-month course of anti-HCV medications as recommended by the treating provider); and 7) achievement of SVR

(undetectable HCV viral load at least 12 or 24 weeks after finishing treatment, depending on treatment regimen).

Lapses in care—A reason for lapses in HCV care along the care cascade was determined by consensus among authors using information documented in provider notes or the New York State Department of Corrections database. Reasons were coded as: patient not stable for treatment (typically, because of uncontrolled mental health or substance use disorders), transferred care, provider did not address HCV, patient refused, patient re-incarcerated (within 12 months of last medical visit), waiting for better treatment options, currently undergoing evaluation, or not specified/lost to follow-up.

Data Analysis—Steps of the HCV cascade and reasons for lapse in care are reported in frequencies and percentages.

Results

Among the BTC patients with chronic HCV infection, median age was 50, and most were male (95%), Hispanic (65%), and had Medicaid (96%). Common co-morbidities included HIV infection (44%), depression (30%), and either current (67%) or past (17%) opioid use disorder [see Table 1].

HCV cascade

Of 451 BTC patients accessing care at the transition clinic between July 2009 and September 2014, 317 (70%) were screened for presence of HCV antibody, and 106 (33%) screened positive. Of the 106 anti-HCV positive participants, 93 (88%) were evaluated for HCV viremia and 84 (79%) were confirmed to have chronic HCV infection. Therefore, of the total BTC population, 19% of patients were confirmed to have chronic HCV. Of the 84 with chronic HCV infection, 48 (57%) were referred for HCV specialty care, 30 (36%) were evaluated by an HCV specialist (on-site or off-site), 8 (10%) initiated HCV treatment, 5 (6%) completed HCV treatment, and 3 (4%) achieved SVR [see Figure 1]. 4 of the 5 (80%) who completed treatment received an interferon-based regimen. Of these 4, 2 had negative viral loads following treatment completion but did not undergo confirmatory testing at 24 weeks and therefore did not meet our definition of SVR. The mean length of follow up from initial presentation was 30.7 months (SD $\pm$ 17.29).

Lapses in care

Of the 84 patients with chronic HCV infection, 16 had no lapse in care (8 had started treatment and 8 were being evaluated for HCV treatment). We found that significant lapses in care occurred: 1) following identification of chronic HCV infection but prior to referral for further evaluation; and 2) after referral for further evaluation was made but prior to specialist evaluation. Among the 68 with lapses in care, we found that 13 (15%) were waiting for better treatment options, 10 (12%) were deemed not to be stable for treatment by their provider due to mental health or substance use disorders, 7 (8%) transferred care, 5 (6%) refused further evaluation, 4 (5%) were re-incarcerated during evaluation, and two (2%) did not have documentation that their HCV infection was addressed. 27 (32%) patients

were lost to follow up for unspecified reasons [See Figure 2]. On chart review, we attributed re-incarceration as the reason for lapse in care for four patients; however, overall 16 (19%) patients with chronic HCV were re-incarcerated after their initial BTC visit, but there was insufficient documentation to determine whether this was the reason for the lapse in care for most.

Discussion

In this retrospective cohort study of formerly incarcerated individuals who received medical care at a post-incarceration transitions clinic, chronic HCV infection was very common (19%), but few patients were treated (10%) and cured (4%). The majority of patients lost contact with the treatment cascade before they could be considered for antiviral therapy. Our data suggest that even with access to medical care and some measures to support patients (e.g., a community health worker at the BTC), high risk populations, like formerly incarcerated individuals, may not receive HCV treatment.

Our findings are relevant for efforts to optimize HCV care delivery. At the BTC, steps that were dependent on primary care providers were performed at rates greater than those reported in the general population, specifically, screening (70% vs 50%) and confirmatory viral load testing (88% vs 63%) [17,18]. This is likely because incarceration is a known risk factor for HCV. However, referral to HCV specialists and retention in care were equally low when compared to the general population. 12% of patients were deemed to be unstable for treatment, and nearly one in five patients were re-incarcerated following their initial visit to the BTC.

These findings are consistent with other studies, which have demonstrated that an overwhelming majority of patients have yet to start treatment for HCV infection, now a curable disease. Models created by Linas et al have predicted that imperfect follow-up reduces the effectiveness of HCV therapy by 75% and that without improvements in retention in care, it is unlikely that a greater proportion of HCV-infected patients will ever start treatment [19]. Specialist referral has previously been documented as a major barrier to care [20]. Two population studies, the National Health and Nutrition Examination Survey and the Chronic Hepatitis Cohort Study demonstrated that only 32–38% of HCV patients in the United States have received specialist care [21]. Others have proposed onsite or integrated HCV care in primary care settings as a means to achieve greater HCV treatment [22,23]. Since 2011, the BTC has offered onsite HCV care from a primary care provider trained in HCV treatment. Offering onsite referral addressed one potential barrier, because patients did not have to travel to a new location to receive HCV treatment, and rates of referral and HCV specialist evaluation did increase after implementation of the onsite HCV specialist [data not shown]. However, patients still required an internal referral, because primary care providers who had not received training in HCV treatment were reluctant to treat HCV. In our efforts to reduce HCV prevalence, making HCV treatment easily accessible should be a high priority.

For individuals with criminal justice involvement, high rates of recidivism and re-incarceration are known to complicate management of other chronic disorders, such as HIV

infection, following release from incarceration [24]. Among our patients, a surprising number of patients (5) who were interested in HCV referral and treatment were re-incarcerated before they could fully engage in care. The Bureau of Justice Statistics estimates that nationally, 40% of those released from state prisons for drug-related crimes are re-incarcerated for a new crime within three years of release. Moreover, patients with mental health and substance use disorders, both common in our sample, are at increased risk for re-incarceration [25]. Re-incarceration often occurs for technical violations, such as missing parole meetings or committing misdemeanor offense; one study demonstrated that a quarter of New York City parolees were re-incarcerated for technical violations within three years of release [26]. For providers treating patients with prior criminal justice history, understanding the risk of recidivism is an important factor in managing their care.

More intensive models of HCV care and support may be necessary to fully engage high-risk populations. Given the relationship between injecting drug use and HCV infection, and the strong correlation between these two factors and a history of incarceration, integrating HCV treatment within opioid treatment programs or primary care settings that offer opioid agonist treatment can produce synergistic results. [27] A significant portion (12%) of patients in our study were not referred for further evaluation due to an unstable substance use disorder, indicating that integrated treatment may be crucial for a subset of HCV-infected patients. Others have demonstrated that peer educators, who have previously been treated for HCV, can promote treatment initiation and completion by recruiting new patients and facilitating peer support groups [28]. At the BTC, new projects are being implemented to enhance support for patients in need of HCV therapies. The project will add an HCV-specific case manager, a full-time patient navigator, and a peer educator who has previously undergone HCV therapy to run educational and support groups for patients initiating or undergoing HCV treatment. Optimizing treatment models for individuals with substance use disorders could also reduce the overall burden of HCV-related morbidity and mortality.

Our study has several limitations. First, patients were referred to the BTC by a community-based organization, and therefore, study participants may not be representative of populations with criminal justice involvement who do not have access to social services or medical care. Therefore, our study may overestimate the proportion of criminal justice-involved individuals who complete the HCV cascade of care. However, focusing on the BTC clinic population selects for a population amenable to seeking medical care, a realistic target for providers. Second, because only 70% of patients were screened, we were unable to determine the exact prevalence of chronic HCV infection among this sample. Third, our method of chart review only allowed for assessment of documented reasons for care received and lapses in care. A prospective cohort study or qualitative design could better elucidate reasons for lapses in care. Like many small studies, our results reflect a very specific population (urban poor with recent history of incarceration) and may not be generalizable to other populations or geographic areas.

As the public health burden of HCV continues to grow, marginalized populations, such as those with criminal justice involvement, are at risk of missing the opportunity for treatment and cure. Some have proposed that all-oral DAA regimens will greatly increase the proportion of those with chronic infection who begin treatment and complete it. While

interferon-free treatment regimens should improve acceptability of treatment, it is clear that access to care, referral for specialist evaluation, and the decision to initiate treatment will remain hurdles. Though additional studies including individuals with criminal justice involvement are needed, our findings suggest that robust treatment delivery models, which include supportive services to improve retention in care, will be necessary to increase the proportion of HCV carriers who are treated and cured of their disease.

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Figure 1.

The Hepatitis C Virus cascade* among 451 patients at the Bronx Transitions Clinic.

* Adapted from: Yehia BR, Schranz AJ, Umscheid CA, *et al.* The treatment cascade for chronic hepatitis C virus infection in the United States: a systematic review and meta-analysis. *PLoS One* 2014. **9**: e101554.

Total BTC Patients = all patients seen at the BTC between July 2009 and September 2014

AB + = anti-HCV positive

VL = HCV viral load checked

Chronic HCV = HCV RNA > 75 IU/mL

Referral = Documentation of referral to HCV specialist

Specialist evaluation = Attendance at least one specialist appointment)

Tx Started = At least one prescription for HCV medications

Tx completed = Completion of a 3-, 6-, or 12-month course of anti-HCV medications

SVR = sustained viral response (undetectable HCV viral load 12–24 weeks after finishing treatment)

Figure 2.
Reasons for lapse in follow-up among 84 chronically HCV-infected patients at the Bronx Transitions Clinic.

Table 1

Characteristics of 84 chronic HCV patients at the Bronx Transitions Clinic

Sociodemographics	N (%)
Age [median (IQ range)]	50 (46 – 52)
Male	79 (95)
Race/Ethnicity *	
Hispanic	55 (65)
Non-Hispanic Black	21 (25)
Other	5 (6)
Medicaid	81 (96)
Co-Morbidities	
HIV	37 (44)
Opioid use disorder (current)	56 (67)
Any serious mental illness	32 (38)

* missing in 3