

Persistent Challenges in the Hepatitis C Virus Care Continuum for Patients in a Central Texas Public Health System

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Background. Direct-acting antiviral treatment regimens cure >95% of chronic hepatitis C virus (HCV) infections, but recent studies indicate that <25% of patients in the United States receive treatment. Patients need to overcome barriers on the steps of the care continuum in order to be prescribed treatment. We aimed to examine the steps of the HCV care continuum up to prescription of HCV therapy among patients receiving care within a large safety net health care system in Houston, Texas.

Methods. We used electronic medical records to identify patients with positive screening tests for HCV antibodies between July 1, 2017, and June 30, 2018, and abstracted data on their advancement through the care continuum for HCV. We used logistic regression to identify factors associated with patient navigation through the continuum.

Results. Of the 2450 patients screening positive for HCV antibodies, 2016 (82.3%) received quantitative RNA testing, of whom 1081 (53.6%) exhibited chronic infection. Providers referred 915 (84.6%) to specialty care for evaluation, 540 of these patients (50.0%) received their specialist evaluation, and 299 (27.7%) received a prescription for treatment. Patients with history of substance use were less likely to be prescribed treatment (adjusted odds ratio, 0.66; 95% CI, 0.49–0.88).

Conclusions. We found substantial attrition at each stage of the HCV care continuum. In particular, history of substance abuse was a predictor of nonprescription. Challenges in the care continuum motivate increased provider education as well as the adoption of recent innovations in patient care.

Keywords. care continuum; health care access; hepatitis C virus; substance abuse.

With the recent introduction of direct-acting antiviral (DAA) therapy, treatment of hepatitis C virus (HCV) infection is all-oral and more efficacious compared with previous interferon-based regimens. Typical treatment regimens require patients to take 3 tablets orally per day for 8 weeks, and >95% of patients are cured (ie, achieve sustained viral response [SVR]) [1, 2]. However, the population-level impact of these curative therapies is threatened by important gaps in the HCV care continuum, the sequence of necessary steps an individual with HCV will experience as they approach cure.

While the continuum for HCV care varies across different health care settings [3–5], it generally involves (1) receiving a screening test for hepatitis C antibodies; (2) receiving a

quantitative RNA test to confirm ongoing infection (confirmatory testing); (3) undergoing evaluation for liver disease staging and the creation of a treatment plan; (4) receiving a prescription for treatment; and (5) successfully initiating/completing treatment and achieving SVR.

In such an extended process, patients encounter a variety of barriers to care that may be system-, patient-, and/or provider-related. Following the introduction of DAAs, studies of individual health care environments report that 88%–98% of patients screening positive for HCV antibodies received confirmatory testing [3, 4, 6], while earlier studies indicated that only 63% [7] or as few as 27% [5] received confirmatory testing. The percentage of patients with chronic HCV infection attending and receiving specialist evaluations has varied from 36% to 69% of patients in recent years [3, 4, 6], perhaps as a function of populations served and health plans available in different health care systems. Despite the advent of DAAs, recent studies indicate that only 10% to 24% of patients with chronic HCV infection are prescribed treatment [3, 4, 6], and reported rates of SVR range between 6% and 8% [3, 4].

A variety of sociodemographic variables impede individuals with chronic infection from advancing through the care continuum. While the majority of chronic HCV infections are

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among people born from 1945 to 1965, contemporary HCV infections are attributable to injection drug use [8, 9]. People with substance use disorder tend to earn less income, demonstrate lower health literacy, and are less likely to have health insurance [10–14]. Additionally, homeless persons exhibit increased prevalence of HCV, likely due to high rates of injection drug use [15]. The prevalence of chronic HCV among the homeless in the United States is estimated to be 20% [16]. The prohibitive price of DAAs, the wholesale acquisition cost of which can reach upwards of \$100 000 [17], makes pursuing treatment virtually impossible for most individuals without health coverage. Even among individuals with coverage, insurance companies may still deny coverage of the treatment if the patient is deemed, for example, to have less advanced liver fibrosis, to not meet sobriety restrictions, or to have not had consultation with a specialist [18].

The present study sought to examine contemporary barriers to HCV treatment in a large safety net health care system in Texas by identifying the points at which individuals fail to advance in the care continuum and the risk factors associated with these lapses. Several factors specific to Texas motivate this analysis. Hispanic individuals, a large constituency in Texas and frequent users of the local public health system [19], demonstrate higher rates of HCV than non-Hispanic white individuals, and HCV rates increase with proximity to the US–Mexico border [20]. Additionally, Texas has an estimated HCV prevalence of 1.8% [20], and, perhaps relatedly, the highest rate of hepatocellular carcinoma [21]. Further, this public health system largely serves individuals of minority ethnicity, the under- and uninsured, and the homeless [19], traditionally disenfranchised populations that warrant particular attention in the care continuum.

METHODS

We performed a retrospective cohort study among patients receiving care in the Harris Health System, a safety net public health care system serving Harris County in Houston, Texas. The Harris Health system is comprised of 2 hospitals, 18 community health centers, 3 multispecialty clinics, 10 homeless shelter clinics, and 5 clinics offering homeless eligibility services. More than 60% of patients are uninsured, and 30% utilize public insurance programs [19]. This study was approved by the Institutional Review Boards at Baylor College of Medicine and Harris Health System, and informed consent was waived because the study was retrospective and involved no more than minimal risk.

We identified all Harris Health patients testing positive for HCV antibodies between July 1, 2017, and June 30, 2018, and followed through June 30, 2019. Following the identification of an antibody-positive patient, we manually abstracted information about the patient's course of evaluation and treatment from the patient's electronic medical record (EMR). Confirmatory testing was indicated by record of a quantitative HCV RNA test

following the patient's positive antibody test. EMRs indicated whether patients received a referral to a hepatologist in the gastrointestinal (GI) clinic at Harris Health and whether the patient attended the clinic. Finally, if the patient received a treatment plan and prescription for an antiviral drug to treat HCV, the patient was marked as receiving a prescription. Importantly, this record does not indicate whether the patient successfully filled the prescription, completed treatment, or achieved SVR. A patient whose specialist evaluation only resulted in pretreatment counseling, liver imaging, or instructions to return to the clinic at a later date was not considered to have received a prescription unless he or she was prescribed an antiviral drug regimen to treat the HCV infection at a later appointment. We evaluated the EMRs of patients until June 30, 2019, ensuring that all individuals screened positive on and before June 30, 2018, had adequate time to advance through the care continuum (up to 2 years for patients diagnosed in July 2017, and at least 1 year for those diagnosed in June 2018).

In addition to the information on the care continuum, patient sociodemographic data were abstracted from the EMR, including age, sex, race, and ethnicity. Behavioral factors were abstracted from provider notes, including history of homelessness, history of multiple sex partners, use of drugs, and consumption of alcohol. In addition to being included in provider notes, history of homelessness is indicated by the patient's payer source, with homeless persons enrolled in a dedicated financial plan administered by Harris Health. The study was approved by the Institutional Review Boards of Baylor College of Medicine and Harris Health.

We calculated the percentage of patients who transitioned into each phase of the HCV care continuum overall and by race/ethnicity (Hispanic, non-Hispanic black, non-Hispanic white, other), sex, year of birth (born in 1945–1965: yes vs no), homelessness (yes vs no), documented history of substance use (yes vs no), documented high-risk sexual activity (high risk vs no risk), and heavy alcohol use (yes vs no). First, we used multivariable logistic regression to estimate odds ratios (ORs) and 95% confidence intervals for associations with receiving confirmatory HCV RNA testing and being HCV RNA positive. Next, using only those positive for HCV viral RNA, we performed similar multivariable logistic regression analyses to investigate significant factors associated with a referral to specialist, specialist evaluation, and receipt of HCV treatment. We found no evidence of multicollinearity among regressors, as indicated by a variance inflation factor <5. Patients with missing data were excluded from the logistic regression analyses. All analyses were performed using SAS, version 9.1. Statistical significance was determined at $\alpha = .05$, and all *P* values for statistical significance were 2-sided.

RESULTS

Table 1 shows selected characteristics of 2450 patients screened positive for HCV antibodies and included in the primary

Table 1. Number and Prevalence of Patients Screening Positive for HCV Antibodies (July 31, 2017, and June 30, 2018) and Subsequent Advancement Through the HCV Care Continuum Until June 30, 2019

Characteristic ^c	Screened HCV Antibody Positive		Received Confirmatory Testing		HCV Viral RNA Positive		Referred to Specialist		Received Specialist Evaluation		Prescribed Treatment	
	No.	%	No.	%	No.	% ^a	No.	% ^b	No.	% ^b	No.	% ^b
Total	2450	82.3	2016	82.3	1081	53.6	915	84.6	540	50.0	299	27.7
Race & ethnicity												
Hispanic	690	86.1	594	86.1	249	41.9	213	85.5	141	56.6	79	31.7
NH black	1021	81.2	829	81.2	502	60.6	424	84.5	250	49.8	139	27.7
NH white	602	81.7	492	81.7	296	60.2	248	83.8	130	43.9	73	24.7
Other	137	73.7	101	73.7	34	33.7	30	88.2	19	55.9	8	23.5
Gender												
Male	1495	81.2	1214	81.2	746	61.4	619	83.0	350	46.9	202	27.1
Female	954	84.1	802	84.1	335	41.8	296	88.4	190	56.7	97	29.0
Birth cohort												
1945–1965	1642	82.0	1347	82.0	769	57.1	659	85.7	391	50.8	212	27.6
Other	808	82.8	669	82.8	312	46.6	256	82.1	149	47.8	87	27.9
Homelessness												
Homeless	155	87.1	135	87.1	83	61.5	76	91.6	40	48.2	29	34.9
Not homeless	2295	82.0	1881	82.0	998	53.1	839	84.1	500	50.1	270	27.1
History of substance use												
Yes	820	82.4	676	82.4	441	65.2	365	82.8	195	44.2	104	23.6
No	1400	81.5	1141	81.5	545	47.8	472	86.6	294	53.9	170	31.2
Sexual activity												
Risk activity	23	87.0	20	87.0	15	75.0	13	86.7	9	60.0	4	26.7
No risk activity	2197	81.8	1797	81.8	971	54.0	824	84.9	480	49.4	270	27.8
Alcohol												
Alcohol use	513	83.2	427	83.2	273	63.9	235	86.1	138	50.5	73	26.7
No alcohol use	1707	81.4	1390	81.4	713	51.3	602	84.4	351	49.2	201	28.2

Abbreviations: EMR, electronic medical record; HCV, hepatitis C virus; NH, non-Hispanic.

^aPercentage of all individuals receiving quantitative RNA testing.

^bPercentage of all individuals testing positive for HCV RNA.

^cInformation on some risk factors was not recorded in EMRs for some patients.

analysis. The majority of antibody-positive patients were baby boomers (67.0%), with an average age (SD) of 53.7 (11.1) years. The cohort was predominantly male (61.0%) and had higher proportions of patients self-identified as non-Hispanic black (41.7%) and Hispanic (28.2%) than non-Hispanic white (24.6%). Twenty-one percent of patients (n = 513) had a documented history of alcohol use, one-third (n = 820) indicated a history of substance use, 0.94% (n = 23) had a documented history of high-risk sexual activity, and 6.3% (n = 155) were homeless.

We characterized the numbers and proportions of patients advancing through the care continuum at each stage (Table 1). Among 2450 patients who screened positive for HCV antibodies, 82.3% (n = 2016) received confirmatory testing. Of the 2016 patients who received testing, 53.6% (n = 1081) tested positive for HCV viral RNA. Providers referred 84.6% (n = 915) of patients positive for HCV viral RNA to specialists, but only 50% (n = 540) of those positive for HCV viral RNA received evaluations. Ultimately, 27.7% (n = 299 of 1081) of patients positive for HCV viral RNA were prescribed treatment for HCV (Figure 1).

In the multivariable model among all positive patients, Hispanics (adjusted OR [aOR], 1.45; 95% CI, 1.05–0.99) and females (aOR, 1.32; 95% CI, 1.05–1.67) were more likely than non-Hispanic whites and males, respectively, to receive confirmatory testing (Table 2). Conversely, of those receiving confirmatory testing, Hispanics (aOR, 0.50; 95% CI, 0.38–0.66) and females (aOR, 0.48; 95% CI, 0.39–0.59) were less likely to have chronic HCV infection compared with non-Hispanic

whites and males, respectively. Patients with a documented history of substance use (aOR, 1.69; 95% CI, 1.38–2.09) or alcohol use (aOR, 1.40; 95% CI, 1.10–1.77) were more likely to have chronic HCV infection compared with patients without documented use (Table 2). Compared with patients who were not homeless and had no history of substance use, patients who were homeless and had a history of substance use were 2-fold more likely to be HCV viral RNA positive (aOR, 2.00; 95% CI, 1.18–3.48).

Compared with males, females with chronic HCV infection were more likely to receive referral to specialty care (aOR, 1.74; 95% CI, 1.16–2.68) and specialist evaluation (aOR, 1.67; 95% CI, 1.26–2.22), but not treatment (aOR, 1.20; 95% CI, 0.88–1.62). Patients with a documented history of substance use were less likely to receive specialist evaluation (aOR, 0.68; 95% CI, 0.52–0.88) and prescriptions for HCV treatment (aOR, 0.66; 95% CI, 0.49–0.88). Conversely, homelessness was associated with an increased rate of specialist referral (aOR, 2.24; 95% CI, 1.06–5.54) and prescription for treatment (aOR, 1.73; 95% CI, 1.02–2.86). The lower likelihood of referral to a specialist and receipt of treatment among patients with a history of substance use were only observed among patients who were also not homeless. Compared with patients who were not homeless and had no history of substance use, patients who were homeless and had a history of substance use were not less likely to be referred to a specialist or receive treatment (aOR, 1.12; 95% CI, 0.58–2.10). Hispanics received specialist evaluations at higher rates than non-Hispanic whites (aOR, 1.84; 95% CI, 1.28–2.65) (Table 3).

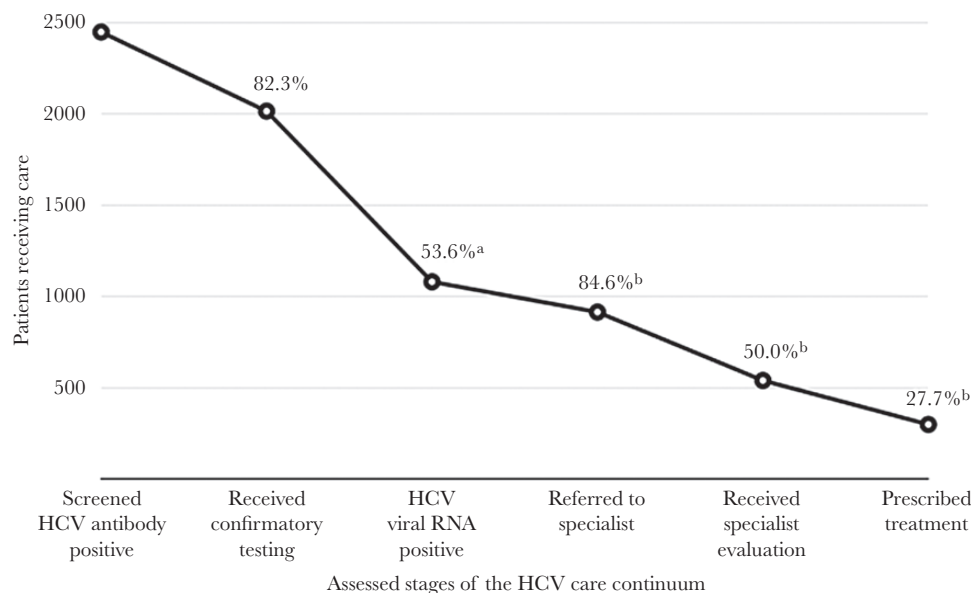


Figure 1. Advancement through the hepatitis C virus (HCV) care continuum for patients screening positive for HCV antibodies between July 31, 2017, and June 30, 2018. ^aPercentage of all individuals receiving quantitative RNA testing. ^bPercentage of all individuals testing positive for HCV RNA.

Table 2. Multivariate Logistic Regression Results for the Effect of Sociodemographic and Behavioral Risk Factors on the Rates of Confirmatory Testing and Chronic HCV Infection

Characteristic	Received Confirmatory Testing		HCV Viral RNA Positive	
	aOR ^a	95% CI	aOR ^{a,b}	95% CI ^b
Race & ethnicity				
Hispanic	1.45	1.05–1.99	0.50	0.38–0.66
NH black	0.97	0.74–1.29	0.98	0.75–1.26
NH white	Ref		Ref	
Other	0.66	0.41–1.07	0.47	0.28–0.77
Gender				
Male	Ref		Ref	
Female	1.32	1.05–1.67	0.48	0.39–0.59
Birth cohort				
1945–1965	1.05	0.82–1.34	1.19	0.96–1.47
Other	Ref		Ref	
Homelessness				
Homeless	1.53	0.94–2.64	1.16	0.77–1.75
Not homeless	Ref		Ref	
History of substance use				
Yes	1.06	0.84–1.34	1.69	1.38–2.09
No	Ref		Ref	
Sexual activity				
Risk activity	1.37	0.46–5.85	2.28	0.85–7.18
No risk activity	Ref		Ref	
Alcohol				
Alcohol use	1.15	0.88–1.51	1.40	1.10–1.77
No alcohol use	Ref		Ref	

Abbreviations: aOR, adjusted odds ratio; HCV, hepatitis C virus; NH, non-Hispanic.

^aAdjusted odds ratio controlling for all other variables listed.

^bCalculated from total number of individuals receiving confirmatory testing.

DISCUSSION

In this study of mostly minority, uninsured patients, we found that 82% of patients who screen positive received confirmatory testing for chronic HCV infection. However, among those with chronic infection, only 50% received specialty care and 27.7% were prescribed HCV treatment. The subset of HCV-infected patients with a history of substance abuse in their provider notes was >30% less likely to receive specialty care and treatment than the rest of patients.

The proportion of confirmatory testing in this report (82%) is below other recent studies [4, 6] but exceeds the results seen in a large-scale multistate cohort [7]. Confirmatory testing identified chronic HCV infections in 53.6% of tested patients. Interestingly, this is a lower prevalence rate than other studies [3] or estimates from the Centers for Disease Control and Prevention [8] and may be due to the population-based screening-related sampling frame where false positives are more likely than from targeted testing. Providers referred 84.6% of chronic HCV patients to specialty care, consistent with or above recent studies [3, 4, 6, 7]. The most porous stage of the care continuum proved to be receiving specialist evaluations: only 50% of patients with chronic HCV received specialty care. Rates in other studies vary between 36% and 69% [3, 4]. Finally, less

than one-third of patients with chronic HCV were prescribed treatment. While less than optimal, this proportion compares favorably with other studies [3, 6].

People with substance use disorder have an increased risk of incident infection and higher prevalence of chronic HCV infection [8, 9]. In this study, we also showed that patients with substance use disorders were less likely to be referred to specialist care. Importantly, according to clinical guidelines and consensus statements, current or recent injection drug use is not a contraindication to HCV treatment or a reason to deny a patient a referral to specialist evaluation [22–25]. While people with substance use disorder exhibited notably lower SVR rates in interferon-based therapies [26], the advent of DAAs has reduced this disparity [27–29]. The lack of referrals or prescriptions for patients with a documented history of substance use suggests that care providers may benefit from further education on the latest treatment guidelines for chronic HCV, as well as ways to address stigma and bias against patients with substance use disorders that may impact their care.

Interestingly, homeless patients had higher rates of referral to specialty care and prescription for treatment than patients who were not homeless. This is likely attributable to the high quantity of services at Harris Health designed for homeless persons,

Table 3. Multivariate Logistic Regression Results for the Effect of Sociodemographic and Behavioral Risk Factors on the Rates of Referral to Specialists, Evaluation by Specialists, and Prescription of Treatment for HCV Among Individuals With Chronic HCV Infection

Characteristic	Received Referral to Specialist		Received Specialist Evaluation		Received Prescription for Treatment	
	aOR ^{ab}	95% CI	aOR ^{ab}	95% CI ^b	aOR ^{ab}	95% CI ^b
Race & ethnicity						
Hispanic	1.09	0.66–1.80	1.84	1.28–2.65	1.45	0.97–2.16
NH black	0.96	0.61–1.49	1.26	0.91–1.74	1.27	0.88–1.83
NH white	Ref		Ref		Ref	
Other	1.12	0.40–3.99	1.17	0.54–2.55	0.72	0.26–1.76
Gender						
Male	Ref		Ref		Ref	
Female	1.74	1.16–2.68	1.67	1.26–2.22	1.20	0.88–1.62
Birth cohort						
1945–1965	1.48	0.99–2.20	1.16	0.86–1.56	0.93	0.67–1.30
Other	Ref		Ref		Ref	
Homelessness						
Homeless	2.24	1.06–5.54	1.28	0.78–2.08	1.73	1.02–2.86
Not homeless	Ref		Ref		Ref	
History of substance use						
Yes	0.72	0.50–1.03	0.68	0.52–0.88	0.66	0.49–0.88
No	Ref		Ref		Ref	
Sexual activity						
Risk activity	Ref		Ref		Ref	
No risk activity	1.06	0.28–6.93	1.49	0.52–4.55	0.95	0.26–2.85
Alcohol						
Alcohol use	1.24	0.83–1.88	1.13	0.85–1.51	0.98	0.26–2.85
No alcohol use	Ref		Ref		Ref	

Abbreviations: aOR, adjusted odds ratio; HCV, hepatitis C virus; NH, non-Hispanic.

^aAdjusted odds ratio controlling for all other variables listed.

^bCalculated from total number of individuals with confirmed chronic HCV infection.

including dedicated health coverage plans and 10 clinics based in shelters [19]. Additionally, this success underscores the role that safety net health care systems play in eliminating HCV.

The present study highlights potential barriers in the steps of the HCV care continuum. People with substance use disorder exhibit many of the same barriers to treatment as homeless individuals, including low health literacy, inconsistent housing, and a lack of health coverage [10, 13, 30]. As evidenced by success treating HCV in homeless populations, these barriers may be overcome for patients with history of substance use.

The greatest attrition in the care continuum occurred between the referral for specialty care and the receipt of evaluation by a specialist. While exact circumstances varied, records indicate many patients simply failed to attend their scheduled appointment. As the population served by the public health system is primarily low-income and as Harris Health administers specialist evaluation and treatment of HCV exclusively at a dedicated GI clinic, these patients may have difficulty traveling to the specialty clinic located away from their primary care physician. In a study of specialty care among HCV patients, Foster and colleagues found that patients with Medicaid coverage, with no health care coverage, and with

limited income experienced greater difficulty receiving specialist evaluations than other patients [31]. As a safety net health care system, these factors are overrepresented in Harris Health's patient population [19]. The increasing availability of telehealth programs and relative ease of DAA treatment regimens allow primary care providers to manage a growing share of uncomplicated chronic HCV cases, allowing patients to be treated where they are tested [32–34]. Primary care clinics may be more accessible and convenient to patients, increasing attendance. Importantly, individuals who engage in substance use demonstrate high rates of SVR when treated at primary care clinics and at substance use treatment facilities [35, 36], suggesting that integrated models of HCV care may help to address disparities in this population. Further, the adoption of reflex testing aims to reduce the number of patients who never receive confirmatory testing following their positive antibody screening. This institutional practice refers to performing automatic confirmatory testing of all HCV antibody-positive specimens before reporting the screening result to patients, consistent with recommendations by the Centers for Disease Control and Prevention as early as 1998 [37, 38]. Implementation of reflex testing is

integral for minimizing false-positive test results, identifying chronic infection, and advancing patients with serologically confirmed infections through the care continuum [38–40]. Harris Health implemented reflex testing following the conclusion of the present study, addressing attrition at this stage.

While this study builds on past research with an expansive and sociodemographically diverse sample in a setting with a large burden of HCV, several constraints limit the interpretation of the results. Importantly, patient behavioral factors impacting treatment were abstracted from provider notes in the patient's medical record; discrepancies between provider definitions of high-risk sexual behavior or alcohol use may confound the results, as would recall biases. Given that patients with a history of substance abuse were significantly less likely to receive specialty care and treatment, misclassification of exposure due to underreporting of substance use in the notes would have resulted in attenuation of the true effect.

Following prescription for treatment, the next steps in the care continuum are treatment initiation, completion, and finally SVR, all of which remain beyond the scope of this analysis. Patients with a prescription for treatment may still struggle with their coverage providers. Texas Medicaid requires patients to have abstained from drugs or alcohol for at least 3 months and to have advanced fibrosis (Metavir stage F3) before the patient can receive HCV treatment [41]. Notably, these requirements are in contrast with HCV treatment guidelines [22]. Even individuals with private insurance may still be denied coverage for treatment for similar reasons [18].

The present study delineated attrition and associated risk factors at each stage of the HCV care continuum. Many patients are lost at each point of care, though patients with a history of substance use experience the most substantial challenges. Our results highlight a need for increased efforts to adhere to clinical guidelines for the treatment of HCV in these patients. Further, the results motivate the adoption of increasingly popular innovations in HCV health care, including the integration of patient navigators, reflex testing of antibody-positive samples, and the implementation of telehealth programs in primary care provider clinics.

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