

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

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## Abstract

**Background & Aims:** Direct-acting antiviral treatment regimens cure greater than 95% of chronic Hepatitis C Virus (HCV) infections, but recent studies indicate fewer than 25% of patients in United States receive treatment. To be prescribed treatment, patients must complete a series of patient encounters, the care continuum, with barriers and attrition at each stage. We aimed to examine the HCV care continuum among patients receiving care within a large safety-net healthcare system in Houston, Texas.

**Methods:** We used electronic medical records to identify patients with screening positive tests for HCV antibodies between July 1<sup>st</sup>, 2017, and June 30<sup>th</sup>, 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 2,450 patients screening positive for HCV antibodies, 2,016 (82.3%) received quantitative RNA testing, of whom 1,081 (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. Substance users 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. Despite treatment recommendations, substance users experienced even more disadvantages. Challenges in the care continuum motivate increased provider education as well as the adoption of recent innovations in patient care.

**Keywords:** care continuum; hepatitis c virus; healthcare access; substance abuse

## Introduction

With the recent introduction of direct-acting antiviral (DAA) therapy, treatment of hepatitis C virus (HCV) infection is easier and more efficacious compared with previous interferon-based regimens. Typical treatment regimens require patients to take one tablet orally per day for eight to 12 weeks, and greater than 95% of patients are cured (i.e., achieve sustained viral response, or SVR)<sup>1,2</sup>. 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 cascade for HCV care varies across different healthcare settings,<sup>3-5</sup> it generally involves 1) receiving a screening test for Hepatitis C antibodies; 2) receiving a quantitative RNA test to confirm an active, chronic infection (confirmatory testing); 3) undergoing evaluation by a specialist for liver disease staging and the creation of a treatment plan; 4) receiving a prescription for treatment they can afford; and 5) successfully 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. While studies of individual health care environments report that 88 – 98% of patients screening positive for HCV antibodies receive confirmatory testing,<sup>6,7</sup> a multi-state cohort of screened patients only found documentation of confirmatory testing for 62%<sup>8</sup>. The percentage of chronic HCV patients attending and receiving specialist evaluations varies from 36% to 85% of patients,<sup>3,4,6,7</sup> perhaps as a function of populations served and financial plans available in different health care systems. A 2014 meta-analysis estimated that 16% of patients

with chronic HCV infection are prescribed treatment,<sup>5</sup> while more recent studies indicate a range from 10% to 24%<sup>3,4,6</sup>. As a result of deficits at multiple levels, the reported rates of SVR range between 3 to 10% of patients with chronic HCV infection<sup>3-5,7</sup>.

A variety of sociodemographic variables impede individuals with chronic infection from advancing through the care continuum. While chronic infection is endemic to baby boomers (persons born between 1945-1965), the majority of contemporary HCV infections are attributable to injection drug use<sup>8,9</sup>. Drug users earn less income, demonstrate lower health literacy, and are less likely to have health insurance<sup>10-14</sup>. Additionally, homeless persons exhibit increased prevalence of HCV, likely due to high rates of injection drug use.<sup>15</sup> The prevalence of chronic HCV amongst the homeless in the United States is estimated to be 20%.<sup>16</sup> The prohibitive price of DAAs, the wholesale acquisition cost of which can reach upwards of \$100,000,<sup>17</sup> makes pursuing treatment virtually impossible for most individuals without health coverage. Even amongst individuals with coverage, insurance companies may still deny coverage of the treatment.<sup>18</sup>

The present study sought to examine contemporary barriers to HCV treatment in a large safety-net healthcare 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,<sup>19</sup> demonstrate higher rates of HCV than non-Hispanic white individuals, and HCV rates increase with proximity to the US-Mexico border.<sup>20</sup> Additionally, Texas has an estimated HCV prevalence of 1.8%,<sup>20</sup> and, perhaps relatedly, the highest rate of

hepatocellular carcinoma.<sup>21</sup> Further, this public health system largely serves individuals of minority ethnicity, the under- and uninsured, and the homeless,<sup>19</sup> 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 healthcare system serving Harris County and Houston, Texas. The Harris Health system is comprised of two hospitals, 18 community health centers, three multi-specialty clinics, 10 homeless shelter clinics, and five clinics offering homeless eligibility services. More than 60% of patients are uninsured and 30% utilize public insurance programs.<sup>19</sup>

We identified all Harris Health patients testing positive for HCV antibodies between July 1<sup>st</sup>, 2017, and June 30<sup>th</sup>, 2018. Following the identification of an antibody-positive patient, patient navigators collected 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. EMR indicated whether patients received a referral to a hepatologist or other specialty care provider capable of treating HCV. Patient navigators contacted the primary care providers of patients with no record of a referral in their EMR in order to instigate one. Further, the patient navigators recorded whether or not the patient attended that appointment, and the appointment's primary outcomes. 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 or not 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 is not considered to have received a prescription unless he or she is

prescribed an antiviral drug regiment to treat the HCV infection at a later appointment. The patient navigators continued to evaluate the EMRs of patients until June of 2019, ensuring that all individuals screened positive on and before June 30<sup>th</sup>, 2018, had adequate time to advance through the care continuum.

In addition to the information on the care continuum, patient sociodemographic data was 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. Among all patients testing positive for HCV antibodies, we used multivariable logistic regression models to estimate odds ratios (OR) and associated 95% confidence intervals (CI) for associations with receiving confirmatory testing and being HCV RNA positive (i.e., chronic HCV infection). In the subset of patients with chronic HCV infection, we estimated ORs and 95% CIs for associations with referral to specialist, specialist evaluation, and receipt of HCV treatment. All analyses were performed using SAS version 9.1. Statistical significance was determined at  $\alpha = 0.05$ , and all  $p$  values for statistical significance were 2-sided.

## Results

Table 1 shows selected characteristics of 2,450 patients screened positive for HCV antibodies and included in the primary analysis. The majority of antibody-positive patients were baby boomers ( $n = 1642$ ; 67.0%), with an average age of 53.7 years (*standard deviation* = 11.1). The greatest number of patients self-identified as non-Hispanic Black ( $n = 1021$ ) or Hispanic ( $n = 690$ ), and there were more males ( $n = 1495$ ) than females ( $n = 954$ ). Twenty-one percent of patients ( $n = 513$ ) had documented history of alcohol use, one-third ( $n = 820$ ) indicated a history of substance use, 0.94% ( $n = 23$ ) engaged in 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 2,450 patients screened positive for HCV antibodies, 82.3% ( $n = 2016$ ) received confirmatory testing. Of those who received testing, 53.6% ( $n = 1081$ ) tested positive for HCV viral RNA. Providers referred 84.6% ( $n = 915$ ) of chronic HCV patients 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 were prescribed treatment for HCV (Figure 1).

In the multivariable model among all screened positive patients, Hispanics (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 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 to patients without documented use (Table 2).

Compared to 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). Substance users 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). Hispanics received specialist evaluations at higher rates than non-Hispanic Whites (aOR, 1.84; 95% CI, 1.28-2.65) (Table 3).

## Discussion

In this study of mostly minority, uninsured patients, we found that 82% of screened positive patients 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 over 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,<sup>4,6</sup> but exceeds results seen in a large-scale multi-state cohort.<sup>7</sup> Confirmatory testing identified chronic HCV infections in 1,081 patients, a little more than half of tested patients. Interestingly, this is a lower prevalence rate than other studies,<sup>3</sup> or estimates from the Centers for Disease Control,<sup>8</sup> and may be due to the population-based screening-related sampling frame where false positives are more likely than from targeted testing. Providers referred 915 chronic HCV patients to specialty care, or 85%, consistent with or above recent studies.<sup>3,6,4,7</sup> The most porous stage of the care continuum proved to be receiving specialist evaluations: only 540 of the 1,081 patients with chronic HCV, or 50%, received specialty care. Rates in other studies vary between 36% and 69%.<sup>3,4</sup> Only 299 patients were prescribed treatment, representing less than a third of patients with chronic HCV. While less than optimal, this proportion compares favorably with other studies.<sup>3,6</sup>

Substance users demonstrate increased risk of chronic HCV infection.<sup>8,9</sup> However, in this study they also experienced disadvantages receiving referrals to specialists and prescriptions for treatment. Importantly, current or recent injection drug

use is not a contraindication for HCV treatment, none the less a reason to deny a patient a referral for specialist evaluation. The American Association for the Study of Liver Diseases and Infectious Disease Society of America confirm in their HCV treatment guidelines that no patient should be denied treatment on the basis of substance use,<sup>22</sup> as does the American Society of Addiction Medicine,<sup>23</sup> the Substance Abuse and Mental Health Services Administration and the National Institute of Health's Consensus Development Program.<sup>24,25</sup> While substance users exhibited notably lower SVR rates in interferon-based therapies,<sup>26</sup> the advent of DAAs has reduced this disparity.<sup>27-29</sup> The lack of referrals or prescriptions for patients with documented history of substance use suggests that care providers may benefit from further education on the latest treatment guidelines for chronic HCV.

Interestingly, homeless individuals benefitted from significantly higher rates of referral to specialty care and prescription for treatment than other patients. This is likely attributable to the high quantity of services at Harris Health designed for homeless persons, including dedicated health coverage plans and 10 clinics based in shelters.<sup>19</sup> Additionally, this success underscores the role that safety-net healthcare systems play in eliminating HCV.

The present study substantiates the need for recent paradigm changes in the HCV care continuum. Substance users exhibit many of the same barriers to treatment as homeless individuals, including low health literacy, inconsistent housing, and a lack of health coverage.<sup>10,13,30</sup> As evidenced by success treating HCV in homeless populations, these barriers may be overcome for substance users.

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 arrive at their scheduled appointment. As the population served by the public health system is primarily low-income, these patients may have difficulty traveling to the specialty clinic. Harris Health administers specialist evaluation and treatment of HCV primarily at a dedicated GI clinic, which may also have contributed to attrition. The increasing availability of telehealth programs and relative ease of DAA treatment regimens allows primary care providers to manage a growing share of uncomplicated chronic HCV cases, allowing patients to be treated where they are tested.<sup>31-33</sup> Primary care clinics may be more accessible and convenient to patients, increasing attendance. 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, as recommended by the Centers for Disease Control and Prevention as early as 1998.<sup>34</sup> Implementation of reflex testing is integral for identifying chronic infection and advancing these patients through the care continuum.<sup>35,36</sup> 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. 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 be three months sober and have advanced fibrosis before the patient can receive HCV treatment.<sup>37</sup> Notably, both of these requirements are in contrast with HCV treatment guidelines.<sup>22</sup> Even individuals with private insurance may still be denied coverage for treatment for similar reasons.<sup>18</sup>

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 substance users experience the most substantial challenges. These results highlight a need for increased provider education to promote adherence to AASLD guidelines for the treatment of HCV in substance users. Further, the results motivate the adoption of increasingly-popular innovations in HCV healthcare, 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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Table 1

*Number and prevalence of patients screening positive for HCV antibodies (July 31<sup>st</sup>, 2017, and June 30<sup>th</sup>, 2018) and subsequent advancement through the HCV care continuum.*

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

- † Percentage of all individuals receiving quantitative RNA testing
- ‡ Percentage of all individuals testing positive for HCV RNA
- \* Information on some risk factors was not recorded in EMR for some patients

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 <sup>1</sup>	95% CI	aOR <sup>1†</sup>	95% CI <sup>†</sup>
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	
Substance Use				
User	1.06	0.84 – 1.34	1.69	1.38 – 2.09
Non-User	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	

<sup>1</sup>Adjusted Odds Ratio controlling for all other variables listed

<sup>†</sup>Calculated from total number of individuals receiving confirmatory testing

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 amongst individuals with chronic HCV infection.*

Characteristic	Received Referral to Specialist		Received Specialist Evaluation		Received Prescription for Treatment	
	aOR <sup>1‡</sup>	95% CI	aOR <sup>1‡</sup>	95% CI <sup>†</sup>	aOR <sup>1‡</sup>	95% CI <sup>†</sup>
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	
Substance Use						
User	0.72	0.50 – 1.03	0.68	0.52 – 0.88	0.66	0.49 – 0.88
Non-User	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	

<sup>1</sup>Adjusted Odds Ratio controlling for all other variables listed

<sup>‡</sup>Calculated from total number of individuals with confirmed chronic HCV infection

*Figure 1.* Advancement through the HCV care continuum for patients screening positive for HCV antibodies between July 31<sup>st</sup>, 2017, and June 30<sup>th</sup>, 2018