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Abstract

Background: Many people living with chronic Hepatitis C Virus (HCV) have seen delays in accessing treatment or been denied entirely due to Medicaid restrictions requiring patients to meet certain criteria prior to receiving approval for medication pre-authorization.

Methods: This study identified a cohort of Medicaid-insured patients with chronic HCV infection within New Orleans, LA. Patient medical records were reviewed and information regarding HCV care was gathered. This study sought to determine the degree to which HCV care was delayed for this population and describe common reasons for prior-authorization denials for direct-acting antiviral (DAA) medications.

Results: For this population of Medicaid-insured patients with HCV RNA assay-confirmed chronic infection, the average number of days it took to reach a specialist was three-times greater than the number of days it took to reach a primary care physician. After attending an appointment with a specialist to seek HCV care, patients experienced wait periods of an average of 150 days before being deemed eligible for treatment per Medicaid requirements. After being deemed eligible for treatment, patients experienced an average wait period of 194.4 days to initiation of treatment, with low fibrosis status being cited as the most common reason for treatment delay.

Conclusion: This population of Medicaid-insured patients in New Orleans, LA with chronic HCV infection experienced delays in treatment related to reduced accessibility of a specialist who was eligible to request DAA prior-authorization. Prior-authorization was most frequently denied based on low fibrosis status or recent alcohol/drug use.

Keywords

Health inequities; hepatitis C; Medicaid; direct-acting antiviral

Cover Page Footnote

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INTRODUCTION

In 2015, an estimated 3.5 million people in the United States were chronically infected with the hepatitis C virus (HCV), with the potential for underestimation indicating that the true prevalence could be much greater (Edlin et al., 2015). An important public health implication of untreated chronic and progressive HCV infection is the potential for further transmission of the virus. Chronic infection leads to increased morbidity and mortality, including potential cirrhosis, end-stage liver disease, and hepatocellular carcinoma (Liang et al., 2000). Fortunately, recent

pharmacologic innovations in the form of direct-acting antivirals (DAA) have made safe and highly effective eradication of HCV possible (Afdhal et al., 2014). A study of Veterans Affairs patients documented that progression to cirrhosis and a decompensation event in the setting of HCV infection may occur more quickly than previously thought (Butt et al., 2015). Moreover, sustained virological response following antiviral treatment has been shown to decrease liver-related morbidity and all-cause mortality among patients with chronic HCV infection, even those with advanced hepatic fibrosis (van der Meer et al., 2012). As a result, the current guidelines recommend treatment of all genotypes of HCV with DAAs (AASLD/IDSA, 2017).

Since their advent in 2013, the US Food and Drug Administration has approved numerous types of DAAs for the treatment of HCV (FDA, 2017). However, the high costs of DAAs have caused both private and public insurers in the US to limit access to these medications (Trooskin et al., 2015). Like other insurers, Medicaid has set specific reimbursement criteria such as consultation with a specialist, sobriety from alcohol and illicit drugs, and evidence of advanced fibrosis or cirrhosis (Barua et al., 2015). These Medicaid restrictions vary from state to state (Barua et al., 2015). Multiple studies have shown the negative impact of these Medicaid restrictions. A prospective cohort study across four Northeast states showed significantly higher rates of DAA absolute denial among those insured by Medicaid (46%) compared to those insured by Medicare (5%) and by commercial insurance (10%) (Re et al., 2016). Another cohort study in Southeast Michigan yielded similar results (Bourgi, et al., 2016).

From 2015 to May 2018, Louisiana Medicaid required abstinence from illicit substances and alcohol use for 12 months, one of only two states to do so, with other states ranging from no requirements to 6 months of abstinence (Barua et al., 2015). Prescribing physicians were required to provide proof of abstinence with a negative urine drug screen and blood alcohol level within 30 days of initiating treatment in addition to conducting random drug and alcohol screenings every 30 days throughout the course of treatment (Louisiana Department of Health, 2016). At that time, Louisiana was one of 14 states that only permitted physicians within the specialties of gastroenterology, hepatology, or infectious disease to request DAA pre-authorization (Barua et al., 2015). Louisiana Medicaid also required that the patient met criteria for advanced fibrosis or cirrhosis prior to DAA pre-authorization (Louisiana Department of Health, 2016).

Heterogeneity of Medicaid pre-authorization criteria for DAAs between states has led to confusion for policy-makers and providers. Anecdotally, providers are well-aware of institutional and policy barriers to accessing treatment for their patients, though there is a paucity of published data regarding the impact of Medicaid restrictions and reasons for treatment denial and delay at the state level. In this study, medical records of Medicaid-insured patients with chronic HCV infection within New Orleans, LA were reviewed to better understand their clinical course and evaluate the effects of restrictive Medicaid reimbursement criteria. It was hypothesized that Louisiana's restrictive Medicaid reimbursement criteria would create considerable barriers to treatment and cause delays in treatment for patients medically indicated for DAA treatment.

METHODS

Study patients were selected retrospectively from a pool of patients with chronic HCV infection within the treatment cascade of "Acacia NOLA," a student-run HCV screening and treatment program in New Orleans, LA. Program sites were primarily located at homeless shelters and substance abuse treatment centers across the city. Patients were initially included if they screened antibody positive for HCV and were referred for further evaluation and treatment by

Acacia NOLA between March 1, 2015 (inception of Acacia NOLA) and June 30, 2018 (conclusion of study period). Included patients were further refined to those who had been scheduled for an appointment with an HCV specialist after completing the necessary evaluation for referral, including a quantitative HCV RNA screen.

Primary outcomes were the average number of days to attain each step in the treatment process, including attending a specialist appointment, completing eligibility for DAA access, and starting treatment. Secondary outcomes included reasons for DAA eligibility delay and reasons for pre-authorization denial, as detailed in provider notes. Information about achievement along the treatment cascade was obtained by reviewing the electronic medical records (EMR) of both a local federally qualified health center (FQHC) and a local community hospital to which Acacia NOLA refers its patients. Data gathered from the FQHC included dates of scheduled primary care physician (PCP) appointments and dates of attended PCP appointments. These dates were used to calculate average number of days to access a PCP following a positive HCV antibody screen as a baseline measure of access to physician services. Average time in days to PCP appointments was compared with average time in days to specialist appointments.

Dates of scheduled viral hepatitis clinic (VHC) appointments with a specialist, dates of attended VHC appointments, reasons for pre-eligibility delays, reasons for post-eligibility delays, dates of treatment initiation, and dates of treatment completion were gathered from the local community hospital EMR. The dates were used to calculate the number of days between each step of the treatment cascade required by Medicaid to describe a care timeline for this patient population. Patients who completed a treatment eligibility workup with a PCP comprised the "VHC eligible" cohort, while those attending at least one VHC appointment were defined as "VHC attained." Pre-eligibility delays were defined as the amount of time in days between first VHC appointment and being deemed eligible to apply to Medicaid for treatment. Patients whose DAA application to Medicaid was submitted during their first clinic appointment served as a baseline. Post-eligibility delays were defined as the amount of time in days between being deemed eligible to apply to Medicaid for treatment by a specialist and treatment initiation, with 21 days from eligibility to initiation serving as a baseline. Reasons for pre- and post-eligibility delays as described by providers were documented. Patient demographics and self-described characteristics were extracted from Acacia NOLA's preliminary intake survey of clients during initial antibody screening session. The study was approved by the Tulane University Institutional Review Board.

RESULTS

Demographics and self-reported characteristics

Between March 1, 2015 and June 30, 2018, 99 patients completed eligibility requirements for HCV specialist referral and were included in this study. These patients were confirmed to be living with chronic HCV infection by quantitative RNA assay and were scheduled for a VHC appointment. Of this group, 38 (38.4%) attended at least one VHC appointment (VHC attained) over the study period while the remaining 61 (61.7%) did not (VHC eligible). Patient demographics were described by VHC attainment status (Table 1). Self-reported prior experience with healthcare, perceived barriers to accessing care, and risk factors were assessed for differences between 'VHC eligible' and 'VHC attained' sub-groups (Table 2). There was a high awareness of HCV status at intake, with 53.5% of clients previously knowing their status. Just 17% of patients reported having a personal PCP upon intake, though 88% of patients reported having tried to access healthcare previously. Patients attending at least one VHC appointment were less likely to report

distrust of the healthcare system and more likely to perceive incarceration as a barrier to accessing healthcare. Otherwise, no significant differences exist between subgroups.

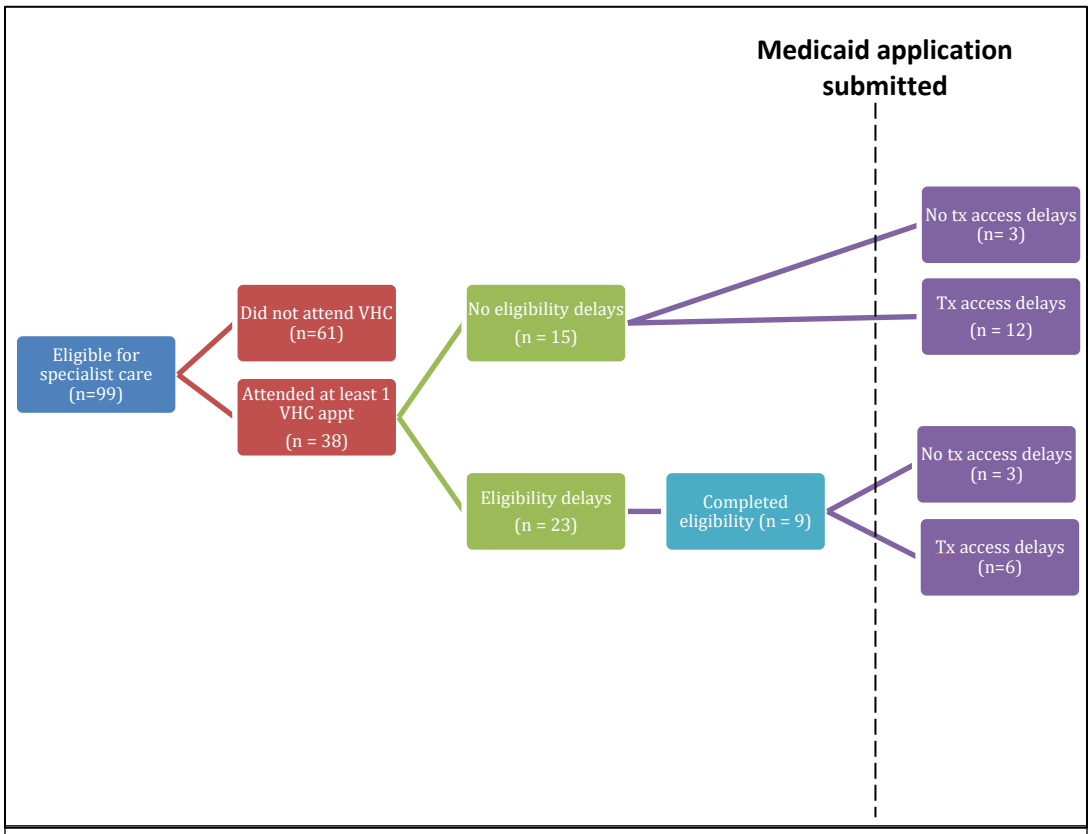

Figure 1. Attainment and associated delays along the HCV treatment cascade.

[a]Tx = treatment

Table 1. Demographics

Testing site type	VHC Eligible	VHC Attained	Total

	n	%	n	%	n
Homeless	31	62.0%	19	38.0%	50
SATC[a]	29	63.0%	17	37.0%	46
Community	1	33.3%	2	66.7%	3
Total	61	61.6%	38	38.4%	99
Race					
White	42	65.6%	22	34.4%	64
Black	17	51.5%	16	48.5%	33
Hispanic	1	100.0%	0	0.0%	1
Native American	1	100.0%	0	0.0%	1
Total	61	61.6%	38	38.4%	99
Gender					
Male	49	59.0%	34	41.0%	83
Female	12	75.0%	4	25.0%	16
Total	61	61.6%	38	38.4%	99

[a]SATC = substance abuse treatment centers

Primary outcomes

58.6% of patients (n = 58) were seen by a PCP at a local FQHC, at an average of 60 days after initial screening (Table 3). 65.8% of the VHC attained subgroup (n=25) were seen by a PCP at an average of 57 days post-antibody screening, while 54.1% of the VHC eligible group were seen by a PCP (n=33). Average time to viral RNA confirmation and ultrasound (US) were 87 days and 89 days, respectively. For those attending one VHC appointment, average time to RNA testing and ultrasound were 96 and 94 days, respectively. Average time from HCV screening to scheduled VHC appointment was nearly seven months (218 days). Average time to first VHC appointment for the 38 achieving this cascade level was 196 days from initial antibody screen, while average time to scheduled VHC appointment was 190 days.

Table 2. Self-reported characteristics by VHC status

	VHC Eligible		VHC Attained		Total		p-value
	n	Ave	n	Ave	n	Ave	
Age	56	42.6	37	45.6	93	43.8	
Prior access to healthcare (HC)	n	% yes	n	% yes	n	% yes	
Previous HIV test	60	91.7%	36	100.0%	96	94.8%	
Previous HCV test	59	78.0%	37	78.4%	96	78.1%	
Previous HCV antibody +	38	92.1%	24	75.0%	62	85.5%	
Previous treatment	13	30.8%	9	66.7%	22	45.5%	
Insurance	26	76.9%	16	75.0%	42	76.2%	
PCP	26	23.1%	16	6.3%	42	16.7%	
Accessed HC previously	39	92.3%	19	78.9%	58	87.9%	
Self-reported barriers to HC access							
Distrust	40	25.0%	19	0.0%	59	16.9%	*
Financial	44	59.1%	25	60.0%	69	59.4%	
Drugs	41	46.3%	19	31.6%	60	41.7%	
Alcohol	39	17.9%	19	10.5%	58	15.5%	
Transportation	40	42.5%	22	50.0%	62	45.2%	
Incarceration	39	0.0%	20	15.0%	59	5.1%	*
None	48	22.9%	26	30.8%	74	25.7%	
History of							
Blood splash	61	27.9%	38	47.4%	99	35.4%	
Organ transplant	61	0.0%	38	0.0%	99	0.0%	
Alcohol use	61	47.5%	38	55.3%	99	50.5%	
Substance	61	63.9%	38	73.7%	99	67.7%	
Tattoo	61	77.0%	38	84.2%	99	79.8%	
Amateur tattoo	32	25.0%	18	33.3%	50	28.0%	
Jail or prison	61	93.4%	38	89.5%	99	91.9%	
Jail	45	86.7%	21	100.0%	66	90.9%	
Prison	45	42.2%	21	47.6%	66	43.9%	
Blood transfusion	61	18.0%	38	7.9%	99	14.1%	
Intravenous drug use (IVDU)	61	67.2%	38	78.9%	99	71.7%	
Shared injection equipment	45	46.7%	21	71.4%	66	54.5%	
Diagnosed psychiatric condition	61	31.1%	38	28.9%	99	30.3%	
Schizophrenia	45	4.4%	21	0.0%	66	3.0%	
Depression	45	31.1%	21	19.0%	66	27.3%	
Bipolar	45	13.3%	21	9.5%	66	12.1%	
Anxiety	45	20.0%	21	19.0%	66	19.7%	

ADHD	45	2.2%	21	0.0%	66	1.5%

*p<0.05 **p<0.01

Secondary outcomes

Pre-eligibility delays were defined as the amount of time between first VHC appointment and being deemed eligible to apply to Medicaid for treatment. Clients completing eligibility during their first VHC appointment (n=15), served as a baseline, with any additional days between first VHC and being deemed eligible considered delays (Figure 1). 23 patients experienced pre-eligibility delays, with incomplete lab work or recent ultrasound cited as the most common reason for deferring Medicaid application (Table 4). Positive urine drug or EtOH screen or self-reported drug or alcohol use were the next most commonly cited reasons. Post-eligibility delays were defined as the amount of time between being deemed eligible to apply to Medicaid for treatment and the actual day of treatment initiation, with 21 days deemed "no delay." Low fibrosis score was the most commonly cited reason for application denial, delaying clients an average of 283 days (Table 5). Insurer preferences for one medication regimen over that initially prescribed by the provider delayed two patients by an average of 82.5 days.

Table 3. Time to various levels of care cascade (days)

	VHC Eligible & Attained			VHC Attained		
Time to	n	Average (days)	St Dev	n	Average (days)	St dev
1st PCP appt	58	60	104	25	57	130
RNA	83	87	141.4	35	96	144.4
US	68	89	106.3	34	94	109.9
Scheduled VHC appt	99	218	154.2	38	190	141.6
1st VHC appt				38	196	144

Table 4. Pre-eligibility delays by reason

Reason	n	Completed tx[a] (n)	Average delay (days)
Lost to follow up	1	1	448
Alcohol use[b]	3	1	126
Drug use[c]	6	0	
Repeat lab work/US	1	0	
Incomplete lab work/US	13	3	110
Total	24	5	150

[a] Tx = treatment
[b] Positive EtOH screen or self-reported alcohol use in past 6 months
[c] Positive urine drugs screen (UDS) or self-reported drug use in past 6 months

Table 5. Post-eligibility delays by reason

Reason	n	Completed tx[a] (n)	Average delays (days)
Drug use[b]	2	1	453
Lost to follow up	2	0	
Low fibrosis score	10	1	283
Repeat lab work/US	2	1	71
Insurance preferences	2	2	82.5
Total	18	5	194.4

[a] Tx = treatment

[b] Positive urine drugs screen (UDS) or self-reported drug use in past 6 months

DISCUSSION

This vulnerable population of people experiencing homelessness and undergoing substance abuse treatment faced significant barriers to accessing HCV treatment. High attrition along the care cascade as evidenced by less than half of eligible patients reaching a specialist, a high rate of Medicaid DAA application denials, and significant overall time to reaching treatment initiation were hallmarks of these patients' experiences accessing HCV treatment. Along almost every stage of the care cascade, patients experienced institutional and policy roadblocks that made achieving sustained virological response (SVR) less and less likely. Given high rates of self-described barriers to accessing healthcare reported by this population, additional regulatory restrictions are particularly onerous for this group.

Provider restriction

Significant discrepancies in access to a PCP and specialist were found for this disadvantaged population. Average time to see a specialist was over three times longer than that to see a PCP. Further, those patients that were scheduled to a see a specialist sooner were more likely to attend the appointment. Given the indigent nature of this vulnerable population, rapid access to a provider was a key element to success along the care cascade. During the majority of the study period, only a specialist in the fields of infectious disease, gastroenterology, or hepatology was able to submit a DAA prior-authorization application to Medicaid (Louisiana Department of Health, 2016). Given the high safety profile and effectiveness of DAAs, the medical necessity of restricting dispensing power has been criticized. A number of prospective studies have compared DAA treatment prescribed by primary care physicians and nurse-practitioners at community-level clinics to those prescribed by specialists at academic HCV clinics. Results revealed high rates of SVR and low rates of adverse effects in both groups (Arora et al., 2011; Kattakuzhy et al., 2017). Given the significant attrition of this population in the time frame of referral from PCP to specialist, it is likely that this requirement decreased access to timely, efficacious HCV treatment.

Liver fibrosis

A low fibrosis score was the most common reason the patients in this study experienced considerable post-eligibility delays. Medicaid's reimbursement criteria require patients to have advanced fibrosis/cirrhosis (Metavir stage ≥3 or Ishak stage ≥4) in order to be eligible for DAA treatment, despite contrary recommendations from expert committees and organizations (Louisiana Department of Health, 2016). For example, the most current AASLD/IDSA

recommendations still support treatment with DAAs for all patients chronically infected with HCV (genotypes 1-6) with or without cirrhosis (AASLD/IDSA, 2017). Given the many complications of untreated chronic HCV infection including advanced liver disease, decompensated cirrhosis, hepatocellular carcinoma (HCC), liver transplant, and death, early treatment and eradication of the virus is crucial. Early treatment of chronic HCV infection and SVR has been shown to reduce all-cause mortality (Backus et al., 2011). Prevention of liver-related diseases may not be the only benefit with early HCV treatment. More recent studies seem to suggest that chronic HCV infection is also linked to increased subclinical cardiovascular disease (CVD) and potentially increased CVD outcomes (Babiker et al., 2017). More importantly, HCV treatment resulting in SVR appears to reduce these CVD risk, raising the importance of early treatment (Babiker et al., 2017). Additionally, in a cohort study, SVR after treatment has shown to reduce the incidence of onset of type 2 diabetes (Arase et al., 2009).

Recent substance use

Recent alcohol or illicit drug use was a key cause of pre-eligibility delays and recent illicit drug use caused significant post-eligibility delays in the study population. During a majority of the study period, Medicaid required patients to remain sober from alcohol and illicit drugs for 12 months in order to be eligible for DAA treatment (Louisiana Department of Health, 2016). However, recent studies suggest that history of alcohol abuse should not serve as a deterrent to HCV treatment. In patients who were closely supported and monitored, history of high pre-treatment alcohol consumption or failure to maintain sobriety for 6 months before treatment did not affect treatment completion rates or SVR (Russell et al., 2012). Furthermore, a cohort study of individuals with alcohol abuse/dependence revealed that chronic HCV infection significantly reduces survival in this group compared to those without infection (Muga et al., 2018). This suggests that patients with concurrent HCV infection and alcohol-abuse should be more readily treated, rather than delaying treatment. Towards the conclusion of the study period, effective May 2018, Louisiana Medicaid made amendments to their reimbursement criteria, loosening restrictions on providers qualified to prescribe DAAs and reducing sobriety requirements (Louisiana Department of Health, 2018).

Limitations

A major limitation of this study is its generalizability outside the relatively isolated healthcare system of New Orleans. These findings may not be applicable to other parts of Louisiana, which potentially present with their own set of barriers to access. Further, low rates of VHC eligibility and attainment resulted in a low sample size for this study despite an extensive enrollment period. Given the complex psychosocial factors impacting this population's decision to pursue medical care, it is difficult to isolate delays caused by institutional and policy barriers from social determinants. Finally, changes to Medicaid DAA policy in May 2018 may have impacted prescribing factors in the tail end of the study. The effects of this recent policy revision are yet unclear and further studies are needed to determine if this revision will truly make DAAs more accessible to Medicaid patients.

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Acacia NOLA was funded by the FOCUS grant, provided by Gilead Sciences. We acknowledge all of the student volunteers at Tulane University School of Medicine that dedicated countless hours to screen clients and aid in navigating them through the treatment cascade.

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