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Original Article

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Barriers to Hepatitis C Virus Care and How Federally Qualified Health Centers Can Improve Patient Access to Treatment

David Lam[a], Robert J. Wong[b], Adla Tessier[a], Yenice Zapata[a], Elsie Saldana[a], Robert G. Gish[a, c, d, e]

Abstract

Background: Despite the availability of direct-acting antiviral agents (DAAs) for hepatitis C virus (HCV) treatment, disparities in HCV care and treatment persist for underserved populations due to demographic-based and insurance-based barriers. We aim to examine the effect of barriers on HCV treatment access for a federally qualified health center (FQHC) population.

Methods: We retrospectively evaluated medical records of adults diagnosed with chronic HCV at an FQHC clinic from 2016 to 2020 with follow-up through 2021. Univariate and bivariate analyses were used to describe the patient population and significant associations between predictors of linkage to HCV care and treatment access. Adjusted multivariate logistic regression analyses were used to identify predictors of starting HCV treatment.

Results: Of 279 total patients with chronic HCV, 162 patients started treatment (58%), 138 patients (50%) completed treatment, and 99 patients (35%) achieved sustained virological response (SVR). Of the total patients, 145 (52%) were seen by their primary care physician (PCP) for their HCV care and treatment, and 134 (48%) were seen by a provider that specializes in management and treatment of HCV (HCV provider). Patients seen by an HCV provider in addition to their PCP were more likely to have had their prior authorization requests for HCV treatment denied by their insurance providers than patients seen only by their PCP for HCV care (30% vs. 14%, P = 0.001). We believe that this discrepancy stems from two issues. One, prior authorizations are reviewed by insurance providers who are not specially trained in HCV management, so the verbiage used perplexes these reviewers, possibly causing them to issue denials. Two, insurance providers often require HCV genotype testing for DAA medication eligibility, and HCV providers order genotype tests for patients only when HCV treatments have failed to cure patients, so this requirement becomes another barrier to DAA medications. Patients who spoke a non-English language, lived in the USA for less than 10 years, and showed inability to pay for treatment had received treatment despite these characteristics being common barriers to HCV treatment. On multivariate regression, factors independently associated with patients starting treatment included prior denial for DAA medication (odds ratio (OR), 8.88; 95% confidence interval (CI), 3.22 - 24.6; P < 0.001) and being seen by an HCV provider (OR, 24.8; 95% CI, 11.7 - 52.5; P < 0.001). However, the most significant barrier to HCV treatment access for the FQHC population was eligibility restrictions from insurance providers.

Conclusions: Demographic-based barriers (e.g., age, race, and income) often impede HCV care and treatment, but insurance-based barriers are the greatest challenge currently that affects treatment outcomes in our study population. Removing these restrictions would, in our opinion, help to increase treatment levels to underserved populations.

Keywords: Direct-acting antivirals; FQHC; Barriers; HCV provider

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[a]Family Practice Department, La Maestra Community Health Centers, San Diego, CA, USA
[b]Division of Gastroenterology and Hepatology, Stanford University School of Medicine and Gastroenterology Section, Veterans Affairs Palo Alto Healthcare System, Palo Alto, CA, USA
[c]Robert G. Gish Consultants, LLC, San Diego, CA, USA
[d]La Maestra Community Health Centers, San Diego, CA, USA
[e]*Corresponding Author:* Robert G. Gish, Robert G. Gish Consultants, LLC, San Diego, CA 92037, USA. Email: rgish@robertgish.com

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Introduction

Approximately 71 million people worldwide are currently living with chronic hepatitis C virus (HCV) [1]. Nearly 2.5 million people in the USA were infected with HCV as of 2020 [2]. HCV currently affects three distinct generations of Americans: people born between 1945 and 1965, adults under the age of 40, and infants born to mothers with HCV [3]. Each year, almost 400,000 people die from complications secondary to HCV, such as hepatocellular carcinoma and/or cirrhosis [1]. HCV is most endemic in North and South Asia and the Middle East [2]; in those regions, countries that lack financial and human resources struggle to consistently diagnose and treat patients infected with HCV. Those who immigrate to the USA continue to experience barriers to care despite the availability of effective antiretrovirals because of language barriers, poverty, and other social determinants of health [1].

Table 1. Insurance Providers That Covered Patients With HCV at the FQHC

Insurance provider	Number (%) of patients (n = 279)
Aetna Better Health of CA (Medicaid)	4 (1.0)
Blue Shield of California Promise (Medicaid)	14 (5.0)
Care First (Medicaid)	21 (7.5)
California Correctional Healthcare Services[a]	31 (11.0)
Community Health Group (Medicaid)	49 (18.0)
HealthNet (Medi-Cal HMO)	9 (3.2)
Humana (HMO)	1 (0.3)
Medi-Cal	53 (19.0)
Medi-Medi Dual Options (Medicaid and Medicare)	11 (3.9)
Molina Healthcare Covered CA	1 (0.3)
Molina Healthcare Dual Options (Medi-Cal and Medicare)	1 (0.3)
Molina Healthcare (Medicaid)	67 (24.0)
Sharp Health Plan (HMO)	2 (0.7)
Sliding fee[b]	12 (4.3)
United Healthcare (Medicaid)	3 (1.0)

[a]Service that provides healthcare to the incarcerated persons of California that has worked with the FQHC to treat HCV. [b]Service through which patients pay for healthcare at the FQHC out of pocket. FQHCs: Federally qualified health centers; HCV: hepatitis C virus; HMO: health maintenance organization.

In the past, treatment for HCV consisted of interferon-based therapies, which were poorly tolerated and generated adverse side effects such as flu-like symptoms and depression [4]. In 2014, new interferon-free treatments called direct-acting antiviral agents (DAA) were approved were approved by the US Food and Drug Administration (FDA) and demonstrated a much higher cure rate than interferon-based treatments and provided markedly improved tolerability and efficacy. However, insurance providers have adopted eligibility restrictions for these medications based on clinical, administrative, and behavioral criteria [5]. Medicaid restricts treatment based on liver disease severity, human immunodeficiency virus (HIV) status, and RNA levels; who prescribed the treatment; and periods of abstinence [6]. Also, patients of racial/ethnic minorities and low socioeconomic status have been shown to have less access and adherence to HCV treatment even in the present day [7].

Federally qualified health centers (FQHCs) are community-based healthcare centers that provide primary care services in underserved areas. We aim to evaluate disparities in access to HCV care and HCV treatment among a multi-center community-based FQHC network in San Diego, CA.

Materials and Methods

This is a retrospective chart review that is exempted from Institutional Review Board approval under 45 CFR § 46.104(d)(4). While the research involves the use of identifiable private information/biospecimens, information about biospecimens is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects. This study was conducted in compliance with the La Maestra Community Health Centers' ethical standards for human subjects as well as with the Helsinki Declaration.

We performed a retrospective cohort study of adult patients (age > 18 years) with chronic HCV seen at La Maestra FQHC centers in San Diego, CA from 2016 to 2020. Chronic HCV was defined as patients with detectable HCV RNA. Patients with HCV who achieved spontaneous clearance without antiviral therapy were excluded. Patients who completed treatment and completed a follow-up consultation 3 months afterward were evaluated to determine whether sustained virologic response (SVR) was achieved. Univariate analysis was performed to describe the number of FQHC patients who initiated treatment, completed treatment, and achieved SVR. Others were deemed as lost to follow-up (LTFU) if the FQHC was unable to contact them for further care. The patient population was split into two time-based cohorts: one for patients seen during 2016 - 2018 and another for patients seen from 2019 to 2020, when there was a decrease in insurance-based HCV treatment barriers. The insurance providers that covered the patients with HCV at the FQHC are depicted in Table 1.

Patient demographic characteristics that were collected included race/ethnicity, primary language, individual income level, and behavioral risk factors (i.e., tattoo, blood transfusions, intravenous drug use, alcohol use). HCV characteristics and liver disease severity of the patients were assessed with HCV antibody, HCV RNA levels (IU/mL), liver stiffness measurement, and controlled attenuation parameter scores derived from Fibroscan assessment, Fibrosis-4 score, aspartate aminotransferase to platelet ratio index (APRI) score, and

presence of non-alcoholic fatty liver disease (NAFLD).

Linkage to care was defined as linkage to a healthcare provider that specializes in HCV treatment. A select few of the FQHC's providers have been specially trained in management and treatment of HCV and were designated as HCV providers for this study. Treatment outcomes evaluated included receipt of HCV treatment, completion of HCV treatment, and achieving SVR following HCV treatment. All patients had a PCP in the FQHC and were either seen by their PCP specifically for HCV care or were referred to an HCV provider by their PCP for HCV care.

Insurance status was categorized by the following variables: managed care plan, paying out of pocket via sliding fee, inability to pay, insurance denials, and pharmaceutical coverage by Gilead Sciences patient assistance program. While pharmaceutical coverage from AbbVie was available, the FQHC did not require its use for glecapravir/pibrentasvir (Mavyret; AbbVie) prescriptions. Patients with managed care plans have insurance coverage provided by the following insurance providers: Community Health Group, Aetna, UnitedHealthcare, Blue Shield of California Promise Health Plan (formerly Care First Health Plan), Molina Healthcare, Sharp Health Plan, Health Net, Medi-Medi Dual Options, and Medi-Cal directly. The managed care plans were all based on Medi-Cal and Medicaid and not private insurance entities. Sliding fee is a clinic-based program in which uninsured patients can pay out of pocket for their clinical care. Inability to pay refers to those without a managed care plan or other medical insurance who could not pay for HCV treatment. Insurance denials indicate patients who were initially denied coverage for HCV from their managed care providers. Pharmaceutical coverage by Gilead, a pharmaceutical company, provides uninsured patients with the necessary funding for HCV medications free of charge.

Confirmation of a blood transfusion, past/current alcohol use disorder, past/current intravenous drug use disorder, and diagnosis of non-alcoholic steatohepatitis (NASH) were also collected from patient medical records; however, not all records contained this information.

The genotypes of the HCV patients were also collected to determine if genotypes had any significant association for treatment denials, as genotype data was a common criterion to determine eligibility for DAA medications for insurance providers.

HCV treatments assessed included at least one of the following medications: glecapravir/pibrentasvir (Mavyret; AbbVie), elbasvir/grazoprevir (Zepatier; Merck), daclatasvir (Daklinza; Bristol-Myers Squibb Company), sofosbuvir/velpatasvir (Epclusa; Gilead Sciences Inc), ledipasvir/sofosbuvir (Harvoni; Gilead Sciences Inc.), sofosbuvir/velpatasvir/voxilaprevir (Vosevi; Gilead Sciences Inc), and sofosbuvir (Solvadi; Gilead Sciences Inc).

Statistical analyses were performed using STATA statistical package (version 14). Patient and disease characteristics were described with proportions and frequencies for categorical variables and mean and standard deviation for continuous variables. Comparisons of patient and disease characteristic were stratified by time period, whether patient was seen by PCP only or also by HCV provider, and by whether HCV treatment was received. Comparisons of categorical variables were performed with Chi-square testing, and comparisons of continuous variables were performed with Student's *t*-tests. Statistical significance was met with two-tailed P value < 0.05. Adjusted multivariate logistic regression analyses were used to identify predictors of starting HCV treatment.

Results

A total of 279 patients with chronic HCV were included in the study. Table 2 describes the characteristics of the study population. Overall, 162 patients had initiated treatment (58%), 138 patients (50%) completed treatment, and 99 patients (35%) achieved SVR. Thirty-nine of the patients who completed treatment were LTFU; thus, the FQHC was unable to confirm whether they attained SVR. Patients received care and were prescribed treatment for HCV from either their PCP or from the FQHC's specialized HCV providers. A total of 145 patients (52%) were seen by their PCP and 134 patients (48%) were seen by an HCV provider. For the 2016 - 2018 cohort, 33 of 70 treated patients (47%) were denied treatment by insurance providers. The FQHC was able to appeal these decisions and get the treatment approved for 28 of these denied patients, while the other five of these patients became LTFU. For the 2019 - 2020 cohort, 27 of 92 treated patients (29%) were denied treatment by insurance providers. The FQHC was able to appeal these decisions and get the treatment approved for 26 (96%) of these denied patients, while the last patient became LTFU.

Table 3 shows the differences in linkage to care for patients in the study. Patients seen by an HCV provider were more likely to have had their prior authorization requests for HCV treatment denied by their insurance providers than patients seen by their PCP for HCV care (29% vs. 14%, P = 0.001). These patients were also more likely to be enrolled in the Gilead Support Path program to get treatment free of charge (7% vs. 1%, P = 0.02). Patients seen by an HCV provider were also more likely to have been diagnosed with NASH (9% vs. 0.7%, P = 0.001).

Table 4 explores the differences in treatment outcomes for patients in the study. Patients who received treatment were also more likely to speak a non-English language (29% vs. 15%, P = 0.017) than those who did not get treatment. These patients were also more likely to have immigrated to the USA over 10 years ago (62% vs. 14%, P = 0.029) and shown inability to pay for HCV treatment (10% vs. 2%, P = 0.006). Adjusted multivariable logistic regression analyses indicated that the factors independently associated with starting HCV treatment were prior treatment coverage denials (odds ratio (OR), 8.88; 95% confidence interval (CI), 3.22 - 24.6; P < 0.001) and being seen by an HCV provider (OR, 24.8; 95% CI, 11.7 - 52.5; P < 0.001).

Discussion

A patient's age, sex, race, ethnicity, birth country, and income

Table 2. Overall Characteristics

Characteristics	2016 - 2018	2019 - 2020	P value
Age, years ± SD (n = 273)	N = 191	N = 82	
Average age	53.4 ± 1.1 years	46.8 ± 1.4 years	0.001
Sex, n (%) (n = 273)	N = 191	N = 82	
Female	78 (40.8)	27 (32.9)	0.218
Male	113 (59.2)	55 (67.1)	
Race, n (%) (n = 273)	N = 191	N = 82	
American Indian	3 (1.6)	1 (1.2)	0.381
Asian	8 (4.2)	2 (2.4)	
Black/African American	24 (12.6)	5 (6.1)	
More than one race	1 (0.5)	0 (0)	
Other Pacific Islander	3 (1.6)	0 (0)	
White	152 (79.6)	74 (90.2)	
Ethnicity, n (%) (n = 273)	N = 191	N = 82	
Hispanic or Latino	70 (36.7)	39 (47.6)	0.204
Not Hispanic or Latino	120 (62.8)	43 (52.4)	
Unknown	1 (0.5)	0 (0)	
Language, n (%) (n = 273)	N = 191	N = 82	
Non-English	43 (22.5)	19 (23.2)	0.577
English	148 (77.5)	63 (76.8)	
Income, annual ± SD (n = 269)[a]	N = 188	N = 81	
Average income	7,834.28 ± 1,436.56	4,920.30 ± 1,056.16	0.206
Insurance, n (%)[a]			
Managed Care (n = 273)	N = 191	N = 82	
	165 (86.4)	64 (78.1)	0.086
Out-of-pocket (n = 273)	N = 190	N = 82	
	26 (13.7)	18 (22.0)	0.089
Inability to pay (n = 273)	N = 191	N = 82	
	5 (2.6)	13 (15.9)	0
Denials (n = 273)	N = 191	N = 82	
	38 (19.9)	19 (23.2)	0.542
Gilead Support Path Services (n = 273)[b]	N = 190	N = 74	
	7 (3.7)	4 (5.4)	0.530
Risk factors, n (%)[a]			
History of incarceration (n = 183)	N = 135	N = 48	
	40 (29.6)	26 (54.2)	0.002
History of blood transfusion (n = 172)	N = 140	N = 32	
	7 (5.0)	1 (3.1)	0.650
History of alcohol use disorder (n = 273)	N = 191	N = 82	
	36 (18.9)	22 (26.8)	0.139
Current alcohol use disorder (n = 273)	N = 191	N = 82	
	18 (9.4)	5 (6.1)	0.364
History of IV drug use (n = 259)	N = 177	N = 82	
	79 (44.6)	39 (47.6)	0.660

Table 2. Overall Characteristics - *(continued)*

Characteristics	2016 - 2018	2019 - 2020	P value
Current IV drug use (n = 259)	N = 177	N = 82	
	13 (7.3)	12 (14.6)	0.065
NASH (n = 271)	N = 189	N = 82	
	5 (2.7)	8 (9.8)	0.012
Genotype, n (%) (n = 130)[a]	N = 88	N = 42	
1	54 (61.4)	34 (81.0)	0.514
2	15 (17.1)	3 (7.1)	
3	9 (10.2)	4 (9.5)	
4	6 (6.8)	1 (2.4)	
5	0 (0)	0 (0)	
6	4 (4.6)	0 (0)	
Liver disease scores ± SD			
APRI score (n = 140)	N = 67	N = 73	
	1.026 ± 0.139	0.846 ± 0.176	0.429
FIB4 score (n = 139)	N = 65	N = 74	
	2.08 ± 0.22	1.58 ± 0.25	0.148
CAP score (n = 107)	N = 55	N = 52	
	243 ± 9	238 ± 7	0.660
kPa score (n = 108)	N = 55	N = 53	
	8.7 ± 0.8	9.2 ± 1	0.665
Seen by PCP, n (%) (n = 273)	N = 191	N = 82	
	140 (73.3)	4 (4.9)	< 0.001
Seen by Hep C provider, n (%) (n = 273)	N = 191	N = 82	
	51 (26.7)	78 (95.1)	< 0.001

[a]Number of patients in each cohort reflect those who responded; responses for these questions were voluntary. [b]Number of patients in 2016 - 2018 cohort, 190; 2019 - 2020 cohort, 74; total, 264. APRI: aspartate aminotransferase to platelet ratio index; FIB4: fibrosis-4; Hep C: hepatitis C; IV: intravenous; kPa: kilopascals; PCP: primary care physician; SD: standard deviation.

are frequent barriers that have been associated with impeding HCV care and treatment. However, in our study, we found no significant associations between these characteristics and linkage to care or treatment outcomes. We did find that insurance-based barriers to care, stemming from eligibility restrictions to receive HCV treatment, impede treatment access more often than any of the aforementioned barriers. We believe this is due to the efforts of the FQHC to ensure linkage to care and treatment for HCV patients regardless of their demographics or socioeconomic status.

At this FQHC, we offer many services to facilitate treatment access for underserved populations, such as immigrant and low socioeconomic status populations, to ensure they get the treatment they need. Specialized HCV providers submit more prior authorizations for HCV medications for patients with HCV, providing a more competent level of care for HCV. Cultural liaisons help immigrant patients and non-English speakers better communicate with HCV providers. A sliding fee program helps patients lacking insurance coverage pay for treatment themselves on affordable payment plans. If other FQHCs follow our model and adopt these programs, this would promote further access to HCV treatment to more patients in more places.

Before 2019, the insurance providers for this FQHC - Molina Healthcare, Aetna, Blue Shield of California Promise Health Plan (formerly Care First Health Plan), Community Health Group, Sharp Health Plan, UnitedHealthcare, Health Net, and also Medi-Cal, had restrictions on eligibility criteria for patients able to receive DAAs for HCV treatment. From 2016 to 2018, the managed care plans - Molina Medicaid, Sharp Health Plan HMO, and Care First Health Plan, required a series of documented evidence of the patient's fibrosis status, confirmation if treatment-naive or -experienced, HCV genotype, HCV viral load, labs, HIV tests, hepatitis B immunizations, and whether their preferred medication in their formulary was unable to be used for the patient's treatment. Since 2019, these health plans have stopped requiring this information, asking only for genotype and proof that preferred medications were unfit for treatment. Similarly, Aetna Better Health of California, Blue Shield of California Promise, and

Table 3. Differences in Linkage to Care

Characteristic	Seen by PCP	Seen by a Hep C provider	P value
Age, years ± SD (n = 279)	N = 145	N = 134	
Average age	52.7 ± 1.2	50.3 ± 1.3	0.157
Sex, n (%) (n = 279)	N = 145	N = 134	
Female	57 (39.3)	50 (37.3)	0.732
Male	88 (60.7)	84 (62.7)	
Race, n (%) (n = 279)	N = 145	N = 134	
American Indian	3 (2.1)	1 (0.8)	0.634
Asian	8 (5.5)	4 (3.0)	
Black/African American	14 (9.7)	15 (11.2)	
More than one race	1 (0.7)	0 (0)	
Other Pacific Islander	1 (0.7)	2 (1.5)	
White	118 (81.4)	112 (83.6)	
Ethnicity, n (%) (n = 279)	N = 145	N = 134	
Hispanic or Latino	52 (35.9)	60 (44.8)	0.213
Not Hispanic or Latino	92 (63.5)	74 (55.2)	
Unknown	1 (0.7)	0 (0)	
Language, n (%) (n = 279)	N = 145	N = 134	
Non-English	28 (19.3)	37 (27.6)	0.095
English	117 (80.7)	97 (72.4)	
Income, annual ± SD (n = 275)[a]	N = 142	N = 133	
Average income	7,984.62 ± 1,859.39	6,153.18 ± 833.49	0.390
Insurance, n (%)[a]			
Managed Care (n = 279)	N = 145	N = 134	
	119 (82.1)	116 (86.6)	0.303
Out-of-pocket (n = 278)	N = 144	N = 134	
	26 (18.1)	18 (13.4)	0.291
Inability to pay (n = 279)	N = 145	N = 134	
	7 (4.8)	11 (8.2)	0.251
Denials (n = 279)	N = 145	N = 134	
	20 (13.8)	40 (29.9)	0.001
Gilead Services (n = 279)	N = 142	N = 128	
	2 (1.4)	9 (7.0)	0.020
Risk factors, n (%)[a]			
History of incarceration (n = 184)	N = 116	N = 68	
	38 (32.8)	28 (41.2)	0.250
History of blood transfusion (n = 173)	N = 118	N = 55	
	6 (5.1)	2 (3.6)	0.673
History of alcohol use disorder (n = 278)	N = 144	N = 134	
	28 (19.4)	33 (24.6)	0.297
Current alcohol use disorder (n = 278)	N = 144	N = 134	
	15 (10.4)	9 (6.7)	0.272
History of IV drug use (n = 265)	N = 137	N = 128	
	65 (47.5)	55 (43.0)	0.464

Table 3. Differences in Linkage to Care - *(continued)*

Characteristic	Seen by PCP	Seen by a Hep C provider	P value
Current IV drug use (n = 265)	N = 137	N = 128	
	12 (8.8)	13 (10.2)	0.697
NASH (n = 277)	N = 144	N = 133	
	1 (0.7)	12 (9.0)	0.001
Genotype, n (%) (n = 133)[a]	N = 57	N = 76	
1	36 (63.2)	53 (69.7)	0.085
2	7 (12.3)	11 (14.5)	
3	9 (15.8)	5 (6.6)	
4	2 (3.5)	5 (6.6)	
5	0 (0)	0 (0)	
6	3 (5.3)	2 (2.6)	
Liver disease scores ± SD[a]			
APRI score (n = 144)	N = 27	N = 117	
	0.965 ± 0.153	0.924 ± 0.132	0.886
FIB4 score (n = 143)	N = 27	N = 116	
	1.86 ± 0.30	1.80 ± 0.19	0.880
CAP score (n = 112)	N = 15	N = 97	
	234 ± 17	243 ± 6	0.600
kPa score (n = 113)	N = 15	N = 98	
	8.3 ± 1.2	8.9 ± 0.7	0.719

[a]Numbers of patients in each cohort reflect those who responded; responses for these questions were voluntary. APRI: aspartate aminotransferase to platelet ratio index; FIB4: fibrosis-4; Hep C: hepatitis C; IV: intravenous; kPa: kilopascals; PCP: primary care physician; SD: standard deviation.

Community Health Group had denied treatment from 2016 to 2018 because the prescribed medication was not preferred in their formularies (and documentation was needed that the formulary-preferred medications were unfit to use to treat their respective patients for HCV infection). Since 2019, these plans have changed their preferred formulary medication, requiring the FQHC providers to change the prescribed medication to medications matching those preferences, leading to more approvals. Likewise, the Molina Medicaid health plan varied their restrictions throughout 2016 and 2018, with patient information documentation requirements and preferred formulary drugs that did not always align with FQHC provider preferences. Starting in spring 2019 and through 2020, the amount of required patient information decreased, allowing patients to more quickly get their approvals for the provider-preferred treatments. Patients in the 2016 - 2018 cohort experienced a lower treatment rate and higher denial rate than patients seen in the 2019 - 2020 cohort. Patients who were initially denied treatment still eventually received treatment via the FQHC's continued attempts at submitting prior authorization requests or enrollment in the Gilead Support Path program.

Risk factors for HCV infection include being incarcerated, having received a blood transfusion, and past or current intravenous drug use disorder [8]. Alcohol use concurrent with HCV infection also contribute to progression of liver disease [9]. For these reasons, data on incarceration history, blood transfusion history, intravenous drug use, alcohol use, viral genotype, and liver disease staging scores (APRI, fibrosis-4 (FIB-4), and Fibroscan scores) have been required for prior authorizations for HCV treatment by all insurance providers for the FQHC population. The absence of this data was the most frequent reason for prior authorizations being denied.

Although the impact of concomitant chronic HCV and NASH needs further study, some studies have shown that patients diagnosed with both HCV and NASH showed further development of liver fibrosis and steatosis [10]. As such, HCV patients who are also diagnosed with NASH would be more likely to have been linked to care from the FQHC's specialized HCV providers. These HCV providers submitted more prior authorizations for HCV treatment to insurance providers compared to PCPs and had more denials. Of 134 patients seen by HCV providers, 40 prior authorizations (30%) were denied. Of 145 patients seen by their PCPs for HCV care, 20 prior authorizations (14%) were denied. HCV providers then used the Gilead Support Path program when their patients had been issued denials.

Despite inability to pay, preferred language being other than English, and length of residency being under 10 years, many patients in the care of the FQHC still received needed treatment. The FQHC has developed a model of care that consists of cultural liaisons, insurance support, and sliding fee pro-

Table 4. Differences in Eventual Treatment

Characteristic	No treatment	Received treatment	P value
Age, years ± SD (n = 278)	N = 116	N = 162	
Average age	51.9 ± 1.4	51.4 ± 1.1	0.775
Sex, n (%) (n = 278)	N = 116	N = 162	
Female	45 (38.8)	62 (38.3)	0.93
Male	71 (61.2)	100 (61.7)	
Race, n (%) (n = 278)	N = 116	N = 162	
American Indian	4 (3.5)	0 (0)	0.20
Asian	5 (4.3)	7 (4.3)	
Black/African American	11 (9.5)	18 (11.1)	
More than one race	1 (0.9)	0 (0)	
Other Pacific Islander	1 (0.9)	2 (1.2)	
White	94 (81.0)	135 (83.3)	
Ethnicity, n (%) (n = 278)	N = 116	N = 162	
Hispanic or Latino	38 (32.8)	73 (45.1)	0.075
Not Hispanic or Latino	78 (67.2)	88 (54.3)	
Unknown	0 (0)	1 (0.6)	
Language, n (%) (n = 278)	N = 116	N = 162	
Non-English	17 (14.7)	47 (29.0)	0.017
English	99 (85.3)	115 (71.9)	
Income, annual ± SD (n = 274)[a]	N = 113	N = 161	
Average income	6,299.61 ± 2,181.38	7,703.93 ± 908.15	0.509
Insurance, n (%)[a]			
Managed care (n = 278)	N = 116	N = 162	
	94 (81.0)	140 (86.42)	0.225
Out-of-pocket (n = 277)	N = 116	N = 161	
	22 (19.0)	22 (13.7)	0.234
Inability to pay (n = 278)	N = 116	N = 162	
	2 (1.7)	16 (9.9)	0.006
Denials (n = 278)	N = 116	N = 162	
	6 (5.2)	54 (33.3)	< 0.001
Gilead Services (n = 269)	N = 115	N = 154	
	0 (0)	11 (7.1)	0.003
Risk factors, n (%)[a]			
History of incarceration (n = 183)	N = 95	N = 88	
	34 (35.8)	31 (35.2)	0.937
History of blood transfusion (n = 172)	N = 95	N = 77	
	4 (4.2)	4 (5.2)	0.761
History of alcohol use disorder (n = 277)	N = 116	N = 161	
	24 (20.7)	37 (23.0)	0.65
Current alcohol use disorder (n = 277)	N = 116	N = 161	
	13 (11.2)	11 (6.8)	0.202
History of IV drug use (n = 264)	N = 108	N = 156	
	53 (49.1)	67 (43.0)	0.326

Table 4. Differences in Eventual Treatment - *(continued)*

Characteristic	No treatment	Received treatment	P value
Current IV drug use (n = 264)	N = 108	N = 156	
	11 (10.2)	13 (8.3)	0.607
NASH (n = 276)	N = 115	N = 161	
	0 (0)	13 (8.1)	0.002
Genotype, n (%) (n = 133)[a]	N = 28	N = 105	
1	21 (75.0)	67 (63.8)	0.318
2	3 (10.7)	15 (14.3)	
3	2 (7.1)	12 (11.4)	
4	0 (0)	7 (6.7)	
5	0 (0)	0 (0)	
6	2 (7.2)	3 (2.9)	
Liver disease scores ± SD[a]			
APRI score (n = 144)	N = 13	N = 131	
	1.119 ± 0.223	0.913 ± 0.120	0.594
FIB4 score (n = 143)	N = 15	N = 128	
	2.26 ± 0.49	1.76 ± 0.18	0.358
CAP score (n = 112)	N = 11	N = 101	
	195 ± 10	247 ± 6	0.005
kPa score (n = 113)	N = 11	N = 102	
	8.1 ± 1.5	8.9 ± 0.6	0.70

[a]Numbers of patients in each cohort reflect those who responded; responses for these questions were voluntary. APRI: aspartate aminotransferase to platelet ratio index; FIB4: fibrosis-4; Hep C: hepatitis C; IV: intravenous; kPa: kilopascals; PCP: primary care physician; SD: standard deviation.

grams to ensure that immigrant status and socioeconomic status do not impede patients from receiving care and treatment for HCV. Thus, implementing this model of care would allow for other FQHCs to provide the same standard of care for HCV patients unimpeded by the common barriers to HCV care.

The advent of DAA medications for HCV care has allowed for more tolerable and effective methods of curing HCV, but access to them has been impeded by restrictions from insurance providers. The cultural liaison and sliding fee programs provided by the FQHC serve to ensure that these patients make it to their appointments and agree to treatment and management of their health conditions. However, these patients are still impeded by restrictions from insurance providers from receiving the treatments they need to recover from HCV. Continuing to remove all insurance restrictions would expand access to HCV treatment for underserved populations nationwide.

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This research received no external funding.

Conflict of Interest

David Lam is an employee/consultant of La Maestra Community Health Centers. Robert G. Gish is an employee/consultant of La Maestra Community Health Centers; he has served as a consultant and/or advisor for Gilead Sciences. Robert J. Wong's institution has received research funding from Gilead Sciences; he has served as a consultant and on advisory board for Gilead Sciences. Adla Tessier is an employee/consultant of La Maestra Community Health Centers; her responsibilities included corresponding with Gilead Sciences to complete and submit applications for uninsured HCV patients wanting to enroll in the Support Path program. Yenice Zapata is an employee/consultant of La Maestra Community Health Centers; her responsibilities included corresponding with Gilead Sciences to complete and submit applications for uninsured HCV patients wanting to enroll in the Support Path program. Elsie Saldana is an employee/consultant of La Maestra Community Health Centers; her responsibilities included corresponding with Gilead Sciences to complete and submit applications for uninsured HCV patients wanting to

enroll in the Support Path program.

Informed Consent

All data collected originates from patient medical records in which all responses to questions about demographic backgrounds were voluntary.

Author Contributions

David Lam: data curation, investigation, visualization, writing - original draft preparation. Robert G. Gish: conceptualization, methodology, project administration, supervision, validation, writing - review and editing. Robert J. Wong: conceptualization, formal analysis, methodology, project administration, validation, visualization, writing - review and editing. Adla Tessier and Yenice Zapata: project administration, supervision, writing - review and editing. Elsie Saldana: writing - review and editing.

Data Availability

Any inquiries regarding supporting data availability of this study should be directed to the corresponding author.

Abbreviations

APRI: aminotransferase to platelet ratio index; CI: confidence interval; DAA: direct-acting antiviral agent; FDA: Food and Drug Administration; FIB4: fibrosis-4; FQHC: Federally qualified health center; Hep C: hepatitis C; HCV: hepatitis C virus; IV: intravenous; LTFU: lost to follow-up; HMO: health maintenance organization; NAFLD: non-alcoholic fatty liver disease; NASH: non-alcoholic steatohepatitis; OR: odds ratio; PCP: primary care physician; SD: standard deviation; SVR: sustained virological response

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