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## Hepatitis C Cure and Medications for Opioid Use Disorder Improve Health-Related Quality of Life in Patients with Opioid Use Disorder Actively Engaged in Substance Use

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### Declaration of interests

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### Ethics approval

This study was approved by the University of Maryland Institutional Review Board (HP-00071577)

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## Abstract

**Background:** This study aims to determine whether Hepatitis C (HCV) treatment improves health-related quality of life (HRQL) in patients with opioid use disorder (OUD) actively engaged in substance use, and which variables are associated with improving HRQL in patients with OUD during HCV treatment.

**Methods:** Data are from a prospective, open-label, observational study of 198 patients with OUD or opioid misuse within 1 year of study enrollment who received HCV treatment with the primary endpoint of Sustained Virologic Response (SVR). HRQL was assessed using the Hepatitis C Virus Patient Reported Outcomes (HCV-PRO) survey, with higher scores denoting better HRQL. HCV-PRO surveys were conducted at Day 0, Week 12, and Week 24. A mixed-effects model investigated which variables were associated with changing HCV-PRO scores from Day 0 to Week 24.

**Results:** Patients had a median age of 57 and were predominantly male (68.2%) and Black (83.3%). Most reported daily-or-more drug use (58.6%) and injection drug use (IDU) (75.8%). Mean HCV-PRO scores at Day 0 and Week 24 were 64.0 and 72.9, respectively. HCV-PRO scores at Week 24 improved compared with scores at Day 0 (8.7;  $p<0.001$ ). Achieving SVR (10.4;  $p<0.001$ ) and receiving medications for OUD (MOUD) at Week 24 (9.5;  $p<0.001$ ) were associated with improving HCV-PRO scores. HCV-PRO scores increased at Week 24 for patients who experienced no decline in IDU frequency (8.1;  $p<0.001$ ) or had a UDS positive for opioids (8.0;  $p<0.001$ ) or cocaine (7.5;  $p=0.003$ ) at Week 24.

**Conclusion:** Patients with OUD actively engaged in substance use experience improvement in HRQL from HCV cure unaffected by ongoing substance use. Interventions to promote HCV cure and MOUD engagement could improve HRQL for patients with OUD.

## Keywords

Patient Reported Outcome Measures; Opioid-Related Disorders; Quality of Life; Hepatitis C, Chronic; Mental Health

## Introduction

Hepatitis C (HCV) infection remains a public health crisis despite recent advances in treatment. At the start of 2020, there were an estimated 56.8 million HCV infections globally (Polaris Observatory HCV Collaborators, 2022), while in the United States, annual HCV infections are estimated to have risen from 24,700 in 2012 to 57,500 in 2019 (Centers for Disease Control and Prevention, 2021). Particularly at risk are individuals with opioid use disorder (OUD), who have a high prevalence of HCV infection resulting from injection drug use (IDU) (Degenhardt et al., 2017).

Although providers and insurance companies often deny HCV treatment with direct acting-antivirals (DAA) to patients who engage in substance use (Barua et al., 2015), studies have shown that patients with OUD engaging in IDU achieve high rates of HCV cure with DAA treatment (Grebely et al., 2018; Read et al., 2017; Scherz et al., 2018). Moreover, by co-locating HCV treatment with medications for OUD (MOUD), patients with OUD experience improved outcomes for both their OUD and HCV (Rosenthal et al., 2020; Severe et al., 2020).

Along with its hepatic and extrahepatic effects, HCV infection has been associated with a reduction in health-related quality of life (HRQL) (Whiteley et al., 2015), as measured by patient-reported outcomes (PRO) (Z. Younossi & Henry, 2015). Recently, major health organizations have put an emphasis on measuring HRQL. Health care insurers have used HRQL to evaluate various patient outcomes (Hanmer et al., 2022), and the Centers for Disease Control and Prevention in the United States has made measuring HRQL a goal of the *Healthy Peoples 2020* initiative (Office of Disease Prevention and Health Promotion, 2022). One tool used for PRO measurements in patients infected with HCV is the Hepatitis C Virus Patient Reported Outcomes (HCV-PRO) survey, a self-administered survey designed for adults with chronic HCV infection that measures the psychological, physical, social, and role-functioning effects of HCV (Anderson, Baran, Dietz, et al., 2014).

Previous research using other PRO measurement tools has shown that HCV treatment with DAA is associated with improved HRQL, particularly in patients who achieve sustained virologic response (SVR) (Marcellin et al., 2017). Improvements in HRQL during HCV treatment have been shown in patients with OUD receiving MOUD (Dalgard et al., 2022; Schulte et al., 2020), including in those who engage in IDU and achieve SVR (Gormley et al., 2021). However, it is unknown whether HCV treatment improves HRQL in patients with OUD not receiving MOUD, or which variables are associated with improving HRQL in patients with OUD during HCV treatment. To answer these questions, we evaluated HCV-PRO survey data from the previously reported ANCHOR study (Rosenthal et al., 2020), which assessed a model of treatment providing HCV DAA therapy and optional co-located MOUD treatment for patients with OUD, recent opioid use, and chronic HCV.

## Methods

### Trial Design

ANCHOR was a prospective, open-label, observational study of patients with OUD and chronic HCV infection (Rosenthal et al., 2020). 198 patients diagnosed with OUD or opioid misuse within 1 year of study enrollment were treated with HCV DAA for 8-12 weeks, with the primary endpoint of SVR. Patients were excluded if they were pregnant or breastfeeding, had decompensated liver disease, or had contraindications to receiving DAA.

After baseline assessments were completed at study enrollment, patients returned within 2 weeks to start DAA. The day of DAA initiation was designated Day 0, and patients were seen for on-treatment visits at Weeks 4, 8, and 12 after Day 0. At Week 24, patients were assessed for SVR, defined as having an undetectable HCV RNA level 12 weeks after receiving the last dose of DAA. Patients not receiving MOUD at study enrollment could initiate buprenorphine at any time during the study. The study was approved by the institutional review board of the University of Maryland, and all procedures were performed in compliance with relevant laws and institutional guidelines. Patients gave their informed consent to participate in ANCHOR.

### Study Visits and Assessments

**Baseline Assessments**—At study enrollment, the patient's demographics, medications, substance use history, IDU history, substance use treatment history, social history, and self-reported history of mental illness were recorded. OUD severity was assessed using the Diagnostic and Statistical Manual of Mental Disorders (Fifth Edition) OUD criteria (American Psychiatric Association, 2013). OUD scores can range from 0 to 11, with higher scores denoting more severe OUD. MOUD status was assessed by asking patients whether they were receiving MOUD.

**Substance Use Behavior and MOUD**—IDU was assessed with the Darke HIV Risk-Taking Behavior Survey (Darke et al., 1991), a validated survey containing six questions that rate IDU behavior, at Day 0, Week 12, and Week 24. Decline in IDU was obtained by measuring changes in IDU frequency—categorized as either daily or more, less than daily, or none—from Day 0 to Week 24. If IDU was not recorded at Week 24, then decline in IDU was obtained by measuring changes in IDU frequency from Day 0 to Week 12. Decline in IDU was categorized into two groups: increase or no change in IDU frequency and decrease in IDU frequency.

Severity of alcohol use was assessed with the Alcohol Use Disorders Identification Test (AUDIT-C), a 3-item screening questionnaire for alcohol consumption that has been validated for identifying hazardous alcohol use and alcohol use disorder (Bush et al., 1998), at Day 0 and Week 24. A urine drug screen (UDS) was obtained to determine if it was positive or negative for non-prescribed opioids; positive or negative for cocaine; and positive or negative for substances besides non-prescribed opioids and cocaine including amphetamines, barbiturates, benzodiazepines, and phencyclidine (PCP). The first UDS was

obtained either at the baseline visit or Day 0, after which UDSs were obtained at Week 12 and Week 24. MOUD status was assessed at Day 0, Week 12, and Week 24.

**HCV-PRO Survey**—HRQL during HCV treatment was assessed using the HCV-PRO survey. The HCV-PRO survey has been validated in patients who are receiving or have completed HCV treatment (Anderson, Baran, Erickson, et al., 2014). The HCV-PRO score is calculated from 16 items that rate specific symptoms on a five-point scale. The total score can range from 0 to 100, with higher scores denoting greater HRQL and better functioning. The HCV-PRO survey was administered at Day 0, Week 12, and Week 24.

## Statistical Analysis

Categorical variables were reported using numbers and percentages. Continuous variables were reported using either means with standard deviations or, when appropriate, medians with quartiles, after assessing normality using Q-Q plots and Shapiro Wilk's tests. Means for HCV-PRO scores by demographic at baseline, Day 0, Week 12, and Week 24 were obtained using either an independent t test or Analysis of Variance (ANOVA) when appropriate. Associations between categorical variables were examined using either a Chi-square or Fisher's exact test when appropriate. The effects of different variables on HCV-PRO scores were estimated using a linear mixed effects model. Variables at baseline (age, gender, history of mental illness, and HIV status) and at Week 24 (achieving SVR, decline in IDU, receiving MOUD, UDS positive for opioids, and UDS positive for cocaine) were considered in the linear mixed effects model. Subject effect was considered as the random effect. The linear mixed effects model was used to determine associations between the outcome variable HCV-PRO scores, the variables included in the model, and the effect of time. All analyses were conducted using SPSS (IBM Corp. Released 2020. IBM SPSS Statistics for Windows, Version 27.0. Armonk, NY: IBM Corp), STATA (Stata Corp. 2019. Stata Statistical Software: Release 16. College Station, TX: StataCorp LLC) and SAS (SAS Institute Inc 2013. SAS/ACCESS® 9.4 Interface to ADABAS: Reference. Cary, NC: SAS Institute Inc.). A p-value of 0.05 was used to indicate statistical significance, and a 95% confidence interval (CI) was used to report results.

## Results

### Baseline Characteristics

**Demographics**—Demographics for the 198 patients enrolled in ANCHOR are listed in Table 1. The median age was 57 years (range 29-72 years), and patients were predominantly male (68.2%) and Black (83.3%). Most were unstably housed (55.1%), received some form of income (56.1%), completed at least a high school level of education (59.6%), and reported a history of incarceration (89.4%). Very few (6.6 %) were co-infected with HIV.

**Substance Use**—At baseline, the median OUD score was 10, indicating severe OUD. In the 3-month period preceding study enrollment, 58.6% of patients reported using drugs daily or more, 36.9% reported using drugs less than daily, and 4.5% reported using no drugs. The vast majority (75.8%) reported IDU within the past three months, nearly a third (30.3 %) engaged in daily IDU during the previous month, and more than half (54.5%) were receiving

MOUD. At Day 0, approximately a third (35.4%) met criteria for hazardous alcohol use based on the AUDIT-C questionnaire. Of the 191 patients who had a UDS at Day 0, 76.3 % had a UDS positive for opioids, 52.5% had a UDS positive for cocaine, and 13.1 % had a UDS positive for other substances besides non-prescribed opioids and cocaine.

**Mental Health**—At baseline, most patients (59.6 %) reported a history of mental illness. Patients reported receiving diagnoses of depressive disorders (27.8%), bipolar disorders (23.7%), anxiety disorders (18.2%), trauma-related disorders (9.6%), and psychotic-spectrum disorders (6.1%). Approximately a third (35.4%) reported taking psychotropic medications. While data regarding mental health engagement were not documented for most (70.2%) patients, 13.1% reported engagement in mental health treatment.

### HCV-PRO Scores

**HCV-PRO Scores at Day 0**—The mean HCV-PRO score at Day 0 was 64.0 ( $\pm 20.6$ ). HCV-PRO scores at Day 0 were higher for males ( $p=0.006$ ), those with at least a high school level of education ( $p=0.017$ ), those without a history of mental illness ( $p<0.001$ ), those engaged in mental health treatment ( $p=0.023$ ), and those not prescribed psychotropic medications ( $p=0.010$ ) (Supplemental Table 1).

**Individual Items of HCV-PRO During HCV Treatment**—As shown in Table 2, there was a significant increase in scores for 13 of the 16 items of the HCV-PRO from Day 0 to Week 24. Almost all the increase in scores occurred between Day 0 and Week 12.

**HCV-PRO Scores at Week 24**—Most participants (83.3 %) remained in the study at Week 24. Patients who did not remain in the study at Week 24 (16.7%) were more likely to lack stable housing ( $p=0.034$ ) and less likely to report a history of incarceration ( $p=0.044$ ) at baseline. They were also more likely to have a UDS positive for cocaine ( $p=0.018$ ) and a UDS positive for substances other than non-prescribed opioids and cocaine ( $p=0.018$ ) at Day 0 (Supplemental Table 2).

For the 165 patients who remained in the study at Week 24, the mean HCV-PRO score was 72.9 ( $\pm 20.4$ ), which was higher than their mean score at Day 0 (63.8;  $p<0.001$ ). As shown in the paired t-tests listed in Table 3, most subgroups had HCV-PRO scores that were higher at Week 24 than Day 0.

### Change in HCV-PRO Scores from the Day 0 to Week 24 Timepoint

A mixed effects model measured the change in HCV-PRO scores from the Day 0 to Week 24 timepoint. 147 patients met criteria for inclusion in the model. Figure 1 shows the changes in HCV-PRO scores for each variable included in the model. Compared with the Day 0 timepoint, the Week 24 timepoint was associated with a significant increase in HCV-PRO scores ( $N=147$ ; 8.7; 95% CI 5.4, 12.1;  $p<0.001$ ).

As shown in Figure 2, significant increases in HCV-PRO scores were associated with achieving SVR ( $N=131$ ; 10.4; 95% CI 7.1, 13.8;  $p<0.001$ ) and receiving MOUD at Week 24 ( $N=118$ ; 9.5; 95% CI 5.9, 13.1;  $p<0.001$ ). There was no significant change in HCV-PRO



scores associated with not achieving SVR (N=16; -5.3; 95% CI -21.2, 10.7; p=0.459) or not receiving MOUD at Week 24 (N=29; 5.5; 95% CI -3.8, 14.8; p=0.230). Age older than 45 was associated with a significant increase in HCV-PRO scores (N=128; 9.4; 95% CI 5.9, 13.0; p<0.001), but age younger than 45 was not associated with a change in HCV-PRO scores (N=19; 4.0; 95% CI -7.7, 15.7; p=0.460).

Other variables associated with increases in HCV-PRO scores were decline (N=53; 9.8; 95% CI 3.7, 15.9; p=0.002) and increase or no change in IDU frequency (N=94; 8.1; 95% CI 4.0, 12.2; p<0.001); UDS positive (N=103; 8.0; 95% CI 4.0, 12.0; p<0.001) and negative (N=44; 10.4; 95% CI 3.9, 16.8; p=0.003) for opioids at Week 24; UDS positive (N=75; 7.5; 95% CI 2.7, 12.4; p=0.003) and negative (N=72; 9.9; 95% CI 5.1, 14.8; p<0.001) for cocaine at Week 24; females (N=45; 13.1; 95% CI 5.3, 20.9; p=0.002) and males (N=102; 6.8; 95% CI 3.3, 10.3; p<0.001) at baseline; history of mental illness (N=88; 8.9; 95% CI 4.3, 13.7; p<0.001) and no history of mental illness (N=59; 8.3; 95% CI 3.5, 13.1; p=0.001) at baseline; and HIV status negative or unknown at baseline (N=142; 8.7; 95% CI 5.3, 12.1; p<0.001). The model only included 5 patients whose HIV status was positive at baseline, which were too few for measuring the change in HCV-PRO score for this variable.

## Discussion

In this cohort of predominantly middle-aged patients with OUD actively engaged in substance use, we found that HRQL improved after receiving DAA for HCV treatment, but it did not improve in those who did not achieve SVR, were not receiving MOUD at Week 24, or were younger than age 45. Critically, ongoing substance use factors at the Week 24 timepoint such as IDU frequency and UDS results for opioids and cocaine did not negate the HRQL improvements associated with achieving SVR. These findings strengthen the evidence for offering HCV treatment to patients with OUD regardless of whether they continue to use non-prescribed substances, and it reinforces that abstinence should not be a prerequisite for receiving HCV treatment.

Unlike previous studies of HRQL, in which only patients receiving MOUD or stabilized in substance use treatment were included (Dalgard et al., 2022; Gormley et al., 2021; Schulte et al., 2020), the majority of patients in ANCHOR were patients with severe OUD and active IDU who had lower baseline HCV-PRO scores than patients in other studies (Ahn et al., 2020; Anderson, Baran, Erickson, et al., 2014; Castelo et al., 2018; Evon et al., 2018). At screening, slightly less than half of patients were not receiving MOUD, and although buprenorphine could be initiated at any time during HCV treatment, a fifth of the patients remaining at the end of the study were not receiving MOUD. For these reasons, our analysis can demonstrate that HCV treatment is associated with an improvement in HRQL in patients with OUD actively engaged in substance use except for those not receiving MOUD or who do not achieve SVR.

While previous studies investigated HRQL only in patients with OUD who achieved SVR (Dalgard et al., 2022; Gormley et al., 2021), over a tenth of the patients in ANCHOR did not achieve SVR. Our results show that in this population with severe OUD who engage in IDU, SVR was associated with improved HRQL, whereas patients who did not achieve SVR

experienced no improvement in HRQL. These findings are both logical, since clearing HCV should resolve the physical and neuropsychiatric impairments responsible for worsening HRQL, and consistent with previous studies measuring HRQL in patient populations with HCV who do not engage in IDU (Fagundes et al., 2020; Saeed et al., 2020; Smith-Palmer et al., 2015; Z. M. Younossi et al., 2014, 2020).

Our results also show that receiving MOUD at Week 24 was associated with an improvement in HRQL, whereas not receiving MOUD at Week 24 was not associated with an improvement in HRQL. These results add to the growing literature of MOUD studies showing that MOUD improves HRQL in OUD patients actively engaged in IDU (Bråbäck et al., 2018; Nosyk et al., 2011), patients stabilized on MOUD experience an improvement in HRQL from HCV treatment (Dalgard et al., 2022; Gormley et al., 2021; Schulte et al., 2020), and providing MOUD during HCV treatment benefits patients with OUD (Rosenthal et al., 2020).

It is notable that HRQL improved for females and those with a history of mental illness, despite HCV-PRO scores being lower at baseline for both groups. Like substance use outcomes in our study, history of mental illness and female gender at baseline did not negate the impact of HCV cure on HRQL during HCV treatment. This highlights how robust the benefits of HCV treatment are even for vulnerable populations and emphasizes how crucial it is to increase the availability of HCV treatment.

One unexpected finding is that those younger than age 45 did not experience a significant improvement in HRQL from HCV treatment. The median age for patients in ANCHOR was 57, and only 19 patients younger than age 45 were included in the mixed effects model. As a result, the sample size in our study may be too low to make meaningful conclusions about how age affects HRQL in patients with OUD receiving HCV treatment.

Finally, our paper addresses a gap in the literature about the cost-effectiveness of HCV treatment for OUD patients. Decisions to treat HCV should account for outcomes other than HCV cure, including changes in HRQL. Information on how HCV treatment affects patients with OUD who engage in IDU can inform clinical decisions, identify areas of intervention, and persuade insurance companies to cover HCV treatment for this population. Previous research has shown that targeted screening of HCV in individuals who engage in IDU is a cost-effective strategy that could increase quality-adjusted life years and improve HCV outcomes (Tatar et al., 2020). Our results show that patients with OUD who engage in IDU not only respond robustly to HCV treatment as evidenced by HCV cure, but also experience subjective benefits from improved HRQL.

There are some limitations to our study. ANCHOR recruited patients from only two sites, which may limit the generalizability of our findings. The patient population enrolled in ANCHOR was predominantly older, Black, male, and urban, so the applicability of our findings to other subsets of the OUD population is limited. The data in ANCHOR were collected at only three timepoints and provided by self-report, which were not verified using other validated sources. There were only 198 patients enrolled in ANCHOR, though using a mixed effects model for our analysis partially addressed the limitations of our sample size.



HCV-PRO scores were only measured for 24 weeks following the start of DAA therapy, so we cannot comment on the change in HRQL and the variables affecting it after Week 24.

Our data demonstrate that patients with OUD actively engaged in substance use experience an improvement in HRQL from receiving HCV treatment unaffected by substance use outcomes. This highlights how HCV treatment provides extrahepatic benefits even for patients who engage in substance use. However, this improvement was not seen in patients who did not achieve SVR or were not receiving MOUD at Week 24. These data reinforce the critical nature of treating and curing HCV in all patients, as well as the importance of making MOUD available to the OUD population. Finally, these data further solidify the large body of evidence showing that ongoing substance use should not prevent people from accessing HCV treatment.

## Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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### Article Highlights

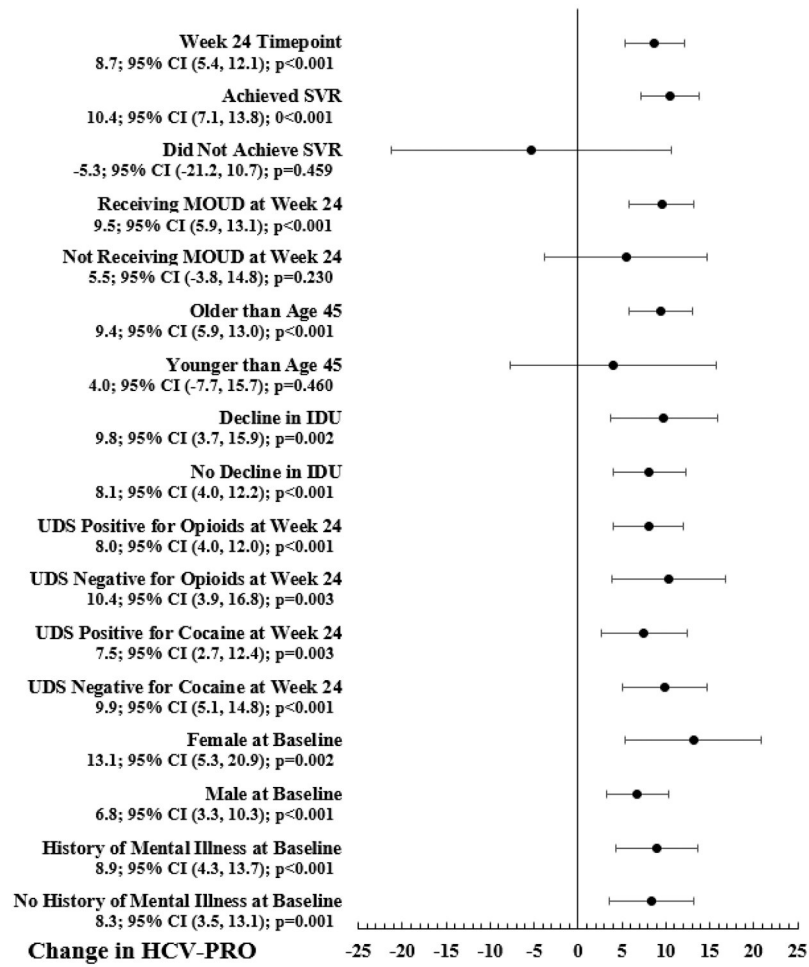
- Hepatitis C cure improves quality of life for opioid use disorder patients
- Medications for opioid use disorder improve quality of life during treatment
- Substance use outcomes during hepatitis C treatment did not negate quality of life
- Patients using substances should not be refused hepatitis C treatment
- Medications for opioid use disorder should be offered during hepatitis C treatment

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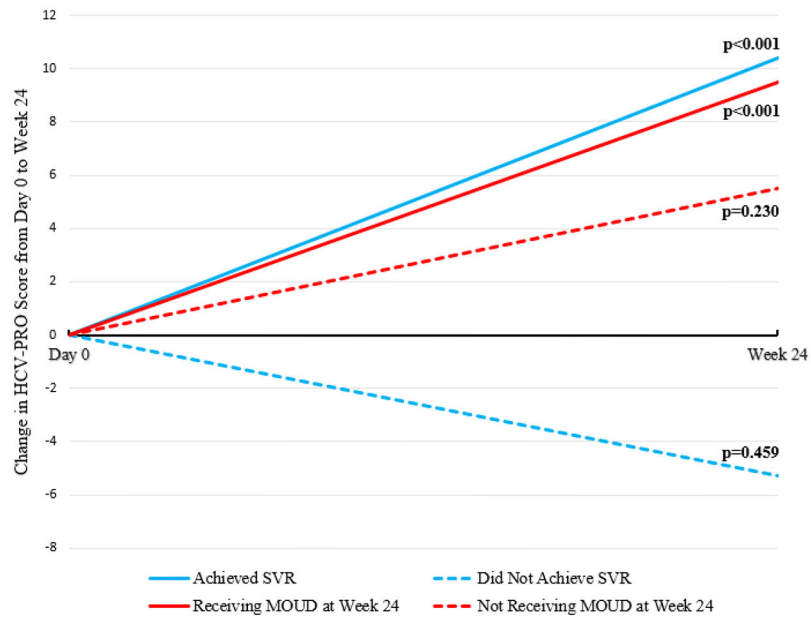
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**Figure 1: Change in HCV-PRO Scores from the Day 0 to Week 24 Timepoint for Variables Included in the Mixed Effects Model**

Abbreviations: CI: confidence interval; SVR: sustained virologic response; MOUD: medication for opioid use disorder; IDU: injection drug use; UDS: urine drug screen  
 \*HIV status at baseline is not shown in Figure 1 because there were too few patients whose HIV status was positive to include them in the mixed effects model



**Figure 2: Change in HCV-PRO Scores from the Day 0 to Week 24 Timepoint by SVR and MOUD Status**  
 Abbreviations: SVR: sustained virologic response; MOUD: medication for opioid use disorder \*p values denote the significance of the increase in HCV-PRO scores from the Day 0 to Week 24 timepoint



**Table 1:**

## Demographics

Characteristic	Number of Patients
Total	198 [100] <sup>a</sup>
Age, median (Q1,Q3), years	57 (52,61)
Gender	
Male	135 [68.2]
Female	63 [31.8]
Race	
Black	165 [83.3]
White	26 [13.1]
Alaska Native or Native American	1 [0.5]
More than one race	4 [2]
Other	2 [1]
Housing	
Stable	89 [44.9]
Unstable	109 [55.1]
Income	
Yes	111 [56.1]
No	87 [43.9]
Level of education	
High school or more	118 [59.6]
Less than high school	80 [40.4]
History of incarceration	
Never incarcerated	13 [6.6]
Within 1 year	23 [11.6]
More than 1 year	154 [77.8]
Missing <sup>b</sup>	8 [4]
HIV status	
Positive	13 [6.6]
Negative/Unknown	185 [93.4]
History of mental illness	
Yes	118 [59.6]
No	68 [34.3]
Missing	12 [6.1]
Engaged in mental health treatment	
Yes	26 [13.1]
No	33 [16.7]
Missing	139 [70.2]

Characteristic	Number of Patients
Psychiatric diagnoses	
Depressive disorders	55 [27.8]
Bipolar disorders	47 [23.7]
Anxiety disorders	36 [18.2]
Trauma-related disorders	19 [9.6]
Psychotic-spectrum disorders	12 [6.1]
Sleep-related disorders	3 [1.5]
Personality disorders	2 [1]
Attention-deficit/hyperactivity Disorder	1 [0.5]
Obsessive compulsive disorder	1 [0.5]
Other	1 [0.5]
Prescribed psychotropic medications	
Yes	70 [35.4]
No	127 [64.1]
Missing	1 [0.5]
Classes of psychotropic medications	
Antidepressants	42 [21.2]
Antipsychotics	34 [17.2]
Anxiolytics	32 [16.2]
Sleep aids	14 [7.1]
Mood stabilizers	11 [5.6]
Stimulants	2 [1]
OUD score, median (Q1,Q3)	10 (7,11)
Hazardous alcohol use	
Yes	70 [35.4]
No	128 [64.6]
Drug use <sup>c</sup> within the past 3 months	
Daily or more	116 [58.6]
Less than daily	73 [36.9]
None within the past 3 months	9 [4.5]
Injection drug use	
Within 3 months	150 [75.8]
Within 3-12 months	7 [3.5]
None within 12 months	41 [20.7]
Injection drug use in the last month	
Daily or more	60 [30.3]
Less than daily	62 [31.3]
None in the last month	76 [38.4]
Opioids in urine drug results	

Characteristic	Number of Patients
Yes	151 [76.3]
No	40 [20.2]
Missing	7 [3.5]
Cocaine in urine drug results	
Yes	104 [52.5]
No	87 [43.9]
Missing	7 [3.5]
Other drugs <sup>d</sup> in urine drug results	
Yes	26 [13.1]
No	165 [83.3]
Missing	7 [3.5]
Medication for opioid agonist therapy	
Methadone	77 [38.9]
Buprenorphine	31 [15.7]
Not currently prescribed	90 [45.5]

Abbreviations: Q1,Q3: first quartile, third quartile

<sup>a</sup> Percent of patients who gave a response in each subgroup

<sup>b</sup> Data not available

<sup>c</sup> Excludes marijuana

<sup>d</sup> Includes amphetamines, barbiturates, benzodiazepines, phencyclidine

**Table 2:**

Changes in Mean Scores of HCV-PRO Items Over 24 Weeks

HCV-PRO Item	Change in Mean from Day 0 to Week 12	P Value	Change in Mean from Day 0 to Week 24	P Value	Change in Mean from Week 12 to Week 24	P Value
<i>I felt too tired during the day to get done what I needed</i>	+0.50	<0.001	+0.58	<0.001	+0.01	0.907
<i>I needed to pace myself to finish what I had planned</i>	+0.26	0.035	+0.27	0.030	-0.01	0.918
<i>I felt forced to spend time in bed</i>	+0.05	0.661	+0.25	0.028	+0.23	0.045
<i>My muscles felt weak</i>	+0.49	<0.001	+0.39	<0.001	-0.05	0.669
<i>I could not get comfortable during the day</i>	+0.48	<0.001	+0.67	<0.001	+0.14	0.211
<i>I was unable to think clearly or focus on my thoughts</i>	+0.49	<0.001	+0.43	<0.001	-0.03	0.776
<i>I was forgetful</i>	+0.26	0.024	+0.33	0.002	-0.03	0.815
<i>Having hepatitis C affected my sex life</i>	+0.06	0.631	+0.12	0.321	+0.05	0.617
<i>I felt bothered by pain or physical discomfort</i>	0.13	0.283	+0.18	0.175	0.12	0.420
<i>I found it hard to meet people or make new friends because of my hepatitis C</i>	+0.20	0.004	+0.12	0.105	-0.03	0.629
<i>Having hepatitis C was very stressful to me</i>	+0.59	<0.001	+0.58	<0.001	-0.08	0.474
<i>I felt downhearted and sad</i>	+0.49	<0.001	+0.50	<0.001	+0.03	0.829
<i>I felt restless or on edge</i>	+0.25	0.022	+0.29	0.014	+0.09	0.394
<i>I felt little interest in doing things</i>	+0.29	0.011	+0.31	0.008	+0.03	0.785
<i>I had difficulty sleeping or slept too much</i>	+0.31	0.024	+0.38	0.004	+0.09	0.550
<i>Hepatitis C lowered my quality of life</i>	+0.44	<0.001	+0.39	0.001	-0.03	0.769

**Table 3:**

Comparison of HCV-PRO Scores at Baseline and Week 24 for Patients Who Remained in the Study at Week 24

Variables Recorded at Baseline				
Characteristic	Number <sup>a</sup>	HCV-PRO Score (SD) at Baseline	HCV-PRO Score (SD) at Week 24	P Value
Total	165	63.8 (±20.3)	72.9 (±20.4)	<0.001
Gender	165			
Male	115	66.4 (±20.9)	74.4 (±19.3)	<0.001
Female	50	57.8 (±17.4)	69.5 (±22.5)	0.002
Race	165			
Black	141	64.1 (±20.7)	73.4 (±20.4)	<0.001
Non-Black	24	62.2 (±17.9)	70.1 (±20.7)	0.088
Housing	165			
Stable	80	64.0 (±21.8)	75.3 (±19.6)	<0.001
Unstable	85	63.7 (±18.9)	70.6 (±20.9)	<0.001
Income	165			
Yes	95	66.0 (±20.5)	75.2 (±20.2)	<0.001
No	70	60.8 (±19.7)	69.8 (±20.4)	0.001
Level of education	165			
High school or more	99	67.0 (±19.7)	76.1 (±19.2)	<0.001
Less than high school	66	59.1 (±20.3)	68.1 (±21.3)	<0.001
History of incarceration	157			
Never incarcerated	8	59.8 (±24.4)	70.5 (±26.6)	0.385
Within 1 year	17	69.4 (±14.0)	71.9 (±19.8)	0.662
More than 1 year	132	62.9 (±20.9)	72.3 (±20.4)	<0.001
HIV status	165			
Positive	9	65.3 (±25.5)	72.7 (±21.6)	0.349
Negative/Unknown	156	63.7 (±20.0)	72.9 (±20.4)	<0.001
History of mental illness	156			
Yes	95	58.8 (±20.4)	68.7 (±20.8)	<0.001
No	61	71.0 (±17.7)	79.4 (±17.4)	<0.001
Engaged in mental health treatment	49			
Yes	22	70.4 (±20.7)	76.9 (±14.3)	0.200
No	27	58.0 (±18.8)	66.2 (±25.3)	0.085
Prescribed psychotropic medications	164			
Yes	55	60.5 (±19.2)	68.8 (±17.6)	0.006
No	109	65.5 (±20.8)	74.9 (±21.5)	<0.001
Drug use within the past 3 months	165			
Daily or more	93	62.6 (±20.1)	71.2 (±20.6)	<0.001

Variables Recorded at Baseline				
Characteristic	Number <sup>a</sup>	HCV-PRO Score (SD) at Baseline	HCV-PRO Score (SD) at Week 24	P Value
Less than daily	66	65.2 (±20.9)	74.8 (±20.1)	<0.001
None within the past 3 months	6	67.5 (±18.0)	78.1 (±20.2)	0.135
Injection drug use	165			
Within 3 months	126	63.7 (±20.8)	72.1 (±21.0)	<0.001
Within 3-12 months	6	62.8 (±11.6)	78.4 (±13.7)	0.011
None within the past 12 months	33	64.3 (±19.8)	74.9 (±19.3)	0.004
Injection drug use in the last month at Day 0	165			
Daily or more	48	63.0 (±20.4)	70.4 (±19.9)	0.009
Less than daily	52	63.0 (±20.9)	71.7 (±22.6)	0.005
None in the last month	65	65.1 (±19.9)	75.7 (±18.8)	<0.001
Injection drug use in the last month at Week 24	163			
Daily or more	23	59.8 (±21.7)	63.5 (±20.2)	0.462
Less than daily	40	63.1 (±20.0)	67.38 (±22.0)	0.178
None in the last month	100	65.0 (±20.2)	77.2 (±18.6)	<0.001
Hazardous alcohol use at Day 0	165			
Yes	58	62.9 (±17.4)	72.4 (±20.8)	<0.001
No	107	64.3 (±21.7)	73.2 (±20.2)	<0.001
Hazardous alcohol use at Week 24	164			
Yes	41	63.2 (±19.6)	70.2 (±24.6)	0.065
No	123	64.1 (±20.6)	74.0 (±18.8)	<0.001
Opioids in urine drug results at Day 0	160			
Yes	125	63.2 (±20.2)	71.2 (±20.8)	<0.001
No	35	67.5 (±21.4)	79.3 (±18.2)	<0.001
Opioids in urine drug results at Week 24	156			
Yes	109	62.4 (±20.3)	70.3 (±20.8)	<0.001
No	47	69.3 (±17.9)	79.5 (±18.3)	0.001
Cocaine in urine drug results at Day 0	160			
Yes	81	63.7 (±20.3)	71.6 (±21.0)	<0.001
No	79	64.6 (±20.7)	74.4 (±20.0)	<0.001
Cocaine in urine drug results at Week 24	156			
Yes	79	61.5 (±19.5)	69.0 (±21.7)	0.002
No	77	67.6 (±19.7)	77.2 (±18.3)	<0.001
Other drugs in urine drug results at Day 0	160			
Yes	17	59.5 (±20.3)	69.0 (±20.8)	0.117
No	143	64.7 (±20.5)	73.4 (±20.5)	<0.001
Other drugs in urine drug results at Week 24	156			
Yes	16	60.9 (±16.3)	57.0 (±19.9)	0.519
No	140	64.9 (±20.1)	74.9 (±19.8)	<0.001



Variables Recorded at Baseline				
Characteristic	Number <sup>a</sup>	HCV-PRO Score (SD) at Baseline	HCV-PRO Score (SD) at Week 24	P Value
Medication for opioid agonist therapy at Day 0	165			
Yes	101	62.7 (±19.4)	73.7 (±20.1)	<0.001
No	64	65.6 (±21.7)	71.7 (±20.9)	0.022
Medication for opioid agonist therapy at Week 24	165			
Yes	133	62.9 (±20.0)	73.0 (±20.0)	<0.001
No	32	67.8 (±21.2)	72.5 (±22.1)	0.265
Achieved SVR at Week 24 <sup>b</sup>	165			
Yes	146	63.6 (±20.2)	74.1 (±19.6)	<0.001
No	19	65.6 (±21.3)	64.1 (±24.7)	0.810

Abbreviations: SD: standard deviation; SVR: sustained virologic response

<sup>a</sup>Only included patients who provided a response

<sup>b</sup>Only obtained at Week 24