

# A novel model to improve access to care for patients with chronic hepatitis C attended in behavioral health facilities

## Abstract

**Background:** Chronic hepatitis C (C-HCV) is more prevalent in individuals with behavioral health (BH) diagnoses and those on opioid replacement therapy than in other groups. Accordingly, our aim was to evaluate the effect of C-HCV treatment on the quality of life (QOL) of individuals receiving opioid replacement therapy in a newly created C-HCV clinic attached to the methadone clinic in our 338 beds and 355,702 annual outpatient visits community hospital, serving the population of East Harlem, New York City, where it is located.

**Methods:** Adult patients with behavioral health diagnoses were screened for C-HCV upon entry to the hospital and were referred for evaluation and treatment, as appropriate.

The effect of treatment of C-HCV on the quality of life (QOL) was assessed by a questionnaire in which a maximum score of 174 is the worst QOL, and a score of zero is the best, at baseline, and at least 12 weeks post treatment.

**Results:** Three hundred and eighty-seven patients with behavioral health diagnoses were screened. One hundred and fifteen of them had confirmed C-HCV. Twenty-one of those patients had attended the BH HCV clinic. Fourteen additional patients were evaluated at a later date. Nineteen patients agreed to participate in the QOL study. Of these, 15 (79%) completed therapy and were cured. A marked improvement in their QOL scores was documented at least 12 weeks after treatment.

**Conclusion:** A model of care that includes C-HCV treatment in BH facilities leads to adherence to therapy and cure, which is associated with improved QOL and should be the standard practice.

**Keywords:** hepatitis C, quality of life, behavioral health, sustained virological response

Volume 12 Issue 3 - 2021

Ahmed Shady,<sup>1</sup> Marybeth Santiago,<sup>2</sup> Holly Totouom-Tangho,<sup>2</sup> Ronnie Swift,<sup>2</sup> Nora V Bergasa<sup>1</sup>

<sup>1</sup>Department of Medicine, New York City Health + Hospitals/ Metropolitan, USA

<sup>2</sup>Department of Psychiatry, New York City Health + Hospitals/ Metropolitan, USA

**Correspondence:** Ahmed Shady, Department of Medicine, New York City Health + Hospitals/Metropolitan, USA, Email [Ahmed.shady@nychhc.org](mailto:Ahmed.shady@nychhc.org)

**Received:** April 25, 2021 | **Published:** May 21, 2021

**Abbreviations:** C-HCV, Chronic hepatitis C; QOL, quality of life; HCV, hepatitis C viral; PCR, polymerase chain reaction; EOT, end of treatment; HIV, human immune deficiency virus; SVR, sustained virological response

## Introduction

Chronic hepatitis C viral (HCV) infection is a major contributor to morbidity and mortality in the United States, prompting recommendations from the United States Preventive Services Task Force (USPSTF) to screen all adults starting at the age of 18 and annual screening for persons who inject drugs.<sup>1</sup> According to the National Survey on Drug Use and Health, heroin use has increased across the US amongst men and women of all income levels and age groups.<sup>2</sup> Intravenous drug use accounts for approximately 70% of new HCV infections.<sup>3</sup> The prevalence of C-HCV in individuals with behavioral health (BH) diagnoses is 17.4%,<sup>5</sup> higher than that of the general population in both groups. Accordingly, the aim of this study was to establish a service in BH and the methadone clinic at a community hospital in East Harlem, New York, and to assess the effect of C-HCV treatment with standard medications on quality of life (QOL)<sup>4</sup> of the patients treated.

## Methods

Patients with BH diagnoses (e.g. depression, schizophrenia, bipolar disorder) were screened for C-HCV at any point of entry to the

hospital and were referred to hepatology for evaluation and treatment as appropriate. A C-HCV clinic was established in physical proximity to the methadone clinic. The clinic was attended by two hepatologists in collaboration with the chief of psychiatry, the internist from BH, and the head nurse from the methadone clinic.

The head nurse referred patients who tested positive for hepatitis C RNA by polymerase chain reaction (PCR) to the C-HCV clinic. Patients were evaluated by the hepatologists who performed a complete liver disease evaluation in preparation for the treatment of HCV. The study on quality of life (QOL) was presented to the patients, and, if interested, consent was obtained. The study consisted of completing a questionnaire adopted from another study on quality of life on patients with chronic liver disease composed of questions driven by patient symptomatology. Results of this questionnaire are used to assess QOL in patients with liver disease,<sup>4</sup> in which a maximum score of 174= worst QOL, and 0= best. Patients completed the questionnaire prior to initiation of treatment, at the end of treatment (EOT), and at 12 weeks post treatment.<sup>4</sup> The study was approved by the Institutional Review Board.

## Results

Of the 387 patients with dual diagnoses, i.e., substance abuse and a mental health disorder, screened from January 2017 to March 2019, 241 had detected anti HCV antibodies. One hundred and fifteen of the 387 (29.7 %) had confirmed C-HCV by PCR. Of these, ten

were co-infected with the human immune deficiency virus (HIV) and were linked to the HIV service (Figure 1). The rest of the patients with C-HCV, 105, were referred as follows: I) 67 were referred to gastroenterology or hepatology clinics, none of whom kept the appointment, II) three declined referral, III) 18 could not be reached

during several attempts, IV) 21 were referred to the established BH HCV clinic, where 14 additional patients on opioid replacement therapy who had been previously diagnosed with C-HCV were also attended, making the total number of patients evaluated at the C-HCV BH clinic 35 (Figure 2).

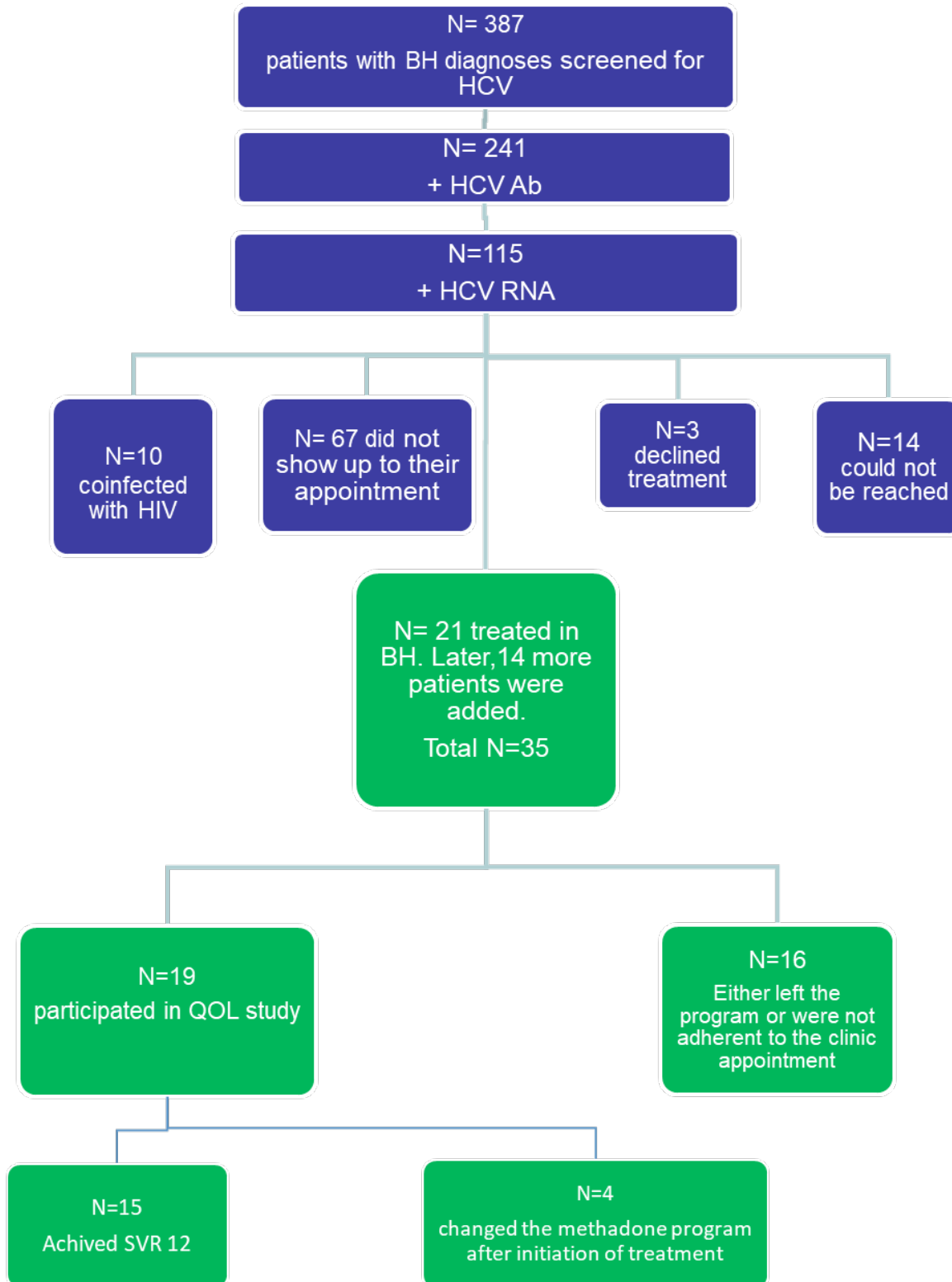
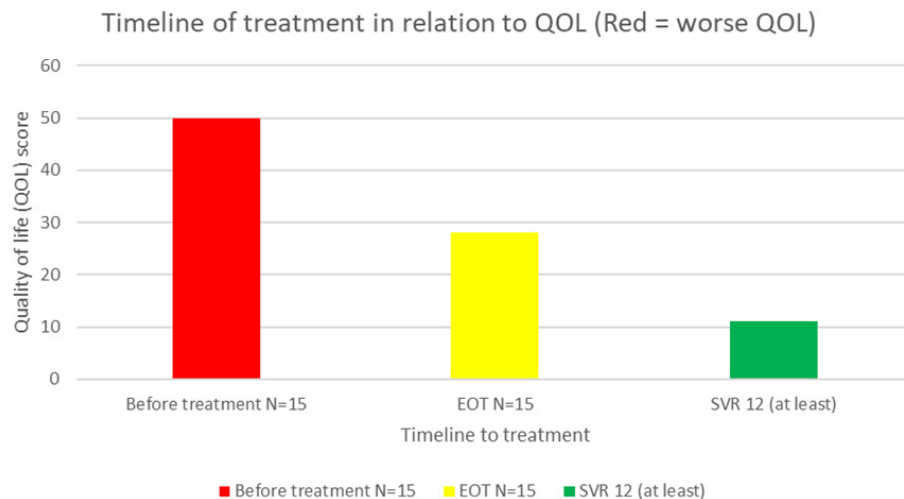


Figure 1 Patients with BH diagnosis screened for HCV.



**Figure 2** Patients had improved QOL with C-HCV cure (green).

Nineteen of the 35 subjects on opioid replacement therapy agreed to participate in this study. Fourteen (70 %) were men, 11 (57.8%) were of Hispanic ethnicity, two were African American, and the rest were white. Only six patients (31%) were in the baby boomers category, defined by the United States Census Bureau, as individuals born between 1945-1965, and the rest were born after 1965. Fifteen patients (79%) completed treatment and achieved sustained virological response (SVR), defined as negative HCV RNA in serum twelve weeks after completion of treatment (SVR 12) and consistent with cure.<sup>7</sup> Median QOL score went from 50 at baseline (range 16-150) to 28 (range 0-67) at the end of treatment (EOT), and to 11 (range 0-37) at SVR 12 consistent with an improvement in their QOL (Figure 2). The remaining four patients moved to another program and did not return for follow up.

## Discussion

Two major goals were accomplished in this study, one was the successful establishment of a C-HCV clinic attended by hepatologists in behavioral health, and the other one was the linkage to care of patients with C-HCV in the same place where they were receiving their medication (i.e. methadone) for addiction treatment (MAT) where they were treated and cured of their infection.

It is estimated that there are 3.5 million persons infected with the hepatitis C virus in the United States, including 2.7 million in the general population,<sup>5</sup> and 800,000 incarcerated, institutionalized, or homeless persons.<sup>6</sup> An estimated 50% of infected individuals do not know that they have C-HCV.<sup>7</sup>

Screening for C-HCV is recommended because benefits of treatment include reduction of the risk of death from complications of liver disease, including hepatocellular carcinoma and all-cause mortality, as well as the potential public health benefit of reducing transmission through treatment because of viral clearance.<sup>1</sup>

The virus's main route of transmission is through exposure to infected blood via transfusion of blood and other products. Intravenous drug use (IVDU) accounts for at least 60% of acute HCV infections in the United States.<sup>8</sup> Other modes of transmission include vertical transmission, contaminated devices shared for non-injection drug use (e.g., straws used in sniffing cocaine), and sexual transmission, which is generally low except among HIV-infected men who have unprotected sex with men.<sup>9</sup>

Prior to the approval of direct acting antivirals (DAAs), patients with C-HCV, who generally had impaired quality of life,<sup>10</sup> were treated with regimens that included interferon and ribavirin, which were associated with considerable side effects, including fatigue, depression, and anemia.<sup>11</sup> The availability of DAAs has changed the approach to patients with C-HCV and their experience during treatment. These medications result in relatively rapid clearance of the virus and increased patient satisfaction and improvement in the QOL in general.<sup>11</sup>

One of the aims of this study was to educate patients about C-HCV treatment, including the absence of injectable medications in current regimens, and the high probability of cure in association with shortened duration of treatment; although not all the patients wanted to be treated, we hoped that the information they received may assist them in reconsidering treatment.

Linkage to care in the established BH HCV clinic was associated with 80% adherence to treatment with resultant cure in 100% of the patients. It is noted that BH diagnoses in association with addiction impede the patients' ability to commit to complicated clinic referral processes and appointments.<sup>12</sup> Accordingly, the hepatology fellow focused on the development of the outpatient C-HCV in behavioral health, and was always available to see patients in the clinic at any time during its hours of operation, if they agreed or requested to be evaluated. The presence of the hepatologist near the physical space of the methadone clinic gave the patients the opportunity to talk to the physician about the indications for treatment and the real possibility of cure without a pre-arranged appointment. The ample time that the dedicated hepatologist provided the patient for conversation allowed for the development of a personalized teaching process and treatment plan. The consistent availability of the hepatologist who worked in close connection with the head nurse fomented trust and improved adherence to treatment of HCV.

In addition, nurses and counselors who had been trained by the hepatologist on the use of liver models of disease educated the patients about C-HCV and its complications. Word of mouth among patients stimulated self-referral, as patients heard from each other that they had a good experience.

In spite of the presence of a C-HCV clinic in BH, patients required reminders to attend the clinic. The hepatologists called all patients who agreed to share their contact numbers to ensure that no one was

lost to follow up or missed laboratory tests. Unfortunately, patients who changed their methadone program did not follow because of a change in geographic location.

Treatment was associated with a 100% cure rate from C-HCV, similar to that documented in patients who are not on medications for addiction treatment. This result provides further evidence to support the safety and efficacy of direct acting agents (DAA) in treating hepatitis C in a population that experiences occasional relapses in drug use, including heroin and cocaine. In this regard, some of the patients reported having used other illicit drugs during treatment; the fact that they still responded to DDA therapy supports the recommendation that treatment of C-HCV in patients who actively use drugs is feasible and efficacious.<sup>13</sup> This statement should not be confused with an encouragement to proceed with drug use; it is information that can be used to encourage patients to get treated with the real possibility of a cure and improvement of quality of life, which may improve their self-esteem. The cure of C-HCV may facilitate the participation of patients who continue to use drugs in needle exchange programs because they were educated about the risk of reinfection by participating in high risk behavior, including the sharing of drug use paraphernalia.

Among the 35 individuals who attended the C-HCV clinic in BH, 19 agreed to participate in the QOL study. The majority, almost 80%, was adherent to therapy, and all the patients achieved SVR12 with improved QOL. The improvement in the quality of life in association with treatment of C-HCV might have been related to the systemic deleterious effect of C-HCV infection, as already documented,<sup>14</sup> in addition, we speculate that improved self-esteem emerging from the experience of a cure had a positive impact on their daily life.

Although the study is limited by its small sample size, we introduce this model as a successful one because approximately 80% of patients who had been living with C-HCV for years were treated and cured, with significant QOL improvement in 100% of the treated group.

## Conclusion

A fruitful collaboration between BH and hepatology led to the treatment of patients with C-HCV on medication for addiction treatment with methadone, associated with cure and improved QOL.

A model of care that incorporates HCV treatment in BH facilities should be the standard practice.

## Acknowledgments

We thank Gilead Sciences, Inc. for the institutional grant support.

## Conflicts of interest

Authors declare that we have no conflicting interests.

## Funding

Supported, in part, by Gilead sciences, Inc.

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