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# Hepatitis C Virus Testing and Treatment Among Persons Receiving Buprenorphine in an Office-Based Program for Opioid Use Disorders

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ABSTRACT

*Aims:* In the United States, hepatitis C virus (HCV) infection is primarily spread through injection drug use. There is an urgent need to improve access to care for HCV among persons with opioid use disorders who inject drugs. The purpose of our study was to determine the prevalence of HCV, patient characteristics, and receipt of appropriate care in a sample of patients treated with buprenorphine for their opioid use disorders in a primary care setting.
*Methods:* This study used retrospective clinical data from the electronic medical record. The study population included patients receiving buprenorphine in the Office Based Opioid Treatment (OBOT) clinic within the adult primary medicine clinic at Boston Medical Center between October 2003 and August 2013 who received a conclusive HCV antibody (Ab) test within a year of clinic entry. We compared characteristics by HCV serostatus using Pearson's chi-square and provided numbers/percentages receiving appropriate care.
*Results:* The sample comprised 700 patients. Slightly less than half of all patients ($n = 334$, 47.7%) were HCV Ab positive, and were significantly more likely to be older, Hispanic or African American, have diagnoses of post-traumatic stress disorder (PTSD) or bipolar disorder, have prior heroin or cocaine use, and be HIV-infected. Among the 334 HCV Ab positive patients, 226 (67.7%) had detectable HCV ribonucleic acid (RNA) indicating chronic HCV infection; only 5 patients (2.21%) with chronic HCV infection ever initiated treatment.
*Conclusions:* Nearly half of patients (47.7%) receiving office-based treatment with buprenorphine for their opioid use disorder had a positive hepatitis C virus antibody screening test although initiation of HCV treatment was nearly non-existent (2.21%).



## 1. Introduction

More than 4 million people in the United States are infected with the hepatitis C virus (HCV) (Ditah et al., 2014). The population most at risk is people who inject drugs (PWID) (Armstrong et al., 2006), where HCV prevalence rates range between 35 and 73% (Amon et al., 2008; Nelson et al., 2011). While HCV treatment regimens have improved significantly, lack of diagnosis (Kwiatkowski, Fortuin Corsi, & Booth, 2002; Volk, Tocco, Saini, & Lok, 2009), lack of individual treatment uptake, and system wide barriers prevent their effective implementation (Bruggmann, 2012; Mehta et al., 2005). PWID are among those least likely to receive HCV treatment with initiation rates as low as 6% (Mehta & Genberg, 2008), despite studies demonstrating a willingness to be treated (Zeremski et al., 2014), successful treatment outcomes (Hellard, Sacks-Davis, & Gold, 2009), and refined national guidelines recommending that HCV treatment be considered for PWID on a case-by-case basis (Ghany, Strader, Thomas, Seeff, & American Association for the Study of Liver Diseases, 2009; Hepatitis C Guidance: AASLD-IDSA Recommendations for Testing, Managing, and Treating Adults Infected with Hepatitis C Virus, 2015).

Less attention has been paid to the specific opportunity that may exist for patients treated with buprenorphine in office-based clinics. Buprenorphine was approved by the Food and Drug Administration (FDA) for treatment of opioid dependence in 2002. Demand for

*Abbreviations:* Ab, antibody; ALT, alanine transaminase; AST, aspartate transaminase; BMC, Boston Medical Center; DAA, directly acting antivirals; EMR, electronic medical record; ETR, end-treatment response; FDA, Food and Drug Administration; FIB-4, fibrosis-4; HIPAA, Health Insurance Portability and Accountability; HCV, Hepatitis C virus; HIV, human immunodeficiency virus; ICD, International Classification of Diseases; ID, infectious disease; OBOT, office-based opioid therapy; OAT, opioid agonist treatment; PTSD, post-traumatic stress disorder; PWID, people who inject drugs; RNA, ribonucleic acid; SVR, sustained virologic response.

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buprenorphine treatment has grown: from 2002 to 2007, total numbers of buprenorphine prescriptions have increased from approximately 50,000 to 5.7 million (Greene, 2010). Patients seeking medication assisted treatment for opioid use disorders may prefer treatment with buprenorphine over methadone (Gryczynski et al., 2013), as it can be prescribed in primary care office-based settings, which may help to increase treatment initiation rates among PWIDs. Given that primary care providers are on the front lines for HCV screening and are likely to have an increased role in HCV treatment in the U.S., there is a unique opportunity to combine treatment for opioid use disorders and HCV in primary care settings. To this effect, the United States Health and Human Services (HHS) department has developed strategic plans which aim to increase HCV screening and treatment in primary care centers and substance abuse programs specifically (Ward, Valdiserri, & Koh, 2012).

The office-based opioid therapy (OBOT) program, established in 2003 within the adult medicine primary care clinic at Boston Medical Center (BMC), offers collaborative care, based on a nurse care management model, to patients seeking both opioid agonist therapy (OAT) and primary care (Alford et al., 2011). It has been highlighted as an innovative state model for achieving treatment-effective and cost-effective results for opioid use disorders (Medicaid Coverage and Financing of Medications to Treat Alcohol and Opioid Use Disorders, 2014). As such, it may provide an ideal opportunity for integrating addiction and HCV treatment within primary care.

The purpose of our study was to determine the prevalence of HCV, characteristics of patients HCV, and describe receipt of appropriate care (i.e. the "treatment cascade") in a sample of opioid dependent patients treated with buprenorphine in a primary care setting, in order to assess their current status of HCV treatment.

## 2. Materials and methods

### 2.1. Study design

This was a descriptive, observational study of HCV screening, prevalence and receipt of care using retrospective clinical data from electronic medical records.

### 2.2. Study population

Our study population was composed of patients receiving buprenorphine in the OBOT clinic within the adult primary medicine clinic at BMC between October 2003 and August 2013 who received a conclusive HCV Ab screening test within a year before or after clinic entry. Antibody tests prior to clinic entry included HCV Ab testing at other Boston Medical Center clinics with a shared electronic medical record. A complete description of the OBOT clinic, including procedures for patient assessment, stabilization and maintenance has been previously published (Alford et al., 2011). Patient assessment during the 10 year study period included a standardized intake and screening for HCV. Briefly, the OBOT clinic provides medication-assisted treatment (primarily buprenorphine) for opioid use disorders within an adult outpatient primary care setting. The clinic is based on a collaborative care model, utilizing nurse care managers with primary care physicians qualified to prescribe buprenorphine to provide care.

### 2.3. Data collection

Data elements were extracted from the BMC clinical data warehouse, which is composed of clinical and administrative data from the electronic medical record (EMR). We identified the OBOT patient cohort by searching the electronic medical record (EMR) for key words ("OBOT", "SUBOX", "SUBUTEX", etc.) in the summary line of an office visit. All direct Health Insurance Portability and Accountability (HIPAA) identifiers were removed to create an anonymous dataset. Information collected included: demographics, visit dates, *International Classification of Diseases (ICD)-9* codes, laboratory testing, medications, initial clinic note information on substance use and HCV specialist referrals.

### 2.4. Study outcomes

The outcomes of interest were: (1) HCV Ab serostatus and (2) receipt of appropriate HCV care including confirmatory HCV viral load test, HCV genotype, components of fibrosis (FIB)-4 values (aspartate transaminase (AST), alanine transaminases (ALT), and platelets), referral to specialist, receipt of HCV treatment, and treatment response. Screening for HCV was part of routine OBOT intake procedures. Further work-up for HCV was left to the discretion of the primary care and OBOT provider. A positive HCV viral load was defined as any value higher than the threshold for detection, and was the basis for defining chronic HCV infection. Specialist referral was defined as a documented referral to an infectious disease (ID) physician or gastroenterologist with HCV documented as a reason for the visit. FIB-4 was calculated using the formula $\text{age(years)} \times \text{AST[U/L]} / (\text{platelets}[10^9/\text{L}] \times (\text{ALT[U/L]}^{1/2}))$ (Vallet-Pichard et al., 2007) with values extrapolated from the tests that occurred closest to the date of the positive HCV RNA test. Receipt of HCV treatment was defined as a prescription that was documented in the EMR for pegylated-interferon and ribavirin, with or without telaprevir or boceprevir. For treated patients, dates and results of viral load tests were assessed relative to prescription dates to determine whether patients were documented to have achieved end-of-treatment response (ETR, i.e. undetectable viral load at the end of treatment) and sustained virologic response (SVR, i.e. undetectable viral load 24 weeks after completion of treatment).

### 2.5. Other variables

Other variables that were included in the analyses were: age, race/ethnicity, insurance status, psychiatric co-morbidities, illicit drug use history (heroin, oxycontin, Vicodin/Percocet, benzodiazepines, alcohol, cocaine, and amphetamines), and injection drug use. Race/ethnicity was separated into Caucasian, Hispanic/Latino, Black/African American and other. Insurance-type was divided into 4 categories: Medicaid, Medicare, private insurance, and other (worker's comp, self-pay, and free care). Psychiatric co-morbidities of interest were captured using the following *ICD-9* codes: schizophrenia (295.0-295.9), bipolar disorder (296.0, 296.1, 296.4-8), depression (296.2, 296.3, 300.4, 311), anxiety (300.0, 300.2, 300.3), and PTSD (309.81). HIV infection was captured using the following *ICD-9* codes: 042, V08 and 079.53. Diagnoses and coding occurred at the discretion of the provider. Prior illicit drug use information was collected from the initial telephone screen or in-person intake assessment by a series of pre-populated questions including 'year of first use', 'route of administration', and 'frequency of use' for all drug types. Two additional free text fields summarizing drug use were also used to capture prior illicit drug use by first searching the text fields for key words and then reviewing these text fields to ensure the search terms were not mentioned in the context of abstinence. Although cannabis information is included in the intake and telephone screen forms, it was believed to be underreported (the staff did not consistently screen for its use), and therefore was excluded from the analyses. Smoking status was defined by a question about current smoking in the initial screening note. Prior injection drug use information was collected from the initial telephone screen and/or in-person intake assessment by a series of pre-populated questions including 'route of heroin administration', 'shared needle' and 'needle exchange' and an additional free text field summary.

### 2.6. Statistical analyses

Descriptive statistics were used to compare characteristics by HCV serostatus (positive versus negative) using Pearson's chi-square test.