

## **Patient-Centered Hepatitis C Treatment via Telemedicine for Individuals on Opiate Substitution Therapy**

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### **Abstract:**

**Background:** Hepatitis C virus (HCV) affects almost 5 million people in the United States and is a major cause of chronic liver disease leading to liver fibrosis, cirrhosis, liver cancer, disability and death. Persons with substance use disorders (PWSUD), specifically injection drug users, have the highest HCV prevalence and incidence rates but only a small minority is treated for the infection. Since PWSUD feel stigmatized and encounter discrimination in conventional healthcare settings, their engagement in clinical care is difficult. The objective of this study is to develop and evaluate the implementation and effectiveness of an integrated, telemedicine-based care model for HCV in PWSUD in opioid treatment programs (OTPs). Our primary aim is to compare the effectiveness of patient-centered delivery of HCV care through telemedicine (Experimental-EXP) versus the standard of care, a referral to an offsite liver or infectious diseases specialist (Control-CON).

**Methods:** This is a non-blinded, stepped-wedge cluster randomized controlled trial (SWCRCT) with two arms: telemedicine (EXP) and usual care (CON). The study is being conducted in twelve OTPs in urban and rural sites in Upstate New York and in New York City over a five-year period. The study was initiated at all sites with the usual care arm, and at regular 9-month intervals, a group of four OTPs cross over, in a randomly assigned order, to the telemedicine intervention. In the usual care arm, patients were referred to an offsite liver specialist. In the telemedicine arm, two-way video-teleconferencing links patients in the OTP to the offsite liver specialist: HCV evaluation, treatment prescription, and treatment appointments are all conducted via telemedicine. The primary outcome is assessed at week 12 post-treatment to establish sustained virologic response. Patients are subsequently followed for 24 months post treatment completion to assess reinfection rates. We aim to recruit a total of 624 patients, with 52 patients per OTP.

**Results:** Patient recruitment started in March 2017, with all 12 sites enrolling patients in the usual care arm. Telemedicine intervention was initiated in December, 2017, and since June, 2019, all OTPs are recruiting patients in the telemedicine study arm. As of December 30<sup>th</sup>, 2019, 577 subjects have been enrolled in the study, with the following baseline characteristics: mean age 47.9±12.91; 39.17% female; 47.66% Caucasian, 21.32% are African American; 30.50% Hispanic.

**Conclusions:** Telemedicine-based HCV treatment integrated in OTPs is well accepted by both patients and site personnel. Engagement activities targeting both OTP staff and patients are important for implementing complex study designs, such as SWCRCTs, at OTPs. The study framework and engagement activities could be used for implementation of telemedicine as a clinical endeavor for a variety of conditions that affect substance users and other populations that are difficult to engage and retain in care.