



Patient-Centered HCV Care via Telemedicine for Individuals on Opiate Substitution Therapy: A Stepped Wedge Cluster Randomized Controlled Trial

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 and death. Persons with substance use disorders (PWSUD), specifically injection drug users, have the highest HCV prevalence (30%-70%) and incidence (16%-42%) rates but only a small minority (1%-6%) is treated for the infection. Referral to an HCV specialist is the current standard HCV management strategy for PWSUD. However, while the majority of PWSUD express willingness to be treated for HCV, only a very small percentage has actually received HCV treatment. Reasons for that are multiple and include lack of knowledge about HCV, mistrust of the health care establishment, and extreme discomfort navigating the referral system. While HCV treatment of PWSUD in opiate substitutions treatment programs (OSTPs) has been shown to be very effective, only a small number of OSTPs have the ability to treat HCV onsite. Therefore, novel models for HCV care in this population are needed as current approaches for HCV treatment of PWSUD are limited in their reach and effectiveness. The objective of this study is to establish an integrated, telemedicine-based care model for HCV in PWSUD in the OSTP. The findings of this study could be of high importance as they could provide a treatment model for HCV in a marginalized population with the highest HCV prevalence that could be a major step toward HCV eradication in a difficult to reach population.

The primary aim of the study is to compare the effectiveness of patient-centered delivery of HCV care through telemedicine versus referral to an offsite liver or infectious diseases specialist, which is the current standard of care. Our secondary aims include: 1) comparison of patient satisfaction with health care delivery between the two arms, 2) comparison of treatment initiation and treatment completion rates between both arms, 3) comparison of patient adherence between both arms, and 4) evaluation of patient satisfaction with the telemedicine-based treatment approach.

The study will be conducted as a non-blinded stepped-wedge cluster randomized controlled trial (SW-RCT) with two arms in twelve geographically distinct OSTPs from throughout New York State over a five year period. All sites will start with applying their standard of care and at regular intervals (9 months) a group of practices (four) will switch in random order to the telemedicine intervention. In the telemedicine arm, two-way video-teleconferencing will link patients in the OSTP to the liver specialist located offsite. HCV evaluation, treatment prescription, and treatment appointments will all be conducted via telemedicine. Patients will be treated with interferon-free HCV treatment regimens that include highly effective direct-acting antivirals (DAAs). In the control arm, patients will be referred to an offsite HCV specialist. The primary outcome will be assessed at week 12 post-treatment to establish sustained virologic response (SVR). Patients will subsequently be followed for 24 months post treatment completion to assess for reinfection. The study case manager will interact with the patients as well as their physicians to assess compliance with the referral and to follow the patient's treatment progress. We aim to recruit a total of 624 patients in the study, with 52 patients recruited per clinic, 13 in each study period.

Project Timeframe: September 2016 to September 2021
Participants: 12 Methadone Treatment Practices and Community Health Centers, 624 patients
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