

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

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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
 - PWSUD are difficult to engage in clinical care because they feel stigmatized and encounter discrimination in conventional healthcare settings
 - Referral to an HCV specialist is the current standard HCV management strategy for PWSUD but it is not effective
- Integration of HCV treatment into opioid treatment programs (OTPs) has been shown to be effective for PWSUD
 - OTPs have their own cultures and communication networks where PWSUD feel comfortable and accepted
- Telemedicine removes geographic barriers from accessing high quality, cost-effective healthcare and permits providers to treat patients statewide from the same location
- 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 OTPs

Study Aims

Primary Aim

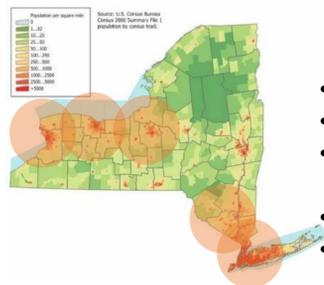
To compare the effectiveness of patient-centered delivery of HCV care through telemedicine (Experimental – EXP) versus referral to an offsite liver or infectious diseases specialist (Control – CON), which is the current standard of care.

Secondary Aims

- To compare:
 - Treatment initiation and completion rates between study arms
 - Patient satisfaction with healthcare delivery between study arms
 - Patient adherence between study arms
- To evaluate patient satisfaction with the telemedicine-based treatment approach

Methods

- A non-blinded, stepped-wedge cluster randomized controlled trial (SW-cRCT) with two arms:
 - Telemedicine (EXP)
 - Usual care (CON).
- Conducted in twelve OTPs in New York State over a five-year period
 - 6 upstate sites, 6 in New York City
 - 2 in Buffalo 5 in Brooklyn
 - 2 in Rochester 1 in Manhattan
 - 1 in Syracuse
 - 1 in Newburgh
- Provides coverage to almost all metropolitan areas in NYS
- Upstate sites include both urban and rural patient population
- We aim to recruit a total of 624 patients, 52 patients per OTP



- The study was initiated at all sites with the usual care arm
- 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
 - HCV medications are co-administered with methadone through directly observed therapy
- 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
- Patient satisfaction with treatment approach and provider is assessed after initial visit with the provider and after completion of HCV treatment
- Case managers were assigned to each site as the primary point of contact and support for study participants
- Patient Advisory Committee (PAC), composed of patient representatives from all sites, meets quarterly to discuss study-related issues, provide patients' perspective and guidance

Group (4 clinics each)	Period (9 months each)			
	Period 1 March 2017	Period 2 December 2017	Period 3 September 2018	Period 4 June 2019
Group 1	Referral	Referral	Referral	Telemedicine
Group 2	Referral	Referral	Telemedicine	Telemedicine
Group 3	Referral	Telemedicine	Telemedicine	Telemedicine

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
- Since June, 2019, all OTPs are recruiting patients in the telemedicine study arm
- As of January 31st, 2020, 587 subjects have been enrolled in the study
 - Usual care (n = 312)
 - Telemedicine (n = 275)

Characteristics	Patients (N = 587)
Age (years)	47.7±12.89
Female sex	39.01%
Race	
Caucasian	49.23%
African American	20.78%
Ethnicity	
Hispanic	30.15%

- Engagement of both OTP staff and patients was crucial for successful implementation of telemedicine-based HCV care model in OTPs
 - Training and educational events as well as continued staff appreciation facilitated their engagement and support for the study
 - Study-provided case management was crucial for patient engagement, successful recruitment and retention
- PAC members expressed strong desire to participate in research beyond PAC meetings (e.g. conferences, facilitation of patient recruitment etc.)

Conclusions

- HCV care via telemedicine is a feasible model for PWSUD
- 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 SW-cRCTs, 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

