Patient-Centered Hepatitis C Treatment via Telemedicine for Individuals on Opiate Substitution Therapy
Marija Zeremski, PhD1; Andrew H. Talal, MD, MPH2; Ponni Perumalswami, MD3; Lawrence S. Brown, Jr., MD, MPH, FASAM4; Marc T. Swogger, PhD5; Marianthi Markatou, PhD2; Jonathan N. Tobin, PhD1,6
1Clinical Directors Network, Inc. (CDN); 2University at Buffalo, State University of New York; 3Icahn School of Medicine at Mount Sinai; 4START Treatment & Recovery Centers; 5University of Rochester Medical Center; 6The Rockefeller University

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
  - 1 in Rochester
  - 5 in Brooklyn
  - 1 in Syracuse
  - 1 in Newburgh
- Provides coverage to almost all metropolitan areas in NYS.
- Upstate sites include both urban and rural patient populations.
- We aim to recruit a total of 624 patients, 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.
- 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%           |

Conclusions
- 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.).
- 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.