



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

Funded by Patient Centered Outcomes Research Institute (PCORI)

PATIENT FLOW DIAGRAM

(N=52 at each site; for the whole study N=624)

TELEMEDICINE ARM

Eligibility

INCLUSION

- Positive HCV Ab test
- Ability/willingness to provide written consent
- Minimum of 18 years of age
- At least 6 months enrolment in the MMTP
- Likely to be adherent to therapeutic regimen
- Covered by medical insurance

EXCLUSION

- Mental instability or incompetence
- Active HCV treatment elsewhere
- HIV positive - not on stable antiviral Tx

Recruitment

Site Liaison will:

- Identify eligible patients using EMR or paper charts
- Approach eligible patients, provide HCV brochure, briefly describe the study
- Introduce patient to Case Manager who should schedule the Screening Appointment

At the Screening Appointment, Case Managers will:

- Discuss the study
- Re-evaluate inclusion and exclusion criteria and consent eligible patients
- Obtain blood for HCV RNA and other blood tests
- Obtain patient's phone number for future communications
- Schedule study Visit 1 (in 1-2 weeks: give enough time to obtain HCV RNA test result)
- Compensate the patient \$25 for signing the consent and providing blood for testing
- Create new patient's profile at MyOwnMed portal

Initial Evaluation – Visit 1 (performed in 2 steps)

Patients with negative HCV RNA test will be excluded from the study

During the first step of the Visit 1 Case Managers will:

- Discuss HCV RNA test result
- Re-confirm patient's eligibility based on inclusion and exclusion criteria
- Conduct questionnaire assessments: Sociodemographic Survey, Modified Mini Screen (MMS), Drug Abuse Screening Test 10 (DAST-10), and NIDA Quick Screen
- Compensate the patient \$60 for completing all assessments

The second step of the Visit 2 will be conducted via telemedicine by on-site clinician, off-site HCV specialist and Case Manager. They will:

- Introduce patient to the clinician conducting telemedicine-based appointments
- Briefly educate patient about principles of telemedicine (address potential concerns, including privacy and confidentiality during the visit, and privacy of medical data)
- Inform patient about specifics of HCV treatment
- Obtain blood for Fibrosure test and 3 additional tubes from patients who consented to participation in sample repository
- Schedule Visit 2 approximately 2 weeks after the Visit 1

HCV Treatment – Visits 2-6

All visits will be conducted via telemedicine by on-site clinician, off-site HCV specialist and Case Manager

Visit 2

- Patients' eligibility will be re-confirmed based on inclusion and exclusion criteria
- If the patient meets treatment eligibility criteria medication will be prescribed/ordered
- Patient will be instructed about the medication regimen and side effects
 - The importance of adherence to the HCV treatment regimen will be emphasized
- Case Manager will conduct Patient Satisfaction Questionnaire
- Visit 3 should be scheduled approximately 2 weeks after the Visit 2

Visit 3 – Treatment Initiation

- Patients' eligibility will be re-confirmed based on inclusion and exclusion criteria
- HCV treatment will be initiated - medication will be dispensed with Methadone (DOT)
- Visit 4 will be scheduled approximately 2 weeks after the visit 3

Visits 4 – Treatment week 2

Visit 5 – Treatment week 6

Visit 6 – End of Treatment

- Patients' eligibility will be re-confirmed based on inclusion and exclusion criteria
- Medication adherence verified from patient's chart
- Blood will be obtained for HCV RNA test to monitor changes in the viral load and to determine end of treatment response

Post-treatment Follow-up – Visits 7-12

All visits will be conducted by on-site clinician and Case Manager

Visit 7 – Post-treatment week 4

Visit 8 – Post-treatment week 12

Visits 9-12 – Post-treatments months 6, 12, 18 and 24

- Inclusion/Exclusion criteria will be reviewed
- Toxicology screen will be completed by case manager, latest results obtained from patient chart will be entered into MyOwnMed Portal
- Blood will be obtained for HCV RNA test to determine sustained virologic response (SVR) and potential relapse or re-infection

Visit 8 – Post-treatment week 12

- DAST and Patient Satisfaction Questionnaire will be administered by the Case Manager and entered into MyOwnMed Portal
- Compensate the patient \$30 for completing the assessments