



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)

REFERRAL ARM

Eligibility

INCLUSION	EXCLUSION
Positive HCV Ab test	Mental instability or incompetence
Ability/willingness to provide written consent	Active HCV treatment elsewhere
Minimum of 18 years of age	HIV positive - not on stable antiviral Tx
At least 6 months enrolment in the MMTP	
Likely to be adherent to therapeutic regimen	
Covered by medical insurance	

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
 - Consent 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

- Patients with negative HCV RNA test will be excluded from the study**
- During the Visit 1 Case managers will:**
- Discuss HCV RNA test and treatment options
 - Re-confirm patient’s eligibility based on inclusion/exclusion criteria
 - Provide the referral to an off-site liver specialist for HCV evaluation and treatment
 - Confirm the permission to follow up with the patient and patient’s provider(s)
 - 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
 - Obtain 3 tubes of blood from patients who consented to participation in sample repository
 - Enter data into MyOwnMed portal
 - Schedule Visit 2 approximately 2 weeks after the Visit 1

Pre-treatment Evaluations and HCV Treatment – Visits 2-5

- All Visits will be conducted by the Case Manager via phone or in person (patient's preference)
- Visits should be approximately one month apart
- **Visit 2:** Conduct Patient Satisfaction Questionnaire and compensate the patient \$15
- **All visits (2-5):**
 - Communicate with the patient to determine if (s)he complied with the referral, whether (s)he initiated HCV treatment, and enquire about medication adherence
 - After the Visit 3, do **not** communicate monthly with patients who did not comply with the referral by the Visit 3 (for those patients the following visit will be Visit 6)
 - Communicate with the off-site specialist/PCP to enquire about treatment initiation, treatment adherence and outcome
- Enter all data into MyOwnMed portal
- Patients who did not comply with the referral for 6 months will be considered treatment failures

Post-treatment Follow-up – Visits 6-11

- All Visits will be conducted by the Case Manager via phone or in person (patient's preference)
- Timing of Visits 6-11 for patients who were HCV treated by an off-site specialist:
 - Visit 6: 4 weeks post-treatment
 - Visit 7: 12 weeks post-treatment
 - Visit 8-11: 6, 12, 18, and 24 months post-treatment
- For patients who did not comply with the referral, timing of Visits 6-11 will be determined based on the referral date (“end of treatment” date - approximately 6 months after the referral)
- At Visits 6-11 blood will be obtained for HCV RNA tests
 - **Visits 6 and 7:** For patients who were treated by an off-site specialist blood will not be drawn if HCV RNA test result could be obtained
 - **Visits 8-11:** Blood will be obtained for HCV RNA test only for patients who consented to participation in sample repository
- At **Visit 7** Case Manager will conduct DAST-10 and Patient Satisfaction Questionnaire and compensate the patient \$30 for completing assessments
 - Patient Satisfaction Questionnaire will be conducted only if patient was HCV treated
- At **Visit 7** Case Manager will discuss with patients who resolved HCV infection healthy ways to remain virus free
- All data and blood test results obtained at these visits will be entered in the study portal