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

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