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

<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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<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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<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 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 1 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
HCV Treatment – Visits 2-6

All visits, except for visit 3, should 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)

Visits 4 – Treatment week 2 (on-site clinician PRN)

Visit 5 – Treatment week 6 (on-site clinician and HCV specialist PRN)

Visit 6 – End of Treatment (on-site clinician and HCV specialist PRN)
- 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 (at visit 6)

Post-treatment Follow-up – Visits 7-12

Visits should be conducted by Case Manager and on-site clinician (PRN)

Visit 7 – Post-treatment week 4
- Patients’ eligibility will be re-confirmed based on inclusion and exclusion criteria
- Blood will be obtained for HCV RNA test to determine potential relapse

Visit 8 – Post-treatment week 12 (Telemedicine visit with off-site HCV specialist)
- Patients’ eligibility will be re-confirmed based on inclusion and exclusion criteria
- Blood will be obtained for HCV RNA test to determine sustained virologic response (SVR)
- 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

Visits 9-12 – Post-treatments months 6, 12, 18 and 24
- Inclusion/Exclusion criteria will be reviewed
- Blood will be obtained for HCV RNA test to determine potential re-infection
- Toxicology screen will be completed by case manager, latest results obtained from patient chart will be entered into MyOwnMed Portal