Patient-Centered Hepatitis C Virus (HCV) Care Via Telemedicine for Individuals on Opiate Agonist Treatment

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Clinical Directors Network, Inc.
Training Overview

• Brief Hepatitis C Virus (HCV) overview
• Introduction to the study
• Study procedures in the Referral Arm
• MyOwnMed portal
HCV Overview

- Virus discovered in 1989
- Most common chronic blood borne infection in US
  - Injection drug use is the principle risk factor for HCV infection
  - HCV prevalence among PWID between 30-70%
- May spontaneously resolve after acute infection, but most often becomes a chronic disease that can lead to cirrhosis and liver cancer
- No vaccine available
- Treatment may lead to viral eradication = CURE
Transmission Via Contact with Contaminated Blood

**Needles and Syringes:**

- Fixed
- Detachable

**Preparation Equipment:**

- Filters
- Cookers
- Water
- Surfaces

Zibbell J, CDC, Presented as part of Hepatitis C Prevention Opportunities Among PWID, April 28, 2015.
HCV-contaminated solution needs to be heated for almost **90 seconds** and reach temperatures of **144°F** for the virus to be at undetectable levels.

Likelihood of HCV Infection: Duration of IDU

Is Positive Anti-HCV Test Result a Diagnosis for Chronic HCV Infection?

• A positive anti-HCV test result is not a diagnosis for chronic HCV infection

• Some individuals become infected with HCV and then spontaneously clear the infection

• Approximately 15%-25% of individuals clear the virus without treatment and do not develop chronic infection
  – The reasons for this are not well known

Chronic HCV Infection May Lead to Chronic Liver Disease and Liver Cancer

~75% of patients infected with HCV will develop a chronic infection and approximately 65% of those are expected to develop chronic liver disease.
HCV Can Now Be Cured in Most Patients

• Unlike HIV and HBV infection, HCV infection is a curable disease

• What does cure mean?
  – Undetectable HCV RNA 12 weeks after completion of antiviral therapy for chronic HCV infection

• Recently approved highly effective interferon-free regimens can cure HCV in more than 90% of patients
  – Near universal efficacy
  – Shortened duration of therapy (8 to 12 weeks)
  – Adverse events have minimal impact on patient’s quality of life
Current Status of HCV in the US:
Screening and Linkage to Care Rates Remain Low
(Even Lower for PWID)

US population with chronic HCV infection
3.2 million

HCV detected
1.6 million (50%)

Referred to care
1.0 – 1.2 million (32%-38%)

HCV RNA test
630,000 – 750,000 (20-23%)

Liver biopsy
380,000 – 560,000 (12%-18%)

Treated
220,000 – 360,000 (7-11%)

Successfully treated
170,000 – 200,000 (5-6%)

### Barriers to HCV Treatment in People Who Inject Drugs (PWID)

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**New models are needed for the successful management and treatment of HCV among former and current drug users**
HCV Treatment in PWID

- HCV treatment outcomes in PWID are improved among those treated for opioid addiction
  - Co-localization of HCV treatment at opioid agonist treatment venues have been shown to be effective
- Significant lack of HCV counseling and treatment on-site substance abuse treatment programs
- Telemedicine offers opportunity to remotely link patients with physicians geographically separated
  - Telemedicine can bring HCV treatment to opioid agonist treatment programs
STUDY OVERVIEW
Telemedicine-Based HCV Care for Individuals on Opiate Agonist Treatment

• Study funded by Patient-Centered Outcomes Research Institute (PCORI)

• Four partnering institutions:
  – University at Buffalo
  – Clinical Directors Network, Inc.
  – START Treatment & Recovery Centers
  – Mount Sinai Beth Israel

• Study will be conducted in 12 Methadone Maintenance Treatment Programs (MMTPs) in New York State
  – 624 patients will be recruited: 52 patients per MMTP

• Project timeframe: September 2016 to September 2021
  – Patient recruitment started in March, 2017
## Participating Sites

<table>
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<th>Name</th>
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<tr>
<td>Pathways - Sisters of Charity</td>
<td>Buffalo</td>
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<tr>
<td>Pathways</td>
<td>Rochester</td>
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<tr>
<td>University of Rochester-Strong Recovery</td>
<td>Rochester</td>
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<tr>
<td>START - Fort Greene</td>
<td>Brooklyn</td>
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<td>START - East New York</td>
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<td>START - Bushwick</td>
<td>Brooklyn</td>
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<td>Dole Clinic</td>
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<tr>
<td>Gouverneur Clinic</td>
<td>Manhattan</td>
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<tr>
<td>Cumberland</td>
<td>Brooklyn</td>
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<tr>
<td>Cornerstone Family Healthcare</td>
<td>Newburgh</td>
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<tr>
<td>Crouse Health Hospital</td>
<td>Syracuse</td>
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Site Key Personnel

- **Project Liaison** - Acting as point of contact for implementation of study procedures
- **Case Manager** – Patient recruitment, assessments, data collection and management, communication with patients, appointment scheduling
- **Clinician** - MD or non-physician clinician responsible for coordinating and conducting telemedicine visits
- **IT Liaison** – Responsible for Information technology issues related to the study and data collection
Study portal

- All data collected in the study will be stored in the data management portal developed by MyOwnMed
- This training will include tutorial on MyOwnMed portal
Telemedicine-Based HCV Care for Individuals on Opiate Agonist Treatment

• Hypothesis:
  – MMTP-integrated telemedicine-based HCV treatment of PWID will be more effective compared to referral to an offsite specialist

• Primary objective of the study:
  – To compare the MMTP-integrated telemedicine-based approach for HCV treatment of PWID with the referral to an offsite specialist
Study Design

- Non-blinded, stepped-wedge cluster randomized controlled trial with two arms:
  - Telemedicine Arm: Onsite HCV management through telemedicine
  - Referral Arm: HCV management through standard of care, referral to an offsite liver specialist
  - Randomization on the MMTP level with all sites starting with the Referral Arm
Study Design

• At regular 9-month intervals one group of clinics will be randomized to cross over from the Referral Arm to the Telemedicine Arm

<table>
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<th>Group (4 MMTPs each)</th>
<th>Period (9 months each)</th>
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<tr>
<td>Group 1</td>
<td>Ref        Ref        Ref  Tel</td>
</tr>
<tr>
<td>Group 2</td>
<td>Ref        Ref        Tel  Tel</td>
</tr>
<tr>
<td>Group 3</td>
<td>Ref        Tel        Tel  Tel</td>
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• Recruitment must be completed by the 7th month
• The remaining 2 months serve as a wash-out period during which no recruitment activities are scheduled and clinics prepare to switch to the Telemedicine Arm
Patient Recruitment

• Sites will provide a list of HCV RNA or HCV Ab positive patients - potentially eligible
• Recruitment goals: 52 patients per site; 13 patients per each study period
• Project liaison will approach those patients and
  – Provide SAMHSA brochure
  – Briefly describe the study
  – Introduce patient to Case Manager
  – Provide the consent form, as per patient’s request
• If a patient expresses interest in the study, Case manager will schedule the Screening Appointment
PROCEDURES IN THE REFERRAL ARM
Screening Appointment

• Screening Appointment will be conducted by the Case Manager, with each patient individually.

• At this appointment the Case Manager will:
  – Describe study in details
  – Review eligibility based on inclusion/exclusion criteria
  – Consent the patient
  – Obtain blood for HCV RNA test and other blood tests
  – Obtain patient’s phone number for future communications
  – Schedule study Visit 1 (give enough time to obtain HCV RNA test results)
  – Give the patient $25 stipend for the blood draw and the study receipt
Screening Appointment

• Inclusion Criteria:
  – Positive HCV antibody test
  – Ability and willingness to provide written consent form
  – Minimum of 18 years of age
  – Minimum of 6-month enrollment in the MMTP
  – Likely to be adherent to HCV care management plan
    • To be determined based on compliance with therapeutic methadone regimen defined as three consecutive missed appointments and/or other indicators of compliance
  – Covered by medical insurance

• Exclusion Criteria:
  – Mental instability or incompetence
  – Active treatment for HCV elsewhere
  – HIV positive - not on stable antiviral therapy
At the screening appointment we will order the following blood tests:

- HCV RNA
- HCV genotype
- HBsAg and HBs Ab
- Prothrombin time (PT) and International Normalized Ratio (INR)
- Comprehensive Metabolic Panel (CMP)
- Complete Blood Count (CBC)

Consent to obtain additional 3 tubes of blood for sample repository at University at Buffalo
- Blood will be obtained at study Visit 1
- This blood will be used to study the virus in more details
Screening Appointment

• Case Manager should create new patient’s profile in MyOwnMed data management portal
  – All data obtained at this appointment (and all other study appointments) should be entered into the portal
  – The most current toxicology results should be collected from the patient’s clinic chart and entered into the portal

• After the Screening Appointment, the Case Manager should:
  – Obtain HCV RNA test results
  – Contact patients with negative HCV RNA test result to cancel study Visit 1
Subsequent Visits

• After the Screening Appointment, all visits will differ depending upon the arm of the study
• This training will focus on the Referral Arm of the study
• Details about subsequent visits in the Telemedicine Arm will be provided on another training
Visit 1 – Referral Arm

- Initially eligible patients with detectable virus who signed informed consent will be further evaluated.
- Visit 1 should be conducted one to two weeks following the Screening Appointment.
- In the Referral Arm, Visit 1, and all subsequent study visits, will be conducted by the Case Manager.
• During the Evaluation Visit 1, the Case Manager should:
  – Provide again brief description of the study
  – Discuss patient’s positive HCV RNA test and HCV treatment options
  – Re-confirm patient’s eligibility to participate in the study based on inclusion/exclusion criteria
  – Re-evaluate medication adherence based on compliance with therapeutic methadone regimen (three consecutive missed appointments)
During the Visit 1, the Case Manager should:

- Provide the referral to an off-site liver specialist for HCV evaluation and treatment according to current clinic policy
- Confirm the permission for study personnel to follow up with the patient and patient’s provider(s) in order to assess whether patient complied with the referral
- Explain the reimbursement schedule: $15 for each assessment, for a total of $60 on Visit 1
- Conduct 4 questionnaire assessments
- If the patient consented to participation in sample repository, 3 tubes of blood will be drawn
Visit 1 – Study Questionnaires

- **Sociodemographic Survey**
  - 18 questions

- **Modified Mini Screen**
  - Measures mental illness
  - 22 questions

- **NIDA Quick Screen**
  - Measures drug, alcohol and tobacco use
  - 4 questions

- **Drug Abuse Screening Test (DAST-10)**
  - Measures drug use/abuse
  - 10 questions
Visit 1 – Study Questionnaires

- Case manager must ensure that confidentiality is not violated in the collection of information
- Questionnaire assessments should be conducted as interviews
  - All questions should be read and answers recorded by the case manager
  - Answers should be directly entered to the study portal
Guidelines for conducting interviews:

– The questions should be read verbatim (not improvised)
– The interviewer should provide neither verbal nor non-verbal responses that can influence the patient's responses
– Never add to or subtract words from a question
– Never change the sequence of questions or try to ask questions from memory
– Do not rush the patient
– Never patronize patients who do not speak English fluently
– Never let another person answer for the patient
Visit 2

- Visit 2 should be scheduled approximately 2 weeks after the Visit 1
  - See schedule of events (available at Manual of Operations)
- Patient’s eligibility to participate in the study should be re-confirm (based on inclusion/exclusion criteria)
- Patient Satisfaction Questionnaire (18 questions) should be completed at this visit
  - Patient will be compensated $15 after the assessment
  - Provide study receipt
Visit 2

- At Visit 2 Case Manager should collect the following information:

1. If patient complied with the off-site referral
   - Name of the off-site provider
   - Date and time of the appointment
   - Confirm the information with the off-site provider

2. If any bloodwork was ordered by the off-site provider
   - If yes, request results from the off-site provider

3. If HCV treatment was initiated
   - Ask if patient have taken the medication as prescribed
   - Contact the off-site provider to find out what medication has been prescribed and the length of treatment
Visits 3-5
(Patients who complied with the referral)

• Visits 3, 4, and 5 should be scheduled at one month intervals, one month following the Visit 2
  – See schedule of events (available at Manual of Operations)
• Case Manager will speak to the patient via phone or in person (patient’s preference)
• Case manager should re-confirm patient’s eligibility to participate in the study (inclusion/exclusion criteria)
Visits 3-5
(Patients who complied with the referral)

- At Visits 3, 4, and 5, Case Manager should also collect the following information:
  1. If patient complied with the off-site referral
     - Name of the off-site provider
     - Date and time of the appointment
     - Confirm the information with the off-site provider
  2. If any bloodwork was ordered by the off-site provider
     - If yes, request results from the off-site provider
  3. If HCV treatment was initiated
     - Ask if patient have taken the medication as prescribed
     - Contact the off-site provider to find out what medication has been prescribed and the length of treatment
Visits 3-5
(Patients who did NOT comply with the referral)

- Patients who did not comply with the referral by Visit 3 will not be contacted at Visits 4 and 5
- At Visits 4 and 5 Case Manager will only communicate with the off-site provider to enquire whether patient scheduled the appointment
- Patients who did not comply with the referral for 6 months will be considered treatment failures
Visit 6

- Visit 6 should be conducted 4 weeks after the end of HCV treatment with all patient in the Referral Arm
  - For patients who were treated by an off-site specialist, Case Manager should determine the end of treatment date and schedule Visit 6 accordingly
  - Patients who did not comply with the referral will be scheduled for the Visit 6 approximately five to six months after the referral was issued
Visit 6

- At Visit 6 blood should be obtained for HCV RNA test
  - For patients who were treated by an off-site specialist blood will not be drawn if HCV RNA test result could be obtained from the off-site specialist
  - For other patients HCV RNA test will be ordered
- If the blood draw is not necessary, this visit could be conducted via phone (depending upon patient’s preference)
Visit 7

• Visit 7 should be conducted 12 weeks after the end of HCV treatment
  – For patients who were treated by an off-site specialist, Case Manager should determine the end of treatment date and schedule Visit 7 accordingly
  – Patients who did not comply with the referral will be scheduled for the Visit 7 two months after the Visit 6

• At Visit 7 blood should be obtained for HCV RNA test to determine sustained virological response
  – For patients who were treated by an off-site specialist blood will not be drawn if HCV RNA test result could be obtained
  – For other patients HCV RNA test will be ordered
The following questionnaire assessments should be conducted by Case Manager at Visit 7:

- Drug Abuse Screening Test (DAST-10)
- Patient Satisfaction Questionnaire, but only if patient followed through with the referral

Patient should be compensated $15 per assessment

Case Manager should discuss with patients who resolved HCV infection healthy ways to remain virus free
Follow up visits – Visits 8-11

• For patients who were treated by an off-site specialist, Visits 8-11 should be scheduled 6, 12, 18, and 24 months after the end of treatment
• For patients who were not treated, visits 8-11 should be scheduled relative to visit 7
  – Visit 8: three months after the visit 7
  – Visits 9-11 at 6 months intervals
• At Visits 8-11 blood will be obtained for HCV RNA test
  – Blood from patients who consented to participation in sample repository will be sent to UB
• The most current toxicology results should be collected from the patient’s clinic chart