Building Capacity for Hepatitis C Treatment at Opioid Treatment Programs On-site and via Telemedicine, New York City

October 2020
Disclosures

• Grant Research Support
  • Merck, Gilead, Abbott, AbbVie, Intercept, Genfit, BMS, Eli Lilly & Co

• Committee/Advisor
  • AbbVie, Gilead, Eli Lily & Co., Intercept, Regeneron

• Speaker’s Bureau
  • Chronic Liver Disease Foundation
Hepatitis C in New York City

• Hepatitis C is a blood-born disease that affects the liver; if left untreated, 1 in 4 will advance to serious liver disease, cancer and premature death
  • Most frequently acquired through sharing injection drug use supplies

• Approximately 116,000 New York City residents are estimated to be living with hepatitis C, and many more have a history of infection

Hepatitis C in Methadone Maintenance Programs in NYC

• **Almost 30,000 people in methadone maintenance in NYC**, more than half have had hepatitis C

• Methadone maintenance programs with primary care:
  • Well positioned to provide hepatitis C care, adequate staff and treatment reimbursement rates

• Stand alone methadone clinics:
  • Hepatitis C clinical care and treatment rates are lower than medication management
  • Limited clinical provider capacity (time, training) to treat
CDC Hepatitis C Care Cascades — Supplemental Funding
NYC Department of Health (January – August 2020)

• Funds special project to support hepatitis C screening, linkage to care and treatment for people who use drugs

• NYC Health Department partnered with:
  • START Treatment and Recovery Centers – Multi-site methadone treatment program in high burden areas of New York City as identified in a situational analysis
  • Andrew Talal, MD, SUNY Research Foundation – conducted hepatitis C treatment via telemedicine in a New York State-wide telemedicine research project at multiple methadone programs

• Project Goals:
  • Build capacity of START to deliver hepatitis C treatment onsite, via telemedicine and by referral after research project
  • Develop and disseminate a hepatitis C treatment via telemedicine implementation guide
  • Convene a workgroup of clinical, State and City stakeholders to build capacity to deliver hepatitis C telemedicine services New York State-wide
Project Foundation

• NYC Health Department – Data to Care Clinical Practice Facilitation Program
  • Surveillance data – hepatitis C patient lists
  • Electronic health record query tools
  • Training and technical assistance

• Empire Liver Foundation – New York State Network of liver specialists, funded by NYC Council to deliver clinical education
  • Supported NY Hepatitis Telehealth Workgroup start-up and meetings
  • Trained START clinical providers in hepatitis C treatment
  • Supported Peer-to-Peer mentoring on hepatitis C reimbursement issues

• Hep Free NYC – New York City based community coalition
  • Supported NY Hepatitis Telehealth Workgroup recruitment, resource and information dissemination
  • Website, email list, social media, contact management system (PHPC/SalesForce)
Hepatitis C Treatment at Opioid Treatment Programs (OTP), Pilot Studies

Andrew Talal, MD, SUNY Research Foundation
Hepatitis C On-Site Telemedicine Model

- **Patient discomfort with seeing new providers**
- **Provider stigma & lack of knowledge**
- **Travel issues**

**Methadone Program**
- Clinical providers have limited time and capacity at OTPs

**Liver Clinic**

Bring the hepatitis C provider to a familiar and comfortable environment for patients

SUNY RF
The Research Foundation for The State University of New York
HCV Treatment via Telemedicine Integrated into OTP

Patient and OTP provider

OTP patient screened for HCV

HCV +

Telemedicine provider

DAA and methadone dispensing
Pilot Study

• One START clinic
• 45 patients enrolled
• HCV treatment is relatively routine
  - 4 telemedicine visits
  - Outcome assessed by blood test

93% cured of HCV via Telemedicine

95% recommend over in-person referral [1]

<table>
<thead>
<tr>
<th>Visit 1</th>
<th>Visit 2</th>
<th>Visit 3</th>
<th>Visit 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial</td>
<td>Start of</td>
<td>End of</td>
<td>Confirm</td>
</tr>
<tr>
<td>assessment</td>
<td>treatment</td>
<td>treatment</td>
<td>cured</td>
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<tr>
<td>20 min</td>
<td>10 min</td>
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Clinical Infectious Diseases
MAJOR ARTICLE

Integrated, Co-located, Telemedicine-based Treatment Approaches for Hepatitis C Virus Management in Opioid Use Disorder Patients on Methadone

Andrew H. Talal,† Phyllis Andrews,‡ Anthony McLeod,² Yang Chen,‡ Cleovert Sylvester,× Marianthi Markatou,§ and Lawrence S. Brown²

†Division of Gastroenterology, Hepatology, and Nutrition, Department of Medicine, University at Buffalo, State University of New York; ‡OSFCT Treatment and Recovery Centers, Downers, and §Department of Obstetrics, University at Buffalo, State University of New York.

Statewide Telemedicine Network

- Patient-Centered Outcomes Research Institute (PCORI) funded a study to integrate HCV treatment into OTPs via telemedicine
- Project recruitment: March 2017-Feb 2020
  - >600 patients enrolled
- 12 sites across NYS, covering most metropolitan areas (6 upstate, 6 in NYC)
- Telemedicine:
  - Removes geography as obstacle from high-quality, cost-effective healthcare
  - Permits providers to treat patients statewide from the same location
COVID in NYC, 2020

- COVID-19 dramatically changed health care delivery in NYC by March 2020
  - Hospital systems were overwhelmed and there was a strict stay at home order
  - The public was terrified to go to a health care facility
  - Risky drug use likely increased due to stress and social isolation

- In response, a few hepatitis champions rapidly accelerated implementation of telemedicine services for hepatitis C, buprenorphine, and other MAT/MOUD.

- As COVID cases are rising, telemedicine continues to be a critical intervention to support continuity of care.

<table>
<thead>
<tr>
<th>Cases, Hospitalizations and Deaths</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Measure</strong></td>
</tr>
<tr>
<td>Case</td>
</tr>
<tr>
<td>Hospitalizations</td>
</tr>
<tr>
<td>Confirmed deaths*</td>
</tr>
<tr>
<td>Probable deaths</td>
</tr>
<tr>
<td>Cause of death reported as “COVID-19” or equivalent, but no positive laboratory test</td>
</tr>
</tbody>
</table>

Updated: October 9, at 1 p.m.

*Due to data collection differences, the City’s reported total of confirmed deaths for any given day is usually different than the State’s data. For more information, visit our GitHub repository.

Daily Counts

This chart shows the number of confirmed cases by diagnosis date, hospitalizations by admission date and deaths by date of death from COVID-19 on a daily basis since February 29. Due to delays in reporting, which can take as long as a week, recent data are incomplete.

NYC Health Department COVID Data, updated daily
Building Capacity to Treat Hepatitis C at START: Onsite, via Telemedicine, and by Referral

Daanish Shaikh, MD, START Treatment and Recovery
START Hepatitis C Project Support

• 9-month contract period starting January 2020
• START Project team included:
  • CEO
  • Medical Director
  • Associate Director of Funded Projects
  • Case Manager/Hep C Navigator
  • Chief Financial Officer
• Project kick-off meeting and monthly meetings with Health Department
• Internal planning and implementation meetings
START Hepatitis C Project Design

- Identify all patients with a positive hepatitis C test in the EMR system (eCW), develop a registry
- Participate in provider training and patient education
- Develop a hepatitis C treatment workflow
- Develop and implement a case management plan to refer patients to treatment onsite, by referral or via telemedicine
- Link 30 patients to treatment by end of project
START Hepatitis C Data Review

• START electronic health record data review
  • Reviewed hepatitis C screening rates, number of antibody and RNA positive patients
  • Reviewed Health Department surveillance-based patient lists

• Developed a list of hepatitis C RNA positive patients in need of treatment
  • Approximately 360 patients
START Provider Training and Patient Education

- Hep C Clinical Training series for providers (4 CME) – provided by Empire Liver Foundation
  - Hep C Treatment in PWUD Session
  - Hep C Treatment Reimbursement at OTPs: Peer-to-Peer mentoring Session
- Referral to Telemedicine Training for providers – provided by Andy Talal
- Hep C Patient Navigation Training for non-clinical providers (2 hour, online) – Provided by NYC Health Department
- Hep C Basics education session for patients (1 hour) – provided by Hep C Mentor and Support Group
START Hepatitis C Clinical Workflow
Step 1: Patient Selection

- Patient selection
- Identify HCV patients & Check with the insurance: Medicaid/Managed Care/Active Insurance?
- Specialty Pharmacy: Accepting Patient’s insurance?
- Pharmacy repacking in single blister pack?
Step 2: Appointment and Blood test

- **Appointment with patient**
  - Accept or Decline
    - If yes: Schedule for Blood test
      - Blood test: CBC (platelets), CMP (AST/ALT/Bili/Albumin/Cr/GFR), VL, Genotype, Fibrosis, HBV/HAV, HIV
    - If no: Follow up after 3 months
Step 3: Linkage to care

Step 3
Follow up 1 week later for test results + Physical Exam

If decompensated: refer to liver specialist

If not decompensated: refer for counselling & start treatment with DDI

GLE/PIB
3T PO QD w/food: 8 or 12 weeks

SOF/VEZ
1T PO QD w/food: 12 weeks
Step 4: Follow up

**Step 4**

Follow up:
- Blood work every 3rd week
- Appointment with provider to review the blood work every 4th week

**Step 5**

- After treatment follow up every 6 months for 3 years and then yearly
- If Treatment is not successful refer to Liver specialist
# Case Management Planning and Implementation

## Treatment Referral Method Rationale

<table>
<thead>
<tr>
<th>Onsite treatment criteria:</th>
<th>Off-site treatment by referral criteria:</th>
<th>Treatment via telemedicine criteria:</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Patient choice</td>
<td>• Patient choice</td>
<td>• Advanced liver disease</td>
</tr>
<tr>
<td>• Insurance type</td>
<td>• Insurance type</td>
<td></td>
</tr>
</tbody>
</table>

Linkage to treatment is carried out by Anthony McLeod, Case Manager who was crossed trained as Hep C Navigator. Anthony recruits patients, performs blood tests as phlebotomist, and liaises with Specialty Pharmacy.
### START Project Outcomes
(January – August 2020)

<table>
<thead>
<tr>
<th>Project area</th>
<th>Outcome</th>
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<tbody>
<tr>
<td>Identify patients, develop registry</td>
<td>Over 360 HCV RNA+ patient identified (Jan 2019-Mar 2020)</td>
</tr>
<tr>
<td>Develop HCV treatment workflow</td>
<td>Developed, refined and implemented workflow</td>
</tr>
<tr>
<td>Training</td>
<td>• 10 Clinical providers trained</td>
</tr>
<tr>
<td></td>
<td>• 12 Non-clinical providers trained</td>
</tr>
<tr>
<td></td>
<td>• 15 Patients Hep C Basics</td>
</tr>
<tr>
<td>List and develop case management plan for 30 patients</td>
<td>Developed methods to determine if patient should be treated onsite, via telemedicine or by referral</td>
</tr>
<tr>
<td>Link 30 patients to treatment</td>
<td>• 21 treated onsite</td>
</tr>
<tr>
<td></td>
<td>• 6 referred for treatment</td>
</tr>
<tr>
<td></td>
<td>• 1 treated via telemedicine (advanced liver disease)</td>
</tr>
<tr>
<td></td>
<td>• 2 declined</td>
</tr>
</tbody>
</table>
START Hepatitis C Project - Key Findings

General
- Feasible to treat hepatitis C at a standalone methadone clinic
- Hepatitis C treatment reimbursement rates are lower than medication management rates at opioid treatment programs in NYS, disincentivizing treatment. Supplemental (grant) funding is needed to sustain services.
- Role of the Specialty pharmacy
  - Helps with prior authorization process – speed of obtaining medications
  - Coordinates with managed care organization and provider
- Drug-drug interactions

Telemedicine Specific
- Importance of onsite provider at the initial evaluation
- Labs and requirements for prescriptions need special coordination
- NYS no longer requires written consent nor in-person visit prior to starting telemedicine
Hepatitis C Telemedicine Implementation Guide: For Opioid Treatment and Other Substance Use Treatment Programs

Andrew Talal, MD, SUNY Research Foundation
Hepatitis C Telemedicine Implementation Guide Goals

• Document steps an opioid treatment program, or other substance use treatment program (such as SSP), need to take to set up hepatitis C treatment via telemedicine.

• Provide a framework for program planning in key domains.

• Provide existing resources to support implementation.

• Describes the model and potential benefits of telemedicine for substance use organizations, patients, and clinical providers.
Hepatitis C Telemedicine Implementation Guide - Readiness Assessment

• Prompts to assess and improve readiness in the following areas
  • Selecting telemedicine providers
  • Preparing and training staff at substance use facilities
  • Legal, data sharing, and shared case management agreements
  • Privacy and confidentiality
  • Protocols for visits, lab coordination, and medication dispensing
  • Billing and reimbursement
  • Evaluation and quality improvement
Hepatitis C Telemedicine Implementation Guide Outcomes and Next Steps

• Developed guide in collaboration with NY Hepatitis C Telehealth Workgroup members

• Working with NASTAD to make guide available on national technical assistance website

• Seeking opportunities to further develop and refine
  • Additional tools & templates
  • Develop telemedicine provider directory
  • Develop hepatitis C visit templates & workflows
  • Develop cost-effectiveness, adherence, and outcome measures
  • Test in upcoming projects
NY Hep C Telemedicine Workgroup
Andrew Talal, MD, SUNY Research Foundation
New York Hep C Telemedicine Workgroup

• Goals
  • **Short Term:** Identify and disseminate strategies for hepatitis C care via telemedicine
  • **Long Term:** Develop New York Telehealth Network to provide education and best practices for hepatitis B and C care via telemedicine

• Leadership
  • Andrew Talal, MD, Chair
  • Planning committee members: NYC Health Department and Empire Liver Foundation

• Stakeholder sectors involved
  • Providers from across the state
  • Telemedicine associations and champions
  • City, State and Federal agencies (NYS DOH, NYS OASAS, Centers for Medicaid and Medicare Services)
  • Third party payers
  • Pharma/industry representatives
New York Hep C Telemedicine Workgroup Activities

- Monthly one-hour virtual meetings
  - See Meeting Highlights
  - Best practices sharing

- Information, resource and opportunity for dissemination
  - NYS Hep Telehealth Resources page

- Project development
  - Letters to NYS and CMS recommending HCV treatment reimbursement and telemedicine policy changes
  - Study on rapid HCV treatment via telemedicine implementation due to COVID
Select NYS Hep C Telemedicine Workgroup Presentations

• **Rapid Implementation of Telemedicine for Hepatitis Care at St. Barnabas Hospital, NJ.** Su Wang, MD

• **Telemedicine to Increase Access to Buprenorphine and HCV Treatment: Where Do We Go From Here?** NYS Hepatitis C and Drug User Health Conference. Judy Griffin, MD, Anthony Martinez, MD, Dan Schatz, MD and Andrew Talal, MD

• Telehealth Services for HIV/HCV Prevention. NJ Syringe Service Program Harm Reduction Institute. Moya Brown, Nirah Johnson, LCSW.

• Hep C and Buprenorphine Telemedicine Implementation at the Mount Sinai REACH Program. Hep Free NYC Meeting. Katherine Dunham.
Telemedicine Advancements During COVID: Opportunities and Challenges

• Emergency related telemedicine policy changes have:
  • Rapidly increased implementation of telemedicine, more familiar for providers and patients
  • Enabled telemedicine treatment by lifting requirement for in-person visit before telemedicine consultation, written consent, and increased reimbursement rates
  • Decreased patient concerns with security and confidentiality
  • Demonstrated the robustness and utility of telemedicine

• Key barriers and challenges
  • Risk of favorable telemedicine policy reversal after emergency
  • Lack of access to technology for some patients
  • Need for in-person labs and evaluations for hepatitis C
  • Lack of interoperability between telemedicine and EMR systems
  • Challenges with clinical content delivery
New York Hepatitis Telehealth Network – Future Directions

• Continuing monthly NYS Hep C Telemedicine Workgroup meetings

• Seek to establish a state-wide telehealth network focusing on hepatitis C, drug user health, and related issues instead of independent, regional networks.

• Plan to further develop tools, resources and evaluation metrics to develop a national telemedicine standard

• To join contact: Andrew Talal, MD ahtalal@buffalo.edu
Summary

• Hepatitis C treatment can be provided at stand alone opioid treatment programs on-site, by referral, or via-telemedicine.
  • Hepatitis C treatment reimbursement rates to opioid treatment programs should be increased to promote HCV treatment.

• Substance use treatment programs can promote hepatitis C treatment by setting up telemedicine referral systems.
  • Thorough planning and implementation is an in-depth and ongoing process.

• Telemedicine for HCV is a new specialized field and providers must network to share information, resources, opportunities, and best practices to advance their expertise.
Stay connected!

• Empire Liver Foundation Trainings
• NY Hepatitis C Telehealth Workgroup information
• START Treatment and Recovery Centers locations
• Find trainings and request technical assistance: hep@health.nyc.gov

Follow us: @hepfreenyc