AN Implementation Guide

PROBLEM

People who use drugs (PWUD) are at high risk for hepatitis C virus (HCV), a blood born virus that can cause liver damage, cirrhosis, liver cancer, and premature death. HCV can be treated and cured in less than 12 weeks with safe and tolerable medications, which prevents ongoing disease transmission. It is feasible to eliminate HCV via widespread testing and treatment. However, PWUD are often left untreated for a variety of reasons including health care system stigmatization, medication coverage restrictions related to sobriety, lack of patient transportation, patient suspicion of traditional health care settings, low awareness, and lack of prioritizing HCV treatment.

SOLUTION

Historically, HCV treatment was provided by hepatology or gastroenterology specialists, but recently HCV treatment has successfully moved into the primary care setting. Unfortunately, barriers remain to treating HCV in the disproportionately impacted patients who primarily access care in substance use treatment programs (opioid treatment programs, residential or outpatient treatment programs and syringe service programs) either due to poor HCV treatment referral systems, lack of clinical capacity (staff, knowledge, skills, time), or low reimbursement rates for HCV treatment in these settings. As such, treating substance use treatment program participants for HCV via telemedicine is a promising model for increasing HCV treatment rates in PWUD in an effort to expand treatment access for all and support HCV elimination.

PURPOSE

This guide aims to help substance use treatment programs offer HCV treatment via telemedicine to patients enrolled in their facilities, delivered by an off-site HCV clinical provider. This guide primarily targets organizations where PWUD seek care, including opioid treatment programs (OTPs), residential and outpatient substance use treatment programs, and syringe service programs.

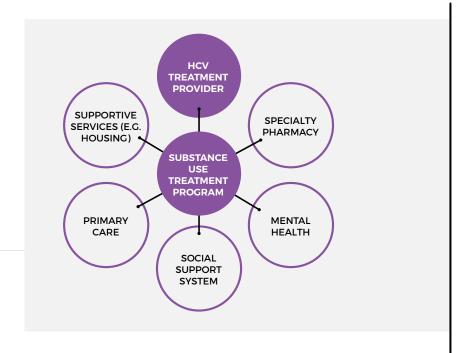
ACKNOWLEDGEMENTS

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The guide builds upon interventions tested in a PCORI-funded research project (IHS-1507-31640) that compared telemedicine to usual care via referral to an off-site provider for HCV among OTPs (https://www.cdnetwork.org/teamc).

MODEL

This guide focuses on the establishment of a telemedicine service linking substance use treatment programs to HCV treatment providers. However, the authors recommend that all components shown below be incorporated into the HCV model of care to optimize patient outcomes.



WHAT ARE THE BENEFITS OF ESTABLISHING HEPATITIS TELEMEDICINE AT SUBSTANCE USE TREATMENT PROGRAMS?

| BENEFITS | SUBSTANCE USE TREATMENT PROGRAM | HCV TREATMENT PROVIDER |
|--|---|---|
| Leverage expertise of substance use treatment and HCV treatment providers | Expertise in addiction medicine and drug user health Patient populations have high rates of HCV Existing linkages with patient's primary care, mental health, and other services Trusted location by PWUD for HCV testing and other services | Expertise in HCV care and treatment, including treatment of advanced liver disease |
| Value assessment | Connecting patients to telemedicine services can "add value" and offer a significant return on investment Increases adherence to HCV medications through co-administration with methadone/buprenorphine. | Increase in number of patients who can be treated Expand reach of clinical expertise Build capacity of clinical providers to treat PWUD |

WHAT ARE THE ROLES OF THE SUBSTANCE USE TREATMENT PROGRAM AND HCV CLINICAL PROVIDER IN PROVIDING HCV TELEMEDICINE?

| | SUBSTANCE USE TREATMENT PROGRAM | HCV TREATMENT PROVIDER |
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| Clinical staff | Clinical provider if available (MD, DO, NP, PA, MA or other medical staff) or support staff (navigators at syringe service programs) assists HCV clinical provider by providing physical exams, coordinating laboratory tests and delivery of results, collecting and sharing patient's insurance information to ensure appropriate referrals. | HCV treatment provider conducts telemedicine verbal assessment with patient, orders and reviews labs, collects clinical information and enters it into electronic health record to track patient outcomes, schedules follow-up appointments, provides or refers patient to other specialty care as needed. |
| Labs | Obtains or confirms laboratory orders. Accompanies patient to local laboratory for onsite phlebotomy services. Provides support for transportation, interpretation, and other services as needed. | Identifies appropriate local laboratory that provides walk-in phlebotomy services, Confirms that location has received appropriate blood sample. Reviews laboratory results. |
| Medication prescription/ dispensing | Physically assists patients in obtaining medication. Provides adherence support. Administer HCV medications as directly observed therapy or stores medications as appropriate. | Selects and prescribes appropriate HCV medications. Obtains the medication for the patient in consultation with a specialty pharmacy. |

Organizational Assessment of HCV Telemedicine Readiness

The following assessment is intended to support substance use treatment programs to identify gaps in readiness for telemedicine implementation at their facilities. The assessment is divided into two sections: (1) readiness for implementation of the "hub and spoke" model of hepatitis care and treatment; and (2) readiness for telemedicine services.

In addition to the resources listed in this guide, readers can find resources at www.hepfree.nyc/ny-hep-telehealth-resources.

READINESS ASSESSEMENT: IMPLEMENTATION OF HCV TREATMENT VIA TELEMEDICINE

| ASSESSMENT QUESTION | IF NO, USE THESE TIPS AND RESOURCES TO HELP YOU |
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| Have you identified one or more HCV clinical providers who are willing and able to deliver HCV treatment via telemedicine services for your program participants? | Tips: |
| | Set up an initial call or meeting to discuss collaboration. |
| | Review the details of your patient population payer mix, characteristics, and needs. |
| | Openly discuss any special concerns your patients have about ideal provider characteristics, expertise and ability to provide respectful quality care – e.g.: gender, sexual orientation, current or past drug or alcohol use, history of incarceration, type of work, housing status, access to technology, other health conditions (HIV, diabetes, mental health), or other issues of concern. |
| DEFINING ROLES AND RESPONSIBILITIES | |
| Have you defined the role of your | Consider who will take responsibility for the following: |
| staff in supporting HCV telemedicine before, during, and after a patient's telemedicine visit? | Method and frequency to identify and monitor lists of HCV patients who need treatment. |
| teleffiedicine visit: | 2. Expectations around HCV patient health education and treatment readiness and preference assessment (onsite, via referral, or via telemedicine). |
| | 3. Assessment of patient access to technology to participate in telemedicine. |
| | 4. Introduction to HCV treatment provider, scheduling, and supporting visits and follow up. |
| | 5. Case note/visit documentation and billing (if needed). |
| | 6. Coordination of labs and in-person evaluations. |
| | 7. Expectations after treatment (support liver health education, reinfection prevention, and liver cancer surveillance for cirrhotic patients). |

| Have you established a case conference schedule with the HCV treatment provider to review patient cases? | Tip: Establish a method for case conferences, frequency, required documentation, and plan to address urgent concerns. |
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| DATA SHARING | |
| Do you have a HIPAA-compliant protocol for | HIPAA Guidance Materials (HHS) |
| bilaterally sharing patient data with the HCV treating provider? | HIPAA Disclosures of Emergency Preparedness: Decision Tool (HHS) |
| | Tip: Agree on basic minimum information needed. |
| Have you defined the patient data that needs to be shared between your program and your HCV treatment provider (e.g. patient demographics and medical history, vital signs, lab results, medications, | Uses and Disclosures for Treatment, Payment, and Health Care Operations (HHS) |
| and patient case summary)? | Tips: |
| | Develop a plan for how each patient data type will be shared between sites, including timeframe for completion after each visit. |
| | You will need visit schedule, lab and evaluation instructions, treatment start date and medication details if assisting with obtaining medications, treatment end date, and date of sustained virological response. |
| LEGAL AGREEMENTS | |
| Do you have a legal agreement with external clinical providers that supports referral for telemedicine services and data sharing that would apply to HCV treatment via telemedicine? If not, do you need a legal agreement or memorandum of understanding? | Tip: Seek advice from Legal Counsel. |
| Are there other providers that you can link with that can support hepatitis treatment initiation/completion? (e.g. buprenorphine treatment via telemedicine, mental health, supportive services, etc.) | Tip: Define your collaborative care team. |

IMPLEMENTING TELEMEDICINE SERVICE WORFLOWS

All facets of the substance use treatment program and HCV treatment provider workflows considered during an in-person visit must be also addressed when establishing a workflow for a telemedicine visit. Providers should take steps to address potential barriers patients may face, such as their ability to access prescribed medications and their ability to access and use the telemedicine platform. Ensuring patient confidentiality and data security should be front and center of any telemedicine process.

| ASSESSMENT QUESTION | IF NO, USE THESE TIPS AND RESOURCES TO HELP YOU | |
|--|---|--|
| Have you established telemedicine services for any health condition at your program? If yes, can you use this | Quick Start Guide to Telehealth (Northwest Regional Telehealth Resource Center, March 2020) | |
| infrastructure to support HCV treatment via telemedicine? What modifications will need to be made? | Getting a New Workflow and Process Started During COVID-19 Pandemic (Adirondack Health Institute, April 2020) | |
| | What Do You Need To Start A Telehealth Program? (Adirondack Health Institute, June 2020) | |
| | HHS Telemedicine Hack Curriculum | |
| REGULATIONS AND BILLING | | |
| Do I know the telehealth regulations and waivers in my state? | Current State Laws and Reimbursement Policies (Center for Connected Health Policy) | |
| Your HCV provider needs to meet State requirements to be able to provide this service at the present time. | Telemedicine Definitions by NYS Agency (Adirondack Health Institute, June 2020) Telehealth During the Public Health Emergency: Billing and Coding Guidance (NYC REACH, May 2020) | |
| Do I know the telehealth provider licensure requirements in | | |
| my state? | CMS Telehealth Guidance: NY Medicaid EHR Incentive Program (NYC PEACLE Tyle 2020) | |
| Do I know the telemedicine policies for the major third party payers for HCV patients I plan to refer at my facility (e.g. | (NYC REACH, July 2020) | |
| telemedicine visit coverage, reimbursements, patient copays)? | Tip: Seek advice from Legal Counsel. | |
| INFORMATION TECHNOLOGY | | |
| Who to contact at patient telemedicine location to provide IT | Telehealth Vendor Resource Guide (Adirondack Health Institute) | |
| support? | Getting a New Workflow and Process Started During COVID-19 | |
| Do I know what type of equipment will provide an optimal telemedicine experience? | Pandemic (Adirondack Health Institute, April 2020) | |
| Does my organization have sufficient broadband for telemedicine encounter conduct without interruption? | | |

| PRIVACY AND CONFIDENTIALITY | |
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| Does your site have a dedicated space for telemedicine encounters that ensures privacy (e.g. soundproof, no visibility from outside the room)? | Center for Excellence for Protected Health Information Resource Center (CAI) |
| For patients taking telemedicine visits at home or at another facility, do they have the support they need to ensure a private visit (e.g. secure internet access, spaces private from household members)? | Tips:Avoid using administrative offices for telemedicine encounters.Use exam rooms. |
| PATIENT WORKFLOW | |
| Do you have a telemedicine pre-visit protocol (e.g. appointment confirmation/reminder/cancelations, obtaining and documenting patient consent)? | Strategies for Provision of Telemedicine Services for HIV, STIs, HCV and Drug User Health in NYS During the COVID-19 Pandemic (Clinical Education Initiative) |
| Do you have the processes for the following in place? Appointment reminders Appointment rescheduling Blocked times for unscheduled telehealth visits Policies for unscheduled telehealth visits | Tips: When developing protocols, define roles for both the substance use treatment program and HCV treatment provider in each component, e.g. appointment reminders, lab report follow-up, insurance coverage issues, etc., and develop methods to communicate these to patients. |
| Do you have a telemedicine visit protocol? | |
| Do you have a visit close-out protocol (e.g. process for ordering bloodwork, scheduling next appointments)? | |
| Are you able to provide language interpretation during telemedicine encounters (e.g. three-way call with professional interpreter, on-site staff member | Telehealth Strategies and Resources for Serving Patients with Limited English Proficiency (HITEQ, June 2020) |
| that can serve as interpreter)? | Tip: Assess patients for interpretation needs when the appointment is scheduled. |
| Do you know how blood testing will be performed? | Large commercial diagnostic labs may have online portals to order tests; e.g. LabCorp Telemedicine toolkit |
| | Mobile phlebotomy services are available in many areas of NYS and may be more acceptable for patients who lack transportation or have other concerns about physically entering a medical office or hospital. |
| | · Some health plans may have smart electronic referrals to clinical laboratories. |

| Do you have a protocol for medication prescriptions, delivery, and dispensing? | Discuss options with HCV treating provider and specialty pharmacy as needed. |
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| | Medications can generally be mailed to anywhere an individual lives or receives services. |
| STAFF & TRAINING | |
| Does your program have a telehealth implementation team or staff dedicated to managing relevant requirements, e.g. billing, technology? | Tip: Suggested staff members to engage in the implementation process are providers, case managers, administrative and IT staff including billing, scheduling, and administration. |
| Do you have a training/education plan for all users of the platform, e.g. providers, | Develop a training on the new HCV treatment via telemedicine program and deliver to involved staff. |
| administrative staff, patients? | Share details about the rationale for the program, roles and responsibilities, policies and procedures, monitoring methods, and performance expectations. |
| | Provide refresher training as new information or systems develop. |
| | Provide a method to receive staff feedback on implementation challenges and successes. |
| QA/EVALUATION | |
| Do you have a plan for testing the telemedicine service protocol prior to implementation? | Select staff members who will be involved in the process and use different scenarios to test and adjust the referral process. |
| Do you have a method/metrics to assess effectiveness of your hepatitis telemedicine service as it relates to patient experience of care, improved health, or reduced costs? | Tip: The effectiveness can be judged not only from the standpoint of value, but also from the patient-centeredness of the telemedicine evaluation. |