Improving Health Outcomes
Moving Patients Along the HIV Care Continuum and Beyond
JUNE 2017

INTERVENTION OVERVIEW & REPLICATION TIPS

Hepatitis Treatment Expansion Initiative
Washington University School of Medicine (MO)

This intervention document is part of a training manual, “Improving Health Outcomes: Moving Patients Along the HIV Care Continuum and Beyond” and is published by the Special Projects of National Significance (SPNS), under the HIV/AIDS Bureau (HAB) of the Health and Human Service’s (HHS), Health Resources and Services Administration (HRSA).

The full manual highlights 10 interventions along the HIV Care Continuum. Individual intervention chapters as well as the full manual are available.
n the U.S., hepatitis C virus (HCV) is the most common blood-borne infection. It affects over 3.5 million people. According to Centers for Disease Control and Prevention (CDC), cases of new acute HCV infections increased by 250% from 2010–2014. The CDC has determined that this increase is linked to the ongoing opioid abuse epidemic in the United States.

HCV is often called the “silent killer” because it slowly damages the liver over many years, without noticeable symptoms. An estimated 75–85% of acute HCV infections become chronic, and approximately 75% of individuals with chronic HCV are unaware of their infection.

HCV is a common and serious coinfection among HIV-positive persons. In the U.S., an estimated 25% of all people with HIV are coinfected with HCV. HIV and HCV have overlapping transmission routes. Coinfection rates are substantially higher among African Americans, prisoners, homeless populations, “baby boomers,” and current and former injection drug users. In urban areas in the U.S., an estimated 50–90% of injection drug users living with HIV are coinfected with HCV.

Now that antiretroviral therapy (ART) has significantly improved health outcomes and longevity among HIV-positive individuals, HCV coinfection has emerged as a significant contributor to morbidity and mortality among people living with HIV (PLWH). HIV accelerates HCV progression. End-stage liver

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disease and liver cancer from HCV are leading causes of death among HIV-positive people, despite use of HIV treatment.144,145,146

The American Association for the Study of Liver Diseases recommends HCV treatment (at any fibrosis stage). This recommendation is in alignment with the Institute of Medicine and the U.S. Department of Health and Human Services’ Action Plan for the Prevention, Care, & Treatment of Viral Hepatitis.

HCV treatment is a lifesaving intervention for coinfected PLWH. Being cured of HCV—an outcome called sustained virologic response (SVR)—lowers AIDS-related, liver-related, and “all-cause” death rates among coinfected people, even if they are cirrhotic.147,148

HCV treatment has improved dramatically. Interferon has been replaced by safe, tolerable oral regimens of direct-acting antivirals (DAAs) that have cured most of the people treated with them, regardless of HIV status. Now that HCV is easy to cure, the focus on screening individuals and linking them to care has increased. Because HIV and HCV have a disproportionate impact on similar populations, an opportunity exists to develop testing and care strategies for HCV simultaneously with HIV-related services.

Opioid Abuse Gives Way to Increased HIV & HCV Infections

Recently, rates of new HCV infections have increased, apparently related to increases in injection-drug use among individuals with a history of prescription opioid abuse. In one important case, an HIV outbreak in a rural county of southeastern Indiana reported in early 2015 where 135 such persons were diagnosed with new HIV infection and 114 (84%) of these individuals were diagnosed with HCV coinfection. The public health emergency in Indiana highlights the need for improved efforts to prevent HIV and HCV transmission among people who inject drugs.

Many coinfected clients are poor and from underserved communities. Often, they face significant barriers that make it difficult for them to enter the healthcare system and to access services. As HCV treatment has become increasingly efficacious, there are new barriers associated with it, such as insurance coverage for costly HCV medication.

As HIV-positive clients move along the Care Continuum, it is critical to address coinfections and comorbidities. Just as HIV viral suppression improves health outcomes and lengthens lives, so does HCV SVR.

Ryan White HIV/AIDS Program grantees and other treating PLWHA are uniquely positioned to help address HCV, given both the high prevalence of this disease among HIV-positive individuals and their familiarity with addressing the barriers facing marginalized communities. The prevalence and severity of HCV coinfection among HIV-positive clients—combined with the known benefits of being cured from HCV—call for expanded HCV care and treatment to coinfected clients within the HIV services system.

To provide an overview of the types of HCV screenings readers may want to consider, a resource sheet is provided on the following page.
Initial HCV Screenings

1) Confirm HCV infection
   - All HCV antibody-positive clients should have confirmatory testing with an HCV ribonucleic acid (RNA), as a proportion of them will clear their infection without treatment.
   - Seronegative HCV infection: Clients with HCV infection may lack HCV antibodies (Ab) due to recent infection, or because of a low CD4 cell count (usually < 200 cell/mm3). HIV-infected clients with low CD4 cell counts that test negative for HCV antibody but have a history of HCV exposure or persistent transaminitis should undergo HCV RNA testing to confirm or rule out active HCV infection.

2) Targeted HCV History
   - Assess for acute HCV infection: If HCV RNA positive, obtain a history for possible acute HCV (new HCV infection within the past 12 months). Acute HCV is often asymptomatic but may present with jaundice, malaise, and right upper quadrant pain. Ask about a known exposure to HCV (such as an HCV-infected sexual partner, particularly if client is a man who has sex with men [MSM], or through injection drug use).
   - Add a note on laboratory confirmation of acute HCV.
   - Estimated duration of infection with HCV.
   - History and signs of hepatic decompensation: Ask about history of hepatic decompensation (variceal bleeding, ascites, hepatic encephalopathy) and signs/symptoms of decompensated disease (increased abdominal girth, reversal of day/night sleep patterns, easy bruising/bleeding).
   - Prior HCV treatment history.

3) Evaluation of Comorbidities
   - Assess current ART and HIV-associated medications, as important drug-drug interactions can exist with certain ART and HCV medications (particularly cobicistat-boosted ART, ritonavir-boosted protease inhibitors or nonnucleotide reverse transcriptase inhibitors like efavirenz and etravirine).
   - Concomitant liver disease: hepatitis B virus (HBV), heavy alcohol, other conditions affecting the liver.
   - Severe cardiac and/or pulmonary disease.
   - Comorbidities that are anticipated to reduce life expectancy (e.g., metastatic cancer, severe pulmonary or cardiac disease).
   - Severe renal impairment.
   - Mental health.

4) Check reproductive capacity and report

5) Review current medications

6) Review substance abuse

7) Review labs

8) Staging of Liver disease

9) Hepatocellular Carcinoma (HCC) Screening
   - HCC screening is only indicated in HCV-infected clients with cirrhosis.

10) Prevention
   - Assess immunity to hepatitis A virus (HAV) and HBV, offer vaccination as indicated.
   - Counsel reduction of alcohol and discuss possible role of marijuana in accelerating liver fibrosis.
   - Discuss HCV routes of transmission and how to reduce the risk of infection to sexual partners (particularly MSM) and, if currently injecting or snorting drugs, harm reduction. HCV-infected clients should be advised to not share potentially blood-contaminated implements with contacts or household members, including razors and toothbrushes.
   - Counsel women of childbearing potential about risk of maternal-child transmission, which is low but does occur. Pregnant women or women seeking pregnancy should discuss their chronic HCV infection with their obstetrician.

Source: Adapted from University of California San Francisco. San Francisco Hepatitis C: A Primary Care Initiative Protocol, Hepatitis C Treatment and Management. May 8, 2012.
Improving Health Outcomes
Moving Patients Along the HIV Care Continuum and Beyond

**INTERVENTIONS AT-A-GLANCE**

### Diagnosing HIV

**INTERVENTION OVERVIEW & REPLICATION TIPS**

Social Networks Testing
Wisconsin Department of Health Services

### Linkage to Care

**INTERVENTION OVERVIEW & REPLICATION TIPS**

Assess, Test, Link: Achieve Success (ATLAS) Program
Care Alliance Health Center (OH)

Enhancing Linkages to Care for Women Leaving Jail
University of Illinois at Chicago

Video Conferencing Intervention
Louisiana Department of Health and Hospitals

Active Referral Intervention
Virginia Department of Health

Louisiana Public Health Information Exchange (LaPHIE)
Louisiana State University, Health Science Center and Louisiana Department of Health Hospitals, Office of Public Health

### Retention in Care

**INTERVENTION OVERVIEW & REPLICATION TIPS**

My Health Profile
New York-Presbyterian Hospital

### Prescription of ART & Medication Access

**INTERVENTION OVERVIEW & REPLICATION TIPS**

Care Coordination Intervention
Virginia Department of Health

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**Beyond the Care Continuum: Addressing HCV Comorbidity and Coinfection**

**INTERVENTION OVERVIEW & REPLICATION TIPS**

Hepatitis Treatment Expansion Initiative
University of California, San Francisco, San Francisco General Hospital HIV Clinic

Hepatitis Treatment Expansion Initiative
Washington University School of Medicine (MO)
INTERVENTION OVERVIEW & REPLICATION TIPS

Hepatitis Treatment Expansion Initiative
Washington University School of Medicine (MO)

The table below provides a general overview of the Hepatitis Treatment Expansion intervention so readers can assess the necessary steps required for replication.

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<thead>
<tr>
<th>Step 1</th>
<th><strong>Develop and Implement HCV Screening Standards</strong></th>
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<tr>
<td></td>
<td>Create standardized screening procedures for HCV infection that identify all persons infected—and coinfect-ed—with HCV. Ensure a mechanism exists to collect and store client-level screening data (e.g., create a database, develop queries to extract data from electronic medical records).</td>
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<th>Step 2</th>
<th><strong>Create a Multidisciplinary HCV Team and HCV Clinic Session</strong></th>
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<td>Designate a specific clinic session to address HIV/HCV coinfection. Standardize evaluation, treatment, and monitoring of coinfect ed clients and identify a physician to serve as medical lead of the program. Train staff.</td>
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<tr>
<th>Step 3</th>
<th><strong>Create Treatment Protocols</strong></th>
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<td>Create treatment protocols and a process to update them to stay aligned with the changing HCV treatment landscape.</td>
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<th>Step 4</th>
<th><strong>Screen Clients</strong></th>
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<td></td>
<td>Screen clients for CD4 count, active substance use, adherence to HIV therapy, psychiatric illness, medication contraindication, and liver fibrosis.</td>
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<th>Step 5</th>
<th><strong>Work With Specialty Pharmacy on Client HCV Treatment Coverage</strong></th>
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<td></td>
<td>Pharmacy should be familiar with HCV treatment and with navigating their way through insurance paperwork and approval processes as well as patient assistance program requirements. Specialty pharmacy doesn't need to be physically close as long as they are HCV and insurance coverage savvy.</td>
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<th>Step 6</th>
<th><strong>Initiate HCV Treatment</strong></th>
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<td>Initiate 12-week treatment regimen and provide adherence information. Identify if clients require laboratory monitoring and review indications and dosing of factors to support neutropenia or anemia.</td>
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<th>Step 7</th>
<th><strong>Monitor Client Database</strong></th>
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<td></td>
<td>Input and track client data. This provides a more complete picture of clinic activities and outcomes as well as the identification of clients for HCV treatment.</td>
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<th>Step 8</th>
<th><strong>Quality Improvement</strong></th>
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<td></td>
<td>Share outcome data with multidisciplinary HCV team. If areas for improvement are identified, implement Plan, Do, Study, Act (PDSA) cycles.</td>
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Organizations should walk through a Resource Assessment (or Readiness) Checklist to assess their ability to conduct this work. If organizations do not have these components in place, they are encouraged to develop this capacity in order to conduct the Hepatitis Treatment Expansion intervention. Questions to consider include:

☐ Does your organization have a physician interested in treating HIV/HCV coinfected clients and dedicated to keeping up with the changing HCV medication landscape?

☐ Does your organization have access to an in-house or specialty pharmacy that can provide support with health insurance companies and pharmacy assistance programs to secure client HCV medication coverage and assess any HIV/HCV drug-drug interactions? If not, are you willing to foster a relationship with a specialty pharmacy?

☐ Are there enough coinfected clients in your clinic to treat, given the time required to keep up with evolving HCV requirements?

Setting the Stage: Grantee Intervention Background

Washington University School of Medicine’s HIV Clinic is a major provider of HIV clinical care and supportive services to PLWH in the seven-county St. Louis region. Washington University is also the Part C and D grantee for the region, which allows the clinic to offer a one-stop-shop integrated model of care. Services include HIV primary care, laboratory services, medical case management, mental health services, client education, treatment adherence counseling, support groups, transportation assistance, and access to clinical trials research.153

Washington University HIV Clinic has the ability to refer clients to the clinic’s affiliate Barnes-Jewish Hospital radiology department for outpatient liver biopsies154 when needed to evaluate the degree of a client’s fibrosis and progression of liver disease.

Washington University received support from the SPNS *Hepatitis C Treatment Expansion SPNS Initiative*. During the award period, the clinic served approximately 1,711 clients each year, among whom 174 had a detectable HCV viral load.155

Injection drug use (IDU), which is correlated with increased risk for both HIV and HCV, is generally lower in St. Louis than in other major U.S. cities. As such, the total number of coinfected clients seen by Washington University is generally lower than in other parts of the country with larger IDU epidemics.

The intervention had three primary objectives:

1. focusing on improved HCV screening within the clinic;
2. implementing a model of integrated care with a designated HIV/HCV coinfection clinic; and
3. providing wraparound services to HIV/HCV coinfected clients to minimize barriers to ongoing engagement in HCV care.156

Washington University sought to demonstrate the potential of a multidisciplinary HCV team and a specific coinfection clinic session to improve evaluation, treatment, and monitoring of coinfected clients.

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154 For uninsured clients, liver biopsies may be covered by the clinic’s Ryan White Part C grant.
Description of Intervention Model

**CHALLENGE ACCEPTED**

**THE CHALLENGE:** The challenge the intervention sought to address was HCV infection (and any fibrosis stage) among HIV-positive clients within the Washington University HIV Clinic.

**Intervention Model:**
**Co-located Care with a Specialist**

Washington University offers integrated, comprehensive care for HIV/HCV coinfected clients onsite at its HIV clinic. This includes integrating expert HCV therapy into the HIV primary care setting to further facilitate a medical home model, without requiring all HIV physicians in the clinic be fully responsible for HCV treatment.

The Washington University treatment model requires a dedicated HCV physician lead. This can be either a hepatologist or an infectious disease doctor with an interest in managing coinfected clients and a dedication to stay abreast of the constantly changing HCV treatment landscape.

Washington University has a coinfection clinic session within the HIV clinic to offer a distinct, coordinated approach to care for this high-need population rather than referring clients out for HCV evaluation and treatment.

At Washington University, although there are some supportive staff members, three primary individuals make up the crux of the care model. These include:

- **A Lead HCV physician.** This individual oversees the intervention. The lead physician also serves as a leading investigator of Washington University’s AIDS Clinical Trial Group, which supports swift access to research trials for new HCV therapies.

- **A Lead HCV nurse.** The HCV lead nurse manages day-to-day responsibilities and offers client education, provides monitoring, oversees scheduling and follow-up on referrals for diagnostic procedures like liver biopsies (though this is becoming less common), and coordinates with clients’ multidisciplinary providers to enhance client care.

- **Specialty pharmacist.** This individual provides support in navigating HCV treatment coverage with health insurance agencies and patient assistance programs. As newer and more effective HCV treatments became available, yet health insurance coverage for such drugs has become more stringent, there has been a shift from the time involved for medical care and oversight on the clinical end to more paperwork and benefits management on the pharmacy end.

With the clinical trials group located at Washington University, the clinic was able to quickly treat clients with new HCV medications early on. This helped attract the attention of a lot of HIV providers as they saw that HCV could be cured, and much more readily.

With the new HCV medications available, all clients who been treated have been cured. Having a smaller coinfected population allows the clinic to more closely tailor its approach to each individual client.
Staffing Requirements & Considerations

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<tr>
<th>Staffing Capacity</th>
<th>Based on the Washington University work, here are the types of staff necessary to replicate this intervention.</th>
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<tr>
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<td><strong>Lead HCV physician.</strong> Responsibilities include:</td>
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<td>• Primary physician of the HCV clinic session</td>
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<td></td>
<td>• Prescribing HCV medications for clients</td>
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<td></td>
<td>• Staying abreast of new HCV care and treatment guidelines and best practices</td>
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<tr>
<td></td>
<td>• Coordinating with nursing and pharmacy staff as needed.</td>
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<td></td>
<td><strong>Lead HCV nurse.</strong> Responsibilities include:</td>
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<tr>
<td></td>
<td>• Managing day-to-day HCV clinic session activities</td>
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<tr>
<td></td>
<td>• Providing client HCV and adherence education</td>
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<tr>
<td></td>
<td>• Providing monitoring</td>
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<td></td>
<td>• Overseeing scheduling</td>
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<tr>
<td></td>
<td>• Following up on any referrals for diagnostic procedures like liver biopsy (though this is becoming less common)</td>
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<tr>
<td></td>
<td>• Coordinating with client's multidisciplinary providers to enhance client care</td>
</tr>
<tr>
<td></td>
<td>• Coordinating with lead physician and pharmacy staff as needed.</td>
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<tr>
<td></td>
<td><strong>Specialty pharmacist.</strong> Responsibilities include:</td>
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<td>• Assisting with client insurance coverage (e.g., health insurance paperwork and processes; patient assistance programs)</td>
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<td></td>
<td>• Familiarity with HIV and HCV and ability to recognize any potential for drug-drug interactions</td>
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<td>• Interest in partnering with a Ryan White clinic.</td>
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<th>Staff Characteristics</th>
<th>Core competencies include:</th>
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<tr>
<td></td>
<td>• Genuine interest in treating HIV/HCV coinfected clients</td>
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<tr>
<td></td>
<td>• Interest in and ability to stay up-to-date on HCV medications and recommendations given the pace at which this field is changing</td>
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<td></td>
<td>• Cultural competency.</td>
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Replication Tips for Intervention Procedures and Client Engagement

This section provides tips for readers interested in replicating the intervention and, where applicable, includes grantee examples for further context.

Intervention procedures include the following:

- **Establish a standardized HCV screening protocol at the start of HCV care.** Screen clients at initiation of HIV primary care and at least annually thereafter. Testing steps for HCV infection can be found in the figure below.

- **Create protocols around laboratory monitoring and frequency of clinic visits.** Clients are monitored for alcohol use, drug treatment, and psychiatric disorders and are evaluated for liver fibrosis (when indicated). Washington University has found that in standardizing the clinic’s process to evaluate clients

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**Hepatitis C Virus (HCV) Infection Testing for Diagnosis**

1. **Negative**
   - Stop

2. **Positive**
   - **CONFIRMED**
     - High s/co ratio of RIBA positive or HCV RNA positive
   - **UNCONFIRMED**
     - And no other test done
   - **UNCONFIRMED**
     - And HCV RNA negative

3. **NAT for HCV RNA**
   - **POS**
   - **NEG**
   - **OR**

4. **RIBA for anti-HCV**
   - **POS**
   - **NEG**
   - **OR**

5. **Repeat anti-HCV in ≥ 1 month**

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1. Samples with high signal-to-cut-off ratios usually (>95%) confirm positive, but supplemental serologic testing was not performed. Less than 5 of every 100 might represent false-positives; more specific testing should be requested, if indicated.

   - **Anti-HCV**: Antibody to HCV
   - **NAT**: Nucleic acid testing
   - **RIBA**: Recombinant immunoblot assay
   - **RNA**: Ribonucleic acid
for active HCV infection, there has also been an improvement in the proportion of coinfected clients who have an undetectable HIV viral load.

- **Create procedures for identifying and tracking client data.** Identify the information your organization wants to track and put as much of this as possible into a database so that there is an accurate picture of all HCV-infected clients. Each quarter, pull the list of clients who have an HCV-positive antibody test and provide this list to the lead HCV physician. The lead HCV physician then reviews each client's medical record to confirm if the client has active HCV infection or is in need of further diagnostic screening, according to the protocol. The list is updated on a quarterly basis. As Dr. Rachel Presti, HCV physician at the Washington University, explains, “It’s really important to do that data analysis piece up front, and separate out who is ready for treatment and who isn't. A full clinic assessment should be done initially when you’re about to kick off HCV treatment. It’s time consuming but well worth it.”

- **Assess client readiness.** Although HCV medication has become increasingly more tolerable, adherence is particularly important. Therefore, all clients are assessed as to their readiness to follow medication regimens. HIV viral load is used as a marker for this. According to Washington University, “Achieving an undetectable HIV viral load is not only a desirable health outcome for all clients with HIV/AIDS, but it also demonstrates a client’s ability to adhere to his/her prescribed medication regimen [as] adherence is an important consideration when assessing a client’s readiness for HCV therapy.”

- **Refer clients to the co-located HCV clinic session.** HCV clinic staff check what HIV medications clients are on and whether or not they are compatible with HCV treatment. If not, the client is switched to a new HIV regimen. Staff then check that the patient is still viral load suppressed, and the request for HCV coverage begins.

- **Provide client education.** Some clients are hesitant to start HCV treatment if they remember the interferon days (with many side effects). As such, clinic staff should work to educate them on new treatments, including disseminating information about the efficacy of new HCV medications and using data to show clients how well new treatments are tolerated.

- **Procure treatment coverage.** Finding specialty pharmacies familiar with HCV and HIV is key. The pharmacies don’t have to be physically close by, as long as they are familiar with navigating their way through paperwork and approval processes. Pharmacists should be looking for any drug-drug interactions to make sure folks are on regimens that are compatible with HCV treatment. Pharmacists should also have relevant client information on record (e.g., fibrosis score, information on HIV care, urine analysis), so that clients can better qualify for insurance coverage and/or pharmaceutical assistance.

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Having a centralized place or person who is familiar with patient assistance programs is very important, because HCV insurance coverage is really hard to obtain, particularly because the requirements are changing so rapidly. Even “easy” clients can take about a month to obtain coverage for HCV medications.

To cover HCV medications, particularly in a non-Medicaid expansion state like Missouri, organizations can look to the State AIDS Drug Assistance Program (ADAP) and pay for insurance for qualifying clients. This will enable some clients to receive HCV treatment, although this is not always the case. For clients who are denied insurance coverage, pharmacists should keep asking insurance companies because, sometimes, if insurance denies a request a certain number of times, then patient assistance will step in or at least assist with co-pays.

- **Have clients begin treatment and have providers stay abreast of available treatment.** Most clients need just 12 weeks of treatment; however, the availability of HCV medications—and for which genotype—is constantly changing.

- **Provide access to services that reduce barriers to care.** A multidisciplinary approach is especially helpful for treating HIV/HCV coinfected clients. Access to case management, mental health counseling, and transportation assistance are important services to reduce barriers and keep clients retained in care.

- **Disseminate information to raise awareness about HCV.** Consider hosting a forum or community meeting. Invite community advocates and providers in the region to come and hear about the experience and importance of screening and tackling HCV. This can help spread the word about and increase interest in the intervention.

### Securing Buy-in

Create awareness among multidisciplinary team members about the needs of coinfected clients. Consider the following activities:

1. **Hold clinic staff meetings devoted to educating multidisciplinary team members about the intervention, its goals and objectives, and the screening protocol.** Place an emphasis on the importance of case managers and mental health staff in retaining coinfected clients and on treatment adherence.

2. **Meet with others who have or who are offering HCV treatment.** For example, Washington University’s HIV clinic nurses and the university’s hepatology clinic staff met to discuss the difficulties of prior hepatology-led HCV treatment of coinfected clients. Discussions helped clarify nursing staff requirements and type of monitoring for HCV treatment.

Keep providers within the broader HIV clinic, as well as in the community, abreast of the importance of addressing HCV and how, today, this work is more feasible and achievable than ever.
Overcoming Implementation Challenges

The largest challenge in doing this work is health insurance coverage. Because of this, it’s important to devote resources to working with a specialized and dedicated pharmacist who is savvy in navigating the health insurance landscape within your organization’s respective state.

Promoting Sustainability

Washington University is able to sustain the HCV intervention work through Ryan White Part C and other grant sources. Organizations are encouraged to similarly assess current funding streams and whether HCV care, treatment, or intervention staff salaries/activities may be covered.

Conclusion

Curing HCV among coinfected clients has never been easier. New regimens have enabled Washington University to cure all clients who have undergone treatment. A specialty pharmacist assists with coverage issues and enrollment while an HCV nurse lead ensures clients are educated on the latest treatments and on the continued importance of medication adherence.

The work being done at Washington University aligns with federal guidelines and recommendations, national goals, and the National Action Plan for the Prevention, Care & Treatment of Viral Hepatitis.

Other Available Resources

- Hepatitis C Treatment Expansion SPNS Initiative
- Washington University ID-CRU and AIDS Clinical Trial Unit
- Washington University, School of Medicine, Infectious Disease Division, HIV/AIDS