



Improving Health Outcomes

Moving Patients Along the HIV Care Continuum and Beyond

JUNE 2017

INTERVENTION OVERVIEW & REPLICATION TIPS

Hepatitis Treatment Expansion Initiative

University of California, San Francisco,
San Francisco General Hospital HIV Clinic

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.



Diagnosing HIV



Linkage to Care



Retention in Care



Prescription of ART & Medication Access



Beyond the Care Continuum: Addressing HCV Comorbidity and Coinfection



HRSA
Health Resources & Services Administration

U.S. Department of Health and Human Services
Health Resources and Services Administration
HIV/AIDS Bureau



Beyond the Care Continuum

Addressing HCV Comorbidity & Coinfection

In the U.S., hepatitis C virus (HCV) is the most common blood-borne infection. It affects over 3.5 million people.¹³⁵ 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.”¹³⁶

HCV is often called the “silent killer” because it slowly damages the liver over many years, without noticeable symptoms.¹³⁷ An estimated 75–85% of acute HCV infections become chronic, and approximately 75% of individuals with chronic HCV are unaware of their infection.¹³⁸

HCV is a common and serious coinfection among HIV-positive persons. In the U.S., an estimated 25% of all people with HIV are coinfecting with HCV.¹³⁹ 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.¹⁴⁰ In urban areas in the U.S., an estimated 50–90% of injection drug users living with HIV are coinfecting with HCV.¹⁴¹

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.^{142,143} End-stage liver

¹³⁵ U.S. Department of Health and Human Services, Office of HIV/AIDS and Infectious Disease Policy. “Hepatitis C Basic Information.” May 13, 2016. Available at: www.hhs.gov/hepatitis/learn-about-viral-hepatitis/hepatitis-c-basics/index.html Accessed September 19, 2016.

¹³⁶ U.S. Department of Health and Human Services, Office of HIV/AIDS and Infectious Disease Policy. “Hepatitis C Basic Information.” May 13, 2016. Available at: www.hhs.gov/hepatitis/learn-about-viral-hepatitis/hepatitis-c-basics/index.html Accessed September 19, 2016.

¹³⁷ National Viral Hepatitis Roundtable. Closing the Gap in Hepatitis C Prevention, Screening and Care. June 27, 2011. Available at: http://nvhr.org/sites/default/files/NVHR_HCV_Advocacy_Brief_06_27_11_0.pdf.

¹³⁸ Institute of Medicine (IOM). *Hepatitis and Liver Cancer: A National Strategy for Prevention and Control of Hepatitis B and C*. Washington, DC: National Academies Press, 2010.

¹³⁹ Sulkowski MS. Current Management of Hepatitis C Virus Infection in Patients with HIV Co-infection. *J Infect Dis*. 2013;207 Suppl 1:S26–32.

¹⁴⁰ Chak E, Talal AH, Sherman KE, et al. Hepatitis C Virus Infection in USA: an Estimate of True Prevalence. *Liver Int*.2011;31(8):1090–101.

¹⁴¹ Strader DB. Coinfection with HIV and Hepatitis C Virus in Injection Drug Users and Minority Populations. *Clin Infect Dis*. 2005;41(Suppl 1):S7–S13.

¹⁴² U.S. Department of Health and Human Services, Health Resources and Services Administration, HIV/AIDS Bureau, Special Projects of National Significance. Hepatitis C Treatment Expansion Initiative: Evaluation and Technical Assistance Center. FOA: HRSA-10-216. 2010.

¹⁴³ Reiberger T, Ferlitsch A, Sieghart W, et al. HIV-HCV Co-infected Patients with Low CD4+ Cell Nadirs are at Risk for Faster Fibrosis Progression and Portal Hypertension. *J Viral Hepat*. 2010;17(6):400–9.

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 coinfecting PLWH. Being cured of HCV—an outcome called sustained virologic response (SVR)—lowers AIDS-related, liver-related, and “all-cause” death rates among coinfecting 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.

Source: Conrad C, Bradley HM, Broz D, Buddha S, et al. Community Outbreak of HIV Infection Linked to Injection Drug Use of Oxycodone—Indiana, 2015. *MMWR Weekly*. 2015;64(16):443–444.

¹⁴⁴ De Ledinghen V, Barreiro P, Foucher J, et al. Liver Fibrosis on Account of Chronic Hepatitis C is More Severe in HIV-positive than HIV-negative Patients Despite Antiretroviral Therapy. *J Viral Hepat*. 2008.15(6):427–33.

¹⁴⁵ Salmon-Ceron D, Rosenthal E, Lewden C, et al. ANRS EN19 Mortalite Study Group and Mortavic. Emerging Role of Hepatocellular Carcinoma Among Liver-Related Causes of Deaths in HIV-infected Patients: The French National Mortalite 2006 study. *J Hepatol*. 2009.50(4):736–45.

¹⁴⁶ Weber R, Sabin CA, Friis-Moller N, et al. Liver-related Deaths in Persons Infected with the Human Immunodeficiency Virus: the D:A:D Study. *Arch Intern Med*. 2006.166(15):1632–41.

¹⁴⁷ Berenguer J, Alvarez-Pellicer J, Martín PM, et al; GESIDA3603/5607 Study Group. Sustained Virological Response to Interferon Plus Ribavirin Reduces Liver-related Complications and Mortality in Patients Coinfected with Human Immunodeficiency Virus and Hepatitis C Virus. *Hepatology*. 2009.50(2):407–13.

¹⁴⁸ Berenguer J, Rodríguez E, Miralles P, et al; GESIDA HIV/ HCV Cohort Study Group. Sustained Virological Response to Interferon Plus Ribavirin Reduces Non-liver-related Mortality in Patients Coinfected with HIV and Hepatitis C Virus. *Clin Infect Dis*. 2012.55(5):728–36.

Many coinfecting 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 coinfecting 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).

- Presence of opiate replacement therapy: document what agents.
- 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 | INTERVENTION SUMMARY TABLE



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



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)

Hepatitis Treatment Expansion Initiative

University of California, San Francisco,
San Francisco General Hospital HIV Clinic



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

Intervention at-a-Glance	
Step 1 	<p>Consult on HCV Coinfected Client Health Record</p> <p>Upon HCV diagnosis, the HIV primary-care physician sends client electronic health record to the internal physician lead at the HCV coinfection clinic. Internal HCV physician lead provides technical review of proposed treatment plan and complexity of client case.</p>
Step 2 	<p>Conduct Electronic Review of Client Health Record</p> <p>HCV physician lead reviews client health record:</p> <ul style="list-style-type: none"> • More complicated cases are referred for in-person evaluation in HCV coinfection clinic for more involved oversight, lab work, and ART regimen change. • For more straightforward cases, the HCV physician lead sends an e-script to the pharmacist for a 12-week treatment regimen.
Step 3 	<p>Conduct Lab Work</p> <p>At 4 weeks into the treatment regimen, conduct lab work to verify beneficial impact to date.</p>
Step 4 	<p>Provide Pharmacist Adherence Monitoring</p> <p>Pharmacist continues adherence monitoring and counseling with the coinfecting client.</p>
Step 5 	<p>Monitor Clients on Ribavirin</p> <p>Clients on ribavirin have lab visits every 2–4 weeks and nursing visits, if necessary, to monitor for anemia until treatment is complete.</p>

Source: Leutkemeyer, A and Robb, V. University of California, San Francisco, San Francisco General Hospital, HIV Clinic. Personal Interview. February 2, 2016

Resource Assessment Checklist

Beyond the Care Continuum

Organizations should walk through a Resource (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 their capacity so that they can successfully conduct the Hepatitis Treatment Expansion intervention. Questions to consider include:

- Does your organization currently have routinized HCV screening in place? If not, is this something it can establish?
- Does your organization currently have an HCV provider champion in place that is dedicated to staying up-to-date on the changing HCV treatment landscape and can serve as the HCV physician lead? If not, is there someone who would be interested in taking this on?
- Does your organization have a hepatitis nurse or other provider who can assist the HCV physician lead with tracking lab work and client HCV treatment adherence education? If not, is there someone who is interested and available to take this on?
- Does your organization have an in-house pharmacist or partner with a specialty pharmacy that can provide HCV treatment coverage support and is familiar with your state Medicaid and pharmaceutical patient assistance program requirements?

Sources: University of California, San Francisco. Hepatitis C Treatment Expansion Initiative. Final Report. 2012.

Leutkemeyer, A and Robb, V. University of California, San Francisco, San Francisco General Hospital, HIV Clinic. Personal Interview. February 2, 2016

Setting the Stage: Grantee Intervention Background

University of California, San Francisco's San Francisco General Hospital (SFGH) HIV Clinic is located on the campus of a large, urban public health hospital with an academic affiliation. The HIV clinic serves nearly 3,000 people living with HIV.¹⁴⁹ SFGH received *Hepatitis C Treatment Expansion SPNS Initiative* funding to expand their HCV work and change to a care model that would increase capacity to evaluate and treat HCV among their coinfecting clients. This included moving from a clinic-wide hepatitis initiative to a dedicated hepatitis clinic with a multidisciplinary team that meets twice monthly.

The hypothesis at the onset of the project was that a dedicated onsite hepatitis clinic model would result in an increase in capacity to evaluate and treat HCV, as well as result in improved treatment outcomes by SVR/cure rates among coinfecting PLWHAs. During the SPNS grant cycle, SFGH increased HCV treatment capacity by 45%.¹⁵⁰

HCV coinfection rate at SFGH decreased from **30-35%** to **20%** due to the number of clients cured.¹⁵¹

SFGH was able to refine their HCV care model infrastructure during the SPNS grant so that when the safe, tolerable, and highly effective HCV DAA medications came out, they had everything necessary to exponentially expand HCV treatment even further. In the interferon era, for example, SFGH treated 10–20 HCV clients a year; today, thanks to increased capacity and more efficacious medications, they treat >90–100 annually. The HCV coinfection rate at the clinic has decreased from 30–35% to less than 20% because of client cure rates. With only 300 HCV-infected clients left to treat, SFGH is on track to eliminate HCV in their clinic over the next 3 years. Continued surveillance will take place for new infections, reinfection, and HCV clients transferring care to this clinic.

SFGH treats **90-100** clients annually. With only **300** HCV-infected clients left to treat, SFGH could **eradicate HCV** in its clinic altogether.¹⁵¹



Why HCV Treatment in an HIV Clinic?

According to SFGH,

“The primary responsibility for managing and treating HCV in persons coinfecting with HIV has gradually shifted away from hepatology clinics to primary care HIV clinics. This transition has occurred, at least in part, because of the need to fill gaps in appropriate management and treatment of HCV in PLWHA and the willingness of some Ryan White HIV clinics to take on a greater role in providing HCV services.”

Source: University of California, San Francisco. Hepatitis C Treatment Expansion Initiative. Final Report. 2012.

To date, **98%** of SFGH's clients treated for HCV have **cleared their infection.**¹⁵¹

¹⁴⁹ University of California, San Francisco. Hepatitis C Treatment Expansion Initiative. Final Report. 2012.

¹⁵⁰ University of California, San Francisco. Hepatitis C Treatment Expansion Initiative. Final Report. 2012.

¹⁵¹ Luetkemeyer A and Robb V. [Personal communication.] University of California, San Francisco, San Francisco General Hospital. February 2, 2016.

Description of Intervention Model



CHALLENGE ACCEPTED

THE CHALLENGE: Modifying the existing HCV care model to improve HCV treatment delivery to, medication adherence among, and treatment outcomes for a large HIV/HCV coinfecting population.

Intervention Model: **Integrated HCV Treatment with a Designated HCV Clinic**

SFGH offers **integrated care within a designated HCV clinic physically located in the HIV primary care clinic**. The twice-monthly HCV coinfection clinic is staffed by an HIV primary care physician who is an infectious disease specialist with extensive experience in HIV management and HIV/HCV coinfection, along with two medical fellows.

A dedicated “hepatitis nurse” has an expanded role in client support, team coordination, and program management. This model relocates responsibility for HCV treatment from primary care providers to a hepatitis coinfection clinic lead physician. By expanding the role of the hepatitis nurse and concentrating care with a dedicated physician and fellows, this model facilitates treatment expansion in a more controlled, organized, and efficient manner that increases access to and completion of HCV treatment for coinfecting clients. Other team members include a pharmacist, pharmacy intern, and a social worker, all of which have been critical to ensuring ongoing appropriate insurance, harm reduction services, and stable housing.

The transition to co-located care with a specialist model facilitated by SPNS and sustained today has led to increases in treatment initiation, as well as improved morale among treatment team members. The clinic is identified as a local resource for HIV/HCV coinfection treatment and offers mentoring and advice to other primary care sites and clinicians.

SFGH is able to provide a full spectrum of care to their coinfecting clients. Although they still hold a twice-monthly dedicated HCV clinic with the HCV-specialized ID physician and hepatitis nurse, the rapidly shifting HCV treatment landscape has since led SFGH to a number of evolutions in day-to-day operations. Less time is spent on doctor’s review and nurse-led client education; instead, selecting the optimal HCV regimen for each client and obtaining medications through insurance are the biggest areas of focus, requiring the pharmacist to become increasingly involved.

During the era of interferon-based treatment, all HCV-coinfecting clients needed to be seen at the HCV clinic because of poor tolerability, side effects, and the need for medical assessment. This limited the number of clients that could be seen and subsequently treated. Today, only complicated cases require more in-depth evaluation at the clinic.

More complicated cases typically include individuals with the following:

- Decompensated liver disease
- Renal dysfunction/renal disease
- Advanced cirrhosis
- Ribavirin treatment, requiring monitoring for anemia
- Drug-drug interactions between HIV and HCV regimens that necessitate a change in ART. For example, clients who are taking tenofovir disoproxil fumarate with a ritonavir- or cobicistat-boosted protease inhibitor (such as darunavir or atazanavir) may be switched to a different regimen and be stabilized before starting HCV treatment with a ledipasvir-based regimen, or they will be more closely monitored for renal impairment if ART is not modified.

All other cases are handled in a more standard manner:

- Upon referral, the lead physician of the HCV clinic conducts an electronic review of the client's record from their regular HIV primary care provider at SFGH.
- After 4 weeks of treatment, clients have laboratory monitoring and an adherence checkup.
- After the checkup, the pharmacist continues to provide adherence counseling.

If the client is taking ribavirin, then every 2–4 weeks, he/she will be monitored for anemia and may see a nurse for additional monitoring. If the HCV RNA is below the limit of detection at week 4 and the client is not on ribavirin, additional laboratory monitoring is usually not needed. HCV RNA is checked 12 weeks after treatment has been completed for SVR₁₂. Throughout treatment and after treatment, clients are counseled about the possibility of HCV reinfection and what steps they can take to reduce this risk, and they are screened for reinfection with HCV RNA on a regular basis.

Given the data supporting that effective HCV therapy is feasible in active substance users, SFGH does not require that clients prove they're drug-free to receive HCV treatment. Those with active substance use are counseled about harm reduction, offered referral for cessation, and, as with all clients being treated at the clinic for HCV, are provided adherence counseling throughout. Demonstration of a suppressed HIV viral load is an excellent marker for ability to adhere to daily medications, and the clinic works to ensure HIV suppression for most HCV/HIV clients prior to initiating HCV treatment.

Currently, more than 80% of SFGH's clients qualify for HCV treatment coverage through California's Medicaid program, called Medi-Cal. Remaining clients are covered through a mix of other public insurance programs and pharmaceutical assistance programs. To date, the clinic's SVR₁₂ rates have exceeded 98% with DAA-based regimens.



Staffing Requirements & Considerations

Staffing Capacity



Based on the SFGH work, here are the types of staff necessary to replicate this intervention.

HCV coinfection physician lead. Responsibilities include:

- Serves as the primary resource person for clients and providers
- Stays up-to-date on HCV treatment and care issues
- Acts as a champion for the HCV work
- Reviews all client results and prescriptions prior to initiating therapy with pharmacy and physician consultant
- Reviews client health records and provides e-scripts for easily managed cases and refers harder-to-treat clients to the HCV clinic
- Monitors and treats complicated coinfecting clients
- Collaborates with hepatitis nurse
- Coordinates e-scripts with pharmacist.

Hepatitis nurse. Responsibilities include:

- Day-to-day management of the HCV clinic
- Conducts lab work and monitoring
- Provides client HCV treatment adherence education
- Coordinates with HCV provider champion, research associate, and pharmacist.

Pharmacist

- Determines payer source issues and assists with prior authorization
- Monitors drug-drug interactions before and at regular intervals during HCV treatment
- Client adherence education and counseling.

Social worker

- Ensures insurance is active
- Provides linkage to substance abuse treatment, mental health services, and housing assistance as needed.

Staff Characteristics



Core competencies include:

- Commitment to treating HIV/HCV coinfecting clients, including those with comorbidities, mental illness, and active substance use
- Interest in, and ability to stay up-to-date on HCV medications and recommendations for their use, given the rapid changes in this field
- Cultural competency.

Source: University of California, San Francisco. Hepatitis C Treatment Expansion Initiative. Final Report. 2012.

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.

To implement and routinize an HCV treatment intervention, it's important to take the time to do the necessary advance think-work required. This includes the following steps:¹⁵²

- **Assess the clinic environment**, including current services, screening assessments, internal capacity, community resources, and HCV treatment gaps.
- **Map out what your HCV coinfection clinic** will look like within your current organization's infrastructure. What elements are already in place, what needs to be modified, and what needs to be added?
- **Evaluate staff expertise and interest** in HCV and coinfection and provide available trainings, if necessary.
- **Establish a coordinated team.** This team includes:
 - ⇒ *A provider champion.* This doesn't necessarily have to be a physician, but it is critical that there be a core person who helps move this work forward, is willing and able to stay up-to-speed on the rapidly changing HCV treatment landscape, and recognizes who they can or can't treat and when to bring clients in.
 - ⇒ *Hepatitis nurse.* This person provides support for the HCV provider champion and checks labs.
 - ⇒ *Specialty pharmacist.* Having a dedicated onsite pharmacist or a specialty pharmacy in the community is necessary to do this work. The pharmacist should review drug-drug interactions, readily work on securing client coverage (e.g., Medicaid, pharmaceutical assistance programs), and process e-scripts.
 - ⇒ *Adherence counseling.* Someone, whether the pharmacist, hepatitis nurse, or other team member, needs to be providing adherence counseling and check-ins to make sure that the client is taking their medications and talking with them about how they will get through the 12 weeks of HCV treatment.
- **Establish an HCV screening system.** A screening system should be in place to screen all clinic clients and to monitor those successfully treated for reinfection.
- **Monitor and evaluate client treatment readiness.** Adherence is important when it comes to HCV medication. Clients need to be ready to adhere to their HCV regimen once initiated. For coinfecting clients, a good indicator of adherence is an undetectable HIV viral load, since it demonstrates that they can take medication consistently. Monitoring client readiness also includes assessing comorbidities

¹⁵² University of California, San Francisco. Hepatitis C Treatment Expansion Initiative. Final Report. 2012.

and ART regimens that may require changing in advance of HCV treatment receipt.

- **Put HCV treatment protocol in place and provide clinic education.** Establish a treatment protocol and ensure staff are aware of and have access to the protocol or utilize protocols/guidelines that are available. Additionally, educate all staff (including front desk staff) about HCV.
- **Monitor labs, any adverse events, and possible presence of liver fibrosis** (when indicated). Evaluate the client’s degree of fibrosis and progression of liver disease before starting treatment and monitor for adverse events during treatment.
- **Establish medication access and payment coverage.** Ensure staff (particularly the pharmacist) are well versed in insurance coverage requirements and know how to tap into private funding sources, such as patient/pharmaceutical assistance programs to help cover medication costs. SFGH suggests that if providers aren’t able to secure coverage from one drug company, they may need to move on to another drug company that has an effective but less popular treatment, since these companies may be more willing to provide assistance.
- **Establish client education** to prevent initial infection and reinfection after successful treatment. Additionally, educate clients about safe dispensing and storage of HCV treatment. With HCV medication costing as much as \$1,000 per pill, SFGH is finding it necessary to talk to clients the way they have with opioid treatment—such as not leaving medications in backpacks, not advertising presence of medication, storing in a safe place, etc.

SFGH Model Replicated

The San Francisco Health Network rolled out a primary care-based HCV initiative with a central pharmacist and physician and other core tenets from the SFGH HIV/HCV clinic. If clients meet criteria as “low complexity clients,” including but not specific to those with HIV, then they are monitored by the primary care provider and primary care nurse. As Dr. Annie Luetkemeyer at SFGH explains, “Although we’re not responsible for staffing that model, I see it as a sign of success because we’ve partnered in this effort to expand HCV-based treatment in primary care settings. It’s exciting to see our experience being used to expand treatment in San Francisco.”

Securing Buy-in

Readers interested in replicating this model can help secure buy-in by providing HCV education to stakeholders (including providers and clients alike), underscoring the unique role HIV clinics have to play in addressing coinfection, and mapping out the staff capacity piece up front.

For example, Dr. Luetkemeyer, the SFGH HCV lead physician, along with Valerie Robb, the hepatitis nurse, provide education to the following groups in an effort to further expand their HCV work:

- *SFGH-based HIV primary care physicians interested in the group's HCV work.* At SFGH there are approximately 30 physicians (most are part-time) who work within the broader HIV clinic and are excited to tackle HCV with their clients after seeing the work of Luetkemeyer and her team. With some initial support, and a walk through of the care model (whereby charts are sent to Dr. Luetkemeyer for preliminary review and low-complexity clients receive e-scripts), these physicians now manage the remaining components of the clients' care.
- *Methadone Clinics.* The HIV/HCV team has partnered with the methadone clinic co-located in the same building to provide directly observed HCV therapy to clinic clients who receive methadone maintenance. By doing so, Dr. Luetkemeyer and her team leverage existing resources to expand HCV offerings as much as possible.

As for clients, there are some who don't think they qualify for new HCV treatments because they didn't previously. Fortunately, because SFGH treats even complicated cases and has cured them, word-of-mouth has spread and created a "snowball effect." Even previously hesitant clients are now coming in to talk about treatment.

Overcoming Implementation Challenges

Organizations looking to replicate this intervention need to take time up front and map out what the model will really look like once implemented within their infrastructure. It's also important that dedicated time for an HCV clinic is truly carved out, and that staff working that clinic are freed up enough to do so. It's easy to like the idea of an HCV clinic; however, the intervention can only be successful if the necessary time and capacity are truly dedicated to this work. Part of this capacity must include a pharmacist who is insurance and pharmaceutical program-savvy and familiar with HIV and HCV, as the pharmacist's role in benefits support is a particularly important one when it comes to HCV.

Today, a primary challenge is simply keeping up with the new information and treatments surrounding HCV. A staff member really has to be interested—and dedicated—to keeping up.

Entities looking to replicate this work may also want to survey what HCV resources and specialists already exist in their community and assess how their clinic's coinfection work fits into the larger picture. People who are already working in this area may be able to offer useful insights about integrating this work into your organization's clinic.

Promoting Sustainability

SFGH's HCV work is fully self-sustaining thanks to Medicaid coverage, pharmaceutical assistance programs, and demonstrated efficacy and subsequent buy-in of their HCV intervention. Because of variability of HCV treatment and Medicaid coverage from place to place, entities should survey available resources, insurance coverage and formularies, and whether existing funding streams may cover either HCV treatment or provider time.

Conclusion

Ryan White HIV/AIDS Program clinics are uniquely positioned to address HCV, given the high rates of coinfection among their clients and grantees' proficiency in providing culturally competent care to high-need, often hard-to-reach populations. Given the prevalence and severity of HCV among HIV-positive clients, coupled with today's easily tolerated, incredibly effective HCV medications, the time is ripe to tackle this work and expand treatment.

As Dr. Luetkemeyer says, "What will be interesting for us is that we talk a lot about elimination of HCV in our clinic. [Now] with only 300 people left to treat, we're nearing that place in another 2 to 3 years. We need to focus on keeping our cured clients HCV free, screening for reinfection, and expanding HCV treatment throughout San Francisco."

Other Available Resources

- [Hepatitis C Treatment Expansion Initiative](#)