

# Integrating Hepatitis C Treatment In Ryan White Clinics Models & Steps

June 2011

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



U.S. Department of Health and Human Services  
Health Resources and Services Administration, HIV/AIDS Bureau  
5600 Fishers Lane, Parklawn Building, Room 7-05  
Rockville, MD 20857  
<http://hab.hrsa.gov>

**June 2011**

This publication was funded by the U.S. Department of Health and Human Services,  
Health Resources and Services Administration, HIV/AIDS Bureau,  
under contract number HSH231200533009C with WriteProcess, Inc. and  
WordPortfolio, Inc. under contract number HHS231200633011C.

## TABLE OF CONTENTS

Purpose of This Document .....	1
Contributors.....	3
Impact of HCV on Persons Living with HIV/AIDS .....	4
Why Ryan White Clinics Should Provide HCV Treatment .....	6
Models Used to Manage HCV/HIV Coinfection .....	10
Steps to Setting Up HCV/HIV Treatment Services .....	15
References .....	30

## Purpose of This Document

Of the 1.1 million Americans infected with HIV/AIDS,<sup>1</sup> various studies estimate that anywhere from 25-35 percent are coinfecting with hepatitis C virus (HCV), or nearly 300,000 persons.<sup>2</sup> HIV/AIDS clinics funded by the Ryan White HIV/AIDS Program see a significant number of coinfecting patients come through their doors. What should they do in response?

*All Ryan White-funded clinics should be monitoring HCV disease among their coinfecting patients and evaluating them for potential HCV treatment. Ryan White agencies should also take the next step and help fill gaps in HCV treatment services not being adequately addressed by HCV specialty clinics.*

This guide presents a rationale for why Ryan White clinics should play a greater role in HCV treatment and steps they can take in deciding how to integrate HCV treatment within their HIV/AIDS primary care services.

The reasons for tackling HCV are compelling. HCV is a leading cause of morbidity and mortality among persons living with HIV/AIDS (PLWHA). Yet, effective and more easily tolerated HCV therapies are now available. A significant number of patients who undergo HCV therapy can be cured.

Providing HCV treatment services, however, entails a separate set of challenging but essential tasks. This guide outlines steps Ryan White agencies can take in deciding how to integrate HCV treatment within their HIV/AIDS primary care services, according to insights from Ryan White clinics that have taken on a greater role in managing and treating HCV. The models and steps that are outlined reflect the varied ways that Ryan White clinics have tackled HCV management and treatment—from setting up referral systems with external HCV services to incorporating HCV care and treatment within their own walls. Typically, clinics spent considerable time planning, reviewing budgets and staffing, and designing new services. As such, their experiences can help inform Ryan White agencies that are struggling with how best to tackle HCV care among their HIV/AIDS clients.

This guide is the latest in a series of technical assistance resources from the U.S. Department of Health and Human Services (HHS), Health Resources and Services Administration (HRSA) to assist Ryan White agencies in tackling HCV care (see <http://hab.hrsa.gov> and <http://careacttarget.org>). While development of this guide was undertaken prior to release of the Federal HHS Action Plan on Hepatitis, the guide aligns with the plan's many insights and strategies for improving hepatitis services (see *Combating the Silent Epidemic, HHS Action Plan for the Prevention, Care and Treatment of Viral Hepatitis*, May 2011, available at <http://aids.gov>).

Clinic insights presented in this guide were first compiled in 2010 in order to guide development of a demonstration grant initiative under the HRSA HIV/AIDS Bureau's Special Projects of National Significance Program (SPNS) to explore HCV/HIV management innovations and best practices. Investigation began with a review of HRSA resources on HCV/HIV care and national guidelines on HCV management and treatment. In addition, and—most importantly—a series of

written and verbal interviews were conducted with 16 Ryan White-funded HIV clinics that have active HCV coinfection treatment programs. Interviewed clinics were identified by HRSA HIV/AIDS Bureau staff and outside experts (see Contributors). Clinics represent different geographic regions with varied clinical care capacity, as measured by their clinic patient volume. Each site assessment consisted of an extensive written interview followed by a telephone interview that was informed by responses to the written interview. Two distinct written interviews were employed—one for clinics serving fewer than 500 HIV-infected clients and one geared to clinics serving more than 500 HIV-infected clients.

Ryan White clinics are well-positioned to address gaps in HCV treatment for HIV-infected clients given their expertise addressing multiple care challenges faced by many PLWHA.

As a result of the quality of the information gathered, HRSA decided to expand the document into this technical assistance guide, which is organized as follows:

- **Impact of HCV on Persons Living with HIV/AIDS** presents data on the scope of HCV/HIV coinfection, with a brief review of epidemiologic data and the natural history of HCV infection in persons living with HIV/AIDS (PLWHA).
- **Why Ryan White Clinics Should Provide HCV Treatment** outlines the rationale for HIV/AIDS clinics to take on HCV treatment, which can be summed up as follows: Ryan White clinics are well-positioned to address gaps in HCV treatment for HIV-infected clients given their expertise addressing multiple care challenges faced by many PLWHA.
- **Models Used to Manage HCV/HIV Coinfection** presents various HCV/HIV management and treatment models found in interviewed Ryan White clinics that should inform other clinics that are contemplating expanding into HCV services. These models fall along a spectrum of involvement—from referral mechanisms to full integration of HCV treatment services in the HIV/AIDS clinic.
- **Steps to Setting Up HCV/HIV Treatment Services** outlines steps that Ryan White clinics can take (besides the all-important issue of securing funding) in establishing HCV services for coinfecting clients. Protocols and tools to help implement these fundamental pieces of an HCV/HIV care program are presented.

Ideally, clinics will review the models and follow the steps as they pick and choose how to put a chosen model in place.

## Contributors

Insights presented in this document were gleaned from a series of written and verbal interviews with 16 Ryan White-funded HIV clinics that have active HCV coinfection treatment programs. Interviewed clinics were identified by HRSA HIV/AIDS Bureau staff and outside experts. They represent different geographic regions with varied clinical care capacity, as measured by their clinic patient volume. Each site assessment consisted of an extensive written interview followed by a telephone interview that was informed by responses to the written interview. Two distinct written interviews were employed—one for clinics serving fewer than 500 HIV-infected clients and one geared to clinics serving more than 500 HIV-infected clients. Interviewed sites included:

Lending Hands for Life, Erie Family Health Center  
Erie, PA  
Rachel O'Mara, MD

Positive Health Program  
San Francisco, CA  
Brad Hare, MD & Val Robb, RN

University of Toledo Medical Center  
Toledo, OH  
Ann Wayson Locher, MSN, RN, ACRN

Wake Forest University Health Sciences Infectious  
Diseases Specialty Clinic  
Winston-Salem, NC  
Marina Nunez, MD, PhD

Pueblo Community Health Center  
Pueblo, Colorado  
Mark Schwartz, MD

St. Thomas St. Clinic  
Houston, TX  
Ben J. Barnett, MD

Emory University School of Medicine, Division of  
Infectious Diseases, Infectious Disease Program at  
Ponce de Leon, Grady Health System  
Atlanta, GA  
Melissa Osborn, MD

Florida Bureau of HIV/AIDS, FL/Caribbean AETC  
Tampa, FL  
Jeffrey Beal, MD

FL/Caribbean AETC, Lee County Health Department  
Fort Myers, FL  
Sean McIntosh

Owen Hepatitis C Clinic  
San Diego, CA  
Edward “Lilo” Cachay, MD, MAS

AIDS Community Health Center  
Rochester, NY  
Michael Mancenido

The Peter Krueger Clinic, Beth Israel Medical Center  
New York, NY  
Charlene Monaco

HIV ACCESS  
Oakland, CA  
Kathleen Clanon, MD

Miriam Hospital  
Providence, RI  
Lynn Taylor, MD

Christiana Care  
Wilmington, DE  
Arlene Bincsik, RN, MS, CCRC, ACRN

Delta Region AETC & Louisiana State University  
Health Sciences Center, School of Public Health  
New Orleans, LA  
Ronald D. Wilcox, MD, FAAP

Multnomah County Health Department  
Portland, Oregon  
Michael MacVeigh, MD

### Medical Editor

David H. Spach, MD  
Director and Principle Investigator for AIDS Medical Education  
Northwest AIDS Education and Training Center  
Professor of Medicine, Division of Infectious Diseases, University of Washington School of Medicine  
Seattle, Washington

# Impact of HCV on Persons Living with HIV/AIDS

## Epidemiology of Hepatitis C Virus in Persons Coinfected with HIV

Approximately 1,100,000 persons were living with HIV/AIDS in the United States, according to 2006 year-end data estimates from the Centers for Disease Control and Prevention (CDC).<sup>1</sup> Among them, an estimated 25-35 percent were coinfecting with hepatitis C virus (HCV)—approximately 300,000 individuals.<sup>2,3</sup> Coinfection rates differ significantly, depending on the group examined. On the lower end, they range from 1-27 percent in persons who acquired HIV through sex<sup>4</sup> and go up from there, to 38 percent in HIV-infected U.S. veterans<sup>5</sup> and as high as 50-90 percent in injection-drug users.<sup>3,6</sup>

Upwards of one-third of PLWHA in the United States are coinfecting with HCV.

## Impact of HCV and HIV Coinfection

Approximately 90 percent of HIV-infected persons who are HCV seropositive have HCV viremia, which means that HCV remains in the body after the period known as acute infection and they therefore have chronic HCV infection.<sup>2,3</sup> Chronic infection with both HIV and HCV has a potential adverse bidirectional impact.

Widespread use of highly active antiretroviral therapy (HAART) has resulted in a dramatic decline in AIDS-related mortality. With patients living longer, the complications associated with long-term chronic HCV infection have emerged as one of the most important clinical issues for PLWHA.

- Liver disease is the leading cause of non-AIDS related death among PLWHA; 66 percent of these deaths occurred in PLWHA coinfecting with HCV.<sup>7</sup>
- From 1995-2005, the number of deaths from HCV-related end-stage liver disease among HIV-infected persons increased, even though most of these coinfecting individuals (62 percent) had an undetectable HIV RNA level near the time of death.<sup>8</sup>

Does HIV worsen the course of HCV disease? Most experts agree it does. Data suggest that the natural history of HCV is accelerated in persons with HIV.<sup>9</sup> A meta-analysis of eight studies that involved a total of 1,871 HCV infected patients (601 HIV-coinfecting and 1,270 HCV mono-infected) showed coinfecting patients have a relative risk of 2.92 (95 percent Confidence Interval [CI] 1.70-5.01) for more severe disease, 2.07 (95 percent CI 1.40-3.07) for histologic cirrhosis, and 6.14 (95 percent CI 2.86-13.20) for decompensated liver disease, when compared with HCV mono-infected patients.<sup>10</sup> In addition, some studies have shown patients with any form of chronic viral hepatitis have an increased risk of developing hepatotoxicity associated with HAART. (Note: Most patients with chronic viral hepatitis do not experience hepatotoxicity when starting HAART and HAART should thus not be withheld in persons with chronic HCV infection.<sup>11</sup>)

Flipping the equation, does HCV worsen the course of HIV disease? Although it is clear that HCV-related liver disease contributes significantly to deaths in persons with HIV, the impact of HCV on HIV-related immune progression and immune reconstitution remains unclear.<sup>9</sup> A recent meta-analysis of more than 30 studies with a total of more than 100,000 patients suggested HCV coinfection did not significantly increase mortality in HIV-infected patients prior to the widespread use of HAART. However, in the current HAART era, HCV coinfection increases mortality in HIV-infected persons when compared with patients who have HIV monoinfection.<sup>12</sup> This is because HIV-infected persons in the pre-HAART era typically died from AIDS-related complications and did not live long enough to suffer the complications of chronic HCV infection.

Does HIV worsen the course of HCV disease? Most experts agree it does.

Does HCV worsen the course of HIV disease? That is unclear.

## Guidance on Screening & Treatment of HCV in HIV-Infected Persons

Information on how to screen and treat HCV infection in HIV-infected individuals is outlined in the following Federal guidelines and protocols. They are presented in order of specificity, which ranges from the first item that presents recommendations to later guidelines that present specific instructions for managing HCV infection:

- **A Guide for Evaluation and Treatment of Hepatitis C in Persons Coinfected with HIV.** This HRSA HIV/AIDS Bureau guide presents detailed protocols and procedures for providers on testing and treating HCV infection in HIV-infected individuals. (See <http://hab.hrsa.gov> and <http://careacttarget.org>.)
- **Guide for HIV/AIDS Clinical Care.** This HRSA HIV/AIDS Bureau guide includes multiple sections and chapters on an array of care topics, including HCV infection, with information on managing HCV in coinfecting persons. (See <http://hab.hrsa.gov> or <http://www.aidsetc.org>.)
- **Guidelines for the Prevention and Treatment of Opportunistic Infections in HIV-Infected Adults and Adolescents.** This document includes a section outlining the epidemiology of hepatitis C along with recommendations for diagnoses, treatment, and management/monitoring of HCV. (See <http://aidsinfo.nih.gov>.)



## Why Ryan White Clinics Should Provide HCV Treatment

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.

Data suggest that HCV is not being appropriately managed in many patients living with HIV/AIDS. Although HCV-related liver disease and death rates among PLWHA are high, only a low percentage are receiving HCV therapy.

### Gaps in HCV Treatment for HIV-Infected Individuals

- National data show that HCV-related liver disease has emerged as a leading cause of death among PLWHA, suggesting that HCV disease is not being appropriately managed in many patients living with HIV/AIDS.<sup>7</sup>
- Patients with HIV/HCV coinfection—and HCV monoinfected patients—often have multiple complex and challenging issues that serve as barriers to initiating and completing HCV treatment. According to multiple studies, fewer than 50 percent of both groups of patients, when evaluated, are considered candidates for HCV therapy.<sup>13,14,15</sup> Among those deemed eligible for treatment, many do not actually initiate or complete therapy.<sup>15,16,17</sup>
- Patients coinfecting with HIV and HCV are often deemed ineligible for HCV treatment, predominantly because of the presence of extensive treatment barriers.<sup>14,18</sup> Management of HCV in HIV-coinfecting patients—at HCV specialty sites—is associated with low HCV treatment rates by hepatologists.<sup>15,19</sup>
- The predominant reason for lower rates of HCV treatment among HIV-infected clients is the presence of more extensive treatment barriers.<sup>16</sup> Clinicians and investigators have identified the following common barriers: non-adherence with visits (i.e., low rates of follow-up among HIV-infected patients when referred to hepatology clinics for management of HCV),<sup>19,20</sup> refusal of treatment, non-adherence with treatment, active psychiatric illness, active drug or alcohol use, decompensated liver disease, and a significant co-morbid medical illness.<sup>13,14,15,21,22,23</sup> Experts have noted many of the barriers to treatment are dynamic—they can change over time. Thus, coinfecting patients should undergo frequent evaluation for treatment, even those who initially do not appear ready for treatment.<sup>23</sup>

### Ryan White Clinic Capacity to Manage HCV-Infected Clients

Many patients with HCV monoinfection—and HIV/HCV coinfection—have multiple complex and challenging issues that serve as barriers to initiating and completing HCV treatment. For that reason, most experts recommend using a multidisciplinary approach for the treatment of HCV-infected persons.<sup>22,23,24,25</sup> In recent years, an increasing number of Ryan White-funded clinics

have pursued this approach and integrated HCV management into the care they provide to their HIV patients.<sup>17,19,26</sup>

For the following reasons, Ryan White clinics are well suited to deliver HCV treatment given their experience dealing with complex treatment challenges and their capacity do to so, once certain modifications are made in their clinic structures.

Ryan White clinics have experience managing complex treatment issues and challenging patients and are thus well suited to deal with HCV—once certain modifications are made in their clinic structures.

- **Experience Managing Complex Treatment Decisions.** Management and treatment of HCV mono-infection is complex. The overlap and interplay between HIV and HCV makes HCV-HIV coinfection management an even more complex endeavor than treatment of HCV mono-infection. Most notably are the following considerations: timing the initiation of HCV and antiretroviral therapies, managing interactions and potential toxicity associated with HCV medications and antiretroviral medications, and managing declines in CD4 count to levels below 200 cells/mm<sup>3</sup> as a result of peginterferon marrow suppression. All of these factors are more likely to be appropriately dealt with in a setting where one provider or one team of providers is overseeing various care and treatment issues.
- **Expertise Managing Complex Client Issues.** Many clients coinfecting with HIV and HCV have issues that may serve as HCV treatment barriers, including complex medical problems, substance abuse, mental health disorders, and lack of stable housing. Most Ryan White clinics have extensive experience with an array of complex social and medical issues that are common to both HIV and HCV.<sup>27</sup> In addition, most Ryan White clinics have programs (or access to programs) for substance abuse counseling and treatment, which is critical to address when managing HCV in coinfecting persons.<sup>27</sup> Further, most HIV medical providers working in a Ryan White-funded clinic have extensive experience addressing and overcoming treatment barriers in the setting of administering antiretroviral therapy to highly-challenging patients. Overall, the primary care relationships and services provided in Ryan White-funded clinics provide an optimal environment in which to deliver HCV services.
- **Established Clinic Infrastructures.** Some Ryan White clinic settings have existing infrastructures that can provide integrative care for HCV in persons coinfecting with HIV. The infrastructure in Ryan White clinics can support screening for HCV infection, preparing patients to initiate HCV therapy, monitoring patient adherence during HCV therapy, and monitoring patients for treatment response and side effects during therapy.
- **Client Comfort with Services.** Providing HCV treatment in the client's primary HIV clinical care setting provides a number of logistical advantages. These include: client familiarity with the clinic location, comfort with existing clinic staff members, enhanced likelihood of follow-up in the setting of ongoing HIV-related clinic visits, and, for many, established support systems in the clinic with case managers, counselors, and mental health professionals. In short, most clients prefer integrated care at the same clinical location.

- **Experience Supporting Client Adherence.** Ryan White clinics have a positive track record in supporting increased adherence to complex drug regimens, which is equally vital to treatment success in HCV treatment. HCV mono-infection studies have shown that greater than 85 percent adherence to peginterferon and ribavirin therapy clearly correlates with increased rates of HCV suppression; adherence appears to be particularly important from the standpoint of patients receiving the recommended weight-based ribavirin dose.<sup>28</sup> Persons coinfecting with HIV and HCV frequently have indicators for potential non-adherence, such as depression, neurocognitive impairment, and current substance abuse.<sup>29</sup>

Studies have shown that patients with risk factors for poor adherence to HCV therapy, if provided adequate support, can sustain good adherence throughout therapy

In the past decade, with the widespread use of HAART, Ryan White clinics (and providers working in that setting) have accumulated abundant experience related to adherence, including understanding the importance of adherence, developing adherence counseling skills, cultivating clinic expertise in adherence counseling, and establishing systems and programs for adherence monitoring.<sup>30</sup> Studies have shown that patients with risk factors for poor adherence to HCV therapy, if provided adequate support, can sustain good adherence throughout therapy.<sup>31</sup>

## Models and Steps Used By Ryan White Clinics to Manage and Treat HCV/HIV Coinfection

<b>MODELS</b> Used By Ryan White Clinics to Manage HCV/HIV Coinfection				
<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>
Referral to Hepatitis Specialty Treatment Site	Co-Located Treatment	Primary Care Management with Expert Back-up	Integrated HCV Treatment without Designated HCV Clinic	Integrated HCV Treatment with Designated HCV Clinic

<b>STEPS</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>
Setting Up HCV/HIV Treatment Services	Assess Your Environment	Select Model (see above) to Treat HCV-HIV Coinfection	Develop Staffing	Establish a Screening System for HCV Infection
<b>5</b>	<b>6</b>	<b>7</b>	<b>8</b>	<b>9</b>
Develop a System to Both Monitor Clients and Evaluate Them for Treatment Readiness	Put a Treatment Protocol in Place	Establish Medication Access and Payment, Coverage	Monitor Patient Co-morbidities and Conditions	Provide Patient Education

## Models Used to Manage HCV/HIV Coinfection

Among the 16 Ryan White-funded HIV clinic sites interviewed for this guide, five basic models were identified for treating hepatitis C virus in persons coinfecting with HIV. They range from a model more easily put into place (referral systems with HCV clinics) to progressively more resource-intensive activities, culminating in full-fledged HCV care and treatment within the HIV clinic. Regardless of the models, the core elements of HCV diagnosis, care, and treatment include:

- Staffing.
- Screening/Assessment.
- Monitoring HCV and Evaluating HCV Treatment Readiness.
- Treatment Protocols.
- Medication Access and Payment/Coverage.
- Monitoring Patient Co-morbidities and Conditions.
- Patient education.

Programs seeking to establish HCV/HIV treatment will need to secure funding to deliver these services. Agencies seeking funding, and those with funds in hand, should review the range of approaches offered in these models, and the options they offer, as they explore their own clinic's capacity and resources to establish HCV services for their coinfecting clients. Although significant experience exists with these models in Ryan White clinics, agencies should feel free to combine aspects of these models or even come up with new ones. HCV/HIV care models are being developed by HRSA's Special Projects of National Significance (SPNS) Hepatitis C Treatment Expansion Initiative. This initiative will evaluate the effectiveness of the interventions to deliver HCV treatment among HIV-positive populations and share best practice models with Ryan White grantees and other HIV medical providers to improve access and quality of Ryan White services for HIV patients.

If a tentative decision is made to explore the clinic's involvement in HCV treatment, review the models outlined in this document. Then, proceed to the next section and go through the suggested steps for setting up HCV services, referring back to these models as planning proceeds. The model selected may change given the emergence of new information and even new resources and opportunities.

## HCV Care Models: Who Does What and Where

<b>Model</b>	<b>Common Setting</b>	<b>Initial Evaluation Conducted</b>	<b>On Treatment Monitoring Conducted</b>	<b>Liver Biopsies Conducted</b>
Model 1: Referral to Hepatitis Specialty Treatment Site	Clinics without significant HCV treatment experience	Off-site hepatologist	Off-site hepatologist	Off-site by hepatologist
Model 2: Co Located Treatment	Clinics with relatively low volume of HIV-infected patients  Larger academic center with strong relationship between HIV and hepatology clinics and providers	On-site hepatologist (sees patients in hepatology clinic at same center or academic institution as Ryan White clinic)	On-site hepatologist, primary care provider, or a combination of both	On-site by hepatologist, or obtained through interventional radiology
Model 3: Primary Care Management with Expert Back up	Clinics with relatively low volume of patients on HCV therapy and with no formal HCV treatment program	On-site or off-site HCV expert (hepatologist or infectious disease specialist)	Primary care clinician with back-up assistance by HCV specialist	Interventional radiology
Model 4: Integrated HCV Treatment without Designated HCV Clinic	Ryan White clinic with multiple medical providers involved	Multiple medical providers and team at HIV clinic	Medical provider and team at HIV clinic (often nurse or pharmacist)	Interventional radiology
Model 5: Integrated HCV Treatment with Designated HCV Clinic	Clinics with high-volume of HIV-infected patients and substantial number of HCV coinfecting patients	On site at Ryan White Clinic during designated HCV treatment clinics	Team member (usually a nurse, nurse practitioner, or pharmacist) with frequent interaction with a physician	Interventional radiology

Core Elements of the Models	<b>Model 1: Referral to Hepatitis Specialty Treatment Site</b>
Staffing	Under this model, a formal HCV treatment program generally does not exist within the HIV primary care clinic setting. Rather, coinfecting clients are referred to a hepatitis treatment specialist, generally a hepatologist, for evaluation and management of HCV infection.
Screening/Assessment	<ul style="list-style-type: none"> <li>▪ The referral specialist performs any necessary tests to evaluate the patient's stage of liver disease, including liver biopsy (if indicated).</li> <li>▪ The referral specialist/hepatologist also decides whether the patient is a treatment candidate, and, if treatment is initiated, monitors the patient for treatment response and adverse effects.</li> <li>▪ The client continues to receive primary HIV care at the HIV clinic.</li> </ul>
Monitoring HCV and Evaluating HCV Treatment Readiness	Until recently, this model was the predominant system in place for evaluation and treatment of coinfecting patients. However, many Ryan White clinics are using more involved models, like those outlined below, because few of their patients actually receive and complete HCV therapy when referred to a hepatitis specialty site.
Treatment Protocols	
Medication Access and Payment/Coverage	
Monitoring Patient Co-morbidities and Conditions	
Patient Education	

## **Model 2:**

### **Co-Located Treatment (Specialist Manages HCV Care at Ryan White Site)**

This model entails integration of hepatology experts into the HCV treatment care program at the primary care site and generally requires a hepatologist who has significant expertise and interest in managing HCV-HIV coinfecting persons. This hepatology expert position typically requires funding support for this clinic-related activity. The goal of this model is to integrate expert HCV therapy within the patient's primary care setting. This treatment model usually involves clinics with a relatively low volume of HIV and HCV coinfecting patients or a larger academic center with a strong relationship between the HIV and hepatology clinics and providers. Features include the following:

- In general, the hepatologist conducts initial evaluation and coordinates treatment candidate decisions.
- If needed, liver biopsies (conducted to evaluate the stage of liver disease prior to initiating HCV therapy) are performed by the hepatologist, or obtained through interventional radiology.
- Responsibility for on-treatment monitoring varies and may be performed by the hepatologist, the primary care provider, or a combination of both. Treatment-related complications would typically be managed or co-managed by the hepatologist. With this system, the responsibility for ongoing treatment monitoring and follow-up may utilize a combination of a nurse practitioner/gastrointestinal/hepatology specialist, a physician hepatologist, and the patient's primary medical provider.

## **Model 3:**

### **Primary Care Management with Expert Back-up**

In this model, a collaborative management arrangement is made involving a primary care HIV provider (who is not considered an expert in HCV management) and consultation with a specialist (an expert in HCV management). Typically, the HCV expert is either a hepatologist or infectious diseases specialist. This treatment model typically involves clinics that have a relatively low volume of patients receiving therapy for HCV and that do not have a formal HCV treatment program. In addition, these sites generally do not have an option for a specialist to perform on-site evaluation and treatment of HCV in the coinfecting patients. This arrangement may or may not require funding. Features include:

- Initial patient evaluation is conducted by the specialist, who also provides recommendations for treatment initiation, treatment regimen, and treatment duration. If it is not possible to have the specialist perform the initial evaluation, the primary care HIV provider would perform the initial evaluation with consultation help from the specialist.
- Liver biopsies, if indicated, are typically obtained through interventional radiology.
- If the patient undergoes HCV therapy, the primary care clinician monitors the patient for response and adverse effects, utilizing the specialist for consultation advice and assistance during the treatment course.
- The clients receive HCV therapy in the setting of their primary HIV care clinic.



## **Model 4:**

### **Integrated HCV Treatment without a Designated HCV Coinfection Clinic**

In this model, the clinic provides HCV treatment but not as a designated HCV coinfection clinic. Rather, patients receive HCV clinical care and treatment in the setting of their primary HIV care clinic, with services provided by their primary care clinician. This model requires several clinicians that have an interest in treating HCV and in establishing a core level of expertise. The clinicians acquire a baseline level of HCV treatment expertise prior to treating coinfecting persons and most subsequently develop a high level of HCV treatment expertise.

- This clinic model usually involves a team approach. The medical provider and team at the HIV clinic are responsible for the initial evaluation, initiating treatment (if indicated), evaluating response to therapy, and careful monitoring for adverse reactions.
- Liver biopsies, if indicated, are usually obtained through interventional radiology.
- Expert consultation with outside providers is used only for patients who have significant complications related to the HCV treatment or related to their underlying liver disease.

## **Model 5:**

### **Integrated HCV Treatment with a Designated HCV Coinfection Clinic**

Several Ryan White clinics with high-capacity care have established a formal on-site designated coinfection clinic that is integrated into the HIV/AIDS clinic setting. Typically the coinfection clinic is held at a designated time, with a team of providers who have experience, interest, and training in the management of HCV in coinfecting persons. Lead clinicians in this setting typically have a high level of HCV treatment expertise. Some of the programs with a formal coinfection clinic have provided treatment for clients referred from other Ryan White clinics, but most limit their designated coinfection clinic to clients enrolled in their Ryan White clinic.

- Initial patient treatment evaluation is conducted by the patient's primary HIV provider, often with input from other team members who may have more HCV treatment expertise.
- Liver biopsies are generally obtained through interventional radiology.
- Decisions regarding initiation of treatment would occur at the designated HCV treatment clinic. On-treatment monitoring of the patients generally occurs by a team member that has frequent interaction with a physician provider. The team member who provides the careful on-treatment monitoring is often a nurse, nurse practitioner, or a pharmacist. The ongoing monitoring generally involves close collaboration with the patient's primary HIV provider.

## Steps to Setting Up HCV/HIV Treatment Services

Interviews with 16 Ryan White-funded programs provided the following insights into common steps undertaken by Ryan White agencies in successfully initiating, implementing, and managing HCV treatment programs for PLWHA. These steps and considerations under each are offered as a guide to clinics exploring establishment of HCV treatment programs.

Steps	Setting Up HCV/HIV Treatment Services
1	Assess Your Environment
2	Select Model to Use to Treat HCV-HIV Coinfection
3	Develop Staffing
4	Establish a Screening System for HCV Infection
5	Develop a System to Monitor & Evaluate Clients for Treatment Readiness
6	Put a Treatment Protocol in Place
7	Establish Medication Access and Payment/Coverage
8	Monitor Patient Co-morbidities and Conditions
9	Provide Patient Education

## Step 1

### Assess Your Environment

The first step in deciding whether to tackle HCV treatment is to undertake an assessment of current HCV services in order to identify what gaps exist that need to be filled—by the clinic and/or other agencies. This assessment should be kept simple and straightforward as most clinics lack the resources to do formal assessments. Also, the reality is that many of the HIV/AIDS clinics that have thus far expanded into HCV care and treatment have been motivated to act by clinic staff who feel passionate about creating HCV services to address gaps in care for their coinfecting clients. An assessment of HCV services can be conducted on two levels:

- **The Clinic.** Undertake an in-house review of your clinic’s operations.
- **The Broader Community.** Assess HCV treatment services in the broader community (i.e., outside your own clinic) as external agencies might be well positioned to deliver HCV treatment services to the clinic’s coinfecting clients as part of a referral network or through cross-clinic collaboration. An individual clinic should not undertake a community-wide needs assessment on HCV. Rather, the clinic should limit its assessment to a review of existing HIV/AIDS needs assessments that have been conducted by Ryan White planning bodies or others in order to determine what information they contain about HCV and related services in the community. In particular, clinics should determine what assessment and planning activities are underway in the locality or state as part of efforts to implement the 2011 HHS Action Plan on Viral Hepatitis.

Use the following questions (and the below chart, Step 1: Assess Your Environment: HCV Treatment Services) as a guide. Come back to them periodically during each step of planning.

- **What HCV Treatment Services Are Currently Available?** What HCV services are available in the community? What HCV services does your clinic provide? What are the characteristics of current HCV services (e.g., are HCV services in the community and your clinic geographically accessible; do clinics accept reimbursement from public programs including Ryan White; do clinics have open slots for new patients)?
- **What Gaps in HCV Treatment Exist for Your Clients?** How many of your patients are coinfecting (i.e., what is the base level of demand for HCV services)? How many of your coinfecting clients are receiving needed HCV monitoring and treatment services (in-house or through referrals to external agencies)? For your clients not receiving needed HCV treatment services, are providers in the community able to address their needs?
- **How Might Gaps Be Addressed?** Are resources currently available in your clinic to expand and provide treatment for HCV? What additional resources are needed to expand HCV services? (Note: Resources to examine should include funding [e.g., grants, reimbursement sources] as well as programs/staff.) Can agencies in the community help fill gaps?

If the outcome of this assessment identifies a role for your clinic in providing HCV services, proceed to Step 2 and select a model.

## Step 1: Assess Your Environment: HCV Treatment Services

What HCV Treatment Services Are Currently Available?	What Gaps in HCV Treatment Exist for Your Clients?	How Might Gaps Be Addressed?
In Your Clinic	How many of your clients are coinfecting?	What resources are currently available in your clinic to expand and provide treatment for HCV?
In the Community	How many of your coinfecting clients are receiving needed HCV treatment services)?	What additional resources are needed to expand HCV services?
Characteristics of Current HCV Services (e.g., geographically accessible, accept reimbursement from public programs)	For your clients not receiving needed HCV treatment services, are providers in the community able to address their needs?	Can agencies in the community help fill gaps?
Summary Statement Current HCV Treatment Services	Summary Statement Gaps in HCV Treatment for Your Clients	Summary Statement How Gaps Might Be Addressed

## Step 2

### Select Model to Use to Treat HCV-HIV Coinfection

Select the basic model to use in managing and treating HCV in persons coinfecting with HIV by reflecting on the need for HCV services and determining the “fit” for your clinic. Follow these steps as a guide to making a decision.

- Determine the need for HCV treatment services—in your clinic and community. Refer back to Step 1 assessment data, which may have provided strong indicators of service gaps and your agency’s role in filling them.
- Find out if you have leadership and buy-in from clinic directors, administrators, and staff to take on HCV work. (Such passion is a main reason many Ryan White clinics have expanded into HCV services.)
- Determine the capacity of your clinic to deliver HCV services (e.g., presence of staff to fill positions and responsibilities).
- Decide if your clinic has the ability to manage HCV activities (e.g., ability of clinic senior staff to add new responsibilities versus the need for new staff).
- Availability of resources to expand HCV activities (existing and/or potential funding).

Next, compare your clinic’s current operations to the core elements that are crucial in each model and determine:

- Which elements are already in place?
- Which elements exist but need to be modified?
- Which elements need to be created from scratch?

Again, these core elements are:

- Staffing.
- Screening/Assessment.
- Monitoring HCV and Evaluating HCV Treatment Readiness.
- Treatment Protocol.
- Medication Access and Payment/Coverage.
- Monitoring Patient Co-morbidities and Conditions.
- Patient education.

## Step 2A: Summary of Clinic's Current Status in Relation to HCV Core Elements

<b>Part 1: Clinic's Current Status</b> <i>(Review Needs Assessment Data)</i>
<b>What is Your Clinic's Need for HCV Services?</b> (in terms of number of coinfecting patients)
<b>What is Your Clinic's Capacity to Deliver HCV Services?</b> (e.g., presence of staff to fill positions and responsibilities)
<b>What is Your Clinic's Ability to Manage HCV Activities?</b> (e.g., ability of clinic senior staff to add new responsibilities versus the need for new staff)
<b>What Are Your Clinic's Available Resources?</b> (existing and/or potential funding options)
<b>Summary</b>

## Step 2A: Summary of Clinic’s Current Status in Relation to HCV Core Elements

Part 2: Compare Your Clinic’s Current Operations to Core Elements			
Core Elements	<i>In place.</i>	<i>Exists but needs to be modified.</i>	<i>Need to create from scratch.</i>
Staffing for HCV			
Screening & Assessment			
Monitoring HCV and Evaluating HCV Treatment Readiness			
HCV Treatment Protocols			
HCV Medication Access and Payment, Coverage			
Monitoring Patient Co-morbidities and Conditions			
HCV Patient Education			

## Step 3

### Develop Staffing

A successful coinfection program requires staff expertise in key areas (e.g., HCV care, medical management of coinfecting patients). Staff training may be needed. In addition, the medical staff needs to be organized to function as a coordinated team so that coinfecting clients receive a comprehensive and consistent approach to evaluation for treatment, management of barriers that may prohibit treatment, support during treatment, and careful monitoring and management of treatment responses and treatment complications. Below is a description of each of these staffing requirements.

#### Staff Expertise Needed

**HCV Treatment Knowledge.** A coinfection program needs to have a provider team that is knowledgeable in the current standards of care in the rapidly changing fields of HIV and HCV. Knowledge areas for treating providers include:

- Potential drug interactions and toxicities among antiretrovirals and HCV treatment medications.
- Recommended HCV treatment regimens and duration of therapy based on patient's HCV genotype.
- Monitoring of HCV treatment response.
- Monitoring and management of HCV treatment-related complications.
- Management of HCV treatment-related complications.
- Use of psychotropics in patients who develop peginterferon-related psychiatric complications.

**Medical Management Experience.** Management of HCV extends far beyond medication treatment. In fact, medical therapy for HCV is often a small part of the care of coinfecting patients. Thus, medical management of a coinfecting patient requires skills in the following areas:

- Screening and diagnosing HCV infection.
- Evaluation for treatment.
- Close monitoring for adverse events of HCV therapy.
- Attentive monitoring of liver related complications.
- Alcohol and drug abuse counseling, mental health care, and long-term follow-up care.



## **Staff Training Needed and Training Venues**

Ryan White clinics can undertake training of staff members through various means. Options include in-house training sessions, AIDS Education and Training Centers (AETC) training courses, and preceptorships (see <http://www.aids-ed.org>). The latter is reportedly an optimal way to provide training in HCV care in that participants can get a first hand look at how another clinic delivers HCV treatment services in a real world setting. The scope of training to undertake depends on the role of staff in HCV management and treatment, with more comprehensive training necessary for clinics that take on HCV services in-house.

## **Establish a Coordinated Team**

A coinfection program requires the coordinated efforts of multiple medical providers. This coordination can take place among staff (e.g., case conferencing) as well as between providers located in various partner agencies.

Below is a list of the team members and their general roles. Adjust these descriptions as needed in order to clearly describe the roles these medical providers will carry out in the HCV program. Also give consideration to the management structure to use in handling patient and program issues and the estimated Full Time Equivalent (FTE) effort by each individual.

### ***Medical Director Dedicated to Treating HCV***

Identify and designate a physician to serve as lead medical provider for the program.

Successful management of HCV in Ryan White clinics tends to involve a highly dedicated medical provider who serves as a lead to establish HCV therapy for patients in the Ryan White clinic. Typically, this individual is the person who identified gaps within the existing system that was simply referring patients to specialty care for management of HCV, with unfortunate consequences. These leaders were motivated by seeing dramatic declines in AIDS-related complications as a result of widespread use of antiretroviral therapy but a simultaneous, and significant, increase in patient deaths related to chronic HCV and liver disease.

Lead clinicians almost always play a key role in terms of:

- Establishing the HCV program.
- Generating a clinic-specific treatment model.
- Handling clinical management of coinfecting clients.

A lead (“champion”) medical director is critical regardless of the capacity and formal structure of the coinfection program. For example, clinics that provide HCV treatment without a formal HCV treatment program rely on a lead physician who has a strong interest in HCV therapy in coinfecting persons. This clinician typically takes on the primary responsibility of HCV treatment and monitoring, or establishing and organizing a system for evaluation, treatment, and monitoring.

## **Key Medical Provider for Treatment and Monitoring**

Ryan White HCV treatment programs typically identify a “core provider”—a nurse practitioner, pharmacist, or nurse—who plays a critical role in the day-to-day coordination of treatment and monitoring of patients receiving peginterferon and ribavirin therapy. This “core provider” is generally viewed as a critical component of the HCV treatment program. In most HCV/HIV programs, this “core provider” is:

- At the level of ARNP, PA, or pharmacist.
- Highly involved in all aspects of the patient’s HCV therapy, including treatment education, treatment adherence, monitoring and management of side effects, checking laboratory results, corresponding with patients on therapy, and interacting with physician providers (when applicable).

If a designated “core provider” is not utilized, then the mechanism for patient on-treatment monitoring should be described. Some programs that do not have funding for a “core provider” instead assign responsibility for the day-to-day coordination of all aspects of the HCV treatment and monitoring to the primary care physicians.

## **Other Staff**

Some coinfection programs make use of additional staff. They include hepatologists, educators, addiction specialists, and psychiatrists. Determinations about which staff are needed can be made by considering the following:

- Patient characteristics and needs.
- Number of coinfecting patients.
- Funding (existing and potential).
- Availability of current staff to fill new roles.

## **Training Clinicians in HCV**

HIV ACCESS is a Ryan White program in Oakland that trained its HIV specialists in HCV care, giving them the skills to deliver HCV services in house. Clinician training was through the AETC program. Costs were mostly for honoraria for HCV experts. Some funds went to support the nurse specialist. Training included:

- **Mini residencies With an HCV Expert.** In order to obtain hands on training, HIV ACCESS found an HCV specialist and set up an arrangement for four HIV specialists and the nurse specialist to do mini residencies with her for five half days. The hands on time with other experts seeing coinfecting patients reportedly gave them knowledge that’s not in the books. Mini residencies followed a set of learning goals set forth by the HCV expert, with journal readings to support specific topics like side effects management and counseling patients on difficult issues.
- **On Site Consultations with HCV Expert.** Simultaneously, another HCV expert (a GI physician) came to the HIV clinic and established a coinfection clinic ½ day a month. Clinic staff met with the expert prior to opening to discuss patients to be seen, from a case conferencing and skills transfer point of view, in both directions. The coinfection clinic has been in operation for multiple years and HIV treaters now do primary care for their coinfecting clients. Time with the hepatology specialist is reserved for complex cases (e.g., those dealing with side effects, patients at higher risk such as those with more advanced liver disease).
- **Presentations.** HIV ACCESS has held clinician journal clubs for HIV clinicians, with didactic presentations covering topics including HCV coinfection.

## Step 4

### Establish a Screening System for HCV Infection

The clinic should establish a system for screening all HIV-infected clients for chronic HCV infection. Most Ryan White-funded clinics already have an effective system in place for HCV screening.

To learn more about the components of HCV screening, see the HRSA document *A Guide for Evaluation and Treatment of Hepatitis C in Adults Coinfected with HIV*.

## Step 5

### Develop a System to Monitor & Evaluate Clients for Treatment Readiness

Develop a system to regularly evaluate clients as potential HCV treatment candidates. Patients with chronic HCV infection (HCV viremia documented) should be evaluated for potential HCV treatment on a regular basis, according to criteria outlined in the document referenced in Step 4, above. The rationale for this frequency is that many modifiable factors can change over time and patients previously considered ineligible may transition to an eligible status. Accordingly, yearly evaluation of patients for possible HCV therapy should be performed, even for those who do not initially appear interested in receiving HCV therapy. Overall, this system should provide a mechanism to move clients in the direction of readiness for HCV treatment, if treatment is indicated. For example, patients should receive counseling and education regarding treatment of HCV, and attempts should be made to address existing barriers to treatment, such as ongoing substance abuse, active psychiatric issues, or living situations not conducive to HCV treatment.

Part of evaluating clients for their readiness for treatment is patient education and assessment of potential challenges they may face in being treatment adherent. Options include:

- Client education that explains the natural history of HCV and the importance of HCV therapy. Many programs offer these education programs, which typically include an integrated approach that also seeks to identify and address issues that may serve as barriers to initiating therapy for HCV.
- A “treatment contract” to help communicate to patients the importance of adherence to the HCV therapy regimen.

## Step 6

### Put a Treatment Protocol in Place

Establish or identify an existing treatment protocol that addresses laboratory monitoring, frequency of clinic visits, and indications and dosing of factors to support patients who develop neutropenia or anemia.

The treatment protocol used by HCV/HIV clinics varies substantially, but many cover the following common elements:

- HCV screening.
- Indications for treatment.

- Medication dosing.
- Duration of therapy.
- Clinical and laboratory monitoring for medication-related toxicity.

For more information on treatment protocol essentials, see the HRSA document *A Guide for Evaluation and Treatment of Hepatitis C in Adults Coinfected with HIV*.

### **Protocol: Monitoring Labs and Adverse Events**

Treatment of HCV can result in numerous adverse clinical side effects and laboratory abnormalities. As a result, all programs should have a formal protocol in place for regularly evaluating patients on HCV therapy for clinical adverse effects as well as monitoring specific laboratory parameters. Maintaining an optimal ribavirin dose may play an important role in treatment success and thus a system should be in place for support of patients who develop anemia, including the use of factors such as erythropoietin.

### **Protocol: Evaluation of Liver Fibrosis**

Establish a mechanism for evaluating liver fibrosis (when indicated), whose purpose is to determine the stage of HCV-related liver disease.

Evaluation of the patient's degree of fibrosis and progression of liver disease can play a critical role in deciding to initiate treatment, particular for patients with HCV genotypes 1 and 4. Accordingly, all clinics need to have access to liver biopsy to evaluate the extent of liver fibrosis. If the clinic plans to use non-invasive methods for evaluating liver fibrosis (in lieu of liver biopsy), the specific tests used in this process should be listed and the rationale for this approach justified.

Many clinics utilize referral to interventional radiology for liver biopsy and some utilize referral to hepatologists. Clinics generally have access to pathologists to read liver biopsies. Liver biopsies are generally not provided in Ryan White clinics as part of their regular primary care services.

## **Step 7**

### **Establish Medication Access and Payment/Coverage**

Reimbursement of HCV-related services is, of course, a crucial part of a successful HCV treatment program. In general, coinfecting clients are less likely to be privately-insured and more likely to rely on public payers: Medicare, Medicaid, and Ryan White. Sites should also seek out private sources of funding, such as HCV pharmaceutical companies, to cover such costs as HCV medications and patient education.

Services and considerations for covering their costs are summarized below.

## HCV Coverage: Medicare, Medicaid, Ryan White HIV/AIDS Program – May 2011

<b>HCV Services</b>	These services include time of staff in conducting tasks such as screening, assessment, monitoring, clinic visits, and patient education.
<b>Medicare</b>	<p>Medicare will cover laboratory testing for HCV and will pay for office visits to monitor, treat, and manage the disease. Medicare fee for service allows physicians or nurse practitioners to bill according to the amount of time spent face-to-face with patients with HCV.</p> <p>A hepatitis C screening test is covered under Medicare but only when signs or symptoms of the disease may be present and the test is medically necessary for diagnostic purposes. Routine hepatitis C screening tests are not covered. Select Medicare Advantage PPO plans cover hepatitis C screening—both routine and diagnostic.</p> <p>Medicare fee for service will allow billing for visits when the majority of the visit is spent on counseling. If more than 50% of the time of the visit is spent on counseling or education, then physicians or nurse practitioners are able to bill according to the amount of time spent face-to-face with the patients with HCV. Documentation requires that providers list the total time of the visit, the time spent in counseling, and the subject discussed. Payments will vary depending on the amount of time spent and whether counseling is performed with a new or established patient.</p>
<b>Medicaid</b>	<p>Medicaid coverage for HCV services varies from state-to-state.</p>
<b>Ryan White HIV/AIDS Program</b>	<p>Ryan White funds can be used to pay for a set of HIV core medical and support services, which include HCV services. The Ryan White HIV/AIDS Program is the payer of last resort. Therefore, when other payer sources (public, private, and self-pay) are available, services may not be billed to Ryan White. Ryan White funds can also be used to pay for patient education that is associated with the delivery of medical care for eligible Ryan White clients.</p>
<b>HCV Medications</b>	Medications include peginterferon and ribavirin to treat HCV as well as medications associated with HCV treatment (e.g., erythropoietin)
	<p>Ryan White clinics that provide HCV treatment typically obtain peginterferon and ribavirin to treat HCV through Medicare, Medicaid, or ADAP. Access to HCV services (treatment, supportive medications, and vaccines) is crucial for coinfecting people, and many rely on State ADAP Programs to provide these treatments as well as antiretroviral therapy and treatment and prophylaxis for opportunistic infections. However, as of 2011, only 29 State ADAPs cover both peginterferon and ribavirin on their formularies. In cases where a payment mechanism for medication is not available, medical providers and patients can seek out pharmaceutical manufacturers' drug assistance programs to obtain peginterferon. Similarly, when assistance for medications, such as erythropoietin, is needed, clinics should have systems in place to access medications through ADAP and pharmaceutical drug assistance programs. The need to use pharmaceutical drug assistance programs tends to be much greater with erythropoietin and granulocyte macrophage colony-stimulating factor than with peginterferon.</p>
<b>Looking Ahead</b>	
	<p>For a summary of changes in HCV coverage as a result of the Affordable Care Act, see <i>Combating the Silent Epidemic of Viral Hepatitis, Action Plan for the Prevention, Care &amp; Treatment of Viral Hepatitis</i>, pp. 4-5, available at <a href="http://aids.gov">http://aids.gov</a></p>

## Step 8

### Monitor Patient Co-morbidities and Conditions

Clinics should next develop a system for evaluating and managing patient alcohol use, drug treatment, and psychiatric disorders—including referrals to services or access to such services in-house. These services should be in place for clients prior to, at the time of, and after starting HCV therapy, for the following reasons:

- Ongoing psychiatric and/or mental health disorders often serve as barriers that prevent a client from initiating therapy for HCV.
- Treatment with peginterferon can cause or exacerbate psychiatric disorders, necessitating access to psychiatric services during therapy.
- Optimal treatment with peginterferon and ribavirin requires excellent adherence: relapses in alcohol or drug use can impair a client's ability to remain adherent with therapy.

#### Clinic-Based Administration of Peginterferon Injections

For patients averse to administering self-injections, many clinics provide the option for clients to receive weekly peginterferon injections at the clinic. A nurse or pharmacist generally provides the peginterferon injections. This option can be particularly valuable for former injection drug users who have concerns and fears related to needle access and self-injection, including the concern these activities may trigger relapse.

#### Access to Psychiatry/Mental Health Services

Evaluation and management are typically provided by a mental health professional, usually a psychiatrist. Access to and availability of mental health/psychiatry services in an HCV clinic is considered a high priority by clinics because of the potential severe adverse psychiatric manifestations associated with peginterferon therapy. The involvement of mental health services ranges from formal evaluation for all patients prior to treatment with peginterferon to referral for active psychiatric issues after starting peginterferon therapy.

#### Access to Chemical-Drug Dependency Counseling and Treatment

Most HCV clinics provide on-site evaluation, counseling, and management of drug dependency. These services are frequently used prior to initiating therapy for HCV. Clinics vary in their willingness to provide ongoing HCV treatment in the setting of active drug use. Some clinics view active drug/alcohol use as a direct contraindication to continued therapy. However, other clinics make treatment allowances for mild-to-moderate drug use on a case-by-case basis, generally basing their decision on the client's clinic attendance, reported adherence, and evidence of response to therapy.

## Step 9

### Provide Patient Education

Patient education on coinfection and HCV should target clients who are not on HCV therapy as well as those who are initiating/taking HCV therapy. The approach to take can vary, based upon patient needs. Sessions can take such forms as ongoing counseling of patients (during clinic encounters) as well as formal classes and support groups. Many clinics offer opportunities for one-on-one counseling that is targeted, for example, to family members or substance abusers and their unique issues.

Clinics should make it possible for patients to be partners in their care. A strong relationship between the support staff and the patient will help sustain the patient's motivation for and adherence to therapy and, in turn, improve responses to therapy.

#### ***Organizing Formal Patient Education Sessions***

Below is a discussion of considerations in developing formal patient education.

**Content of Education Sessions.** Topics to cover in education sessions are fairly standard but should vary depending on whether sessions are targeted to all coinfecting patients versus those initiating or taking HCV therapy.

**For All Coinfecting Patients.** Topics typically cover how hepatitis C can affect your liver and your health, why it is important not to drink alcohol, when should someone receive treatment for hepatitis C, and what to expect when you are treated for hepatitis C.

**For Patients Initiating/Taking HCV Therapy.** All clinics interviewed for this TA guide provide some form of patient education prior to initiating therapy with peginterferon and ribavirin. The content of patient education for those initiating therapy can, of course, vary but should include the following elements, at a minimum:

- **Timing.** Treatment education should be available prior to starting therapy as well as during therapy.
- **Topics.** Understanding the need for treatment, the importance of high level of adherence, self-monitoring for adverse effects, and the importance of regular clinic visits for laboratory monitoring.

#### ***Ways to Deliver Patient Education***

**Designated Staff.** Patient education varies significantly in terms of assigned personnel. Most interviewed clinics have a designated core provider on staff (nurse, nurse practitioner, pharmacist, or patient educator) who serves as the primary resource for pre-treatment patient education. Several clinics have used an RN educator for group education. Feedback for the RN educator program was very positive. In addition, some sites use external agencies to provide patient education.

**Periodic Presentations.** Some clinics offer presentations on HCV. These sessions can be exclusively for consumers, both patients and providers, or even the community at large. Sessions are often held several times a year, such as quarterly and might include an expert presenter and/or a panel discussion (e.g., a clinical expert and a consumer). The clinic health educator is typically responsible for organizing these sessions. Topics might include:

- Disease progression.
- Coinfection management.
- Treatment.

**Funding Education Sessions.** Sources of funding for patient education often include patient education funds of the clinic. (Ryan White Part C patient education funds can be used, for example.) In some cases, clinics partner with pharmaceutical companies to fund educational sessions in order to cover such costs as an expert presenter as well as refreshments.

### ***Client Support Groups***

Approximately one-half of interviewed programs provide support groups for clients coinfecting with HCV and HIV. The support groups differed in their make-up of participants, with four models reported:

- All coinfecting clients (including clients not on active therapy) can attend a clinic-organized support group.
- Coinfecting clients on active HCV treatment can attend a clinic-organized support group.
- Coinfecting clients on active HCV treatment can attend a community support group that primarily consists of clients monoinfected with HCV.
- Coinfecting clients and clinic staff members (these included a support group run by the clinic hepatitis C team) can attend a clinic organized support group.

Support groups are generally a critical component of the support services provided to patients receiving or contemplating HCV treatment. Patients benefit from the mutual support they received from groups, which also provide a forum for learning more about living with HCV and going on therapy. However, a support group may not be critical for all clients, especially those who have established an intensive relationship with their clinic educator and staff members, providing them with a primary support mechanism.

The Jordan Hospital ACCESS Program in Massachusetts has provided education and health counseling about coinfection management, treatment, and disease progression for patients and the broader community. They have offered quarterly community-based educational programs targeting consumers and providers, using expert clinician presenters and panels of consumers living with coinfection. The focus is on treatment options. A health educator organizes their sessions.



## References

1. Campsmith ML, Rhodes PH, Hall HI, Green TA. Undiagnosed HIV Prevalence Among Adults and Adolescents in the United States at the End of 2006. *J Acquir Immune Defic Syndr*. 2009 Oct 15. [Epub ahead of print].
2. Sherman KE, Rouster SD, Chung RT, Rajicic N. Hepatitis C Virus prevalence among patients infected with Human Immunodeficiency Virus: a cross-sectional analysis of the US adult AIDS Clinical Trials Group. *Clin Infect Dis*. 2002 Mar 15;34(6):831-7.
3. Singal AK, Anand BS. Management of hepatitis C virus infection in HIV/HCV coinfecting patients: clinical review. *World J Gastroenterol*. 2009 Aug 14;15(30):3713-2.
4. Alter MJ. Epidemiology of viral hepatitis and HIV coinfection. *J Hepatol*. 2006;44(1 Suppl):S6-9. Epub 2005 Nov 21.
5. Backus LI, Phillips BR, Boothroyd DB, Mole LA, Burgess J, Rigsby MO, Chang SW. HIV treated with highly active antiretroviral therapy. *J Acquir Immune Defic Syndr*. 2005 Aug 15;39(5):613-9.
6. Strader DB. Coinfection with HIV and hepatitis C virus in injection drug users and minority populations. *Clin Infect Dis*. 2005 Jul 1;41 Suppl 1:S7-13.
7. Weber R, Sabin CA, Friis-Møller N, et al. Liver-related deaths in persons infected with the human immunodeficiency virus: the D:A:D study. *Arch Intern Med*. 2006 Aug 14-28;166(15):1632-41.
8. Rosenthal E, Salmon-Céron D, Lewden C, et al. Liver-related deaths in HIV-infected patients between 1995 and 2005 in the French GERMIVIC Joint Study Group Network (Mortavic 2005 study in collaboration with the Mortalité 2005 survey, ANRS EN19). *HIV Med*. 2009 May;10(5):282-9.
9. Kaplan JE, Benson C, Holmes KH, et al. Guidelines for prevention and treatment of opportunistic infections in HIV-infected adults and adolescents: recommendations from CDC, the National Institutes of Health, and the HIV Medicine Association of the Infectious Diseases Society of America. *MMWR Recomm Rep*. 2009 Apr 10;58(RR-4):1-207.
10. Graham CS, Baden LR, Yu E, Mrus JM, Carnie J, Heeren T, Koziel MJ. Influence of human immunodeficiency virus infection on the course of hepatitis C virus infection: a meta-analysis. *Clin Infect Dis*. 2001 Aug 15;33(4):562-9.
11. Sulkowski MS, Thomas DL, Chaisson RE, Moore RD. Hepatotoxicity associated with antiretroviral therapy in adults infected with human immunodeficiency virus and the role of hepatitis C or B virus infection. *JAMA*. 2000 Jan 5;283(1):74-80

12. Chen TY, Ding EL, Seage Iii GR, Kim AY. Meta-analysis: increased mortality associated with hepatitis C in HIV-infected persons is unrelated to HIV disease progression. *Clin Infect Dis.* 2009;49:1605-15.
13. Fleming CA, Craven DE, Thornton D, Tumilty S, Nunes D. Hepatitis C virus and human immunodeficiency virus coinfection in an urban population: low eligibility for interferon treatment. *Clin Infect Dis.* 2003 Jan 1;36(1):97-100.
14. Adeyemi OM, Jensen D, Attar B, Ghaoui R, Gallagher M, Wolen D, Cotler SJ. Hepatitis C treatment eligibility in an urban population with and without HIV coinfection. *AIDS Patient Care STDS.* 2004 Apr;18(4):239-45.
15. Restrepo A, Johnson TC, Widjaja D, et al. The rate of treatment of chronic hepatitis C in patients coinfecting with HIV in an urban medical centre. *J Viral Hepat.* 2005 Jan;12(1):86-90.
16. Fultz SL, Justice AC, Butt AA, Rabeneck L, Weissman S, Rodriguez-Barradas M; VACS-3 Project Team. Testing, referral, and treatment patterns for hepatitis C virus coinfection in a cohort of veterans with human immunodeficiency virus infection. *Clin Infect Dis.* 2003 Apr 15;36(8):1039-46.
17. Mehta SH, Lucas GM, Mirel LB, et al. Limited effectiveness of antiviral treatment for hepatitis C in an urban HIV clinic. *AIDS.* 2006 Nov 28;20(18):2361-9.
18. Butt AA, Khan UA, Shaikh OS, McMahan D, Dorey-Stein Z, Tsevat J, Lo Re V 3rd. Rates of HCV treatment eligibility among HCV-monoinfected and HCV/HIV-coinfecting patients in tertiary care referral centers. *HIV Clin Trials.* 2009 Jan-Feb;10(1):25-32.
19. Clanon KA, Johannes Mueller J, Harank M. Integrating treatment for hepatitis C virus infection into an HIV clinic. *Clin Infect Dis.* 2005 Apr 15;40 Suppl 5:S362-6.
20. Fishbein DA, Lo Y, Reinus JF, Gourevitch MN, Klein RS. Factors associated with successful referral for clinical care of drug users with chronic hepatitis C who have or are at risk for HIV infection. *J Acquir Immune Defic Syndr.* 2004 Nov 1;37(3):1367-75.
21. Thompson VV, Ragland KE, Hall CS, Morgan M, Bangsberg DR. Provider assessment of eligibility for hepatitis C treatment in HIV-infected homeless and marginally housed persons. *AIDS.* 2005 Oct;19 Suppl 3:S208-14.
22. Nunes D, Saitz R, Libman H, Cheng DM, Vidaver J, Samet JH. Barriers to treatment of hepatitis C in HIV/HCV-coinfecting adults with alcohol problems. *Alcohol Clin Exp Res.* 2006 Sep;30(9):1520-6.
23. Mehta SH, Thomas DL, Sulkowski MS, Safaein M, Vlahov D, Strathdee SA. A framework for understanding factors that affect access and utilization of treatment for hepatitis C virus infection among HCV-monoinfected and HIV/HCV-coinfecting injection drug users. *AIDS.* 2005 Oct;19 Suppl 3:S179-89.

24. Fleming CA, Tumilty S, Murray JE, Nunes D. Challenges in the treatment of patients coinfecting with HIV and hepatitis C virus: need for team care. *Clin Infect Dis.* 2005 Apr 15;40 Suppl 5:S349-54.
25. McLaren M, Garber G, Cooper C. Barriers to hepatitis C virus treatment in a Canadian HIV-hepatitis C virus coinfection tertiary care clinic. *Can J Gastroenterol.* 2008 Feb;22(2):133-7.
26. Taylor LE. Delivering care to injection drug users coinfecting with HIV and hepatitis C virus. *Clin Infect Dis.* 2005 Apr 15;40 Suppl 5:S355-61.
27. Kresina TF, Bruce RD, Cargill VA, Cheever LW. Integrating care for hepatitis C virus (HCV) and primary care for HIV for injection drug users coinfecting with HIV and HCV. *Clin Infect Dis.* 2005 Jul 1;41 Suppl 1:S83-8.
28. Lo Re V 3rd, Amorosa VK, Localio AR, et al. Adherence to hepatitis C virus therapy and early virologic outcomes. *Clin Infect Dis.* 2009 Jan 15;48(2):186-93.
29. Wagner GJ, Ryan GW. Hepatitis C virus treatment decision-making in the context of HIV coinfection: the role of medical, behavioral and mental health factors in assessing treatment readiness. *AIDS.* 2005 Oct;19 Suppl 3:S190-8.
30. Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the use of antiretroviral agents in HIV-1-infected adults and adolescents. Department of Health and Human Services. November 3, 2008;1-139. Accessed November 9, 2009.
31. Bruggmann P, Falcato L, Dober S, et al. Active intravenous drug use during chronic hepatitis C therapy does not reduce sustained virological response rates in adherent patients. *J Viral Hepat.* 2008 Oct;15(10):747-52.