ATTC

Addiction Technology Transfer Center Network

Funded by Substance Abuse and Mental Health Services Administration

HCVCurrent

Resources for Medical and Behavioral Health Professionals.

Increasing Hepatitis C Knowledge for Behavioral Health and Medical Providers

Trainer Manual

Substance Abuse and Mental Health Services Administration

SAMHSA

www.samhsa.gov • 1-877-SAMHSA-7 (1-877-726-4727)

Jointly published in 2015 by the:

Northeast and Caribbean Addiction Technology Transfer Center
NDRI-USA, Inc.
71 West 23rd Street, 4th Floor
New York, New York 10010
SAMHSA Grant Number: 5 UR1 TI024251

Pacific Southwest Addiction Technology Transfer Center
UCLA Integrated Substance Abuse Programs
11075 Santa Monica Boulevard, Suite 200
Los Angeles, California 90025
SAMHSA Grant Number: 5 UR1 TI024242

At the time of this publication, Pamela Hyde, JD, served as SAMHA Administrator. Daryl W. Kade, MA, served as the Acting CSAT Director, and Andrea Kopstein, PhD, MPH, served as Director of CSAT's Division of Services Improvement and Acting ATTC Government Project Officer.

Increasing Hepatitis C Knowledge for Behavioral Health and Medical Providers

Table of Contents

Increasing Hepatitis C Knowledge for Behavioral Health and Medical Providers

Background Information – *HCV Current Initiative*

HCV Current is a national initiative of the Addiction Technology Transfer Center (ATTC) Network to increase hepatitis C (HCV) knowledge among behavioral health and medical providers, especially staff at Federally Qualified Health Centers (FQHCs). To disseminate the latest on the rapidly evolving field of HCV, this initiative provides comprehensive resources for health professionals, including: online and face-to-face curricula and training; downloadable provider tools; and region-specific resources. *HCV Current* is funded by the Substance Abuse and Mental Health Services Administration (SAMHSA).

Approximately 2.5 to 4 million people are infected with hepatitis C virus (HCV) in the United States (SAMHSA, 2014). Baby boomers (those born between 1945 and 1965) and persons with mental health and substance use disorders face an increased risk for infection. Among people who have used or currently use intravenous drugs, one in three young adults and three in four older adults are HCV-infected (CDC, 2014). Dramatic medical advances in the past year have revolutionized the course of HCV treatment, increasing the role of primary care and behavioral health settings in addressing this public health concern.

HCV Current offers multiple educational opportunities and resources, including:

- ***HCV Snapshot: An Introduction to Hepatitis C for Health Care Professionals*** – a free, 90-minute online course providing an overview of HCV. The four self-paced modules cover: populations at risk, overview of HCV, screening processes, and treatment options. Continuing education is available. Additional course enrollment information is available at: http://www.healtheknowledge.org.

- ***Increasing Hepatitis C Knowledge for Behavioral Health and Medical Providers*** – A six-hour training curriculum that builds upon the information provided in the *HCV Snapshot* online course. A total of five training modules cover opportunities for promoting HCV screening and testing, strategies for linking patients to treatment, available treatment options, and patient considerations for treatment. The curriculum can be downloaded free of cost from the *HCV Current* website: http://www.attcnetwork.org/Projects/HCV_Home.aspx.
- The ***HCV RNA Provider Card*** is a small pocket card to help behavioral health and medical providers discuss HCV RNA test results with patients. The front provides a visual of the testing algorithm and the back provides step-by-step instructions for discussing results with patients. The product can be viewed or downloaded at for free on the *HCV Current* Products & Resources page: http://www.attcnetwork.org/Projects/HCV_Products.aspx.Hard copies will also be distributed at live training events.
- ***Regional Resources***: To address the local conditions and needs of communities, each ATTC Regional Center has compiled region-specific HCV resources and contact information. Additional details are available at: http://www.attcnetwork.org/Projects/HCV_Search.aspx.

What Does the Training Package Contain?

- PowerPoint Training Slides (with notes)
- Trainer's Guide with detailed instructions for how to convey the information and conduct the interactive exercises, embedded references used to develop the content of the presentation, and participant handouts

What Does This Trainer's Manual Contain?

- Slide-by-slide notes designed to help the trainer effectively convey the slide content
- Supplemental information (including references used) for select content to enhance the quality of instruction and suggestions for facilitating the group activities/role plays
- Copy of all participant handouts

How is This Trainer's Guide Organized?

For this manual, text that is shown in bold italics is a "***Note to the Trainer.***" Text that is shown in normal font relates to the "Trainer's Script" for the slide.

It is important to note that some slides in the PowerPoint presentation contain animation. Animations are used to call attention to particular aspects of the information or to present the information in a stepwise fashion to facilitate both the presentation of information and participant understanding. Getting acquainted with the slides, and practicing delivering the content of the presentation are essential steps for ensuring a successful, live training experience.

Suggested Trainer Criteria

The curriculum development team recommends that trainers (1) be experienced in conducting training for behavioral health and primary care providers (minimum of two years of general training experience); (2) have a background in behavior health and infectious diseases; and (3) have a baseline level of knowledge of current and emerging trends in screening, testing, diagnosis and treatment of hepatitis C.

General Information about Conducting the Training

The training is designed to be conducted in medium-sized groups (30-50 people). It is possible to use these materials with larger groups, but the trainer may have to adapt the small group exercises to ensure that there is adequate time to cover all of the content.

Materials Needed to Conduct the Training

- Computer with PowerPoint software installed (2003 or higher version) and LCD projector to show the PowerPoint training slides.
- When making photocopies of the PowerPoint presentation to provide as a handout to training participants, it is recommended that you print the slides three slides per page with lines for notes. Select "pure black and white" as the color option. This will ensure that all text, graphs, tables, and images print clearly.
- Flip chart paper and easel/white board, and markers/pens to write down relevant information, including key case study discussion points.

Overall Trainer Notes

It is critical that, prior to conducting the actual training, the trainer practice using this guide while showing the slide presentation in Slideshow Mode in order to be prepared to use the slides in the most effective manner.

Icon Key

Note to Trainer

Activity

References

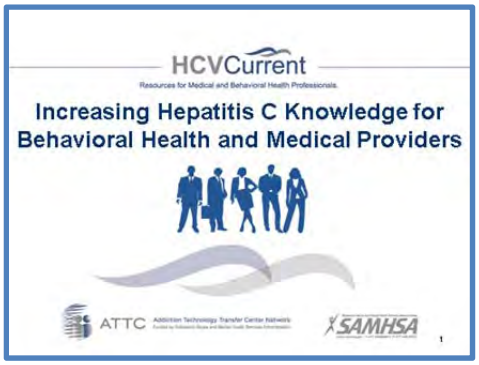
In Memoriam – A Tribute to Suzan Swanton, LCSW-C

Suzan Swanton served as the Project Officer for the SAMHSA-funded Addiction Technology Transfer Center Network. As a social worker, she was the epitome of the profession—empathetic and passionate, an advocate for the substance use disorder treatment field, and an unwavering supporter of those projects she believed would have a direct and profound impact. Suzan was dedicated to improving the quality of life for those most in need. She was particularly invested in our ATTC project focused on training behavioral health and medical providers about the silent disease of hepatitis C, and served as a valuable resource for us in designing the *HCV Current* Initiative. Suzan passed away on January 15, 2015 and left a major void in the lives of those she touched. In memory of our valued project officer, colleague, and friend, the ATTC Viral Hepatitis Workgroup members dedicate this Trainer Manual.

Increasing Hepatitis C Knowledge for Behavioral Health and Medical Providers

Slide-By-Slide Trainer Notes

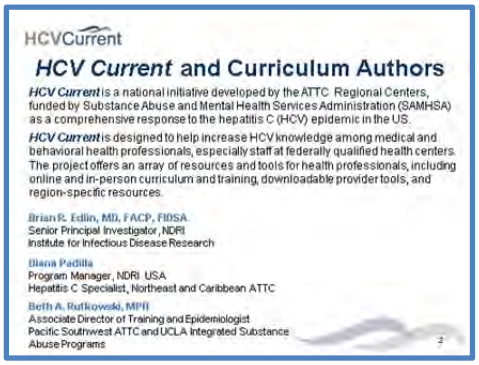
The notes below contain information that can be presented with each slide. This information is designed as a guidepost and can be adapted to meet the needs of the local training situation. Information can be added or deleted at the discretion of the trainer(s).



Slide 1: Title Slide

Before you begin, welcome participants and take care of housekeeping announcements, such as location of restrooms, turning off cell phones, participating actively, etc.

Welcome to "Increasing Hepatitis C Knowledge for Behavioral Health and Medical Providers," a face-to-face training and one of several components that makes up the ATTC Network's **HCV Current** ***Initiative.***

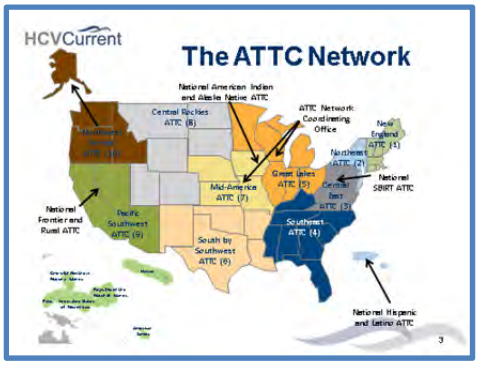


Slide 2: *HCV Current* and Curriculum Authors

The Substance Abuse and Mental Health Services Administration (SAMHSA) is the agency within the U.S. Department of Health and Human Services that leads public health efforts to advance the behavioral health of the nation. SAMHSA's mission is to reduce the impact of substance abuse and mental illness on America's communities.

Hepatitis C is an infection most commonly transmitted through injection drug use and is prevalent in persons within substance abuse treatment programs. In the last several years, research has also estimated that members of the baby boomer population are potentially at risk for hepatitis C infection.

In 2012, SAMHSA charged and funded the ATTC Network to develop a suite of products that would assist behavioral health and medical providers to be able to address hepatitis C. The collaboration between the centers resulted in the *HCV Current* initiative which provides expert information through online and face to face trainings, and other resources and tools for FQHCs across the country to integrate and enhance hepatitis C health care within their clinical settings.



Slide 3: The ATTC Network

Established in 1993 by the Substance Abuse and Mental Health Services Administration (SAMHSA), the ATTC Network is comprised of 10 Regional Centers, four National Focus Area Centers, and a Network Coordinating Office. Together the Network serves the 50 U.S. states, the District of Columbia, Puerto Rico, the U.S. Virgin Islands, and the U.S. Affiliated Pacific Jurisdictions of Guam, American Samoa, Palau, the Republic of the Marshall Islands, Federated States of Micronesia, and the Commonwealth of the Northern Mariana Islands.

Building on a rich history, the ATTC Network continuously strives to improve the quality of addictions treatment and recovery services by facilitating alliances among front line counselors, treatment and recovery services agency administrators, faith-based organizations, policy makers, the health and mental health communities, consumers and other stakeholders. By connecting them to the latest research and information through activities such as skills training, academic education, online and distance education, conferences, workshops, and publications, the ATTC Network responds to the emerging needs of the field.

As a nationwide, multidisciplinary resource for professionals in the addictions treatment and recovery services field, the ATTC Network serves to:

- Raise awareness of evidence-based and promising treatment and recovery practices,
- Build skills to prepare the workforce to deliver state-of-the-art addictions treatment and recovery services, and

(Notes for Slide 3, continued)

Slide 3: The ATTC Network

- Change practice by incorporating these new skills into everyday use for the purpose of improving addictions treatment and recovery outcomes.

Additional information is available at http://www.attcnetwork.org.

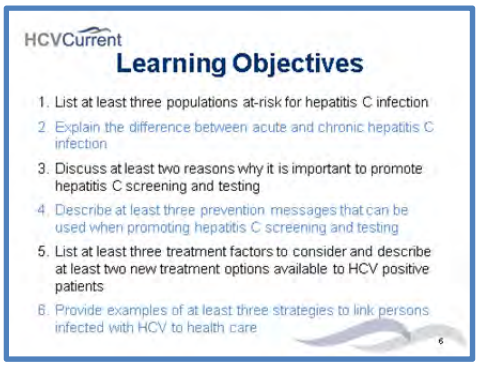
Slide 4: Logistics

The training is designed to be presented as either one 6-hour training, or as two 3-hour training sessions. The modules can be mixed and matched, depending on the background and experience of the training audience. The agenda includes time for breaks and lunch. Evaluation and accreditation will vary, depending on which ATTC Regional Center is presenting the training.

Slide 5: Training Goals

The goal of this training is to inform practice for medical and behavioral health providers in clinical settings, especially Federally Qualified Health Centers, (FQHCs).

This training can be provided either as a a single 6-hour (daylong) training or as two separate 3-hour trainings. All modules build on one another and are designed with lecture and interactive skills building activities.



Slide 6: Learning Objectives

Briefly review each of the six learning objectives with the audience.

Slide 7: Training Agenda

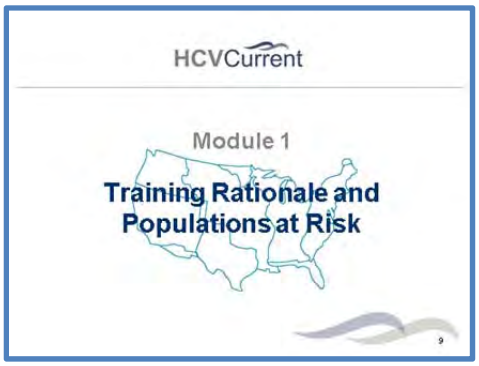
Module content builds upon content presented in previous modules, and this 6-hour training can easily be delivered in two separate segments. Modules 1-3 are focused on the need to increase hepatitis C education and testing- and counseling-specific information. Modules 4-5 are treatment-focused and include information on the integration of hepatitis C services into the existing health care infrastructure.

Slide 8: Introductions

In an effort to break the ice and encourage group interaction, take a few minutes to ask training participants to briefly share the answers to these three questions (e.g., Name, Organization, and Position). You can ask for several volunteers to share their responses, if the size of your audience prevents all participants from sharing.

If the group is too large for formal introductions, the trainer can quickly ask participants the following two questions to gauge their work setting and professional training:

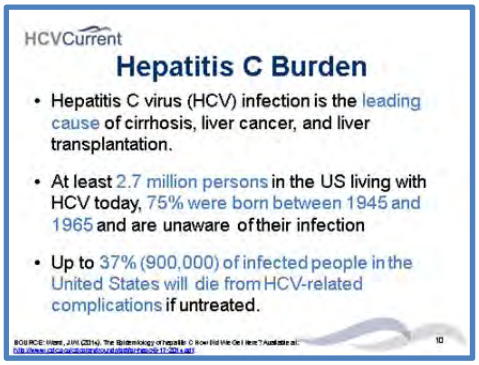
> ***1. How many [case managers, MFTs or LCSWs, counselors, administrators, physicians, PAs, nurse practitioners, nurses, medical assistants, dentists, etc.] are in the room? Did I miss anyone? {elicit responses}***
>
> ***2. How many people work in a [substance abuse, mental health, primary care, infectious disease] setting? Did I miss any settings? {elicit responses}***



Slide 9 [Transition Slide]: Module 1 – Training Rationale and Populations at Risk

Module 1 Goal: To review the training rationale and key populations at risk for hepatitis C.

Module 1 Objective: Participants will be able to list three populations at risk for hepatitis C infection.



Slide 10: Hepatitis C Burden

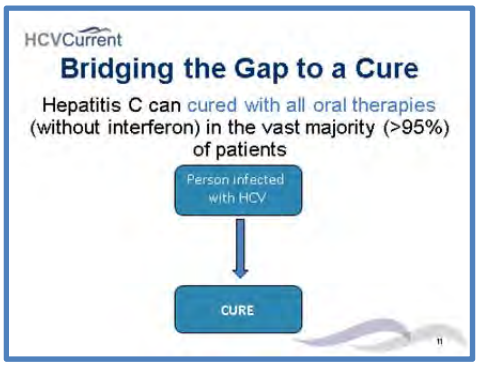
Hepatitis C (HCV) is a virus that infects the liver and causes inflammation. It is the leading cause of cirrhosis, liver cancer, and the most common reason for liver transplantation.

Because HCV is commonly asymptomatic, it tends to go undiagnosed. About 2.7 million people are infected with HCV in the US. According to the CDC, persons born between 1945 and 1965 make up 75% of all HCV infections. Because of the latent characteristics of HCV, persons with HCV are unaware of their infection.

More than 70% of registered deaths of HCV-infected individuals in 2007 were those born in the birth cohort, from 1945 to 1965. From 1999 to 2010, HCV deaths increased by 50%. Up to 350,000 will develop liver cancer or more specifically hepatocelullar carcinoma (HCC). Up to 900,000 people will die of HCV related complications, particularly if efforts are not focused on increasing screening and testing and facilitating linkage to health care for persons infected with HCV.

REFERENCE:

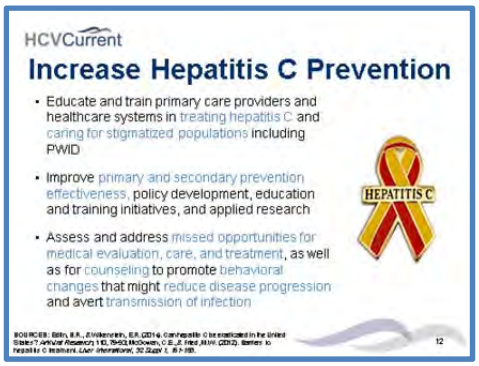
Ward, J.W. (2014). *The Epidemiology of hepatitis C How Did We Get Here?* Available at: http://www.cdc.gov/cdcgrandrounds/pdf/gr-hepc-6-17-2014.pdf.



Slide 11: Bridging the Gap to a Cure

Recent developments have resulted in highly tolerable (non-interferon) oral treatments for HCV, with a high cure rates. Despite the effectiveness of available treatment, many persons infected with HCV are not accessing health care and treatment.

The challenge, particularly in Federally Qualified Health Centers, is to identify persons with HCV risk, promote screening and testing, and facilitate linkage to health care and potentially a cure.



Slide 12: Increase Hepatitis C Prevention

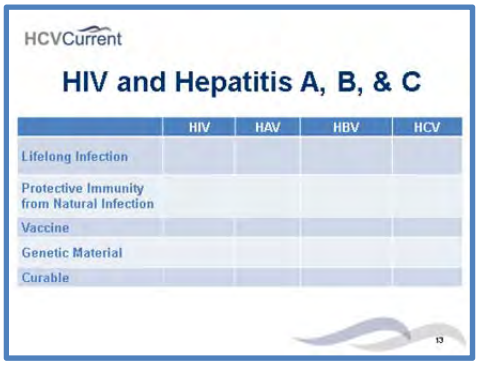
Various prevention steps can be used to help increase access to essential HCV healthcare and treatments. National surveys, such as the Hepatitis and Liver Cancer: A National Strategy for Prevention and Control of Hepatitis B and C (http://www.nap.edu/catalog/12793.html), have identified limited knowledge among health care professionals, persons at risk, and the public at large, which warrants a concerted effort to provide education to increase the knowledge of primary care providers and health care systems to address hepatitis C with potential persons at risk, including active drug injecting populations.

Other initiatives should include an increase in policies, funding, and systems that promote integrated services, access to education and training to increase primary and secondary prevention efforts, and application of current research to inform practice.

It is critical to evaluate clinical infrastructures for opportunities to implement HCV screening and testing, and develop and strengthen linkages to HCV health care within the continuum of care.

REFERENCES:

1. Edlin, B.R., & Wilkenstein, E.R. (2014). Can hepatitis C be eradicated in the United States? *Antiviral Research*, 110, 79-93; McGowan, C.E., & Fried, M.W. (2012). Barriers to hepatitis C treatment. *Liver International , 32 Suppl 1, 151-156.*
2. Ward, J.W. (2014). *The Epidemiology of hepatitis C How Did We Get Here?* Available at: http://www.cdc.gov/cdcgrandrounds/pdf/gr-hepc-6-17-2014.pdf.



Slide 13: HIV and Hepatitis A, B, & C

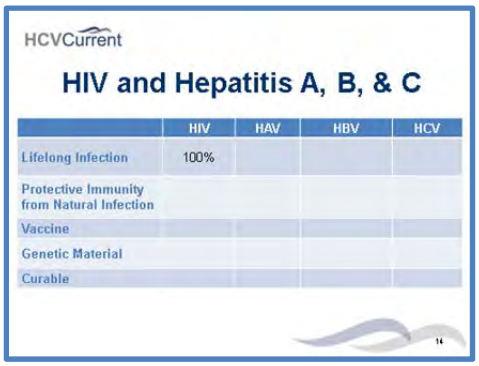
Slides 13-34 present a series of factors related to infectious diseases, including lifelong infection, protective immunity from natural infection, vaccine availability, genetic material, and whether or not a cure is available. This series of slides is best presented as an interactive conversation with the audience, where you allow them to provide their best guess, before you reveal the accurate information. To reveal a new piece of information, advance forward one slide. The following notes pertain to the entire slide series:

The viral infections featured in this series of slides share common and reflect distinctively different disease characteristics, from acute and/or chronic to lifetime immunity for some. Understanding the specific aspects of these infections is critical to understanding transmission, and appropriately tailoring counseling messages.

Most persons infected with HAV and HBV will spontaneously clear the virus (up to 90% for HBV) and may experience flu-like symptoms, which may or may not include jaundice (bilirubin accumulation in the blood) that causes yellowing of the skin and eyes. Both HAV and HBV can be vaccine preventable and lifetime protective immunity results from clearing or vaccinating against HAV and HBV.

Up to 10% of persons infected with HBV will develop chronic illness and can progress to cirrhosis, liver complications, and liver cancer.

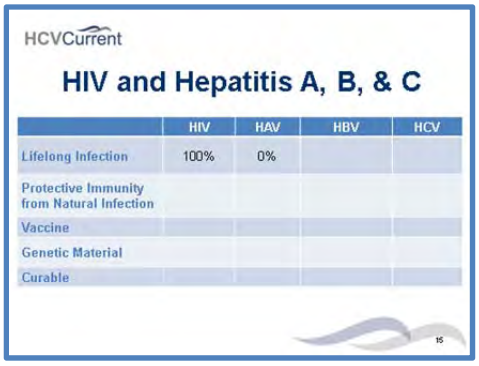
HBV and HIV cannot be cured but are preventable diseases. HCV can be cured.



Slide 14: HIV and Hepatitis A, B, & C (Continued)

This is a continuation from the previous slide. Refer to the Slide 13 notes for additional details.

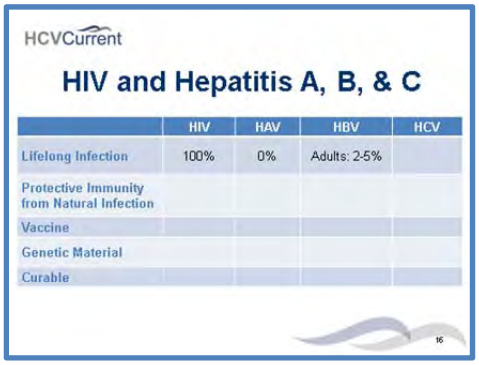
One hundred percent (100%) of people infected with HIV will have lifelong infection.



Slide 15: HIV and Hepatitis A, B, & C (Continued)

This is a continuation from the previous slide. Refer to the Slide 13 notes for additional details.

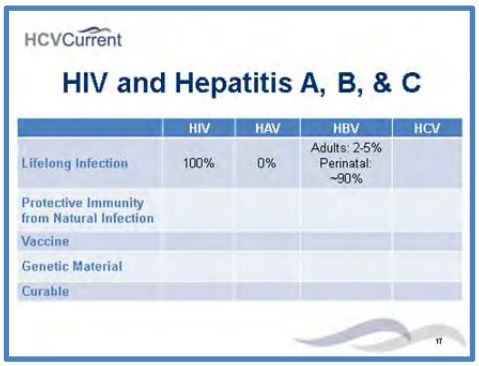
Zero percent (0%) of HAV-infected persons will have lifelong infection.



Slide 16: HIV and Hepatitis A, B, & C (Continued)

This is a continuation from the previous slide. Refer to the Slide 13 notes for additional details.

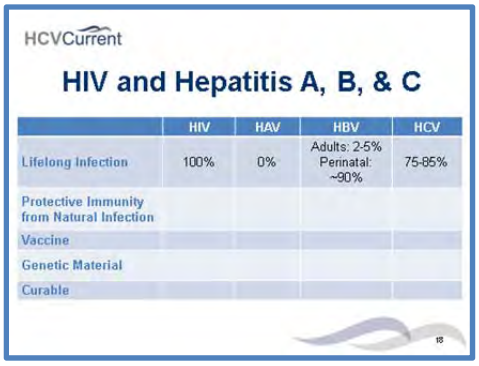
A very small percentage (2-5%) of adults infected with HBV will have lifelong infection.



Slide 17: HIV and Hepatitis A, B, & C (Continued)

This is a continuation from the previous slide. Refer to the Slide 13 notes for additional details.

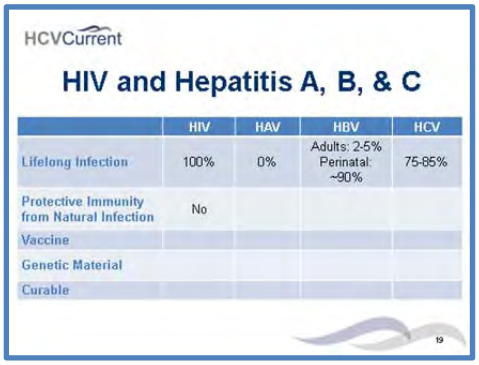
The vast majority (approximately 90%) of perinatal HBV infections will have lifelong infection.



Slide 18: HIV and Hepatitis A, B, & C (Continued)

This is a continuation from the previous slide. Refer to the Slide 13 notes for additional details.

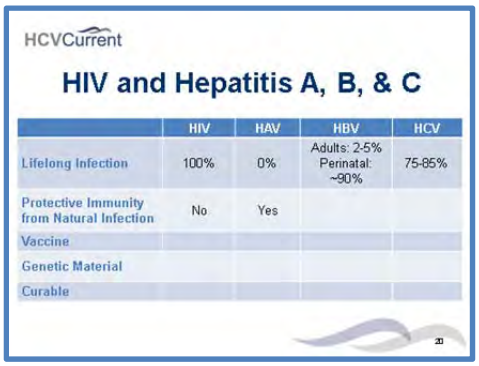
Approximately 75-85% of individuals infected with HCV will have lifelong infection.



Slide 19: HIV and Hepatitis A, B, & C (Continued)

This is a continuation from the previous slide. Refer to the Slide 13 notes for additional details.

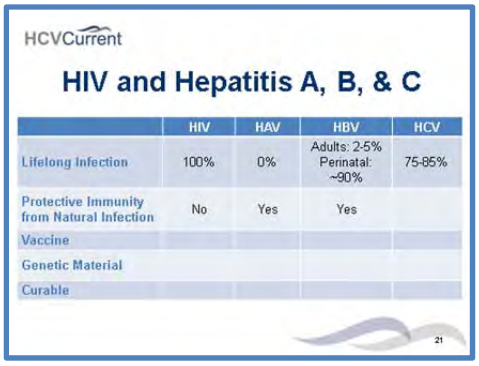
Protective immunity from natural infection of HIV does not exist.



Slide 20: HIV and Hepatitis A, B, & C (Continued)

This is a continuation from the previous slide. Refer to the Slide 13 notes for additional details.

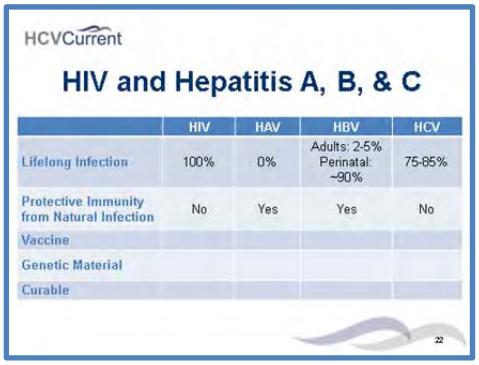
Protective immunity from natural infection of HAV does exist.



Slide 21: HIV and Hepatitis A, B, & C (Continued)

This is a continuation from the previous slide. Refer to the Slide 13 notes for additional details.

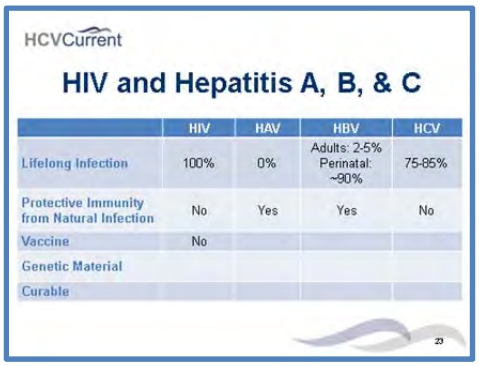
Protective immunity from natural infection of HBV does exist.



Slide 22: HIV and Hepatitis A, B, & C (Continued)

This is a continuation from the previous slide. Refer to the Slide 13 notes for additional details.

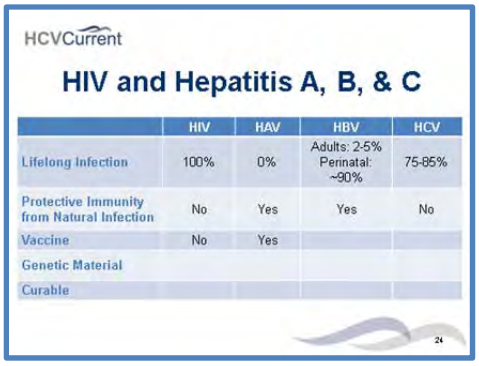
Protective immunity from natural infection of HCV does not exist.



Slide 23: HIV and Hepatitis A, B, & C (Continued)

This is a continuation from the previous slide. Refer to the Slide 13 notes for additional details.

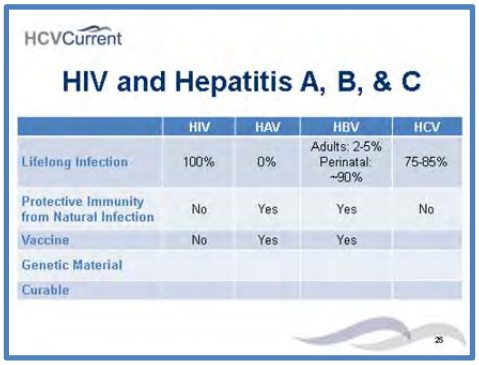
An HIV vaccine does not exist.



Slide 24: HIV and Hepatitis A, B, & C (Continued)

This is a continuation from the previous slide. Refer to the Slide 13 notes for additional details.

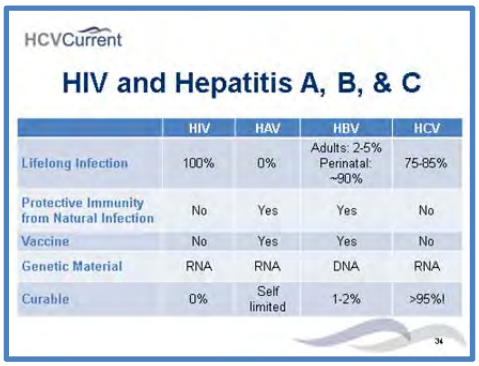
An HAV vaccine does exist.



Slide 25: HIV and Hepatitis A, B, & C (Continued)

This is a continuation from the previous slide. Refer to the Slide 13 notes for additional details.

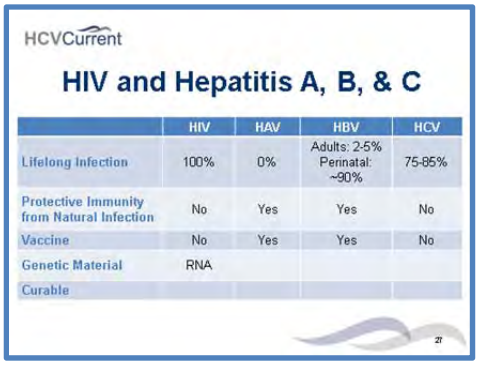
An HBV vaccine does exist.



Slide 26: HIV and Hepatitis A, B, & C (Continued)

This is a continuation from the previous slide. Refer to the Slide 13 notes for additional details.

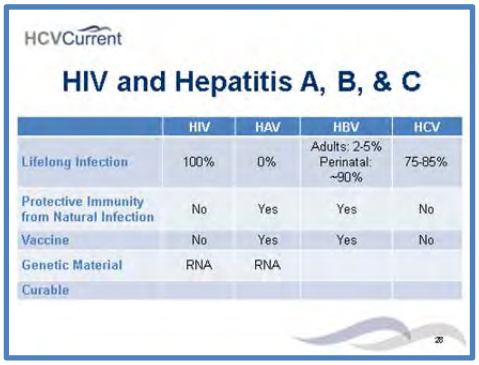
An HCV vaccine does not exist.



Slide 27: HIV and Hepatitis A, B, & C (Continued)

This is a continuation from the previous slide. Refer to the Slide 13 notes for additional details.

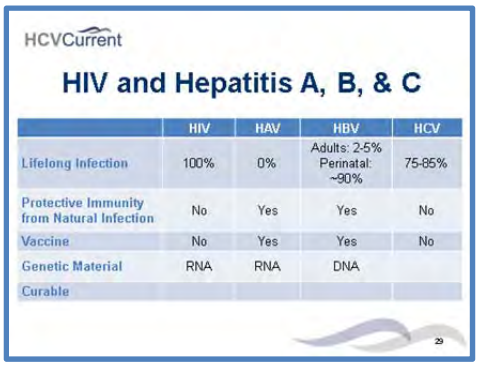
The genetic material of HIV consists of RNA.



Slide 28: HIV and Hepatitis A, B, & C (Continued)

This is a continuation from the previous slide. Refer to the Slide 13 notes for additional details.

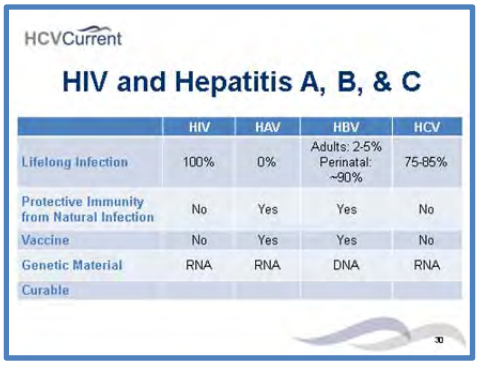
The genetic material of HAV consists of RNA.



Slide 29: HIV and Hepatitis A, B, & C (Continued)

This is a continuation from the previous slide. Refer to the Slide 13 notes for additional details.

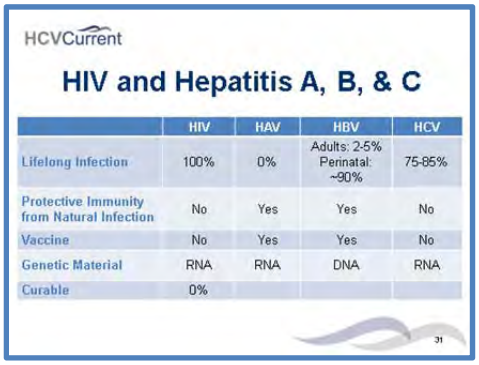
The genetic material of HBV consists of DNA.



Slide 30: HIV and Hepatitis A, B, & C (Continued)

This is a continuation from the previous slide. Refer to the Slide 13 notes for additional details.

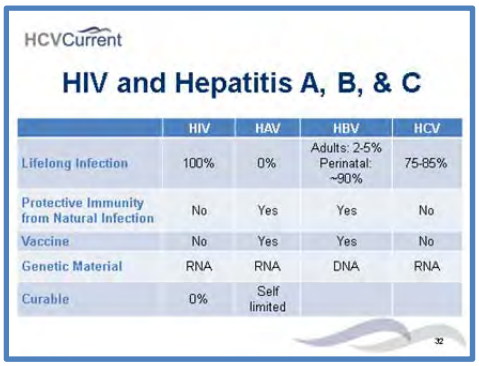
The genetic material of HCV consists of RNA.



Slide 31: HIV and Hepatitis A, B, & C (Continued)

This is a continuation from the previous slide. Refer to the Slide 13 notes for additional details.

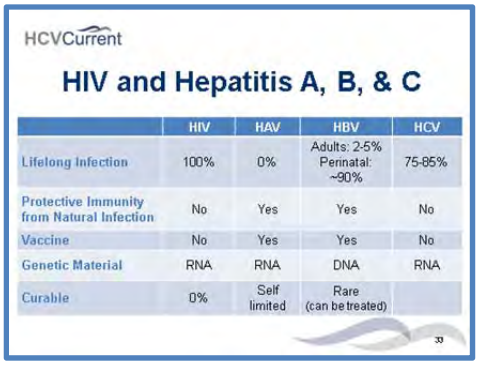
A cure to HIV does not exist.



Slide 32: HIV and Hepatitis A, B, & C (Continued)

This is a continuation from the previous slide. Refer to the Slide 13 notes for additional details.

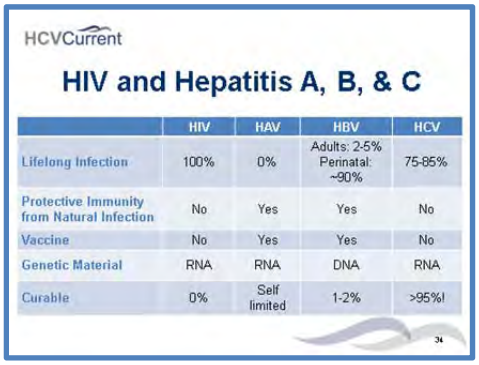
HAV is a self-limiting illness, which means it usually goes away on its own.



Slide 33: HIV and Hepatitis A, B, & C (Continued)

This is a continuation from the previous slide. Refer to the Slide 13 notes for additional details.

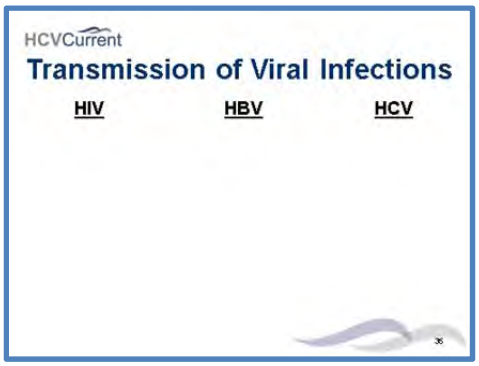
HBV is rarely curable, but can be treated.



Slide 34: HIV and Hepatitis A, B, & C (Continued)

This is a continuation from the previous slide. Refer to the Slide 13 notes for additional details.

The cure rate for HCV is now greater than 95%.



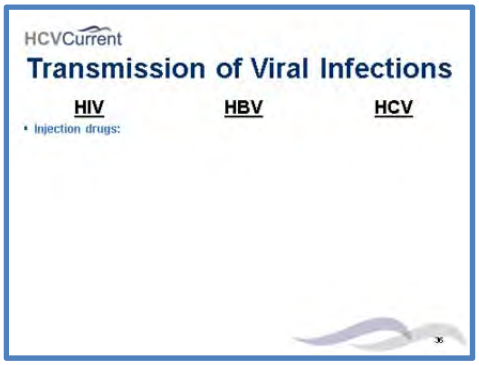
Slide 35: Transmission of Viral Infections

Slides 35-56 present a series of factors related to the transmission of viral infections. This series of slides is best presented as an interactive conversation with the audience, where you allow them to provide their best guess, before you reveal the accurate information. To reveal a new piece of information, advance forward one slide. The following notes pertain to the entire slide series:

Transmission of HIV, HBV, and HCV has been well-documented in health care settings. Although all three viruses are blood borne and share common routes of transmission, the epidemiology of transmission of each infection differs based on the virus involved and circumstances of the exposure.

HBV is more efficiently transmitted than HCV or HIV. In fact, when HBeAg is present, HBV is 100 times more likely than HIV to be transmitted after a percutaneous exposure to infected blood. HCV, while less infectious than HBV, is on average six times more likely than HIV to be transmitted after a percutaneous exposure.

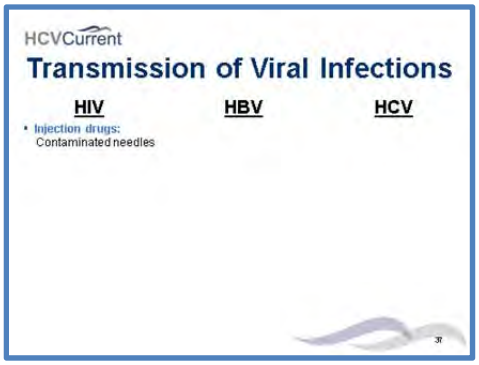
Although much attention has focused on preventing HIV transmission, it is important for health care providers to be mindful of all of these common blood borne pathogens. Measures for preventing transmission are common to all three of these viruses.



Slide 36: Transmission of Viral Infections (Continued)

This is a continuation from the previous slide. Refer to the Slide 35 notes for additional details.

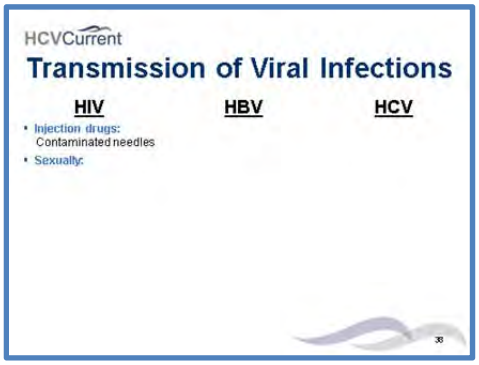
HIV can be transmitted through injection drug use.



Slide 37: Transmission of Viral Infections (Continued)

This is a continuation from the previous slide. Refer to the Slide 35 notes for additional details.

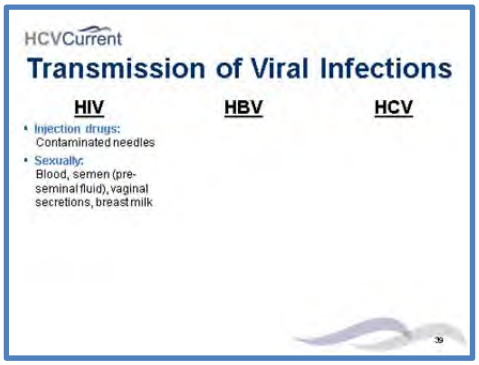
More specifically, HIV can be transmitted through the sharing of contaminated needles.



Slide 38: Transmission of Viral Infections (Continued)

This is a continuation from the previous slide. Refer to the Slide 35 notes for additional details.

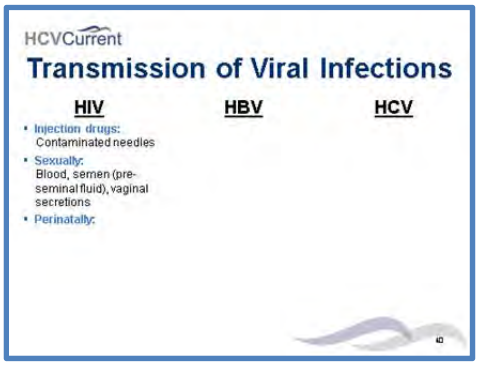
HIV can also be transmitted through sexual contact.



Slide 39: Transmission of Viral Infections (Continued)

This is a continuation from the previous slide. Refer to the Slide 35 notes for additional details.

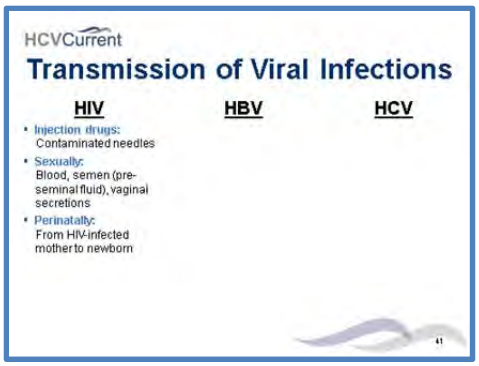
More specifically, HIV can be transmitted through blood, semen (pre-seminal fluid), and vaginal secretions.



Slide 40: Transmission of Viral Infections (Continued)

This is a continuation from the previous slide. Refer to the Slide 35 notes for additional details.

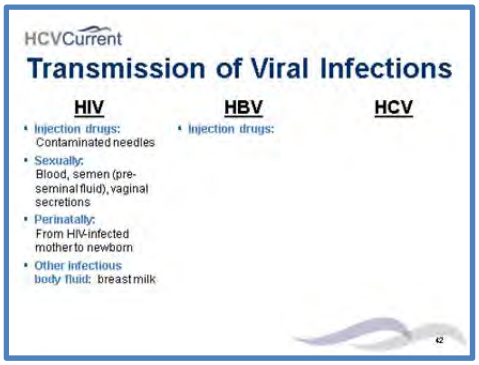
Perinatal transmission of HIV is possible, as well.



Slide 41: Transmission of Viral Infections (Continued)

This is a continuation from the previous slide. Refer to the Slide 35 notes for additional details.

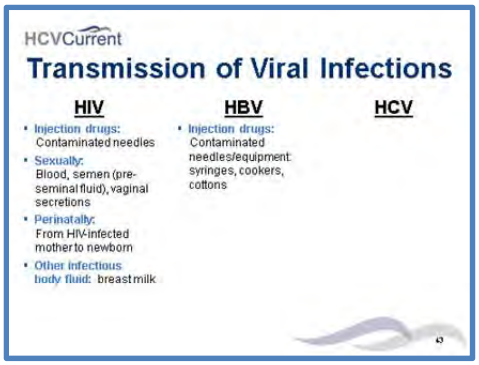
More specifically, HIV can be transmitted from an HIV-infected mother to her newborn.



Slide 42: Transmission of Viral Infections (Continued)

This is a continuation from the previous slide. Refer to the Slide 35 notes for additional details.

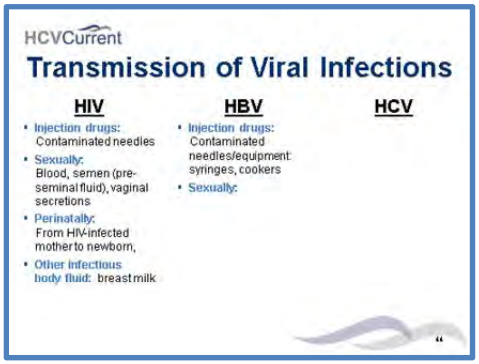
HIV can also be transmitted by other infectious body fluid, such as breast milk.



Slide 43: Transmission of Viral Infections (Continued)

This is a continuation from the previous slide. Refer to the Slide 35 notes for additional details.

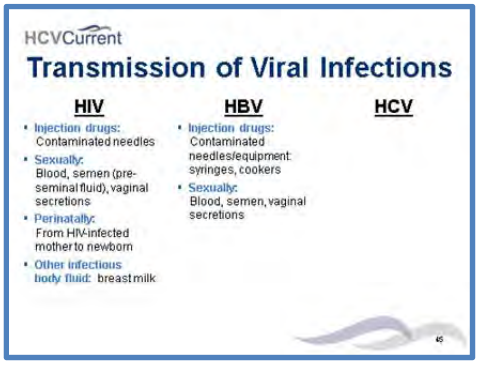
HBV can be transmitted by injection drug use, more specifically through sharing of contaminated needles/equipment, syringes, cookers, and cotton.



Slide 44: Transmission of Viral Infections (Continued)

This is a continuation from the previous slide. Refer to the Slide 35 notes for additional details.

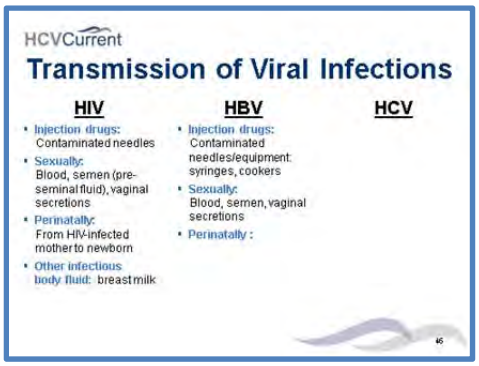
HBV can also be transmitted by sexual contact.



Slide 45: Transmission of Viral Infections (Continued)

This is a continuation from the previous slide. Refer to the Slide 35 notes for additional details.

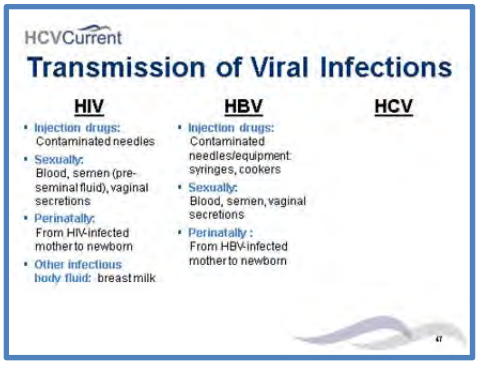
More specifically, HBV can be transmitted sexually by blood, semen, and vaginal secretions.



Slide 46: Transmission of Viral Infections (Continued)

This is a continuation from the previous slide. Refer to the Slide 35 notes for additional details.

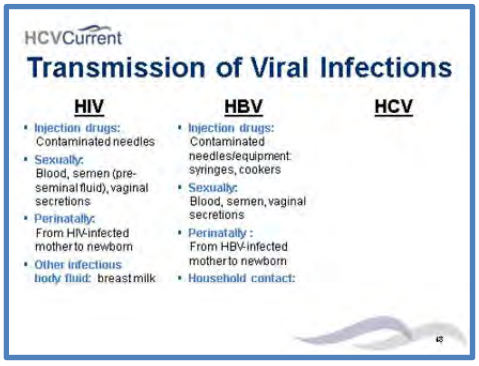
Perinatal transmission of HBV is possible, as well.



Slide 47: Transmission of Viral Infections (Continued)

This is a continuation from the previous slide. Refer to the Slide 35 notes for additional details.

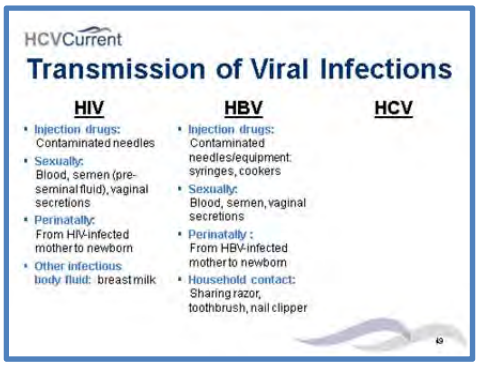
More specifically, HBV can be transmitted from an HBV-infected mother to her newborn.



Slide 48: Transmission of Viral Infections (Continued)

This is a continuation from the previous slide. Refer to the Slide 35 notes for additional details.

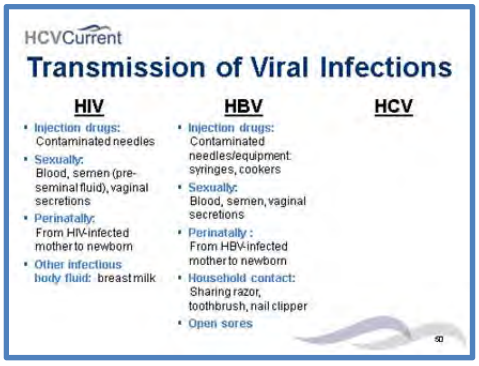
HBV can also be transmitted through household contact.



Slide 49: Transmission of Viral Infections (Continued)

This is a continuation from the previous slide. Refer to the Slide 35 notes for additional details.

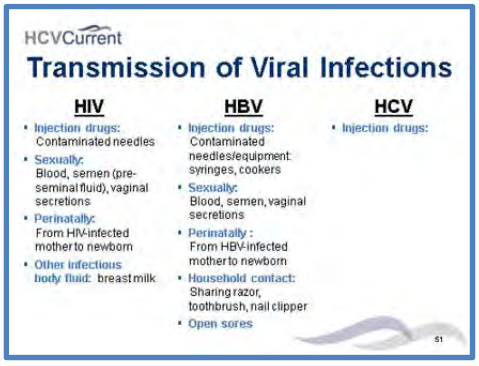
More specifically, HBV can be transmitted by sharing a razor, toothbrush, or nail clipper.



Slide 50: Transmission of Viral Infections (Continued)

This is a continuation from the previous slide. Refer to the Slide 35 notes for additional details.

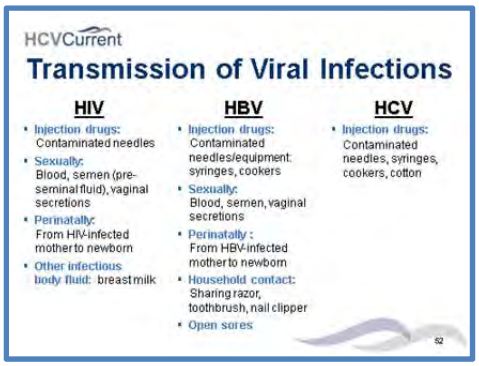
Lastly, HBV can be transmitted through open sores.



Slide 51: Transmission of Viral Infections (Continued)

This is a continuation from the previous slide. Refer to the Slide 35 notes for additional details.

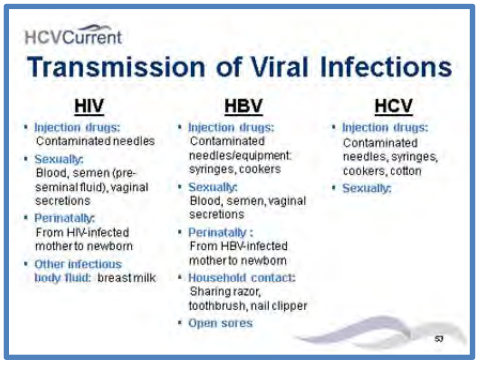
HCV can be transmitted through injection drug use.



Slide 52: Transmission of Viral Infections (Continued)

This is a continuation from the previous slide. Refer to the Slide 35 notes for additional details.

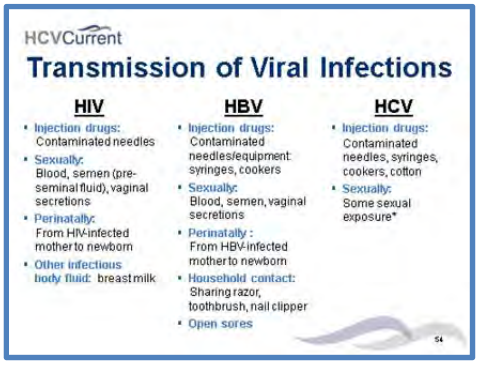
More specifically, HCV can be transmitted by sharing contaminated needles, syringes, cookers, and cotton.



Slide 53 Transmission of Viral Infections (Continued)

This is a continuation from the previous slide. Refer to the Slide 35 notes for additional details.

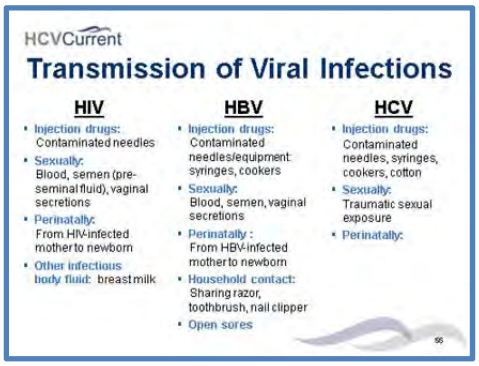
HCV can be transmitted through sexual contact.



Slide 54: Transmission of Viral Infections (Continued)

This is a continuation from the previous slide. Refer to the Slide 35 notes for additional details.

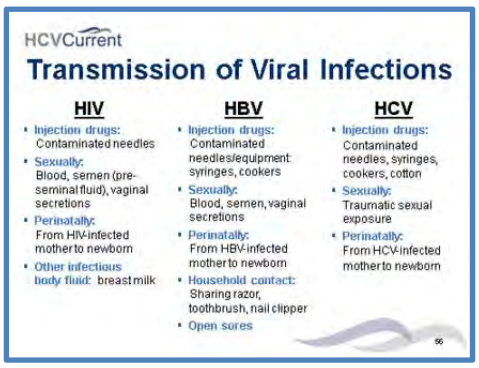
More specifically, HCV can be transmitted through some sexual exposure (next slide will reveal the type of sexual exposure).



Slide 55: Transmission of Viral Infections (Continued)

This is a continuation from the previous slide. Refer to the Slide 35 notes for additional details.

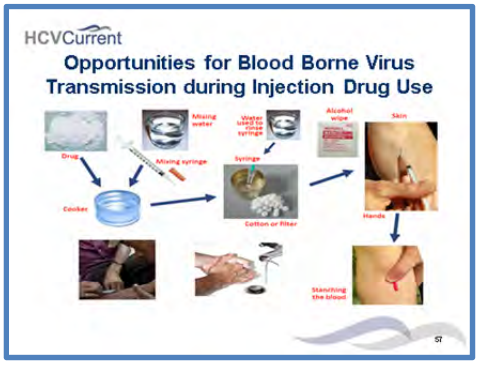
The sexual exposure that can result in HCV is traumatic sexual exposure. In addition, perinatal transmission HCV is possible.



Slide 56: Transmission of Viral Infections (Continued)

This is a continuation from the previous slide. Refer to the Slide 35 notes for additional details.

More specifically, HCV can be transmitted from an HCV-infected mother to her newborn.



Slide 57: Opportunities for Blood Borne Virus Transmission during Injection Drug Use

It is important to understand the opportunities for contamination during the preparation and injection of drugs, so we can educate our patients about these matters. Using syringes safely is something we understand very well and teaching safe injection practices to our patients can be lifesaving.

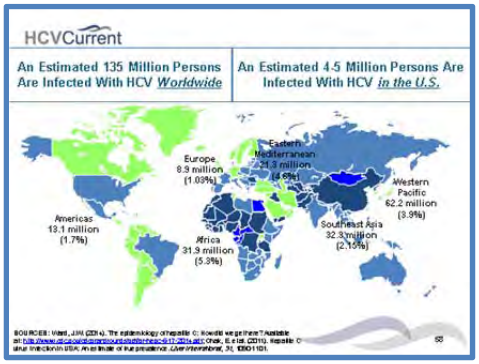
The drug itself is not usually contaminated with either viral or bacterial pathogens. But we put the drug into a container, a cooker, in order to mix it with water. If the cooker has been used previously by another person, it may be contaminated. Contaminated cookers are one of the most common routes of HCV transmission. Then, the drugs will need to get mixed with water. If the water is in a cup, who has used the cup previously? If the water is pink, or if someone has already put their needle into it, it may be contaminated. The water needs to get into the cooker, and usually a syringe will be used for that. If the syringe is not a new sterile syringe but one that has been used before, you can use your own new sterile syringe to inject the drug, but the solution you use may already be contaminated.

Material, such as cotton, is needed to filter the drug solution. If you place the cotton in the cooker with your fingers, and your fingers have blood on them, the solution may become contaminated. You will want to wipe the injection site with alcohol to prevent a bacterial infection, such as an abscess or endocarditis. If the cotton swab has already been used by another person to stanch the bleeding after an injection, it may be contaminated.

(Notes for Slide 57, continued)

Slide 57: Opportunities for Blood Borne Virus Transmission during Injection Drug Use

Finally, giving injections to another person turns out to be extremely common, because some people aren't able to access their own veins. It is important to emphasize the importance of washing hands before and after giving an injection. You wash your hands beforehand to protect the person to whom you are giving an injection. You wash your hands afterwards to protect yourself.



Slide 58: [No Title]

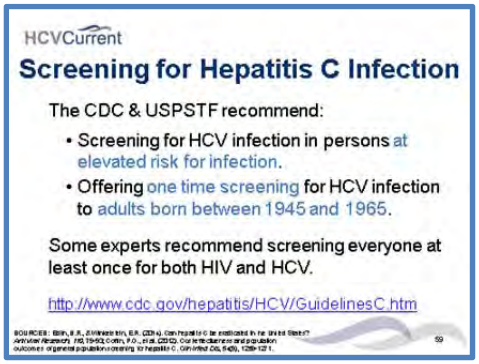
****ANIMATIONS****

According to the CDC Public Health Rounds report dated June 7, 2014, 135 million people throughout the world are infected with HCV; in the U.S. there are over 5 million, including hard to reach and marginalized populations.

The National Health and Nutrition Examination Survey (NHANES) samples only the civilian, non-institutionalized population of the USA and may have underestimated the prevalence of hepatitis C virus (HCV) in this country. Research done by Chak and colleagues added previously excluded populations such as incarcerated, homeless, nursing home residents, hospitalized and active military personnel, health care workers, and long term dialysis patients, suggesting that there are at least 5.2 million persons with HCV living in the USA today, approximately 1.9 million of whom were unaccounted for in the NHANES survey.

REFERENCES:

1. Chak, E., Talal, A. H., Sherman, K. E., Schiff, E. R. and Saab, S. (2011). Hepatitis C virus infection in USA: An estimate of true prevalence. *Liver International, 31*, 1090–1101.
2. Ward, J.W. (2014). The epidemiology of hepatitis C: How did we get here: Available at http://www.cdc.gov/cdcgrandrounds/pdf/gr-hepc-6-17-2014.pdf.



Slide 59: Screening for Hepatitis Infection

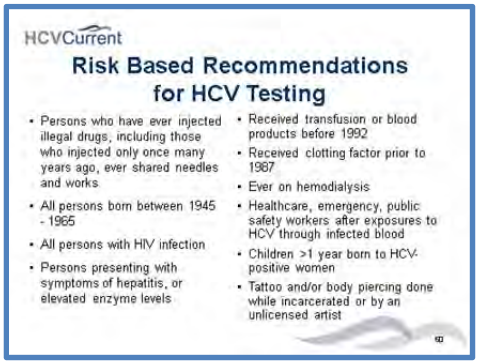
As a result of surveillance outcomes, the CDC and United States Preventive Services Task Force (USPSTF) recommend that screening for hepatitis C infection occur with all symptomatic adults at high risk of infection without known liver disease or functional abnormalities.

According to the CDC and USPSTF, persons born between 1945 and 1965 account for three quarters (75%) of all HCV infections and should be offered a one time screening for HCV. This birth cohort is at highest risk for liver cancer and HCV related disease and cirrhotic liver complications

The CDC's testing recommendations for Hepatitis C Infection are available at: http://www.cdc.gov/hepatitis/HCV/GuidelinesC.htm. Advantages of universal screening for HIV and HCV include simultaneous screening for both viruses, which capitalizes on a one-time visit.

REFERENCES:

1. Edlin, B.R., & Winkelstein, E.R. (2014). Can hepatitis C be eradicated in the United States? *Antiviral Research, 110,* 79-93.
2. Coffin, P.O., et al. (2012). Cost-effectiveness and population outcomes of general population screening for hepatitis C. *Clin Infect Dis*, 54(9), 1259-1271.



Slide 60: Risk-Based Recommendations for HCV Testing

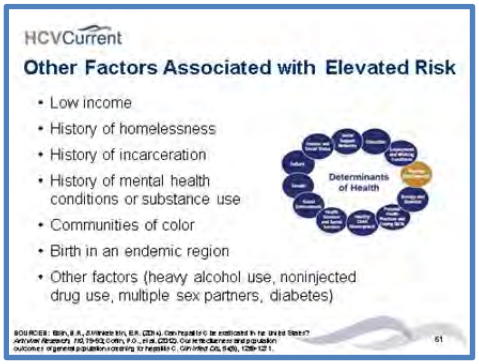
CDC risk-based recommendations for HCV testing identifies the populations to whom HCV screening should be offered, but also correlates with the high-risk era prior to HCV disease identification in 1989.

Percutaneous exposure is the most efficient mode of HCV transmission, which identifies persons who have ever injected drugs even once at highest risk for HCV infection. Most studies report a prevalence of 50% or more through injection drug use.

Although the USPSTF identifies persons born between 1945-1965 to be at high risk and they should be offered a one time HCV screening test, the recommendations do not conclusively identify risk factors for this population. Reports and studies show that during the early 1980s, there were high rates of injection drug use, syringe exchange programs and other harm reduction strategies had not been implemented then, universal precautions had yet to be adopted in clinical settings, and current blood screening protocols were not initiated until after 1992 resulting from HCV research.

Hepatitis C is often asymptomatic during the early years of HCV infection, however symptoms and/or elevated enzyme levels may be indicative of advanced liver disease. These persons should be readily offered an HCV screening.

The CDC's testing recommendations for Hepatitis C Infection are available at: http://www.cdc.gov/hepatitis/HCV/GuidelinesC.htm.



Slide 61: Other Factors Associated with Elevated Risk

Several groups not listed in the CDC risk-based recommendations have also been identified in studies as sharing common factors from a social, demographic, and behavioral perspective, including:

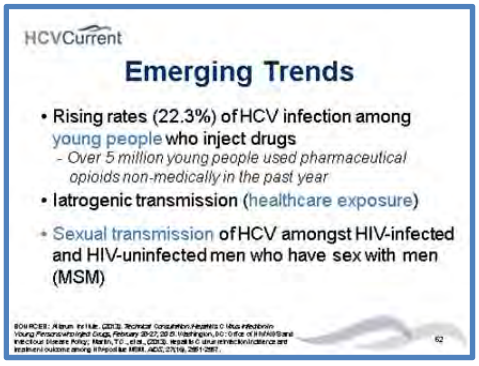
- Low income communities
- History of homelessness
- History of incarceration
- History of mental health conditions or substance use
- African American ethnicities
- Immigrants from endemic regions

Offering a one-time screening for all populations as a standard of health care would simplify integration of HCV services into clinical settings and maximize health care opportunities for identification and engagement of persons at risk.

Information regarding cost-effectiveness and population outcomes of general population screening for hepatitis C is available at: http://cid.oxfordjournals.org/content/54/9/1259.full.pdf+html

REFERENCES:

1. Edlin, B.R., & Winkelstein, E.R. (2014). Can hepatitis C be eradicated in the United States? *Antiviral Research, 110,* 79-93.
2. Coffin, P.O., et al. (2012). Cost-effectiveness and population outcomes of general population screening for hepatitis C. *Clin Infect Dis*, 54(9), 1259-1271.



Slide 62: Emerging Trends

Recent studies from across the country have reported that urban and rural youth account for the newest increases in the rate of HCV infection. Many youth initiated drug use as early as 10 years of age with opioids such as hydrocodone and oxycodone and have progressed to injecting heroin.

Between 2006 and 2012, at least 30 states had experienced increases in their hepatitis C infection rates, with more than half reporting at least a 200 percent increase in acute infections among their under-30 population. Overall, the prevalence of acute HCV cases among people under 30 rose from 36 to 49 percent in just six years.

Although rare, iatrogenic transmission has played a role in HCV infection rates in health care settings. Outbreaks have been reported in non-hospital settings where infection control oversight are often lacking in adhering to principles of infection control. Standard precautions and training of appropriate practices and techniques with augmented oversight and uniform regulation can address this type of transmission.

Iatrogenic is especially possible in ambulatory surgery centers, and in places there endoscopy procedures are conducted, especially when multidose medication vials are used.

Studies are presently reflecting an increase in HCV infection amongst men who have sex with men, particularly those who have spontaneously cleared or successfully treated past HCV infection with sexual exposure as the only identified risk behavior. Additional information is available at: http://aids.gov/pdf/hcv-and-young-pwid-consultation-report.pdf.

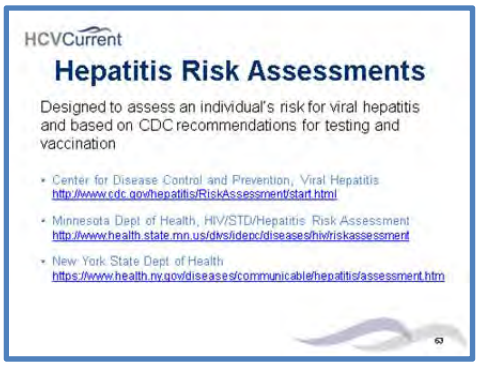
(Notes for Slide 62, continued)

Slide 62: Emerging Trends

REFERENCES:

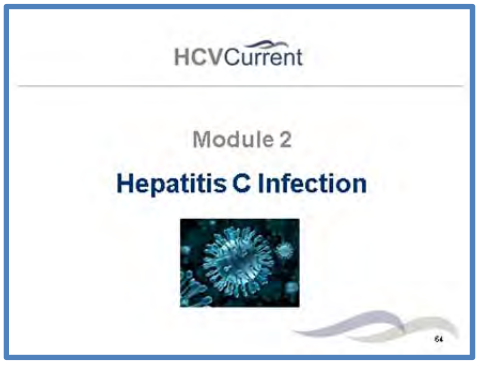
1. Altarum Institute. (2013). *Technical Consultation: Hepatitis C Virus Infection in Young Persons who Inject Drugs, February 26-27, 2013*. Washington, DC: Office of HIV/AIDS and Infectious Disease Policy.
2. Martin, T.C., et al., (2013). Hepatitis C virus reinfection incidence and treatment outcome among HIV-positive MSM. *AIDS, 27*(16), 2551-2557.

Slide 63: Hepatitis Risk Assessments



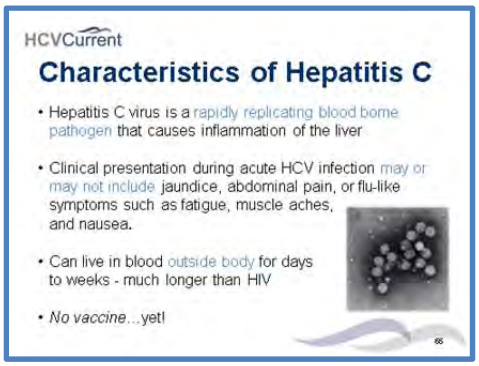
A variety of hepatitis risk assessments have been developed and can serve as helpful tools to use in practice. Hepatitis rick assessment tools are designed to be self-administered or can be used in a variety of settings where immunizations or screenings are available. Some settings distribute the assessment to patients waiting to be called for consultation or patients can be encouraged to access assessments online.

Slide 64: Module 2 – Hepatitis C Infection



Module 2 Goal: To review basic information about hepatitis C infection, including the history of HCV, the definition of acute and chronic HCV infection, nonspecific symptoms of HCV, cirrhosis and decompensated cirrhosis, and a review of why it is important to monitor liver health and disease progression.

Module 2 Objective: Participants will be able to describe the difference between acute and chronic hepatitis C infection.



Slide 65: Characteristics of Hepatitis C

Hepatitis C is a chronic blood-borne pathogen (infectious agent) that infects liver cells (hepatocytes) replicating trillions of virions a day and causing hepatitis, or liver inflammation.

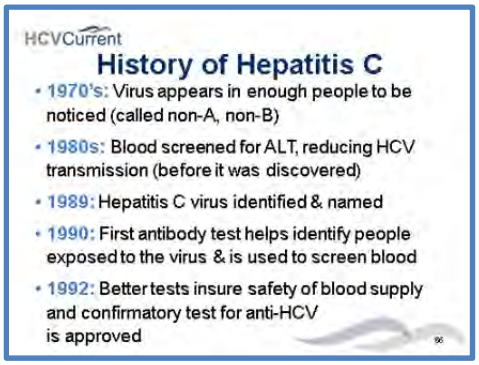
In the growth of viruses, a single virus infects a cell and the infectious process produces many, typically a hundred or more, new viruses. Given the "amplification" of viruses from one, to a hundred, to thousands in just two or three generations, it is easy to see why viral infections can move swiftly within an organism, or between organisms. Once they have escaped the host cell, the newly created viruses infect new cells, endlessly repeating this process - each time creating thousands of new viruses and causing disease, or even death, in their hosts.

Those who are acutely symptomatic may exhibit fever, fatigue, decreased appetite, nausea, vomiting, abdominal pain, dark urine, grey-colored faces, joint pain, and jaundice (yellowing of skin and the whites of the eyes).

The HCV virus can live in blood, even on dry surfaces for 16 hours but not more than 4 days.

REFERENCES:

1. The C. Everett Koop Institute, *Hepatitis C, An Epidemic for Anyone*, available at: http://www.epidemic.org/thefacts/viruses/viralreplication.php.
2. World Health Organization, *Hepatitis C*, available at: http://www.who.int/mediacentre/factsheets/fs164/en.



Slide 66: History of Hepatitis C

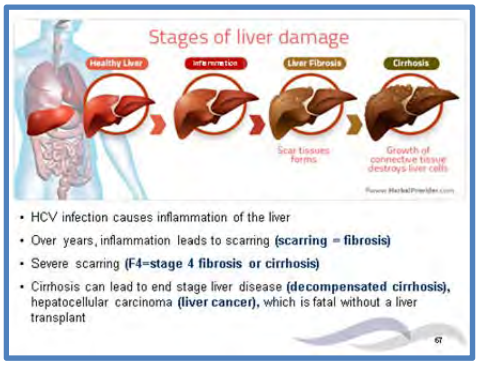
Review the time line of the various points of disease identification and research developments.

It is believed that hepatitis C has been around for hundreds of thousands of years. Between 1963 and 1973, blood tests were developed for identifying hepatitis A (HAV) and hepatitis B. (HBV). Many transfusion-related blood samples tested negative for both HAV and HBV and were considered non-A, and non-B. It is now believed that approximately 90-95% of cases previously classified as non-A, non-B (NA/NB) were actually HCV.

In 1989, hepatitis C virus was identified and named. In 1992, a highly sensitive antibody blood test was implemented nationwide to screen blood donors and to identify people exposed to the HCV and is still being used today.

<u>REFERENCE</u>:

HCV Advocate, *HCSP Fact Sheet, A Brief History of Hepatitis C*, available at: http://hcvadvocate.org/hepatitis/factsheets_pdf/Brief_History_HCV.pdf.



Slide 67: Stages of Liver Disease

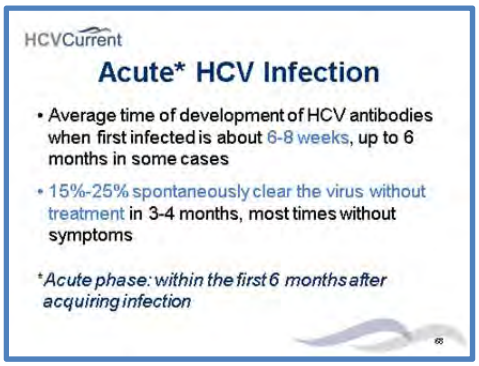
HCV infection causes liver inflammation over time (10-15 years) and the infected person many not notice any obvious symptoms.

A normal liver is smooth, red, and rubbery. Uninterrupted liver inflammation (no treatment) progresses to scarring. Scar tissue replaces healthy liver cells causing fibrosis and may impact liver functions. Eventually, the liver becomes hardened, nodular, and turns a dark yellow, green, or brown color. Because there is generally no pain or symptoms during this stage, fibrosis can progress further to cirrhosis.

Once a person has been diagnosed with cirrhosis, treatment will focus on keeping the condition from getting worse. It may be possible to stop or slow the progression of liver damage. It is important to protect the individual's healthy liver tissue. Cirrhosis can lead to end stage liver disease, and liver cancer.

REFERENCE:

American Liver Foundation, *The Progression of Liver Disease*, available at: http://hcvadvocate.org/hepatitis/factsheets_pdf/Brief_History_HCV.pdf.



Slide 68: Acute* HCV Infection

Most commonly, acute (initial stage or short term) hepatitis C infection is defined as the 6-month time period following acquisition of hepatitis C virus. The definition of acute hepatitis C is irrespective to whether the patient has clinical signs or symptoms of acute hepatitis. The rationale for choosing six months as the time period to define acute infection is based on evidence that most individuals who clear HCV will do so within six months.

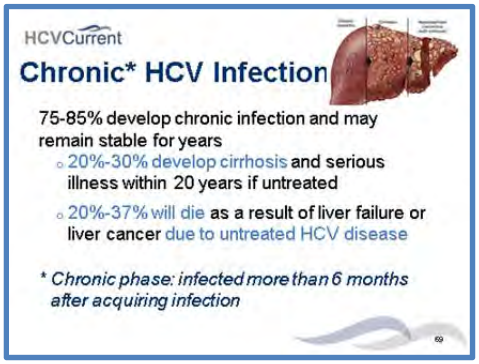
If symptoms from acute infection develop, they usually do so within 4 to 12 weeks (mean timeframe is 6 to 7 weeks) after infection has occurred and persist for 2 to 12 weeks. Only 15 to 20% of symptomatic acute liver disease in the United States is thought to result from acute HCV.

For patients with acute HCV infection in the United States, an estimated 60 to 70% will have no obvious symptoms, 20 to 30% will have jaundice, and 10 to 20% will have non-specific symptoms.

Approximately 15%–25% of persons clear the virus from their bodies without treatment and do not develop chronic infection; the reasons for this are not well known.

REFERENCES:

1. University of Washington, *Hepatitis C Online*, available at: http://www.hepatitisc.uw.edu/go/screening-diagnosis/acute-diagnosis/core-concept/all.
2. Centers for Disease Control and Prevention, *Hepatitis C Information for Professionals*, available at: http://www.cdc.gov/hepatitis/HCV/HCVfaq.htm.



Slide 69: Chronic* HCV Infection

Chronic refers to long-lasting (e.g., more than 6 months) liver infection. During the first 6 months of the infection, it is called acute hepatitis. For most people with acute hepatitis C – up to 80% – their illness moves on to a chronic, lasting hepatitis C infection.

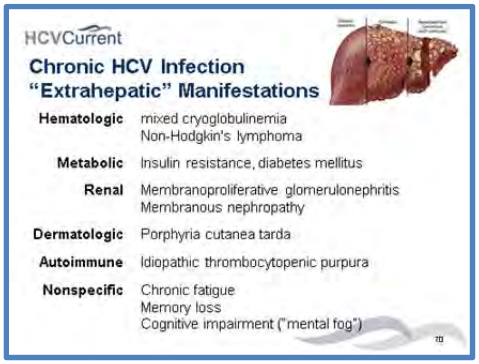
About 85% of people with acute hepatitis C develop chronic hepatitis C, according to the CDC. Of those, up to 70% will suffer from severe liver damage. An additional 20% will develop cirrhosis.

Of those with chronic HCV infection, the risk of cirrhosis of the liver is 15-30% within 20 years.

Mortality is under estimated. Only 33% of liver-related deaths among HCV infected persons are reported on Vital Records. Approximately 350,000 to 500,000 people each year die from hepatitis C-related liver diseases.

REFERENCES:

1. World Health Organization, *Hepatitis C Fact Sheet, April 2014*, available at: http://www.who.int/mediacentre/factsheets/fs164/en.
2. Healthline, *Chronic Hepatitis C: Symptoms, Diagnosis, and Treatment*, available at: http://www.healthline.com/health-slideshow/chronic-hepatitis-c#2.



Slide 70: Chronic HCV Infection "Extrahepatic" Manifestations

"Extra-hepatic" means outside the liver. Approximately 40% of persons with chronic HCV infection may experience at least one of several extrahepatic manifestations of hepatitis C. Clinicians may or may not recognize, diagnose, and treat such extrahepatic syndromes, particularly for patients with asymptomatic HCV infection. Awareness of the range of potential extrahepatic manifestations could facilitate earlier HCV diagnosis and more appropriate and timely treatment of these disorders.

Hematologic: Mixed cryoglobulinemia is a condition in which antibodies ("globulins") against HCV in the bloodstream clump together with the virus into what are called "immune complexes." These are clumps of antibody and virus that congeal in a test tube when blood is taken out of the body and cooled down – hence "cryo-globulinemia." In the body, immune complexes can be deposited in the skin, kidneys, nerves, blood vessels, and other tissues, causing inflammation and other problems. This can cause many types of symptoms, including fatigue, muscle or joint aches, pain in the extremities, purple skin spots or sores (often caused by vasculitis, an inflammation of blood vessels), or kidney disease.

Lymphoma is a cancer of immune cells, causing swelling of the lymph glands and other problems.

Metabolic: A variety of endocrine gland dysfunctions have been found to be more common in patients with hepatitis C. The most well-described disorders are type II diabetes, insulin resistance (which can cause diabetes), and hypothyroidism (an underactive thyroid gland).

(Notes for Slide 70, continued)

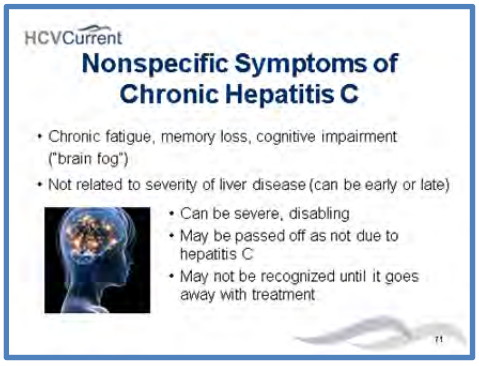
Slide 70: Chronic HCV Infection "Extrahepatic" Manifestations

Renal: Renal (kidney) involvement is commonly the greatest cause of morbidity in patients with mixed cryoglobulinemia and often justifies more aggressive treatment of the disease. The most common clinical findings from renal disease in patients with mixed cryoglobulinemia are proteinuria (the presence of protein in the urine) with microscopic hematuria (tiny amounts of blood in the urine), renal insufficiency, and hypertension (high blood pressure).

Membranoproliferative glomerulonephritis is a kidney disorder that involves inflammation and changes to kidney cells. It may lead to kidney dysfunction. **Membranous nephropathy** is caused by the thickening of part of the glomerular basement membrane. The glomerular basement membrane is a part of the kidneys that helps filter waste and extra fluid from the blood. The exact reason for this thickening is not known.

Dermatologic: Porphyria cutanea tarda (pronounced por-FEAR-ee-uh cue-TAY-nee-uh TARD-uh) and lichen planus (pronounced LIKE-un PLAN-us) are skin conditions that may be caused by hepatitis C. Porphyria cutanea tarda (PCT) can cause skin fragility, bruising, blisters, spots, pigmentation, depigmentation, and iron overload. Treatment usually involves avoiding sunlight and bleeding to reduce iron stores. Lichen planus causes raised plaques on the skin or mucous membranes.

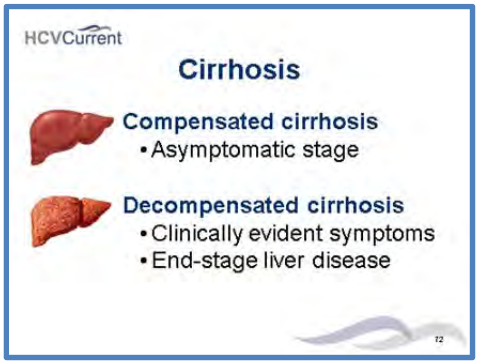
Autoimmune: Idiopathic thrombocytopenic purpura (ITP) causes low platelet levels in the blood, which can lead to excessive bruising and bleeding, purple skin spots, bleeding gums, blood in urine, prolonged bleeding from cuts, and fatigue.



Slide 71: Nonspecific Symptoms of Chronic Hepatitis C

About 75% of people have no symptoms when they first acquire HCV infection. The remaining 25% may complain of fatigue, loss of appetite, muscle aches or fever. Yellowing of the skin or eyes (jaundice) is rare at this early stage of infection.

Over time, people with chronic infection may begin to experience the effects of the persistent inflammation of the liver caused by the immune reaction to the virus. Blood tests may show elevated levels of liver enzymes, a sign of liver damage, which is often the first suggestion that the infection may be present. Patients may become easily fatigued or complain of nonspecific symptoms.



Slide 72: Cirrhosis

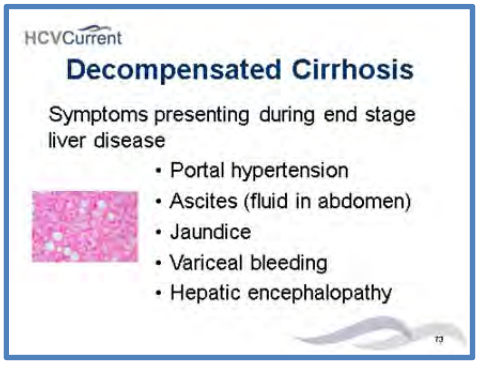
Compensated cirrhosis (early) means that the liver is heavily scarred but can still perform many important bodily functions. Compensated cirrhosis may develop a variety of physical symptoms such as fatigue, exhaustion, loss of appetite, nausea, jaundice, weight loss, and stomach pain.

Some experts divide compensated cirrhosis into two categories: ***stage 1*** (absence of varices [a permanent abnormal dilation and lengthening of a vein]) and ***stage 2*** (presence of varices without bleeding and absence of ascites [accumulation of serous fluid in the peritoneal cavity]).

Decompensated cirrhosis (late) means that the liver is extensively scarred and unable to function properly; it is characterized by the presence of portal hypertension, one of several clinical symptoms of end stage liver disease.

REFERENCE:

HCV Advocate, *HCSP Fact Sheet, What is Cirrhosis?*, available at: http://www.hcvadvocate.org/hepatitis/factsheets_pdf/Cirrhosis.pdf.

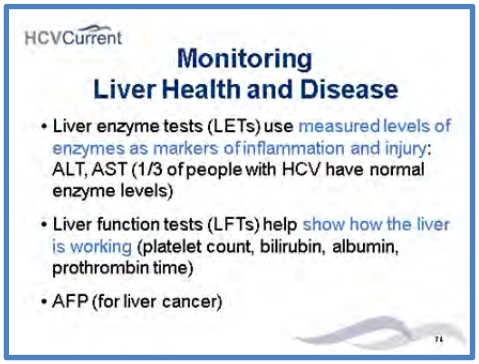


Slide 73: Decompensated Cirrhosis

Decompensated cirrhosis means that the liver is extensively scarred and unable to function properly. Patients with decompensated cirrhosis may develop a variety of symptoms:

- Scar tissue in the liver restricts the flow of blood and leads to **portal hypertension** resulting in complications such as ascites, spontaneous bacterial peritonitis, varices and other potentially life-threatening complications.
- **Ascites** is the accumulation of fluid in the abdominal cavity
- **Variceal bleeding** refers to when veins in the stomach, esophagus and rectum become so stretched and dilated (due to portal hypertension) that a condition called varices develops which can lead to internal bleeding.
- **Hepatic encephalopathy** refers to the changes in the brain that occur in patients with advanced acute or chronic liver disease.

For more information, visit the Hepatitis C Central website: http://www.hepatitiscentral.com.



Slide 74: Monitoring Liver Health and Disease

Liver enzymes are secreted into the blood as liver cells are damaged or die, which is a normal process. Two liver enzymes that are measured by blood tests are:

- ALT (alanine aminotransferase), sometimes called SGPT – normal range is 5-60 IU/mL
- AST (aspartate aminotransferase), sometimes called SGOT – normal range is 5-43 IU/mL

Enzyme levels tend to be high when a person is sick and processing medication but without these factors, consistently high levels of enzymes may indicate liver problems. Liver function tests measure amounts of:

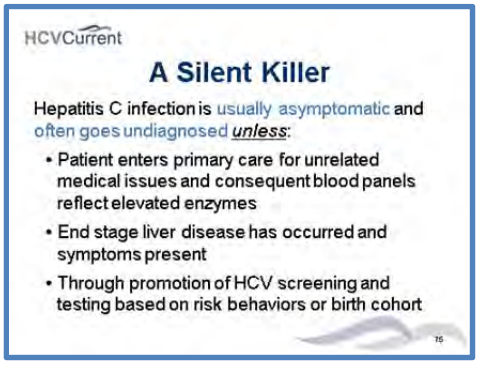
- **Platelet Count:** Thrombocytopenia (platelet count <150,000/microL) is a common complication in patients with cirrhosis that has been observed in up to 76% of patients. Moderate thrombocytopenia (platelet count of 50,000/microL-75,000/microL) occurs in approximately 13% of patients with cirrhosis; this can occur with compensated cirrhosis (i.e., early, asymptomatic cirrhosis).
- **Bilirubin:** a byproduct of red blood cells, produced when the liver breaks down old red blood cells. Bilirubin is removed from the body through the stool (feces) and gives stool its normal color. When the liver is damaged, bilirubin may not be appropriately discarded from the blood and builds up causing jaundice (yellowing of eyes and skin). Jaundice is a sign of decompensation (late stage disease).

(Notes for Slide 74, continued)

Slide 74: Monitoring Liver Health and Disease

- **Albumin:** a protein synthesized by the liver that circulates in blood. Low albumin is a sign of decompensation.
- **Prothrombin Time (PT):** PT is a test that is prolonged or elevated if levels of blood clotting factors that the liver makes are low. Elevated PT is a sign of decompensation (late stage disease).
- **Alpha fetoprotein (AFP):** this test looks for high levels of AFP, a protein that is produced by cancerous liver cells. People with advanced liver disease are at an increased risk of liver cancer (hepatocellular carcinoma or HCC), so health care providers often order this test every six to 12 months.

For more information, visit the Hepatitis C Central website: http://www.hepatitiscentral.com.

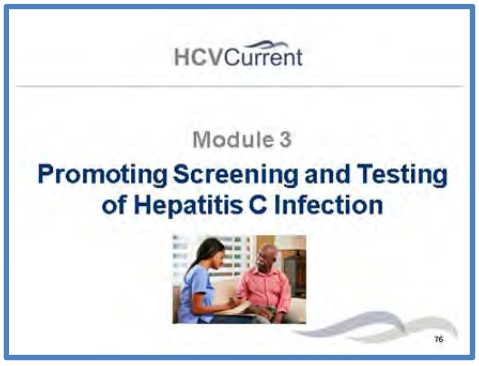


Slide 75: A Silent Killer

The diagnosis of acute hepatitis C virus (HCV) infection is infrequently made, primarily because more than 70% of patients do not have symptoms associated with the acute infection. Overall, approximately 25% of all patients with acute HCV present with jaundice, and 10 to 20% develop gastrointestinal symptoms (nausea, vomiting, or abdominal pain).

Patients may learn of their liver disease as a result of blood tests for medical issues that may reflect elevated enzyme levels (e.g., blood panels ordered to diagnose allergic reactions). At times, HCV may be diagnosed from symptoms related to the complications of end stage liver disease. Risk-based screening and counseling works to correlate past or present risk factors and behaviors with the potential for HCV infection, providing the rationale to promote HCV screening. The insidious characteristics of HCV disease speaks to why it is often referred to as a silent killer with symptoms and liver complications occurring long after initial infection and when treatment options may be limited.

For more information, visit the University of Washington, Seattle STD/HIV Prevention Training Center website: http://depts.washington.edu/hepstudy/hepC/clindx/acute/discussion.html.



Slide 76: Module 3 – Promoting Screening and Testing of Hepatitis C Infection

Module 3 Goal: To review the two-step process of screening and testing for hepatitis C, and counseling messages that correspond to non-reactive and reactive results.

Module 3 Objectives: Participants will be able to (1) discuss at least two reasons why it is important to promote hepatitis C screening and testing; and (2) describe at least three prevention messages that can be used when promoting hepatitis C screening and testing.

Slide 77: Keys to Promoting HCV Testing

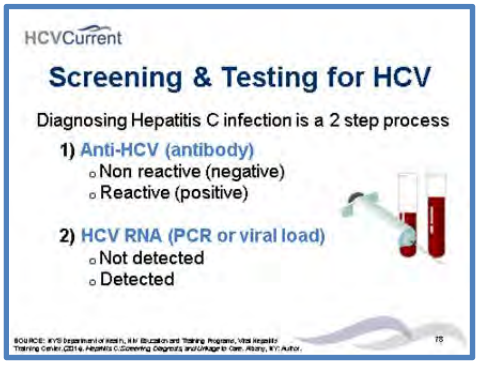
Establishing rapport with the patient is essential to providing support and addressing barriers to screening and testing such as fear, lack of information, or how hepatitis specifically relates to the patient. When developing and offering tailored counseling messages, providers should consider patient factors or concerns that may keep them from agreeing to undergo an anti-HCV test.

Raising a conversation about HCV screening and testing should be based on an identified patient risk behavior as the motivation to get tested providing the benefits of learning HCV serostatus.

Providers should explain the entire process, including how the anti-HCV and HCV RNA test work, and the possible test results. It is also important to offer risk reduction options, reinforce the benefits of testing and knowing your HCV serostatus, and follow up with the offer to escort patient to have the anti-HCV test done. Providers should always ask the patient if he/she has any questions.

<u>REFERENCE</u>:

HIV Education & Training Programs, Viral Hepatitis Training Center, New York State Department of Health. (2014). *Hepatitis C: Screening, Diagnosis, and Linkage to Care Trainer Manual*. Albany, NY: Author.



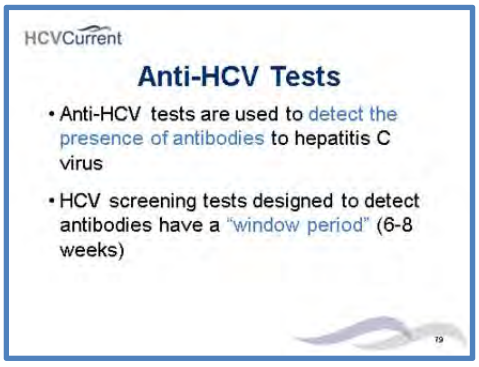
Slide 78: Screening & Testing for HCV

The screening test is called an anti-HCV test, and has two possible lab results – non-reactive or reactive.

The HCV RNA Polymerase Chain Reaction (PCR) test detects the presence or absence of HCV RNA in the blood. If no HCV RNA is present, it is said to be not detected. If HCV RNA is present, the result is detected and hepatitis C infection is diagnosed.

REFERENCES:

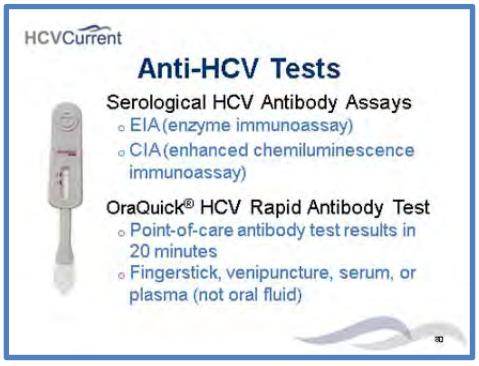
1. HIV Education & Training Programs, Viral Hepatitis Training Center, New York State Department of Health. (2014). *Hepatitis C: Screening, Diagnosis, and Linkage to Care Trainer Manual*. Albany, NY: Author.
2. HCV Advocate. (2014). *HCSP Fact Sheet – HCV Viral Load Tests*, available at: http://www.hcvadvocate.org/hepatitis/factsheets_pdf/viralload.pdf.



Slide 79: Anti-HCV Tests

HCV screening tests detect the presence of antibodies to the hepatitis C virus. The immune response is how your body recognizes and defends itself against bacteria, viruses, and substances that appear foreign and harmful.

HCV screening tests designed to detect antibodies have a "window period." This is the length of time it takes for an infected person's body to develop enough antibodies to be detected by an HCV screening test. The body's immune system responds to HCV infection by developing HCV antibodies within 6 to 8 weeks following infection.

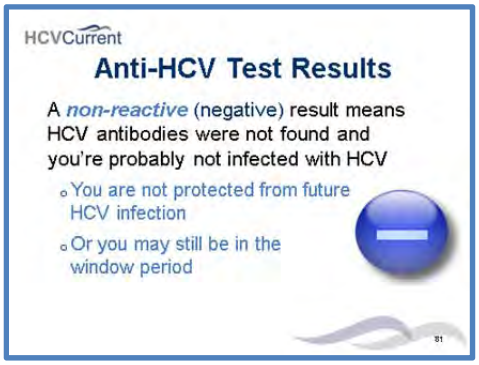


Slide 80: Anti-HCV Tests

Current screening serologic tests to detect HCV antibodies include EIA (enzyme immunassay) and CIA (chemiluminescence immunoassay); both are typically performed in laboratories.

OraQuick® HCV Rapid antibody tests are easy to perform, do not require expensive equipment or experienced personnel, and results can be obtained within 20 minutes. They have the potential to provide better accessibility and flexibility in various clinical settings.

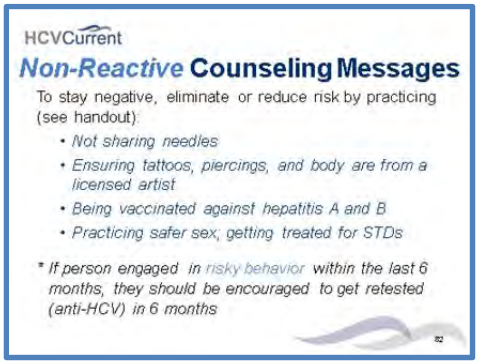
"OraQuick®" can be a confusing name for the test because it is not an oral test; it is a test done on blood. It is called "OraQuick®" only because the company that manufactures it OraSure.



Slide 81: Anti-HCV Test Results

When providing a non-reactive test result, the provider should reiterate the information given to patient prior to taking the anti-HCV test. A non-reactive anti-HCV test result means that there were no HCV antibodies found in the blood sample. The patient is likely not infected if they have not engaged in any risk behaviors 6 months prior to taking the anti-HCV test. If they did engage in a risk behavior, it is possible that the test may be inaccurate. In other words, they are infected and are testing within the 6-8 week window period.

If the patient has not engaged in risk behavior, then they are not likely infected with HCV. Because the anti-HCV test is typically recommended because of identified patient risk behavior, tailored counseling messages should be provided.



Slide 82: Non-Reactive Counseling Messages

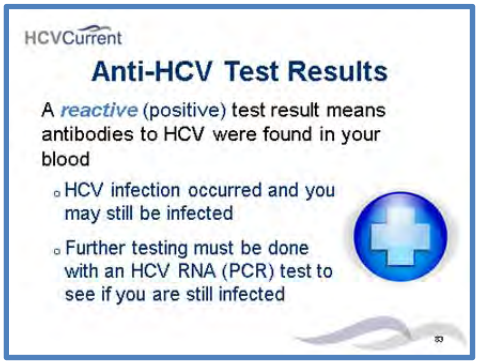
Review the non-reactive counseling messages and the key points to cover with patients. Refer to Handout #1 – Counseling Messages at the end of this Trainer Manual.

Sharing needles is the most efficient means of HCV infection because it can readily transmit HCV virus through blood-to-blood contact. Any items that can penetrate the skin and draw blood, and are shared, can potentially transmit the HCV virus.

Tattoos, piercings, and body art typically draw blood. These artistic services should be obtained from a licensed artist that follows state guidelines. Advise patients about what they are entitled to as a consumer, including the use of new equipment and opening ink bottles in front of consumer.

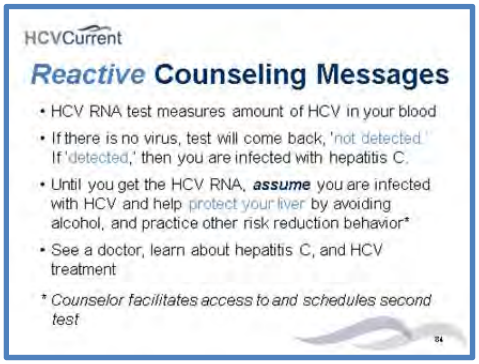
Counseling on vaccinating against hepatitis A and B should also be accompanied with a list of locations where the patient can access vaccinations.

Offer information regarding safer sex practices and the importance of getting screened treated for STDs, which would compromise the body's immune system.



Slide 83: Anti-HCV Test Results

A reactive anti-HCV test result means that antibodies to HCV were found in the blood. HCV infection occurred at some point in time.



Slide 84: Reactive Counseling Messages

Review the reactive counseling messages and the key points to cover with patients. Refer to Handout #1 – Counseling Messages at the end of this Trainer Manual.

When providing reactive counseling messages, the provider should reiterate what was explained prior to the patient agreeing to take the anti-HCV test.

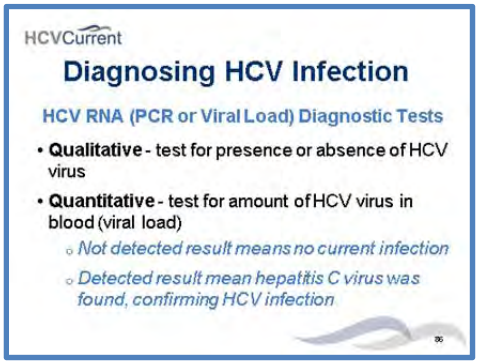
The patient was infected with hepatitis C at some point in time, which is the only way the body's immune system would develop HCV antibodies. The only way to know if the patient is currently infected or if he/she cleared the virus is to undergo an HCV RNA test. The provider should encourage patient to undergo the HCV RNA test.

An HCV RNA test uses an amplification technology that is sensitive enough to detect HCV RNA strands in the blood sample and measures the amount of HCV in blood. Results can be either not detected (if no virus is found) or detected (if the patient's HCV viral load was detected, and patient is currently infected).

Until the patient receives the HCV RNA test, the provider should encourage and provide counseling messages for the patient to protect his/her liver, explain the importance of avoiding alcohol consumption, get vaccinations for HAV and HBV, and eat a healthy diet. It is also important to emphasize the need to access health care, learn about hepatitis C infection (some of which the provider can provide), and discuss available HCV treatment options and possible outcome of a cure for HCV. The provider should encourage and facilitate a referral for the patient to have the HCV RNA test.

Slide 85: Antibody Tests cannot Tell the Difference between…

Antibody tests look for specific white blood cells that the immune system develops as a response to a foreign antigen that can cause illness and harm. Anti-HCV tests can only detect HCV antibodies. It provides no other information regarding hepatitis C virus infection.



Slide 86: Diagnosing HCV Infection

Hepatitis C RNA tests are tools clinicians use to confirm a diagnosis and guide treatment.

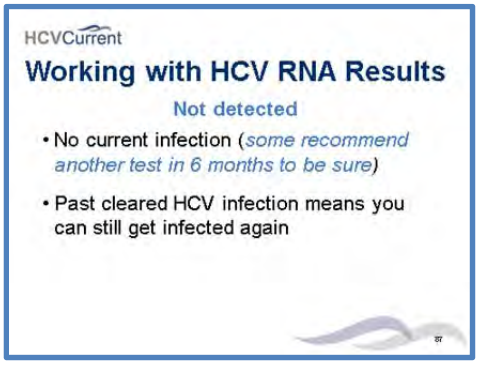
Qualitative Test – This kind of test detects the presence or absence of HCV RNA. It is reported as either detected (positive) or not detected (negative). The qualitative test is useful to confirm an active HCV infection. The L in qualitative can be equated to a label – as in it is used to label someone as having or not having the virus.

Quantitative Test – This kind of test measures the actual number of copies of HCV RNA in the blood. It is commonly referred to as the viral load, and is typically used to monitor how a person is responding to HCV treatment. The N in quantitative can be equated to a number – as in it is used to report the number of HCV viral particles present.

Most clinical settings perform the quantitative test because it provides both confirmation of HCV infection and the amount of hepatitis C virus in the blood.

REFERENCE:

Hepatitis C Central, *How to Better Understand Your HCV Viral Load Tests*, available at: http://www.hepatitiscentral.com/news/how_to_better_u.

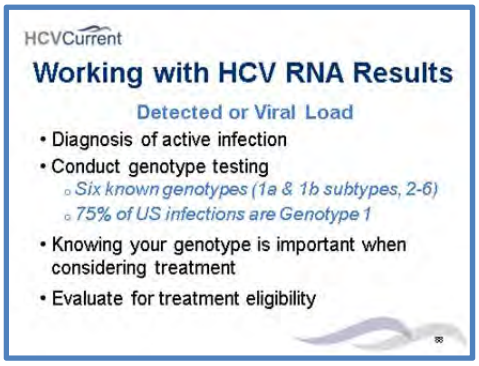


Slide 87: Working with HCV RNA Results

Results of HCV RNA tests:

An **Not detected** HCV RNA result means no virus was found and patient is not infected with HCV. Some clinicians advise the patient to return in six months to undergo another HCV RNA test to ensure accuracy of the result.

Past cleared (the body resolves the infection on its own without treatment) HCV infection does not provide lifetime immunity and it is possible to become reinfected.

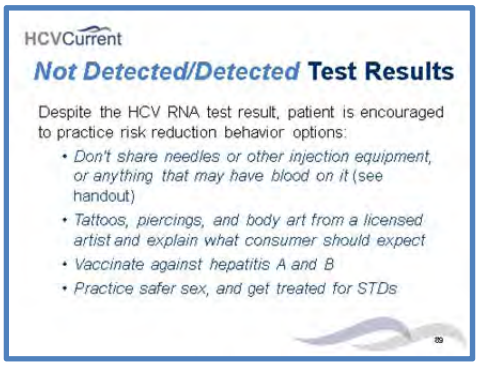


Slide 88: Working with HCV RNA Results

Results of HCV RNA tests:

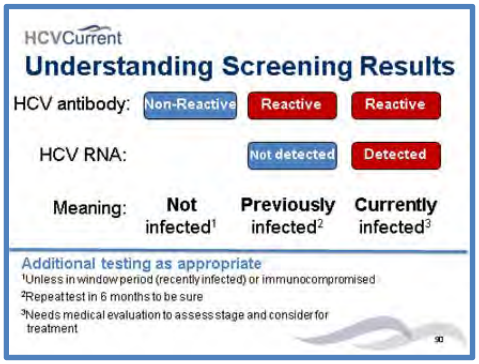
A **Detected** HCV RNA result, also referred to as viral load, means that the HCV virus was found and patient currently has an active infection.

HCV viral genotyping is used to find out which genotype of the HCV virus is present. HCV has six genotypes, and some are easier to treat than others. HCV viral genotype testing along with other clinical factors is used to guide treatment recommendations.



Slide 89: Not Detected/Detected Test Results

Not detected and detected test results should be accompanied by the same counseling messages provided prior to anti-HCV testing, HCV RNA testing, and as prevention to address risk behavior.



Slide 90: Understanding Screening Results

This slide is animated to bring up test results individually and encourage large group discussion. Review each possible result scenario and process with the participants.

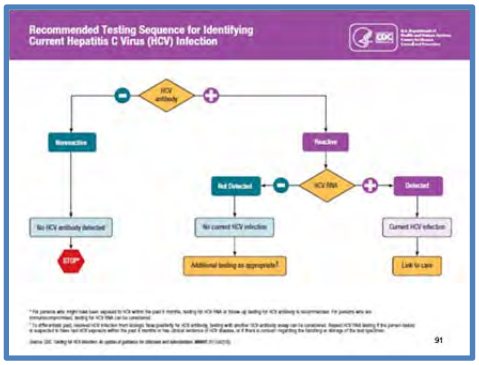
- ***Bring up first animated antibody result, 'non-reactive,' and ask participants to explain the result before revealing the meaning.*** RESULT: no antibodies, no HCV RNA needed, not infected.
- ***Bring up the second animated antibody result 'reactive' and HCV RNA result 'not detected,' and ask participants to explain and define next steps before revealing the meaning.*** RESULT: not detected, previously infected but not currently infected.
- ***Bring up the third animated antibody result 'reactive' and HCV RNA result 'detected,' and ask participants to explain and define next steps before revealing the meaning.*** RESULT: currently infected.

Additional testing as appropriate:

The immune system of some HIV/HCV co-infected persons may be substantially compromised and not strong enough to develop HCV antibodies. If HCV is suspected, encourage and schedule an HCV RNA test.

If there is a suspicion of risk behavior within the prior 6 months when receiving a non- reactive anti-HCV test, encourage retesting in 6 months.

(Notes for Slide 90, continued)



Slide 90: Understanding Screening Results

More informaiton regarding HIV/HCV co-infection is available at: http://www.hcvadvocate.org/hcsp%5Carticles/HIV-HCV%20Coinfection%20Update.html.

Slide 91: Recommended Testing Sequence for Identifying Current Hepatitis C Virus (HCV) Infection

This flow chart can be found on the CDC website and reflects the HCV testing sequence. Participants may find this to be a useful tool for promoting and educating clients about the HCV screening and testing process, potential test results and what they mean, and suggested next steps.

An electronic copy of the CDC algorithm is available at: http://www.cdc.gov/hepatitis/HCV/PDFs/hcv_flow.pdf. ***Refer to Handout #2 – CDC Algorithm at the end of this Trainer Manual.***

Slide 92: Activity – Promoting HCV Testing – Role Plays

****Activity: HCV Test Results – allow 45 minutes for this activity****

The trainer should assign participants to dyads. Each dyad should pick a card provided by the trainer (*refer to Handout #3 – Role Play Instructions at the end of this Trainer Manual*). Each card features a test result case scenario that the dyad will review and use to inform and select the test result and appropriate counseling messages the service provider will give during the skills practice. Encourage participants to consider the patient issues or concerns identified in the case scenario, and integrate all available information into a conversation that communicates the specific HCV screening or testing results as indicated by the Goal on the card.

Each participant will have 15 minutes to practice as the provider giving an HCV test result to a patient while acting out the scenario on their card. Each dyad should choose who will start as the provider. When ready, instruct the dyads to begin their conversation and monitor the time. The trainer should walk around the room, listen-in, and offer support as need or requested.

After 15 minutes, call time and let participants know they will have another 15 minutes to switch roles and go through the scenario again as if it's for the first time. Encourage the new service provider to use what she/he learned from the first go round.

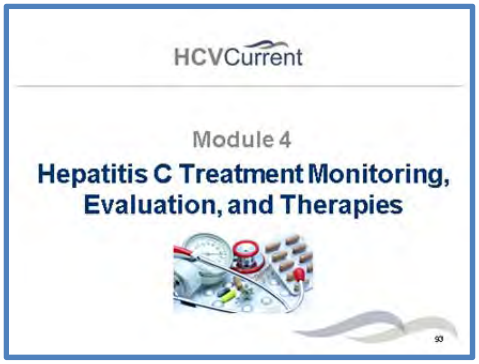
(Notes for Slide 92, continued)

Slide 92: Activity – Promoting HCV Testing – Role Plays

When another 15 minutes is up, call time and de-brief/process with the large group.

Use the following questions as a guide:

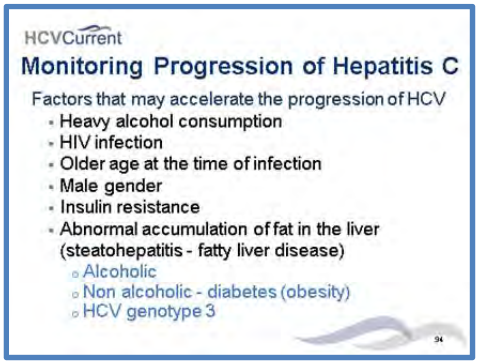
- How did you successfully promote your card scenario?
- What seemed difficult to do and why?
- What else was a concern for you as a provider?



Slide 93: Module 4 – Hepatitis C Treatment Monitoring, Evaluation, and Therapies

Module 4 Goal: To review the importance of monitoring progression of hepatitis C, clinical evaluation procedures and treatment factors to consider, and the latest available medical treatments for hepatitis C.

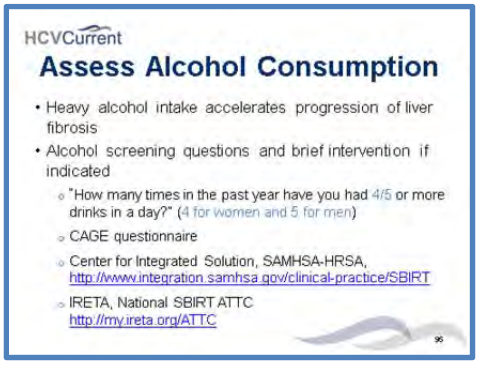
Module 4 Objective: Participants will be able to list at least three treatment factors to consider and describe at least two new treatment options available to hepatitis C positive patients.



Slide 94: Monitoring Progression of Hepatitis C

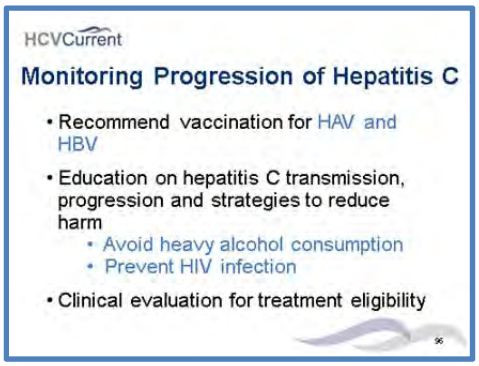
Studies show factors that can accelerate disease progression including the following:

- Excessive alcohol consumption (40-50 grams)is associated with an increased risk of cirrhosis, and to some extent with HCC and mortality. Patients should be assessed and provided interventions when appropriate, and counseled on alcohol cessation.
- Studies show that HIV infection accelerates HCV disease in coinfected persons and is associated with higher viral load , increased risk of cirrhosis, and HCC.
- Being 40 years of age or older at time of infection has consistently been a factor among HCV infected persons and disease progression. The current data suggests that persons with HCV infection at younger age, less than 25 years, are less likely to have chronic hepatitis C than those infected at older ages.
- Studies also reflect that HCV chronic infection is more prevalent in men than in women.
- Obesity and metabolic factors such as insulin resistance and Steatosis correlate with HCV disease progression, HCC, and decreased successful treatment outcomes.
- Steatosis (fatty liver) is an accumulation of fat in the liver. When inflammation is present, this becomes non-alcoholic steatohepatitis (NASH), which can progress to cirrhosis and hepatocellular carcinoma. The prevalence of diabetes is higher among people with HCV than the general population.



Slide 95: Assess Alcohol Consumption

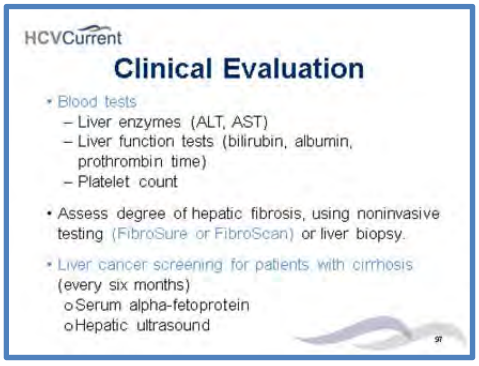
Excessive alcohol consumption (40-50 grams) is associated with an increased risk of cirrhosis, and to some extent with HCC and mortality. Patients should be assessed and provided interventions when appropriate, and counseled on alcohol cessation.



Slide 96: Monitoring Progression of Hepatitis C

Persons with current (active) HCV infection should receive education and interventions aimed at reducing progression of liver disease and preventing transmission of HCV, and other risk reduction behavior options. Providers can educate the patient on hepatitis C transmission, disease progression, and strategies to reduce the harm of risk behavior such as reducing or eliminating alcohol consumption, and avoiding acetaminophen.

The definition of clinical evaluation is as follows: the patient has attended a medical care visit with a practitioner able to complete a full assessment, discussed the pros and cons of antiviral therapy, and has transitioned the patient into treatment, if appropriate.



Slide 97: Clinical Evaluation

Evaluation for advanced fibrosis using liver biopsy, imaging, or noninvasive markers is recommended for all persons with HCV infection, to facilitate an appropriate decision regarding HCV treatment strategy and to determine the need for initiating additional measures for the management of cirrhosis (e.g., hepatocellular carcinoma screening). Refer to Slide 74, Monitoring Liver Health and Disease, for additional information.

Slide 98: Treatment Factors to Consider

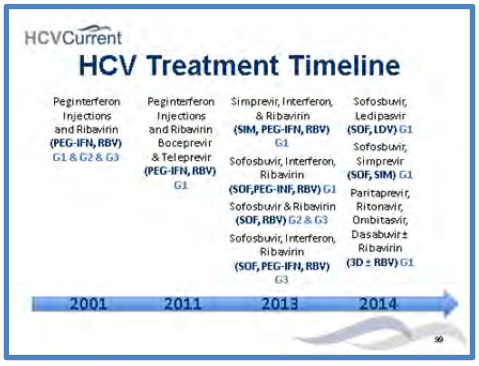
Appropriate recommendations of treatment therapies involve assessment of various clinical patient factors and are key to successful treatment outcomes.

The management of genotype 1 patients with decompensated cirrhosis, renal impairment, HIV coinfection, acute hepatitis C infection, or post-liver transplantation can impact choice of treatment regimens and duration of therapy.

For the patient, making a decision to undergo HCV treatment is dependent on the practitioner's reasons of why treatment is necessary and a clear understanding of what the patient will experience during treatment. Patient concerns need to be addressed and patienst should be advised of how to manage potential adverse effects that can impact treatment adherence.

REFERENCE:

Hepatitis C Support Project, A Guide to Making Treatment Decisions for Hepatitis C, available at: http://www.hcvadvocate.org/hepatitis/factsheets_pdf/Treatment_Decision_Guide.pdf.



Slide 99: HCV Treatment Timeline

Review the hepatitis C therapy timeline and note the rapidly changing landscape of treatments to date which also speaks to the increased likelihood of successful outcomes for persons infected with HCV. For more information, refer to* Handout #4 – Treatment Options*, in the back of this Trainer Manual.

Pegylated interferon and ribavirin were the standard treatments for G1 for over a decade, and were associated with harsh adverse effects, limited efficacy of 45-50% viral suppression, and less successful outcomes for African American communities.

In 2011, boceprevir and teleprevir were added to the list of standard treatments, as a 3rd medication regime with increased successful outcomes of 85%, but with difficult adverse effects including extreme fatigue and low white blood cell counts, sometimes resulting in the need for blood transfusions.

In November-December 2013, simprevir and sofosbuvir were approved and became the recommended course of treatment for G1, and were added to ribavirin for G2 & G3.

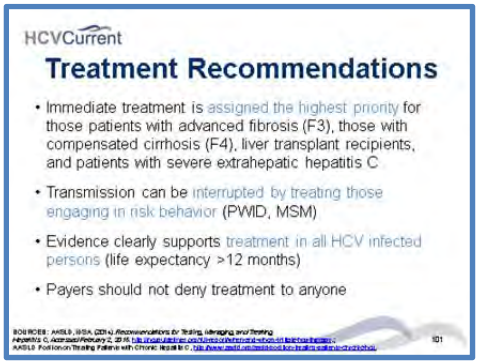
The newest and current treatment medications were approved in October, November, and December 2014, respectively, and include paritaprevir, ritonavir, ombitasvir, and dasabuvir with or without ribavirin (Harvoni®, Viekira Pak™, and Olysio/Sovaldi®); these were the current treatment recommendations at the time this curriculum was developed (spring 2015).

Slide 100: Treatment Markers & Benefits

A successful treatment outcome (referred to as a 'cure,') is when a sustained virologic response (SVR), validated through HCV RNA or viral load tests, is achieved 12 weeks after treatment completion.

Benefits of treatment may not always include a cure, but studies show that the rates of progression to liver failure, liver cancer, and liver related deaths are reduced.

Oral therapies are easier to tolerate and adhere to and therapy can be as short as eight weeks or up to 24 weeks (compared to past regimens of 24-48 weeks of treatment).



Slide 101: Treatment Recommendations

According to the AASLD & ISDA HCV Guidelines Full Report (February 3, 2015; http://www.hcvguidelines.org):

- Highest priority for treatment should be given to those patients with advanced liver disease, decompensated cirhosis, liver transplant recipients, and end stage liver disease (this does not mean that people who are not the "highest priority" should not be treated).
- Annual HCV testing is recommended for persons who inject drugs and for HIV seropositive men who have unprotected sex with men. Periodic testing should be offered to other persons with ongoing risk factors for exposure to HCV.
- Except for those with life expectancy of less than a year, all those infected with HCV would benefit from treatment.
- Now that highly effective and well-tolerated direct-acting antiviral regimens are available, some experts are calling for treatment for everyone living with hepatitis C. But due to the high cost of treatment, many national health systems and private insurers are limiting treatment to the sickest patients.

(Notes for Slide 101, continued)

Slide 101: Treatment Recommendations

REFERENCES:

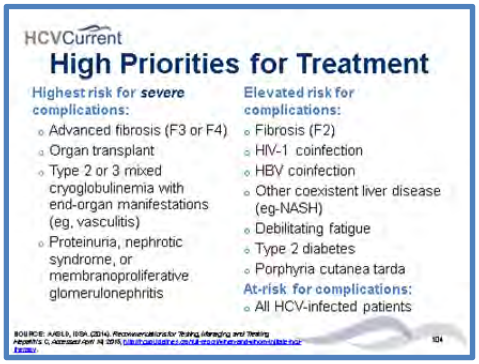
1. American Association for the Study of Liver Disease (AASLD) & Infectious Diseases Society of America (IDSA). (2014). *Recommendations for Testing, Managing, and Treating Hepatitis C*. Accessed April 14, 2015, http://hcvguidelines.org/full-report/when-and-whom-initiate-hcv-therapy.
2. AASLD Position on Treating Patients with Chronic Hepatitis C, available at: http://www.aasld.org/aasld-position-treating-patients-chronic-hcv.

Slide 102: Treatment Restrictions

HCV treatments are costly, and many payers place restrictions on who they are willing to cover.

Slide 103: Treatment Resources

A variety of patient assistance programs are available. Specialty pharmacies can help doctors and patients obtain medications.



Slide 104: High Priorities for Treatment

An estimated 813,000 people with diagnosed hepatitis C in the U.S. have undergone liver disease staging and meet the "highest" or "high" priority criteria for immediate treatment, according to an analysis presented at the American Association for the Study of Liver Diseases (AASLD) Liver Meeting held in Boston, MA in 2014. This number would be even higher if undiagnosed individuals and prisoners and others excluded from household surveys were included in the analysis.

Other populations at high risk for liver disease progression (F2) or with substantial extrahepatic manifestations are also expected to garner appreciable benefits, although the time course for realizing these benefits may be more protracted.

Cryoglobulinemia, which literally means "cold antibody in the blood," refers to the chemical properties of the antibodies (cryoglobulins) that cause this disease. Cryoglobulins are antibodies that precipitate under cold conditions. Drug use is a prime risk factor for cryoglobulinemia because more than 90% of cases of cryoglobulinemic vasculitis are associated with hepatitis C infections. Hepatitis C is acquired by injection drug use (e.g., needle sharing), tainted blood products, and (probably rarely) sexual transmission. Treatment of the underlying hepatitis may be an effective therapy for this type of vasculitis. For more information, visit the Johns Hopkins Vasculitis Center website at: http://www.hopkinsvasculitis.org/types-vasculitis/cryoglobulinemia/.

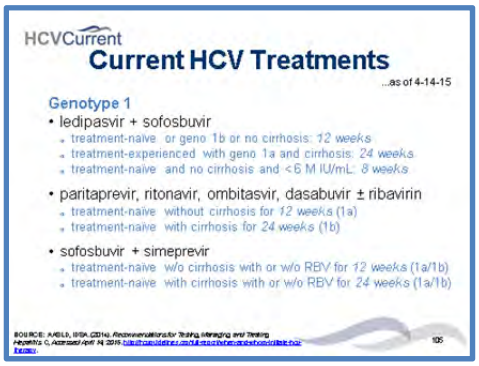
(Notes for Slide 104, continued)

Slide 104: High Priorities for Treatment

REFERENCE:

American Association for the Study of Liver Disease (AASLD) & Infectious Diseases Society of America (IDSA). (2014). *Recommendations for Testing, Managing, and Treating Hepatitis C*. Accessed April 14, 2015, http://hcvguidelines.org/full-report/when-and-whom-initiate-hcv-therapy.

Slide 105: Current HCV Treatments



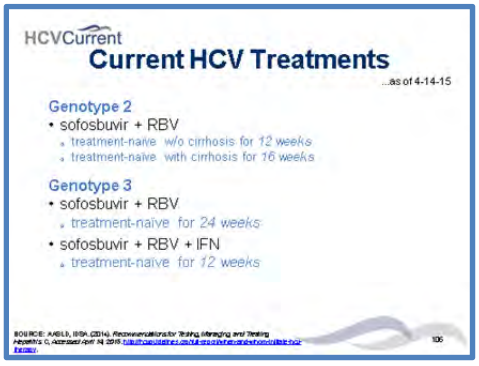
Sofosbuvir - $84,000 for 12-week treatment regimen

Ledipasvir/sofosbuvir - $94,500 for 12-week treatment regimen

REFERENCE:

American Association for the Study of Liver Disease (AASLD) & Infectious Diseases Society of America (IDSA). (2014). *Recommendations for Testing, Managing, and Treating Hepatitis C*. Accessed April 14, 2015,

http://hcvguidelines.org/full-report/when-and-whom-initiate-hcv-therapy.



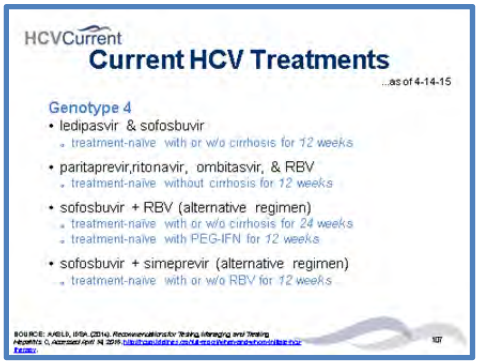
Slide 106: Current HCV Treatments

G2 & G3 are typically easier to treat. The current recommended courses of treatments are indicated on the slide.

REFERENCE:

American Association for the Study of Liver Disease (AASLD) & Infectious Diseases Society of America (IDSA). (2014). *Recommendations for Testing, Managing, and Treating Hepatitis C*. Accessed April 14, 2015,

http://hcvguidelines.org/full-report/when-and-whom-initiate-hcv-therapy.



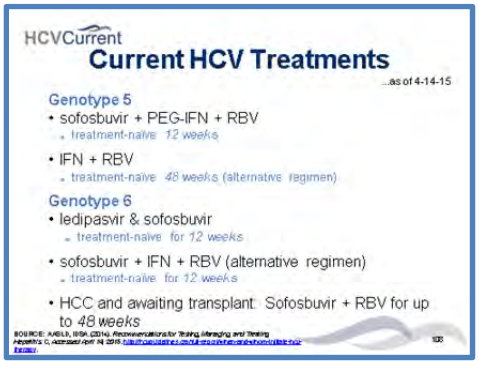
Slide 107: Current HCV Treatments

G4 has similar treatment options as G1.

REFERENCE:

American Association for the Study of Liver Disease (AASLD) & Infectious Diseases Society of America (IDSA). (2014). *Recommendations for Testing, Managing, and Treating Hepatitis C*. Accessed April 14, 2015,

http://hcvguidelines.org/full-report/when-and-whom-initiate-hcv-therapy.

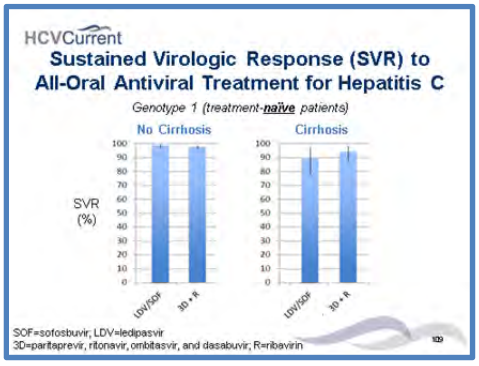


Slide 108: Current HCV Treatments

IMPORTANT NOTE: The trainer may not have to provide an in-depth overview of this slide, unless the audience works with persons from Asian countries such as Hong Kong, Thailand, Indonesia, China, Vietnam, Myanmar and Korea. Because genotypes 5 and 6 are uncommon in the U.S., data is limited. G5 is more prevalent in the northern part of South Africa (40%) and G6 in Asia. G6 in the US is seen mostly in immigrants communities form these regions. Cost of treatment regimens range from approximately $27,000 to $97,000.

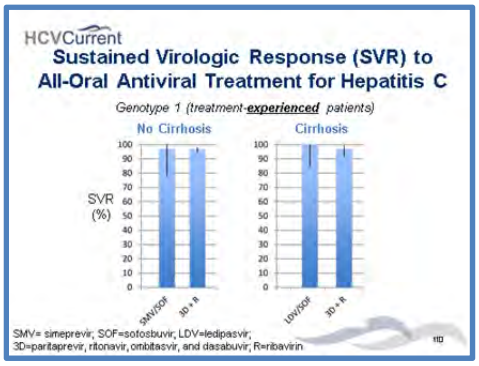
REFERENCE:

American Association for the Study of Liver Disease (AASLD) & Infectious Diseases Society of America (IDSA). (2014). *Recommendations for Testing, Managing, and Treating Hepatitis C*. Accessed April 14, 2015, http://hcvguidelines.org/full-report/when-and-whom-initiate-hcv-therapy.



Slide 109: Sustained Virologic Response (SVR) to All-Oral Antiviral Treatment for Hepatitis C

It is nearly impossible to talk about hepatitis C without talking about the incredible advances occurring right now in therapeutics. If we can eradicate the infection in people who are actively injecting drugs, we can stop onward transmission of virus before it occurs. These graphs show the incredible sustained virologic response rates with the new all-oral antiviral regimens. The graphs features regimens that were approved recently. **Treatment-naïve patients** with infected with G1 (either with or without cirrhosis) saw upwards of 95%+ SVR as a result of completing the indicated treatments. These treatments provide extremely powerful new tools to prevent the sequelae – and transmission – of HCV infection.



Slide 110: Sustained Virologic Response (SVR) to All-Oral Antiviral Treatment for Hepatitis C

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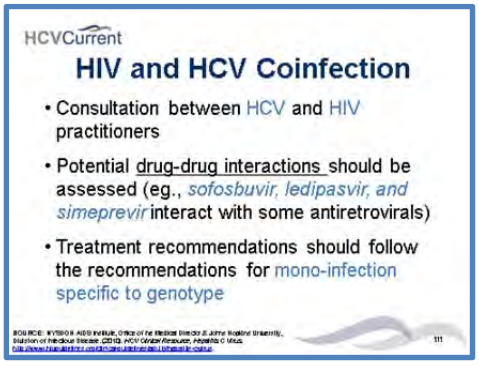


Slide 111: HIV and HCV Co-Infection

Possible antiretroviral drug switches, when needed, should be done in collaboration with the patient's HIV practitioner. Regular treatment updates and ongoing consultation with the HIV practitioner is recommended, as well.

Some drug combinations may incur harmful interactions. For combinations expected to increase tenofovir levels affecting kidney function, baseline and ongoing assessment for tenofovir nephrotoxicity is recommended.

According to the AASLD/EASL, recommended treatment therapies for HIV and HCV co-infection follow the same recommendations for mono infection. For more information, visit: http://www.hcvguidelines.org/full-report/unique-patient-populations-patients-hivhcv-coinfection

REFERENCE:

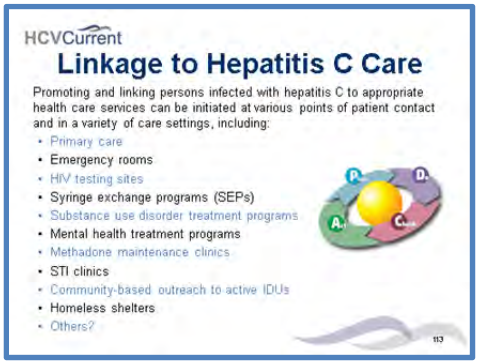
New York State Department of Health, AIDS Institute, Office of the Medical Director, & Johns Hopkins University, Division of Infectious Disease. (2010). *HCV Clinical Resource, Hepatitis C Virus.* Available at: http://www.hivguidelines.org/clinical-guidelines/adults/hepatitis-c-virus.

Slide 112: Module 5 – Linking Patients Infected with Hepatitis C to Health Care Services

Module 5 Goal: To review potential strategies to link hepatitis C-infected persons to health care services.

Module 5 Objective: Participants will be able to provide examples of at least three strategies to link persons infected with HCV to health care.

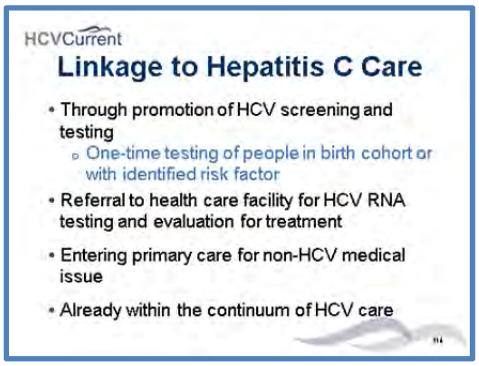
Module 5 reviews the importance of linking HCV-positive patients with appropriate health care. Many individuals identified as HCV-infected do not receive recommended medical evaluation and care after their diagnosis of HCV infection; this gap in linkage to proper care can be attributed to several factors that will be described in more detail in Module 5. The lack of necessary care, or a substantial delay in care can negatively impact the long-term health outcomes of HCV-infected individuals. To improve these health outcomes, persons testing positive for HCV MUST be provided with appropriate care and treatment. Linkage to care, together with early identification and clinical evaluation are the critical elements of HCV disease prevention and intervention. Key concepts discussed in Module 5 include (1) settings and points of contact in which linkage to HCV health care can occur; (2) the HCV Cascade; (3) barriers for HCV treatment and strategies to improve linkages to care; (4) patient and provider-focused interventions and initiatives; (5) and additional resources.



Slide 113: Linkage to Hepatitis C Care

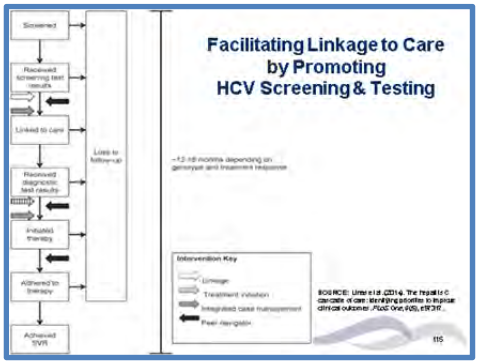
Review the list with the training participants, and ask/elicit any additional care settings that may be missing from this list.

Linkage to care for hepatitis C-infected persons can happen at various points of patient contact and in a variety of care settings.



Slide 114: Linkage to Hepatitis C Care

Initiation of care linkage can occur at a variety of time points, beginning with HCV screening and testing. Subsequent referral to a health care facility for HCV RNA testing and evaluation for treatment represents another point in time in which a HCV infected person can be linked with care. Furthermore, accessing the health care system for a non-HCV related medical issue represents yet another opportunity for linkage to ongoing HCV care. Lastly, if an individual is already receiving HCV care, each interaction with the patient allows for a medical provider to ensure ongoing linkage to appropriate care. The next slide provides a graphical look at the "HCV Cascade."



Slide 115: Facilitating Linkage to Care by Promoting HCV Screening and Testing

For more information, refer to* Handout #5 – HCV Cascade *in the back of this Trainer Manual.

Nearly two decades of experience with HIV treatment has led to a sophisticated understanding of the ‘‘cascade of care’’ that occurs between diagnosis and achieving sustained HIV virologic suppression[1]. A similar cascade exists for HCV, and features the required element of linkage to HCV care, along with a receipt of diagnostic testing, disease staging, initiation of HCV therapy, and adherence to therapy despite adverse effects[2].

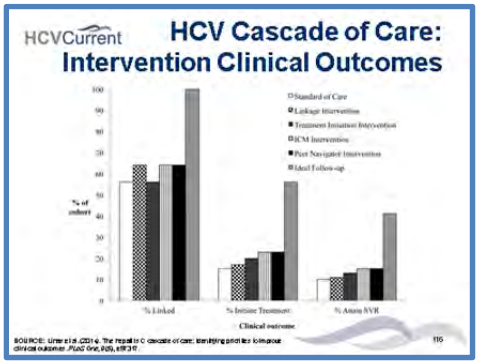
This slide features the “Cascade of Care Flow Diagram[3].” The flow diagram represents the multiple steps of the HCV cascade of care, as well as key factors related to loss to follow-up. When individuals fail to navigate a step in the cascade, they are considered lost to follow-up. Arrows noted in the key represent points along the cascade at which candidate interventions improved follow-up. Individuals lost to follow-up prior to receiving their screening test results maintained a rate of re-screening such that their HCV status could be identified in the future (median time to first re-screen = 50 months). In addition, those who were lost to follow-up after obtaining screening test results had a monthly probability of re-linking to HCV care (median time to re-link = 32 months).

(Notes for Slide 115, continued)

Slide 115: Facilitating Linkage to Care by Promoting HCV Screening and Testing

REFERENCES:

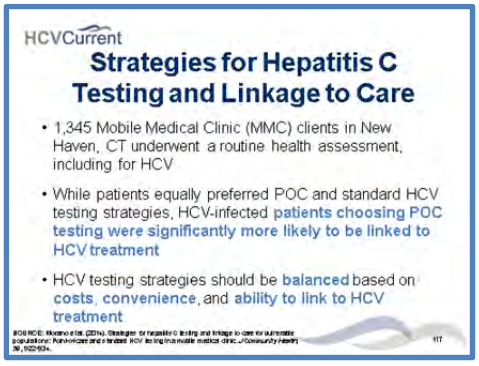
1. Gardner, E.M., McLees, M.P., Steiner, J.F., Del Rio, C., & Burman, W.J. (2011). The spectrum of engagement in HIV care and its relevance to test-and-treat strategies for prevention of HIV infection. *Clin Infect Dis, 52,* 793-800.
2. Holmberg, S.D., Spradling, P.R., Moorman, A.C., & Denniston, M.M. (2013). Hepatitis C in the United States. *NEJM 368,* 1859-1861.
3. Linas, B.P., Barter, D.M., Leff, J.A., Assoumou, S.A., Salomon, J.A., et al. (2014). The Hepatitis C Cascade of Care: Identifying Priorities to Improve Clinical Outcomes. *PLoS ONE, 9*(5), e97317.



Slide 116: HCV Cascade of Care – Intervention Clinical Outcomes

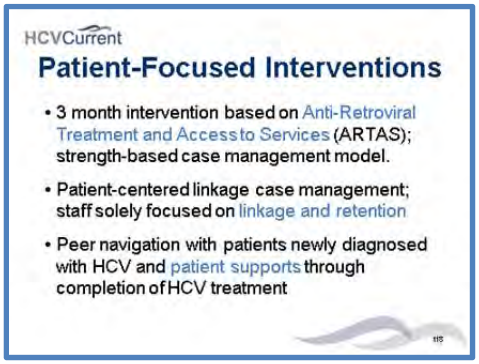
With regard to clinical outcomes of "imperfect" follow-up, when Linas and colleagues assumed the current standard of care (SOC), they estimated that 15% ever initiated HCV treatment, and 10% ultimately attained sustained virologic response (SVR). But when they assumed "ideal" follow-up along the HCV Cascade of Care, they estimated that 56% ever initiated HCV treatment and 41% attained SVR. In other words, imperfect follow-up reduces the real-world effectiveness of HCV therapies by approximately 75%.

Linas and colleagues conclude that their mathematical model shows that modestly effective interventions to improve follow-up would likely be cost-effective, and priority should be given to developing and evaluating interventions that address multiple points along the Cascade, rather than options focusing solely on single points. The bar graph featured on this slide illustrates the percent of the cohort attaining clinical outcomes along the HCV cascade of care. Each bar shading represents a specific intervention scenario.



Slide 117: Strategies for Hepatitis C Testing and Linkage to Care

Despite new HCV therapeutic advances, challenges remain for HCV testing and linking patients to care. Moran and colleagues compared a point-of-care (POC) HCV antibody testing strategy to traditional serological testing to determine whether patients preferred one type of testing and linkage to treatment over another. The study was conducted in an innovative mobile medical clinic (MMC). Outcomes included: (1) accepting HCV testing; (2) preference for rapid POC HCV testing; and (3) linkage to HCV care. All clients with reactive test results were referred to a HCV specialty clinic.

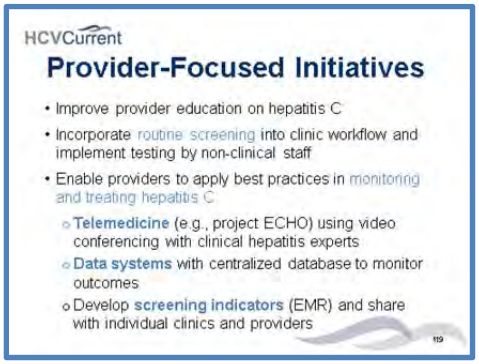


Slide 118: Patient-Focused Interventions

Anti-Retroviral Treatment and Access to Services (ARTAS) is an individual-level, multi-session, time-limited intervention with the goal of linking recently diagnosed persons with HIV to medical care soon after receiving their positive test result. ARTAS is based on the Strengths-based Case Management (SBCM) model, which is rooted in Social Cognitive Theory (particularly self-efficacy) and Humanistic Psychology. SBCM is a model that encourages the client to identify and use personal strengths; create goals for himself/herself; and establish an effective, working relationship with the Linkage Coordinator (LC). Additional information is available at: https://www.effectiveinterventions.org/en/HighImpactPrevention/PublicHealthStrategies.aspx.

With **patient-centered linkage case management**, the case manager ensures that HCV patients receive recommended preventive care interventions on-site in a clinic, as well as counseling for substance abuse and care for depression and other mental health issues. All of the activities are coordinated closely in conjunction with the primary care practice as in the model of the patient-centered medical home.

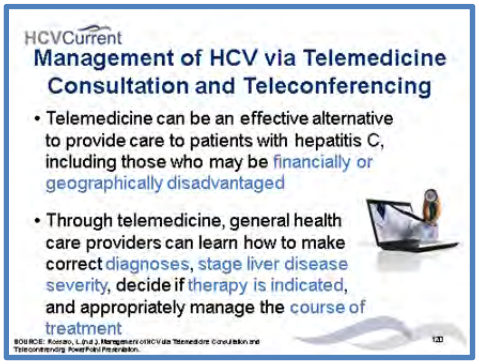
Lastly, **peer navigators** can be utilized to work with clients from the time they are diagnosed as HCV-infected through the completion of HCV treatment. One example of a peer navigator intervention is the New York City Department of Public Health and Mental Hygiene's "Check Hep C" program. This particular intervention encompasses the 3-6 month period patients spend in HCV care prior to starting therapy through the following 6-12 months (exact length of time depends on HCV genotype and response to treatment).



Slide 119: Provider-Focused Initiatives

It is critical for health care providers to receive education on the diagnosis, evaluation, and treatment of hepatitis C. Provider education helps to enhance the ability to track HCV-positive patients through better integration of clinical and public health data systems, and as a result, make it easier to identify patients who have fallen out of treatment and help them get back on track. One specific provider-focused strategy is to incorporate routine HCV screening into the standard clinic workflow, and train non-clinical staff to conduct HCV screening. Several types of strategies exist to link providers together (especially those in rural areas) to collectively monitor and treat hepatitis C. One specific example of a telemedicine system that has been shown to be quite effective is Project ECHO, which utilizes video conferencing with clinical hepatitis experts. This, coupled with centralized data, allows for outcomes to be monitored.

Hepatitis C specialists are best qualified to treat, but there is a huge cultural divide between those with expertise in treating hepatitis and those with expertise working with people who use drugs. It is critical to create collaborations between hepatitis C treaters and substance use disorder treatment providers, for those in substance use treatment, but also with community-based groups for those who are not in substance use treatment, to provide the adequate linkage and comprehensive support that people will need to become engaged in and complete treatment. The number of hepatitis C specialists in the U.S. is insufficient to treat everyone with hepatitis C. So we need to engage primary care clinicians. They will need education in hepatitis C but also help creating a nonstigmatizing environment in which to treat people who use drugs.

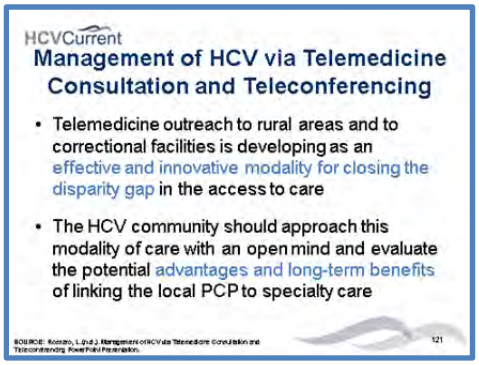


Slide 120: Management of HCV via Telemedicine Consultation and Teleconferencing

With regard to telemedicine (TM) and access to care, TM raises the standards of care in underserved areas by eliminating the distance barrier for many specialties. It allows specialist consultation in the patient's community, and saves money and time spent traveling to urban areas or major medical centers. TM encourages the participation of the primary care provider in the direct care of the patient; with this opportunity, primary care providers can collaborate with and learn from the specialists about the current management of specialized diseases.

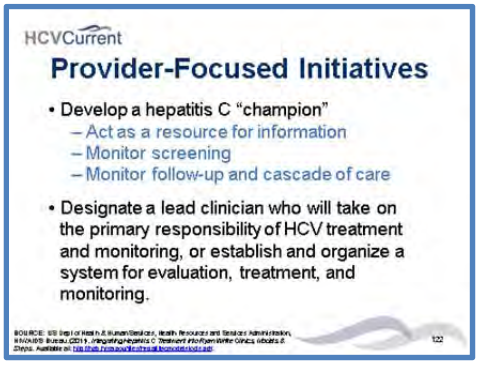
REFERENCE:

Rossaro, L. (n.d.). Management of HCV via Telemedicine Consultation and Teleconferencing PowerPoint Presentation. Available at: http://www.viralhepatitisaction.org/sites/default/files/upload/pdf/09%20Rossaro-HCV-Telemed.pdf.



Slide 121: Management of HCV via Telemedicine Consultation and Teleconferencing

The UC Davis Model of telemedicine (TM) consultation involves a "triangle" of real-time direct consultation – patient and the primary care provider in the same room with a video specialist. The UC Model differs from the ECHO model that provides primary care providers with HCV treatment training via Televideo-conferencing (no direct patient interaction). The UC Davis Model enables simultaneous communication among the three different parties – two medical providers and the patient.

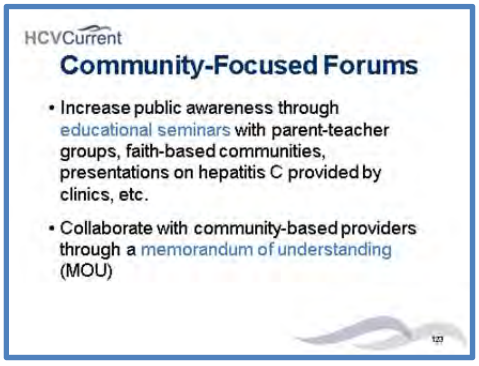


Slide 122: Provider-Focused Initiatives

A lead ("champion") medical provider is critical to ensuring effective and consistent linkage to care, regardless of the capacity and formal structure of the care setting. As an example, a medical clinic that provides HCV treatment without a formal HCV treatment program must rely on a lead provider (e.g., physician) who has a strong interest in HCV therapy. This clinician typically takes on the primary responsibility of HCV treatment and monitoring, or establishing and organizing a system for evaluation, treatment, and monitoring. The HCV champion needs to have substantial viral hepatitis knowledge, and have the capability to direct clinical decisions (e.g., gastroenterology, infectious disease, or adult medicine). In addition, an HCV Care Coordinator can help to assess eligible patients, provide education, support medication and laboratory adherence, manage side effects, facilitate appropriate interdepartmental referrals, and follow established protocols.

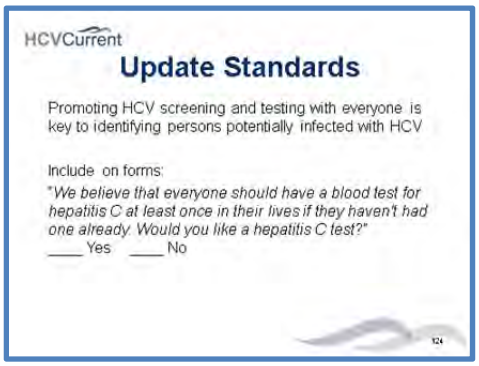
REFERENCE:

US Department of Health & Human Services, Health Resources and Services Administration, HIV/AIDS Bureau. (2011). *Integrating Hepatitis C Treatment into Ryan White Clinics, Models & Steps*. Available at: http://hab.hrsa.gov/files/hepatitiscmodelstools.pdf.



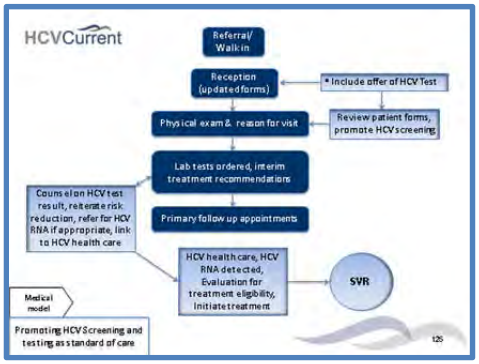
Slide 123: Community-Focused Forums

Community members can function as hepatitis C advocates to help eliminate harmful and discriminatory barriers to hepatitis C treatment access. Community-based program staff need to learn about hepatitis C treatment, either on site or through close linkages with hepatitis C specialists and other medical providers. Strong collaboration is essential, as are integrated multidisciplinary services, lots of support, and a focus on stigma and the historically poor relations between doctors and drug users. Community-based providers can formalize collaborations by establishing a memorandum of understanding (MOU) to outline key contributions of each provider agency.



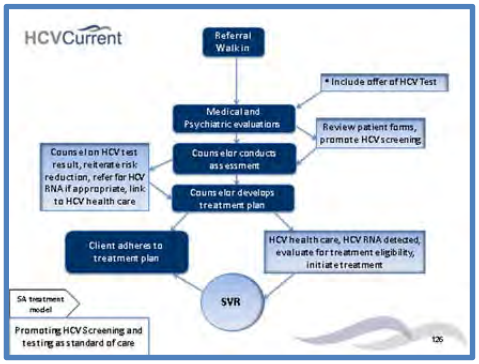
Slide 124: Update Standards

Providers can update their intake forms to include a statement asking the patient if he/she would like to receive a hepatitis C test.



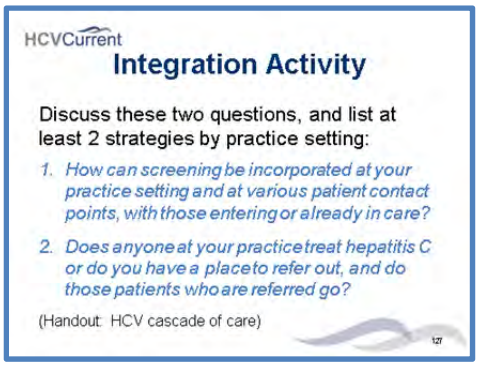
Slide 125: [No Title]

The trainer can present this slide and the next slide to show other treatment and health settings where promoting HCV screening and testing can conceivably be integrated, and then move on to the final training activity.



Slide 126: [No Title]

The trainer can present this slide and the previous slide to show other treatment and health settings where promoting HCV screening and testing can conceivably be integrated, and then move on to the final training activity.



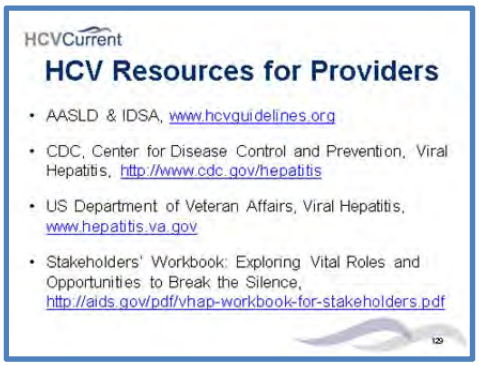
Slide 127: Integration Activity

****Integration Activity – allow 20-25 minutes for this activity****

The purpose of this activity is to break training participants into pairs or small groups of 3-5 individuals by discipline if possible (the number of people in each group will depend on the size of the audience), and based on what they have learned through the course of the training, ask that each group engage in a conversation about how HCV screening, testing, and treatment could be incorporated into (or is currently being conducted) in their practice setting. Provide 7-10 minutes for the discussion, and 7-10 minutes to de-brief as a large group.

Slide 128: HCV Resources for Patients

This slide contains links to key resources that can be utilized by hepatitis C patients.



Slide 129: HCV Resources for Providers

This slide contains links to key resources that can be utilized by hepatitis C providers.

Slide 130: Final Slide

This concludes the training. At this time, the trainer should take care of any final questions, administer the post-training evaluations, thank the participants for their time, and adjourn the training. For additional information, the trainer can direct the participants to the HCV Current* Initiative *website.

PARTICIPANT HANDOUT #1

Promoting Hepatitis C Screening and Testing – Counseling messages for HCV test results (Module #3)

Promoting Hepatitis C Screening and Testing

Counseling messages for HCV test results

Promoting HCV screening (anti HCV) and diagnostic testing (HCV RNA or viral load) includes an understanding of a person's risk behavior to encourage testing, what the HCV tests are, what the potential results can be, and the counseling messages that should be provided with each result before a patient undergoes the test.

Two different tests are used to diagnosis HCV infection. Specific test and test result will warrant the appropriate next step that the patient should be encouraged to take. All test results should be given along with risk reduction options and next steps.

***Anti-HCV (HCV antibody)**

Nonreactive/negative
(Risk reduction)

Reactive /positive
(Risk reduction & HCV RNA)

HCV RNA (PCR or viral load)

Not detected
(Risk reduction)

Detected
(Risk reduction & link to care)

***Additional testing as appropriate:**

Unless in window period (recently infected) or immunocompromised, repeat test in 6 months to be sure

OR

may need medical evaluation to assess stage and consider for treatment

RISK REDUCTION COUNSELING MESSAGES

- Don't share needles or other injection equipment, or anything that may have blood on it
- Get tattoos, piercings, and body art from a licensed artist
- Protect your liver by avoiding alcohol
- Vaccinate against hepatitis A and hepatitis B
- Practice safer sex practices, and get treated for STDs
- Avoid heavy alcohol consumption

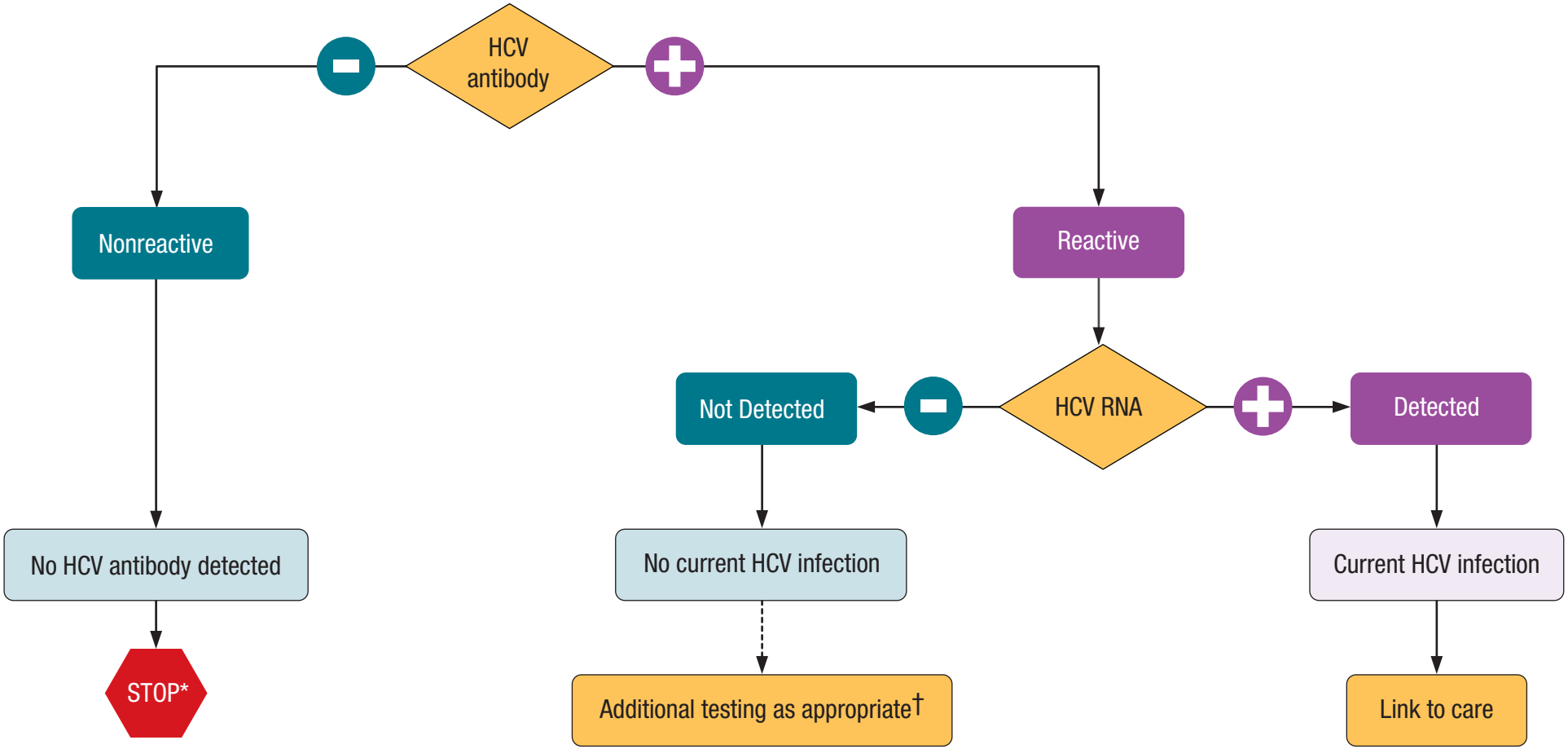
HCVCurrent
Resources for Medical and Behavioral Health Professionals.

PARTICIPANT HANDOUT #2

Recommended Testing Sequence for Identifying Current Hepatitis C (HCV) Infection (a.k.a., HCV Algorithm; Module #3)

Recommended Testing Sequence for Identifying Current Hepatitis C Virus (HCV) Infection

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention



* For persons who might have been exposed to HCV within the past 6 months, testing for HCV RNA or follow-up testing for HCV antibody is recommended. For persons who are immunocompromised, testing for HCV RNA can be considered.

† To differentiate past, resolved HCV infection from biologic false positivity for HCV antibody, testing with another HCV antibody assay can be considered. Repeat HCV RNA testing if the person tested is suspected to have had HCV exposure within the past 6 months or has clinical evidence of HCV disease, or if there is concern regarding the handling or storage of the test specimen.

Source: CDC. Testing for HCV infection: An update of guidance for clinicians and laboratorians. MMWR 2013;62(18).

PARTICIPANT HANDOUT #3

Role Play Instructions for Counseling on HCV Test Results Activity (Module #3)

HCVCurrent

Increasing Hepatitis C Knowledge for Behavioral Health and Medical Providers

Module 3
Activity: Counseling on HCV Test Results – 45 minutes

Trainer divides participants in dyads. Each dyad picks a card from card set that the trainer will provide (*see role play scenarios below*). Each card is a test result case scenario that they will review and use to inform on selected test result and the appropriate counseling messages the service provider will give during the skills practice. Encourage participants to use the HCV antibody results handouts, consider the client issues or concerns identified in the case scenario, and integrate all into a conversation that communicates the specific HCV screening or testing results to achieve the **Goal** of the session as indicated on the card.

Each participant will have 15 minutes to practice as the provider giving an HCV test result to a patient while acting out the scenario on their card. Have each dyad choose who will start as the provider. When ready tell them to begin and monitor the time.

Trainer(s) should circulate, listen-in, and offer support as requested.

After 15 minutes call time and let participants know they will have another 15 minutes to switch roles and go through the scenario again *as if it's for the first time*. Encourage the new service provider to use what she/he learned from the first go round.

Call time in 15 minutes and process with the large group. Use the following questions:

- *How did you successfully promote your card scenario?*
- *What seemed difficult to do and why?*
- *What else was a concern for you as a provider?*

Use the following as templates of case scenarios (colored by the same provider/client scenario) to create your own trainer props of activity cards.

Provider role plays

1) **David is attending his first appointment at your health facility and wants to have a physical examination done since it's been over a year since his last one. He moved into the neighborhood recently and has filled out intake forms for first time patients which include his birth date of December 17, 1960.**

Goal: As a nurse practitioner you notice that David's birthday identifies him as a person at-risk for hepatitis C infection because he belongs to the birth cohort. You begin to initiate a conversation to promote HCV screening and testing including counseling messages.

2) **Madeline wants to access mental health services at your health center. She has a diagnosis of depression, a past history of injection drug use and has completed a 9 month outpatient treatment program. She is seeking to schedule therapy sessions.**

Goal: You are processing Madeline's intake documents and note that she used to inject heroin which makes you think about the potential for hepatitis C infection. You proceed to engage Madeline in a conversation to promote HCV screening and testing, including counseling messages.

3) **Jaime is a 34 year old Latino currently attending the outpatient program at your clinic, and has a past history of injecting heroin. You met with Jaime earlier to talk about screening and testing for HCV. At that time he agreed to take the Oraquick HCV rapid antibody test and is now meeting with you again to obtain his results.**

Goal: Jaime's anti-HCV test result is reactive. You have to inform and encourage him to get the HCV RNA test.

4) **Dante is an MSM who you've encouraged to take an anti-HCV test because of his clubbing life style and his occasional use of drugs and engaging in unprotected sex with partners. The last time you saw him was over 6 months prior to today. He just tested non-reactive for an anti-HCV test. But after taking the test, he stated that although he didn't inject drugs recently, he did engage in unprotected sex with more than one partner.**

Goal: Encourage Dante to return for another anti-HCV test and correlate his risk factors with counseling messages.

5) **Stephanie is 53 years old and a new patient at your HIV clinic. She has never been tested for hepatitis C infection and is presently feeling very fatigued. You notice that her records show a CD4 count of 350 and her HIV viral load is around 18000. After you spoke to her earlier and discussed HCV screening and testing, she took the anti-HCV test and tested non-reactive.**

Goal: Discuss with Stephanie the importance of the HCV RNA test and encourage her to schedule the test. Inform her that you can escort her if she'd like.

Patient Role Plays

1) **David is attending his first appointment at your health facility and wants to have a physical examination done since it's been over a year since his last one. He moved into the neighborhood recently and has filled out intake forms for first time patients which include his birth date of December 17, 1960.**

2) **Madeline wants to access mental health services at your health center. She has a diagnosis of depression, a past history of injection drug use, and has completed a 9 month outpatient treatment program. She is seeking to schedule therapy sessions.**

3) **Jaime is a 34 year old Latino currently attending the outpatient program at your clinic, and has a past history of injecting heroin. You met with Jaime earlier to talk about screening and testing for HCV. At that time he agreed to take the Oraquick HCV rapid antibody test and is now meeting with you again to obtain his results.**

4) **Dante is an MSM who you've encouraged to take an anti-HCV test because of his clubbing life style and his occasional use of drugs and engaging in unprotected sex with partners. The last time you saw him was over 6 months prior to today. He just tested non-reactive for an anti-HCV test. But after taking the test, he stated that although he didn't inject drugs recently, he did engage in unprotected sex with more than one partner.**

5) **Stephanie is 53 years old and a new patient at your HIV clinic. She has never been tested for hepatitis C infection and is presently feeling very fatigued. You notice that her records show a CD4 count of 350 and her HIV viral load is around 18000. After you spoke to her earlier and discussed HCV screening and testing, she took the anti-HCV test and tested non-reactive.**

PARTICIPANT HANDOUT #4

Treatment Options (Module #4)

THE BODY
The Complete HIV/AIDS Resource

INFORMATION

I Have Hepatitis C. What Are My Treatment Options?

From Project Inform

January 20, 2015

As the options for treating hepatitis C (HCV) are increasing, so is the confusion. This is a good problem to have: with more treatment options come more opportunities for people with various HCV genotypes (GT), treatment history and varying levels of cirrhosis to get cured. But which regimen is right for which genotype or treatment history, and so on?

At the 2014 Liver Meeting of the American Association for the Study of Liver Diseases, Dr. Andrew Muir of Duke University, and a leading expert in HCV care and treatment, delivered a lecture called "Efficacy of Current and Future All-Oral Regimens". His presentation explained the various treatment regimens available for medical providers to prescribe in an extremely clear and accessible manner.

Project Inform believed that this presentation would also be valuable for patients. With Dr. Muir's permission, we have adapted his presentation, made minor adjustments and re-wrote it into a more patient-friendly manner to help those living with HCV make informed choices about the HCV regimens available to them.

This brief article will provide you with a list of approved and "off-label" (that is, not FDA approved but effective in treating HCV) for people with HCV, the length of treatment, and the sustained virologic rates (SVR, or cure) that each had during their clinical studies. As you will see in the list below, treatments are shorter and more effective than ever before.

You will also see below that pegylated interferon -- a once-weekly shot that carries a host of challenging side effects -- is nowhere to be found! These new regimens have the added benefit of being better tolerated with mild side effects. This list in not exhaustive, and any treatment decision will be done with your medical provider. We hope it provides you with a clear starting point in your journey to a cure from HCV.

I have genotype 1, have never been on treatment and do not have cirrhosis. What can I take?

Regimen	Length of Treatment	Clinical Trial SVR
Harvoni (viral load <6 million)	8 weeks	97%
Harvoni (viral load >6 million)	12 weeks	95%
Viekira Pak (GT 1a)	12 weeks	97%
Viekira Pak (GT 1b)	12 weeks	99.5%
Sovaldi + Olysio	12 weeks	95%

I have genotype 1, have never been on treatment, but I do have cirrhosis. What can I take?

Regimen	Length of Treatment	Clinical Trial SVR
Harvoni	12 weeks	97%
Viekira Pak	12 weeks	94%
Sovaldi + Olysio	24 weeks	100%

I have genotype 1, I took treatment before and it didn't work, and I don't have cirrhosis. What can I take?

Regimen	Length of Treatment	Clinical Trial SVR
Harvoni	12 weeks	95%
Viekira Pak	12 weeks	95%
Sovaldi + Olysio	12 weeks	95%

I have genotype 1, I took treatment before and it didn't work, and I do have cirrhosis. What can I take?

Regimen	Length of Treatment	Clinical Trial SVR
Harvoni	24 weeks	100%
Viekira Pak (GT 1a)	12 weeks	89%
Viekira Pak (GT 1a)	24 weeks	94%
Viekira Pak (GT 1b)	12 weeks	99%
Viekira Pak (GT 1b)	24 weeks	100%
Sovaldi + Olysio	24 weeks	100%

I am genotype 2, have never been on treatment and I do not have cirrhosis. What should I take?

Regimen	Length of Treatment	Clinical Trail SVR
Sovaldi + ribavirin	12 weeks	98%

I am genotype 2, have either been on treatment and it didn't work and/or I have cirrhosis. What should I take?

Regimen	Length of Treatment	Clinical Trail SVR
Sovaldi + ribavirin	16 weeks	Treatment experienced: 98%Cirrhosis: 60%

I am genotype 3, have never been on treatment and I do not have cirrhosis. What should I take?

Regimen	Length of Treatment	Clinical Trail SVR
Sovaldi + ribavirin	24 weeks	93%

I am genotype 3, have either been on treatment and it didn't work and/or I have cirrhosis. What should I take?

Regimen	Length of Treatment	Clinical Trail SVR
Sovaldi + ribavirin	24 weeks	Treatment experienced: 85%Cirrhosis: 60%

I am genotype 4. What should I take? (Note, results for both treatment naïve and experienced were the same)

Regimen	Length of Treatment	Clinical Trail SVR
Sovaldi + ribavirin	24 weeks	93%

I am co-infected with hepatitis C and HIV. What should I take?

All the regimens listed above can be taken in people living with HIV and HCV, and clinical data show similar response rates as people living with HCV alone. It should be noted that although Sovaldi and Viekira Pak are FDA approved for HCV treatment in people living with HIV as well, Olysio and Harvoni have not. They have been studied in people living with co-infection, and off-label use of these treatments is possible.

Conclusions

There are many treatment choices available for people living with HCV. The above charts are a snap-shot of these choices, but there are many other considerations such as side effects, other co-morbidities (such as kidney disease), and matters that one must consider before making that treatment decision.

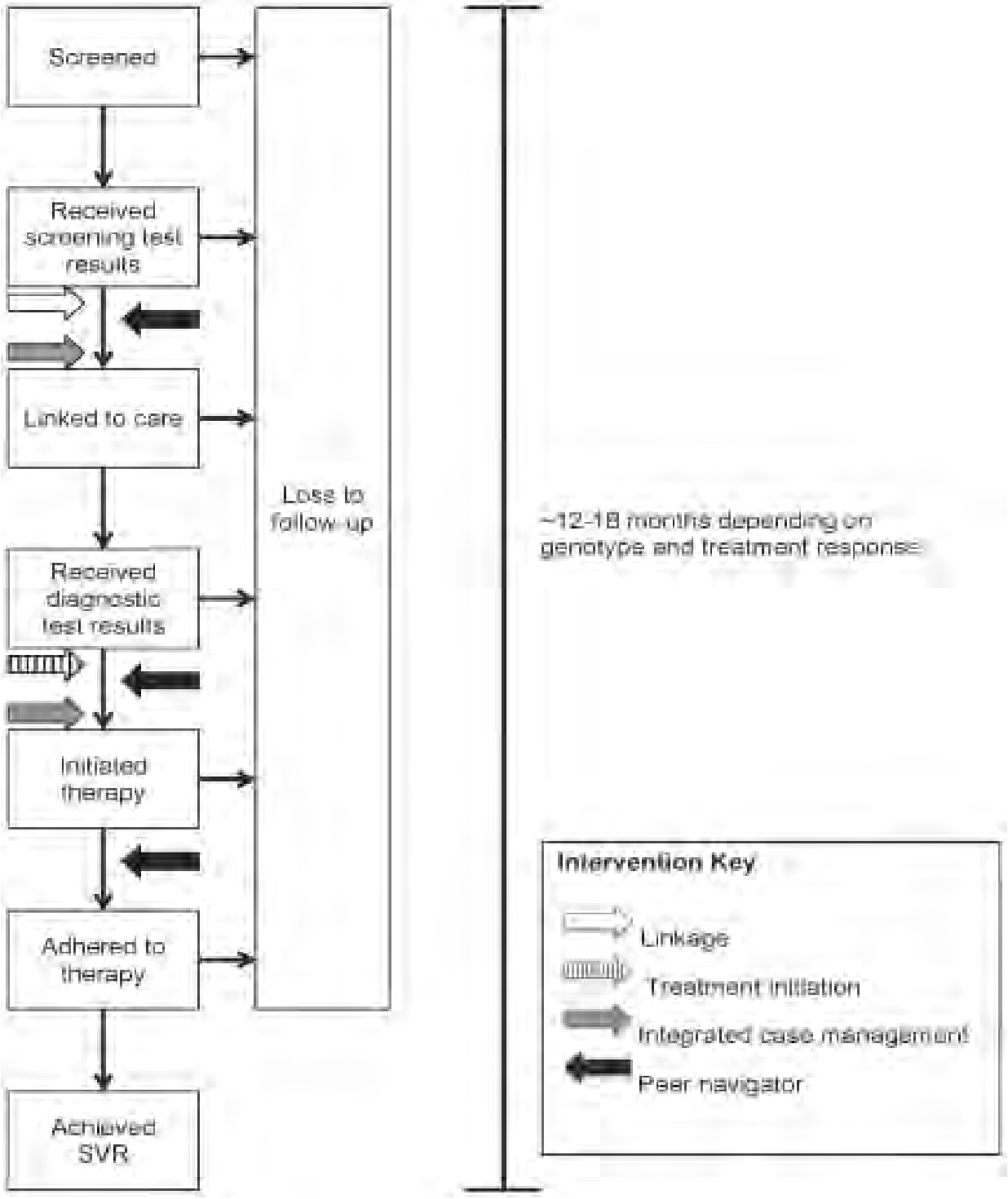
Gather the help you need to make that decision: Speak with your medical provider, pharmacist of nurse about these options. Go to a support group and speak with other patients to hear about their experiences. Project Inform has joined with four other HCV organizations to staff The Support Partnership's "Help-4-Hep" national phone line. Call us at 1-877-HELP-4-HEP (1-877-435-7443) and speak with a trained counselor about your treatment options.

http://www.thebody.com/content/75456/i-have-hepatitis-c-what-are-my-treatment-options.html?ap=2009

PARTICIPANT HANDOUT #5

HCV Cascade (Module #5)

The Hepatitis C Cascade of Care: Identifying Priorities to Improve Clinical Outcomes



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