Increasing Hepatitis C Knowledge for Behavioral Health and Medical Providers

(Revised December 2016)

HCV Current is a national initiative developed by the ATTC Regional Centers, funded by Substance Abuse and Mental Health Services Administration (SAMHSA) as a comprehensive response to the hepatitis C (HCV) epidemic in the US. HCV Current is designed to help increase HCV knowledge among medical and behavioral health professionals, especially staff at federally qualified health centers. The project offers an array of resources and tools for health professionals, including online and in-person curriculum and training, downloadable provider tools, and region-specific resources.

Brian R. Edlin, MD, FACP, FIDSA
Senior Principal Investigator, NDRI
Institute for Infectious Disease Research

Diana Padilla
Program Manager, NDRI USA
Hepatitis C Specialist, NeC ATTC

Beth A. Rutkowski, MPH
Associate Director of Training and Epidemiologist
PSATTC UCLA Integrated Substance Abuse Programs
The ATTC Network

ATTC Network Coordinating Office

Central Rockies ATTC (8)
Mid-America ATTC (7)
Great Lakes ATTC (5)
Central East ATTC (3)
Northeast ATTC (4)
New England ATTC (1)
Northwest Frontier ATTC (10)
National Hispanic and Latino ATTC

Logistics

• 9:00am – 4:00pm
• Training design
  - One 6-hour or two 3-hour deliveries
  - ‘Movable’ parts
• Breaks and lunch
• Evaluation and accreditation
Training Goals

- Instruct behavioral health and medical providers in clinical settings (especially FQHCs & OTPs) on hepatitis C and its impact on communities served.
- Help providers to develop tools and skills to integrate hepatitis C prevention, education, counseling, and linkage to care in their settings.

Learning Objectives

1. List at least three populations at-risk for hepatitis C infection
2. Explain the difference between acute and chronic hepatitis C infection
3. Discuss at least two reasons why it is important to promote hepatitis C screening and testing
4. Describe at least three prevention messages that can be used when promoting hepatitis C screening and testing
5. List at least three treatment factors to consider and describe at least two new treatment options available to patients with HCV
6. Provide examples of at least three strategies to link persons infected with HCV to health care
Training Agenda

Module 1: Training Rationale and Populations at Risk
Module 2: Hepatitis C Infection
Module 3: Promoting Screening and Testing for Hepatitis C Infection
Module 4: Hepatitis C Treatment Monitoring, Evaluation, and Therapies
Module 5: Linking Patients Infected with Hepatitis C to Health Care Services

Introductions

• Name
• Organization
• Position
Hepatitis C Burden

- Hepatitis C virus (HCV) infection is the *leading* cause of cirrhosis, liver cancer, and liver transplantation.

- Of all persons living with HCV infection, about 75% were born during 1945-1965.

- Persons with chronic hepatitis C infection have an estimated mortality rate 12 times higher than the general population.

• Acute hepatitis C infections increased 250% from 2010 to 2014
• Acute hepatitis C infections increased 364% from 2006 to 2012 in four states affected by the opioid epidemic (Kentucky, Tennessee, Virginia, West Virginia)

Bridging the Gap to a Cure

Hepatitis C can be cured with all oral therapies in the vast majority (>95%) of patients
Increase Hepatitis C Prevention

- Educate and train primary care providers and healthcare systems in treating hepatitis C and caring for stigmatized populations including PWID
- Improve primary and secondary prevention effectiveness, policy development, education and training initiatives, and applied research
- Assess and address missed opportunities for medical evaluation, care, and treatment, as well as for counseling to promote behavioral changes that might reduce disease progression and avert transmission of infection

**HIV and Hepatitis A, B, & C**

<table>
<thead>
<tr>
<th></th>
<th>HIV</th>
<th>HAV</th>
<th>HBV</th>
<th>HCV</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lifelong Infection</td>
<td>100%</td>
<td>0%</td>
<td>Adults: 2-5%</td>
<td>75-85%</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Perinatal: ~90%</td>
<td></td>
</tr>
<tr>
<td>Protective Immunity</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>from Natural Infection</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vaccine</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Genetic Material</td>
<td>RNA</td>
<td>RNA</td>
<td>DNA</td>
<td>RNA</td>
</tr>
<tr>
<td>Curable</td>
<td>0%</td>
<td>Self limited</td>
<td>1-2%</td>
<td>&gt;95%!</td>
</tr>
</tbody>
</table>

**Sources**
**Blood Borne Pathogens**

**Transmission of Viral Infections**

<table>
<thead>
<tr>
<th>HIV</th>
<th>HBV</th>
<th>HCV</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Injection drugs:</strong> Contaminated needles, syringes, cooker, cotton</td>
<td><strong>Injection drugs:</strong> Contaminated needles, syringes, cooker, cotton</td>
<td><strong>Injection drugs:</strong> Contaminated needles, syringes, cooker, cotton</td>
</tr>
<tr>
<td><strong>Sexually:</strong> Blood, semen (pre-seminal fluid), vaginal secretions</td>
<td><strong>Sexually:</strong> Blood, semen, vaginal secretions</td>
<td><strong>Sexually:</strong> Traumatic sexual exposure</td>
</tr>
<tr>
<td><strong>Perinatally:</strong> From HIV-infected mother to newborn</td>
<td><strong>Perinatally:</strong> From HBV-infected mother to newborn</td>
<td><strong>Perinatally:</strong> From HCV-infected mother to newborn</td>
</tr>
<tr>
<td><strong>Other infectious body fluid:</strong> breast milk</td>
<td></td>
<td><strong>Open sores</strong></td>
</tr>
</tbody>
</table>

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**Opportunities for Blood Borne virus Transmission During Injection Drug Use**

- Mixing water
- Mixing syringe
- Water used to fill syringe
- Alcohol wipe
- Skin
- Syringe
- Cotton or filter
- Hands
- Stanching the blood
An Estimated 135 Million Persons Are Infected With HCV Worldwide

Europe: 8.9 million (1.03%)  
Americas: 13.1 million (1.7%)  
Africa: 31.9 million (5.3%)  
Eastern Mediterranean: 21.3 million (4.6%)  
Western Pacific: 62.2 million (3.9%)  
Southeast Asia: 32.3 million (2.15%)  

An Estimated 4-5 Million Persons Are Infected With HCV in the U.S.

Screening for Hepatitis C Infection

The CDC & USPSTF recommend:

• Screening for HCV infection in persons at elevated risk for infection.
• Offering one time screening for HCV infection to adults born between 1945 and 1965.

Some experts recommend screening everyone at least once for both HIV and HCV.

Sources:

History of Hepatitis C

- **1970’s**: Virus appears in enough people to be noticed (called non-A, non-B)
- **1980s**: Blood screened for ALT, reducing HCV transmission (before it was discovered)
- **1989**: Hepatitis C virus identified & named
- **1990**: First antibody test helps identify people exposed to the virus & is used to screen blood
- **1992**: Better tests insure safety of blood supply and confirmatory test for anti-HCV is approved

Risk Based Recommendations for HCV Testing

- Persons who have ever injected illegal drugs, including those who injected only once many years ago, ever shared needles and works
- All persons born between 1945 - 1965
- All persons with HIV infection
- Persons presenting with symptoms of hepatitis, or elevated enzyme levels
- Received transfusion or blood products before 1992
- Received clotting factor prior to 1987
- Ever on hemodialysis
- Healthcare, emergency, public safety workers after exposures to HCV through infected blood
- Children >1 year born to HCV-positive women
- Tattoo and/or body piercing done while incarcerated or by an unlicensed artist
Other Factors Associated with Elevated Risk

- Low income
- History of homelessness
- History of incarceration
- History of mental health conditions or substance use
- Communities of color
- Birth in an endemic region
- Other factors (heavy alcohol use, non-injected drug use, multiple sex partners, diabetes)


Emerging Trends

- Rising rates (22.3%) of HCV infection among young people who inject drugs
  - Over 5 million young people used pharmaceutical opioids non-medically in the past year
- Iatrogenic transmission (healthcare exposure)
- Sexual transmission of HCV amongst HIV-infected and HIV-uninfected men who have sex with men (MSM)

Hepatitis Risk Assessments

Designed to assess an individual’s risk for viral hepatitis and based on CDC recommendations for testing and vaccination

- Center for Disease Control and Prevention, Viral Hepatitis
  http://www.cdc.gov/hepatitis/RiskAssessment

- Minnesota Dept of Health, HIV/STD/Hepatitis Risk Assessment
  http://www.health.state.mn.us/divs/idepc/diseases/hiv/riskassessment

- New York State Dept of Health

Module 2

Hepatitis C Infection
Characteristics of Hepatitis C

• Hepatitis C virus is a rapidly replicating blood borne pathogen that causes inflammation of the liver.

• Clinical presentation during acute HCV infection may or may not include jaundice, abdominal pain, or flu-like symptoms such as fatigue, muscle aches, and nausea.

• Can live in blood outside body for days to weeks - much longer than HIV.

• No vaccine…yet!

HCV infection causes inflammation of the liver.

• Over years, inflammation leads to scarring (scarring = fibrosis).

• Severe scarring (F4=stage 4 fibrosis or cirrhosis).

• Cirrhosis can lead to end stage liver disease (decompensated cirrhosis), hepatocellular carcinoma (liver cancer), which is fatal without a liver transplant.
Acute* HCV Infection

- Average time of development of HCV antibodies when first infected is about 6-8 weeks, up to 6 months in some cases

- 15%-25% spontaneously clear the virus without treatment in 3-4 months, most times without symptoms

*Acute phase: within the first 6 months after acquiring infection

Chronic* HCV Infection

75-85% develop chronic infection and may remain stable for years
- 20%-30% develop cirrhosis and serious illness within 20 years if untreated
- 20%-37% will die as a result of liver failure or liver cancer due to untreated HCV disease

*Chronic phase: infected more than 6 months after acquiring infection
### Chronic HCV Infection “Extrahepatic” manifestations

<table>
<thead>
<tr>
<th>Category</th>
<th>diseases</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hematologic</td>
<td>mixed cryoglobulinemia, Non-Hodgkin’s lymphoma</td>
</tr>
<tr>
<td>Metabolic</td>
<td>Insulin resistance, diabetes mellitus</td>
</tr>
<tr>
<td>Renal</td>
<td>Membranoproliferative glomerulonephritis, Membranous nephropathy</td>
</tr>
<tr>
<td>Dermatologic</td>
<td>Porphyria cutanea tarda</td>
</tr>
<tr>
<td>Autoimmune</td>
<td>Idiopathic thrombocytopenic purpura</td>
</tr>
<tr>
<td>Nonspecific</td>
<td>Chronic fatigue, memory loss, Cognitive impairment (“mental fog”)</td>
</tr>
</tbody>
</table>

### Nonspecific Symptoms of Chronic Hepatitis C

- Chronic fatigue, memory loss, cognitive impairment (“brain fog”)
- Not related to severity of liver disease (can be early or late)
  - Can be severe, disabling
  - May be passed off as not due to hepatitis C
  - May not be recognized until it goes away with treatment
Cirrhosis

Compensated cirrhosis
• Asymptomatic stage

Decompensated cirrhosis
• Clinically evident symptoms
• End-stage liver disease

Decompensated Cirrhosis
Symptoms presenting during end stage liver disease
• Portal hypertension
• Ascites (fluid in abdomen)
• Jaundice
• Variceal bleeding
• Hepatic encephalopathy
Monitoring Liver Health and Disease

- Liver enzyme tests (LETs) use measured levels of enzymes as markers of inflammation and injury: ALT, AST (1/3 of people with HCV have normal enzyme levels)
- Liver function tests (LFTs) help show how the liver is working (platelet count, bilirubin, albumin, prothrombin time)
- AFP (for liver cancer)

A Silent Killer

Hepatitis C infection is usually asymptomatic and often goes undiagnosed unless:
- Patient enters primary care for unrelated medical issues and consequent blood panels reflect elevated enzymes
- End stage liver disease has occurred and symptoms present
- Through promotion of HCV screening and testing based on risk behaviors or birth cohort
Module 3
Promoting Screening and Testing of Hepatitis C Infection

Keys to Promoting HCV Testing

- Keeping in mind patient factors such as fear, stigma, lack of HCV information, and relatedness, initiate a conversation around a patient’s identified risk behavior for HCV and the benefits of screening and testing.

- Discuss the entire testing process and possible test results. Include availability of provider support, tailored risk reduction counseling, and current treatment options.
Screening & Testing for HCV

Diagnosing Hepatitis C infection is a 2 step process

1) **Anti-HCV (antibody)**
   - Non reactive (negative)
   - Reactive (positive)

2) **HCV RNA (PCR or viral load)**
   - Not detected
   - Detected


Anti-HCV Tests

- Anti-HCV tests are used to detect the presence of antibodies to hepatitis C virus
- HCV screening tests designed to detect antibodies have a “window period” (6-8 weeks)

Source: Open AID Alliance, HIV and Hepatitis C Testing, http://www.openaidalliance.org/find-help/testing
Anti-HCV Tests

Serological HCV Antibody Assays
- EIA (enzyme immunoassay)
- CIA (enhanced chemiluminescence immunoassay)

OraQuick® HCV Rapid Antibody Test
- Point-of-care antibody test results in 20 minutes
- Fingerstick, venipuncture, serum, or plasma (not oral fluid)

Anti-HCV Test Results

A *non-reactive* (negative) result means HCV antibodies were not found and you’re probably not infected with HCV
- You are not protected from future HCV infection
- Or you may still be in the window period
Non Reactive Counseling Messages

To stay negative, eliminate or reduce risk by practicing (see handout):

- Don’t share needles or other injection equipment, or anything that may have blood on it
- Tattoos, piercings, and body art from a licensed artist and explain what consumer should expect
- Vaccinate against hepatitis A and B
- Practice safer sex, and get treated for STDs

* If person engaged in risky behavior within the last 6 months, they should be encouraged to get retested (anti-HCV) in 6 months

Anti-HCV Test Results

A reactive (positive) test result means antibodies to HCV were found in your blood

- HCV infection occurred and you may still be infected
- Further testing must be done with an HCV RNA (PCR) test to see if you are still infected
Reactive Counseling Messages

- HCV RNA test measures amount of HCV in your blood
- If there is no virus, test will come back, ‘not detected.’
- If ‘detected,’ then you are infected with hepatitis C.
- Until you get the HCV RNA, **assume** you are infected with HCV and help protect your liver by avoiding alcohol, and practice other risk reduction behavior*
- See a doctor, learn about hepatitis C, and HCV treatment

* Counselor facilitates access to and schedules second test

Antibody Tests Cannot Tell the Difference Between…

- Someone who has a chronic infection
- Someone who had a past infection
  - Someone who has ‘cleared’ the virus spontaneously
  - Someone who has been effectively treated
Diagnosing HCV Infection

HCV RNA (PCR or Viral Load) or confirmatory testing

- **Qualitative** - test for presence or absence of HCV virus
- **Quantitative** - test for amount of HCV virus in blood (viral load)
  - *Not detected* result means no current infection
  - *Detected* result means hepatitis C virus was found, confirming HCV infection

Working with HCV RNA Results

**Not detected**

- No current infection (*some recommend another test in 3-6 months to be sure*)
- Past cleared HCV infection means you can still get infected again
**Working with HCV RNA Results**

**Detected or Viral Load**

- Diagnosis of active infection
- Conduct genotype testing
  - *Six known genotypes (1a & 1b subtypes, 2-6)*
  - *75% of US infections are Genotype 1*
- Knowing your genotype is important when considering treatment
- Evaluate for treatment eligibility

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**Not Detected/Detected Test Results**

Despite the HCV RNA test result, patient is encouraged to practice tailored risk reduction behavior options

- "If you’re HCV RNA test result is, ‘not detected,’ then you’re not currently infected. But you can change your risky behavior that first got you infected, so as not to become re-infected."

- "If you’re HCV RNA test result is, detected,’ (viral load) then understand how you can modify your risky behavior to not infect someone else."

….allow me (provider) to link you to a specialist that can work to monitor you and perhaps treat your HCV infection."
Understanding Screening Results

HCV antibody:  
- Non reactive
- Reactive
- Reactive

HCV RNA:  
- Not detected
- Detected

Meaning:  
- Not infected\(^1\)
- Previously infected\(^2\)
- Currently infected\(^3\)

Additional testing as appropriate:

\(^1\)Unless in window period (recently infected) or immunocompromised
\(^2\)Repeat test in 6 months to be sure
\(^3\)Needs medical evaluation to assess stage and consider for treatment

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

1. **HCV antibody**
   - Nonreactive: No HCV antibody detected
     - Additional testing as appropriate\(^1\)
   - Reactive: Not detected
     - HCV RNA: Not detected
       - Current HCV infection
         - Link to care
     - HCV RNA: Detected
       - Not current HCV infection
         - No HCV antibody detected
         - Stop

\(^1\)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 is recommended.
Activity
Promoting HCV Testing: Role Plays

Using SBIRT to promote testing with Eddie
Using SBIRT to promote HCV testing with Tony
Using SBIRT to promote testing with Eva
Using SBIRT to promote testing with Jorge
Using SBIRT to promote testing with Concetta
IRETA, Institute for Research, Education and Training in Addictions
Module 4
Hepatitis C Treatment Monitoring, Evaluation, and Therapies

Monitoring Progression of HCV
Factors that may accelerate the progression of HCV
- HIV infection
- Older age at the time of infection
- Male gender
- Insulin resistance
- Abnormal accumulation of fat in the liver (steatohepatitis - fatty liver disease)
  - Alcoholic
  - Non alcoholic - diabetes (obesity)
  - HCV genotype 3
Assess Alcohol Consumption

Heavy alcohol intake accelerates progression of liver fibrosis

- Alcohol screening questions and brief intervention if indicated
  - “How many times in the past year have you had 4/5 or more drinks in a day?” (4 for women, <65 and 5 for men)
  - CAGE questionnaire

- SBIRT, (Screening Brief Intervention and Referral to Treatment)
  - IRETA, National SBIRT ATTC [http://my.ireta.org/ATTC](http://my.ireta.org/ATTC)

More Aspects of Monitoring

- Recommend vaccination for HAV and HBV
- Monitor patients with low or undetectable HBV DNA levels
- Education on hepatitis C transmission, progression and strategies to reduce harm
- Clinical evaluation for treatment eligibility
Clinical Evaluation

- Blood tests
  - Liver enzymes (ALT, AST)
  - Liver function tests (bilirubin, albumin, prothrombin time)
  - Platelet count
  - Screen for HBV

- Assess degree of hepatic fibrosis, using noninvasive testing (FibroSURE™, FibroScan®, sometimes combined with FibroMeter®) or liver biopsy.

- Liver cancer screening for patients with cirrhosis (every six months)
  - Serum alpha-fetoprotein
  - Hepatic ultrasound


Treatment Factors to Consider

- Extent and severity of liver disease
- Extrahepatic manifestations (e.g., cryoglobulinemia, nonspecific symptoms)
- Patient preference
- Drug-drug interactions
- Comorbid HIV or other liver disease
- Adherence issues and possibility of resistance
- Reinfection
- Insurance coverage

Source: Core Concepts. Making a Decision on When to Initiate HCV Therapy
http://www.hepatitisc.uw.edu/go/evaluation-treatment/treatment-initiation-decision/core-concept/all
**HCV Treatments & Timeline**

- **2016**
  - *Epclusa* (sofosbuvir/velpatasvir) first all-oral, single tablet regimen for adults with genotypes 1-6 (without cirrhosis, compensated or decompensated cirrhosis)
  - *Harvoni* (ledipasvir/sofosbuvir) first once-daily pill that doesn’t require interferon or ribavirin, treatment option for patients with genotype 1

- **2015**
  - *Zepatier* (elbasvir and grazoprevir) with or without ribavirin for patients with genotypes 1 and 4 (treatment naive without cirrhosis, compensated or decompensated cirrhosis)
  - *Technivie* (ombitasvir, paritaprevir and ritonavir) is used in combination with ribavirin for the treatment of patients with genotype 4 that do not have scarring and poor liver function (cirrhosis)

- **2014**
  - *Viekira Pak* (ombitasvir/paritaprevir/ritonavir and dasabuvir) oral combination therapy for the treatment of patients with genotype 1 (with compensated cirrhosis)
  - *Olysio* (simeprevir) capsules in combination with peginterferon alfa and ribavirin or with sofosbuvir, in treatment naive patients with genotype 1
  - *Sovaldi* (sofosbuvir) tablets to be used in combination with ribavirin or with pegylated interferon and ribavirin, for patients with genotypes 1, 2, 3 or 4

Source: Hepatitis Central, Medications to Treat Hepatitis C – A Timeline

**HCV Treatments & Timeline**

- **2011**
  - *Victrelis* (boceprevir) in combination with peginterferon alfa and ribavirin, for the treatment of genotype 1 (treatment naive, experienced, with compensated or decompensated cirrhosis)
  - *Incivek* (telaprevir) in combination with peginterferon alfa and ribavirin for the treatment of genotype 1 (treatment naive, experienced, with compensated or decompensated cirrhosis)

- **2002**
  - *Pegasys* (peginterferon alfa-2a) for the treatment of chronic HCV as part of a combination therapy
  - *Copegus* (ribavirin) in combination with Pegasys in patients 5 years of age and older (with compensated liver disease that were not previously treated with interferon alpha as well as in adults coinfected with HIV)

- **2001**
  - *Peginteron* (peginterferon alfa-2b) injections for treatment of chronic HCV patients with compensated liver disease

- **1998**
  - *Rebetol* (ribavirin) to be used in combination with interferon alfa-2b (both pegylated and non-pegylated) injections for the treatment of chronic hepatitis c in patients 3 years of age and older with compensated liver disease.

Source: Hepatitis Central, Medications to Treat Hepatitis C – A Timeline

http://www.hepatitiscentral.com/medications-to-treat-hepatitis-c-a-timeline
**HCV Treatment Update Sites**

- **Hepatitis C New Drug Research And Liver Health**
  Approved Treatments For Hepatitis C

- **HCV Guidance: Recommendations for Testing, Managing, and Treating Hepatitis C**
  [http://www.hcvguidelines.org](http://www.hcvguidelines.org)

- **Hepatitis C Treatment & Management**

**HBV and HCV Coinfection**

**New Guidance 2016**

All patients initiating HCV DAA therapy should be assessed for HBV coinfection with HBsAg, anti-HBs, and anti-HBc

- HBV vaccination for all susceptible individuals.
- Obtaining a test for HBV DNA prior to DAA therapy in patients who could be actively replicating.
- For those indicated, treat active HBV infection at the same time or before HCV DAA therapy is started.
- Monitoring patients with low or undetectable HBV DNA levels at regular intervals as recommended by the AASLD’s HBV treatment guidelines.

**SOURCE:** Monitoring Patients who are Starting Hepatitis C Treatment, are on Treatment, or Have Completed Therapy. [http://www.hcvguidelines.org/full-report/monitoring-patients-who-are-starting-hepatitis-c-treatment-are-treatment-or-have](http://www.hcvguidelines.org/full-report/monitoring-patients-who-are-starting-hepatitis-c-treatment-are-treatment-or-have)
HIV and HCV Coinfection

• Consultation between HCV and HIV practitioners

• Potential drug-drug interactions should be assessed (eg., sofosbuvir, ledipasvir, and simeprevir interact with some antiretrovirals) http://www.hep-druginteractions.org

• Treatment recommendations should follow the recommendations for mono-infection specific to genotype (no 8 week treatment regimen)


Methadone and Buprenorphine

• Generally, methadone and buprenorphine are safe for the liver and most people are often able to complete HCV treatment
  • For some people, the medications for HCV make them feel like they’re going through withdrawal and their methadone dose needs to be adjusted so they’re comfortable
  • For others, the HCV medications make their body more sensitive to methadone and they need a smaller amount of methadone
• HCV medications may also increase or decrease the amount of buprenorphine in the body, so a person may need to have their buprenorphine dose adjusted after starting treatment

Treatment Markers & Benefits

- Sustained virologic response (SVR) 12 weeks after treatment completion, (no virus detected) means cure
- Reduction in liver failure, liver cancer, and liver-related deaths
- Oral therapies
- HCV therapy is shorter duration (8-24 weeks)
- Increased treatment tolerability

Treatment Recommendations

- Treatment is recommended for all patients with chronic HCV infection, except those with short life expectancies
- In cases where there is limited treatments available, immediate treatment is assigned the highest priority for those patients with advanced fibrosis (F3), those with compensated cirrhosis (F4), liver transplant recipients, and patients with severe extrahepatic hepatitis C
- Transmission can be interrupted by treating those engaging in risk behavior (PWID, MSM)
- Persons on Buprenorphine, Methadone, and Naltrexone can be treated for hepatitis C infection

SOURCES:
### High Priorities for Treatment

**Highest risk for severe complications:**
- Advanced fibrosis (F3 or F4)
- Organ transplant
- Type 2 or 3 mixed cryoglobulinemia with end-organ manifestations (e.g., vasculitis)
- Proteinuria, nephrotic syndrome, or membranoproliferative glomerulonephritis

**Elevated risk for complications:**
- Fibrosis (F2)
- HIV-1 coinfection
- HBV coinfection
- Other coexistent liver disease (e.g., NASH)
- Debilitating fatigue
- Type 2 diabetes
- Porphyria cutanea tarda

**At-risk for complications:**
- All HCV-infected patients


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### Estimated Cost* of Recommended Regimens for Treatment of GT 1 HCV

<table>
<thead>
<tr>
<th>Regimens(^\dagger) and Duration of Therapy</th>
<th>Cost of Regimen*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Elbasvir-Grazoprevir x 12 weeks</td>
<td>$54,600</td>
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<tr>
<td>Elbasvir-Grazoprevir x 16 weeks</td>
<td>$72,800</td>
</tr>
<tr>
<td>Ledipasvir-Sofosbuvir x 12 weeks</td>
<td>$94,500</td>
</tr>
<tr>
<td>^Ombitasvir-Paritaprevir-Ritonavir + Dasabuvir x 12 weeks</td>
<td>$84,000</td>
</tr>
<tr>
<td>Sofosbuvir + Simeprevir x 12 weeks</td>
<td>$150,000</td>
</tr>
<tr>
<td>Sofosbuvir-Velpatasvir x 12 weeks</td>
<td>$74,760</td>
</tr>
<tr>
<td>Daclatasvir + Sofosbuvir x 12 weeks</td>
<td>$147,000</td>
</tr>
</tbody>
</table>

*Cost estimates based on Wholesale Acquisition Cost (WAC)
\(^\dagger\)For genotype 1a, this regimen includes ribavirin for 12 weeks (add approximately $500 to cost)

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Estimated Cost of Medication Regimens Used to Treat Genotype 1 Chronic HCV. This figure shows the approximate cost of different regimens used for treatment-naive patients with genotype 1 chronic HCV. Cost estimates based on wholesale acquisition cost (July 11, 2016).
Treatment Restrictions

• Medications are costly ($64,000 to $189,000 per treatment course*)

• Many payers (United Health care, Anthem (Wellpoint), and 30 state Medicaid programs) restrict who they will cover
  – Many say patient must have F3 or F4 (advanced fibrosis or cirrhosis)
  – Many say patient must be alcohol and drug free (and some require urine testing)
  – Many say physician must be hepatitis specialist or have hepatitis treatment experience

*Wholesale acquisition cost

Payment Assistance Resources

• Prices are dropping (discounts) and access may improve

• Insurance

• Patient assistance programs
  o Gilead patient assistance program (“Support Path”)
    http://www.gilead.com/responsibility/us-patient-access/support%20path%20for%20sovaldi%20and%20harvoni
  o AbbVie patient assistance program (“proCeed”)
    http://www.patientassistanceprograms.net/?gclid=CLnKwdefiNACFQRhegdognyoB8Q

• Specialty pharmacies can help doctors and patients obtain medications
Payment Assistance Resources

**Patient Access Network Foundation (PAN)**
Contact Information: 866-316-PANF (866-316-7263) or www.panfoundation.org
Program Details: The Patient Access Network Foundation offers help to people with chronic or life-threatening illnesses for whom cost limits access to medical treatments

**HealthWell Foundation**
Contact Information: 800-675-8416 or www.healthwellfoundation.org/hepatitis-c
Program Details: The HealthWell Foundation provides financial assistance to eligible individuals to cover coinsurance, copayments, health care premiums and deductibles for certain medications and therapies.

**HCV-HIV Coinfection**
To find patient assistance and co-pay programs if you are coinfect ed with HCV and HIV, check out: Help Paying for Meds: Patient Assistance and Co-Pay Programs for HIV and Viral Hepatitis Drugs
Linkage to Hepatitis C Care

Promoting and linking persons infected with hepatitis C to appropriate health care services can be initiated at various points of patient contact and in a variety of care settings, including:

- Primary care
- Emergency rooms
- HIV testing sites
- Syringe exchange programs (SEPs)
- Substance use disorder treatment programs
- Mental health treatment programs
- Methadone maintenance clinics
- STI clinics
- Community-based outreach to active IDUs
- Homeless shelters
- Others?

- Through promotion of HCV screening and testing
  - One-time testing of people in birth cohort or with identified risk factor
- Referral to health care facility for HCV RNA testing and evaluation for treatment
- Entering primary care for non-HCV medical issue
- Already within the continuum of HCV care
Facilitating Linkage to Care by Promoting HCV Screening & Testing

HCV Cascade of Care: Intervention Clinical Outcomes

Strategies for Hepatitis C Testing and Linkage to Care

• 1,345 Mobile Medical Clinic (MMC) clients in New Haven, CT underwent a routine health assessment, including for HCV

• While patients equally preferred POC and standard HCV testing strategies, HCV-infected patients choosing POC testing were significantly more likely to be linked to HCV treatment

• HCV testing strategies should be balanced based on costs, convenience, and ability to link to HCV treatment


Patient-Focused Interventions

• 3 month intervention based on Anti-Retroviral Treatment and Access to Services (ARTAS); strength-based case management model.

• Patient-centered linkage case management; staff solely focused on linkage and retention

• Peer navigation with patients newly diagnosed with HCV and patient supports through completion of HCV treatment
Provider-Focused Initiatives

• Improve provider education on hepatitis C
• Incorporate routine screening into clinic workflow and implement testing by non-clinical staff
• Enable providers to apply best practices in monitoring and treating hepatitis C
  o Telemedicine (e.g., project ECHO) using video conferencing with clinical hepatitis experts
  o Data systems with centralized database to monitor outcomes
  o Develop screening indicators (EMR) and share with individual clinics and providers

Management of HCV via Telemedicine Consultation and Teleconferencing

• Telemedicine can be an effective alternative to provide care to patients with hepatitis C, including those who may be financially or geographically disadvantaged

• Through telemedicine, general health care providers can learn how to make correct diagnoses, stage liver disease severity, decide if therapy is indicated, and appropriately manage the course of treatment

Management of HCV via Telemedicine Consultation and Teleconferencing

- Telemedicine outreach to rural areas and to correctional facilities is developing as an effective and innovative modality for closing the disparity gap in the access to care

- The HCV community should approach this modality of care with an open mind and evaluate the potential advantages and long-term benefits of linking the local PCP to specialty care


Thank you for your time!
Provider-Focused Initiatives

• Develop a hepatitis C “champion”
  – Act as a resource for information
  – Monitor screening
  – Monitor follow-up and cascade of care

• Designate a lead clinician who will take on the primary responsibility of HCV treatment and monitoring, or establish and organize a system for evaluation, treatment, and monitoring.


Community-Focused Forums

• Increase public awareness through educational seminars with parent-teacher groups, faith-based communities, presentations on hepatitis C provided by clinics, etc.

• Collaborate with community-based providers through a memorandum of understanding (MOU)
Update Standards

Promoting HCV screening and testing with everyone is key to identifying persons potentially infected with HCV

Include on forms:
"We believe that everyone should have a blood test for hepatitis C at least once in their lives if they haven't had one already.
Would you like a hepatitis C test? ____ Yes ____ No"

Referral/Walk in
Reception (updated forms)
Physical exam & reason for visit
Lab tests ordered, interim treatment recommendations
Primary follow up appointments
Counsel on HCV test result, reiterate risk reduction, refer for HCV RNA if appropriate, link to HCV health care
HCV health care, HCV RNA detected, Evaluation for treatment eligibility, Initiate treatment
(SVR) Cure

Medical model
Promote HCV screening and testing as standard of care
Integration Activity

Discuss these two questions, and list at least 2 strategies by practice setting:

1. How can screening be incorporated at your practice setting and at various patient contact points, with those entering or already in care?

2. Does anyone at your practice treat hepatitis C and have a place to refer out to? Do those referred patients go?

(Handout: HCV cascade of care)
HCV Resources for Patients

- Caring Ambassadors, http://caringambassadors.org/
- National Viral Hepatitis Roundtable, http://nvhr.org/
- Hepatitis C Careline, 1-800-532-5274 Managed by the Patient Advocate Foundation to provide Hepatitis C patients with hands-on case management support
- American Liver Foundation Support Services, http://www.liverfoundation.org/support

HCV Resources for Providers

- AASLD & IDSA, www.hcvguidelines.org
- CDC, Center for Disease Control and Prevention, Viral Hepatitis, http://www.cdc.gov/hepatitis
- Project ECHO, http://echo.unm.edu