Prevention, Screening and Treatment for Viral Hepatitis Among Patients With Behavioral Health Disorders
(Recorded Webinar, Available July 9, 2014)

Webinar link: https://www2.gotomeeting.com/register/476323426
Presenters

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Sonia Vibhakar, PharmD., is also from the CORE Center. Dr. Vibhakar provides direct patient care in general medicine and specialty clinics, including psychiatry and HIV, which focuses on pharmacotherapy consultations, patient/disease assessment, drug therapy evaluation, selection of therapeutic regimens, appropriate drug therapy and disease monitoring, and medication adherence.
Objectives

• Assess cost concerns and coverage for screening, vaccination, and medical therapies
• Become familiar with medications and current treatment options
• Anticipate changes in the approaches to treatment and the role of the behavioral health care provider
Outline

• Viral Hepatitis and transmission

• Costs and coverage
  • Hepatitis A and B Vaccination
  • Hepatitis C screening
  • Hepatitis C therapies

• Behavioral Health Impact
  • Change in Hepatitis C therapies will increase treatment options for patients with existing behavioral health disorders

• Frequently Asked Questions
Viral Hepatitis and Transmission

Hepatitis A - preventable by vaccine
- Never becomes chronic, recovery in about 6 months
- Transmission: Oral contact (mouth) with contaminated objects, food, drinks

Hepatitis B - preventable by vaccine
- Acute (usually those infected in adulthood)
- Chronic (usually those with perinatal transmission)
- Transmission: Infected blood, semen, other bodily fluids

Hepatitis C – no vaccine
- Acute: no symptoms, 15-30% spontaneously clear the infection
- Chronic: after 20 years, up to 20% develop cirrhosis
- Transmission: Blood on shared needles, razors, toothbrushes; blood transfusion, organ transplant (pre-1992); perinatal; unprotected sex
Costs for Vaccinating Hepatitis A and B

Estimated Cost for comparison
Local state health department is the least expensive

CDC.gov: price range varies between $10 to $110 per shot

- Hep A Adult - $50-150 and Hep A Child $129
  - Includes 2 shots
  - Lifetime immunity

- Hep B Adult - $60-165 and Hep B Child $129
  - Includes 3 shots
  - Immunity can wane over time
Changes in Coverage for Hepatitis A/B Vaccinations

- **Private Insurance**
  - All health insurance marketplace plans, most private plans must cover A and B vaccines without charging co-payment and even if yearly deductible has not yet been met

- **Medicaid**
  - Adults - varies by state
  - Children’s Health Insurance Plans (CHIP) - covers both A and B for children turning two in coverage year

- **Medicare**
  - For A vaccine - Medicare coverage varies by plan
  - For B vaccine - Currently high or medium risk or at end stage renal disease, but will expand to include baby boomer
Overview for HCV Testing

Hepatitis C Virus (HCV) Screening

• HCV Abs - Antibody test screens for exposure

If screening is positive

• HCV RNA Viral Load test finds the number of viral RNA particles in blood. Checked before and during treatment

• HCV Genotype test – 6 major genotypes of HCV
  • Type 1a/1b: Most common, less likely to respond to treatment
  • Types 2 and 3: Respond better to medication
  • Types 4 and 6: not in the US, Middle and Far East, North Africa
Average Costs for HCV Screening

Estimates for comparison

HCV Abs: Free to $60
  • Looks for antibodies
  • Indicates previous exposure to virus

HCV Genotype: $100 to $330
  • Qualitative: Type 1a, 1b, 2, 3, 4 and 6
  • Indicates what therapy is needed

HCV RNA PCR $100 to $330
  • Quantitative: detects the amount of virus in blood
  • Indicates how active the virus is
Recent Changes in Coverage for HCV Screening

- Coverage for Screening has recently expanded due to CDC Guidelines and ACA
- CDC Guidelines: recommends testing for baby-boomers (born 1945-65) and those at medium to high risk (most behavioral health patients)
- Affordable Care Act (ACA) means better, more widespread coverage
- US Preventive Services Task Force (USPSTF) revised recommendation for HCV screening to Grade “B”
Coverage for HCV Screening - Medicaid

- Medicaid, Non-expansion States
  - Covers “medically necessary” screening for high risk groups
  - Can elect to cover as routine screening – varies by state
  - May elect to receive 1% increase in federal match to cover cost

- Medicaid, Expansion States
  - Covers more patients so covers more screening
  - Required to cover all USPSTF “A” and “B” grade services without cost sharing
  - Screening for “at-risk” and baby boomers covered in Medicaid expansion plans
Coverage for HCV Screening - Medicare

- Medicare covers Grade USPSTF “A” and “B” graded preventive services after National Coverage Determination (NCD)
- Currently covers HCV screening only for those at “increased risk”
- CMS conducted new NCD, released proposed decision memo for both “at risk” and “baby boomers”
  - Will cover per revised USPSTF grade
- ACA removes beneficiary cost sharing for Medicare-approved preventive services
American Association for the Study of Liver Disease (AASLD) Testing and Counseling

Persons with HCV infection should be counseled

- to avoid sharing toothbrushes and dental or shaving equipment, and cover any bleeding wound.
- to stop using illicit drugs and enter substance abuse treatment.
- to avoid reusing or sharing syringes, needles, water, cotton, and other drug preparation equipment; use new sterile syringes and filters and disinfected cookers; clean the injection site with a new alcohol swab; and dispose of syringes and needles after one use in a safe, puncture proof container.
- To NOT donate blood and to discuss HCV serostatus prior to donation of body organs, other tissue, or semen.
AASLD: Testing and Counseling

- Persons with HIV Infection and multiple sexual partners or sexually transmitted infections should be encouraged to use barrier precautions to prevent sexual transmission. Other persons with HCV infection should be counseled that the risk of sexual transmission is low and may not warrant barrier protection.

- Household surfaces and implements contaminated with visible blood from an HCV infected person should be cleaned using a dilution of 1 part household bleach to 9 parts water. Gloves should be worn when cleaning up blood spills.
Historical Treatment for HCV

- Cost, duration, and effectiveness was variable based on genotype

- **Tolerance to Pegylated-Interferon is limited by psychiatric side effects**
  - Psychiatric side effects included depression and suicidality
  - All patients required screening for depression and suicide
  - Patients at high risk for suicidality or with unstable psychiatric and substance use disorders were often “not eligible“ for treatment

- **Up to 2010**
  - Pegylated-Interferon –with ribavirin (injection and tabs) for 24 to 48 weeks

- **2011 to 2013**
  - Pegylated Interferon –with ribavirin and telaprevir or boceprevir (injection, tabs) for 24 to 48 weeks
Treatment for HCV today

- 2013 to present: Standard of care: 12 week treatment
- Interferon free options are currently available
  - More patients with psychiatric and behavioral health disorders will be eligible for interferon-free treatments
  - Pegylated-Interferon – with ribavirin and sofosbuvir (Genotype 1) (Injection and tabs)
  - Pegylated-Interferon – with ribavirin and simeprevir (Genotype 1) (Injection and tabs)
  - Sofosbuvir and ribavirin (Genotype 2 and 3) (tabs)
- For 2015
  - Sofosbuvir and simeprevir – AASLD guidelines
  - Not yet FDA approved (Genotype 1) (tabs)
## Estimated Cost Comparison Summary

<table>
<thead>
<tr>
<th>HCV Therapy</th>
<th>Cost</th>
<th>Treatment Duration</th>
<th>Treatment Success</th>
<th>Side Effects</th>
</tr>
</thead>
<tbody>
<tr>
<td>Peg-Interferon &amp; ribavirin</td>
<td>30-40K</td>
<td>24-48 weeks</td>
<td>30-40%</td>
<td>Interferon can cause flu-like symptoms; thyroid problems neuro-psychiatric symptoms, depressive syndrome 20-50%, antidepressants effective for prophylaxis. Ribavirin can cause severe anemia.</td>
</tr>
<tr>
<td>Peg-interferon, ribavirin &amp; sofosbuvir</td>
<td>85-90K</td>
<td>12 weeks</td>
<td>&gt; 90%</td>
<td></td>
</tr>
<tr>
<td>Peg-interferon, ribavirin &amp; simeprevir</td>
<td>65-70K</td>
<td>12 weeks</td>
<td>&gt; 90%</td>
<td></td>
</tr>
<tr>
<td>Sofosbuvir &amp; ribavirin</td>
<td>85-90K for 12 weeks</td>
<td>12-24 weeks</td>
<td>&gt; 90%</td>
<td>Ribavirin can cause severe anemia.</td>
</tr>
<tr>
<td>Simeprevir &amp; Sofosbuvir</td>
<td>150K</td>
<td>12 weeks</td>
<td>&gt; 90%</td>
<td></td>
</tr>
</tbody>
</table>
**AASLD Guidelines**

### Genotype 1 (1a and 1b)

<table>
<thead>
<tr>
<th>Treatment Naïve eligible for Peg-Interferon</th>
<th>Daily Sofosbuvir and weight based Ribavirin plus weekly Peg-Inf for 12 weeks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment Naïve <strong>NOT</strong> eligible for Peg-Interferon</td>
<td>Daily Sofosbuvir plus Simepreveir, with or without weight based Ribavirin for 12 weeks</td>
</tr>
</tbody>
</table>

- Alternative therapies are available
- Those who have previously failed treatment will need different treatments
Who will get treated first?

<table>
<thead>
<tr>
<th>Issues</th>
<th>Need</th>
<th>Goal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical Stability (Diabetes, heart problems, HIV, etc)</td>
<td>Primary care provider to evaluate other medical problems</td>
<td>All other medical problems should be under control</td>
</tr>
<tr>
<td>Liver status (based on testing)</td>
<td>Hepatitis specialist to evaluate damage to the liver</td>
<td>Those with more advanced disease will likely get treatment first</td>
</tr>
<tr>
<td>Other important issues (Alcohol use, Psychiatric Disorders, Cognitive problems, etc)</td>
<td>Behavioral Health to stabilize other substance use and co-occurring disorders</td>
<td>Behavioral health patients may now be eligible for interferon-free treatment</td>
</tr>
<tr>
<td>Medication coverage</td>
<td>Insurance coverage</td>
<td>Cost Coverage</td>
</tr>
</tbody>
</table>
AASLD Recommendations

Persons with current (active) HCV infection should receive education and interventions aimed at reducing progression of liver disease and preventing transmission of HCV.

1. Abstinence from alcohol and, when appropriate, interventions to facilitate cessation of alcohol consumption should be advised for all persons with HCV infection.

Rating: Class IIa, level B
AASLD: The Harms of Alcohol

- Excess alcohol intake may also cause fat deposits in the liver.
- The daily consumption of more than 50 grams of alcohol is likely to worsen liver fibrosis.
- Some studies indicate that daily consumption of smaller amounts of alcohol also have negative effects on the liver—controversial.
- Alcohol screening and brief interventions have been demonstrated to reduce alcohol consumption and episodes of binge drinking in the general population and among HCV-infected persons who consume alcohol heavily.
- Persons identified as abusing alcohol and having alcohol dependence require treatment and possible referral to an addiction specialist.
Coverage for HCV Therapies - Medicaid

- Current standard of care (peg-interferon - with ribavirin and a third medication)
  - Enrollment criteria must be met
  - Non-expansion - varies from state to state
  - Expansion - therapies variably covered
  - Aids Drug Assistance Programs (ADAP) – not covered
  - Patient Assistance Program for those who do not qualify under Medicaid or ADAP

- New oral medications
  - Medicaid agencies questioning costs of medications
  - Varies in both non-expansion and expansion states
Coverage for HCV Therapies - Medicare

• Current standard of care (peg interferon - with ribavirin and third medication) WILL CHANGE IN THE NEXT YEAR
  • Depends on coverage and the medications covered

• New oral medications
  • Medicare to follow American Association for the Study of Liver Disease guidelines
  • For Hepatitis C genotype 1 and for those ineligible for interferon-based treatment, AASLD guidelines are 12 weeks
1. Why is it important for patients with behavioral health disorders to know if they are infected with Hepatitis C?

• Answer:
• Hepatitis C is a virus that can be transmitted when the infection is active. Patients with Hepatitis C can take steps to prevent transmission.
• Patients may change their behaviors if they know that they have Hepatitis C and that treatment is available. In particular, alcohol use can make the Hepatitis C infection progress faster.
Frequently Asked Questions

2. If the symptoms for chronic hepatitis infection are mild, does it really make sense to screen and treat a patient who is already coping with a behavioral health disorder?

• Answer:
• Many persons with active Hepatitis C have no symptoms at all. Treatment for Hepatitis C is more effective when the liver is healthy. All patients with behavioral health disorders can benefit from education on how to prevent transmission of Hepatitis C and how they can make healthy decisions for their liver.
Frequently Asked Questions

3. What are some of the strategies you use to keep patients with behavioral health disorders engaged in Hepatitis C treatment?

   • Answer:
   • Peer Counseling
   • Education on Healthy Living and Medications
   • Motivational Interviewing
   • Frequent visits and follow-up calls
   • Celebrate every success, even the small ones
   • Encourage treatment and recovery for all behavioral health disorders
Frequently Asked Questions

5. How do you address relapse during the course of treatment, especially on alcohol?

• Answer:
  • Relapse in drug and alcohol recovery is common. The most important thing is to get back into treatment and to encourage all patients to remain engaged in their recovery program. The most important this is to be honest to the medical providers so they can help patients stay on their treatment. The most important thing for successful Hepatitis C treatment is adherence to the medications.
Frequently Asked Questions

6. What actions do you take if the patient suddenly becomes non-compliant or stops coming back for screening and assessment?

• Answer:

The most important thing for successful Hepatitis C treatment is to take all the medications everyday. Patients who do not come back for screening and assessment are not started on treatment until they have regular engagement in treatment. If the patient stops coming back for regular medical appointments, the treatment cannot be continued. Some insurance will not cover the medications unless there is evidence that the patient is coming to all appointments and is taking all the medications.
Frequently Asked Questions

7. When your patient has a behavioral health disorder, how closely do you work with the behavioral health professional and/or psychiatrist during the course of treatment? How often is the patient screened for the emergence of psychiatric symptoms?

• Answer:

• Patients who are be exposed to Peg-Interferon must undergo screening for depression and suicide before Hepatitis C treatment. If a patient has depression, they must be stabilized and followed regularly during hepatitis treatment. It is important for the behavioral health team and the Hepatitis team to discuss how the patient is reacting to the medications. The patient is then asked about depression at every medical visit.
Frequently Asked Questions

8. How can the behavioral health provider play a more active role in the patient’s successful treatment? What kind of support would be most helpful?

• Answer:
The behavioral health provider can play a significant role when a patient is undergoing treatment by encouraging adherence to the medication and appointments. A behavioral health provider can also encourage patients to ask questions about their health and medications. Most importantly, behavioral health providers need to help patients obtain and maintain their recovery during treatment.
Conclusion

- Treatment, prevention and vaccination must be offered those with behavioral health disorders
- Treatment is much more expensive than prevention and vaccination, so behavioral health providers should start with screening, prevention and vaccination
- Although new oral medications are expensive, duration is shorter and more easily tolerated; new medications are coming
- Shorter HCV therapy with fewer side effects means treatment is more accessible for those with behavioral health disorders
Presenters

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