Facts vs. Fiction: What patients with Chronic Liver Disease want to know about COVID-19

Moderated By: Karen Hoyt, BA; Nancy Reau, MD, FAASLD; & Elizabeth K. Goacher, PA-C, MHS, AF-AASLD
Webinar
Moderator

Karen Hoyt, BA

• Patient Advocate
• Teacher
• Author – I Help C: Your Best Friends Guide to Hepatitis C & Cirrhosis
• Hepatitis C Treatment Survivor
• Liver Transplant Recipient

© 2021 AMERICAN ASSOCIATION FOR THE STUDY OF LIVER DISEASES
WWW.AASLD.ORG
Webinar Moderator

Elizabeth K. Goacher, PA-C, MHS, AF-AASLD

- Physician Assistant – Gastroenterology
- Duke University
- Chair – AASLD Hepatology Associates Committee
Webinar Agenda

**Talks**

Webinar and Presenter Introductions

“What people with liver disease should know about COVID-19”

“Types COVID-19 Vaccines: Which One is Right for Me?”

"Variants: What Does This Mean for Me?”

“CDC Guidelines: What should I do pre- & post-vaccination to protect myself?”

Panel Discussion / Q&A

**Speakers**

Karen Hoyt, Nancy Reau, Elizabeth Goacher

Su Wang

Corrie Berk

All
Webinar Q&A

• Submit your questions anytime during the webinar in the Q&A box at the top or bottom of your screen.

• Questions will be answered at the end of the presentations.
Webinar Presenter

Su Wang, MD MPH FACP

• Medical Director, Viral Hepatitis Programs & Center for Asian Health
• Saint Barnabas Medical Center, RWJBarnabas Health
• President, World Hepatitis Alliance
• Living with Hepatitis B
Webinar Presenter

Corrie Berk, DNP, MBA, APRN

• Nurse Practitioner at Loma Linda University Health Transplant Institute
• Clinical Director of the Las Vegas Campus

© 2021 AMERICAN ASSOCIATION FOR THE STUDY OF LIVER DISEASES
WWW.AASLD.ORG
Webinar Panelist

Nancy Reau, MD, FAASLD

- Professor of Internal Medicine
- Richard B. Capps Chair of Hepatology
- Associate Director of Solid Organ Transplantation
- Section Chief of Hepatology
- Rush University Medical Center in Chicago, IL
Webinar Panelist

Oren K. Fix, MD, MSc, FAASLD

- University of North Carolina
- Co-Chair of the AASLD Clinical Oversight and Education Subcommittee
What people with liver disease should know about COVID-19

Su Wang, MD MPH FACP
Medical Director, Viral Hepatitis Programs & Center for Asian Health
Saint Barnabas Medical Center, RWJBarnabas Health
President, World Hepatitis Alliance
Living with Hepatitis B

April 22, 2021
I report the following disclosures:
Research funding from Gilead Sciences
FOR PATIENTS

- COVID-19 Vaccine Recommendations for Patients with Liver Disease
- COVID-19 and Chronic Liver Disease
- COVID-19 in Children and Teenagers With Liver Disease or Liver Transplant
- COVID-19 and Viral Hepatitis
- COVID-19 and Nonalcoholic Fatty Liver Disease
- COVID-19 Myth Busters
- COVID-19 and Liver Transplantation
- COVID-19 and Hepatocellular Carcinoma
- COVID-19 and Liver Cirrhosis
- COVID-19 and Autoimmune Liver Disease
- COVID-19 and Alcohol-associated Liver Disease

COVID-19 and Liver Transplantation
Important Information for Patients and Their Families

The American Association for the Study of Liver Diseases (AASLD) is committed to helping you understand coronavirus disease 2019 (COVID-19) infection and prevention in people who have undergone liver transplantation.

What We Know

Our understanding of COVID-19 in liver transplant recipients is evolving. When making decisions related to COVID-19 infections or prevention, having up-to-date information is critical.

- Symptoms of COVID-19 infection include any of the following: fever, chills, drowsiness, cough, congestion or runny nose, difficulty breathing, fatigue, body aches, headache, sore throat, abdominal pain, nausea, vomiting, diarrhea, and loss of sense of taste or smell.
- Recent reports suggest that liver transplant recipients may not have a greater risk of developing severe illness from COVID-19 infection. However, most require hospital admission and approximately 15% intensive care unit admission; mortality has been observed only in patients 60 years of age or older and was higher among males. More epidemiologic data of COVID-19 in transplant recipients will be
COVID-19 and the Liver

- COVID-19 virus binds to ACE2 receptors
- ACE2 receptors are in the liver, liver could be a viral target
- But there other possible causes of liver injury during COVID-19 infection
- 14-83% of hospitalized COVID-19 patients have elevated liver tests
  - Liver enzymes (AST/ALT) may be elevated 1-2 times normal in mild Covid; self-resolves
  - Liver injury is more common in severe COVID-19 and lead to higher liver enzymes


© 2021 AMERICAN ASSOCIATION FOR THE STUDY OF LIVER DISEASES WWW.AASLD.ORG

It matters what kind of liver condition you have

- Liver conditions associated with higher mortality from COVID-19
  - Cirrhosis
  - End stage liver disease
  - Alcohol associated liver disease
  - Hepatocellular cancer
  - Liver transplant recipients - unclear - when adjusting for other risk factors, may not be significantly increased

- Not associated with higher mortality from COVID-19
  - Hepatitis B or C (non-cirrhotic)
  - Autoimmune hepatitis (and 83% of patients in the study were on immunosuppressives)
If you have Nonalcoholic Fatty Liver disease (NAFLD)

• Obesity, diabetes, heart disease and hypertension alone are associated with COVID-19 severity and poor outcomes
  • It is even more important to continue care & treatment for these conditions during this time
  • Don’t miss your regular visits with your physician- utilize telehealth if concerned about going in person
  • Blood pressure and glucose control are important
  • Can request 90 day supply of your medications and utilize home delivery

• But independent of obesity and comorbidities, fatty liver disease is associated with progressive COVID-19 & worse outcomes
How does COVID-19 impact your liver care?

• Follow regular symptom screening, masking and social distancing protocols
• Continue regular visits to providers; can use telehealth if concerned or are at more risk of severe COVID-19
• Test for COVID-19 if you have any symptoms
• If at higher risk for severe COVID-19
  • Have lower threshold to see your doctor if you have been exposed or have symptoms
  • Have low suspicion to get COVID-19 testing
What about treatment for Hepatitis B or C, autoimmune hepatitis or primary biliary cholangitis (PBC) during the pandemic?

- Already on treatment? Stay on it
- How about starting new treatment for your liver condition?
  - If you do not have COVID-19
    - You can start treatment if your doctor recommends it
  - If you do have COVID-19,
    - You can start HBV treatment, especially if there is hepatitis flare or if needed to prevent reactivation (chemotherapy, transplant, etc)
    - You can defer HCV or PBC treatment initiation. It is not routinely warranted when you have active COVID-19
How about COVID-19 & Immunosuppressive Therapy?

- **If on immunosuppressives, not necessarily at more risk for severe Covid-19**
  - But if you get infected, you may have higher viral titers & might be more infectious
  - It is important to get vaccinated!

- **For autoimmune hepatitis**
  - If you do not have COVID-19, no need to adjust medications
  - If you have COVID-19, dose may be lowered (particularly azathioprine or mycophenolate), based on severity of COVID-19

- **For post-transplant patients with COVID-19**
  - Consider lowering immunosuppression, based on severity of COVID-19 (Follow NIH guidelines)

- **How about starting immunosuppressive medication?**
  - Do not leave autoimmune conditions uncontrolled
  - May start if there are good indications whether or not if you have Covid
  - If with active COVID-19, your team will weight out benefits vs risks
Outpatient Management of COVID-19

• Supportive care, isolate, monitor for worsening symptoms
• No data supporting hydrochloroquine, azithromycin use

• Monoclonal antibodies:
  • 70% reduction in hospitalization & death
  • Casirivimab/Imdevimab (Regeneron), Bamlanivimab/Etesevimab (Eli Lilly)

• Eligibility criteria
  • Mild to moderate confirmed COVID-19; not requiring oxygen
  • If you are at high risk for progression to severe COVID-19 or hospitalization
    • Have a body mass index ≥35, chronic kidney disease or diabetes;
    • Have immunosuppressive disease or currently receiving immunosuppressives
    • Are ≥65 years of age;
    • Are ≥55 years of age AND have cardiovascular disease, OR hypertension, OR chronic obstructive pulmonary disease/other chronic respiratory disease;

• Given as infusion, usually in emergency departments
Types COVID-19 Vaccines: Which One is Right for Me?

Su Wang, MD MPH FACP
Vaccines: The End of the Pandemic in Sight

How we contain COVID-19 transmission:

- Social distancing, masking, quarantine, contact tracing, etc
- Immunity from infection (risky, short term)
- Immunity from **vaccination**:
  - To get to herd immunity, we must vaccinate quickly & thoroughly
  - Thus, the best vaccine for you is the one you can get the soonest.

Graphic from: https://www.cdc.gov/vaccines/vac-gen/whatifstop.htm
COVID-19 Vaccine: Nationwide Status

- President Biden has ordered all states make COVID-19 vaccines eligible to every adult starting April 19th.

- Current vaccination status:

<table>
<thead>
<tr>
<th>People Vaccinated</th>
<th>At Least One Dose</th>
<th>Fully Vaccinated</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td>134,445,595</td>
<td>87,592,646</td>
</tr>
<tr>
<td>% of Total Population</td>
<td>40.5%</td>
<td>26.4%</td>
</tr>
<tr>
<td>Population ≥ 18 Years of Age</td>
<td>133,010,036</td>
<td>87,255,919</td>
</tr>
<tr>
<td>% of Population ≥ 18 Years of Age</td>
<td>51.5%</td>
<td>33.8%</td>
</tr>
<tr>
<td>Population ≥ 65 Years of Age</td>
<td>44,061,754</td>
<td>35,873,848</td>
</tr>
<tr>
<td>% of Population ≥ 65 Years of Age</td>
<td>80.6%</td>
<td>65.6%</td>
</tr>
</tbody>
</table>

© 2021 AMERICAN ASSOCIATION FOR THE STUDY OF LIVER DISEASES WWW.AASLD.ORG

CDC COVID Data Tracker: https://covid.cdc.gov/covid-data-tracker/#vaccinations
Types of Vaccines Available in US

- mRNA vaccine
  - Pfizer BioNTech
  - Moderna
- Viral vector (adenovirus)
  - Johnson & Johnson

Both COVID-19 vaccines teach your body how to create antibodies to the virus (via the spike protein)
**Vaccine Development:**

What does Emergency Use Authorization (EUA) mean for safety?

**Clinical Trials | Community Engagement Alliance (nih.gov)**  
[https://covid19community.nih.gov/resources/understanding-clinical-trials](https://covid19community.nih.gov/resources/understanding-clinical-trials)

What's the Difference Between FDA Emergency Use Authorization and FDA Approval?  

---

**FDA required median follow up of 2 months**

**Post-authorization safety monitoring required & conducted by CDC/FDA**
## Profile of Covid-19 Vaccines in the US: Data submitted to FDA

<table>
<thead>
<tr>
<th></th>
<th>Pfizer/BioNTech</th>
<th>Moderna</th>
<th>Johnson &amp; Johnson</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Participants in study who received vaccine</strong></td>
<td>43,448</td>
<td>30,351</td>
<td>43,783</td>
</tr>
<tr>
<td><strong>Trial inclusion of participants with liver disease</strong></td>
<td>124 vaccine/90 placebo Participants with stable chronic liver disease including HBV/HCV were eligible. Excluded those on immunosuppressives</td>
<td>100 vaccine/96 placebo Participants with stable chronic liver disease including HBV/HCV were eligible. Excluded those on immunosuppressives</td>
<td>103 vaccine /103 placebo - Global 54 vaccine /44 placebo - US Participants with stable chronic liver disease including HBV/HCV were eligible 10 vaccine/ 5 placebo - Global+US Small number of solid organ transplant included</td>
</tr>
<tr>
<td><strong>Age approved for</strong></td>
<td>16 and older (12-15 years submitted to FDA)</td>
<td>18 and older</td>
<td>18 and older</td>
</tr>
<tr>
<td><strong>Vaccine timing</strong></td>
<td>2 shots; 21 days apart</td>
<td>2 shots; 28 days apart</td>
<td>1 shot</td>
</tr>
</tbody>
</table>
## Profile of Covid-19 Vaccines in the US:
### Data submitted to FDA

<table>
<thead>
<tr>
<th>Vaccine Efficacy</th>
<th>Pfizer/BioNTech</th>
<th>Moderna</th>
<th>Johnson &amp; Johnson</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Hospitalizations &amp; Deaths</strong></td>
<td>100% effective against hospitalizations &amp; deaths</td>
<td>89% against hospitalizations</td>
<td>100% against hospitalizations &amp; deaths</td>
</tr>
</tbody>
</table>
| **Symptomatic COVID-19 Infection** | 95% effective at preventing at least 7 days after 2nd dose | 94.1% effective at preventing infection at least 14 days after 2nd dose | 14 days after:  
   - 66.9% effective preventing moderate to severe infection,  
   - 76.7% effective at preventing severe/critical infection  
28 days after:  
   - 85.4% effective preventing severe-critical infection |

### Contraindications
- History of severe or immediate allergic reaction to any components, including to Polyethylene glycol (PEG), or previous vaccination
- History of severe or immediate allergic reaction to any components, including to Polyethylene glycol (PEG), or previous vaccination
- History of severe or immediate allergic reaction to any components, including to polysorbate 80
COVID-19 vaccines: Facts vs Fiction

• The vaccines cannot give you COVID-19 Infection
  • The vaccine does not include the SARS-Cov2 virus

• The vaccines will not change your DNA or genes
  • The mRNA enters the cells but not the nucleus where the DNA resides
  • It quickly breaks down after stimulating the immune system

• Even if you had COVID-19 infection, you should still get vaccinated.

• The vaccine does not affect a woman’s fertility

• The vaccine was made with routine vaccine ingredients
  • These ingredients stabilize the active ingredients
  • It does not include any materials such as implants, microchips, tracking devices, stem cells or fetal tissue
Some other questions

• Should I test for antibodies before or after getting the vaccine?
  • No, this is not recommended at this time. Commercial tests do not confirm vaccine immunity; needs to be specific test to spike protein.

• What about reactions to the vaccine?
  • You will be monitored for 15-30 minutes after the vaccine
  • Most reactions will be mild and resolve in a few days
    • Injection site soreness, swelling, redness
    • Fever, headache, tiredness, muscle pain, chills & nausea
  • If symptoms seem more severe or you are concerned, let your doctor know so they can monitor you

• When should I postpone my vaccine?
  • If you are feeling ill or have any signs of COVID-19
  • If you had another vaccine within 2 weeks
Real Life Data on COVID-19 Vaccine Protection

• Studies are following people who have received the vaccines
  • 3,950 healthcare professionals followed w weekly COVID-19 PCR testing¹
    • After 1ˢᵗ dose of Moderna or Pfizer → 80% protection
    • After 2ⁿᵈ dose → 90% protection
  • Moderna & Pfizer report antibodies persist to at least 6 months²,³
  • Booster likely needed, maybe 6-12 months after vaccine- to be determined

• How about in patients with liver disese? Ongoing studies happening, immune response may be blunted in transplant recipients

• It is a race between the vaccines and the variants!

Pause on J&J Janssen COVID-19 vaccination

- April 13- CDC/FDA recommended a pause for Johnson & Johnson’s Janssen COVID-19 Vaccine for further investigation.
- 6 reports of a rare & severe type of blood clot & low platelets reported
  - All reports in women between the ages of 18 and 48
  - Symptoms occurred six to 13 days after vaccination
- ~7 million doses administered so far in the United States
  - < 1 per 1 million doses
  - Probability context
    - Clots are very common with Covid: Up to 30% of Covid patients in ICU develop clots
    - Chance of being hit by lightning is 1 in a 1 million, dying in a car accident is 38 in a million
- Of the more than 180 million doses administered so far of the Pfizer-BioNTech or Moderna vaccines, no reports matching

https://www.cdc.gov/vaccines/covid-19/info-by-product/index.html
Variants: What Does This Mean for Me?

Corrie Berk, DNP, MBA, APRN
Disclosures

• Speakers Bureaus
  • Salix – HE
  • Gilead – HCV

• Spouse consults for Biovie, Natera, Bausch
Variants of COVID-19
What We Know

• Viruses constantly change through mutation, and new variants are expected
  • Sometimes they emerge and disappear
  • Sometimes they emerge and persist

• Scientists monitor and analyze these changes to understand it

• CDC established three classifications:
  • Variant of Interest (VOI)
  • Variant of Concern (COV)
  • Variant of High Consequence (VOHC)
Why Surveillance Is Important

- Potential Consequences of Emerging Variants
  - Ability to spread more quickly (Example: D614G)
  - Ability to cause milder or more severe disease
  - Ability to evade detection
    - Multiple targets on RT-PCR tests
  - Decrease susceptibility to therapies such as monoclonal antibodies
  - Ability to evade natural or vaccine-induced immunity
    - Virus would need to accumulate multiple mutations in the spike protein in order for this to happen
    - Immune pressure could favor by selecting for “escape mutants”
      - Experts believe this is unlikely because of the nature of the virus
Currently Five VOCs in the U.S.

- **B.1.1.7**: Initially detected in UK, first identified in US December 2020
- **B.1.351**: Initially detected in South Africa in Dec 2020. First identified in the US at the end of January 2021
- **P.1**: Initially identified in travelers from Brazil, who were tested during routine screening at an airport in Japan, in early January. First identified in the US in January 2021
- **B.1.427 and B.1.429**: These two variants were first identified in California in February 2021 and were classified as VOCs in March 2021
Which Variant Am I Most Likely to Encounter?

• At this time, likely B.1.1.7
  • Mutation allows this version to more effectively attach to cells
  • Carriers shed higher levels of the virus and stay infectious longer
  • Main concern is the highly infectious virus spreading quickly among the unvaccinated

• A variant is likely what you will encounter at this point, not the original COVID 19
Variants and Vaccines
Can the Covid Vaccine Still Protect Me?

- Lots of muddled messages surrounding the rise of variants
- All of the major vaccines have performed relatively well against the variant B.1.1.7.
- Also protective against infection and serious illnesses in areas where B.1.1.7 is circulating
- There is concern that B.1.351 and P.1 are better at dodging vaccines but that doesn’t mean the vaccines don’t work at all!
- There is a lot of “cushion” provided by this crop of vaccines
  - Even if they are less effective against a variant, it may still protect you from serious illness
If Vaccines Are Working…

• Why are we hearing about “breakthrough” cases?!
  • No vaccine is foolproof
  • These “breakthrough” cases are rare, even as variants fuel surges in case counts

• What is the risk of getting infected after vaccination?!
  • Nobody knows for sure but we have some clues
  • For now, the variants don’t appear to be increasing the rate of infection in vaccinated people, but that could change as more data is collected

• Will I need a booster?!
  • Vaccine developers are already working on this
  • Not yet sure when a booster will be needed
Now what?
Bottom Line

• The risk still lies with the unvaccinated
• The perception that vaccines don’t work against variants at all is incorrect
• Vaccines prevent infection, serious illness and hospitalization
• “Go get vaccinated—that’s the message.” –Dr. Fauci
• In the meantime, keep wearing a mask and avoid gathering in groups, especially to protect the unvaccinated
CDC Guidelines: What should I do pre- & post-vaccination to protect myself?

Corrie Berk, DNP, MBA, APRN
Disclosures

• Speakers Bureaus
  • Salix – HE
  • Gilead – HCV

• Spouse consults for Biovie, Natera, Bausch
Before the Vaccine
How to Protect Yourself & Others

• Wear a mask that covers nose & mouth
• Stay 6 feet apart from others that don’t live with you
• Avoid crowds & poorly-ventilated indoor spaces
• Wash your hands often
• Cover coughs & sneezes
• Clean & disinfect
• Get a COVID-19 vaccine when it’s available to you
  • The best vaccine for liver transplant recipients and patients with liver disease is any vaccine that is available!
Routine Procedures & Screenings

- Most routine medical procedures can be performed before or after getting a COVID-19 vaccine
- Separate COVID-19 vaccine from other immunizations by at least 14 days
- Mammogram
  - Lymphadenopathy may cause false readings
  - Some experts recommend before vaccination or waiting 4-6 weeks after vaccine completion
Protection Against Side Effects

• CDC does NOT recommend to pre-medicate with:
  • Ibuprofen, aspirin, or acetaminophen to prevent side effects
  • Antihistamines to prevent allergic reaction

• To reduce site pain
  • Apply a clean, cool, wet washcloth
  • Use and exercise your arm

• To reduce discomfort from fever
  • Drink fluids
  • Dress lightly

• OK to medicate post-vaccine side effects if needed
  • Acetaminophen up to 2g/day
When You’ve Been Fully Vaccinated
Have You Been Fully Vaccinated?

• According to the CDC, people are considered “fully vaccinated”
  • 2 weeks after 2nd dose series (Pfizer or Moderna)
  • 2 weeks after single dose series (J&J)

• We may not be able to assume patients with liver disease/liver transplant are necessarily “fully vaccinated”
  • We have no test available to reliably tell us if someone is protected so efficacy in these populations is unclear
What You Should Keep Doing

• Masks & social distancing especially when
  • In public
  • Gathering with unvaccinated people from more than one other household
  • Visiting with an unvaccinated person at increased risk or lives with a person at increased risk
• Avoid crowds and large gatherings
• Follow workplace and travel precautions
• Still watch out for symptoms of COVID-19
What You Can Start Doing

• Gather indoors with
  • Fully vaccinated people without wearing a mask or staying 6 feet apart
  • Unvaccinated people of any age from one other household without mask or staying 6 feet apart, unless anyone has increased risk for severe illness from COVID-19

• If you’ve been around someone who has COVID-19, you do not need to stay away from others or get tested unless symptomatic
  • Unless you live in a group setting
Travel

• Avoid unnecessary travel
• Pay close attention to the situation at your destination
• Travel within the U.S.
  • No testing before/after travel
  • No self-quarantine after travel
• International travel
  • No testing BEFORE leaving the U.S. unless required by destination
  • Still need to show negative test or documented recovery BEFORE boarding a flight to U.S.
  • Should still get tested 3-5 days AFTER international travel
  • No need to self-quarantine AFTER arriving to U.S.
What We Know & What We’re Learning

• **We know** vaccines are effective at preventing COVID-19 disease, severe illness, & death
  - **We’re still learning** how effective the vaccines are against variants

• **We know** that prevention helps stop the spread and that these steps are still important
  - **We’re still learning** how well vaccines keep people from spreading the disease (early data show they may help)
  - **We’re still learning** how long vaccines offer protection

• **We are still learning** about vaccine efficacy in patients with liver disease / liver transplants
New Patient Resources

Access patient resources and useful links, including downloadable COVID-19 and the liver patient flyers:

aasldfoundation.org/patients

*RECENTLY RELEASED*
COVID-19 Vaccine Recommendations for Patients with Liver Disease
Follow Us on Twitter

- @hepatitishelpc
- @orenkfix
- @GoachPA_DukeGI
- @NancyReau
- @swang8
Panel Discussion

Please submit your questions to the Q&A Chat now.