

**A statement regarding COVID-19 from the Hepatitis B Foundation Scientific and Medical Advisory Board (SMAB) to the hepatitis B community**

*This letter is in response to the countless consult calls, emails and social media posts we have received from concerned people living with hepatitis B. This letter is not official policy of the HBF or the members of its SMAB, but it reflects the expert opinions of SMAB members and is based on the best information we have at this time.*

In the past months, the U.S. Food and Drug Administration (FDA) has approved Emergency Use Authorization (EUA) for three new vaccines to provide protection against SARS-CoV-2 (the virus that causes COVID-19). After independently reviewing the clinical trial data from Moderna and Pfizer, the FDA concluded that these vaccines were effective in preventing COVID-19 in >90% of those who received two doses, across age and ethnic groups. Similarly, the FDA found that the Janssen/Johnson & Johnson vaccine was 67% effective in preventing moderate and 85% effective in preventing severe COVID-19.

The FDA did not identify any specific safety concerns with any of the three vaccines approved for EUA. The data indicate that the new vaccines are as good as, if not better than, other vaccines that are routinely given around the world to prevent infectious diseases. The data also indicate that these vaccines are safe – with few mild to moderate side effects for most people.

Vaccination will be key to preventing spread and reducing serious illness and death due to COVID-19. We encourage all those within the hepatitis B community to talk with their clinical care providers about getting vaccinated.

**Are the Moderna, Pfizer and Janssen/J&J vaccines effective in people with hepatitis B and liver disease?**

We believe that people with hepatitis B and liver disease, who are not immunosuppressed, will respond to these vaccines similarly as do those without liver disease. We know of no scientific or biological reason why people living with chronic hepatitis B would respond differently to these vaccines compared to people without hepatitis B, regardless of whether they have active or inactive hepatitis B infection.

**Are people with hepatitis B or liver disease included in priority vaccination in the U.S.?**

The Advisory Committee on Immunization Practices (ACIP) and CDC have developed [a multi-phase plan](#) for rolling out the vaccines in the U.S., based upon risk. As of now and based on current data, CDC does not list hepatitis B, specifically, as a [medical condition](#) that is known to put people at increased risk for serious disease from COVID-19. Instead, CDC states that adults with liver disease “might be at increased risk for severe illness from the virus that causes COVID-19.” Therefore, people with liver disease are not specifically included in the [Phase 1](#) roll-out for priority vaccination. It looks like people with liver disease will be included in [Phase 2](#) of vaccine roll-out.

People who have been diagnosed with liver cancer (hepatocellular carcinoma, HCC) *are* considered to be at increased risk for serious disease from COVID-19, according to CDC. If you have been diagnosed with liver cancer (or any other type of cancer), you are included in [phase 1C](#) of vaccination roll out, according to CDC.

Different states across the U.S. are opening vaccine availability at different rates. But the expectation is that COVID-19 vaccination will be open to all adults age 18 and over by May 2021.

### **What do we know about mRNA vaccines?**

Both the [Moderna](#) and [Pfizer](#) vaccines are mRNA vaccines, meaning that they do not include a weakened version of the virus, as many vaccines do. Instead, they have mRNA containing particles that direct production of Coronavirus proteins and teach our immune system to make antibody against one of the proteins on the surface of the COVID-19 virus. This helps us to build an immune response to protect against future COVID-19 virus infections. The technology behind mRNA vaccines has been studied for over a decade, and the mRNA vaccines have been rigorously tested for safety. The mRNA vaccines do not contain live virus, so you cannot get COVID-19 infection from these vaccines. Also, the mRNA from these vaccines never enters the nucleus of the cell and never interacts with a person's DNA.

### **Does having hepatitis B put me at increased risk of severe disease from COVID-19 infection?**

There have only been a few small, published studies on this topic (see reference list below). Overall, researchers have found that those with hepatitis B and COVID-19 did not differ from those who only had COVID-19, in terms of disease severity, time to recovery, duration of hospitalization or treatment response. These studies also found that the risk of HBV re-activation or flare during acute COVID-19 infection was low, though one study found some reactivation among patients who received steroids or interferon to treat COVID-19. There is some evidence that people with cirrhosis are at risk for more severe outcomes from COVID-19 infection. Studies done over the past months have found that the COVID-19 disease process itself could be associated with liver injury. So, it is important for those who know they have hepatitis B to talk with doctors who are treating them for COVID-19, so that they can closely monitor liver function and liver injury, and consider prophylactic antiviral treatment as necessary.

### **For more information on the vaccines currently approved for EUA in the U.S.:**

mRNA vaccine overview:

<https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/mrna.html>

Pfizer: <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/Pfizer-BioNTech.html>

Moderna: <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/Moderna.html>

Janssen/J&J: <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/janssen.html>

For more information about other COVID-19 vaccines currently in clinical trial:

<https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines.html>

For more information on COVID-19 vaccine development and roll-out:

<https://www.cdc.gov/coronavirus/2019-ncov/vaccines/index.html>

Peer-reviewed journal articles on HBV/COVID-19 co-infection (as of 12/29/2020)

- Marjot T, Webb GJ, Barritt AS 4th, Moon AM, Stamataki Z, Wong VW, Barnes E. COVID-19 and liver disease: mechanistic and clinical perspectives. *Nat Rev Gastroenterol Hepatol*. 2021 Mar 10:1–17. doi: 10.1038/s41575-021-00426-4. Epub ahead of print. <https://www.nature.com/articles/s41575-021-00426-4>
- Chen L, Huang S, Yang J, Cheng X, Shang Z, Lu H, Cheng J. Clinical characteristics in patients with SARS-CoV-2/HBV co-infection. *J Viral Hepat*. 2020 Dec;27(12):1504-1507. Epub 2020 Aug 16. <https://onlinelibrary.wiley.com/doi/full/10.1111/jvh.13362>
- Chen X, Jiang Q, Ma Z, Ling J, Hu W, Cao Q, Mo P, Yao L, Yang R, Gao S, Gui X, Hou W, Xiong Y, Li J, Zhang Y. Clinical Characteristics of Hospitalized Patients with SARS-CoV-2 and Hepatitis B Virus Co-infection. *Viol Sin*. 2020 Aug 24:1–4. Epub ahead of print. <https://link.springer.com/article/10.1007/s12250-020-00276-5>
- Lin Y, Yuan J, Long Q, Hu J, Deng H, Zhao Z, Chen J, Lu M, Huang A. Patients with SARS-CoV-2 and HBV co-infection are at risk of greater liver injury. *Genes Dis*. 2020 Nov 18. Epub ahead of print. <https://www.sciencedirect.com/science/article/pii/S2352304220301367>
- Liu J, Wang T, Cai Q, Sun L, Huang D, Zhou G, He Q, Wang FS, Liu L, Chen J. Longitudinal changes of liver function and hepatitis B reactivation in COVID-19 patients with pre-existing chronic hepatitis B virus infection. *Hepatol Res*. 2020 Nov;50(11):1211-1221. Epub 2020 Aug 29. <https://onlinelibrary.wiley.com/doi/full/10.1111/hepr.13553>
- Liu R, Zhao L, Cheng X, Huan H, Li C, Li D, Liu A, Gao G, Zhou F, Liu F, Jiang Y, Zhu C, Xia Y. Clinical Characteristics of COVID-19 Patients with Hepatitis B Virus Infection - a Retrospective Study. *Liver Int*. 2020 Dec 22. Epub ahead of print. <https://onlinelibrary.wiley.com/doi/10.1111/liv.14774>
- Rodríguez-Tajes S, Miralpeix A, Costa J, López-Suñé E, Laguno M, Pocurull A, Lens S, Mariño Z, Forns X. Low risk of hepatitis B reactivation in patients with severe COVID-19 who receive immunosuppressive therapy. *J Viral Hepat*. 2021 Jan;28(1):89-94. Epub 2020 Oct 12. <https://onlinelibrary.wiley.com/doi/10.1111/jvh.13410>
- Zou X, Fang M, Li S, Wu L, Gao B, Gao H, Ran X, Bian Y, Li R, ShanshanYu, Ling J, Li D, Tian D, Huang J. Characteristics of Liver Function in Patients With SARS-CoV-2 and Chronic HBV Coinfection. *Clin Gastroenterol Hepatol*. 2020 Jun 15:S1542-3565(20)30821-1. Epub ahead of print. <https://www.sciencedirect.com/science/article/abs/pii/S1542356520308211>