



September 24, 2021

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RE: Comments for the September 2021 Meeting of the Advisory Committee on Immunization Practices (**Docket No. CDC-2021-0075-0001**) / Recommendation of Hepatitis B Universal Vaccination

To the Advisory Committee on Immunization Practices (ACIP):

Thank you for the opportunity to provide comments related to the upcoming decision regarding universal adult hepatitis B vaccination. The **HIV+Hepatitis Policy Institute** is a leading HIV and hepatitis policy organization promoting quality and affordable healthcare for people living with or at risk of HIV, hepatitis, and other serious and chronic health conditions. **HIV+Hep strongly supports a recommendation for universal hepatitis B vaccination for all adults.** The hepatitis B vaccine is safe and effective, with over 1 billion doses administered worldwide and is estimated to have prevented over 310 million infections worldwide between 1990 and 2020.¹ Despite highly effective vaccines, up to 2.4 million people in the United States may be living with chronic hepatitis B, and there are up to 80,000 new cases of hepatitis B each year.² With the proper guidance and resources, each new infection is preventable.

According to the Centers for Disease Control and Prevention (CDC), approximately 10% of people with HIV in the United States also have HBV. Infection with both HIV and HBV is called HIV/HBV coinfection. And chronic HBV advances faster to cirrhosis, end-stage liver disease, and liver cancer in people with HIV/HBV coinfection than in people with only HBV infection.³

The Need for an Inclusive Recommendation

It is imperative that the Committee consider recommending universal adult hepatitis B vaccination for all adults instead of limiting a potential recommendation to those 59 years of

¹ Cooke et al., on behalf of The Lancet Gastroenterology & Hepatology Commissioners. (2019). Accelerating the elimination of viral hepatitis: a Lancet Gastroenterology & Hepatology Commission. *The Lancet Gastroenterology & Hepatology*;4:135-184.

² Wong, R. J., Brosgart, C. L., Welch, S., Block, T., Chen, M., Cohen, C., Kim, W. R., Kowdley, K. V., Lok, A. S., Tsai, N., Ward, J., Wong, S. S., & Gish, R. G. (2021). An Updated Assessment of Chronic Hepatitis B Prevalence Among Foreign-Born Persons Living in the United States. *Hepatology (Baltimore, Md.)*, 10.1002/hep.31782. Advance online publication. <https://doi.org/10.1002/hep.31782>

³ HIV and Opportunistic Infections, Coinfections, and Conditions, HIV.info, NIH.gov, accessed September 23, 2021, <https://hivinfo.nih.gov/understanding-hiv/fact-sheets/hiv-and-hepatitis-b>.

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age and under. Data from the CDC's 2018 Viral Hepatitis Surveillance Report shows that while acute hepatitis B cases are highest in people aged 30-49, adults 60 and older have seen a slight, but steady increase in cases beginning in 2014.⁴ This rise is particularly concerning in view of the COVID-19 pandemic as many essential public health services and facilities were closed for extended periods of time. Early data show that substance abuse and injection drug use, risk factors for hepatitis B, have been exacerbated by the pandemic while key preventative services have declined.

With nearly one million adults 65 and older living with a substance abuse disorder in the US, it is important to ensure that they are included in hepatitis B prevention efforts.⁵ Additionally, research shows that between 2014 and 2017, adults over the age of 60 accounted for the largest increase of in-office services for sexually transmitted infections (STIs), and that in 2020, STIs amongst this age group have reached historic highs. Recent data shows that 38.3% of new infections in adults 60 and older are sexually transmitted - a clear indication that this group remains vulnerable to hepatitis B. Despite common hepatitis B transmission via sexual activity in older Americans, providers are not required to discuss this risk factor during visits, and the important conversation about hepatitis B risk factors may be missed.

Most Adults Have at least One Risk Factor for Hepatitis B

The hepatitis B community is also deeply concerned with the stagnant rates of adult hepatitis B infection. For the past several years, adult hepatitis B vaccination rates have remained at 25% - a figure that shows clear missed opportunities for prevention. According to the CDC and the U.S. Preventive Services Task Force, there are 18 subpopulations that are recommended to be vaccinated, including incarcerated individuals, healthcare workers, and those on dialysis. Initial calculations of people who have at least one risk factor for hepatitis B indicate that about 84% of the population meet the current recommended vaccination guidelines (HBF, unpublished data).

In addition, it is important to note that several of the high-risk categories are expected to continue to grow, such as people with diabetes (projected increase of 165% by 2050) and sexually transmitted diseases (20 million new cases/year)^{6,7}. With such a large portion of adults in the US meeting or expected to develop one of the risk factors for vaccine recommendations,

⁴ <https://www.cdc.gov/hepatitis/statistics/2018surveillance/pdfs/2018HepSurveillanceRpt.pdf>

⁵ Substance Abuse and Mental Health Services Administration. (2019). Results from the 2018 National Survey on Drug Use and Health: Detailed tables. Rockville, MD: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration. Retrieved from <https://www.samhsa.gov/data/>

⁶ Boyle, J., Honeycutt, A., Narayan, K., Hoerger, T., Geiss, L., Chen, H., & Thompson, T. (2001). Projection of Diabetes Burden Through 2050: Impact of changing demography and disease prevalence in the U.S. *Diabetes Care*, 24(11), 1936-1940. <https://doi.org/10.2337/diacare.24.11.1936>.

⁷ Office of Disease Prevention and Health Promotion. (2020). *Sexually Transmitted Diseases Healthy People 2020*. Healthypeople.gov. Retrieved 20 August 2020, from <https://www.healthypeople.gov/2020/topics-objectives/topic/sexually-transmitted-diseases#:~:text=The%20Centers%20for%20Disease%20Control,much%20as%20%2416%20billion%20annually.>

a universal hepatitis B vaccination recommendation would help to stress the importance of the hepatitis B vaccine and encourage high risk individuals to seek care. Assessing for current risk-based guidelines serves as a barrier to hepatitis B vaccination of adults. Universal adult hepatitis B vaccination would make it much easier for clinicians to vaccinate patients without inquiring about 18 different risk factors and would remove the need for clinicians to have uncomfortable risk-based conversations with their adult patients.

Achieving a Healthier Population by Overcoming Barriers

Better utilization of hepatitis B vaccines is essential to the health of our nation. The World Health Organization and the National Academies of Science, Engineering, and Medicine (NASEM) have declared that it is possible to eliminate viral hepatitis with our current tools, including hepatitis B vaccines. The US also recently released the *Viral Hepatitis National Strategic Plan: A Roadmap to Viral Hepatitis Elimination 2021 – 2025*.⁸ In this plan the Department of Health and Human Services calls for the elimination of hepatitis as a public health threat by 2030 and includes a key strategy to “increase viral hepatitis vaccination uptake.”

However, there are several logistical barriers to accessing the hepatitis B vaccine, including lack of funding for clinics to provide the vaccine at no or a reduced cost to those who are uninsured or underinsured, and complex reimbursement systems for pharmacies that do provide the hepatitis B vaccine. Such restrictions and burdens on the administrative level can make it difficult to access the vaccine or even discourage individuals from getting vaccinated, especially amongst certain high-risk groups without access to traditional care such as those experiencing homelessness and people who inject drugs. Additionally, many states programs and insurance companies will cover the cost of the hepatitis B vaccines for adults if a person is in one of the high-risk categories named by ACIP, but despite recommendations that anyone who wants to be vaccinated for hepatitis B can be immunized, many programs - including Medicare - will not cover this group. A federal recommendation of universal vaccination can open doors for states to aid clinics, pharmacies, and individuals in accessing the vaccines.

In summary, a recommendation for universal adult hepatitis B vaccination is integral to addressing long-standing barriers to increasing the adult hepatitis B vaccination rate. An updated recommendation is critical to achieving health equity, improving access to the vaccine, and working towards viral hepatitis elimination.

If you have any questions or need any additional information, please do not hesitate to reach out via phone at (202) 462-3042 or email at cschmid@hivhep.org.

Thank you again for the opportunity to offer comments.

⁸ *Viral Hepatitis National Strategic Plan: A Roadmap to Viral Hepatitis Elimination 2021 – 2025*, Department of Health and Human Services, <https://www.hhs.gov/sites/default/files/Viral-Hepatitis-National-Strategic-Plan-2021-2025.pdf>.

Sincerely,

A handwritten signature in blue ink, appearing to read 'Carl E. Schmid II', written in a cursive style.

Carl E. Schmid II
Executive Director

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