

June 3, 2022

Carolyn Wester, MD, MPH
Director, Division of Viral Hepatitis
National Center for HIV, Viral Hepatitis, STD, and TB Prevention
Centers for Disease Control and Prevention

Re: Draft CDC Recommendations for Hepatitis B Screening and Testing – United States, 2022

Dear Dr. Wester:

On behalf of the Hep B United coalition and the undersigned ### organizations, thank you for the opportunity to provide comments on the draft CDC recommendations for hepatitis B screening and testing. We appreciate and commend CDC's leadership in this undertaking to update and expand hepatitis B screening and testing recommendations.

Overall, we are pleased to see the expansion of hepatitis B screening to a universal recommendation for adults 18 and older. Additionally, we strongly support the recommendation to provide hepatitis B screening with the 3-part panel for all adults including pregnant persons, providing a more complete picture of potential infection and clear steps for clinical management. The addition of risk factors to include persons currently or formerly incarcerated, with current or past STIs or multiple sex partners, with current or past HCV infection and anyone who requests a hepatitis B test, *regardless of disclosure of risk*, are reflective of the current trajectory of hepatitis B epidemiology in the United States and will be supportive of the work of hepatitis B service providers to reach *all* highly impacted populations. We believe these new recommendations will greatly increase access to hepatitis B screening and testing, removing barriers such as individual and community stigma and anxiety related to hepatitis B risk factors, and improve testing rates.

Additionally, we appreciate the timeliness of the expanded screening recommendations to align with the recent decision by the Advisory Committee on Immunization Practices (ACIP) to recommend all adults aged 19-59 years be vaccinated against hepatitis B infection. We believe it is critical to coordinate clinical guidance for screening and vaccination. We believe screening for hepatitis B infection, with the 3-part panel, is primary and essential to finding susceptible persons and preventing new infections and agree that offering a first dose of the vaccine at the same time as screening *to the hardest to reach populations* is beneficial.

While the key updates to the hepatitis B screening and testing recommendations are clear, we believe certain components of the recommendations can be strengthened to avoid any confusion and provide health care providers the most specific guidance for implementation. We offer the following suggestions, listed by section titles of the draft recommendations document, for consideration.

Introduction

- *Hepatitis B prevalence* - We recommend updating the number of persons of living with hepatitis B infection in the United States to "up to 2.4 million persons" per the referenced article below.

- Wong RJ, Brosgart CL, Welch S, Block T, Chen M, Cohen C, et al. An Updated Assessment of Chronic Hepatitis B Prevalence Among Foreign-Born Persons Living in the United States. *Hepatology*. 2021.
- *Hepatitis B transmission routes* - “Hepatitis B is transmitted through contact with infected blood or body fluids, such as through sex, injection-drug use, or from birth to an infected mother.” We suggest including additional examples of transmission routes such as healthcare associated infections (e.g., transfusions, dialysis, glucometers, etc.) to avoid suggesting there are only three methods of transmission. Additionally, we recommend reordering examples of transmission methods and listing “from birth to an infected mother” first, as perinatal transmission is the primary route globally and for a large majority of highly impacted communities in the United States. Listing methods such as sex and injection drug use first can contribute to hepatitis B-related stigma.

Hepatitis B Screening and Testing Recommendations

- *Overview of new recommendations* (page 2) - “The following recommendations for hepatitis B screening augment those issued by CDC in 2008 (13).” The usage of “augment” can be confusing and interpreted in multiple ways such as implying providers should still refer to the 2008 recommendations. We suggest replacing “augment” with “supersede” or “replace” to clarify the 2022 recommendations are the most up to date guidance.
- *Language regarding screening tests* (page 3) – “Screening with the three tests (“3-test panel”) can help identify persons who have a current HBV infection, have resolved infection and who may be susceptible to reactivation, are susceptible and need vaccination, or are vaccinated¹. “ The use of “3-test panel” can be confusing to many providers, and lead to the misperception that three separate tests are needed to screen for HBV. Sending the message that HBV screening is simple, is key – we suggest replacing “3-test panel” with “3-part panel” or “triple panel.”
- *List of persons at increased risk for HBV infection* (page 4-5) – We suggest listing “persons born in regions with HBV prevalence $\geq 2\%$ (Box 2)” and “U.S.-born persons not vaccinated as infants whose parents were born in regions with HBV prevalence $\geq 8\%$ (Box 2)” first given these persons represent the majority of those with hepatitis B infection in the United States.
 - Additionally, for the category, “Anyone who requests hepatitis B testing may receive it, regardless of disclosure of risk, because many may be reluctant to disclose stigmatizing risks (new recommendation),” we suggest a stronger statement to replace “may receive” such as “should receive”. This language will have future implications for health insurance coverage for the screening test, especially when the U.S. Preventive Services Task Force considers updating their recommendation. Strengthening this statement will provide clear guidance for health care providers.
- *Incorporating hepatitis B screening and testing into a clinic workflow, by age* (Figure 1, page 39) – We suggest clarifying the top box in the workflow, “offer screening and vaccine,” to ensure providers have specific guidance on timing of screening and starting the hepatitis B vaccine series, per the 2020 ACIP recommendations.

Virus Description and Transmission

- *Methods of transmission* (page 8) – “Transmission can occur during sex with an infected partner; birth to an infected person...” The language used to describe perinatal transmission can be confusing and misinterpreted, for example, the infected person could be misinterpreted as someone other than the pregnant person like the healthcare provider or any person assisting with childbirth. We suggest rephrasing such as “from an infected person to a baby during labor and delivery (mother-to-child transmission).”

Rationale for Screening

- *Rationale for screening* (page 32) - “While screening can identify persons who are unvaccinated and susceptible, screening is not a requirement for HepB vaccination (cite 2022 ACIP).” This statement does not provide clear guidance for providers. We suggest providing more specific guidance or reference to corresponding sections of the recommendation document, so as not to conflict with the expanded recommendations to offer a one-time test for all adults. To ensure alignment of the screening and vaccination recommendations, we urge CDC to replace the language in this section to encourage screening for *all* adults, as we are concerned that this statement takes away from the universal screening message.

Follow-up After Hepatitis B Virus Testing

- *Persons with current HBV infection and addressing hepatitis B-related discrimination* (page 33) – “People should not be excluded from practicing in the health care field, school, play, childcare, work, or other settings because they are infected with HBV” (133, 134). We appreciate and applaud CDC for including this statement in the recommendations document. Addressing hepatitis B-related discrimination is a high priority for our community. Despite existing federal legal protections, people living with hepatitis B continue to face stigma and discriminatory policies. We recommend expanding and elevating this statement to increase awareness among health care providers and the public that hepatitis B is a protected condition under the Americans with Disabilities Act. *Persons with isolated core antibody* (page 35) – We suggest updating the reference related to the specificity of core antibody testing (99.8%) per the citation below, which will help to dispel beliefs regarding high rates of false-positives.
 - Gish, R.G., Basit, S.A., Ryan, J. *et al.* Hepatitis B Core Antibody: Role in Clinical Practice in 2020. *Curr Hepatology Rep* 19, 254–265 (2020).
<https://doi.org/10.1007/s11901-020-00522-0>.

Screening for Hepatitis Delta Infection

Finally, we believe the expansion of the recommendations for hepatitis B screening and testing is an opportunity to promote awareness and screening for hepatitis delta infection. There are very low levels of awareness and knowledge about hepatitis delta in the U.S. among the persons at risk for infection and health care providers. Given the promising treatments currently in clinical trial and anticipated dissemination of research related to hepatitis delta prevalence, we encourage the CDC to take the opportunity to include a statement on hepatitis delta.

Thank you again for this opportunity to comment on the draft recommendations. Hep B United is a national coalition of over 50 organizations and local coalitions dedicated to reducing the health disparities and inequities associated with hepatitis B among highly impacted communities across the United States by increasing awareness, screening, vaccination, and linkage to care. We are excited to see the expansion of hepatitis B screening in the U.S. These updates will improve access to and increase screening and testing rates, bringing the United States closer to achieving global viral hepatitis elimination goals.

Supporting Organizations:

Hep B United

Hepatitis B Foundation