October 19, 2022

USPSTF
5600 Fishers Lane
Mail Stop 06E53A
Rockville, MD 20857

RE: Topic Reconsideration for U.S. Preventive Services Task Force Recommendation - Hepatitis B Virus Infection in Adolescents and Adults: Screening

To the U.S. Preventive Services Task Force:

On behalf of the 39 undersigned organizations, we greatly appreciate the U.S. Preventive Services Task Force's (USPSTF) commitment to disease prevention and evidence-based recommendations.

The Centers for Disease Control and Prevention (CDC) has proposed a universal, one-time hepatitis B (HBV) screening for adults aged 18 and older. This recommendation has the potential to help the U.S. make significant progress toward national HBV elimination goals. We strongly support this new recommendation from the CDC and what it will mean for the communities that are impacted by HBV. However, the success of the recommendation will require a unified approach from key stakeholders and participants.

We strongly urge the USPSTF to align their HBV screening recommendation for all adults with the CDC's new universal HBV screening recommendation by upgrading the current HBV recommendation from a "B" grade that only includes individuals for increased risk for infection to an "A" grade that recommends universal one-time screening for all adults aged 18 and over.

It is imperative that USPSTF reconsider their decision in a timely manner, as to ensure that universal HBV screening will be covered by health insurance companies that rely on USPSTF recommendations to determine services. We respectfully request that USPSTF reconsider the current recommendation and reach a decision to align with CDC within 12 months of the published final CDC recommendation.

<u>We would like to present new evidence for USPSTF to consider:</u>

Hepatitis B is Growing in the United States

In 2021, an updated assessment of chronic HBV prevalence in the U.S. found that between U.S. born and foreign-born individuals, there are up to 2.4 million people living with HBV. This number is almost three times higher than the conservative estimate of 880,000 that is often

cited by federal agencies.[1,2] The findings of this study indicate that HBV has continued to grow in the U.S., and that risk-based guidelines continuously fail to identify and prevent HBV infections. Data shows that just 33% of all reported HBV cases are identified by risk factor, which makes it nearly impossible to capture those living with HBV and link them to care.[3]

Hepatitis B related disparities are growing as well. New research from the CDC's Division of Viral Hepatitis shows an alarming gap in screening at-risk communities. New chronic HBV cases are 12 times higher in Asian American and Pacific Islanders compared to non-Hispanic whites. Additionally, HBV-related death rates were nine times greater than amongst non-Hispanic whites.[4] These numbers indicate the failures of the current risk-based guidelines to capture at-risk individuals and link them to the care they need.

Universal Screening Improves Hepatitis B related Health Outcomes

An article published in January 2022 provided an updated assessment of the cost-effectiveness of screening all adults for HBV. Using an estimated prevalence of .3% of undiagnosed HBV cases, the authors found that universal adult screening for HBV would save an additional 23,000 deaths from chronic hepatitis B related liver disease and liver cancer compared to current risk-based and country of origin screening recommendations. According to the study, universal adult screening would prevent 7.4 cases of compensated cirrhosis, 3.3. cases of decompensated cirrhosis, 5.5 cases of liver cancer, 1.9 liver transplants, and 10.3 deaths from HBV.HBV patients have reported having poorer health-related quality of life when diagnosed with advanced liver disease. By capturing HBV infections before they progress, universal HBV screening can gain 135 quality-adjusted life years per 100,000 adults screened.[5,6]

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[1]Roberts H, Ly KN, Yin S, Hughes E, Teshale E, Jiles R. Prevalence of Hepatitis B Virus (HBV) Infection, Vaccine-Induced Immunity, and Susceptibility among At-Risk Populations: U.S. Households, 2013-2018. Hepatology. 2021.

[2] Roberts H, Ly KN, Yin S, Hughes E, Teshale E, Jiles R. Prevalence of Hepatitis B Virus (HBV) Infection, Vaccine-Induced Immunity, and Susceptibility among At-Risk Populations: U.S. Households, 2013-2018. Hepatology. 2021.

[3] Centers for Disease Control and Prevention. Viral Hepatitis Surveillance Report – United States, 2019. https://www.cdc.gov/hepatitis/statistics/2019surveillance/index.htm. Published May 2021. Accessed Sept. 16, 2022

[4] Centers for Disease Control and Prevention. Viral Hepatitis Surveillance Report – United States, 2020. https://www.cdc.gov/hepatitis/statistics/2020surveillance/index.htm. Published September 2022. Accessed Sept.15, 2022

[5] Mehlika Toy, David Hutton, Aaron M Harris, Noele Nelson, Joshua A Salomon, Samuel So, Cost-Effectiveness of 1-Time Universal Screening for Chronic Hepatitis B Infection in Adults in the United States, *Clinical Infectious Diseases*, Volume 74, Issue 2, 15 January 2022, Pages 210–217, https://doi.org/10.1093/cid/ciab405

[6] Spiegel BM, Bolus R, Han S, et al. Development and validation of a disease-targeted quality of life instrument in chronic hepatitis B: the hepatitis B quality of life instrument, version 1.0. Hepatology. 2007;46(1):113–21. https://doi.org/10.1002/hep.21692.

We would also like to share additional evidence for consideration:

Liver Cancer

Both liver cancer incidence and death rates are increasing faster than any other cancer in the U.S., and with significant health disparities.[7,8] Asians and Black Americans living with HBV have an 11-fold risk of developing primary liver cancer when compared to whites. Between 2013-2017, liver cancer was the second most common cause of death among Asian American and Pacific Islander males. [9,10] As the leading cause of liver cancer globally, universal screening for HBV is critical to improving diagnosis, linkage to care and treatment, and decreasing rates of liver cancer incidence and mortality.

Cost Effectiveness

Toy *et. al,* who conducted the 2022 study mentioned above on how universal adult screening for HBV could save lives, found that universal adult screening would be cost-effective and likely cost-saving compared to current risk-based screening, saving an estimated $596 million in the U.S., with a saving of $263,000/100 000 adults screened.[5]

Challenges to Implementing Risk-Based Screening

We urge the Task Force to consider challenges to real-life implementation when discussing the effectiveness of current guidelines. The vast majority of people living with HBV in the U.S. remain undiagnosed. Current risk-based strategies have failed to improve hepatitis B screening and diagnosis rates. Country of birth risk factors are not consistently collected by health care providers. Health systems overall have not effectively found ways to incorporate country of birth into electronic medical records. Additionally, collecting immigration and behavioral risk factors is sensitive for both healthcare providers and patients, and there is hesitation to have these conversations on both sides. This is especially concerning for communities of color who face considerable stigma and discrimination due to country of origin and immigrant status.[11,12]

The current screening strategy of targeting those labeled as high risk for HBV infection -- which includes foreign-born individuals who face multiple barriers to health care access -- exacerbates stigma and discrimination for already marginalized communities. Moving to universal screening

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[7] Ryerson AB, Eheman CR, Altekruse SF, et al. (2016). Annual Report to the Nation on the Status of Cancer, 1975-2012, featuring the increasing incidence of liver cancer. Cancer;122:1312-1337.

[8] Jemal A, Ward EM, Johnson CJ, et al. (2017). Annual Report to the Nation on the Status of Cancer, 1975-2014, featuring survival. J Natl Cancer Inst;109.

[9] Chayanupatkul M, Omino R, Mittal S, Kramer JR, Richardson P, Thrift AP, et al. Hepatocellular carcinoma in the absence of cirrhosis in patients with chronic hepatitis B virus infection. J Hepatol 2017;66:355-362.

[10] Henley SJ, Ward EM, Scott S, Ma J, Anderson RN, Firth AU, Thomas CC, Islami F, Weir HK, Lewis DR, Sherman RL, Wu M, Benard VB, Richardson LC, Jemal A, Cronin K, Kohler BA.
2020. Annual Report to the Nation on the Status of Cancer, part I: National cancer statistics. Cancer. 2020 Mar 12. doi:10.1002/cncr.32802. [Epub ahead of print].

[11] IOM (Institute of Medicine). 2014. Capturing social and behavioral domains and measures in electronic health records: Phase 2. Washington, DC: The National Academies Press

[12] Hasnain-Wynia R, Baker DW. Obtaining data on patient race, ethnicity, and primary language in health care organizations: current challenges and proposed solutions. *Health Serv Res*. 2006;41(4 Pt 1):1501-1518.

of all asymptomatic adults is the best way to reduce labeling associated with infectious diseases, as has been demonstrated by population-based screening for HIV infection. Universal screening eliminates significant barriers and allows primary care providers to broadly test their patients.

It should also be recognized that both the prevalence of HBV infection and unknown diagnosis rates of HBV far exceed those of other infectious diseases with USPSTF universal adult screening recommendations; this includes HIV infection, which affects an estimated 1.2 million people with 13% undiagnosed.[13] In comparison, the number of people living with HBV is nearly double that of those living with HIV, and over 80% of individuals are undiagnosed.[14]

In conclusion, the current targeted, high-risk group based approach to hepatitis B screening has proven to be difficult to implement, ineffective at improving diagnosis rates, and stigmatizes the most highly impacted communities. The CDC recognizes that universal adult screening is the most effective way to increase diagnosis rates, move people with hepatitis B into care, and make progress towards hepatitis B elimination goals. Aligning the USPSTF HBV screening guidelines with CDC's upcoming universal screening recommendation is necessary to ensure that individuals are able to receive equitable care, and that the U.S. meet their goals for eliminating viral hepatitis by 2030.[15]

We thank you again for the opportunity to offer comments. For additional information, please contact Michaela Jackson, Program Director, Prevention Policy at the Hepatitis B Foundation, at michaela.jackson@hepb.org.

Sincerely,
Hepatitis B Foundation
Hep B United
AIDS United
American Liver Foundation
Asian Center - Southeast Michigan
Asian Health Coalition
Asian Liver Center at Stanford University
Asian Pacific Health Foundation
Caring Ambassadors Program
Center for Disease Analysis Foundation
Charles B. Wang Community Health Center
Clary Strategies
Community Welfare Services of Metro Detroit
End Hep C SF
Hep B United Philadelphia
Hep Free Hawai'i

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[13] Centers for Disease Control and Prevention (CDC), HIV Basic Statistics, last reviewed June 21, 2022, available at https://www.cdc.gov/hiv/basics/statistics.html.
[14] Ogawa E, Yeo YH, Dang N, Le MH, Jeong D, Tran S, Henry L, Cheung R, Nguyen MH. Diagnosis Rates of Chronic Hepatitis B in Privately Insured Patients in the United States. JAMA Netw Open. 2020 Apr 1;3(4):e201844. doi: 10.1001/jamanetworkopen.2020.1844. PMID: 32271388; PMCID: PMC7146097.
[15] Centers for Disease Control and Prevention
(CDC). Division of Viral Hepatitis 2025 Strategic Plan, CDC; 2020

Hep Free S-W Organization
Hepatitis B Initiative of Washington, D.C.
HepFree KY
HIV + Hepatitis Policy Institute
Immunize.org
International Association of Providers of AIDS Care
La Maestra Community Health Centers
LiveWell Initiative LWI
Louisiana Families for Vaccines
Maplewood Health Department
Med Charitable Trust
National Viral Hepatitis Roundtable (NVHR)
New Jersey Hepatitis Coalition
North East Medical Services
ONG ADILO
Robert G Gish Consultants LLC
The AIDS Institute
The National Organisation for People Living with Hepatitis B
Treatment Action Group
Utah Hepatitis Coalition
Vaccine Ambassadors
Vietnamese American Cancer Foundation (VACF)
Virginia Hepatitis Coalition