



June 1, 2020

To the U.S. Preventive Services Task Force:

Re: Comments on the Draft Recommendation Statement: Screening for Hepatitis B Virus Infection in Nonpregnant Adolescents and Adults

On behalf of the Hep B United coalition and the undersigned 29 organizations and 113 individuals, we appreciate the opportunity to comment on the *Draft Recommendation Statement: Screening for Hepatitis B Virus Infection in Nonpregnant Adolescents and Adults*. Based on the evidence presented in this draft Recommendation Statement, we believe the USPSTF came to the right conclusions in some ways, but not in others.

While we support a highly graded recommendation for hepatitis B (HBV) screening, especially for its critical role in removing barriers and increasing access to screening and treatment, we believe in order to achieve HBV elimination goals, it is time to move beyond risk-based screening. **We urge the USPSTF to expand its recommendation to universal screening of all adults with an “A” grade in order to close major gaps in identifying the 65% to 75% of undiagnosed cases in the U.S.**

We offer the following evidence and viewpoints for consideration.

Please provide additional evidence or viewpoints that you think should have been considered by the USPSTF.

Limited Effectiveness of Current Screening Strategies and Progress in Diagnosis Rates

The current USPSTF risk-based screening recommendation that has been in place for nearly six years (and 10 years since the Centers for Disease Control and Prevention’s HBV risk-based screening guidelines) have had limited effectiveness and progress in decreasing the prevalence of HBV infections. It is estimated that about 2.2 million people are living with HBV infection in the United States, yet a significant majority -- about 65-75% of those, remain undiagnosed.¹ Both the prevalence of HBV infection and unknown diagnosis rates far exceed those of other infectious diseases with USPSTF universal adult screening recommendations; this includes HIV infection, which affects an estimated 1.1 million people, with 14% undiagnosed.²

Additionally, risk-based screening strategies increase potential labeling, anxiety and stigma of individuals and communities. It is important to take into account that a targeted screening strategy of 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 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.

¹ Cohen C, H. S., McMahon BJ, Block JM, Brosgart CL, Gish RG, London WT, Block TM. (2011). Is chronic hepatitis B being undertreated in the United States? *Journal of Viral Hepatitis*, 18, 377-383

² Centers for Disease Control and Prevention (CDC), HIV Basic Statistics, last reviewed March 20, 2020, available at <https://www.cdc.gov/hiv/basics/statistics.html>.

In the U.S., rates of HBV-related mortality including hepatocellular carcinoma are on the rise. Hepatitis B continues to be a leading cause of primary liver cancer, which is the second leading cause of cancer deaths worldwide. According to the 2020 Annual Report to the Nation on the Status of Cancer, while overall cancer incidence rates are leveling off, the incidence of liver cancer increased by 2.5% overall and by 3.5% in women, the largest increase in incidence of any cancer between 2012-2016. Additionally, liver cancer was the fifth most common cause of cancer death for men overall and death rates continue to increase among women overall.³ A strategy for universal screening for HBV infection is key to improving diagnosis, linkage to care and treatment, decreasing rates of liver cancer incidence and mortality.

Risk-based screening for HBV infection is not routinely implemented in health care systems and places the burden on under-resourced community-based organizations. Risk-based screening recommendations that are based on country of birth and stigmatizing risk behaviors are difficult to implement and face many challenges that often cannot be implemented within health care systems in the U.S. Targeted HBV screening strategies are implemented primarily through community-based settings by smaller and often under-resourced community-based organizations and clinics; these strategies are not sustainable in the long term. While this approach reaches persons at high risk for infection, outreach has been challenging and misses a substantial proportion of the populations considered at high risk for HBV infection. At the community level, not only are there challenges in screening communities that are hard to reach, but the asymptomatic nature of HBV infection presents an additional barrier to the demand for screening.

Targeted screening is difficult to implement in hospitals and health care systems where there is little provider awareness and incentive. Data from a recent analysis of community-based HBV testing events with over 3,000 persons in Philadelphia screened, reveal that almost half (46.1%) of those who tested positive for HBV infection already had a regular source of care.⁴ Yet, despite the current USPSTF recommendations and known risk factors, these individuals were not screened for HBV infection in the primary care setting. Risk-based testing for HBV puts great burden on clinicians, who are typically unaware of the risks, are unsure of who to test, and overburdened in primary care settings to learn the intricacies of who to test. There are not many incentives for providers to change their clinical patterns.

Additionally, electronic clinical decision support technology which can assist providers in identifying high-risk patients is extremely challenging to integrate. For example, electronic health records currently do not capture country of birth which is one of the major factors for those at high risk for HBV infection. Instituting electronic Clinical Decision Support faces its own challenges – current risk-based HBV screening has a complexity of risk determination – institutions have difficulty implementing electronic data collection and flags based on country of birth. Electronic health records used by most health systems do not include a field for country of birth. Nor does it include information about parental infection or parental HBV risk. It is even difficult to identify behavior risks – as patients are often hesitant to share stigmatizing factors such as sexual and drug use behaviors. All of this makes it complicated for clinicians to figure out who is at risk, making risk-based screening guidelines difficult to implement.

³ Henley SJ, Ward EM, Scott S, et al. Annual report to the nation on the status of cancer, part I: National cancer statistics. *Cancer*. 2020;126(10):2225-2249. doi:10.1002/cncr.32802.

⁴ Freeland C., Vader D., Cohen C., George B. A Predictive Model for Hepatitis B Infection Among High-Risk Adults Using a Community-Based Sample in Greater Philadelphia. *Journal of Viral Hepatitis* (submitted February 2020, under review).

There are substantial gaps in risk-based testing for HBV infection and missed opportunities to identify persons vulnerable to infection and improve hepatitis B vaccination coverage among adults. Reported state HBV prevalence data has revealed gaps in the risk-based screening strategy and have missed high-risk groups. The opioid epidemic and injection drug use in the U.S. have substantially increased the incidence of hepatitis B infection. Spikes in HBV infection rates range from 56% to 457% in states most heavily affected by the opioid epidemic, including in Kentucky, Tennessee, West Virginia, North Carolina, and Maine.^{5,6,7} Studies also show a high prevalence of HBV infection among the homeless population, seven to 10 times higher than in the U.S. general population, revealing significantly lower screening rates than for HIV.⁸ There are clearly gaps in targeted screening approaches; with a universal screening strategy, we will ensure all health care and other settings for public health interventions have the incentive and resources to identify infected individuals and vaccinate those adults who are vulnerable to infection.

Cost-Effectiveness of Routine Screening

We urge the Task Force to review evidence related to the cost-effectiveness of HBV screening, including screening followed by immunization or treatment. There are a number of studies that have focused on the cost effectiveness of HBV screening. These studies indicate that screening is cost effective in populations where HBV prevalence is as low as 0.3%, well below the prevalence of hepatitis B surface antigen (HBsAg) of 2% or greater as noted in the assessment of risk.⁹

Finally, we encourage the USPSTF to review the HHS Health Resources and Services Administration's Uniform Data System and data from federally qualified health centers that have adopted universal HBV screening of adults into their practice. Hepatitis B screening, vaccination, and treatment data from these datasets may present models for effective expansion into the larger health care system.

Thank you again for this opportunity to comment on the Draft Recommendation Statement. Hep B United is a national coalition of over 40 organizations and local coalitions dedicated to reducing the health disparities associated with hepatitis B by increasing awareness, screening, vaccination, and linkage to care for high-risk communities across the United States.

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⁵ Harris AM, Iqbal K, Schillie S, et al. Increases in acute hepatitis B virus infections—Kentucky, Tennessee, and West Virginia, 2006-2013. *MMWR Morb Mortal Wkly Rep.* 2016;65(3):47-50. doi:10.15585/mmwr.mm6503a2

⁶ Maine Center for Disease Control and Prevention. Maine surveillance report 2018: acute hepatitis B.

<https://www.maine.gov/dhhs/mecdc/infectious-disease/epi/publications/index.shtml#surveillance>.

⁷ Hepatitis B, C on rise in N.C.; health officials encourage precautions, testing [press release]. Raleigh, NC: North Carolina Department of Health and Human Services; May 30, 2017. <https://www.ncdhhs.gov/news/press-releases/hepatitis-b-c-rise-nc-health-officials-encourage-precautions-testing>.

⁸ Khouzam N, Gelberg L, Guo R, Tseng CH, Bhattacharya D. Opiate Dependence: A Risk Factor for Hepatitis B Virus Exposure in Homeless Adults. *Fam Community Health.* 2020;43(2):161-169. doi:10.1097/FCH.0000000000000246.

⁹ Eckman MH, Kaiser TE, Sherman KE. The cost-effectiveness of screening for chronic hepatitis B infection in the United States. *Clin Infect Dis.* 2011;52(11):1294-1306. doi:10.1093/cid/cir199

Supporting Organizations:

Hep B United

Hepatitis B Foundation

Association of Asian Pacific Community Health Organizations (AAPCHO)

Asian American Pacific Islander Health Research Group (AAPIHRG)

Asian Health Coalition

Asian Pacific Community in Action

Asian Pacific Health Foundation

Center for Disease Analysis Foundation (CDA Foundation)

Charles B. Wang Community Health Center

Community Welfare Services of Metro Detroit

Dynavax

Hawaii Health & Harm Reduction Center

Hep B United Philadelphia

Hep Free Hawaii

Hepatitis B Initiative of Washington DC (HBI-DC)

HIV + Hepatitis Policy Institute

Immunization Action Coalition

Liver Health Connection

Midwest Asian Health Association

Migrant Clinicians Network

NASTAD

National Task Force on Hepatitis B Focus on Asian and Pacific Islander Americans

NYU Center for the Study of Asian American Health

Ohio Asian American Health Coalition

SF Hep B Free - Bay Area

The AIDS Institute

Treatment Action Group

WHO Collaborating Centre for Viral Hepatitis, Doherty Institute, Melbourne, Australia

Yale Viral Hepatitis Program