November 2nd, 2021

Stephanie Thomas
ACIP Committee Management Specialist
Centers for Disease Control and Prevention
1600 Clifton Road, N.E., Mailstop A-27
Atlanta, GA 30329-4027

RE: Comments for the November Meeting of the Advisory Committee on Immunization Practices (Docket No. CDC-2021-0112) / Recommendation of Adult Hepatitis B Universal Vaccination

To the Advisory Committee on Immunization Practices (ACIP):

On behalf of the 123 undersigned organizations, we are grateful for the ACIP's efforts to address adult hepatitis B vaccination. The Committee's consideration of a universal hepatitis B recommendation is critical in addressing the consistently low adult hepatitis B vaccination rates and eliminating viral hepatitis in the United States.

The hepatitis community strongly supports a recommendation for universal adult hepatitis B vaccination. Failure by the Committee to recommend universal adult hepatitis B vaccination for all adults is a missed opportunity to stem the tide of spikes in hepatitis B infections across the country and will be detrimental to the elimination of viral hepatitis inequities in the United States.

We would like to directly address several concerns raised by the Committee during the September 29, 2021 ACIP meeting:

The Importance of a Universal Adult Hepatitis B Recommendation

Hepatitis B remains a significant public health problem in the United States despite the presence of highly effective vaccines. Adult hepatitis B vaccine coverage reached just 30% in 2018, which is an incremental increase of less than 5% from 2017[1]. Prior to 2018, the adult hepatitis B vaccine coverage remained stagnant at just 25% for several years. The continuously low rates of adult hepatitis B vaccine coverage highlight numerous missed opportunities for prevention. It is impossible to achieve viral hepatitis elimination without significant increases in adult hepatitis B vaccination coverage and effective community outreach.

Rises in Acute Hepatitis B

Despite highly effective vaccines, hepatitis B cases in the United States rose by 11% between 2014 and 2018. The CDC's Division of Viral Hepatitis reported that 36% of all new hepatitis B

[1]Lu P, Hung M, Srivastav A, et al. Surveillance of Vaccination Coverage Among Adult Populations — United States, 2018. MMWR Surveill Summ 2021;70(No. SS-3):1–26. DOI: http://dx.doi.org/10.15585/mmwr.ss7003a1

cases are amongst people who inject drugs (PWID). [2] The opioid epidemic has also driven alarming increases in rates of acute hepatitis B. States heavily impacted by the opioid crisis, including Kentucky, West Virginia, Tennessee, Maine, Massachusetts, and North Carolina, have experienced significant increases in acute hepatitis B cases ranging from 56% to 457% in a short amount of time.[3,4,5,6] These tremendous increases are indicative that current recommendations for vaccinating at-risk populations are not effective.

Hepatitis B infections amongst PWIDs is also of growing concern. In 2019, new acute and chronic hepatitis B cases were primarily found in adults 30-49 years of age[7]. As hepatitis B is commonly transmitted from mother-to-child during birth, increased hepatitis B vaccinations in this age group could lead to the prevention of perinatal transmission.

Eliminating Hepatitis B Inequities

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.[8] Chronic hepatitis B disproportionately impacts Asian Americans, Pacific Islanders, and African immigrants. While Asian Americans account for just 6% of the U.S. population, they account for nearly 60% of all chronic hepatitis B cases. Chronic hepatitis B is also six times more prevalent amongst Blacks than non-Hispanic whites. Moreover, the hepatitis B-related mortality rate for Black individuals is more than 2.5 times the mortality rate for non-Hispanic whites.[2] Preventing hepatitis B infections in these communities is critical given that Asian Americans and Blacks living with hepatitis B have a primary liver cancer risk that is 11 to 17 fold higher than Whites.[9]

A Universal Recommendation Increases Vaccination Coverage Amongst High-Risk Groups

We can look to the influenza vaccine for evidence that universal vaccination recommendations increase vaccination coverage amongst high-risk groups. In 2000, the influenza recommendation was expanded to include all individuals ages 50-64, rather than just high-risk

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[2] U.S. Department of Health and Human Services. 2020. Viral Hepatitis National Strategic Plan for the United States: A Roadmap to Elimination (2021–2025). Washington, DC.

[3] Centers for Disease Control and Prevention. https://www.cdc.gov/hai/pdfs/bbp/exp_to_blood.pdf. Updated July 2003. Accessed January 25, 2018. ; Centers for Disease Control and Prevention. https://www.cdc.gov/hepatitis/featuredtopics/youngpwid.htm. Accessed March 25, 2019

[4] 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. Centers for Disease Control and Prevention. https://www.cdc.gov/hai/pdfs/bbp/exp_to_blood.pdf. Updated July 2003.

[5] 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.

[6] 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/pressreleases/hepatitis-b-c-rise-nc-health-officials-encourage-precautions-testing.

[7] 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 October 5, 2021.

[8] 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

[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;66:355-36

persons.[10] The coverage rate in high-risk individuals ages 50-64 increased from 43.4% in 1998 to 49.6% in 2008. In 2010, the guidelines were expanded once again to cover all individuals over 6 months of age. Research showed a substantial increase from 29.8% in 2008 to 44.4% in 2019 for coverage of high-risk adults 18-49 years old. It is evident that universal vaccination recommendations greatly increases vaccination coverage amongst high-risk groups.

A Universal Recommendation is Cost-Effective in Adults 60 Years of Age and Older

When evaluating incremental cost-effectiveness ratios (ICER) for individuals 60 and older, it is integral to remember that a universal recommendation is meant to act as a catch-up recommendation as there has been a universal hepatitis B recommendation for infants since 1991. The cost-effectiveness ratio for older adults represents the necessary price we must pay to accelerate the elimination of a deadly disease. The universal recommendation is not meant for continuous prevention on a regular basis, but rather the ICER is also likely to be lower than shown in the base case, as the base case did not model any increase in vaccination coverage amongst high-risk individuals. As shown with influenza, it is highly likely that a universal recommendation will result in increased coverage in high-risk groups.

There are also several other critical points to consider:

Risk-based guidelines have continuously failed to prevent hepatitis B infections. Data shows that just 33% of all reported hepatitis B cases are identified by risk factor.[7] According to the CDC and the U.S. Preventive Services Task Force, there are 18 subpopulations that are recommended to be vaccinated. Initial calculations of people who have at least one risk factor for hepatitis B infection indicate that approximately 84% of the U.S. population meets the current recommended vaccination guidelines.[11] It should be noted 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)[12,13]. With such a large portion of adults in the U.S. meeting or expected to develop one of the risk factors for vaccination recommendations, a universal hepatitis B vaccination recommendation would amplify the importance of the hepatitis B vaccine.

Risk-based guidelines encumber health care providers and place a burden upon the patient. Providers, especially primary care providers, have an extensive list of requirements and concerns that they must discuss with a patient in an extremely short amount of time. Risk-based vaccination guidelines increase the number of topics a provider must cover, which may impact the amount of attention they can provide to a patient's other concerns. By overwhelming providers, risk-based guidelines expect patients to bring up their risk factors, of which they might not even be aware. Many hepatitis B risk factors, such as sexual history and injection drug use, are sensitive and stigmatized topics that a patient may not feel comfortable disclosing. Self-reporting for sensitive topics is selective and misses a large number of people who may truly be at risk. Furthermore, risk-based guidelines are dependent upon demand. Although

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[10] https://www.cdc.gov/mmwr/preview/mmwrhtml/rr4903a1.htm

[11] (Hepatitis B Foundation, unpublished data)

[12] 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

[13] 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.

current recommendations state that any person who would like to access the hepatitis B vaccine can do so, many people seeking the vaccine report that it is not accessible because pharmacies and/or providers do not keep them in stock due to low demand. Universal adult hepatitis B vaccination would allow clinicians to vaccinate patients without inquiring about 18 different risk factors and would remove the burden of disclosing sensitive information from the patient.

The Committee must consider real-life implementation when discussing the effectiveness of current guidelines. Although current recommendations state that all adults requesting protection from hepatitis B infection may be vaccinated, many people seeking the vaccine report that it is not accessible because pharmacies and/or providers do not keep the vaccine in stock due to low demand. Patients seeking the vaccine are often forced to call multiple provider offices or pharmacies and still cannot access the vaccine. If the vaccine is only accessible to those who live close to a facility that keeps it in stock, we cannot claim that everyone has an equal opportunity to receive it. Individuals who do not fall into a high-risk category have also reported that cost is prohibitive to accessing the hepatitis B vaccine. Many insurance programs provide coverage for ACIP-recommended vaccines, but will only cover those who are at high risk for hepatitis B infection. Universal coverage eliminates cost and other systemic barriers, which will help increase vaccine uptake.

We must also consider the impacts of the COVID-19 pandemic on healthcare services. There is great concern the COVID-19 pandemic may have significantly reduced what little progress we have been able to achieve. Approximately 93% of health departments reported a reduction in their viral hepatitis programs, including outreach, education, and linkage to care, which are all essential to maintaining and increasing adult hepatitis B vaccination rates. More than 70% of health departments also reported a reduction in hepatitis B vaccination services. Additionally, over 40% of community-based organizations were unable to provide hepatitis B vaccination services during the early months of the pandemic.[14] Based upon previous patterns and emerging outcomes on delayed services that we have seen with similar infectious diseases such as HIV and hepatitis C, we can anticipate an increase in acute hepatitis B cases in the next few years. Universal adult hepatitis B vaccination is crucial to preventing a widespread outbreak as a consequence of the COVID-19 pandemic.

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

Sincerely,
Hepatitis B Foundation
Hep B United
Academy of Medical & Public Health Services
Access Support Network
Africa Hepatitis Initiative (AHI)
African Cultural Alliance of North America (ACANA)
African Services Committee
Albert Einstein Cancer Center
Alliance for Immunizations in Michigan (AIM)

[14] Local Health Departments as Leaders in the Prevention & Elimination of Viral Hepatitis. (2020, December 29). Retrieved February 01, 2021, from ww.naccho.org/blog/articles/local-health-departments-as-leaders-in-the-prevention-elimination-of-viral-hepatitis

American Academy of HIV Medicine
American Liver Foundation
APAMSA Chapter of TouroCOM Harlem NYC
APLA Health
APSAD MALI
Asian Center - Southeast Michigan
Asian Health Coalition
Asian Liver Center at Stanford University
Asian Pacific Community in Action
Asian Pacific Health Foundation
Association of Asian Pacific Community Health Organizations
Association of Diabetes Care & Education Specialists
Bienestar Human Services
Blessings of Aloha
Blue Faery: The Adrienne Wilson Liver Cancer Association
BOOMHEALTH
Building Lives Around Sound Truth
California Hepatitis Alliance
Caring Ambassadors Program
CDA Foundation
Center for Pan Asian Community Services (CPACS)
Charles B. Wang Community Health Center, Inc.
Chicago Department of Public Health
Chronic Care Collaborative
Colorado Department of Public Health and Environment
Community Liver Alliance
DAP Health
Drive For Health Foundation Ghana
Empowerment for Sustainable Livelihood
End Hep C SF
Family Service Association of Bucks County
Family Wellness Pharmacy
Filipino American Arts Exposition
GLIDE
Global Liver Institute
GoodWorks: North Alabama Harm Reduction
Greater Salt Lake Immunization Coalition
Harm Reduction MidAmerica
Hawaii Health and Harm Reduction Center
Hawaii Immunization Coalition
Help & Education for Liver Patients (HELP!)
Hep B United Philadelphia
Hep Free Hawaii
Hepatitis B Initiative of Washington, D.C.

Hepatitis C Association
Hepatitis C Mentor and Support Group, Inc. - HCMSG
Hepatitis Zero Commission
HepTREC
Herbert Irving Comprehensive Cancer Center, *Office of Community Outreach and Engagement, Columbia University Irving Medical Center*
HIV + Hepatitis Policy Institute
HIV Medicine Association
Illinois Public Health Association
Immunization Action Coalition (IAC)
Immunize Colorado
Immunize Ohio
Immunize South Dakota
Infectious Diseases Society of America
Justice Resource Institute
Korean Community Services of Metropolitan New York, Inc.
Kumukahi Health + Wellness
La Maestra Family Clinic, Inc.
Langlade Co Immunization Coalition
LifeMoves
Liver Coalition of San Diego
LiveWell Initiative LWI
Med Charitable Trust
Midwest Asian Health Association
NASTAD
National Association of County and City Health Officials
National Consumers League
National Foundation for Infectious Diseases
National Nurse-Led Care Consortium
National Task Force on Hepatitis B
National Viral Hepatitis Roundtable (NVHR)
New York City Department of Health and Mental Hygiene
North East Medical Services
Northeast Ohio Liver Alliance
Nosauyi Foundations
NYU Langone- Perlmutter Cancer Center
One Voice Recovery, Inc.
ONG ASADH
Pacific Health Alliance
Paterson Counseling Center, Inc.
Peninsula Health Care District
Pennsylvania Immunization Coalition
Prevent Cancer Foundation
Project H+EAL

Reiner Associates, Inc.
San Francisco AIDS Foundation
San Mateo County Health Department
SF Hep B Free - Bay Area
SLO Bangers Syringe Exchange and Overdose Prevention Program
SOS Hépatites Mali
South Pacific Express Mgmt
STCheath LLC
Stony Brook University Cancer Center
Texas DSHS Immunization Section
The AIDS Institute
The National Organisation for People Living with Hepatitis B
The Sandra and Edward Meyer Cancer Center at Weill Cornell Medicine
The Tisch Cancer Institute at Mount Sinai
Treatment Action Group
Tulsa Area Immunization Coalition
Utah Hepatitis Coalition
Vaccine Ambassadors
Vietnamese American Cancer Foundation (VACF)
Virginia Hepatitis Coalition
VTC APAMSA
West Virginia Hepatitis Academic Mentoring Partnership
WithinReach
Women of a Certain Age
World Hepatitis Alliance - African Members
WV Immunization Network, *a program of The Center for Rural Health Development, Inc.*
Zemma Awareness Initiative