



March 11, 2019

Tammy R. Beckham, DVM, PhD
Director, Office of HIV/AIDS and Infectious Disease Policy
Office of the Assistant Secretary for Health
U.S. Department of Health and Human Services
330 C Street, SW, Room L001
Washington, DC 20024

Re: Request for Information (RFI) - Improving Efficiency, Effectiveness, Coordination, and Accountability of HIV and Viral Hepatitis Prevention, Care, and Treatment Programs

Dear Dr. Beckham,

On behalf of Hep B United, a national coalition of over 40 organizations in 20 states dedicated to reducing the health disparities associated with hepatitis B (HBV) by increasing awareness, screening, vaccination, and linkage to care for high-risk communities across the United States, we appreciate the opportunity to provide recommendations towards the development of the next iteration of the National Viral Hepatitis Action Plan (NVHAP).

Viral hepatitis continues to be a serious public health threat affecting millions in the United States. **It is critical that we continue to work towards collective national goals and strategies in order to measure our progress and achieve the 2030 viral hepatitis elimination goals established by the World Health Organization (WHO) and supported by the National Academies of Sciences, Engineering, and Medicine (NASEM) recommendations.** In the next iteration of the NVHAP, we recommend that the goals and strategies are aligned with the WHO and NASEM elimination goals and focus on achieving 2030 targets for elimination of hepatitis B and C.

Additionally, we offer the following recommendations for your consideration towards the development of the next iteration of the National Viral Hepatitis Action Plan.

(1b) What components of the NVHAP do you think should be maintained? What changes should be made to the NVHAP? This may include changes to the structure, goals, and indicators, key areas of focus and/or populations, and annual reporting processes by federal agencies. This may also include areas of the current strategy that should be scaled back or areas of the current strategy that should be expanded or scaled up.

- **Goal 1: Achieve universal HBV vaccination for all adults, not just vulnerable adults.** In order to achieve HBV elimination, we need to increase HBV vaccination coverage and develop specific strategies/activities to achieve this goal. The recent rise in acute HBV infection rates as a

consequence of the opioid crisis reveals significant gaps in HBV testing and vaccination; less than 25% of adults age 19 and older are vaccinated against hepatitis B.¹ New HBV infections related to injection drug use are particularly prevalent among adults aged 30 to 49 who were not vaccinated as children.² In addition, newly infected young women may be unaware of their HBV infection and may infect their children with HBV via perinatal transmission, subsequently causing these infants to be at significantly higher risk of developing chronic HBV infection, early onset liver failure, and liver cancer. Furthermore, with the availability of a new, two-dose hepatitis B vaccine, there is opportunity to improve coverage and prevent transmission in high risk and hard to reach populations including the homeless, PWID, people with diabetes, and people living with HIV.

- **Goal 2: Reduce deaths and improve the health of people living with viral hepatitis and Goal 3: Reduce viral hepatitis health disparities.** We recommend changing “reduce” for both of these goals to “goals 2: eliminate deaths and improve the health of people living with viral hepatitis” and “goal 3: eliminate viral hepatitis health disparities.” We recommend focusing the NVHAP more towards elimination to align with global elimination goals.
- **Scale up and improve efficiency and effectiveness of strategies to increase HBV screening and provider capacity to treat HBV.** As potential key strategies to scale up for **goal 2: reduce deaths and improve the health of people living with viral hepatitis**, we recommend the following activities to support strategy 2.1 – *build the capacity of the health care workforce to diagnose viral hepatitis and provide care and treatment to persons infected with viral hepatitis* and strategy 2.2 – *identify persons infected with viral hepatitis early in the course of their disease*. 1) Develop a “*Know Your Status*” campaign to ensure that those susceptible to HBV infection receive vaccination, in addition to education on HBV reactivation for those with prior infection, and linkage to care for those with current infection. When screening for HBV as per current CDC guidelines, the recommended tests are HBsAg (Hepatitis B surface antigen), Anti-HBs (Hepatitis B surface antibody), and Anti-HBc (Hepatitis B core antibody). Those who have recovered from a past HBV infection will test positive for both Anti-HBs and Anti-HBc – and it is important that these individuals are counselled to be aware of their risk for reactivation with immune suppression (and associated with initiation of Direct Acting Antiviral treatment for hepatitis C). Additionally, a subset of the population will test positive for Anti-HBc alone (isolated Anti-HBc). These individuals need further testing to assess their current HBV infection status, as they could be chronically infected. 2) We recommend training front-line providers, e.g. primary care providers, to not only screen and vaccinate for HBV but to manage and treat uncomplicated chronic hepatitis B in the primary care setting.
- **Add African immigrant communities as a priority population and include an objective within goal 3 to address health disparities impacting African Immigrant communities.** African immigrants (AI) living in the U.S. are disproportionately and increasingly affected by HBV, with infection rates

¹ Centers for Disease Control and Prevention. Vaccination coverage among adults in the United States, National Health Interview Survey, 2016. Available at: www.cdc.gov/vaccines/imzmanagers/coverage/adultvaxview/pubs-resources/NHIS-2016.html. Accessed March 11, 2019.

² 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

upwards of 8-10%, rivaling that of Asian American and Pacific Islander populations.^{3,4,5,6,7,8} Sub-Saharan Africa is known to have some of the highest rates of HBV worldwide, and AIs are estimated to comprise 29% of chronic hepatitis B patients living in the U.S., thus the need to prioritize and address HBV in this population is vital.^{9,10} Although CDC recommends all immigrants living in the U.S. be screened for hepatitis B, this group continues to represent an unaddressed disparity and face unique barriers to testing, vaccination and care. While data and interventions have thus far mainly encompassed Asian American and Pacific Islander populations, tailored and culturally-appropriate interventions are needed to address the unique barriers AIs face.

In order to reduce viral hepatitis disparities, education and community engagement efforts should expand to prioritize AIs and include collaborations with African community-based organizations to foster increased awareness, testing and linkage to care in AI communities. AIs represent nearly one third of chronic hepatitis B infections in U.S. but lack prioritization and subsequent community resources to address this burden, making these capacity-building initiatives important in reducing disparities and premature deaths.

- **Add liver cancer to NVHAP goals to improve awareness and screening for hepatocellular carcinoma (HCC).** In the U.S., liver cancer is on the rise and has now become the fastest increasing cause of cancer-related deaths.¹¹ The CDC reports that viral hepatitis is attributable to 65% of new liver cancer cases.¹² Studies have also shown that liver cancer-related deaths are highest amongst people living with chronic hepatitis B and C.¹³ Due to lack of surveillance for hepatitis B and C, many viral hepatitis cases go undiagnosed until it progresses into liver disease or liver cancer. Screening high-risk groups and those with viral hepatitis can prevent liver cancer, lead to early detection, and may help to reduce early deaths from liver cancer. In addition, improving awareness about the link between viral hepatitis and liver cancer can reduce deaths amongst the target populations by making them aware of risk factors and behaviors that put them at an increased risk for liver cancer.

³ J Immigr Minor Health. 2011 Apr;13(2):333-44. doi: 10.1007/s10903-009-9243-x. Epub 2009 Apr 4.

⁴ Yoo, G. J., Fang, T., Zola, J., & Dariotis, W. M. (2012). Destigmatizing hepatitis B in the Asian American community: Lessons learned from the San Francisco hep B free campaign. *Journal of Cancer Education*, 27(1), 138-144.

⁵ Chandrasekar, E., Song, S., Johnson, M., Harris, A. M., Kaufman, G. I., Freedman, D., et al. (2016). A novel strategy to increase identification of African-born people with chronic hepatitis B virus infection in the Chicago metropolitan area, 2012-2014. *Preventing Chronic Disease*, 13, E118.

⁶ Edberg, M., Cleary, S., & Vyas, A. (2011). A trajectory model for understanding and assessing health disparities in Immigrant/Refugee communities. *Journal of Immigrant and Minority Health*, 13(3), 576-584.

⁷ Kowdley, K. V., Wang, C. C., Welch, S., Roberts, H., & Brosgart, C. L. (2012). Prevalence of chronic hepatitis B among foreign-born persons living in the United States by country of origin. *Hepatology*, 56(2), 422-433.

⁸ Ugwu C, Varkey P, Bagniewski S, Lesnick T. (2008). Sero-epidemiology of hepatitis B among new refugees to Minnesota. *Immigr Minor Health*, 10(5):469-74.

⁹ Centers for Disease Control and Prevention. (2008). Recommendations for routine testing and follow-up for chronic hepatitis B virus (HBV) infection. Retrieved February/25 from <https://www.cdc.gov/hepatitis/hbv/pdfs/chronichepbtestingflwup.pdf>

¹⁰ Kim WR, Benson JT, Therneau TM, Torgerson HA, Yawn BP, Melton LJ 3d. Changing epidemiology of hepatitis B in a U.S. community. *Hepatology* 2004;39(3):811-6. <https://www.ncbi.nlm.nih.gov/pubmed/22105832>

¹¹ American Association for Cancer Research. (2018). Why Is Liver Cancer on the Rise?. Retrieved from <https://blog.aacr.org/liver-cancer-rising/>

¹² Centers for Disease Control and Prevention. (2016). CDC Fact Sheet: Viral Hepatitis and Liver Cancer (pp. 1-2). CDC National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention.

¹³ American Liver Foundation. (2016). Liver Cancer on the Rise. Retrieved from <https://liverfoundation.org/liver-cancer-rise/>

- **Goal 4: Coordinate, monitor, and report on implementation of viral hepatitis activities.** We support the strategies to increase communications and improve coordination of viral hepatitis activities. We recommend developing and including indicators for goal 4 in order to effectively measure our progress.

(2b) Specific recommendations you think will improve the efficiency, effectiveness, accountability, and impact of the national response to viral hepatitis.

- **Develop specific strategies and activities to combat viral hepatitis-related discrimination.** We strongly support maintaining goals and strategies related to decreasing viral hepatitis-related stigma and discrimination and emphasizing federal legal protections for persons living with viral hepatitis. In the next iteration of the NVHAP, we recommend developing specific activities to support strategies within goals 1 and 2; there is an opportunity to achieve discrimination-related goals by scaling up collective efforts to actively address discrimination. Unfortunately, HBV-related discrimination still occurs, especially within academic and employment settings, and often go underreported. We must continue to increase awareness about federal legal protections and take action to ensure individuals living with viral hepatitis have equitable opportunity to pursue successful careers and have improved health and quality of life. We recommend adding as a strategy under goal 1, working together, with federal input and partnership, to address discrimination at health care schools, hospitals and institutions, treatment facilities, and in the military. Federal partners play a significant role in leading and convening community stakeholders and increasing public awareness about viral hepatitis-related discrimination.
- **Increase awareness about hepatitis B and the opioid epidemic and improve integration of hepatitis B testing and vaccination within harm reduction programs.** Persons who inject drugs are at a high risk of contracting HBV infection through blood-borne transmission, sharing contaminated needles and drug use paraphernalia. About 20% of new HBV infections occur among injection drug users, mainly through sharing of contaminated injection equipment and unprotected sexual contact. Previous studies have found that over 80% of injection drug users who have been injecting for longer than 10 years are infected with HBV.¹⁴

State surveillance reports reveal a recent nationwide increase in acute HBV and HCV infection, with the largest increases occurring east of the Mississippi river, especially along Appalachia, that is directly related to the current opioid crisis.¹⁵ In an analysis of the National Notifiable Diseases Surveillance System (NNDSS) from 2006–2013, the CDC assessed the incidence of acute HBV infection in three Appalachian states (Kentucky, Tennessee, and West Virginia), noting an increase of 114% among non-Hispanic whites aged 30–39 years among individuals who reported injection drug use.¹⁶ The state of Maine saw a 729% increase in new acute HBV cases from 2015–2017, while North

¹⁴ Seal KH, Edlin BR, Ochoa KC, Tulskey JP, Moss AR, Hahn JA. Risk of hepatitis B infection among young injection drug users in San Francisco: Opportunities for intervention. *West J Med.* 2000;172(1):16–20. doi:10.1136/ewjm.172.1.16.

¹⁵ Patel A, Tohme R, Ward JW, et al. Emerging Epidemic of Hepatitis C Virus Infections Among Young Nonurban Persons Who Inject Drugs in the United States, 2006–2012. *Clin Infect Dis.* 2014;59(10):1411–1419. doi:10.1093/cid/ciu643.

¹⁶ 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.

Carolina and Southeastern Massachusetts saw a 78% increase in new acute HBV cases in 2017.^{17,18} Aside from CDC surveillance data capturing new (acute) HBV infections, there is limited data and few community-based serology studies on the risk of HBV infection in persons who inject drugs across the U.S. There is a need within the NVHAP to incorporate hepatitis B and comprehensive harm reduction strategies to include screening in settings such as medication assisted treatment centers (MAT) and syringe exchange programs. Additionally, prevention strategies should incorporate awareness surrounding vaccination for HBV to prevent infection and transmission within this high-risk population.

- **Promote universal hepatitis B screening.** We believe in order to achieve HBV elimination goals, we must move beyond targeted screening to universal hepatitis B screening in order to close the major gaps in identifying all undiagnosed cases. A recent study of HBV, HCV, and HIV infections among patients newly diagnosed with cancer found that 6.5% of patients tested positive for previous HBV infection; many of the patients had no known risk factors for infection, underscoring the need for universal HBV testing.¹⁹ Furthermore, targeted or risk-based HBV screening strategies are being implemented primarily through community-based settings by smaller and often under-resourced organizations and clinics. While this approach reaches high-risk individuals, it has been challenging to reach a majority of high-risk populations. Additionally, targeted screening is difficult to implement in hospitals and health care systems where there is little provider awareness and incentive. 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. Risk-based screening guidelines that are based on country of birth and stigmatized risk behaviors (such as injection drug use or sexual activity) are difficult to implement within health care systems in the U.S. Risk-based testing for HBV puts great burden on clinicians, who are typically unaware of the risks, are unsure of who to test, and too overburdened in primary care settings to learn the intricacies of who to test.

(3b) What specific actions should the federal government and others take to improve the coordination of funding and delivery of viral hepatitis services?

- **Improve coordination of funding and delivery of viral hepatitis services.** We would like to see greater coordination and communication among federal partners. For example, viral hepatitis prevention, surveillance, and response efforts within the CDC fall under both the National Center for Immunization and Respiratory Diseases (NCIRD) and the National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention (NCHSTP). CDC should work to improve collaboration and coordination across these centers by including guidance in upcoming funding opportunity announcements that encourages collaboration of resources among state immunization and infectious disease prevention programs. As another example, in federal efforts to prevent perinatal hepatitis B transmission, there is opportunity to collaborate across systems to ensure individuals who are at risk for and impacted by hepatitis B are monitored and treated appropriately across the

¹⁷ Hepatitis - Disease Surveillance Epidemiology Program - MeCDC; DHHS Maine.

<https://www.maine.gov/dhhs/mecdc/infectious-disease/epi/hepatitis/index.shtml>. Accessed February 21, 2019.

¹⁸ NCDHHS: Hepatitis B, C on Rise in N.C.; Health Officials Encourage Precautions, Testing.

<https://www.ncdhhs.gov/news/press-releases/hepatitis-b-c-rise-nc-health-officials-encourage-precautions-testing>. Accessed February 20, 2019.

¹⁹ Ramsey SD et al. JAMA Oncol. 2019 Jan 17. doi: 10.1001/jamaoncol.2018.6437.

lifespan. Due to gaps in prevention activities, which include identification and case management of infected pregnant women and their infants, an estimated 800-1,200 infants are infected with hepatitis B each year. Although limited, data suggests that the majority of HBV-infected pregnant women are not referred to medical management; a recent publication found only 21% of women had peripartum HBV specialist follow-up care.²⁰ This is a missed opportunity for preventing perinatal HBV transmission and liver disease progression for HBV-infected women. The federal government should therefore provide funding and stronger guidance for state and local health departments to coordinate on perinatal HBV prevention projects and to share surveillance data to proactively link HBV positive pregnant women and their household contacts into testing, vaccination, and care services, if needed.

- **Increase transparency and communication.** We would also like to see more transparency and communication from federal agencies to viral hepatitis community stakeholders. This would include regular reporting around federal funding streams related to viral hepatitis services to help stakeholders track what is being done at the federal level. Additionally, federal agencies should provide stronger guidance to state and local health departments and provide more opportunities for communication at the health department level to ensure that the delivery of viral hepatitis services is better coordinated, streamlined, and efficient. Stronger guidance and increased funding from the federal level for state and local health departments to test new strategies and scale-up evidence-based strategies would also help improve the delivery of services across the country and help address racial, ethnic, and geographic health disparities.

(4b) What monitoring and evaluation strategies would further improve viral hepatitis prevention, care, and treatment?

- **Prioritize development of a national surveillance system for chronic HBV.** Gaps in viral hepatitis data and lack of a robust coordinated surveillance system in the U.S. persists. Prioritizing and building a local and national infrastructure is integral to stopping the spread of viral hepatitis and monitoring progress to successfully end the epidemic. The NVHAP highlights current state-by-state estimates or state epidemiological profiles for HCV, which develops a baseline and will enable us to measure impact, but we cannot do the same for hepatitis B. We recommend improving HBV surveillance including not only to track HBsAg+, but those who screen susceptible to hepatitis B and those with prior HBV infection.
- **Develop quality measures for HBV.** Currently, the healthcare effectiveness data and information set (HEDIS) currently include only measures related to HBV immunization, but we need quality indicators for HBV testing. We recommend additional specific strategies under Goal 2, strategy 2, the establishment and monitoring of quality measures to increase provider awareness about HBV testing.

Thank you again for this opportunity to provide input on the next iteration of the NVHAP. There is great momentum and effective tools to eliminate viral hepatitis in the U.S. and we look forward to working with federal and community partners to end the epidemics. Please do not hesitate to contact Kate Moraras, Director of Hep B United (kate.moraras@hepb.org), with any questions or to request additional information.

²⁰ Chang MS, Wharam JF, Zhang F, et al. Peripartum maternal hepatitis B care in a US nationwide data set [published online August 24, 2018]. *J Clin Gastroenterol*. doi: 10.1097/MCG.000000000000112

Sincerely,

Hep B United

National Non-Profit Partners:

Hepatitis B Foundation
Association of Asian Pacific Community Health Organizations
Asian & Pacific Islander American Health Forum
Asian Pacific American Medical Students Association
Immunization Action Coalition
National Center for Reducing Asian American Cancer Health Disparities (AANCART)
National Task Force on Hepatitis B
National Viral Hepatitis Roundtable
Team HBV

Community Partners:

Asian American Health Coalition (HOPE Clinic), Houston, TX
Asian American Community Services, Arlington, OH
Asian Center – Southeast Michigan, Grand Rapids, MI
Asian Health Coalition, Chicago, IL
Asian Pacific Community in Action, Phoenix, AZ
Asian Pacific Health Foundation, San Diego, CA
Asian Services in Action, Inc., Cleveland, OH
CCACC Pan Asian Volunteer Health Clinic, Gaithersburg, MD
Center for Pan Asian Community Services, Atlanta, GA
Charles B. Wang Community Health Center, New York, NY
Colorado Viral Hepatitis Task Force, Denver, CO
Dallas-Fort Worth Hepatitis B Free Project, Dallas, TX
HBI-Minnesota, Minneapolis, MN
HepAware Coalition, Dover, DE
Hep B United Philadelphia, Philadelphia, PA
Hep B United Twin Cities (Lao Assistance Center of MN), Minneapolis, MN
Hep B Free Las Vegas, Las Vegas, NV
Hep B Free Los Angeles, Los Angeles, CA
Hep Free Hawaii, Honolulu, HI
Hepatitis B Coalition of Washington State (International Community Health Services), Seattle WA
Hepatitis B Initiative of Washington DC, Washington, DC
Mercy Housing and Human Development, Gulfport, MS
Midwest Asian Health Association, Chicago, IL
North East Medical Services, San Francisco, CA
New Jersey Hepatitis B Coalition, Trenton, NJ
NYC Hepatitis B Coalition/Center for Asian Health at Saint Barnabas Medical Center, Livingston, NJ
NYU Center for the Study of Asian American Health, New York, NY
Ohio Asian American Health Coalition, Columbus, OH
Project Prevention, Merced, CA
San Francisco Hep B Free – Bay Area, San Francisco, CA