



May 31, 2020

To the Department of Health and Human Services (HHS), Centers for Medicare & Medicaid Services (CMS), Office of Minority Health (OMH)

Re: Request for Information Regarding Maternal and Infant Health Care in Rural Communities

On behalf of the Hepatitis B Foundation, we appreciate the opportunity to provide input on improving health care access, quality, and outcomes for women and infants in rural communities before, during, and after pregnancy. Our organization is dedicated to improving the lives of people affected by hepatitis B, and our national Hep B United coalition, which is comprised of over 40 organizations and local coalitions, is 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. This includes helping to ensure that women living with or at risk of hepatitis B in rural areas are able to access the care, treatment, and vaccination necessary for preventing mother-to-child (perinatal) hepatitis B transmission.

Every year, 800 to 1,200 infants in the United States become infected with the hepatitis B virus (HBV) at birth.¹ Without post-exposure prophylaxis, infants exposed to HBV at birth have a 40-90% risk of infection and, if infected, a 90% risk of developing chronic hepatitis B.² One in four people with chronic hepatitis B die prematurely of HBV-related complications such as cirrhosis, liver failure, or liver cancer.^{3,4,5} Fortunately, we have the tools necessary to eliminate mother-to-child transmission of hepatitis B – by testing all pregnant women, linking to care those who test positive, and ensuring that their babies receive timely administration of hepatitis B immune globulin (HBIG) and the first dose of hepatitis B vaccination at birth, followed by completion of the hepatitis B vaccine series at one and six months of age.

Additionally, injection drug use is a major risk factor for contracting hepatitis B. In recent years, we have seen significant increases in acute hepatitis B cases across the United States, primarily in areas hardest hit by the opioid epidemic. Despite the availability of a safe and highly effective hepatitis B vaccine for adults, only 25% of Americans 19 and older are fully vaccinated against HBV.⁶ This includes women of reproductive age, compounding the risk of perinatal HBV transmission. This low rate of protection among adults and the high proportion of people who have not been tested – and thus are unaware if they are already infected with hepatitis B – leaves significant gaps and barriers to progress in stopping the spread of this disease.

¹ National Academies of Sciences, Engineering, and Medicine. 2016. *Eliminating the public health problem of hepatitis B and C in the United States: Phase one report*. Washington, DC: The National Academies Press.

² Edmunds WJ, Medley GF, Nokes DJ, Hall AJ, Whittle HC. (1993). The influence of age on the development of the hepatitis B carrier state. *Proc Biol Sci.* 253(1337):197-201.

³ *Hepatitis B FAQs for health professionals*. <http://www.cdc.gov/hepatitis/hbv/hbvfaq.htm#overview>

⁴ Smith EA, Jacques-Carroll L, Walker TY, Sirotkin B, Murphy TV. The national Perinatal Hepatitis B Prevention Program, 1994–2008. *Pediatrics*. 2012;129(4):609–616.

⁵ Beasley RP, Hwang LY, Lee GC, et al. Prevention of perinatally transmitted hepatitis B virus infections with hepatitis B immune globulin and hepatitis B vaccine. *Lancet*. 1983;2(8359):1099–11026.

⁶ Vaccination Coverage Among Adults in the United States, National Health Interview Survey, 2017.

<https://www.cdc.gov/vaccines/imz-managers/coverage/adultvaxview/pubs-resources/NHIS-2017.html#box2>

It is critical to increase overall awareness about hepatitis B and to ensure that the tools we already have to detect and prevent hepatitis B are widely available and utilized, including in rural areas. To achieve these goals, we offer the following input for consideration.

1. What barriers exist in rural communities in trying to improve access, quality of care, and outcomes in prenatal, obstetrical, and postpartum care?

Lack of insurance coverage and access to medical care are major barriers for people in rural areas who have chronic conditions such as hepatitis B. Managing hepatitis B requires ongoing monitoring at least every six months and may require lifelong treatment consisting of one pill a day. People living in rural areas may have limited access to specialty care facilities and pharmacies, which can make managing one's chronic hepatitis B a complicated, time-consuming, and expensive process. Transportation issues, language barriers, social or cultural isolation, and a lack of overall education and awareness around hepatitis B transmission and prevention can create additional hurdles. On the provider side, limited staff capacity and difficulties in locating or maintaining contact with individuals also present barriers to follow-up care and case management for HBV positive women, as well as follow-up testing and vaccination for their babies.

In terms of health disparities, it is important to note that up to 81% of HBV-infected pregnant women identified by the CDC's Perinatal Hepatitis B Prevention Program (PHBPP) are foreign-born⁷ and, thus, have many of the same healthcare access barriers that are common among underserved, minority communities. One study found that among babies born to infected pregnant women, those who were born to Asian American or Pacific Islander (AAPI) mothers were significantly more likely to become infected at birth.⁸

A recent publication found only 21% of hepatitis B infected women had peripartum hepatitis B specialist follow-up care.⁹ This is a missed opportunity for preventing liver disease progression and cancer, and for preventing hepatitis B perinatal transmission in subsequent pregnancies.

2. What opportunities are there to improve the above areas (i.e., access, quality and outcomes)?

Following the guidelines to screen all pregnant women for hepatitis B is the first step in being able to provide appropriate and timely prenatal, obstetrical, and postpartum care for hepatitis B positive mothers. Federally Qualified Health Centers (FQHCs) or local health departments should be equipped to offer follow-up education, case management, and medical care for HBV-infected pregnant women. They can also advocate to ensure – as recommended by CDC, ACOG, and AAP – timely administration of the hepatitis B birth dose and completion of the vaccine series for ALL infants, in addition to HBIG for babies born to HBV-infected women.

Unfortunately, up to 10% of infants born to HBV-infected women will still develop chronic HBV infection despite timely vaccination and HBIG at birth. The risk is greatest for infants born to women who have high viral loads at delivery. Treatment of women with antiviral medications during the third trimester of

⁷ Din ES, Waxley A, Jacques-Carroll L, Sirotkin B, Wang S. 2011. Estimating the number of births to hepatitis B virus-infected women in 22 states, 2006. *Pediatr Infect Dis J.* 30(7):575-9.

⁸ Schillie S, Walker T, Veselsky A, Crowley S, Dusek C, Lazaroff J, Morris SA, Onye K, Ko S, Fenlon N, Nelson NP, Murphy TD. (2015). Outcomes of infants born to women infected with hepatitis B. *Pediatrics.* 135(5):e1141-1147.

⁹ Smith EA, Jacques-Carroll L, Walker TY, Sirotkin B, Murphy TV. 2012. The national Perinatal Hepatitis B Prevention Program, 1994-2008. *Pediatrics.* 129(4):609-16.

pregnancy to decrease HBV viral load can help to reduce these vaccine-breakthrough perinatal infections.^{10,11,12} In addition, the health of the mother has a significant impact on her entire family. Furthermore, if the mother is infected, other family members might be as well, and follow-up with the mother can serve as an entry point to providing appropriate care to close household contacts. Limited resources (funding, time, staffing), however, often prohibit such outreach.

Additionally, as the prevalence of hepatitis B infection in rural areas is largely related to opioid or other substance use, hepatitis B education, testing, and vaccination should be prioritized in harm reduction settings. As previously noted, as a consequence of the opioid epidemic and injection drug use, HBV infections among U.S.-born persons are rising at alarming rates, impacting young women of reproductive age. With only 25% of the adult population vaccinated against hepatitis B, there is much room for improvement to ensure that people who use drugs are aware of the transmission risk and have access to hepatitis B vaccination in their communities at low or no cost.

For ongoing care and medical management of HBV-infected women, telehealth initiatives may also provide an opportunity to expand access to care in rural areas and increase quality and outcomes for these individuals. Many of these women need comprehensive support services to access affordable culturally and linguistically appropriate life-long care that is not readily available to them in rural communities.

3. What initiatives, including community-based efforts, have shown a positive impact on addressing barriers or maximizing opportunities?

Targeted education among high-risk populations, such as foreign-born individuals and people who use drugs, is an important strategy. FQHCs, local health departments, and partnerships with community-based organizations can provide outreach, attend health fairs, and provide classes to prenatal and postpartum mothers. Strong community partnerships and diverse staff and health care providers also have a positive impact on addressing the barriers discussed above, particularly any cultural or language barriers.

The CDC's Perinatal Hepatitis B Auxiliary Prevention Project is an example of the increased support that can be provided to women when supplemental funding is available to address perinatal hepatitis B transmission. The first three years of the Perinatal Hepatitis B Auxiliary Prevention Project supported increased coordination and innovative initiatives that were not always possible before this funding was made available. The program facilitated innovative interventions that can now inform perinatal hepatitis B prevention programs nationwide, providing opportunities to further refine efforts and expand services for emerging patient populations and rural communities.

4. How can CMS/HHS support these efforts?

¹⁰ Greenup, A.J., P. K. Tan, V. Nguyen, A. Glass, S. Davison, U. Chatterjee, S. Holdaway, D. Samarasinghe, K. Jackson, and S. A. Locarnini. 2014. Efficacy and safety of tenofovir disoproxil fumarate in pregnancy to prevent perinatal transmission of hepatitis B virus. *Journal of Hepatology* 61(3):502-507.

¹¹ Pan, C. Q., L. J. Mi, C. Bunchorntavakul, J. Karsdon, W. M. Huang, G. Singhvi, M. G. Ghany, and K. R. Reddy. 2012. Tenofovir disoproxil fumarate for prevention of vertical transmission of hepatitis B virus infection by highly viremic pregnant women: A case series. *Digestive Diseases and Sciences* 57(9):2423-2429.

¹² Wiseman, E., M. A. Fraser, S. Holden, A. Glass, B. L. Kidson, L. G. Heron, M. W. Maley, A. Ayres, S. A. Locarnini, and M. T. Levy. 2009. Perinatal transmission of hepatitis B virus: An Australian experience. *Medical Journal of Australia* 190(9):489-492.

CMS/HHS can continue to support to prevent perinatal hepatitis B transmission by prioritizing this issue through dedicated funding, technical assistance, and capacity-building initiatives to help rural communities increase education, testing, and vaccination. Promoting intra-agency collaboration would also be helpful, for example if there are opportunities to partner with or leverage any existing funding and infrastructure for immunization, telehealth, harm reduction, and other infectious disease prevention programs in rural areas. Continued funding and guidance for programs like the CDC's Perinatal Hepatitis B Prevention Project could further facilitate and sustain local health department's adult and perinatal hepatitis B program integration.

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