



Technical Consultation on the Elimination of Perinatal Hepatitis B in the U.S.

Meeting Report



December 2015



Combating the Silent
Epidemic of Viral Hepatitis
Action Plan for the Prevention,
Care & Treatment of Viral Hepatitis



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Executive Summary

As part of a national coordinated response to the epidemic of viral hepatitis, and efforts towards the goal of eliminating perinatal hepatitis B transmission in the United States, the U.S. Department of Health and Human Services (HHS) Office of HIV/AIDS and Infectious Disease Policy (OHAIDP) convened a one-day technical consultation with diverse experts to discuss strategies for meeting this perinatal HBV elimination goal. The annual number of infants born to hepatitis B-infected mothers who become perinatally infected has remained stubbornly constant at approximately 1,000 per year over the last decade, despite the existence of effective tools including maternal hepatitis B screening, infant prophylaxis, and universal infant vaccination recommendations. However, the development of new strategies and advances in the field provide unique opportunities to further the collaboration and coordination of efforts needed to eliminate perinatal hepatitis B transmission in the United States.

The elimination of mother-to-child transmission of hepatitis B is one of the four overarching goals of the *Action Plan for the Prevention, Care and Treatment of Viral Hepatitis* (Action Plan), which describes a range of activities including educating communities about viral hepatitis prevention, care, and treatment, and improving screening and management of viral hepatitis. The national Action Plan requires the participation and engagement of many partners in order to achieve its goals, including the unique challenge of eliminating perinatal hepatitis B transmission in the United States.

The consultation was held September 29, 2015 in Washington, DC. Over 40 individuals participated, including healthcare providers, hepatitis B experts and advocates, and representatives from community-based organizations (CBOs), health professional groups, clinical laboratories, and HHS agencies. Select participants presented model programs and strategies that could be replicated to prevent and ultimately eliminate perinatal hepatitis B transmission. These presentations also provided context on existing barriers to elimination. Participants then engaged in strategic discussions to identify effective approaches to:

- Improve public health, prevention and surveillance efforts for perinatal hepatitis B,
- Routinize birth dose hepatitis B vaccination and post-exposure prophylaxis (PEP), and
- Improve identification and management of mothers at high risk of transmitting hepatitis B.

The recommendations made by consultation participants fall into three broad categories:

- Engaging patients and communities disproportionately impacted by hepatitis B,
- Strengthening systems to enhance prevention efforts, and
- Expanding and refining research efforts.

In addition to recommending specific approaches, the participants discussed which stakeholders would be suited to contribute to these efforts. A summary of considerations and recommendations from the consultation is provided in this document.

Background

Chronic hepatitis B infection impacts an estimated 700,000 – 1.4 million people in the United States, many of whom have been infected for many years and are unaware of their infection. While treatments exist that can reduce viral replication and the liver damage caused by it, there is no cure for hepatitis B. However, there is a safe and effective vaccine to protect infants, children and adults from hepatitis B.

Among the ways that the hepatitis B virus can be transmitted is perinatally – from a pregnant woman to her baby. Without intervention, approximately 45% of all babies born to infected mothers will themselves be infected with HBV.¹ Infants infected with hepatitis B have a 90% risk of developing a chronic infection, and 25% of those chronically infected as infants die prematurely due to hepatitis B-related complications.² These potentially devastating consequences can be prevented. Appropriate and timely post-exposure prophylaxis (PEP) is approximately 85% effective in preventing perinatal HBV transmission.

In 1990, the U.S. Centers for Disease Control and Prevention (CDC) created the National Perinatal Hepatitis B Prevention Program (PHBPP), designed to identify pregnant women infected with hepatitis B and to provide case management to ensure that their infants receive timely PEP and the complete hepatitis B vaccine series. While this program has successfully case managed thousands of pregnant women and their babies, still an estimated 1,000 babies have been infected with hepatitis B each year during the past decade.³

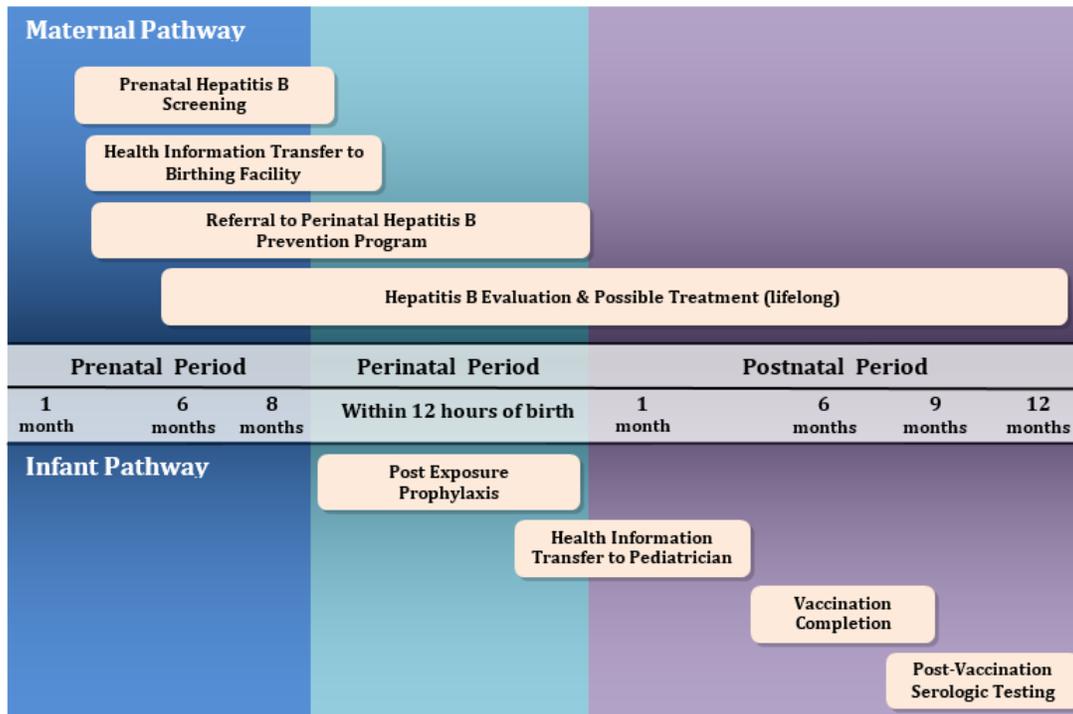
Because we have the tools necessary to prevent these infections, the national Viral Hepatitis Action Plan established as one of its four major goals the elimination of mother-to-child hepatitis B transmission. This goal is achievable if we can optimize the use of appropriate tools and interventions along both the maternal and infant pathways of perinatal hepatitis B prevention, see the “Perinatal Hepatitis B Prevention Pathways” figure on the next page (page 3).

¹ Schillie, S., Division of Viral Hepatitis, U.S. Centers for Disease Control and Prevention (Personal communication, November 25, 2015).

² Smith, E. A., Jacques-Carroll, L., Walker, T. Y., Sirotkin, B., & Murphy, T. V. (2012). The National Perinatal Hepatitis B Prevention Program, 1994-2008. *Pediatrics*, 129(4), 609-616.

³ Ko, S. C., Fan, L., Smith, E. A., Fenlon, N., Koneru, E. A., & Murphy, T. V. (2014). Estimated Annual Perinatal Hepatitis B Virus Infections in the United States, 2000–2009. *J Pediatric Infect Dis Soc*, 3(4), 1-8.

Perinatal Hepatitis B Prevention Pathways



Eliminating perinatal hepatitis B transmission requires engagement and vigilance from multiple Federal and non-Federal stakeholders, including healthcare providers, community-based organizations, policymakers, advocacy groups, payer systems, disproportionately affected communities, and the general public. The following section summarizes the major strategies identified during the consultation for eliminating perinatal hepatitis B transmission in the United States.

Recommendations

Recommendations identified by the consultants fall broadly into three categories: engaging patients and communities disproportionately impacted by hepatitis B, strengthening systems to enhance prevention efforts, and expanding and refining research efforts.

Engaging Patients and Communities Disproportionately Impacted by Hepatitis B

The consultation participants agreed that improving communication with the general public, communities disproportionately impacted, and especially pregnant women, is required to increase screening and referral rates, reduce stigmatization of hepatitis B infection, and provide women with the information and resources necessary to make informed decisions about hepatitis B prevention and care for themselves and their babies.

Expanding hepatitis B community awareness efforts

Increasing awareness of the importance of hepatitis B prenatal screening and infant vaccination among women and families from communities with high rates of chronic hepatitis B can improve the acceptance of routine hepatitis B testing and vaccination. If chronic infection is identified, these efforts will also facilitate perinatal hepatitis B prevention efforts including infant PEP within 12 hours of birth and linkage to care for the mother. During pregnancy, women are often provided with an overwhelming amount of health information from various sources including healthcare providers, the media, and familial and social circles. Therefore, expanding existing outreach efforts that reach the broader at-risk community and that use validated tools for community education and engagement to include perinatal hepatitis B prevention is an important strategy. This should be done in collaboration with community-based organizations (e.g., Hep B United, Hep B Moms), healthcare systems, and government agencies (e.g., CDC, HRSA). There is also a need to identify novel opportunities for engagement with disproportionately impacted communities. Combined, these approaches can extend the reach of ongoing communication efforts, normalize hepatitis B prevention services and reduce stigma, empower women and their families to take the steps needed to prevent perinatal hepatitis B transmission, and improve the management of chronic hepatitis B.

Strengthening Systems to Enhance Prevention Efforts

The participants discussed at length opportunities to improve programs and systems and increase adherence to policies and guidelines for screening, linkage to care, and management of women at risk for perinatal hepatitis B transmission and their babies.

Examples of programs and systems that participants suggested could be utilized more effectively to prevent perinatal hepatitis B included the CDC's PHBPP, laboratory evaluation and reporting systems, and electronic health record systems. Policies and guidelines identified for enhanced implementation included the CDC and the U.S. Preventive Services Task Force (USPSTF) recommendation that pregnant women undergo prenatal hepatitis B screening and that infants

born to hepatitis B surface antigen (HBsAg)-positive mothers receive the hepatitis B vaccine and hepatitis B immunoglobulin (HBIG), together—often called hepatitis B post-exposure prophylaxis (PEP)—within 12 hours of birth. Furthermore, the CDC and the Advisory Committee on Immunization Practices (ACIP) recommend that all infants, regardless of the hepatitis B status of their mothers, receive the 3-dose hepatitis B vaccine series, beginning with the “universal birth dose” administered within 12 hours of delivery. Despite these recommendations, only 72% of infants receive the birth dose within their first 3 days of life, highlighting a need to develop and implement effective policies to ensure adherence to national guidelines.⁴

Recommendations are presented as they apply to activities along the pathways of perinatal hepatitis B prevention, beginning with maternal testing during prenatal care and ending with infant post-vaccination serologic testing approximately nine months after birth.

Incentivizing hepatitis B prevention activities

Participants discussed the need to create incentives for providers, institutions, and health care systems to implement recommendations for hepatitis B vaccination and/or PEP for infants. The degree to which ACIP, CDC, and USPSTF recommendations are implemented varies widely across hospitals, birthing centers, and pediatric practices. Use of incentives may increase adoption of the recommendations, and sharing examples of successful efforts may further motivate improvement. Participants shared possible incentive strategies, including an “honor roll” program to recognize institutions that achieve a targeted level of hepatitis B prophylaxis for infants prior to leaving the hospital or birth facility. Institutions earning a place on the recognition list could be further incentivized – one example given was the provision of free or reduced-cost hepatitis B vaccines to help mitigate the institutional cost associated with birth dose administration.

Strengthening perinatal hepatitis B testing protocols and interpretation of laboratory findings

An educated and empowered healthcare workforce is needed to support effective national efforts to eliminate perinatal hepatitis B transmission. Participants highlighted the need for educational support for clinician understanding and interpretation of hepatitis B-related test results for both maternal screening and for infant post-vaccination serologic testing. These were noted as key areas for improvement that can be addressed with targeted brief training modules. While many hepatitis B tests exist (e.g., HBsAg, HBeAg, hepatitis B antibodies, hepatitis B DNA), there is a need to support clinicians to correctly order and interpret the appropriate tests for pregnant women (HBsAg) and infants (HBsAg and anti-HBs) to facilitate effective patient management and timely interventions and to improve implementation of institutional policies.

Recommended Perinatal Hepatitis B Tests	
Pregnant Women	Infants Born to HBsAg-positive Women
HBsAg	HBsAg and anti-HBs

⁴ U.S. Centers for Disease Control and Prevention. (2014). National Immunization Survey. Available at: http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6433a1.htm?s_cid=mm6433a1_w

Improving laboratory testing and reporting protocols

A critical component of timely identification of pregnant women infected with hepatitis B is ensuring that HBsAg positive test results are linked to pregnancy status and reported to the healthcare provider and referred to the PHBPP. When hepatitis B tests are ordered as part of a comprehensive prenatal screening panel, it facilitates seamless reporting; however, not all tests are ordered in this manner. Tests that are not part of a prenatal screening panel may require additional communication with providers and/or patients to obtain pregnancy status information.

One approach to optimizing hepatitis B testing and reporting of pregnancy status is the inclusion of electronic prompts in electronic health records (EHRs) requiring providers to enter a patient's pregnancy status at the time the hepatitis B test is ordered. Participants noted that mandating the report of pregnancy status may be difficult to achieve through the laboratory accreditation processes. An alternative approach discussed was to modify laboratory checklists and standard operating procedures to include reporting of pregnancy status for hepatitis B tests. This strategy can increase accurate reporting and identification of pregnant women with hepatitis B. Use of this strategy can be reinforced during regular quality assurance activities. Additionally, creating lab algorithms which automatically prompt additional testing for hepatitis B DNA following an HBsAg-positive result would preclude the need for additional medical appointments and blood draws and would facilitate a more rapid assessment of a pregnant woman's transmission risk and appropriate follow up for consideration for hepatitis B treatment.

Harmonizing hepatitis B testing terminology

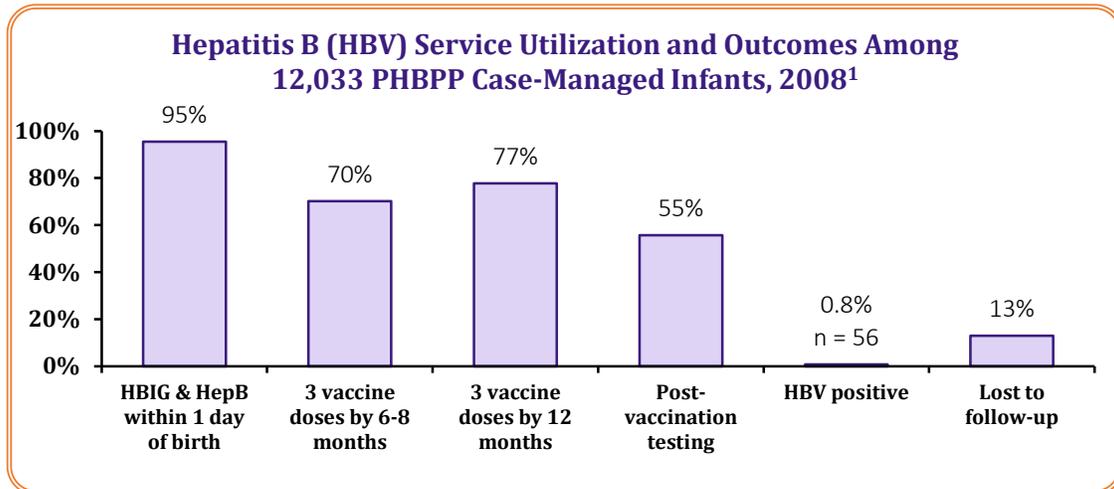
Adoption of consistent, common viral hepatitis testing terminology by all laboratories was recommended by several participants as a means to facilitate ordering and interpretation of recommended hepatitis B tests. The CDC has been working with four major commercial laboratories⁵ that offer prenatal panels and among these, five distinct hepatitis B test names are used. Because this can add unnecessary complexity and lead to confusion regarding hepatitis B testing, CDC included these examples as part of their recently released tool, [*Screening Pregnant Women for Hepatitis B Virus \(HBV\) Infection and Screening and Referral Algorithm for HBV Infection among Pregnant Women*](#). Use of consistent test names across laboratories would improve provider education efforts, interpretation of hepatitis B tests, and facilitate the efficient use of electronic reporting and surveillance systems.

Increasing awareness of the Perinatal Hepatitis B Prevention Program (PHBPP)

According to 2008 estimates, only about half the number of infants expected to be born to HBsAg-positive mothers were reported to the PHBPP¹, suggesting that prenatal providers may not be aware of, or understand, the value of the PHBPP program. Women referred to the program can receive education and linkage to hepatitis B specialty care; 95% of infants who were case managed by the PHBPP received the first dose of hepatitis B vaccine within 12 hours of birth.¹

⁵ ARUP Laboratories, LabCorp, Mayo Medical Laboratories, and Quest Diagnostics.

The graph below provides an overview of the outcomes among infants case managed by the PHBPP in 2008.



Better communicating the benefits of the PHBPP for pregnant women and their babies to health departments, prenatal care providers, community organizations, and women who may be at risk will increase the likelihood of referrals to the program.

Developing and disseminating recommendations for treatment of high-risk expectant women

Pregnant women with high levels of hepatitis B DNA, which is often accompanied by a positive hepatitis B e antigen (HBeAg)-test result, have an increased risk of transmitting hepatitis B to their infants, despite administration of HBIG and hepatitis B vaccine within 12 hours of birth. This is often called “breakthrough transmission.” Evidence from over 30 studies suggests that hepatitis B antiviral treatment during pregnancy can decrease the risk of breakthrough transmission. However, at the time of the consultation, there were no current Food and Drug Administration (FDA) approved therapies or formal guidelines in the U.S. for the use of antiviral agents in pregnant women to reduce the risk of perinatal hepatitis B transmission. Participants acknowledged the urgent need for clinical guidance for managing pregnant women at high risk for transmitting hepatitis B to their infants. The ongoing NIH- and CDC-sponsored study evaluating tenofovir use during the third trimester to reduce breakthrough perinatal hepatitis B transmission was lauded as an important study that will yield further evidence to guide the use of this prevention strategy. Following the meeting, in November 2015, the American Association for the Study of Liver Disease (AASLD) published updated [Guidelines for Treatment of Chronic Hepatitis B](#) with a section on treatment of chronic hepatitis B in pregnancy.⁶ These guidelines and other evidence-based information must be broadly disseminated to prenatal care providers.

Improving transfer of medical information

Case management of mothers infected with hepatitis B and their babies, through the PHBPP as well as in other contexts, represents an important area in which effective and evidence-based practices can improve outcomes. Participants described the process of managing perinatal hepatitis B

⁶ Terrault NA, Bzowej NH, Chang K-M, Hwang JP, Jonas MM, Murad MH. (2015). AASLD Guidelines for Treatment of Chronic Hepatitis B. *Hepatology*. doi: 10.1002/hep.28156.

prevention as “passing the baton” among providers since successful prevention efforts require coordinated communication and action by multiple providers at various stages of care: preconception planning in primary care; prenatal and post-partum care in OB/GYN offices; labor, delivery, and post-partum care at the birth location; and pediatric care. These services are often located in separate offices. Ideally, a woman’s hepatitis B status is transmitted and received by the birth facility and the birth facility staff administer the universal birth dose of hepatitis B vaccine and are aware of the guidelines for HBIG administration. To ensure that appropriate and timely prevention measures are taken, birth facilities should implement intake procedures to confirm that the HBsAg status of the parturient is on file or immediately initiate stat hepatitis B testing to determine a woman’s status prior to discharge of the mother-infant pair. As noted by several participants, systems that are developed in collaboration with providers and support staff, health information technology experts, and relevant institutional partners (e.g., local health departments), can facilitate routine perinatal hepatitis B prevention practices.

Determining maternal hepatitis B status at intake and implementing an infant management plan

Hospital intake serves as a critical opportunity to identify a mother’s hepatitis B status and, when necessary, implement an infant management plan to prevent transmission. As discussed in the section above on improving transfer of medical information, participants emphasized the need for institutional level policies (e.g., standing orders) or other safeguards to be put in place to ensure that the mother’s hepatitis B status is captured and recorded for all women prior to delivery.

Because all infants should receive the birth dose of hepatitis B vaccine (i.e., universal birth dose) institutional policies on infant hepatitis B vaccination need not depend upon maternal hepatitis B status. The first 12 hours of life may include care provided by a wide variety of medical staff including (but not limited to): obstetricians, nurse midwives, labor and delivery nurses, post-partum nurses, hospitalists, in-house pediatricians, neonatal specialists, and surgical support staff. Effective institutional policies must take into account the diversity of staff involved and identify opportunities for infant immunization and/or PEP. One hospital policy highlighted by participants that has shown to be effective is a requirement that the birth dose of hepatitis B vaccine and/or PEP be administered in the delivery room. This promotes near-universal hepatitis B vaccine administration to newborns and the timely administration of PEP for infants born to HBsAg-positive women. This policy also removes the need for transfer of hepatitis B status information across the entire care team.

Training birthing facility staff about the importance of point-of-care administration of hepatitis B PEP

Participants articulated that awareness and prioritization of the birth dose of hepatitis B vaccine and HBIG administration (i.e., PEP) can vary widely by institution and may depend, in part, upon the training and education provided to labor and delivery staff. Since nearly all infant and pediatric vaccinations take place in primary care or pediatrician offices, the delivery of timely and complete hepatitis B PEP in birthing facilities by labor and delivery staff requires additional and ongoing staff training. Issues that should be addressed during training include: current recommendations for hepatitis B testing for pregnant women and infant prophylaxis; misperceptions that infants are not

at risk for hepatitis B infection (e.g., limited knowledge of hepatitis B, epidemiology); risks of mother-to-infant hepatitis B transmission; health disparities in hepatitis B; and counseling messages for infected family members and others in the household.

Improving communication with pediatric providers

Completion of the recommended 3-dose hepatitis B vaccine series is facilitated by timely and accurate transfer of infant hepatitis B immunization records from the birth site to the pediatrician's office. Hospitals and birthing centers can facilitate communication to pediatricians by providing new mothers with written documentation of hepatitis B vaccine or PEP administration prior to discharge. It is important to consider that the providers, and even the healthcare system in which an infant receives pediatric care, may be different from those that provided prenatal care; therefore, procedures that ensure a woman is aware of and given documentation of any vaccine or PEP administered (e.g., an infant vaccination card or printed record clearly marked, "For Pediatrician") can help avoid delays in information transfer that may, in turn, prevent delayed hepatitis B series completion.

Reducing the hepatitis B vaccine dosing interval

Currently, the CDC recommends that all infants complete the full 3-dose hepatitis B vaccine series by 6 to 18 months of age. Many participants agreed that reducing the timeframe within which the hepatitis vaccine series is completed and providing stronger guidance as to when dosing should occur, rather than using a range, may increase timely series completion and hepatitis B vaccine effectiveness. There are numerous hepatitis B vaccines available for infants, and all are indicated to be completed within 6 to 18 months of age. In the past, the COMVAX[®] vaccine, which contained hepatitis B vaccine, was indicated for dosing at 2, 5, and 12 to 15 months of age. However, COMVAX was recently discontinued. In fact, the currently available hepatitis B vaccines are all indicated for a dosing schedule that is completed by 6 months of age, presenting an opportunity to revise the recommended timeframe for administration of the hepatitis B vaccination series to within the first 6 months of life.

Emphasizing the importance of timely post-vaccination serological testing

Even among infants receiving case management through the PHBPP, post-vaccination serological testing rates of infants are only 55%. Participants shared that pediatricians and other providers may not appreciate the importance of post-hepatitis B vaccination serologic testing, especially if they are unaware of a mother's HBsAg-positive status. Confirming immunological protection against hepatitis B following completion of the vaccination series is an important final step in the prophylaxis protocol because it provides the final determination of the infant's hepatitis B status and documents whether prevention efforts were successful.

In October 2015, the CDC released [updated guidance for post-vaccination serologic testing](#) for infants born to HBsAg-positive mothers, recommending that testing be conducted at age 9 to 12 months (or 1 to 2 months after the final dose of vaccine if the series is delayed) and that the testing include both HBsAg and anti-HBs. The updated guidance recommends a shorter timeframe than the

previous recommendation of 9 to 18 months.⁷ Testing at age 9 to 12 months provides opportunities to perform the test at two standard “well-child” visits, which are generally recommended at 9 and 12 months and supports timely revaccination in infants who did not achieve adequate protection during the initial hepatitis B vaccination series.

Expanding and Refining Research Efforts

While the elimination of perinatal hepatitis B transmission in the U.S. is within our reach, the persistence of approximately 1,000 perinatally infected infants born each year warrants a thorough consideration and analysis of the barriers to progress towards the elimination goal. In addition to developing new research programs to increase understanding of barriers to elimination and effective ways to overcome them, participants emphasized the need to revisit existing datasets that may be rich sources of information. Participants suggested reviewing data from the PHBPP and health systems to identify and analyze additional information on hepatitis B prevalence, perinatal transmission rates, and outcomes for mothers and their babies.

Understanding the true burden of hepatitis B disease

One area of need identified by participants is a refinement of the prevalence estimates of infants born to hepatitis B-infected mothers. Current estimates rely upon applying data from the 2014 National Health and Nutrition Examination Survey (NHANES) data to U.S. natality data, both stratified by race/ethnicity. However, other methods (e.g., estimates based on country of origin rather than race/ethnicity) could allow for a more accurate approximation of the number of infants who may be at risk. Given that the majority of individuals with chronic hepatitis B in the U.S. were infected outside of the U.S. in their country of origin, improved surveillance approaches could facilitate outreach efforts to specific communities that are at increased risk.

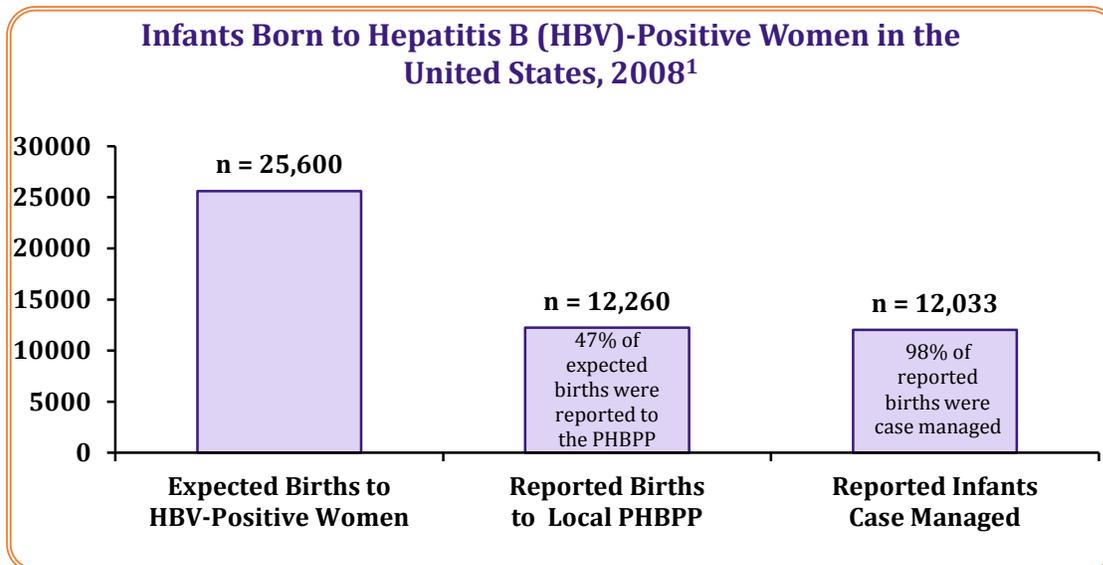
Targeting additional perinatal hepatitis B prevention efforts to areas of highest need

The CDC’s PHBPP currently supports a coordinator for each of the 50 states, as well as five metropolitan areas, and five U.S. territories. This approach ensures coverage of all areas of the U.S.; however, some states have a large number of individuals at high risk and/or infected with chronic hepatitis B. These areas may need additional resources to identify and case manage all pregnant women chronically infected with hepatitis B. Several participants noted the lack of geographic-specific data on hepatitis B prevalence in the U.S. and suggested that an enhanced surveillance effort to identify areas of higher prevalence of hepatitis B infection would allow both Federal and non-Federal stakeholders to focus expanded efforts on areas of highest need to more rapidly close the gap on elimination goals.

⁷ Schillie S, Murphy TV, Fenlon N, Ko S, Ward JW. Update: Shortened Interval for Postvaccination Serologic Testing of Infants Born to Hepatitis B-Infected Mothers. *MMWR*. 2015;64(39):1118-1120.

Identifying barriers to PHBPP referral

While almost all women receive prenatal HBsAg screening, and 98% of those who are referred to the PHBPP receive case management, the program only captures about half of the babies expected to be born to HBsAg-positive women as shown in the graph below.¹



The dramatic drop-off between screening and referral warrants investigation to identify strategies to maximize the number of women referred to and receiving case management. Participants described a combination of factors such as low provider awareness and poor patient follow-up as possible reasons for suboptimal PHBPP referral rates. However, a more focused study of barriers to referral is needed to ensure that all pregnant women with chronic hepatitis B are effectively linked to services.

Understanding the reasons for parental refusal of hepatitis B vaccination and PEP

Even in the context of robust institutional guidelines and high rates of provider adherence to same, rates of administration of the birth-dose of hepatitis B vaccine do not always reach 100%. Participants reported varying rates of parental refusal of the birth-dose vaccine; however, to date no comprehensive study of the reasons for refusals have been conducted. As providers and health systems develop policies to improve perinatal hepatitis B prevention, an understanding of parental concerns and questions can inform practices and help reduce refusals during the critical postnatal period.

Analyzing perinatally transmitted hepatitis B within the PHBPP

Despite the case management of 98% of women referred to the PHBPP, a small number of their infants go on to develop chronic hepatitis B infection. In 2008, 56 infants or 0.8% were infected among the 12,033 infants born to identified women with chronic hepatitis B. Anecdotal reports include delayed PEP administration or indications that these mothers may have been at increased risk of transmitting hepatitis B, but the factors leading to known perinatal hepatitis B transmission

among these case managed women have not been well-studied to date. Participants acknowledged that collecting and analyzing information about prevention failures among case managed women would be helpful in further refining programmatic efforts and clinical recommendations.

Conducting implementation research to determine perinatal hepatitis B prevention best practices

The successes observed by the PHBPP and other efforts aimed at eliminating perinatal hepatitis B transmission can provide key insights and support to tailor and expand best practices. Conducting implementation research on current perinatal hepatitis B prevention and management practices was identified as an important step, both in understanding real-world challenges to elimination efforts as well as in leveraging existing work to replicate successful practices.

Moving Forward Together

The Technical Consultation on the Elimination of Perinatal Hepatitis B in the U.S. brought together a diverse group of individuals invested and experienced in addressing various aspects of hepatitis B prevention and care. In addition to the recommendations described in this report, participants strongly emphasized the need to identify opportunities for strategic collaborations to reduce mother-to-infant transmission of hepatitis B and finally achieve the goal of elimination. While much work has been done to date, meeting this goal will require thoughtful and productive partnerships among policymakers, professional organizations, healthcare workers, managed care organizations, laboratories, state and local health departments, community-based organizations, and disproportionately affected communities. The national Viral Hepatitis Action Plan's goal of perinatal hepatitis B elimination can only be achieved through impactful and strategic collaborations such as professional organizations' endorsement of existing and emerging recommendations, health information technology partnerships with providers and laboratories to improve information quality and sharing; and collaboration among providers and organizations serving communities disproportionately impacted.

We have all of the necessary tools to get the job done, but we must make perinatal hepatitis B prevention a priority, foster effective collaborations, and engage in creative implementation of strategies to eliminate perinatal hepatitis B transmission once and for all. The insights that emerged from this expert consultation hold promise for attaining that goal.



Summary of Recommendations

Engaging Patients and Communities Disproportionately Impacted by Hepatitis B

- Expanding hepatitis B community awareness efforts

Strengthening Systems to Enhance Prevention Efforts

- Incentivizing hepatitis B prevention activities
- Strengthening perinatal hepatitis B testing protocols and interpretation of laboratory findings
- Improving laboratory testing and reporting protocols
- Harmonizing hepatitis B testing terminology
- Increasing awareness of the Perinatal Hepatitis B Prevention Program (PHBPP)
- Developing and disseminating recommendations for treatment of high-risk expectant women
- Improving transfer of medical information
- Determining maternal hepatitis B status at intake and implementing an infant management plan
- Training birthing facility staff about the importance of point-of-care administration of hepatitis B PEP
- Improving communication with pediatric providers
- Reducing the hepatitis B vaccine dosing interval
- Emphasizing the importance of timely post-vaccination serological testing

Expanding and Refining Research Efforts

- Understanding the true burden of hepatitis B disease
- Targeting additional perinatal hepatitis B prevention efforts to areas of highest need
- Identifying barriers to PHBPP referral
- Understanding the reasons for parental refusal of hepatitis B vaccination and PEP
- Analyzing perinatally transmitted hepatitis B within the PHBPP
- Conducting implementation research to determine perinatal hepatitis B prevention best practices

Appendix A: Agenda

<p align="center">Technical Consultation on the Elimination of Perinatal Hepatitis B in the U.S. <i>Tuesday, September 29, 2015, 8:30 a.m – 4:00 p.m. ET</i> <i>Hubert H. Humphrey Building (Department of Health and Human Services)</i> <i>200 Independence Avenue S.W., Washington, D.C., 20201</i> <i>5th Floor Conference Room 505A</i></p>	
8:00am – 8:30am	Registration
8:30am – 8:50 am	<p>Welcome, Introductions & Meeting Purpose <i>Ronald Valdiserri, Office of HIV/AIDS & Infectious Disease Policy</i></p> <ul style="list-style-type: none"> • Presentation of meeting objectives • Brief introductions of participants • Charge to the group: Elimination of mother-to-child transmission of hepatitis B
8:50am – 9:00am	<p>Setting the stage: Perinatal HBV Elimination & the Viral Hepatitis Action Plan <i>Ronald Valdiserri</i></p> <ul style="list-style-type: none"> • A brief overview of perinatal HBV prevention in the U.S.
9:00am – 10:30am	<p>Improving Perinatal HBV Public Health, Prevention, & Surveillance Efforts Discussants: <i>Julie Lazaroff and Sarah Schillie</i> Moderator: <i>Corinna Dan</i></p> <ul style="list-style-type: none"> • Identification & case management of HBV positive pregnant and post-partum women by the national Perinatal HBV Prevention Program • Post-vaccination serologic testing for infants • Lab-based reporting opportunities
10:30am – 10:45am	Break
10:45am – 12:15pm	<p>Routinizing Perinatal HBV Prophylaxis and Immunization in Hospitals & Birthing Centers Discussants: <i>Deborah Wexler and Robin Neale</i> Moderator: <i>Corinna Dan</i></p> <ul style="list-style-type: none"> • HBV birth dose • Ensuring post-exposure prophylaxis by 12 hours
12:15pm – 1:15pm	Lunch on your own
1:15pm – 2:15pm	<p>Identifying and Treating Mothers at Highest Risk for Transmitting HBV Discussants: <i>Su Wang and Trudy Murphy</i> Moderator: <i>Corinna Dan</i></p> <ul style="list-style-type: none"> • Maternal HBV testing & identification of women at high risk • Clinical trial & use of Tenofovir in HBsAg women (e antigen +/high VL)
2:15pm – 2:30pm	Break
2:30pm – 4:00pm	<p>Identifying Priority Strategies to Eliminate Perinatal HBV Transmission in the U.S. Moderator: <i>Ronald Valdiserri</i></p> <ul style="list-style-type: none"> • Improving public health, prevention & surveillance • Routinizing birth dose & PEP • Identifying and managing high risk mothers • Roles and responsibilities
4:00pm	Adjourn

Appendix B: Participant List

Eileen Beard CNM, FNP, MS, FACNM

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Debra Bingham, DrPH, RN

Vice President of Research, Education, and
Publications
Association of Women's Health, Obstetric, and
Neonatal Nurses

Joan Block, RN

Executive Director
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Martha (Marty) Bond, MA

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Michael Brady, MD

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Julie Breen

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Bureau of Primary Health Care
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Nathalie Bzowej, MD

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Appendix C Perinatal Hepatitis B (HBV) Elimination Facts

The Importance of Perinatal Hepatitis B Elimination

- Hepatitis B (HBV) is a leading cause of liver cancer in the U.S. HBV can be passed from a mother to her baby during birth (perinatal infection). Infants infected at birth may later experience potentially fatal complications, including cirrhosis, chronic liver disease, and liver cancer.
- Perinatally infected infants have a 90% risk of chronic infection. 25% of chronically infected infants are at risk for premature death due to HBV.ⁱ
- Post-exposure prophylaxis (PEP) is **85%-95% effective** when given within 12 hours of birth to infants born to mothers with HBV. PEP includes hepatitis B immune globulin (HBIG) and the first dose of HBV vaccine.
- According to a 2009 analysis, an estimated 952 perinatal HBV infections occur each year in the U.S.ⁱⁱ
- One of the four goals of the national Viral Hepatitis Action Plan is to eliminate mother-to-child transmission of HBV.

Hepatitis B Prevention Recommendations

Both the U.S. Preventive Services Task Force (USPSTF) and Centers for Disease Control and Prevention (CDC) provide clinical guidelines/recommendations on HBV screening and immunization.^{iii,iv} The USPSTF recommends HBV screening at the first prenatal visit (A Grade). CDC recommends that all pregnant women should be routinely tested in the first trimester, even if they were previously vaccinated or tested. Both recommend:

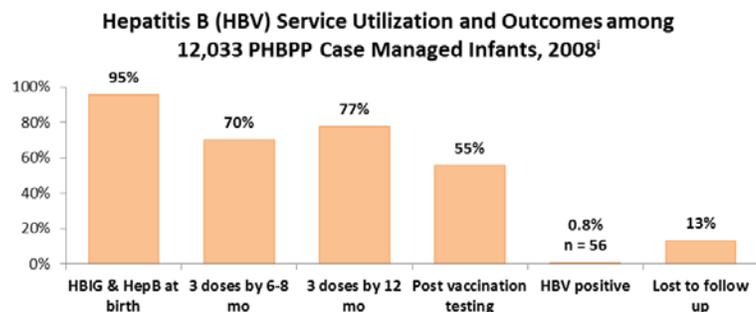
- Screening women with unknown status or at higher risk when admitted for delivery.
- PEP within 12 hours of birth for infants born to mothers who test HBsAg positive (i.e. chronically infected).
- Infants born to mothers with unknown HBV status should receive HBV vaccine within 12 hours of birth. If the mother is determined to have HBV, administer HBIG to the infant as soon as possible (up to 7 days after birth).
- Pregnant women who test HBsAg positive should receive referral to the Perinatal Hepatitis B Prevention Program (PHBPP), counseling and medical management, and information about HBV.

CDC and the Advisory Committee on Immunization Practices recommend 3 doses of HBV vaccination for all infants, the first dose administered within 12 hours of birth (“universal birth dose”). The 2014 National Immunization Survey reported 72% of infants received the birth dose of hepatitis B vaccine within 3 days of life and 92% of children completed the 3 dose series by 35 months of age.^v CDC recommends post-vaccination testing (PVST) at 9 months of age (no earlier) if the HBV series is completed on time.

The CDC Perinatal Hepatitis B Prevention Program

CDC created the National Perinatal Hepatitis B Prevention Program (PHBPP) in 1990 to identify pregnant women with chronic HBV and ensure that their infants complete timely PEP through case management. Elements of the PHBPP include:

- 1) Identify HBsAg positive pregnant women and enroll them in the PHBPP,
- 2) Coordinate care (e.g. ensure delivery hospital is aware of woman’s HBsAg positive status and pediatric provider is aware of newborn exposure and understands how to manage the infant),
- 3) PEP completion,
- 4) HBV vaccination series completion
- 5) Post-vaccination testing, and
- 6) Monitoring and evaluating the program.



According to 2008 estimates, only 47% of more than 25,000 infants expected to be born to HBsAg positive mothers were reported to the PHBPP but 98% of identified infants received case management.ⁱ While nearly all identified infants received case management, only 55% of all case managed infants had post vaccination testing (see graph).ⁱ

Perinatal Hepatitis B (HBV) Elimination Facts

Perinatal Hepatitis B Prevention - Best Practices

Educate and Empower Healthcare Providers to Eliminate Perinatal HBV

- Evidence suggests that the strongest predictor of a newborn receiving HBV vaccine is having a written hospital policy about administering the universal birth dose. However, a 2006 survey indicated that:
 - Only 80.6% of hospitals had an HBV birth dose policy.
 - 37% of delivery hospitals had no policies about HBV testing for women admitted with unknown status.^{vi}
- In 2013, the Immunization Action Coalition launched the Hepatitis B Birth Dose Honor Roll to recognize hospitals and birthing centers that attain a 90% HBV birth dose vaccination rate and have written policies, procedures, and protocols to protect all newborns from HBV virus infection prior to hospital discharge.
- Kaiser Permanente utilized a system of electronic reminders for pediatric providers in advance of the first scheduled check-up and at time post-vaccination tests were due achieving higher than national rates of timely PEP, HBV vaccine completion, and post-vaccination testing.^{vii}

Scale Up Post-Exposure Prophylaxis (PEP)

- Despite timely post-exposure prophylaxis, mother to child transmission occurs in 5%–15% of infants born to HBsAg positive mothers.^{viii} Emerging evidence suggests that HBV treatment of pregnant women in the 3rd trimester is safe and reduces rates of transmission.^{ix} In partnership with the American Congress of Obstetricians and Gynecologists (ACOG), CDC developed a *Screening and Referral Algorithm for Hepatitis B Virus Infection among Pregnant Women*.

Share Data and Collaborate with the PHBPP

- **Laboratories:** Insert the word “PRENATAL” into a pregnant woman’s reported test results in paper/faxed forms or in the OBR-13 results field sent by electronic laboratory reporting (ELR).
- **Clinicians: (1)** Select a test designated as “prenatal” or indicate prenatal/obstetric panel when ordering an HBsAg screening test for a pregnant woman, **(2)** inform the laboratory of a woman’s pregnancy status, and **(3)** include any and all ICD-9/10 diagnosis codes indicating current or recent pregnancy when ordering HBsAg tests.
- **Health Departments: (1)** Be aware of how local laboratories are reporting pregnancy information, **(2)** include prenatal indicators from both paper-based and ELR reports, and **(3)** ensure prenatal indicators are shared with PHBPP Coordinators.

For more information

- **CDC Division of Viral Hepatitis:** <http://www.cdc.gov/hepatitis/hbv/perinatalxmtn.htm>
- **CDC/ACOG Screening Algorithm:** <http://www.cdc.gov/hepatitis/hbv/pdfs/prenatalhbsagtesting.pdf>
- **Hep B Moms:** <http://www.hepbmoms.org/>
- **Immunization Action Coalition Hepatitis B Birth:** www.immunize.org/protect-newborns/

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