Perinatal Hepatitis B

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NCHHSTP/Centers for Disease Control and Prevention

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Outline

- Overview of Perinatal Hepatitis B and Prevention Strategies
- Hepatitis B Vaccination
- Post-vaccination Serologic Testing
- Perinatal Hepatitis B Prevention Program
Perinatal Hepatitis B

- Hepatitis B virus (HBV) transmission occurs through percutaneous or mucosal exposure to infectious blood or body fluids

- 80%-90% of infants who are infected with HBV become chronically infected

- About 25% of individuals chronically infected will develop cirrhosis or liver cancer and die prematurely

- HBV infected infants are usually asymptomatic

Perinatal Hepatitis B Case Definition

- **Confirmed**
  - Child born in the United States to a **HBV-infected mother** and infant is positive for hepatitis B surface antigen (HBsAg) at ≥ 1 month of age and ≤ 24 months of age OR positive for HBeAg or HBV DNA ≥9 months of age and ≤ 24 months of age.

- **Probable**
  - Child born in the United States and infant is positive for HBsAg at ≥ 1 month of age and ≤ 24 months of age OR positive for HBeAg or HBV DNA ≥9 months of age and ≤ 24 months of age, but whose **mother’s hepatitis B status is unknown** (i.e. epidemiologic linkage not present).

Steps to Prevent Perinatal Transmission of HBV

- **Maternal screening**
  - Test all women for Hepatitis B surface antigen (HBsAg) with each pregnancy
  - American Association for the Study of Liver Diseases (AASLD) suggests antiviral therapy to reduce perinatal HBV transmission when maternal HBV DNA is >200,000 IU/mL

- **Infant vaccination**
  All infants born to HBsAg-positive women need to:
  - Receive hepatitis B vaccine (with passive immunoprophylaxis [HBIG]) within 12 hours of birth
  - Complete the hepatitis B vaccine series

- **Post Vaccination Serologic Testing (PVST)**
Elements of Performance Related to Maternal Status Documentation Prior to Delivery

**Provision of Care, Treatment, and Services (PC)**

**PC.01.02.01**
The organization assesses and reassesses its patients.

**Elements of Performance for PC.01.02.01**

14. For organizations that provide obstetric services: Upon admission to labor and delivery, the mother’s status of the following diseases (during the current pregnancy) is documented in the mother’s medical record:

   - Human immunodeficiency virus (HIV)
   - Hepatitis B
   - Group B streptococcus (GBS)
   - Syphilis

15. For organizations that provide obstetric services: If the mother had no prenatal care or the disease status is unknown, testing for the following diseases are performed and the results documented in the mother’s medical record:

   - Human immunodeficiency virus (HIV)
   - Hepatitis B
   - Group B Streptococcus (GBS)
   - Syphilis

   **Note:** Because GBS test results may not be available for 24-48 hours, organizations may elect not to perform this test but instead administer prophylactic antibiotics to the mother.

16. For organization that provide obstetric services: If the mother tests positive for human immunodeficiency virus (HIV), hepatitis B, group B streptococcus (GBS), or syphilis when tested in labor and delivery or during the current pregnancy, that information is also documented in the newborn’s medical record after delivery.
Hepatitis B Vaccine
Hepatitis B Vaccine

- Introduced in 1982
  - Safe, immunogenic, effective
- Administered as 3- or 4-dose series, starting at birth
- Primary 3-dose series efficacy, 90-95%
- Hepatitis B vaccine induces antibody to hepatitis B surface antigen (anti-HBs)
  - Protection against infection is associated with initial antibody concentration ≥10 mIU/mL after a complete vaccine series
  - Estimate that ≥90% of participants had evidence of protection 30 years later*
  - Booster doses not routinely recommended

HBIG and Hepatitis B Vaccine Efficacy

- Hepatitis B immune globulin (HBIG), passive immunoprophylaxis, provides a short-term increase (i.e., 3-4 months) in the antibody to hepatitis B surface antigen (anti-HBs) which might improve protection until the infant responds to vaccine.


- For prevention of mother to child transmission of HBV the efficacy of:
  - HBIG and HepB vaccine combined is ~94%
  - HBIG alone is ~71%
  - Hepatitis B vaccine alone is ~75%

  Based on infants of mothers HBsAg-positive and HBeAg-positive.

Birth Dose Provides a “Safety Net”

- The birth dose provides a “safety net” for:
  - Infants of HBsAg-positive women not identified for post-exposure prophylaxis (PEP) because of:
    - Medical errors in interpreting or documenting maternal screening results
    - Failure to test women at delivery who are admitted without prenatal HBsAg test results
    - Infants who have contact with a HBsAg-positive caretaker or household member
  - Infants at risk for exposure after the perinatal period

Birth Dose

- All infants born to HBsAg-positive women should receive HepB vaccine and HBIG within **12 hours of birth**, administered at different injection sites.
  - Only single-antigen HepB vaccine should be used for the birth dose

- Recommend hepatitis B vaccine birth dose within **24 hours of birth** for medically stable infants weighing ≥2,000 grams and born to HBsAg-negative mothers.
  - Aligns with the World Health Organization (WHO) recommendations
ACIP Recommendations PEP: For all infants born to KNOWN HBsAg-positive women (all birth weights)

- Administer HBIG and monovalent hepatitis B vaccine within 12 hours of birth (separate injection sites – separate limbs)
- Document date and time of administration
- Timely completion of ≥3-doses HepB vaccine, either as monovalent or combination vaccine

Question - 1

- For infants with birth weight <2000 grams born to mothers with unknown HBsAg status, what post-exposure prophylaxis should the infant receive within 12 hours of birth?

A. Hepatitis B vaccine alone
B. HBIG alone
C. HBIG + hepatitis B vaccine
D. None of the above
Question - 1

- For infants with birth weight <2000 grams born to mothers with unknown HBsAg status, what post-exposure prophylaxis should the infant receive within 12 hours of birth?

A. Hepatitis B vaccine alone
B. HBIG alone
C. HBIG + hepatitis B vaccine
D. None of the above
ACIP Recommendations PEP: Maternal HBsAg Status UNKNOWN Infant Low Birth Weight (<2000 grams)

- Test mother as soon as possible; document, and communicate HBsAg results to mother’s provider(s)

- Administer both HBIG and monovalent hepatitis B vaccine within 12 hours of birth at separate injection sites

- For infants weighing <2000 grams, the birth dose is not counted toward a ≥3-dose HepB vaccine series
ACIP Recommendations PEP: Maternal HBsAg Status UNKNOWN Infant Birth Weight ≥2000 grams

- Test mother for HBsAg as soon as possible
- Administer monovalent hepatitis B vaccine within 12 hours of birth - Do not wait for mother’s results
- If infant is discharged before results known, inform:
  - Mother
  - Pediatric provider
  - Perinatal Hepatitis B Prevention Coordinator
- If results are positive or remain unknown, administer HBIG to infant within 7 days of life
Hepatitis B Vaccine Policy and Reported Number of Acute Hepatitis B Cases – United States, 2000-2016

<table>
<thead>
<tr>
<th>Year</th>
<th>Number of Cases</th>
<th>Infants born to HBsAg positive women, 1984</th>
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<tr>
<td>1980</td>
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<tr>
<td>2015</td>
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</tbody>
</table>

*Health care providers, MSM, IDU, hemodialysis patients, household & sexual partners of persons with chronic HBV, persons in certain institutional settings, e.g., inmates of long-term correctional facilities.

Source: National Notifiable Diseases Surveillance System (NNDSS)
Question - 2

According to the National Immunization Survey-Child, the percent of infants 0-3 days of age who received the hepatitis B vaccine birth dose in 2017 was closest to:

A. 60%
B. 70%
C. 80%
D. 90%
Question - 2

The percent of infants 0-3 days of age who received the hepatitis B vaccine birth dose in 2017 was closest to:

A. 60%
B. 70%
C. 80%
D. 90%
Hepatitis B Birth Dose (0 to 3 Days of Age) Vaccine Coverage, U.S., 2003-2017

Source: National Immunization Survey, CDC

Healthy People 2020 target: 85%

Source: National Immunization Survey, CDC
Post-vaccination Serologic Testing (PVST)
Question - 3

Post-vaccination serologic testing of infants born to HBsAg-positive mothers should be done after how many months of age?:

A. 6 months
B. 9 months
C. 12 months
D. 15 months
Question - 3

Post-vaccination serologic testing of infants born to HBsAg-positive mothers should be done after how many months of age?:

A. 6 months  
B. 9 months  
C. 12 months  
D. 15 months
Post-vaccination Serologic Testing

- Infants born to Hepatitis B-infected mothers should undergo post-vaccination serologic testing (PVST) after completion of the HepB vaccine series to identify:
  - Infected infants so that they can receive treatment
  - Infants not responding to vaccination so they can be revaccinated

- Post-vaccination serologic testing:
  - At 9-12 months of age, if series completed on schedule
  - 1-2 months after final dose in series, if series completion is delayed
  - Never before 9 months of age (NO GRACE PERIOD)
  - Test for both HBsAg and anti-HBs
    - Don’t test for antibody to hepatitis B core antigen (anti-HBc)
PVST for Infants, cont.

- Why wait and test at 9 months of age or older?
  - Earlier testing may detect anti-HBs from HBIG administered at birth and not vaccination outcome
  - Maximize the likelihood of detecting late HBV infection

Perinatal Hepatitis B Prevention Program (PHBPP)
U.S. Perinatal Hepatitis B Prevention Program (PHBPP)

- In 1990, CDC funded the PHBPP
  - Funded in CDC Immunization Cooperative Agreements (Section 317 funding)

- Programs in 64 jurisdictions (50 states, 6 cities, 5 territories & 3 freely associated island nations)

- PHBPPs aim to ensure:
  - Identification of all Hepatitis B-infected pregnant women
  - Timely receipt of infant prophylaxis
  - Infant post-vaccination testing after completion of Hepatitis B vaccine series
  - Revaccination of infants with non-response to Hepatitis B vaccine
Perinatal Hepatitis B

- In 2016, **32** cases of perinatal hepatitis B were reported to CDC from 13 states

<table>
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<th>Year</th>
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Source: CDC, National Notifiable Diseases Surveillance System.

- A 2009 modeling study estimated that **952** chronic hepatitis B cases occur each year among persons infected with HBV at birth, for a baseline annual rate of 3.84%, among infants of HBsAg-positive women

Identified Births to HBsAg-positive Women Compared to Total Expected Births to HBsAg-positive Women, 2008-2014
Expected Births to HBsAg-positive Women 2015-2016 by Mother’s Region of Birth (PE)

Perinatal Hepatitis B Prevention Program

National Trends in PHBPP Indicators, 2008-2016

Provisional Data: Do Not Reference
Conclusions

To decrease perinatal hepatitis B infections the following are needed:

– Increase identification of HBsAg-positive pregnant women
  • Maternal management
  • Maternal 3rd trimester antivirals if indicated
– Timely infant prophylaxis and infant management
– Increase hepatitis B birth dose coverage overall
– Increase post-vaccination serologic testing of infants born to HBsAg-positive mothers
Hepatitis B Virus (HBV) infection in a pregnant woman poses a serious risk to her infant at birth. Without postexposure immunoprophylaxis, approximately 40% of infants born to HBV-infected mothers in the United States will develop chronic HBV infection, approximately one-fourth of whom will eventually die from chronic liver disease.

Perinatal HBV transmission can be prevented by identifying HBV-infected (i.e., hepatitis B surface antigen [HBsAg]-positive) pregnant women and providing hepatitis B immune globulin and hepatitis B vaccine to their infants within 12 hours of birth.

Preventing perinatal HBV transmission is an integral part of the national strategy to eliminate hepatitis B in the United States. National guidelines call for the following:

- Universal screening of pregnant women for HBsAg during each pregnancy
- Testing infants born to HBsAg-positive mothers in accordance with local maternal infant management protocols
- Providing hepatitis B immune globulin and hepatitis B vaccine to infants born to HBsAg-positive mothers within 12 hours of birth
- Routine vaccination of all infants with the hepatitis B vaccine series, with the first dose administered within 24 hours of birth

**Guidelines and Recommendations**

Prevention of Hepatitis B Virus Infection in the United States: Recommendations of the Advisory Committee on Immunization Practices

MMWR 2016;65(1):1-31

https://www.cdc.gov/hepatitis/hbv/perinatalxmtn.htm
## Information for Pregnant Women

### "Protect Your Baby For Life" fact sheet

This 2-page fact sheet is for pregnant women who have Hepatitis B and explains the importance of the Hepatitis B vaccine in preventing the spread of hepatitis B to their infants.

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### Vaccinate Your Baby Against Hepatitis B

This two-page infographic answers commonly asked questions about hepatitis B and explains the importance of the vaccine for infants.

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### Hepatitis B and a Healthy Baby

This audio-visual presentation explains why infants need to get the hepatitis B vaccine if their mother has hepatitis B. This presentation is available in English, Chinese, Vietnamese, Korean, Hmong and Tagalog, and allows participants to read and listen along to the presentation.

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### Hepatitis B and Your Healthy Baby

This presentation provides details on the Hepatitis B vaccine that an infant will receive at birth if the infant’s mother has Hepatitis B. It also includes information on how common Hepatitis B is and how it is spread. The presentation contains pictures along with written text and is available in English and Spanish.

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[https://www.cdc.gov/knowhepatitisb/materials.htm#pregnantwomen](https://www.cdc.gov/knowhepatitisb/materials.htm#pregnantwomen)
Resources - III

• 2018 ACIP Recommendations

• IAC Website: Birth dose initiative
  – http://www.immunize.org/protect-newborns/

• Asian Liver Center
  – http://liver.stanford.edu/

• Patient Education Resources - CDC Materials and Links
  – https://www.cdc.gov/hepatitis/hbv/patienteduHBV.htm