



# Perinatal Hepatitis B

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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  $\geq 1$  month of age and  $\leq 24$  months of age OR positive for HBeAg or HBV DNA  $\geq 9$  months of age and  $\leq 24$  months of age.
- Probable
  - Child born in the United States and infant is positive for HBsAg at  $\geq 1$  month of age and  $\leq 24$  months of age OR positive for HBeAg or HBV DNA  $\geq 9$  months of age and  $\leq 24$  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

APPLICABLE TO CRITICAL ACCESS HOSPITALS AND HOSPITALS

**Effective xxx**

## 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:

*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

- 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*

*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  $\geq 10$  mIU/mL after a complete vaccine series
  - Estimate that  $\geq 90\%$  of participants had evidence of protection 30 years later\*
  - Booster doses not routinely recommended



# HBIG and Hepatitis B Vaccine Efficacy

- HBIG (passive immunoprophylaxis) provides a short-term increase (i.e., 3-4 months) in anti-HBs which might improve protection until the infant responds to vaccine

Schillie, S.F. and T.V. Murphy, *Vaccine*, 2013. 31(21): p. 2506-16.

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

Based on infants born to HBsAg-positive and HBeAg-positive mothers

Beasley RP, et al. *Lancet*. Nov 12 1983;2(8359):1099-1102.

Lee C, Gong Y, Brok J, Boxall EH, Gluud C. *BMJ*. Feb 11 2006;332(7537):328-336.

# 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

MMWR Recomm Rep. 2018 Jan 12;67(1):1-31.

Willis, B.C., et al., 2010. 125(4): p. 704-11.

# 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  $\geq 2,000$  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  $\geq 3$ -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)

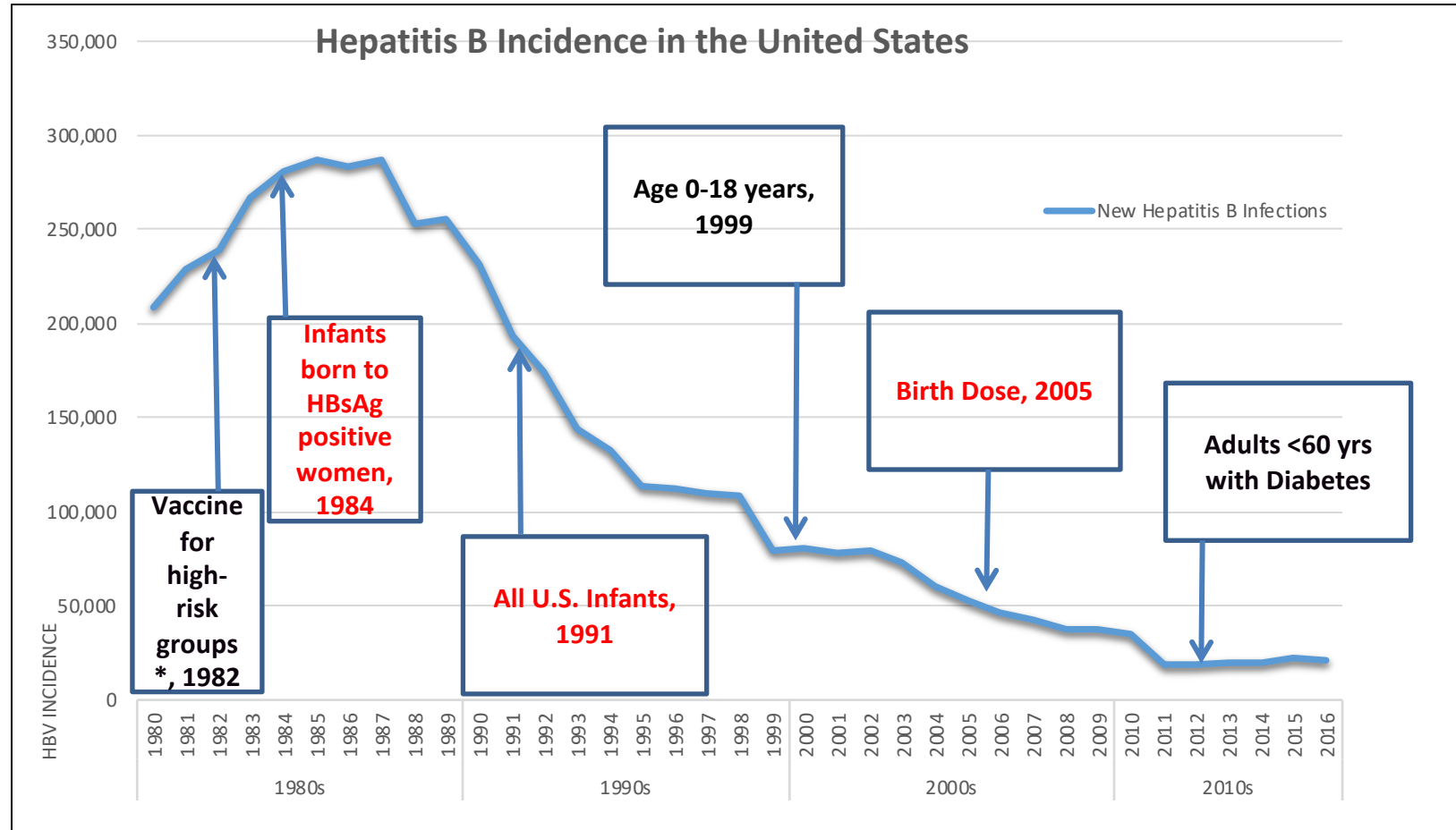
- Test mother as soon as possible; document, and communicate HBsAg results to mother's provider(s)
- Administer both HBIG and monovalent hepatitis B vaccine within 12 hours of birth at separate injection sites
- For infants weighing <2000 grams, the birth dose is not counted toward a ≥3-dose HepB vaccine series

# ACIP Recommendations PEP: Maternal HBsAg Status UNKNOWN Infant Birth Weight $\geq 2000$ 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



\*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.

## 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%

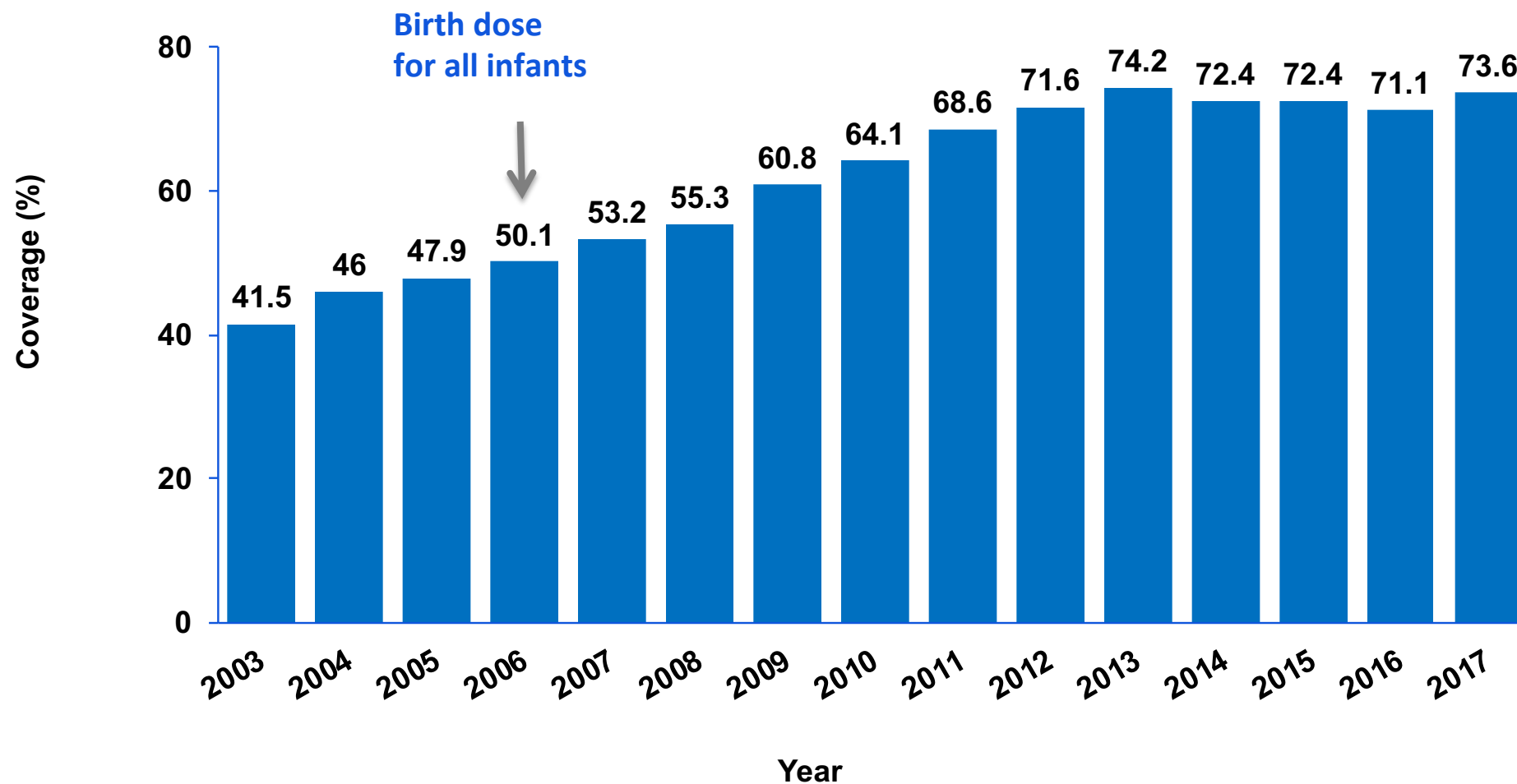
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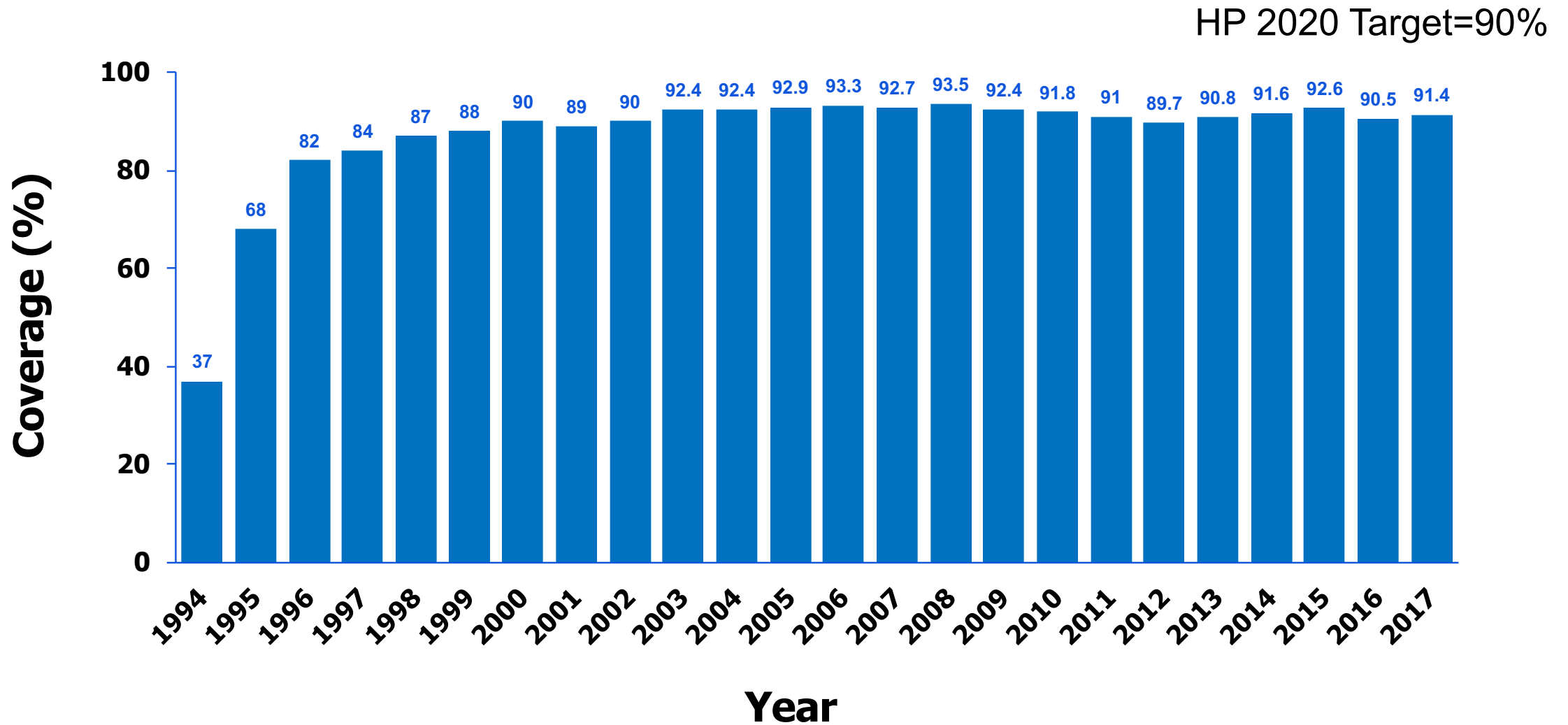
# Hepatitis B Birth Dose (0 to 3 Days of Age) Vaccine Coverage, U.S., 2003-2017

Healthy People  
2020 target: 85%



Source: National Immunization Survey, CDC

# Estimated Hepatitis B Vaccination Coverage 19-35 Months of Age, U.S., 1994-2017



# 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

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- 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

MMWR Recomm Rep. 2018 Jan 12;67(1):1-31.

Euler, G.L., et al., *Pediatr Infect Dis J*, 2003. 22(2): p. 123-9.

Ko, S.C., et al., *Vaccine*, 2014. 32(18): p. 2127-2133.

# 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

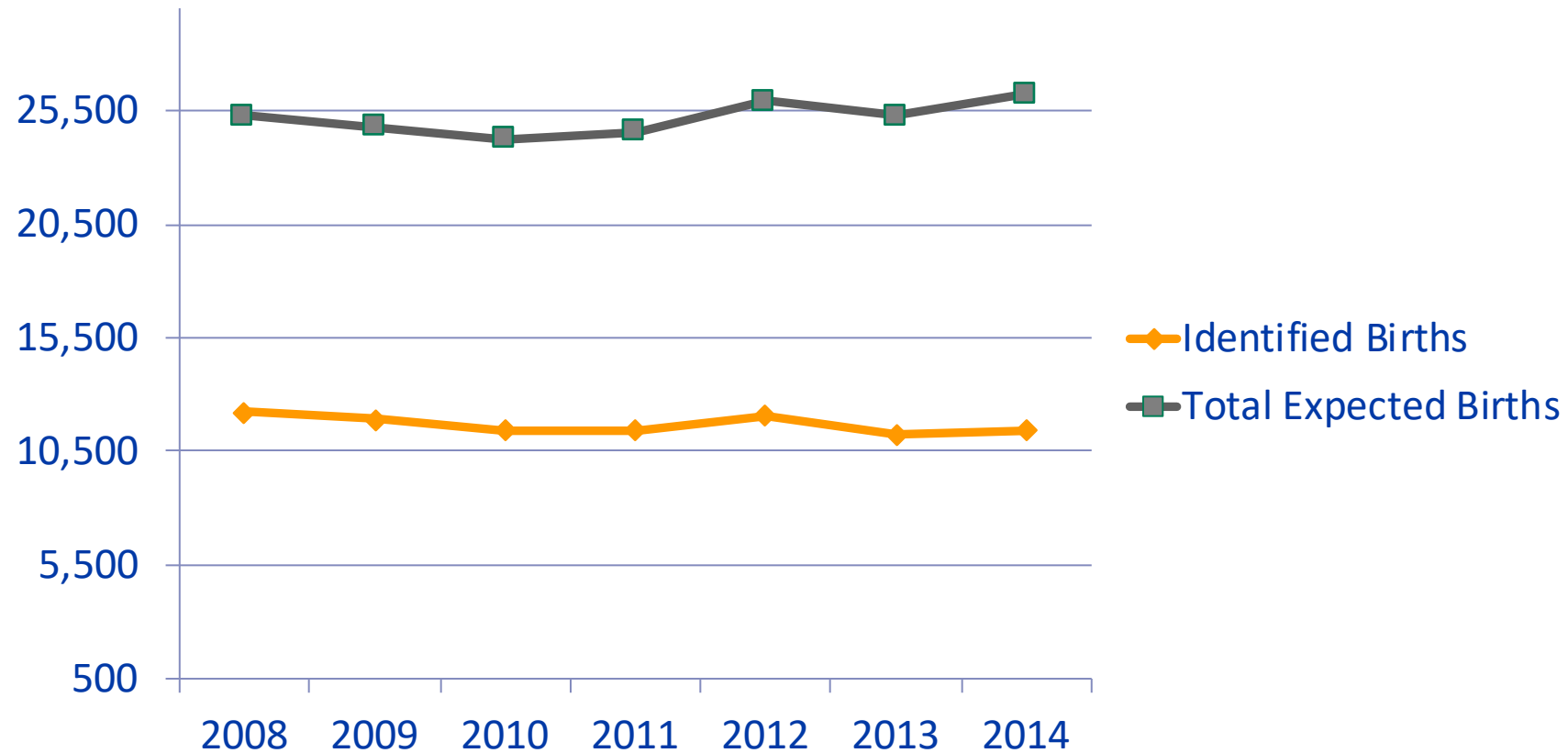
- In 2016, **32** cases of perinatal hepatitis B were reported to CDC from 13 states

Year	Perinatal B Cases (HBsAg-positive infants)
2016	32
2015	37
2014	47
2013	48
2012	40

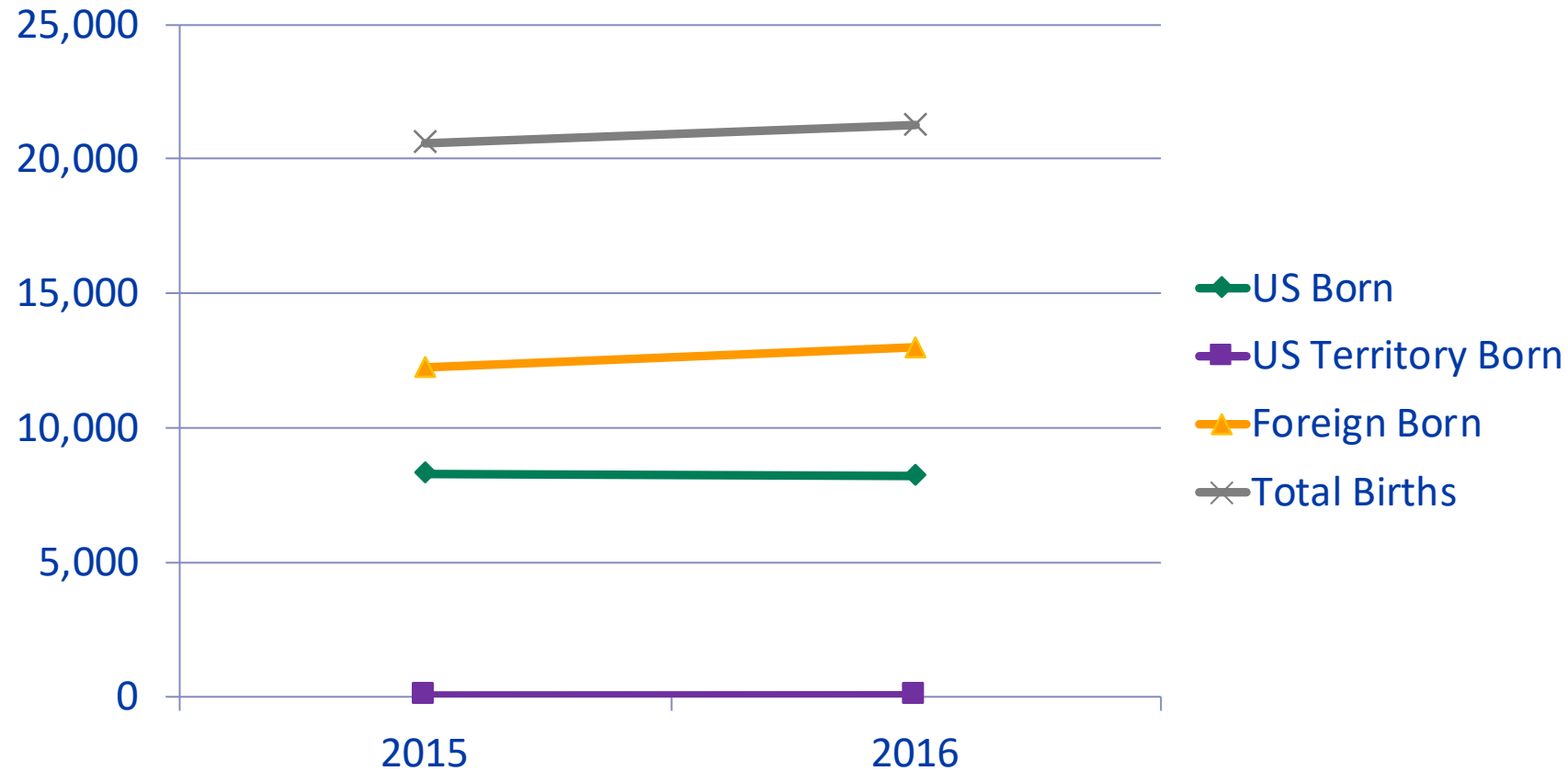
Source: CDC, National Notifiable Diseases Surveillance System.

- 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



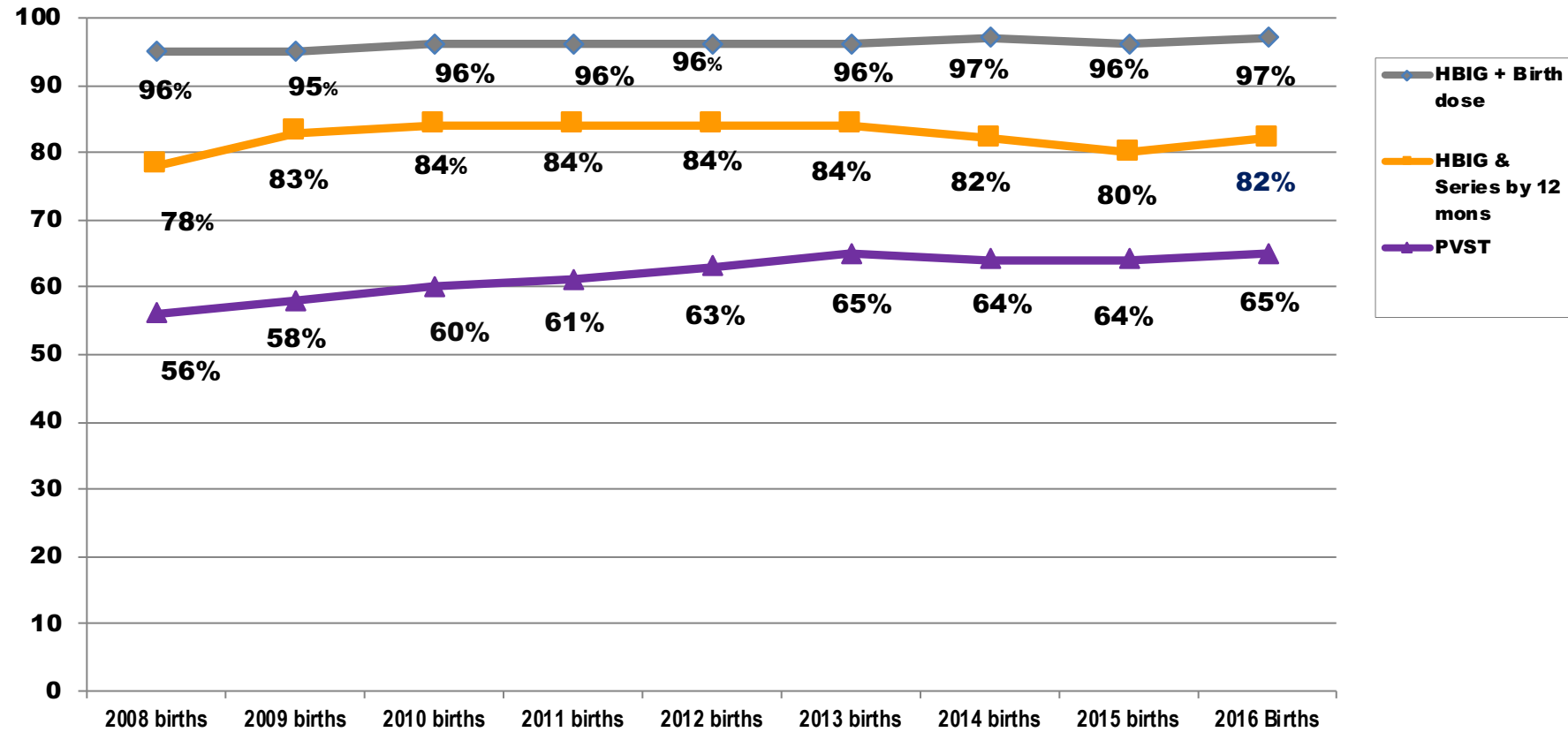
# Expected Births to HBsAg-positive Women 2015-2016 by Mother's Region of Birth (PE)



Perinatal Hepatitis B Prevention Program

Koneru A, Schillie S, Roberts H, Sirotkin B, Fenlon N, Murphy TV, Nelson NP. Estimating Annual Births to Hepatitis B Surface Antigen-Positive Women in the United States by Using Data on Maternal Country of Birth. Public Health Rep. 2019 Apr

# 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 3<sup>rd</sup> 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

### Viral Hepatitis

Viral Hepatitis > Hepatitis B Information

#### Home Hepatitis B Information

Q&As for Health Professionals

Q&As for the Public

Vaccination of Infants, Children, and Adolescents

Vaccination of Adults

#### Perinatal Transmission

Laboratory Reporting

PVST panels for infants born to HBV-infected women

Chronic Infection Testing

Statistics & Surveillance +

Postexposure Prophylaxis

Professional Resources

Patient Education Resources

**A** Hepatitis A

**B** Hepatitis B

## Perinatal Transmission



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
- Screening all HBsAg-positive pregnant women for HBV DNA to guide the use of maternal antiviral therapy during pregnancy. AASLD suggests maternal antiviral therapy when HBV DNA is >200,000 IU/mL
- Case management of HBsAg-positive mothers and their infants
- Provision of immunoprophylaxis for infants born to infected mothers, including hepatitis B vaccine and hepatitis B immune globulin 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 2018; 67 (RR 1):1–31

#### On This Page

[Guidelines and Recommendations](#)

[Scientific Tools and Resources](#)

[Policies and Procedures for Prenatal Care and Delivery Hospitals](#)

[Additional Resources](#)

[Patient Education Tools](#)







# Protect Your Baby for Life

## When a Pregnant Woman Has Hepatitis B

# Resources - II

<https://www.cdc.gov/knowhepatitisb/materials.htm#pregnantwomen>

## Information for Pregnant Women

<p><b>“Protect Your Baby For Life” fact sheet</b></p>  <p>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.</p>	<p><a href="#">English</a> [PDF – 839KB]      <a href="#">Hmong</a> [PDF – 1.4MB]  <a href="#">Chinese</a> [PDF – 1.4MB]      <a href="#">Khmer</a> [PDF – 2.7MB]  <a href="#">Vietnamese</a> [PDF – 1.7MB]      <a href="#">Lao</a> [PDF – 5.9MB]  <a href="#">Korean</a> [PDF – 1.1MB]      <a href="#">Russian</a> [PDF – 0.6MB]  <a href="#">Burmese</a> [PDF – 2.9MB]      <a href="#">Spanish</a> [PDF – 0.7MB]  <a href="#">French</a> [PDF – 0.7MB]      <a href="#">Tagalog</a> [PDF – 1.5MB]</p>
<p><b>Vaccinate Your Baby Against Hepatitis B</b></p>  <p>This two page infographic answers commonly asked questions about hepatitis B and explains the importance of the vaccine for infants</p>	<p><a href="#">English</a> [PDF – 2 MB]      <b>Customizable version files</b>  <a href="#">Spanish</a> [PDF – 2 MB] <a href="#">Perinatal Infographic-Customizable Version</a> [PDF – 3 MB]  <a href="#">Logo + Og Info PDF Template</a> [DOC – 28 KB]  <a href="#">Customized Infographic Directions</a> [PDF – 443 KB]</p>
<p><b>Hepatitis B and a Healthy Baby</b></p>  <p>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 Tagish, and allows participants to read and listen along to the presentation.</p>	<p><a href="#">English</a>  <a href="#">Chinese</a>  <a href="#">Vietnamese</a>  <a href="#">Korean</a>  <a href="#">Hmong</a>  <a href="#">Tagish</a></p>
<p><b>Hepatitis B and Your Healthy Baby</b></p>  <p>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.</p>	<p><a href="#">English</a>  <a href="#">Spanish</a></p>

# Resources - III

- **2018 ACIP Recommendations**
  - <https://www.cdc.gov/mmwr/volumes/67/rr/pdfs/rr6701-H.pdf>
- **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>

For more information, contact CDC  
1-800-CDC-INFO (232-4636)  
TTY: 1-888-232-6348 [www.cdc.gov](http://www.cdc.gov)

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

