Webinar Series
Hepatitis B: Education and Support for Health Departments

Exploring National and Local Approaches to Perinatal Hepatitis B Prevention

Wednesday, May 1st 2019
11:00 AM - 12:00 PM PDT / 2:00 - 3:00 PM EDT

Speakers:
Noele Nelson, MD, PhD, MPH
Acting Branch Chief, Prevention Branch, Division of Viral Hepatitis
CDC

Essi Havor, MSN, RN, APHN-BC
Chief Nurse,
Houston Health Department

NACCHO
National Association of County & City Health Officials

Hepatitis B Foundation
Hep B United
United States:
+1 (631) 992-3221

Access Code:
413-007-215 (muted)

Note: *If you call in from outside the United States – you may incur international calling fees!*
Have a Question?

Questions? Submit questions in the chat box at anytime throughout the webinar.

Poll #1
Poll Q1: Which of the following best describes your job title?

- Perinatal hepatitis B coordinator
- Disease Intervention Specialist
- Nurse
- Epidemiologist
- Other
Poll Q2: If you are representing a health department, please tell us more about your jurisdiction and the population size you serve:

- Small jurisdiction (49,999 or less)
- Medium jurisdiction (50,000 – 199,999)
- Large jurisdiction (200,000 +)
Poll Q3: How would you describe your community?

- Rural
- Suburban
- Urban
Thank you for joining today’s webinar!

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Perinatal Hepatitis B

Noele Nelson, MD, PhD, MPH
Acting Branch Chief, Prevention Branch

Division of Viral Hepatitis
NCHHSTP/Centers for Disease Control and Prevention of
Viral Hepatitis

May 1, 2019
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 an **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

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:

- 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

*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

Healthy People 2020 target: 85%

Source: National Immunization Survey, CDC

Source: National Immunization Survey, CDC

HP 2020 Target=90%
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>
<thead>
<tr>
<th>Year</th>
<th>Perinatal B Cases (HBsAg-positive infants)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2016</td>
<td>32</td>
</tr>
<tr>
<td>2015</td>
<td>37</td>
</tr>
<tr>
<td>2014</td>
<td>47</td>
</tr>
<tr>
<td>2013</td>
<td>48</td>
</tr>
<tr>
<td>2012</td>
<td>40</td>
</tr>
</tbody>
</table>

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
Perinatal Transmission

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

- Universal screening of pregnant women for HBsAg during each pregnancy
- Offering all HBsAg-positive pregnant women for HBV DNA to guide the use of maternal antiviral therapy during pregnancy, which reduces maternal viral load and vertical transmission.
- Care management of HIV-infected pregnant women and their infants.
- Provision of chemoprophylaxis 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

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.

### 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.

### 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.

### 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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**Resources (Cont.)**

https://www.cdc.gov/knowhepatitisisb/materials.htm#pregnantwomen
Resources (Cont.)

- 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
Poll Q4: How many perinatal hepatitis B cases did you manage last year (2018)?

- Less than 50
- 50 - 100
- 100 – 200
- 200 or more
Innovative Strategy to Increase Identification of Infants Born to Chronic Hepatitis B Mothers

Presented by Essi M. Havor MSN, RN, PHNA-BC
Houston Health Department, Immunization Bureau
May 1, 2019
Learning Objectives

At the end of the session, participants will learn about and have opportunity to discuss….

➢ challenges to the identification of HBsAg-positive women and their infants
➢ promising practices to increase identification of HBsAg-positive women and their infants
➢ lessons learned and next steps
Part 1:
Overview of Perinatal Hepatitis B Prevention Program
INTRODUCTION

~ 25,000 infants are born to women chronically infected with hepatitis B every year

~ 10,000 of these infants would become chronically infected without timely PEP

~ 2,500 would die of liver failure or liver cancer as early as age 10

~ 1,000 newborns are infected annually

Healthy People 2020 target (among infants and children aged 1 to 24 months) : 400 cases

2007 baseline: 799

Acute HBV must be reported within 1 week

Chronic HBV is NOT reportable except:
- Prenatal & Delivery, reportable within 1 week
- Perinatal (<24 months), reportable within 1 work day

Not all hospitals report electronically
Six Responsibilities of the Perinatal Hepatitis B Prevention Program

- Identify ALL HBsAg positive pregnant women and their infants.
- Identify and vaccinate susceptible household contacts ≤ 24 months of age; household contacts > 24 months of age and sexual contacts are referred out.
- Universal hepatitis B vaccine birth dose administration.
- Assure administration of postexposure prophylaxis within 12 hours of birth to exposed infants.
- Assure completion of hepatitis B vaccine series and postvaccination serologic testing (PVST) of exposed infants.
- Conduct active surveillance, quality assurance, outreach, and education to improve the PHBPP program.

Part 2: City of Houston 2016 Program Evaluation
City of Houston (COH) Program Background

- Funded by CDC since 1991
  - City of Houston residents only
- CDC Estimates:
  - 255 - 422 infants born to HBsAg-positive mothers in 2015
- 90% of the estimated births to HBsAg-positive pregnant mothers should be identified.
- State of COH program

<table>
<thead>
<tr>
<th>Jurisdiction</th>
<th>2013</th>
<th>2014</th>
<th>2015</th>
</tr>
</thead>
<tbody>
<tr>
<td>COH</td>
<td>37</td>
<td>51</td>
<td>76</td>
</tr>
</tbody>
</table>

Table 1. Number of Identified Infants Prior to 2016 Audit
Under-reporting of HBsAg-positive mothers is a threat

4 out of 10 infants were not reported in 2014 & 2015

Figure 1: Observed Discrepancy Between Cases Reported and Not Reported
Part 3: City of Houston 2018 Program Evaluation
Houston PHBPP has been conducting hospital audit every year

- December 31, 2015: 51 infants born in 2014 were identified Vs. 301/412
- 2016 audit: 71 additional infants
- December 31, 2015: 76 infants born in 2015 were identified Vs. 255/422

- U.S. 11,157 infants Vs. 18,945/26,444
- **Note:** excluded out of jurisdiction cases

<table>
<thead>
<tr>
<th></th>
<th>2013</th>
<th>2014</th>
<th>2015</th>
</tr>
</thead>
<tbody>
<tr>
<td>Before</td>
<td>37</td>
<td>51</td>
<td>76</td>
</tr>
<tr>
<td>After</td>
<td>----</td>
<td>122</td>
<td>158</td>
</tr>
</tbody>
</table>

Table 2. Number of Infants Identified Before and After 2016 Audit
2016 Methodology:
- 24 Labor and Delivery hospitals in Harris County
- Old Methodology
  - CDC Policy Survey
  - Record Review: Hepatitis B birth dose administration & HBsAg screening with CDC developed tool
- 2016 Methodology
  - Old methodology &
  - Review of \textbf{ALL HBsAg} positive mother-baby records (list provided by the hospitals)
  - Compare positive records with cases managed by the assessment date

2018 Methodology:
- 25 L & D
- Evaluation Period: 2016-2017
- Previous Method: 2016
- New Method:
  - 2016 methodology
  - \textbf{Pharmacy/HBIG log}
2016-2017 Record Review Results

Table 3. Positive HBsAg and Administration of HBIG

<table>
<thead>
<tr>
<th>Hospital Code</th>
<th>Positive HBsAg Records 2016</th>
<th>2017</th>
<th>HBIG Given 2016</th>
<th>2017</th>
</tr>
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<tbody>
<tr>
<td>19</td>
<td>1/56</td>
<td>4/57</td>
<td>1/1</td>
<td>3/3</td>
</tr>
<tr>
<td>13</td>
<td>15/71</td>
<td>15/70</td>
<td>20/20</td>
<td>19/19</td>
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<tr>
<td>10</td>
<td>4/57</td>
<td>4/53</td>
<td>6/6</td>
<td>4/4</td>
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<tr>
<td>3</td>
<td>9/65</td>
<td>10/68</td>
<td>9/10</td>
<td>10/10</td>
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<tr>
<td>9</td>
<td>10/68</td>
<td>9/58</td>
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<td>5</td>
<td>1/50</td>
<td>4/61</td>
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<td>246/1612</td>
<td>275/281</td>
<td>269/276</td>
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</tbody>
</table>

60 additional infants identified from HBIG/pharmacy log:
27 (~10%) in 2016 &
33 (~12%) in 2017

Out of jurisdiction cases excluded, 2 out of 10 infants were not reported.
Other Findings

- Policy issues (reporting to LHD not specified…)
- Mother’s HBsAg status documentation
- Infant’s records
- Vaccine & HBIG administration documentation
## Houston Program
- Policy and Procedures survey during record review
- Poor communication between program staff and hospitals
- Reporting Process is an issue
- Pregnancy status is not force field (usually not reported on the laboratory reports)
- Post audit feedback to the hospitals was very helpful to the hospitals

## Hospitals
- Poor quality in data reported by hospitals
- Laboratory report Vs. L&D logs
- Pharmacy logs of HBIG administration Vs. Nursery logs Vs EMR data
- Inconsistency in reporting process
- Turn-over effect
- Shift/schedule effect
- Hospitals where delivery nurse is required to report +HBsAg mother, have low underreporting rates
PROGRAM CHALLENGES

- Low and late identification of HBsAg-positive mothers is a challenge nationwide
  - U.S. **11,157 infants** Vs. 18,945/26,444
- Pregnancy status on laboratory reports remains a big problem
- All laboratories are not reporting electronically
- Serving transient populations
- **Tourism effect** = high number of HBsAg-positive mothers move out of the country within 1-3 months after delivery (Growing problem)

- Policies focusing on Infants not mothers
- Chronic HBV surveillance
- Underfunded
- Providers’ Knowledge & behaviors
- Develop Perinatal HBV toolkit for clinicians (completed)
- Implementing quarterly reporting of HBsAg-positive mothers
- Working with internal surveillance team to recruit more laboratories (in progress)
- Continue to review HBsAg-positive mothers during program evaluation:
  - Nursery log
  - Pharmacy log
  - Laboratory annual report
  - EMR data
- Plan to collaborate with surrounding counties for next audit
Recommendations

- Resource and labor intensive
- Consider partnership with colleges/universities
- Consider alternative audit schedule: one hospital every other month/quarter
- Conduct post-audit session with the hospitals
- Provide incentives: certificates
Thank You!
Q & A

Please submit questions in the chat box!
Resources

NACCHO HBV Toolkit
Available at: toolbox.naccho.org

Additional HBV information & printable fact sheets

Subscribe to Hepatitis B Foundation, Hep B United and NACCHO Newsletters
Available at: www.hepb.org
Save the Date!

May 22\textsuperscript{nd} (11am-12pm PDT/ 2-3pm EDT)
Part 3: Hidden Consequences: The Opioid Epidemic and Rising Hepatitis B Rates
Thank you for joining!

For more information:
www.hepb.org
www.hepbunited.org

Hepatitis B help-line
(for patient/provider use):
215-489-4900
Info@hepb.org

Contact NACCHO:
Michelle Cantu
Director of Infectious Disease & Immunization
immunization@naccho.org
www.naccho.org