MA PERINATAL HEPATITIS B PREVENTION PROGRAM

Massachusetts Department of Public Health

Immunization Program

MIAP 2016

1

Presenter Disclosure Information

I, Theodora Wohler, have been asked to disclose any significant relationships with commercial entities that are either providing financial support for this program or whose products or services are mentioned during my presentations. I have no relationships to disclose.

I may discuss the use of vaccines in a manner not approved by the U.S. Food and Drug Administration

- But in accordance with ACIP recommendations

2

Massachusetts Perinatal Hepatitis B Prevention Program

- **Program Mission**: Prevent perinatal and early childhood transmission of HBV through identification of Hepatitis B positive mothers, education and case management.
- **Program Goal**: To reduce infant HBV mortality and morbidity rates.

3

Perinatal Hepatitis B and Hepatitis B Vaccine Requirements in MA

- 105 CMR 300.000: Requires all hepatitis B positive labs be reported to MDPH (1985)
- Perinatal Hepatitis B Program started (1989)
- Universal Hep B vaccination of all children (1991)
- Provides hepatitis B vaccine free of charge to birth hospitals and providers (1992)
- 105 CMR 130.627: Requires all pregnant women be tested for hepatitis B during each pregnancy (1993)

4

Perinatal Transmission of Hep B

- An infant can acquire Hep B from:
  - An infected mother (transmitted at birth)
  - A chronically infected member of the household
- Risk of chronic infection
  - If mother is positive for HBsAg and HBeAg
    - 70% - 90% of infants infected
  - If mother positive for HBsAg only
    - 10% of infants infected
  - 90% of all those infected as infants become chronically infected

But, timely post-exposure prophylaxis protects up to 98% of infants
(MMWR 10/9/15)

5

Prevention of Perinatal Hepatitis B Virus Infection

- Begin treatment within 12 hours of birth
  - Hepatitis B vaccine (first dose) and HBIG (Hepatitis B Immunoglobulin)
- 2nd dose of Hep B vaccine: 1-2 months of age
- Final dose of Hep B Vaccine: 6 months of age
- Test for response (HBsAg and anti-HBs) after completion of at least 3 doses of the HepB series at 9 through 12 months of age (generally at the next well-child visit)

Please note:

- Pediarix dose given at 4 months of age is NOT the final dose. Another dose at 6 months of age is needed.
- Babies born to Hep B+ women that weigh less than 2000 grams at birth will need an extra dose of Hepatitis B vaccine.

6

Hepatitis B Vaccine formulations to be used for pediatric vaccination

Recombivax HB (Merck)

- Single antigen Hep B

Engerix-B (GSK)

- Single antigen Hep B

Pediarix (GSK)

- Combination vaccine
  - DTaP, Hep B, IPV
- Approved for ages 6 weeks through 6 years old
- Approved for 3 doses at 2, 4, and 6 months
- Not approved for birth dose or booster doses
- Not recommended for use for revaccination
- May be used in infants whose mothers are HBsAg positive or status unknown

7

Shortened Interval for Postvaccination Serologic Testing of Infants Born to Hepatitis B-Infected Mothers

- Postvaccination serologic testing consists of two tests:
  - HBsAg (hepatitis B surface antigen)
  - Anti-HBs (antibody to hepatitis B surface antigen)
- CDC recently shortened the recommended age intervals for postvaccination serologic testing to **9-12 months of age**
  - In the past, recommendation was to perform test at age 9-18 months
- If completion of the series is delayed, the optimal timing for PVST to detect a vaccine response is 1-2 months after the last vaccine is administered.

http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6439a6.htm

8

Benefits and Goals of Shortened PVST Interval

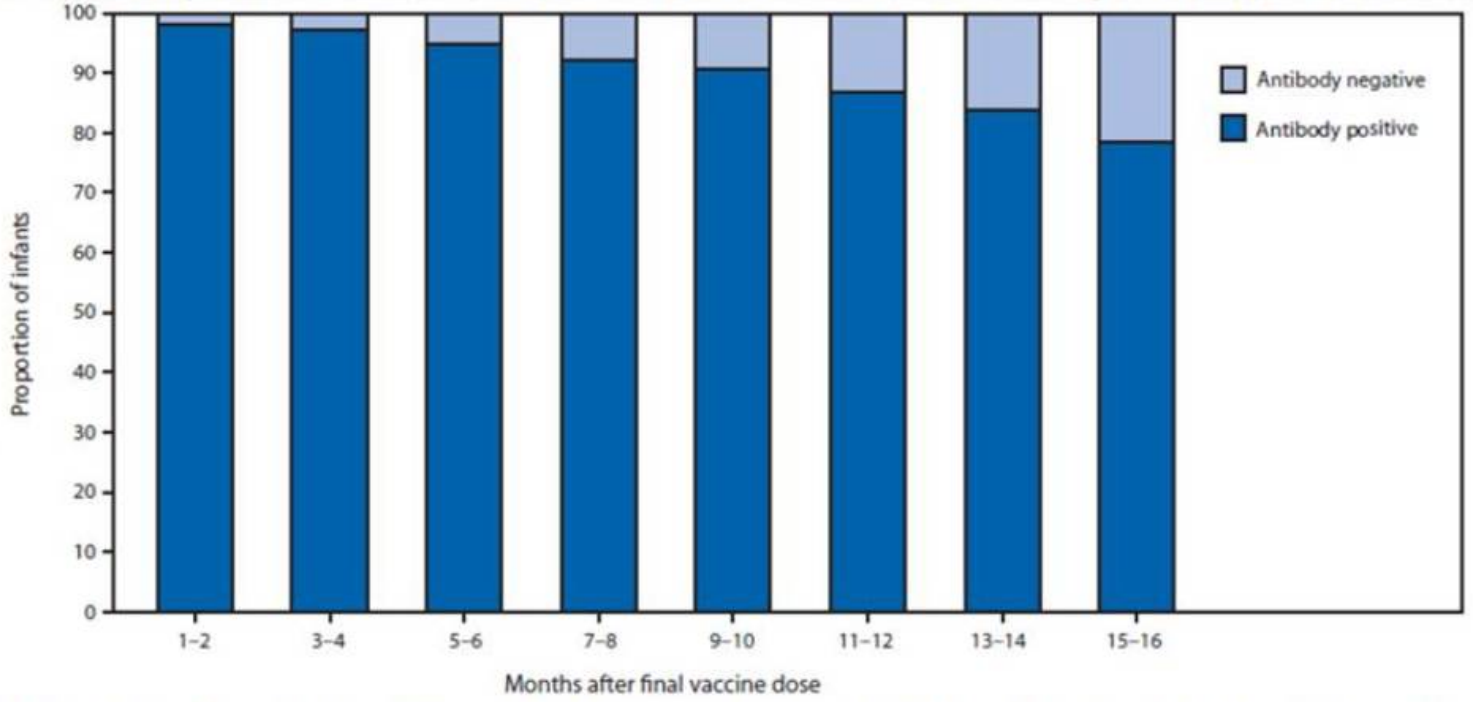
- Earlier identification of vaccine failures for referral
- Reduction in the time that non-responder infants are at risk for transmission from household contacts with Hep B
- Enables prompt revaccination for those infants needing a second series
- PVST occurring at an increasing interval after the final vaccine dose misclassifies some infants as vaccine non-responders and results in unnecessary revaccination

CDC. MMWR 2015;64:1118-1120.

9

Anti-HBs Levels and Interval to Postvaccination Serologic Testing

FIGURE. Proportion of infants with anti-HBs ≥10 mIU/mL with increasing interval from final vaccine dose*



Source: Reprinted with permission of publisher from: Ko SC, Schillie SF, Walker T, et al. Hepatitis B vaccine response a infants born to hepatitis B surface antigen-positive women. Vaccine 2014;32:2127–33.

* p<0.01, Mantel-Haenszel chi square.

CDC. MMWR 2015;64:1118-1120.

10

Interpretation of Hepatitis B Serologic Test Results

Hepatitis B serologic testing involves measurement of several hepatitis B virus (HBV)-specific antigens and antibodies. Different serologic "markers" or combinations of markers are used to identify different phases of HBV infection and to determine whether a patient has acute or chronic HBV infection, is immune to HBV as a result of prior infection or vaccination, or is susceptible to infection.

HBsAg **anti-HBc** **anti-HBs**	negative negative negative	Susceptible
HBsAg **anti-HBc** **anti-HBs**	negative positive positive	Immune due to natural infection
HBsAg **anti-HBc** **anti-HBs**	negative negative positive	Immune due to hepatitis B vaccination
HBsAg **anti-HBc** **IgM anti-HBc** **anti-HBs**	positive positive positive negative	Acutely infected

- **Hepatitis B surface antigen (HBsAg):** A protein on the surface of hepatitis B virus; it can be detected in high levels in serum during acute or chronic hepatitis B virus infection. The presence of HBsAg indicates that the person is infectious. The body normally produces antibodies to HBsAg as part of the normal immune response to infection. HBsAg is the antigen used to make hepatitis B vaccine.
- **Hepatitis B surface antibody (anti-HBs):** The presence of anti-HBs is generally interpreted as indicating recovery and immunity from hepatitis B virus infection. Anti-HBs also develops in a person who has been successfully

http://www.cdc.gov/hepatitis/hbv/pdfs/serologicchartv8.pdf

11

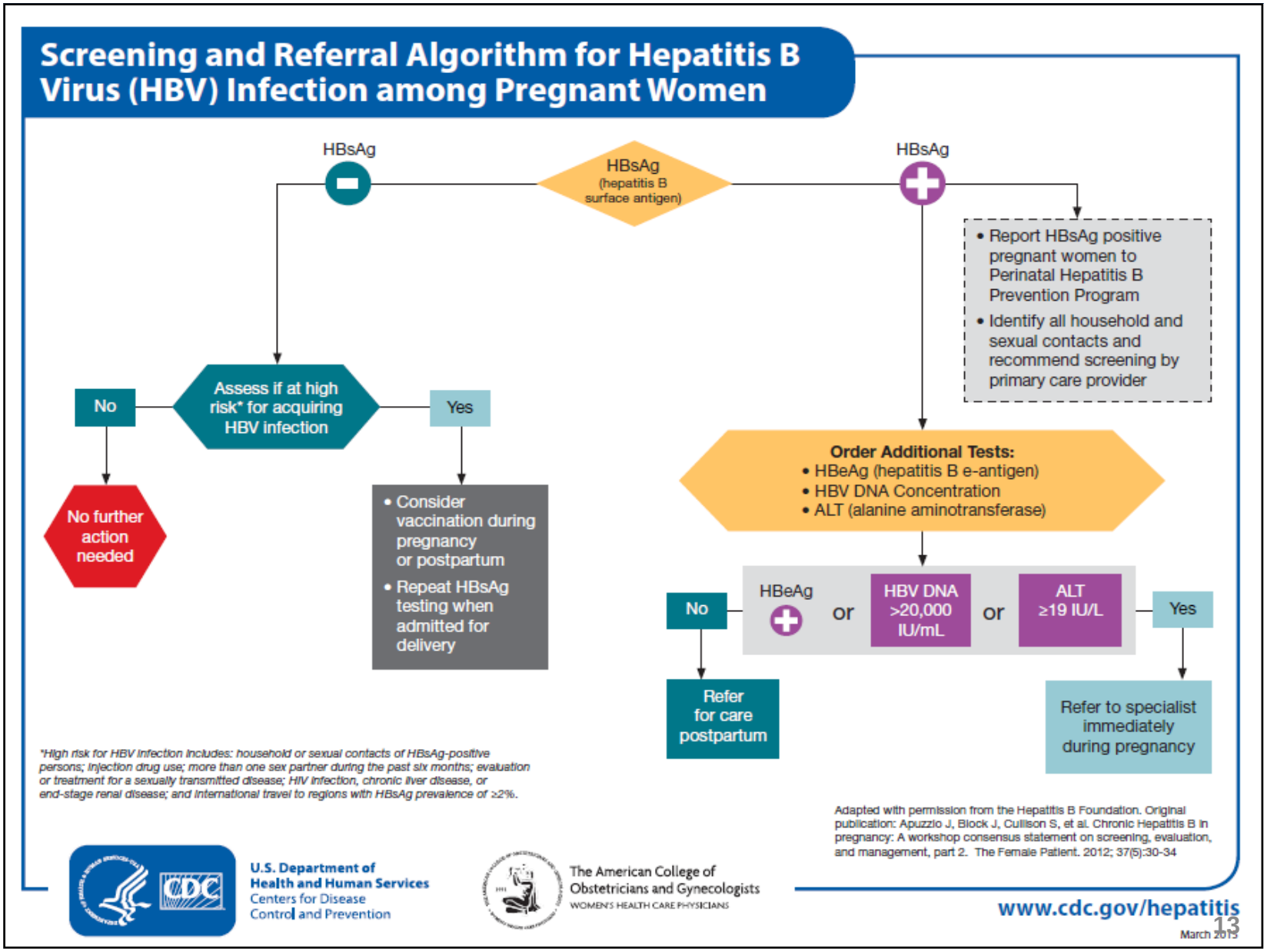
Screening for Risk Factors & Referrals for Perinatal HBV Infection

- Despite post exposure prophylaxis, mother to child transmission occurs in approximately 1% of infants born to HBsAg positive mothers.
- Risk factors for transmission include*:
  - Hepatitis B e-antigen (HBeAg positive)
  - High HBV DNA concentration (DNA >20,000 IU/mL, approximately 112,000 viral copies per mL)
  - Elevated alanine aminotransferase (ALT) (≥19 IU/L)
- Emerging evidence suggests that HBV treatment of pregnant women with antiviral agents in the 3rd trimester is safe and reduces rates of transmission
- CDC and ACOG have developed a *Screening and Referral Algorithm for HBV Infection among Pregnant Women*

* Another risk factor is low birth weight (<2,000 grams) who receive the 1st dose of hepB vaccine before 1 month of age.

http://www.cdc.gov/hepatitis/hbv/pdfs/prenatalhbsagtesting.pdf

12


Screening and Referral Algorithm for Hepatitis B Virus (HBV) Infection among Pregnant Women
HBsAg
HBsAg (hepatitis B surface antigen)
HBsAg
• Report HBsAg positive pregnant women to Perinatal Hepatitis B Prevention Program
• Identify all household and sexual contacts and recommend screening by primary care provider
Assess if at high risk* for acquiring HBV infection
No
Yes
No further action needed
• Consider vaccination during pregnancy or postpartum
• Repeat HBsAg testing when admitted for delivery
Order Additional Tests:
• HBeAg (hepatitis B e-antigen)
• HBV DNA Concentration
• ALT (alanine aminotransferase)
No
HBeAg
or
HBV DNA >20,000 IU/mL
or
ALT ≥19 IU/L
Yes
Refer for care postpartum
Refer to specialist immediately during pregnancy
*High risk for HBV infection includes: household or sexual contacts of HBsAg-positive persons; injection drug use; more than one sex partner during the past six months; evaluation or treatment for a sexually transmitted disease; HIV infection, chronic liver disease, or end-stage renal disease; and international travel to regions with HBsAg prevalence of ≥2%.
Adapted with permission from the Hepatitis B Foundation. Original publication: Apuzzio J, Block J, Cullison S, et al. Chronic Hepatitis B in pregnancy: A workshop consensus statement on screening, evaluation, and management, part 2. The Female Patient. 2012; 37(5):30-34
U.S. Department of Health and Human Services
Centers for Disease Control and Prevention
The American College of Obstetricians and Gynecologists
WOMEN'S HEALTH CARE PHYSICIANS
www.cdc.gov/hepatitis
13
March 2015

Regional Immunization Nurses

Denise Dillon – Northeast	978-851-7261
Linda Jacobs – Southeast	508-984-0621
Lila Coverstone – Metro Boston	617-983-6811
Theodora Wohler – Metro West	617-983-6837
Katie Reilly, Nurse Manager	617-983-6833

THANK YOU!