Hepatitis B: What Hospitals Need to Do to Protect Newborns
A resource for birthing institutions to prevent perinatal transmission

Prepared by the Immunization Action Coalition (IAC)
Agenda

I. Welcome and Agenda
   Debra Blog, MD, MPH, Director of the Division of Epidemiology, New York State Department of Health

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   Trudy V. Murphy, MD, Team Lead, Vaccine Research and Policy, Division of Viral Hepatitis, National Center for HIV, Viral Hepatitis, STD, and TB Prevention, Centers for Disease Control and Prevention

III. Case Study from Albany Medical Center
   Lynn Pollock, RN, MSN, Perinatal Hepatitis B Coordinator, New York State Department of Health
   Mary Miller, RNC, Nurse Manager of Postpartum and Newborn Nursery, Albany Medical Center

IV. Overview of IAC’s Complete Guide to Implementation
   Deborah Wexler, MD, Executive Director, Immunization Action Coalition
Disease Overview & Recommendations

Trudy V. Murphy, MD
Background on hepatitis B

• Hepatitis B is a liver disease caused by the hepatitis B virus (HBV).

• HBV is found in the blood and other body fluids of infected people (e.g., serum, semen, saliva, and vaginal secretions).

• An infant can acquire HBV from:
  - An infected mother (transmitted at birth)
  - A chronically infected member of the household
Natural history of hepatitis B virus (HBV) infection

HBV can cause acute or chronic infection.

Chronic HBV infection can lead to liver failure and liver cancer.
Risk of developing chronic hepatitis B by age at infection

- Infant: 90%
- 1-5 Years: 30%
- > 5 years: <5%
Why a birth dose?

• The primary goal of administering hepatitis B vaccine at birth is to protect babies from chronic HBV infection, which can lead to liver failure and liver cancer.
  - Most morbidity and mortality from HBV-related liver failure and liver cancer occurs in people with chronic HBV infection.
  - Treatment can decrease liver damage and the chance of liver cancer, but there is no cure.
  - Many people with chronic HBV are not aware of their infection and can unknowingly spread the infection.
Effectiveness of hepatitis B vaccine starting at birth?

- Post-exposure prophylaxis of infants born to infected mothers is 85-95% effective when started within 12 hours of birth.
  - Post-exposure prophylaxis: hepatitis B vaccine + hepatitis B immune globulin (HBIG) at birth, completion of hepatitis B vaccine series, post-vaccination testing for outcomes.
  - Timing of the birth dose is critical to achieve the highest rates of protection.

- Hepatitis B vaccination starting at birth even without HBIG will prevent transmission of the infection in 70-95% of infants born to chronically infected mothers.
The Opportunity

• Hospitals have an opportunity to protect the future health of infants born in their facilities
  - Each year in the U.S., more than 24,000 infants are born to mothers who are infected with HBV, and not all of their infants receive post-exposure prophylaxis.
  - Some infants are first exposed shortly after birth to HBV by household members or caretakers who have chronic HBV infection.

• Most infants can be protected if hospitals routinely provide a birth dose of hepatitis B vaccine to all newborn infants.

Smith EA. Pediatrics 1012;129:609-616; MMWR 2005;57(RR-8):1-20
The Problem

• Many infants in the United States are not receiving the birth dose of hepatitis B vaccine.
  - Only 70% of U.S. infants received hepatitis B vaccine within 3 days of birth.*
  - States’ coverage rates varied between 29% and 88%.*

• There is room for improvement in protecting newborn infants in every state.

Why should we give hepatitis B vaccine to all newborns?

- **Prevents mother-to-infant transmission:** Prevents 70-95% of infection among infants born to HBsAg-positive women.

- **Prevents household transmission:** Protects infants from infected family members and other caregivers.

- **Protects when medical errors occur:** Provides a safety net to prevent perinatal HBV infection when medical errors occur.
Why is a safety net needed?

Because medical errors happen!
Types of medical errors reported

- Ordering the wrong hepatitis B screening test
- Misinterpreting or mis-transcribing the hepatitis B test results
- Failing to communicate the HBsAg test results to or within the hospital
- Not giving hepatitis B vaccine to infants born to mothers of unknown HBsAg status within 12 hours of birth
- Not giving prophylaxis to an infant even when the mother’s HBsAg-positive status is documented
Because of these types of errors, children are chronically infected with hepatitis B (HBV)

A universal hepatitis B vaccine birth dose policy helps to protect newborn infants from human error and resulting chronic HBV infection which can cause serious liver disease.
All birthing hospitals should:

1. Implement policies and procedures to administer the recommended universal hepatitis B vaccine birth dose, ensuring that every newborn infant receives hepatitis B vaccine at birth, or no later than hospital discharge, regardless of the mother’s HBsAg test result.

2. Implement standing orders for administration of hepatitis B vaccine as part of routine medical care of all medically stable infants weighing ≥2,000 g at birth.

3. Follow national recommendations for prophylaxis of all newborn infants born to women with HBsAg-positive test results, and all infants born to women whose HBsAg status is unknown.

All birthing hospitals should also:

4. Ensure that a copy of the original laboratory report from the mother’s HBsAg screening test is placed in the infant’s medical record.

5. Educate staff and parents about the importance of administering the first dose of hepatitis B vaccine in the hospital or birthing facility, not delaying it until after discharge.

Only in rare circumstances, and on a case-by-case basis, should the first dose be delayed until after discharge. Such a delay should be considered only for an infant who weighs ≥2,000 grams and whose mother is HBsAg negative during this pregnancy. If the first dose is delayed, then a physician’s order to withhold the dose should be placed in the infant’s medical record along with a copy of the mother’s original laboratory report demonstrating that she was HBsAg negative during this pregnancy.

Hepatitis B birth dose is recommended by ACIP, AAP, AAFP, and ACOG

“Administer monovalent Hep B vaccine to all newborns before hospital discharge.”

Birth Dose Coverage: National Quality Forum (NQF) Measure 0475

- **NQF measure 0475 endorsed on 4/2/2012**

- Recommends that hospitals measure and report the “percent of live newborn infants that receive hepatitis B vaccination before discharge at each single hospital/birthing facility during given time period (one year),” excluding infants whose parents refuse vaccination.

- Calculation of measure programmed (e-specified) for electronic medical records; undergoing pilot testing with release expected in 2013.
Summary

Birthing facilities play a critical role in preventing chronic hepatitis B infections through timely initiation of post-exposure prophylaxis, and by creating a birth dose safety net for eliminating perinatal hepatitis B transmission.

The most important steps for birthing facilities to take are:

- Implement a universal birth dose policy
- Ensure universal review of the original maternal HBsAg test results
- Implement standard admission orders for timely administration of hepatitis B vaccine to all newborn infants
- Follow national recommendations for prophylaxis of newborn infants
  - Infants born to women with HBsAg-positive test results and
  - Infants born to women whose HBsAg status is unknown

Complete 2005 ACIP Recommendations are available at www.cdc.gov/mmwr/PDF/rr/rr5416.pdf
Case Study from Albany Medical Center

Lynn Pollock, RN, MSN, and Mary Miller, RNC
Overview of Perinatal Hepatitis B Prevention Efforts in New York State

- NYS PHL 2500-e enacted
- Lot Quality Assurance monitoring began
- AAP and PHS express concern about thimerosal in vaccines
- Survey of hospitals shows cost barrier
- Hospital birth dose initiative began
- ACIP recommends universal birth dose
- Commissioner letter
- Birthing hospital survey
- Best Practices Interviews
- NQF endorsement
Establishes the “standard of care” in the state to administer universal hepatitis B birth dose within 12 hours of birth to all medically stable newborns ≥2000 grams.
Universal Birth Dose Initiative

- Hepatitis B Perinatal prevention program goal
  - Eliminate transmission of hepatitis B
  - Greater than or equal to 90%
- Introduced in NYS October 2003
- All NYS hospitals outside NYC were enrolled by 2008
- Provides hepatitis B vaccine at no cost to hospitals (60% state funded)
- All hospitals must be enrolled in VFC Program
Universal Birth Dose Initiative (cont.)

• Hospital adopts a universal birth dose policy
  - Hospital must have a hepatitis B birth dose standing order in place stating that all newborns, regardless of maternal HBsAg status, individual provider preference or infant’s insurance status, will be offered hepatitis B vaccine

• Parental consent is obtained as per NYS law (may be written or documented verbal)
Give birth to the end of Hep B

NYSDOH Hepatitis B Birth Dose Rates - 90% Healthy People Goal*

* Objective IID-7.9 [www.healthypeople.gov](http://www.healthypeople.gov)
NYSDOH Newborn Dose of Hepatitis B Vaccine

- Albany Medical Center is a 631-bed hospital, increasing to 714 by the end of 2013
- More than 35,000 admissions expected in 2013
- From 2001 to 2012, hospitalized patients have increased by 42%
- 8,500 transfers of patients to Albany Med from other hospitals in 2012
- There are approximately 2,100 deliveries at Albany Medical Center’s Birthplace each year
NYSDOH Newborn Dose of Hepatitis B Vaccine

• Albany Medical Center is the only academic health center in northeastern New York.

• We deliver unique and critical services that our patients, physicians and community hospitals rely on around the clock every day.

• Albany Med reaches more than three million people in northeastern New York and western New England.
Transport and Transfers

![Bar chart showing transport and transfers from 2004 to 2012. The chart is divided into two categories: Maternal and Neonatal. The data for each year is as follows:

- 2004: Maternal 636, Neonatal 237
- 2005: Maternal 578, Neonatal 251
- 2006: Maternal 612, Neonatal 218
- 2007: Maternal 640, Neonatal 246
- 2008: Maternal 654, Neonatal 258
- 2009: Maternal 618, Neonatal 207
- 2010: Maternal 713, Neonatal 254
- 2011: Maternal 798, Neonatal 238
- 2012: Maternal 744, Neonatal 196]
Previous implementation of the birth dose at Albany Medical Center

• In the past, Albany Med attempted to meet the goal of the universal newborn dose of hepatitis B vaccine on all newborns within 12 hours of admission.

• Post-partum staff asked patients during their admission if they wanted their newborn to receive hepatitis B vaccine.

• The vaccine was administered when the mother gave consent.
Challenges resulting in poor implementation

• BARRIERS: When patients are transferred to the postpartum unit, they are screened for multiple parameters: HIV status, blood type, Rhogam status, rubella status, influenza, Tdap and pneumococcal vaccine.

• Screening for the newborn hepatitis B vaccine relied on individual nurse screening prior to discharge.
A process change improved implementation!

• In 2009, Albany Med initiated the Baby Nurse program.

• Postpartum RNs attend all births in labor and delivery (L&D), completing newborn care from birth to transfer to the postpartum unit.

• This process took approximately one year to orient staff for 24/7 availability.

• These mother-baby staff started discussing the hepatitis B vaccine birth dose with the parents in L&D and most agreed to the vaccine.
Why it worked!

• By asking parents in L&D, more parents accepted the birth dose of hepatitis B vaccine.

• Discussing the newborn, separate from maternal screening, gave the couple time to make a decision for their newborn.

• Having a mother-baby nurse dedicated to infant care in L&D facilitates administration of the vaccine prior to the newborn’s admission to the term nursery.
Neonatal Intensive Care Unit at Albany Medical Center

- The NICU is currently a 50-bed unit, but will move to the new Patient Tower this fall and will have 60 private rooms.
- The NICU has approximately 800 admissions annually.
- About 1/3 of these admissions are transported from other hospitals or admitted from our ED.
- About 2/3 of the admissions are born at Albany Med.
Neonatal Intensive Care Unit at Albany Medical Center

• The RNs give the CDC vaccine information sheet to the parents to review.

• Documentation is completed in the electronic medical record that parents have received the vaccine information sheet.

• The medical providers are available to discuss the importance of the vaccine with the parents and answer any questions.
Neonatal Intensive Care Unit at Albany Medical Center

- The medical team discusses in rounds when the infant is eligible for the vaccine.
- Parents give a verbal consent to administer the vaccine.
- An order is written to administer the vaccine, which is given by an RN.
- Documentation of the vaccination and the lot number is recorded in the electronic medical record and the Children's Hospital immunization record for the parents.
Hepatitis B Vaccine at Albany Medical Center

- Education with parents by the RN and medical provider allows families to make informed decisions about the health and welfare of their infant.

- Thank you to the nurses who make this possible. Their vigilance in assuring that all newborns are immunized against hepatitis B is what has helped Albany Med achieve great success in decreasing the transmission of hepatitis B.
Give birth to the end of Hep B

An initiative to eliminate hepatitis B virus infection in the U.S. through the prevention of perinatal transmission

Deborah L. Wexler, MD
Two Tools for Promoting the Hepatitis B Birth Dose

- “Hepatitis B: What Hospitals Need to Do to Protect Newborns” – a comprehensive guide
- Hepatitis B Birth Dose Honor Roll

www.immunize.org/protect-newborns
Hepatitis B: What Hospitals Need to Do to Protect Newborns

Reviewed and endorsed by

- American Academy of Family Physicians
- American Academy of Pediatrics
- American College of Obstetricians and Gynecologists
- Centers for Disease Control and Prevention

Birth Dose Guidebook Sections

1. Preventing Hepatitis B in Newborns: What’s Needed
2. Reducing Medical Errors: Case Reports
3. Addressing the Problem: Practical Tools
4. Obtaining Support: Helpful Contacts
5. Appendix: Authoritative Resources

www.immunize.org/protect-newborns/guide
Chapter 1. Preventing Hepatitis B in Newborns: What’s Needed

1. Executive Summary – What Hospitals Need to Do to Protect Newborns

2. National Quality Forum (NQF) has established newborn hepatitis B vaccination as a national standard for measurement by healthcare settings

Chapter 2. Reducing Medical Errors: Case Reports

1. States Reports Hundreds of Medical Errors in Perinatal Hepatitis B Prevention

2. Unprotected Infant Dies of Fulminant Hepatitis B

3. Medical Errors Put Infants at Risk for Chronic Hepatitis B Virus Infection – Six Case Reports

4. Two More Infants Chronically Infected with Hepatitis B Virus. . . the Medical Errors Continue

5. Give the Birth Dose. . .Hepatitis B Vaccine at Birth Saves Lives!

Chapter 3. Addressing the Problem: Practical Tools for Hospitals

- Guidance for Developing Admission Orders in Labor & Delivery and Newborn Units to Prevent Hepatitis B Virus Transmission
- Sample Text for Developing Admission Orders in Newborn Units for the Hepatitis B Vaccine Birth Dose

Sample Text for Developing Admission Orders in Newborn Units for the Hepatitis B Vaccine Birth Dose

Chapter 3. Addressing the Problem: Practical Tools for Parents

- About Hepatitis B Vaccine Information Statements
- English-language Hepatitis B VIS
- Spanish-language Hepatitis B VIS
- *Hepatitis B Shots Are Recommended for All New Babies*
- Childhood Immunization Records Cards

Hepatitis B Shots Are Recommended for All New Babies

Chapter 4. Obtaining Support: Helpful Contacts

1. Your State or Local Perinatal Hepatitis B Coordinator Can Help Implement the Hepatitis B Birth Dose

2. How the Vaccines For Children (VFC) Program Can Help Your Hospital

Appendix. Authoritative Resources


• Additional Resources

  www.immunize.org/protect-newborns/guide/appendix/authoritative-resources.pdf
The guidebook includes a reprint of the official CDC recommendations with highlighting of crucial points about the birth dose.
IAC’s Hepatitis B Birth Dose Honor Roll

Recognizes hospitals and birthing centers that have attained 90% or greater coverage rates for administering hepatitis B vaccine at birth.

www.immunize.org/honor-roll/birthdose
Criteria for Birth Dose Honor Roll

- At least 90% of babies (weighing 2,000 grams or more) born during a 12-month period receive hepatitis B vaccine prior to discharge.

- Written policies, procedures, and protocols for implementing the universal hepatitis B vaccine birth dose are in place and include the following:
  - Parents are informed about the importance of the hepatitis B vaccine birth dose and that it is recommended for all newborns.
  - All infants routinely receive hepatitis B vaccine before discharge.
Criteria for Birth Dose Honor Roll – cont.

- Staff review the HBsAg test result on all women admitted to L&D. It is recommended to review a copy of the original test report if at all possible.
- If HBsAg test result is not on chart, it is ordered ASAP.
- Infants born to HBsAg-positive mothers receive hepatitis B vaccine and hepatitis B immune globulin (HBIG) within 12 hours of birth.
- Infants born to mothers whose HBsAg status is unknown receive hepatitis B vaccine within 12 hours of birth, and also receive HBIG within 12 hours of birth if they weigh less than 2,000 grams.
- Newborn admission orders include a standing order to administer hepatitis B vaccine to all infants.
- Notification of the state or local health department’s perinatal hepatitis B prevention program is done prior to discharge for all mothers whose HBsAg test result is positive.
Enrollment into the Honor Roll

• Applications at www.immunize.org/honor-roll/birthdose
• Review by IAC
• Notification of acceptance
• Certificate of enrollment
• Placement on Birth Dose Honor Roll web page
• Recognition in *IAC Express*
  www.immunize.org/subscribe
Birth Dose Honor Roll Certificate
What You Can Do

• Download the guidebook, *Hepatitis B: What Hospitals Need to Do to Protect Newborns*
  www.immunize.org/protect-newborns

• Share the guide with hospitals and birthing centers to help them improve birth dose coverage rates

• Distribute the handout “Give birth to the end of Hep B,” to educate others about the importance of the hepatitis B birth dose

• Apply for enrollment into the Birth Dose Honor Roll
  www.immunize.org/honor-roll/birthdose
Promoting the Birth Dose

Give birth to the end of Hep B

Hepatitis B

What Hospitals Need to Do to Protect Newborns

www.immunize.org/protect-newborns
Safety Net

Hepatitis B

What Hospitals Need to Do to Protect Newborns
Thank You for Your Attention!

The webinar’s slide set and recording will be available on IAC’s website in the next few days.

For more information, please visit:
www.immunize.org/protect-newborns

Questions about *Give birth to the end of Hep B*?
Email birthdose@immunize.org