

**Procedures for HBsAg-Positive and Unknown Mothers and Newborns
Non-Patient Specific Standing Order for the Hepatitis B Birth Dose¹**

POLICY STATEMENT:

The Advisory Committee on Immunization Practices (ACIP), American Academy of Pediatrics (AAP), and Centers for Disease Control and Prevention (CDC) recommend identification of women who are HBsAg-positive through screening and prophylaxis of their newborns. Proper prophylaxis and completion of the hepatitis B vaccine series can reduce neonatal infection and the potential sequelae by 95%. New York State Public Health Law (NYSPHL) 2500-e mandates that all pregnant women be tested for hepatitis B infection and that all newborns born to infected mothers must be given hepatitis B immune globulin (HBIG) and hepatitis B vaccine within 12 hours of birth. NYSPHL 2500-e mandates that pregnant women who have not been tested or whose test results are unknown be tested immediately (STAT) after admission. Until the test result is known, the woman is assumed to be HBsAg-positive.

EQUIPMENT/SUPPLIES:

- Hepatitis B Vaccine Information Statement
- Screening and consent form
- Hepatitis B Vaccine (RECOMBIVAX HB or Engerix-B) Intramuscular, Dose: 0.5 mL.
- Hepatitis B immune globulin (HBIG) Intramuscular, Dose: 0.5 mL
- Syringes with 5/8" (22-25 gauge) needles

COMPETENCY REQUIRED: Current CPR certification¹

PROCEDURES:

<p>Vaccination of newborns at birth <i>If mother is HBsAg-positive:</i></p> <ol style="list-style-type: none"> 1. Newborns born to mothers who are HBsAg-positive must receive hepatitis B immune globulin (HBIG) and hepatitis B vaccine within 12 hours of birth. 2. For newborns weighing less than 2,000 grams, the initial dose of vaccine does not count toward the three dose vaccine series.
<p><i>If mother has unknown HBsAg status:</i></p> <ol style="list-style-type: none"> 3. Newborns born to mothers whose HBsAg status is unknown must receive hepatitis B vaccine within 12 hours of birth. 4. The mother must have blood drawn as soon as possible to determine her HBsAg status. 5. If the mother is found to be HBsAg-positive the newborn must receive HBIG as soon as possible, but no later than seven days after birth. 6. Because of the potentially decreased immunogenicity of vaccine in newborns weighing less than 2000g, these newborns must receive both hepatitis B vaccine and HBIG if the mother's HBsAg status cannot be determined \leq 12 hours of birth.²

For HBsAg positive mother upon admission to labor and delivery

1. Examine a copy of the original laboratory report of the pregnant woman's hepatitis B surface antigen (HBsAg) test result to verify that the correct test was performed and to verify that the testing date was during this pregnancy and not a previous one.

- a. Place a copy of the original HBsAg laboratory report into the pregnant woman's medical record and the newborn's medical record.
 - b. HBsAg test results, including date, must be in **both** mother and newborn medical records.³
2. Provide the mother with a Vaccine Information Statement (VIS) upon admission to labor and deliverable or before vaccine administration and ensure the VIS date is accurate.⁴
 3. Obtain written consent for vaccination from the mother upon admission to the hospital preferably before the mother enters the delivery room.
 4. Obtain the name, address, and phone number of the newborn's primary care provider.
 - a. Notify the pediatric provider of the mother's test result
 - b. Obtain an order for HBIG⁵
 - c. There is little benefit in giving HBIG if more than 7 days have elapsed since birth
 5. Provide counsel to the mother. Tell her the following:
 - a. That she may breast-feed her newborn upon delivery, even before hepatitis B vaccine and HBIG are given
 - b. That it is critical for her newborn to complete the full hepatitis B vaccine series on the recommended schedule
 - c. That after completion of at least 3 doses of the hepatitis B vaccine series, blood will need to be drawn from the newborn at 9 months of age (usually done at a well-child visit) to determine if the newborn developed a protective immune response to vaccination or needs additional management
 - d. About modes of hepatitis B virus (HBV) transmission and the need for testing and vaccination of susceptible household, sexual, and needle-sharing contacts
 - e. That she needs to have a medical evaluation for chronic hepatitis B, including an assessment of whether she is eligible for antiviral treatment if not already done
 6. In accordance with NYSPHL 2500-e, if the mother refuses vaccination of the newborn after counseling, then contact Child Protective Services (CPS) and the county health department where the mother resides as soon as possible. Post exposure prophylaxis is significantly reduced the longer vaccine administration is delayed.

For newborn of HBsAg positive mother

1. Administer single-antigen hepatitis B vaccine (0.5 mL, IM) preferably in the delivery room and within 12 hours of birth.
2. Per medical order, administer HBIG (0.5mL, IM) at separate site from vaccine within 12 hours of birth preferably in the delivery room.⁵
3. Document the HBIG and hepatitis B vaccine doses in the newborn's medical record and include date, time, site of administration, and manufacturer lot number.
4. Give the mother an immunization record card that includes the hepatitis B vaccination and HBIG dates.

- a. Explain the need for the complete hepatitis B vaccine series to protect her newborn.
 - b. Remind her to bring the card with her each time her child sees a provider.
5. Notify the county health department where the mother resides within 24 hours of the newborn's birth and provide the date and time of administration of HBIG and hepatitis B vaccine doses.
 6. Indicate the mother's HBsAg status on the NYSDOH Newborn Screening Blood Collection Form as Pos. (positive).
 7. Indicate the HBV vaccine administration on the Statewide Perinatal Data System (SPDS).⁶
 8. In accordance with NYSPHL 2500-e, if the mother refuses vaccination of the newborn after counseling, then CPS and the county health department where the mother resides must be contacted within 24 hours.

For mother with unknown HBsAg status upon admission to labor and delivery

1. NYSPHL 2500-e requires that when any woman who has not been tested for HBsAg during pregnancy or whose test result is not available upon time of admission
 - a. STAT test must be performed, with the date and time of blood collection recorded in both the maternal and newborn medical records.
 - b. Contact the laboratory to confirm receipt of blood sample and need for STAT results.
2. Provide the mother with a Vaccine Information Statement (VIS) upon admission to labor and deliverable or before vaccine administration and ensure the VIS date is accurate.⁴
3. Obtain written consent for vaccination from the mother upon admission to the hospital preferably before the mother enters the delivery room.
4. In accordance with NYSPHL 2500-e, if the mother refuses vaccination of the newborn after counseling and test results are not available within 24-48 hours, then CPS and the county health department where the mother resides must be contacted. *Forty-eight (48) hours is the maximum time for vaccination of a newborn when the mother's test results are pending.* Post exposure prophylaxis is significantly reduced the longer vaccine administration is delayed.

For newborn of mother with unknown HBsAg status

1. If the mother's HBsAg test result is not available, administer single-antigen hepatitis B vaccine (0.5mL, IM) within 12 hours of birth. *Do not wait for test results before giving vaccine.*
2. Give the mother an immunization record card that includes the hepatitis B vaccination date.
 - a. Explain the need for the complete hepatitis B vaccine series to protect her newborn.
 - b. Remind her to bring the card with her each time her child sees a provider.

3. If the mother's result remains unknown at the time of newborn discharge:
 - a. Notify the parents, the newborn's primary care provider and the county health department where the mother resides that the result is pending since there is little benefit in giving HBIG if more than 7 days have elapsed since birth
 - b. The only exception is when the newborn weighs less than 2,000g. In this case, the newborn must be given both hepatitis B vaccine and HBIG within 12 hours of birth if the mother's HBsAg status cannot be determined
 - c. Document contact information for the parents (e.g., addresses, telephone numbers, and emergency contacts) in case further treatment is needed
4. If the mother's test result comes back positive, obtain order and administer HBIG (0.5mL, IM) to the newborn immediately, but definitely within seven days of birth.⁵ (See #3a above.)
5. Indicate the mother's HBsAg status on the NYSDOH Newborn Screening Blood Collection Form as either Pos. (positive) or Neg. (negative). Indicate status as Unk. (unknown) only if mother's test results are not available on newborn discharge.
6. Indicate the hepatitis B vaccine administration and HBIG if given on the Statewide Perinatal Data System (SPDS).⁶

REFERENCES

¹ NYS Nurse Practice Act (Education Law Article 139 §6909) authorizes the administration of non-patient specific orders for certain immunizations, anti-anaphylactic agents, and HIV and tuberculosis tests across all service delivery systems. A registered professional nurse may execute a non-patient specific regimen prescribed or ordered by a licensed physician or certified nurse practitioner, pursuant to regulations promulgated by the Commissioner of Education. www.op.nysed.gov/prof/nurse/immunguide.htm

² NYSPHL 2500-e states if an infant of HBsAg positive mother is medically unstable, the infant's health care provider may defer vaccine and HBIG until the infant is medically stable.

³ NYSPHL 2500-e mandates that all newborns born to HBsAg-positive women are treated with hepatitis B vaccine and HBIG within 12 hours of birth and with the complete vaccine series. Title 10 Subpart 69-3.3 requires health care facilities to screen and report HBsAg status for all pregnant women, record tests results in newborn medical records, respond to inquiries from local health officers, and provide written documents to accompany newborns transferring between facilities.

⁴ Federal law requires that you give parents a Hepatitis B Vaccine Information Statement (VIS) before vaccine administration. To obtain a VIS, download it from the IAC website at www.immunize.org/vis or call your county health department.

⁵ The NYS Nurse Practice Act (Education Law Article 139 §6909) does not authorize the administration of HBIG without a patient specific order.

⁶ This information is automatically transferred to the NYS Immunization Information System (NYSIIS) as required by NYSPHL 2168.

Authorizing Physician or Nurse Practitioner

From ___/___/___ to ___/___/___
Effective Dates