



## Perinatal Hepatitis B Prevention Program Guidelines for District Offices/State Health Centers and County/Municipal Health Departments

[Guidelines for District Offices and SHCs.pdf \(pa.gov\)](#)

### I. Purpose:

The purpose of the Perinatal Hepatitis B Prevention Program is to ensure to identification and treatment of infants born to hepatitis B-positive women to prevent perinatally acquired infection.

### II. Maternal Perinatal Hepatitis B Screening:

Pennsylvania requires all pregnant women to be screened for Hepatitis B surface antigen (HBsAg) on the first prenatal visit, or within 15 days, but no later than the time of delivery, as stated in Pennsylvania Code §27.99 (a). Screening is based on recommendations published by Advisory Committee on Immunization Practices (ACIP) and CDC in 2018 in *Prevention of Hepatitis B Virus Infection in the United States: Recommendations of the Advisory Committee on Immunization Practices*.

Note that some providers may screen pregnant women using lab tests other than HBsAg, such as nucleic acid or HBeAg. For this reason, any test indicative current Hepatitis B infection, whether acute or chronic, should be investigated. Serological markers of current Hepatitis B infection include, but not limited to:

- positive HBsAg or
- positive HBeAg or
- positive Hepatitis B nucleic acid test (HBV DNA)

Providers are required to report cases of infection under Pennsylvania Code §27.21a and laboratory results consistent with infection must be reported under to Pennsylvania Code §27.22. If a public health investigator determines that either: 1) a provider has not performed Hepatitis B screening of a pregnant woman, regardless of testing during prior pregnancies; or 2) that a laboratory has not reported a positive laboratory test, reach out to provider, and investigate what happened. If the provider did not perform a Hepatitis B screening of a pregnant woman, send the provider a copy of “Guidelines for Medical Care Providers” and notify the Perinatal Hepatitis B Coordinator. If the laboratory did not report a positive laboratory test, notify the Perinatal Hepatitis B Coordinator. If a laboratory has failed to report a positive lab test for hepatitis B, the Perinatal Hepatitis B Coordinator will notify Bureau of Epidemiology to address with the clinical laboratory.

### III. Procedure for Follow-up of Maternal Hepatitis B Screening:

- A. If the District/State Health Centers or County Municipal Health Departments are notified of any test indicative of current Hepatitis B infection, acute or chronic, (i.e., positive HBsAg, HBeAg, nucleic acid test for HBV DNA, total hepatitis B core antibody (anti-HBc), or IgM antibody to hepatitis B core antigen (IgM anti-HBc) result in a woman of child-bearing age (12-50 years) via the Pennsylvania National Electronic Disease Surveillance System (PA-NEDSS), laboratory, physician's office, or any other means, these steps are to be followed:
- B. PA-NEDSS instructions for new positive hepatitis B labs:
  1. Follow Epi Manual for investigation guidance and linkage of labs to new or existing investigation.
    - a. Be sure to "open" the investigation and leave open until pregnancy status is determined. If pregnant, leave "open" until delivery.
    - b. Notify assigned staff if other than self because if new labs are linked to case older than 4 months it will not show in their PA-NEDSS inbox or any searches.
  2. Document any contact via phone/letter with parent/guardian or provider in PA-NEDSS in notes section. This information may be requested by CDC.
- C. Contact the physician who ordered the laboratory test to determine if Hepatitis B testing was ordered due to current or recent pregnancy. Document this contact in PA-NEDSS to include name of practice, person with who you spoke and details of call/email. If pregnant:
  1. Confirm the Hepatitis B test results, date of testing, and collect all other current Hepatitis B laboratory results.
  2. Obtain relevant clinical information (i.e., symptoms of viral hepatitis).
  3. Obtain expected date of delivery and expected delivery hospital.
    - a. Put pregnancy and due date in Core Data section in PA-NEDSS.
  4. Advise provider of the recommendation to order an HBV DNA test during first trimester and again at 26-28 weeks. The HBV DNA test at 26-28 weeks will guide the use of maternal antiviral therapy during pregnancy for the prevention of perinatal HBV transmission. AASLD suggests maternal antiviral therapy at 28-32 weeks until birth when the maternal HBV DNA is >200,000 IU/mL.
  5. Verify the woman has been notified of her laboratory findings.
  6. Request that a copy of all current Hepatitis B test results be sent to delivery hospital.
  7. \*\*\*Sent Physician OB letter.
  8. If physician that ordered the laboratory test does not know if patient is pregnant, contact patient. Attempt contact with patient three times via combination of phone and letter (urgent health letter).
- D. Contact the patient to:
  1. Provide her with information and education about hepatitis B, including the importance of immunoprophylaxis for her infant, ways to prevent transmission,

perinatal concerns (e.g., infants born to HBsAg positive mothers may be breastfed), substance abuse treatment (if appropriate), and the need for the mother to receive evaluation and medical management for chronic hepatitis B. Provide both verbal and written information, utilizing a translator if necessary. \*\*\*Send “Congratulations Pregnant” letter and Perinatal Hepatitis B education, See CDC website for most current Hepatitis B education. Hepatitis B education in multiple languages can be obtained at <https://medlineplus.gov/languages/hepatitisb.html>

2. Stress the importance of informing her primary care providers, the birthing hospital, and her intended pediatrician about her hepatitis B status.
  3. Obtain the names of any household and sexual contacts. They are eligible for Hepatitis B screening and vaccination from the DOH (see section V for instructions). This information must be entered on the Perinatal Hepatitis B Case and Contact Report Form and forwarded to the designated contact.
- E. \*\*\*Email letter or call hospital to notify Nurse Manager or Infection Control of mother’s hepatitis B status and her due date.
1. Document details in PA-NEDSS.
  2. Remind the hospital to notify you of birth within 5 days of delivery.
- F. Documentation
1. Initiate a Pennsylvania Department of Health (DOH) “Perinatal Hepatitis B Case and Contact Report for DOH,” [Perinatal Hepatitis B Program](#), by completing all fields as the information becomes available. Complete an electronic copy of this form and send by secure email the initial report and all subsequent updates to Perinatal Hepatitis B Coordinator where they will be entered in the Perinatal Hepatitis B Database.  
Email to:  
Perinatal Hepatitis Program Nurse Coordinator  
PA Department of Health, Division of Immunizations  
Health & Welfare Building, Room 1026  
625 Forster St., Harrisburg, PA 17120  
Phone: 717-787-5681 Fax: 717-214-7223
  2. Ensure the client has a record in PA-NEDSS with all information completed. Classify maternal Hepatitis B case status based on laboratory and clinical findings. See:
    - Acute Hepatitis B: [Hepatitis B, Acute 2012 Case Definition | CDC](#)
    - Chronic Hepatitis B: [Hepatitis B, Chronic 2012 Case Definition | CDC](#)
  3. Also refer to “Handling Perinatal Hepatitis B Investigations in PA-NEDSS.”
  4. Document any contact via phone/letter with parent/guardian or provider in NEDSS in notes section. This information may be requested by CDC.

#### **IV. Procedure for Follow-up of Infants Born to Hepatitis B-Infected Mothers**

- A. Hospitals should notify SHC/County/Municipal Health Department within 5 days of birth via report titled “Perinatal Hep B Case Report for Hospitals,” [Perinatal Hepatitis](#)

- [B Program](#), or put baby in NEDSS as “Infant Born to HBsAg Positive Mother.” If hospital fails to notify you within 5 days of EDC, reach out to them. If HBIG or HBV is not given, notify Perinatal Hepatitis B Nurse Coordinator immediately. Also, notify Perinatal Hepatitis B Nurse Coordinator if hospital fails to notify you within 5 days of birth.
- B. After the client has delivered, verify the dates of Hepatitis B Immune Globulin (HBIG) and hepatitis B vaccine administration to the infant with the hospital or primary care physician. Enter the information on the infant in the case record and start a separate record in PA-NEDSS for the infant for follow-up. Include the infant’s birth weight, insurance information and pediatrician contact information on the case report. Enter HBIG and hepatitis B vaccine in Pennsylvania Immunization Electronic Registry System (PIERS) and PA-NEDSS. Send the Case and Contact Report with birth information to Perinatal Hepatitis B Consultant. Close mother’s PA-NEDSS case. \*\*\*Send mom “Congratulation’s 2<sup>nd</sup> shot needed letter.”
  - C. Contact the infant’s primary care provider to notify them of the case and ensure that the follow-up hepatitis B vaccine doses are administered according to the Advisory Committee on Immunization Practices (ACIP) guidelines for hepatitis B high-risk infants. \*\*\*Send baby’s Provider letter informing them of case. \*\*\*Also, send reminder letters to Provider within 1 month of vaccination due dates for 2<sup>nd</sup>, 3<sup>rd</sup> and possibly 4<sup>th</sup> if birth weight was less than 2000 grams. See “Guidelines for Medical Care Providers” for hepatitis B vaccine schedule. [Guidelines for Medical Providers.pdf \(pa.gov\)](#)
  - D. Contact the parent/guardian prior to the second and third hepatitis B immunization (and 4<sup>th</sup> if infant was preterm, in which case the birth dose does not count towards the series) to remind them of upcoming appointments. Confirm address and telephone information during each contact. \*\*\*Send reminder letters to parent/guardian within 1 month of the vaccination due date.
  - E. Verify the date of administration of each dose of hepatitis B vaccine with the pediatric provider or the Pennsylvania Immunization Electronic Registry System (PIERS). As updates are discovered they are to be forwarded to Perinatal Hepatitis B Coordinator for entry into the Perinatal Hepatitis B Database and update PIERS (if not already there) and PA-NEDSS. If you need access to Philadelphia DOH Immunizations System (<http://vaccines.phila.gov>).
  - F. After the infant has completed the hepatitis B vaccination series, contact parent/guardian, and remind them of the need for post-vaccination testing when the infant has reached the age of 9 months and 1 month after last dose. Explain the importance of follow up testing and what the results will show. If immunity has not been obtained, a single dose of Hep B vaccine should be given as soon as possible. Serology testing should be obtained 1-2 months after the completion of the repeated dose. \*\*\*Send parent/guardian “Completion of Hep B” letter for completion of serology. \*\*\*Also, contact provider and send “Pediatrician Serology Letter” to

inform them that HBsAg AND anti-HBs (quantitative) will need done 9 months with at least 1 month after last Hepatitis B vaccine.

- G. Verify anti-HBs and HBsAg test results of infants with the pediatric provider and discuss follow-up of the infant based on these results.
- To meet ACIP recommendations, HBsAg negative infants with anti-HBs levels of  $\geq 10$  mIU/mL are protected and need no further medical management.
    - If provider did “qualitative” anti-HBs, contact the lab to determine if the results are  $\geq 10$  mIU/mL. If  $\geq 10$  mIU/mL the infant is protected. If  $< 10$  mIU/mL or lab doesn’t know then repeat quantitative anti-HBs test.
  - HBsAg negative infants with anti-HBs levels of  $< 10$  mIU/mL or non-reactive results should be revaccinated with a single dose of Hep B vaccine and receive post-vaccination serologic testing 1-2 months later. Infants who’s anti-HBs remains  $< 10$  mIU/mL following single dose revaccination should receive two additional doses of Hep B vaccine to complete the second series, followed by post-vaccination serologic testing 1-2 months after the final dose.
  - Based on clinical circumstances or family preference, HBsAg-negative infants with anti-HBs  $< 10$  mIU/ml may instead be revaccinated with a second, complete 3-dose series, followed by post-vaccination serologic testing performed 1-2 months after the final dose of vaccine.
  - Infants who are HBsAg positive should be referred for medical evaluation and management of chronic hepatitis B.
- H. Record vaccination dates and results of serologic/post-vaccination testing for the infant on the Data on Newborn section of “Perinatal Hepatitis B Case and Contact Report for DOH,” [Perinatal Hepatitis B Program](#), in PA-NEDSS, and vaccinations in PIERS and provide updates to the Perinatal Hepatitis B Coordinator.
- I. Classify infant’s investigation in PA-NEDSS, based on the Hepatitis B, Perinatal Infection case definition: [Hepatitis B, Perinatal Infection 2017 Case Definition | CDC](#). If the infant has been found to have immunity, the case in PA-NEDSS can be closed and the case in the Perinatal Hepatitis B database will be closed by the DOH Perinatal Hepatitis B Coordinator.
- J. Unless you are waiting for a due date, follow up with parent/guardian, provider, and PIERS minimum of monthly to ensure Hepatitis B doses and serology tests were administered and documented in PA-NEDSS.

**V. Procedure for Follow-up of Household and Sexual Contacts of Hepatitis B-infected Women**

- A. Sexual partners, household contacts, and needle-sharing contacts of HBsAg-positive persons should be identified. Unvaccinated past and present sex partners, household contacts, and needle-sharing contacts should be tested for HBsAg and anti-HBc

and/or anti-HBs. They should also receive the first dose of hepatitis B vaccine as soon as a blood sample for serologic testing has been collected. Susceptible persons should complete the vaccine series using an age-appropriate vaccine dose and schedule.

Those who have not been vaccinated fully should complete the vaccine series.

Contacts determined to be HBsAg-positive should be referred for medical care.

- B. Complete the Data on Contacts section of the “Perinatal Hepatitis B Case and Contact Report for DOH,” [Perinatal Hepatitis B Program](#), and forward the information to the DOH Perinatal Hepatitis B Coordinator.

#### **VI. Procedure for Follow-up of Moms Not Tested During Pregnancy for Hepatitis B or Refused Testing**

- A. Offer mom HBsAg test through DOH, which is done through CDD labs.
  1. See document “Hep B Standing Orders”
  2. See document “Hepatitis B Blood Work Consent”
  3. See document “CDD Hepatitis B Testing for Close Contacts or Untested Mothers or PVST for children”
- B. If mom refuses HBsAg test AND is high risk then treat as a positive case and follow above instructions.

#### **VII. Procedure for Follow-up of “Lost to Follow” Cases or Non-Responders**

- A. If provider does not have new information, contact insurance company.
- B. See document “Patients Lost to Follow.”
- C. Home visit may be warranted.

#### **VIII. Procedure for refusals of HBIG/HBVs or serology of infants born to positive hepatitis B mothers**

- A. Ask provider what “their” policy is in regards of how to deal with parents that refuse treatment for the child which may result in harm.
- B. If they have questions, advise them to contact their legal department for guidance.
- C. Be sure to explain that the child has a 25% chance of premature death from cirrhosis or liver cancer if contracted at this age.
- D. For DOH/Municipal/County staff, “Mandated Reporters” are “a person licensed or certified to practice in any health-related field under the jurisdiction of the Department of State.” Refusals of HBIG/HBVs or serology of infants born to positive hepatitis B mothers may be considered medical neglect. A child does not need to be seen by the mandated reporter for a report to be made.
  1. If report is made to ChildLine, notify Perinatal Hepatitis B Coordinator.

#### **IX. Procedure if Provider Fails to Follow Recommended Vaccine or Serology Schedule(s)**

- A. Speak directly with Office Manager and/or Provider and explain current guidelines and share of copy of “Guidelines for Medical Care Providers.” [Guidelines for Medical Providers.pdf \(pa.gov\)](#)
- B. Explain that by delaying recommended vaccines or serology that they’re delaying “care and services,” especially if the child requires follow up.
- C. If provider continues to not follow guidelines notify Perinatal Hep B Coordinator.

**X. Procedure for Case Transfer Out of State**

- A. Accurate contact information must be obtained to include new pediatrician.
  - 1. Other states are permitted to refuse the transfer if incomplete information.
- B. Case should be up to date unless non-compliant but our monthly follow up should be completed and documented in PA-NEDSS.
- C. Change address in PA-NEDSS and make note that sent to Perinatal Hepatitis B Coordinator to complete transfer and close case in PA-NEDSS.
- D. Send all new contact information to Perinatal Hepatitis B Coordinator.

**XI. Procedure for Miscarriage or Termination of Pregnancy**

- A. Case is still counted in the Perinatal Hepatitis B Database.
- B. If you are informed pregnancy was terminated, fill out Case and Contact report and email to Perinatal Hepatitis B Coordinator.
  - 1. Check “pregnancy terminated” on bottom of Case and Contact Report.
  - 2. Document date of termination under DOB.
  - 3. It’s acceptable to guesstimate EDC if not determined yet.
- C. Refer to “Handling Perinatal Hepatitis B Investigations in PA-NEDSS” to open new investigation in PA-NEDSS and case classification.
  - 1. Document in notes of miscarriage and put EDC and outcome in Core Data.
  - 2. Close case in PA-NEDSS.

**XII. Quick Reference Letter Guide\*\*\***

- A. Congratulations pregnant with Perinatal Hepatitis B education
- B. Letter to OB
- C. Letter to hospital alerting them of mother coming in for delivery with due date
- D. Letter to baby’s provider alerting them of case
- E. Reminder letter to parent/guardian within month to make appointment for 2<sup>nd</sup> HBV
- F. Reminder letter to provider within month of 2<sup>nd</sup> HBV due date
- G. Reminder letter to parent/guardian within month to make appointment for 3<sup>rd</sup> HBV and for 4<sup>th</sup> if necessary
- H. Reminder letter to provider within month of 3<sup>rd</sup> HBV due date and for 4<sup>th</sup> if necessary
- I. Letter to parent/guardian after final vaccine that serology is due 9 mths old
  - J. Letter to provider after final vaccine for serology (include HBsAg and anti-HBs) at 9 months old

Referenced documents without an attached link, can be found on SHC SharePoint “Standard Letters & Forms” site or contact Perinatal Hepatitis B Coordinator.