

# Hepatitis B and Perinatal Hepatitis B Prevention Program Webinar

2024 Changes and Updates

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Ayiasha Pratt, MPH

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# Meeting Agenda

- Hepatitis B Review
  - Transmission
  - Serology
- Recommended Labs and response to incomplete labs
- Changes in Hepatitis B Subgroup Definitions
- Perinatal Hepatitis B Review
  - PHPBB Review
- Regulations and Research Resources
- Proper Perinatal Hep B Surveillance
- Changes in DSQ w/ demonstration
- Lost to Follow-up Handling and Prevention
- Questions and Comments at the end

# Hepatitis B Disease Review

- Caused by hepatitis B virus (HBV)
- Virus can live in the environment for ~7 days
- 9th leading cause of death worldwide
- Primary cause of liver cancer and second leading cause for liver transplant
- Incubation period: 90 days (60-150 days)
- Common symptoms: anorexia, nausea, malaise, fever, vomiting, abdominal pain, dark urine, jaundice
- Likelihood of developing symptoms is age related
  - 1 % of infants
  - 5-15% of children 1-5 years
  - 30-50% of > 5 year olds
  - 50-70% of adults
- No specific treatment is available for acute hepatitis B
- Antiretroviral drugs are approved to treat chronic hepatitis B

# Transmission

- HBV is most commonly spread by coming in contact with blood or body fluids of an infected person
  - Sexual contact
  - Perinatal transmission-mother to child at birth
  - Injection drug users, shared needles, syringes, or drug preparation equipment
  - Contact with blood or open sores of infected person
  - Bites from an infected person
  - Sharing contaminated personal hygiene items, razors, toothbrushes
  - Sharing contaminated objects that pierce the skin, tattoo and body-piercing and acupuncture equipment
  - Needlesticks or other sharp instrument exposures

# Hepatitis B Serology

- **Hepatitis B surface antigen (HBsAg):**
  - A protein on the surface of hepatitis B virus
  - 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.
- **Hepatitis B surface antibody (HBsAb or anti-HBs):**
  - Generally interpreted as indicating recovery and immunity from hepatitis B virus infection
  - Anti-HBs also develop in a person who has been successfully vaccinated against hepatitis B

# Hepatitis B Serology continued

- **Hepatitis B e-Antigen (HBeAg):**
  - This is a viral protein that is secreted by hepatitis B infected cells
  - Marker of active viral disease and a patient's degree of infectiousness
  - Positive result indicates the person has high levels of virus and greater infectiousness
  - Negative result indicates low to zero levels of virus in the blood and a person is considered less infectious
- **Hepatitis B e-Antibody (HBeAb or anti-HBe):**
  - Antibody is made in response to the e-antigen
  - Detected in patients who have recovered from hepatitis B infections as well as those who are chronically infected (with lower infectivity)

# Hepatitis B Serology continued

- **Total hepatitis B core antibody (anti-HBc):**
  - Total includes IgM anti-HBc and IgG anti-HBc
  - Earliest antibody to develop in response to acute hepatitis B virus (HBV) infection
  - Appears at the onset of symptoms in acute hepatitis B and persists for life
  - Indicates previous or ongoing infection with hepatitis B virus in an undefined timeframe
  - Predominantly IgM anti-HBc at about 6 to 8 weeks after infection
  - After about 6 months the total anti-HBc mainly consists of IgG anti-HBc.
- **IgM antibody to hepatitis B core antigen (IgM anti-HBc):**
  - Positivity indicates recent infection with hepatitis B virus (<6 mos) However, with chronic HBV infection, the IgM anti-HBc can remain detectable at very low levels, even years after infection

# Hepatitis B Serology continued

- **HBV DNA:**

- Measure of circulating DNA
- Marker of active HBV replication
- HBV DNA levels are detectable by 30 days following infection; generally reach a peak at the time of acute hepatitis
- Used to assess and monitor treatment of persons chronically infected

- **Liver Function Tests:**

- Alanine Aminotransferase (ALT/SGPT)
- Aspartate Aminotransferase (AST/SGOT)
- Bilirubin, Total and Direct, Serum



# Response for Incomplete Lab Results

- For Pregnant Women
  - Providers should always request a QUALITATIVE HBsAg with any Hep B Panel
  - Most accurate test to determine infection
  - Ordering Anti-HBc, IgM anti-HBc, HBV DNA, HBeAg, or HBsAb individually is NOT recommended
- For Perinatal Case
  - Providers should ONLY be requesting QUALITATIVE HBsAg and QUANTITATIVE HBsAb
  - Any other test may create inaccurate results
- LHD should be prepared to request additional lab results (may be available) or additional testing, if these are not performed correctly

# Hepatitis B Case Definitions

- Recently changed/updated by CSTE in 2024
- Can be classified Acute or Chronic
  - Both classifications can be **Probable** or **Confirmed**
- These subgroups are separate from the program involving the specialized subgroup, PERINATAL (infants only)
- Definitions are specifically for persons >24 months of age OR <24 months of age, who did NOT contract the virus through mother to child transmission (perinatal)
- Patients can be symptomatic or asymptomatic

# Acute Hepatitis B (2024)

- In an acute case, patient must **NOT** be known to have a history of acute or chronic Hepatitis B
- All acute cases must have ONE of the following Clinical Criteria:
  - Provider report of jaundice
  - Peak elevated total bilirubin levels  $\geq 3.0$  mg/dL
  - Peak elevated serum alanine aminotransferase (ALT)  $> 200$  IU/L
- **Probable**
  - Meets Clinical Criteria PLUS Detection Anti-HBc IgM WITH a negative/not done HBsAg/HBeAg/HBV DNA
- **Confirmed (each bullet is independent of the others)**
  - Detection Anti-HBc IgM AND detection of at least one of the following: HBsAg/HBeAg/HBV DNA
  - Detection of HBsAg, HBeAg, or NAT for HBV DNA within 12 months (365 days) of a negative HBsAg test result
  - Meets the Clinical Criteria PLUS detection of at least one of the following: HBsAg/HBV DNA

# Chronic Hepatitis B (2024)

- **Probable**

- One detectable result for HBsAg **OR** HBeAg AND Negative/Not Done Anti-HBc IgM

- **Confirmed**

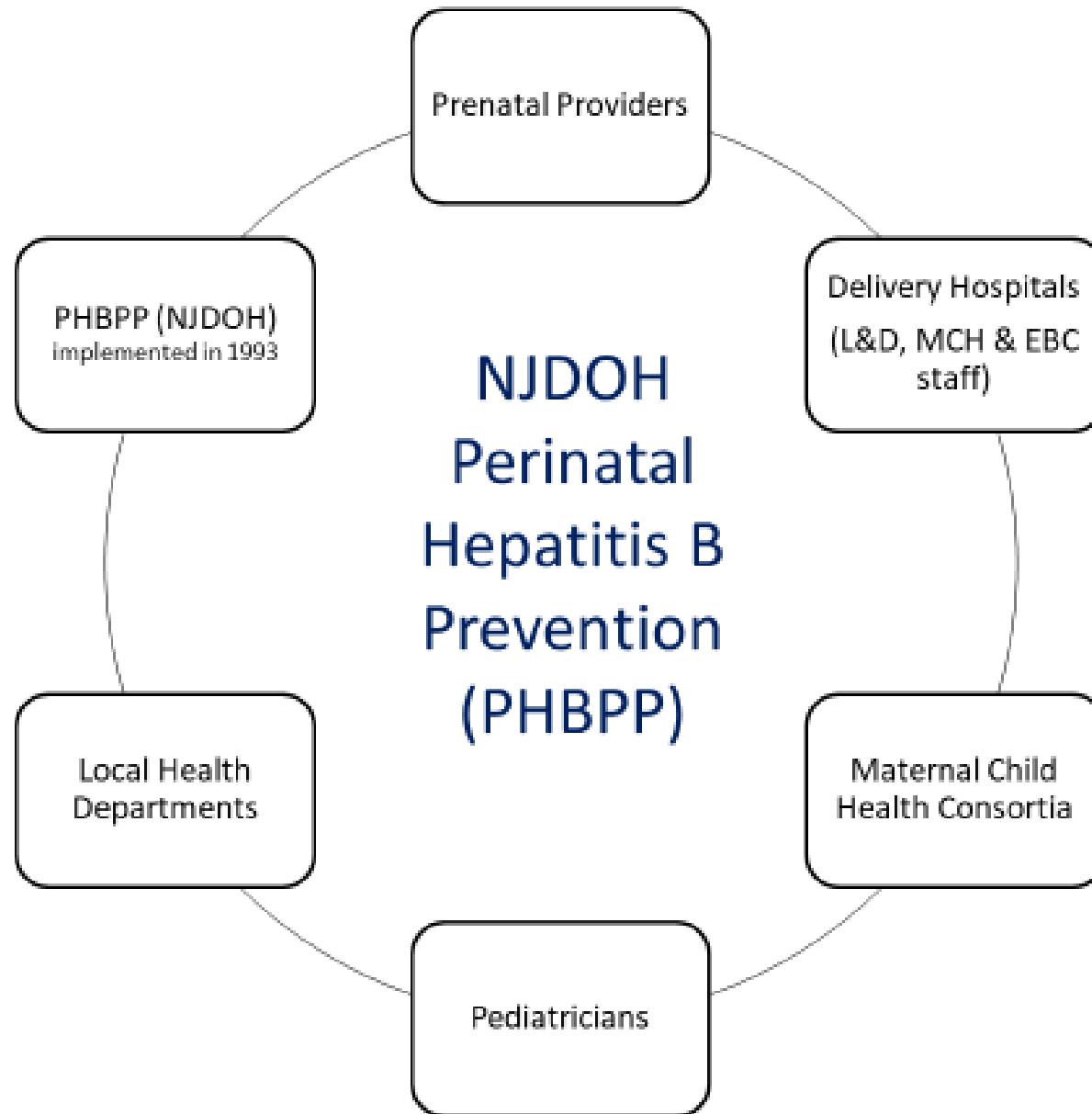
- Detection of hepatitis B surface antigen (HBsAg) in two clinical specimens taken >6 months apart
- Detection of hepatitis B e antigen (HBeAg) in two clinical specimens taken >6 months apart
- Detection of [HBsAg OR HBeAg] AND detection of total antibody to hepatitis B core antigen (anti-HBc)
- Detection of HBsAg AND detection of HBeAg
- Detection of NAT for HBV DNA (including qualitative, quantitative, or genotype testing)

# Perinatal Hepatitis B Disease Review

- Transmission of Hepatitis B from mother to infant at birth
- Without postexposure prophylaxis (Hep B vaccine and Hepatitis B immunoglobulin (HBIG) at birth)
  - 85% of infants will become infected if their mother is positive for both **HBsAg** and **HBeAg**
  - 30% of infants will become infected if their mother is positive for **HBsAg**
- With postexposure prophylaxis (Hep B vaccine and HBIG at birth), followed by completion of the HepB vaccine series, 0.7%–1.1% of infants develop infection.
- As many as 90% of infant HBV infections (perinatal) will progress to chronic infection.

# Perinatal Hepatitis B Prevention Program (PHBPP)

- The Perinatal Hepatitis B Prevention program (PHBPP) focuses on preventing the spread of hepatitis B virus from infected mothers to newborn infants by ensuring that infants who are exposed to Hepatitis B, at birth, are identified and given the proper vaccinations and post serology testing, which are then reported to DOH.
  - Identify pregnant women who are HBV-infected
  - Identify contacts and ensure testing/vaccination
  - Ensure referral of chronically infected for medical care
  - Ensure infants born to HBV-infected women
    - » Receive HBIG and hepatitis B vaccine with 12 hours of birth
    - » Complete the hepatitis B vaccine series on schedule
    - » Complete post-vaccine serology
  - Improve administration of the universal HBV birth dose prior to hospital discharge
- NJ is a **decentralized** state: primary surveillance including case management and education is performed by the LHD and overseen by the investigators at the state level
- Preventing the infection and spread of Perinatal Hepatitis B is a collaborative effort



# NJ Administrative Codes

## ***N.J.A.C. § 8:43G-19.2 (Hospital Licensing)***

- All pregnant women admitted to the hospital with unknown or undocumented hepatitis-B surface antigen (HBsAg) assay results shall be immediately screened for the hepatitis-B virus using the HBsAg test or other standardized hepatitis-B tests. Test results should be available within 24 hours but no later than 48 hours

## ***N.J.A.C. § 8:57-1.6 (Communicable Diseases)***

- Confirmed cases due to hepatitis B, including positive hepatitis B surface antigen test in a pregnant woman, should be reported to Local Health Department within 24 hrs of diagnosis

## ***N.J.A.C. § 8:57-3 (New Jersey Immunization Information Network – NJIIS)***

- A healthcare provider shall report to the NJIIS vaccines administered to children under seven years of age within 30 days of administration. It is the responsibility of the provider – not the entity in which he/she operates to ensure that the data are reported to NJIIS.



# The Importance of These Regulations

- Please understand that these regulations mean that this program is not optional
- You have the right to seek medical information from BOTH the parents and/or physician
- A physician make request a fax to provide your identity, but overall, we are HIPAA EXEMPT because we use this information for “public health activities and purposes.”
- NJDOH is prepared to step in if a physician is not cooperating with recommendations

# Electronic Birth Certificate (EBC)

- Used by all NJ Birthing Hospitals
- Required questions:
  - Mother's HBsAg status
  - HBV Vaccine administration date, lot number
  - HBIG administration date, lot number
- Allows real-time search for women who have unknown pregnancy status
  - Can search for women who were not found by LHD's to see if they gave birth since positive result
  - Helping to address missing births to positive mothers as estimated by CDC
- Provides data required for PHBPP report
  - Birth weight
  - Insurance information

# New Jersey Immunization Information System (NJIS)

- Usage supported by regulation *N.J.A.C. § 8:57-3 (New Jersey Immunization Information Network – NJIS)*
- All providers must report NJIS vaccines to the system for children under seven years of age within 30 days of administering the vaccine
- Interfaces with EBC
  - First dose of hepatitis B vaccine (when given) generates record for child in the registry
  - HBIG is also recorded for children who receive a dose in the hospital
- Should be updated by the health care provider (and future providers) throughout the child's lifespan
- The system is also useful for adult patients (including providers and staff)
- Proven to be immensely useful during Covid-19 vaccination process

# Surveillance of Perinatal Cases

- Pregnancy Status is **required** for all Hep B positive women between the ages of 15-55 years
  - Record status (positive or negative) in the designated section in CDRSS
  - If pregnant, record estimated birth date/delivery hospital in CDRSS
- LHD/Provider should provide education to pregnant persons about the importance of the child receiving HBIG/Hep B #1 within 12 hours of birth
  - Inform patient that they will be contacted after estimated birth date to collect additional information about child and child's provider's information
- After birth, create CDRSS case for child and LINK to the mother's case
  - Complete the **Perinatal Hepatitis B Required Questions**
- LHD should notify child's provider of child's participation in PHBPP and the child's vaccine/lab requirements
- Routinely check child's records for additional vaccinations received, according to the ACIP recommended schedule, and update CDRSS until vaccine series is complete
- 1-2 months after the last Hep B vaccine dose, **post vaccine serology testing (PVST)** with appropriate labs is necessary to ensure that no infection developed and immunity was acquired
  - Send a reminder to patient/provider (preferably a phone call) regarding the need for PVST after the final dose of vaccine
- Perinatal cases are monitored up to a 24-months, under the PHBPP, but the goal is to have the child fully vaccinated and tested by 1 year of age

# Investigate Cases Based on the Schedule

## CDC Recommended schedule for children with Hep B + Moms

- HBIG **AND** Hepatitis B Dose #1 within 12 hours of birth
  - For babies born weighing <2,000 grams, the initial dose of hepatitis B vaccine should still be administered as early as possible but should not be counted as part of the vaccine series.
- Hepatitis B Dose #2 given 4 weeks after dose #1
- Hepatitis B Dose #3 given 8 weeks after dose #2 and at least 16 weeks after dose #1
  - Minimum age for the final dose of HBV vaccine is 24 weeks
  - For babies born weighing <2,000 grams, there will need to be Hepatitis B Dose #4
- PVST should be given 9-12 months of age (minimum 1-2 months after the last vaccine)
- Staying on schedule is the best way to protect and ensure immunity

# Hep B Vaccine Schedule

**Table 1** Recommended Child and Adolescent Immunization Schedule for ages 18 years or younger  
United States, 2019

These recommendations must be read with the Notes that follow. For those who fall behind or start late, provide catch-up vaccination at the earliest opportunity as indicated by the green bars in Table 1. To determine minimum intervals between doses, see the catch-up schedule (Table 2). School entry and adolescent vaccine age groups are shaded in gray.

Vaccine	Birth	1 mo	2 mos	4 mos	6 mos	9 mos	12 mos	15 mos	18 mos	19-23 mos	2-3 yrs	4-6 yrs	7-10 yrs	11-12 yrs	13-15 yrs	16 yrs	17-18 yrs
Hepatitis B (HepB)	1 <sup>st</sup> dose	2 <sup>nd</sup> dose			← 3 <sup>rd</sup> dose →												

## Hepatitis B vaccine schedules for infants ≥2,000 g birthweight

Maternal HBsAg Status	Single-antigen vaccine dose	Single-antigen vaccine age indications	Single-antigen + combination vaccine† dose	Single-antigen + combination vaccine† age indications
Positive	1	Birth (≤12 hrs)	1	Birth (≤12 hrs)
	HBIG <sup>§</sup>	Birth (≤12 hrs)	HBIG <sup>§</sup>	Birth (≤12 hrs)
	2	1-2 mos	2	2 mos
	3	6 mos <sup>¶</sup>	3	4 mos
	N/A	N/A	4	6 mos <sup>¶</sup>

## Hepatitis B vaccine schedules for infants <2,000 g birthweight

Maternal HBsAg Status	Single-antigen vaccine dose	Single-antigen vaccine age indications	Single-antigen + combination vaccine† dose	Single-antigen + combination vaccine† age indications
Positive	1	Birth (≤12 hrs)	1	Birth (≤12 hrs)
	HBIG <sup>§</sup>	Birth (≤12 hrs)	HBIG <sup>§</sup>	Birth (≤12 hrs)
	2	1 mos	2	2 mos
	3	2-3 mos	3	4 mos
	4	6 mos <sup>¶</sup>	4	6 mos <sup>¶</sup>

# Completion of Postvaccination Serologic Testing (PVST)

- Done 1-2 months after final dose in the vaccine series but not earlier than 9 months of age and no later than 12 months of age
  - PVST includes: qualitative HBsAg and quantitative anti-HBs **\*NO OTHER TESTS ARE RECOMMENDED\***
  - HBsAg - and anti-HBs  $\geq 10$  mIU/mL are considered immune → case can be closed as Not A Case
  - HBsAg + are considered infected → call NJDOH if you receive these results
  - HBsAg - and anti-HBs  $< 10$  mIU/mL or negative → will require further follow up
- Children who do not respond to the first HBV series should be revaccinated based on the most current recommendations
  - Child can receive 1 additional dose and then be retested at 1-2 months after that dose.
  - If they still do not have immunity, they should complete the series with 2 more doses and be retested 1-2 months after the final dose
    - If these children remain nonimmune no further immunizations are necessary

# The NEW Disease Specific Questionnaire (DSQ)

- All perinatal cases have a tab labeled *Perinatal Hepatitis B Questions*
- In February we added *Perinatal Hepatitis B Required Questions* tab
  - Different/More Specific Questions
  - The answers align better with questions asked in the CDC Annual Report
- We will soon be removing the old tab in favor of the new DSQ

The screenshot displays a web-based form for 'Disease Information'. The form is organized into several sections, each with a dropdown arrow on the left. The 'Disease Information' section is currently expanded, showing fields for Disease (HEPATITIS B), Subgroup (PERINATAL), Illness Onset Date, Age at Case Creation (1 mos), Age at onset (1 mos), Case Status (NOT A CASE), Reason for Case Status, Date Reported to State or Local Health Department (02/28/2023), Report Status (DHSS APPROVED), Reason for Report Status, Household Size, Type of Insurance, No Follow-up/Investigation, and Incomplete Follow-up/Investigation. Below these fields are two checkboxes: 'Edit Disease Information' and 'Add Comment'. A 'Print' button is located at the bottom right of this section. Below the 'Disease Information' section are several other tabs, including 'Patient Personal Information', 'Addresses', 'Laboratory and Diagnostic Test Information', 'Comments', 'Outbreak Information', 'Clinical Status', 'Contact Tracing', 'Epidemiology Information', 'Immunization Information', 'Investigation Information', 'Investigator Information', 'Medical Facility and Provider Information', 'PERINATAL HEPATITIS B QUESTIONS', 'PERINATAL HEPATITIS B REQUIRED QUESTIONS', 'Pregnancy Information', and 'Risk Factors'. A red arrow labeled 'OLD' points to the 'PERINATAL HEPATITIS B QUESTIONS' tab, and another red arrow labeled 'NEW' points to the 'PERINATAL HEPATITIS B REQUIRED QUESTIONS' tab.

OLD

NEW



# Perinatal Hepatitis B Required Questions

- Please make sure to attempt to answer every question as the information becomes available
- Double check completion before closing the case
- If you are unable to get any questions answered, make a note about it in the comments

# Materials for use by LHD

*Now that your baby is home, what are the next steps...*

## MAKE SURE YOUR BABY GETS THE PROTECTION THEY NEED

At the hospital your baby should have received:

- Hepatitis B Immune Globulin (HBIG)
- First Dose of Single antigen Hepatitis B Vaccine

Now your child will need to finish their Hepatitis B vaccine series. Your child will receive either 2 or 3 more doses from their physician.

It is important they stay on schedule with all childhood immunizations, please find more information at: <http://www.cdc.gov/vaccines>

For more information about the NJDOH Perinatal Hepatitis B Program please visit our website [http://www.nj.gov/health/cd/hepatitisb\\_perinata/index.shtml](http://www.nj.gov/health/cd/hepatitisb_perinata/index.shtml)

*It's time for your baby's post vaccine serology testing...*

## MAKE SURE YOUR BABY IS PROTECTED


Now that your baby has finished their hepatitis B vaccine series, it is time for the final step. One to two months after their last dose of hepatitis B vaccine, at nine months of age or older, they need the following blood tests:

- Hepatitis B surface antigen (HBsAg)
- Hepatitis B surface antibody quantitative test (anti-HBs/HBsAb)

Take this card to your child's physician and request these tests to make sure your child has the protection they need.

For more information about the NJDOH Perinatal Hepatitis B Program please visit our website [http://www.nj.gov/health/cd/hepatitisb\\_perinata/index.shtml](http://www.nj.gov/health/cd/hepatitisb_perinata/index.shtml)


NEW JERSEY DEPARTMENT OF HEALTH  
PERINATAL HEPATITIS B PREVENTION PROGRAM



**NJ Health**  
New Jersey Department of Health

New Jersey Department of Health  
Vaccine Preventable Disease Program  
Perinatal Hepatitis B Program  
PO Box 369  
Trenton, NJ 08625-0369  
Phone: 609-826-4861  
Fax: 609-826-4866

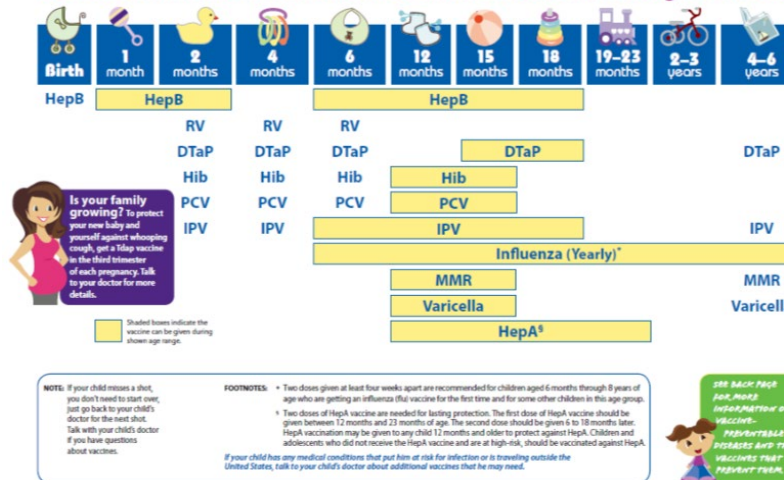
NEW JERSEY DEPARTMENT OF HEALTH  
PERINATAL HEPATITIS B PREVENTION PROGRAM



**NJ Health**  
New Jersey Department of Health

New Jersey Department of Health  
Vaccine Preventable Disease Program  
Perinatal Hepatitis B Program  
PO Box 369  
Trenton, NJ 08625-0369  
Phone: 609-826-4861  
Fax: 609-826-4866

### 2016 Recommended Immunizations for Children from Birth Through 6 Years Old



For more information, call toll free 1-800-CDC-INFO (1-800-232-4636) or visit <http://www.cdc.gov/vaccines>



U.S. Department of Health and Human Services  
Centers for Disease Control and Prevention



American Academy of Pediatrics  
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# Tips and Tricks for Getting in Touch with Cases

- Call the provider's office before sending a fax to let the office know to look for the fax and who/what it is regarding
- Call the patient if you are unable to get in touch with the provider
- Attempt on different days and times
- Set up a "meeting" to call them back at a specific time/date
- Send a certified letter to the patient's residence
- Be sure to check your Reopened Case Section
  - CDRSS has an algorithm to reopen cases for women of childbearing age (15-55)
  - An updated pregnancy status is required for every new positive HBV lab result

# Lost To Follow-up Response

- There may be difficulty reaching a provider or patient, during the investigations
  - For each NEW lab result, make at least 3 attempts to reach case for investigation
    - Recommended forms of communication from “Tips and Tricks” List
    - Document the attempts in the case comments
  - Make sure to complete that case with as much information as you were able to acquire
- For Men’s cases
  - Close the case based on the lab results
- For Women >55 years of age OR <15 years of age (NOT PERINATAL CASES)
  - Close the case based on the lab results

# Lost To Follow-up Response continued

- For Women **between 15-55 years of age** (Childbearing Age in New Jersey), cases **should not** be closed without a pregnancy status
  - Document in case provider/patient was unable to be reached to determine pregnancy status
  - Calculate 9 months (40 weeks) from last lab result date and record date in the comments
    - If the woman is pregnant, the baby should be born by that date
  - During the 9 months, periodically call mother/provider for updates (document attempts in case) and check NJIS using the mother's name
    - NJDOH staff will also check the New Jersey Electronic Birth Certificate (EBC) registry 9 months following last lab result to see if the patient has delivered a baby
  - Close the case, but reopen it after yearly case close out reports are complete (Late May)
  - After it is reopened, periodically check for new labs and call case/provider to try to follow-up
  - After the 40 weeks, if there is no record in EBC or NJIS for a baby and no update was available in that time from patient/provider, document that in the comments and close/approve case.
    - \*If you do find that the patient is pregnant during investigation, still close for case close out, but reopen it after reports are complete. Pregnant cases are kept open until they deliver the child.

# Questions?

- **Contact information:**

- Email: [Ayiasha.Pratt@doh.nj.gov](mailto:Ayiasha.Pratt@doh.nj.gov)
- Phone: 609-826-4861 (VPDP main line)

- **References:**

- <https://www.cdc.gov/hepatitis/hbv/index.htm>
- <https://www.cdc.gov/hepatitis/hbv/perinatalexmtn.htm>
- <https://www.cdc.gov/hepatitis/statistics/surveillanceguidance/HepatitisB.htm#section3.6>
- [https://www.cdc.gov/hepatitis/hbv/testingchronic.htm#:~:text=Screening%20tests,B%20surface%20antigen%20\(HBsAg\)](https://www.cdc.gov/hepatitis/hbv/testingchronic.htm#:~:text=Screening%20tests,B%20surface%20antigen%20(HBsAg)).
- <https://www.cdc.gov/vaccines/pubs/pinkbook/hepb.html#:~:text=HepB%20vaccination%20is%20recommended%20for,and%206%20through%2018%20months>.

# THANK YOU



[nj.gov/health](https://nj.gov/health)