Hepatitis B and Perinatal Hepatitis B Quarterly Call

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Announcements

- Staff Additions & changes
  - Anish Singh, MPH: secondary subject matter expert Hepatitis B and Perinatal Hepatitis B
  - Meredith Bagger, MPH: assisting with surveillance, case management, and communications
    - Meredith should only be contacted if Ayiasha and Anish are unavailable
- Quarterly Progress Reports will be emailed soon
  - Adults and Perinatal reports will be sent
  - These are sent to **EVERY** jurisdiction and are not an indication of job performance
- Case closeout: 2025 adult cases and the 2023/2024 cohort for perinatal cases
  - 2025 adult Hep B cases should be completed and closed, by end of March 2026
  - 2023 perinatal cases should be closed, by end of March 2026
  - 2024 perinatal cases should be **mostly** closed, by end of March 2026, but will be reported on again
- NJDOH has additional investigative resources to assist with case completion, if **NEEDED**
  - Please reach out your REP represented, if you are interested with help

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Meeting Agenda

- Hepatitis B Review:
  - Facts
  - Demographics
  - Definitions
  - Lab results
  - Surveillance requirements and recommendations
- Website Update
  - Deliverables
- Printed materials available for mailing
- Questions or issues

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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

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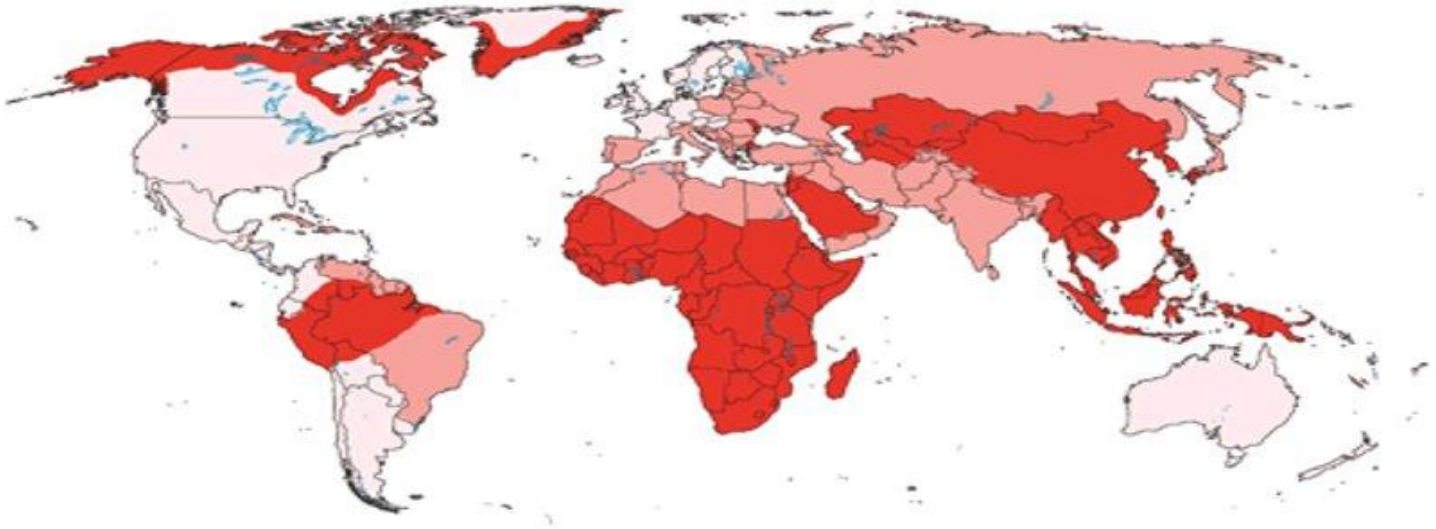
PREVALENCE OF CHRONIC HBV INFECTION



Level of endemicity	% of general population with chronic HBV infection	% of world population
high endemicity	greater than 7%	about 45%
intermediate endemicity	2% to 7%	about 43%
low endemicity	less than 2%	about 12%

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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

HBV Persons at Risk

- Risk behaviors
  - Men who have sex with men (MSM)
  - Person with multiple sexual partners
  - History of STDs
  - Co-infection with HIV/HCV
  - Injection/illicit drug users
  - Healthcare & public safety workers
  - Hemodialysis patients
  - Incarcerated people
- Residents & staff of facility for developmentally disabled
- Household contact of infected person
- Received blood transfusions in the past before blood testing was available (1975)
- Persons with record of incarceration
- Internationally adopted
- Travelers to HBV endemic regions
- Children of first-generation immigrants from countries where HBV is endemic
- Foreign born persons

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Hepatitis B Important Serology

- The following are reportable **POSITIVE** Hepatitis B lab values
  - **Hepatitis B surface antigen (HBsAg)**: Indicates current infection (acute or chronic).
  - **IgM antibody to Hepatitis B core antigen (anti-HBc IgM)**: Suggests acute infection.
  - **Hepatitis B e antigen (HBeAg)**: Indicates active replication.
  - **Hepatitis B DNA (HBV DNA/PCR)**: Confirms active virus presence, often reported with quantitative/qualitative results.
  - **Hepatitis B surface antibody (HBsAb)**: Indicates immunity; only reportable for perinatal cases
- Negative values are only reportable if collected with a positive lab value
  - Example: A positive anti-HBc IgM with a negative HBsAg
- Additionally, Liver Function Tests are important and should be noted **if reported:**
  - Alanine Aminotransferase (ALT/SGPT)
  - Aspartate Aminotransferase (AST/SGOT)
  - Bilirubin, Total and Direct, Serum

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Laboratory Testing and Screening

- CDC recommends use of the triple panel test for adults (since 2023)
  - Hepatitis B surface antigen (HBsAg)
  - Antibody to hepatitis B surface antigen (anti-HBs)
  - Total antibody to hepatitis B core antigen (total anti-HBc)

- CDC recommends HBV screening and testing for the following patients
  - Symptomatic patients, especially without proof of vaccinations
  - Adults ≥ 18 years, at least once in their lifetime, using a triple panel test
  - Pregnant people should be tested for HBsAg during **each** pregnancy (preferably in the first trimester) regardless of vaccination status and history of testing
    - If person has never had a triple panel test, that is recommended. Those with prior triple panel screening only need HBsAg screening during each subsequent pregnancy
  - People with high-risk lifestyles
  - Anyone who requests HBV testing regardless of disclosure of risk

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Hepatitis B Case Definitions

- Recently changed/updated by CSTE in 2024
- Can be classified Acute or Chronic
  - Both classifications can be **Probable** or **Confirmed**
- There is an additional, specialized subgroup, PERINATAL, for infants only (separate program/ will explain later)
- 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

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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 ≥ 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)

Hepatitis B Case Investigation and Surveillance

1. Positive Lab results should be electronically reported to CDRSS and appear in the “pending list” of the designated jurisdiction
   - HBsAg or HBsAg-Confirmation
   - Anti-HBc
   - IgM anti-HBc
   - HBV DNA
   - HBeAg
   - HBsAb (if case is <3 years of age)
2. LHD Investigator should contact BOTH provider and patient and collect information on the following
   - Provider: Demographic information, Clinical features/symptoms, Pregnancy status, Diagnostic test results, Risk behaviors or exposures, and Vaccination information
     *__providers be mindful that THIS is the information that your office needs to collect from the patient__
   - Patient: Risk behaviors or exposures, Education and referral for follow-up, and Identification of contacts requiring post-exposure prophylaxis and testing
     *__Investigators should also ask about any factors that provider office could not answer/confirm__

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Investigation & Surveillance continued

3. Investigators should use the lab test results and information collected from provider/patient to assign a subgroup (acute or chronic) and case status (probable, confirmed, not a case, or OOS) to the CDRSS case
   - OOS
     - If the case left the state, collect the new address, input it into the address section, alert NJDOH SMEs of the change, and choose reporting status “LHD Close”.
     - If the case left the country, leave a comment in the comments section and choose reporting status “LHD Close”.
     - Please DO NOT use this status if a patient has moved out of your jurisdiction, but is still IN NJ. Obtain the new address, change the address section in CDRSS case, and leave case in LHD Open status
4. Reporting status
   - LHD Open: Actively working on the case
   - LHD Review: At a standstill in completion, requires additional information or assistance of another party
   - LHD Closed: all case information is as complete as possible and ready for approval by DOH

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Response for Incomplete/Conflicting Lab Results

- Providers should always request a QUALITATIVE HBsAg with any Hep B Panel
  - Most accurate test to determine infection
  - When ordering titers OR post vaccine serology testing for a perinatal case, order HBsAb AND HBsAg together
  - Ordering Anti-HBc, IgM anti-HBc, HBV DNA, HBeAg, or HBsAb individually is NOT recommended
- LHD should be prepared to request additional testing if HBsAg is not present
  - If results come in without a HBsAg
    - Inquire with ordering provider whether other labs were ordered and resulted as negative
    - Request additional testing
    - Reach out to patient and advise them to follow up with provider
- Conflicting results should be investigated
  - Examples: positive HBV DNA and negative HBsAg OR positive HBsAg with positive HBsAb
    - Vaccination?
    - False positive?
    - Occult Infection?

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Investigation & Surveillance continued

5. Closing the Case
   - For all cases of **MEN**: cases can be LHD Closed once the case is completed
   - For **Women <55 years of age OR >15 years of age** (NOT PERINATAL CASES): cases can be LHD Closed once the case is completed
   - For **Women between 15-55 years of age** (Childbearing Age in New Jersey):
     - Confirmed to NOT be pregnant: case can be LHD Closed once the case is completed
     - Confirmed To BE pregnant: case should be left open until the mother has delivered the child
     - Unknown pregnancy status: follow “Lost to Follow-up” Protocol

Important CDRSS Notes

- The Communicable Disease Reporting and Surveillance System (CDRSS) is NJ's primary tool for case surveillance information collection
  - All positive cases should be recorded in CDRSS
  - It is the investigators responsibility to attempt to collect information on **demographics, symptoms,** and **risk factors** to properly categorize the illness AND create proper records
- Pregnancy status is a primary need for any case of a women within the ages of 15-55yr
  - Please do not close the case without this information; *see loss to follow up document for help*
- The case definitions and algorithm are used to classify cases and assign subgroups, but those tools do NOT override attempting contact with patient/physician's office
- Cases should never be closed without attempting an investigation with the patient and/or physician
  - The outcome of these attempts should be recorded in the comments section
- Please record information in the proper sections of CDRSS rather than recording everything in the comments section: labs, contacts, symptoms, pregnancy status, and risk factors

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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.

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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

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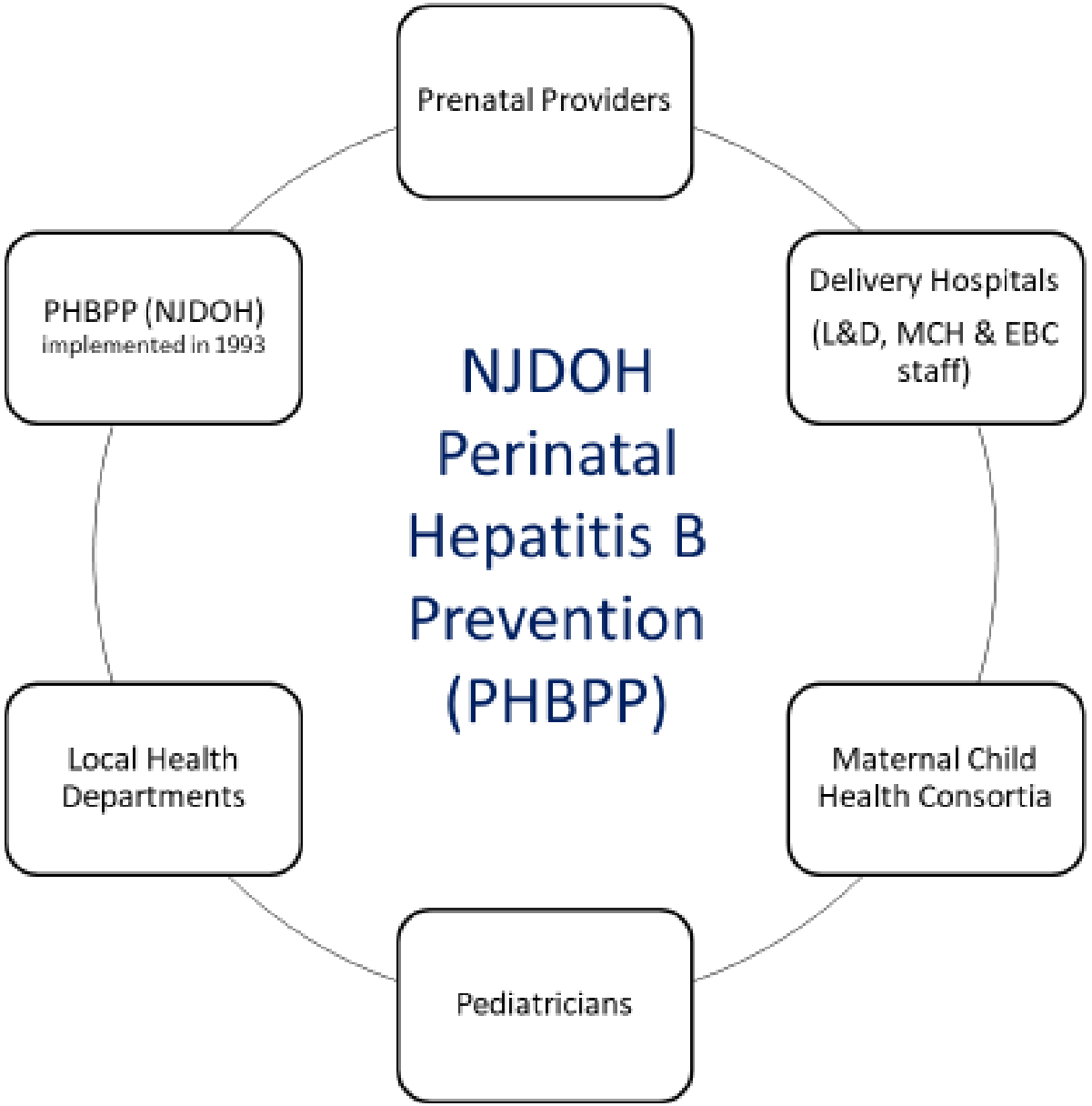

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NJ Administrative Codes

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.

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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

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New Jersey Immunization Information System (NJIIS)

- Usage supported by regulation ***N.J.A.C.§ 8:57-3 (New Jersey Immunization Information Network – NJIIS)***
- All providers must report NJIIS 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

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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

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Hep B Vaccine Schedule

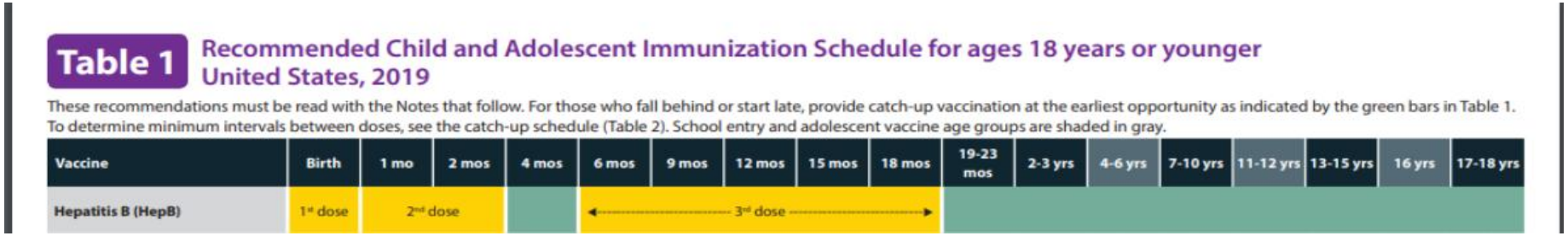

Table 1 Recommended Child and Adolescent Immunization Schedule for ages 18 years or younger United States, 2019

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)	1st dose	2nd dose			3rd 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§	Birth (≤12 hrs)	HBIG§	Birth (≤12 hrs)
	2	1-2 mos	2	2 mos
	3	6 mos¶	3	4 mos
	N/A	N/A	4	6 mos¶

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§	Birth (≤12 hrs)	HBIG§	Birth (≤12 hrs)
	2	1 mos	2	2 mos
	3	2-3 mos	3	4 mos
	4	6 mos¶	4	6 mos¶

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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 >=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

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Website Materials for Surveillance Help

- The disease chapter is the most up to date and complete tool for knowledge and surveillance assistance
- Additional quick reference assistance for case completion, on the NJDOH website
  - Adult page: https://www.nj.gov/health/cd/topics/hepatitisb.shtml
    - Response to CDS-37 interest *NEW*
  - Perinatal Page: https://www.nj.gov/health/cd/topics/hepatitisb_perinatal.shtml
    - Communicable Disease Manual Chapter
    - Perinatal Hepatitis B Investigation Checklist for LHDs
    - Case Management Workflow Chart
    - Lost to Follow-up Protocol

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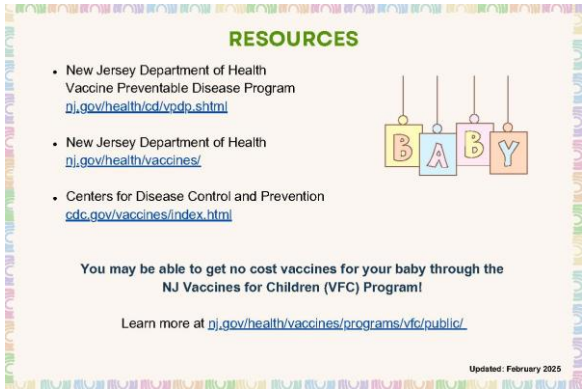
Two New/Updated Postcards available by mail

Front



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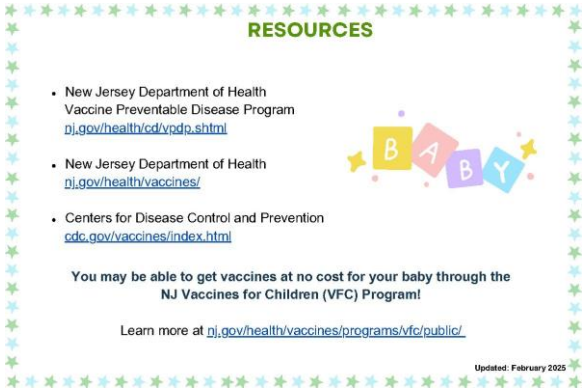

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Questions?

- **Contact information**:
  - Email: 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/perinatalxmtn.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/vaccines/pubs/pinkbook/hepb.html#:~:text=HepB%20vaccination%20is%20recommended%20for,and%206%20through%2018%20months.

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