

Perinatal Hepatitis B Case Management 2023

TATP Webinar

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NC IMMUNIZATION BRANCH

What is hepatitis B?

Figure 2.1. Number of reported cases* of acute hepatitis B virus infection and estimated infections[†] — United States, 2013–2020

Acute Hepatitis B	2013	2014	2015	2016	2017	2018	2019	2020
Reported acute cases*	3,050	2,791	3,370	3,218	3,409	3,322	3,192	2,157
Estimated acute infections [†]	19,800	18,100	21,900	20,900	22,200	21,600	20,700	14,000

Source: CDC, National Notifiable Diseases Surveillance System.

* Reported confirmed cases. For the case definition, see <https://ndc.services.cdc.gov/conditions/hepatitis-b-acute/>.

[†] The number of estimated viral hepatitis infections was determined by multiplying the number of reported cases that met the classification criteria for a confirmed case by a factor that adjusted for underascertainment and underreporting. The 95% bootstrap confidence intervals for the estimated number of infections are displayed in the Appendix.

Reference: Klevens RM, Liu, S, Roberts H, et al. Estimating acute viral hepatitis infections from nationally reported cases. Am J Public Health 2014; 104:482. PMC3953761.

- Liver infection caused by the **hepatitis B virus (HBV)**
- May cause **acute or chronic hepatitis**
- Many chronically infected persons are **asymptomatic**.
- HBV is **resilient** and can remain infectious on surfaces for more than 7 days at room temperature
- HBV **prevalence rates vary greatly throughout the world**.
- During 2020, the number of reported cases of acute hepatitis B was 2,157, which corresponds to 14,000 estimated infections after adjusting for case underascertainment and underreporting. **represents a 32% decrease from the number reported in 2019**
- The sudden decline in 2020 is likely attributed to COVID-19 pandemic related disruptions in healthcare access and reduction in the number of persons tested for hepatitis B virus infection. Furthermore, the ability of viral hepatitis surveillance staff to investigate and accurately determine acute case status was limited due to participation in the public health response to the COVID-19 pandemic.

[CDC Number of reported cases of acute infection/estimated infection US 2013-2020](#)

How is Hep B Spread?

- Birth (spread from an infected mother to her baby during birth)
- Sex with an infected partner
- Sharing needles, syringes, or other drug-injection equipment
- Sharing items such as razors, toothbrushes or glucose monitoring devices with an infected person
- Direct contact with the blood or open sores of an infected person
- Exposure to blood from needlesticks or other sharp instruments
- It can survive outside the body for 7 days

HBV is not spread through food or water, sharing eating utensils, breastfeeding, hugging, kissing, hand holding, coughing, or sneezing.

Vertical (mother to child) transmission

Without post-exposure immunoprophylaxis, approximately 40% of infants born to HBV-infected mothers in the US will develop chronic HBV infection

Approximately one fourth of that 40% will eventually die from chronic liver disease

What is *perinatal* Hepatitis B?

<https://www.cdc.gov/hepatitis/hbv/perinatalxmtn.htm#section1>

Outcomes of Infants born in 2019 to persons infected with Hepatitis B virus and managed by CDC Perinatal hepatitis B Prevention Program through the end of 2020

<https://www.cdc.gov/hepatitis/statistics/2020surveillance/perinatal-hepatitis-b/table-4.1.htm> done

Grantee	All infants managed	Hepatitis B vaccine administration								Post-vaccination serologic testing					
		HBIG & vaccine at birth		Complete series by 12 months of age		Complete series after 12 months of age		Total with complete series		Received*		HBsAg positive		Immune ⁵	
		No.	%	No.	%	No.	%	No.	%	No.	%	No.	% †	No.	% †
North Carolina	191	184	96%	174	91%	4	2%	178	93%	122	64%	0	0%	119	98%

CDC 2020 Number of Newly Reported Cases of Perinatal Hep B Infection

Table 2.4. Number of newly reported cases* of perinatal hepatitis B virus infection, by state or jurisdiction — United States, 2020

State or Jurisdiction	Perinatal Hepatitis B
Alabama	1
Alaska	—
Arizona	—
Arkansas	—
California	1
Colorado	—
Connecticut	—
Delaware	—
District of Columbia	U
Florida	—
Georgia	1
Hawaii	—
Idaho	—
Illinois	—
Indiana	1
Iowa	—
Kansas	—
Kentucky	—
Louisiana	2
Maine	—
Maryland	1
Massachusetts	—
Michigan	—
Minnesota	—
Mississippi	—
Missouri	—
Montana	—
Nebraska	—

Nevada	—
New Hampshire	—
New Jersey	—
New Mexico	—
New York	—
North Carolina	—
North Dakota	—
Ohio	1
Oklahoma	—
Oregon	—
Pennsylvania	—
Rhode Island	U
South Carolina	—
South Dakota	—
Tennessee	—
Texas	—
Utah	—
Vermont	—
Virginia	—
Washington	—
West Virginia	1
Wisconsin	1
Wyoming	—
Total	10

Number of reported cases of PHB infection US 2020

National Guidelines for Preventing Perinatal HBV Transmission

<https://www.cdc.gov/hepatitis/hbv/perinatalxmtn.htm#section1>

- Universal screening of pregnant persons for HBsAg during each pregnancy
- HBV DNA testing for HBsAg-positive pregnant persons at 26-28 weeks to guide the use of maternal antiviral therapy during pregnancy. AASLD (American Association for the Study of Liver Disease) suggests maternal antiviral therapy when HBV DNA is >200,000 IU/mL
- Case management of HBsAg-positive mothers and their infants
- Provision of immunoprophylaxis for infants born to infected mothers, including hepatitis B vaccine and hepatitis B immune globulin within 12 hours of birth
- Routine vaccination of all infants with the hepatitis B vaccine series, with the first dose administered within 24 hours of birth

Roles within the Perinatal Hepatitis B Prevention Program

CDC

- Development of clinical guidelines and recommendations
- National reporting
- Development of standardized reporting requirements

State

- Oversight of LHD case-management
- Statewide reporting to CDC
- Education and outreach to LHDs
- Partner with LHDs and other state agencies

LHD

- Direct case-management of infants born to HBsAg(+) women.
- Coordination with local hospitals and healthcare providers
- Education and prevention

North Carolina Public Health Law

10A NCAC 41A .0101 REPORTABLE DISEASES AND CONDITIONS

10A NCAC 41A .0102 METHOD OF REPORTING

10A NCAC 41A .0210 DUTIES OF ATTENDING PHYSICIANS

10A NCAC 41A .0203 CONTROL MEASURES - HEPATITIS B

10A NCAC 41A .0101

The following named diseases and conditions are declared to be dangerous to the public health and are hereby made reportable within the time period specified after the disease or condition is reasonably suspected to exist:

(26) hepatitis B - 24 hours;

(27) hepatitis B carriage - 7 days;

10A NCAC 41A .0203 CONTROL MEASURES HEPATITIS B



(b) The following are the control measures for persons reasonably suspected of being exposed:

- (5) infants born to HBsAg-positive mothers shall be given hepatitis B vaccination and hepatitis B immune globulin within 12 hours of birth or as soon as possible after the infant is stabilized. Additional doses of hepatitis B vaccine shall be given in accordance with current published Control of Communicable Diseases Manual and Centers for Disease Control and Prevention Guidelines. The infant shall be tested for the presence of HBsAg and anti-HBs within three to nine months after the last dose of the regular series of vaccine; if required because of failure to develop immunity after the regular series, additional doses shall be given in accordance with current published Control of Communicable Diseases Manual and Centers for Disease Control and Prevention guidelines. Copies of the Control of Communicable Diseases Manual may be purchased from the American Public Health Association, Publication Sales Department, Post Office Box 753, Waldora, MD 20604 for a cost of twenty-two dollars (\$22.00) each plus five dollars (\$5.00) shipping and handling. Copies of Center for Disease Control and Prevention guidelines contained in the Morbidity and Mortality Weekly Report may be purchased from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402 for a cost of three dollars fifty cents (\$3.50) each. Copies of both publications are available for inspection in the General Communicable Disease Control Branch, Cooper Memorial Health Building, 225 N. McDowell Street, Raleigh, North Carolina 27603-1382;
- (6) infants born to mothers whose HBsAg status is unknown shall be given hepatitis B vaccine within 12 hours of birth and the mother tested. If the tested mother is found to be HBsAg-positive, the infant shall be given hepatitis B immune globulin as soon as possible and no later than seven days after birth;
- (7) when an acutely infected person is a primary caregiver of a susceptible infant less than 12 months of age, the infant shall receive an appropriate dose of hepatitis B immune globulin and hepatitis vaccinations in accordance with current published Control of Communicable Diseases Manual and Centers for Disease Control and Prevention Guidelines. Copies of the Control of Communicable Diseases Manual may be purchased from the American Public Health Association, Publication Sales Department, Post Office Box 753, Waldora, MD 20604 for a cost of twenty-two dollars (\$22.00) each plus five dollars (\$5.00) shipping and handling. Copies of Center for Disease Control and Prevention guidelines contained in the Morbidity and Mortality Weekly Report may be purchased from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402 for a cost of three dollars fifty cents (\$3.50) each. Copies of both publications are available for inspection in the General Communicable Disease Control Branch, Cooper Memorial Health Building, 225 N. McDowell Street, Raleigh, North Carolina 27603-1382.

Perinatal Hepatitis B Prevention Program Case Management Components for the LHD

1. Test all pregnant women for HBsAg
2. Report and track HBsAg (+) women
3. Provide prenatal HBsAg testing records to delivery hospitals
4. Identify and manage infants born to HBsAg (+) women
5. Identify and manage infants born to women without HBsAg test results
6. Complete the hepatitis b series
7. Complete post-vaccination serology testing
8. Manage and evaluate the LHD's case management program

LHD's role with local birthing hospitals

1

Ensure that providers are transmitting HBsAg status results to birthing hospitals **prior to delivery.**

2

Educate providers on the importance of **educating patients on their HBsAg status** and ensuring that they communicate this status to the birthing hospital.

3

Work closely with birthing hospitals to implement policies and procedures to ensure identification and initiation of PEP of infants born to **HBsAg-positive** mothers. (**request HBIG billing info**)

4

Work closely with birthing hospitals to ensure identification and initiation of PEP of infants born to mothers with **unknown** HBsAg status.

5

Train birthing hospital staff to accurately document the **date and time of birth** and the **date and time of administration for HBIG and Hepatitis B vaccine.**

ACIP Recommendations for Infants Born to Hepatitis B Mothers



**Prevention of Hepatitis B Virus Infection in the
United States: Recommendations of the Advisory
Committee on Immunization Practices**

Recommendations for different scenarios:

1. Case Management of Infants Born to Known Hep B Positive Women
2. Case Management of Infants born to women with Unknown HBsAg status
3. Mother's Status Unknown with infants with birth weights $\geq 2,000$ grams
4. If the Mother's Status Cannot Be Determined Within 12 hours of Birth AND the infant weighs $< 2,000$ grams

Case Management of Infants Born to Known Hep B Positive Women

<https://www.cdc.gov/mmwr/volumes/67/rr/pdfs/rr6701-H.pdf> p. 15

- All infants born to HBsAg-positive women should receive HepB vaccine and HBIG within 12 hours of birth, administered at different injection sites (e.g., separate limbs).
- The HepB vaccine series should be completed according to the recommended schedule for infants born to HBsAg- positive mothers. **SEE CHART BASED ON INFANT'S WEIGHT IN SLIDE**
- Postvaccination serologic testing for anti-HBs and HBsAg should be performed after completion of the vaccine series at age 9–12 months AND 1-2 months after last dose of vaccine

Case Management of Infants born to women with Unknown HBsAg status

- Infants born to women for whom HBsAg testing results during pregnancy are not available but other evidence suggestive of maternal HBV infection exists (e.g., presence of HBV DNA, HBeAg-positive, or mother known to be chronically infected with HBV) should be managed as if born to an HBsAg-positive mother (new recommendation). The infant should receive both HepB vaccine and HBIG within 12 hours of birth
- Women admitted for delivery without documentation of HBsAg test results should have blood drawn and tested as soon as possible.
- While maternal HBsAg test results are pending, infants with birth weights $\geq 2,000$ grams born to women with an unknown HBsAg status should receive the first dose of HepB vaccine (without HBIG) within 12 hours of birth. Only single-antigen HepB vaccine should be used for the birth dose (administer HBIG only if mother's HBsAg comes back positive or results are not available within 12 hours)

Mother's Status Unknown with infants with birth weights $\geq 2,000$ grams Cont.

IF the mother is determined to be positive:

- The infant should receive HBIG as soon as possible but no later than age seven days
- The vaccine series should be completed according to the recommended schedule for infants born to HBsAg-positive mothers
- The final dose in the series should not be administered before age 24 weeks (164 days)
- Create a mother and infant event (link together) and send to Perinatal Case management (PCM) for case management

If the mother is determined to be negative:

- The vaccine series should be completed according to the recommended schedule for infants born to HBsAg-negative mother
- The final dose in the series should not be administered before age 24 weeks (164 days).

If the Mother's Status Cannot Be Determined Within 12 hours of Birth AND the infant weighs < 2,000 grams:

- These infants should receive both single-antigen HepB vaccine and HBIG, administered at different injection sites (e.g., separate limbs)
- The birth dose of vaccine should not be counted as part of the 3 doses required to complete the vaccine series;
- 3 additional doses of vaccine (for a total of 4 doses) should be administered according to a recommended schedule on the basis of the mother's HBsAg test result.
- The final dose in the series should not be administered before age 24 weeks (164 days).

If the Mother's HBsAg status is Not Determined for Whatever Reason:

- Create mother and infant events and follow infant through PCM
- The vaccine series should be completed according to a recommended schedule for infants born to HBsAg-positive mothers.
- The final dose in the series should not be administered before age 24 weeks (164 days).
- These infants should receive postvaccination serologic testing at age 9–12 months and 1-2 months after last dose

PEP Guidelines by Maternal HBsAg Status and Infant Birth Weight

Mother HBsAg Status	Infant Birth Weight	
	>2,000g	<2,000g
Negative	Administer Hepatitis B vaccine within 24 hours	Administer Hepatitis B vaccine one month after birth or at hospital discharge
Unknown	<ol style="list-style-type: none"> Administer Hepatitis B vaccine within 12 hours Draw mother's blood If mother is HBsAg(+), administer HBIG as soon as possible, but no later than 7 days after birth 	<ol style="list-style-type: none"> Administer Hepatitis B vaccine within 12 hours of birth Draw mother's blood If results are not received within 12 hours, administer HBIG within 12 hours of birth. <p>*The birth dose does not count towards the series and will need to be repeated at 1 month of age; 4 doses total are needed.</p>
Positive	Administer Hepatitis B vaccine and HBIG within 12 hours of birth	<p>Administer Hepatitis B vaccine and HBIG within 12 hours of birth</p> <p>*The birth dose does not count towards the series and will need to be repeated at 1 month of age; 4 doses total are needed.</p>

3rd Dose Specifics

<https://www.cdc.gov/mmwr/volumes/67/rr/pdfs/rr6701-H.pdf> MMWR January 12, 2018

TABLE 3. Hepatitis B vaccine schedules for infants, by infant birthweight and maternal HBsAg status

Birthweight	Maternal HBsAg status	Single-antigen vaccine		Single-antigen + combination vaccine [†]	
		Dose	Age	Dose	Age
≥2,000 g	Positive	1	Birth (≤12 hrs)	1	Birth (≤12 hrs)
		HBIG [§]	Birth (≤12 hrs)	HBIG	Birth (≤12 hrs)
		2	1–2 mos	2	2 mos
	Unknown*	3	6 mos [¶]	3	4 mos
		4		4	6 mos [¶]
		1	Birth (≤12 hrs)	1	Birth (≤12 hrs)
	Negative	2	1–2 mos	2	2 mos
		3	6 mos [¶]	3	4 mos
		4		4	6 mos [¶]
<2,000 g	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
	Unknown	4	6 mos [¶]	4	6 mos [¶]
		1	Birth (≤12 hrs)	1	Birth (≤12 hrs)
		HBIG	Birth (≤12 hrs)	HBIG	Birth (≤12 hrs)
		2	1 mos	2	2 mos
	Negative	3	2–3 mos	3	4 mos
		4	6 mos [¶]	4	6 mos [¶]
		1	Hospital discharge or age 1 mo	1	Hospital discharge or age 1 mo
		2	2 mos	2	2 mos
		3	6–18 mos [¶]	3	4 mos
		4		4	6 mos [¶]

Effectiveness of HBV 3-dose series

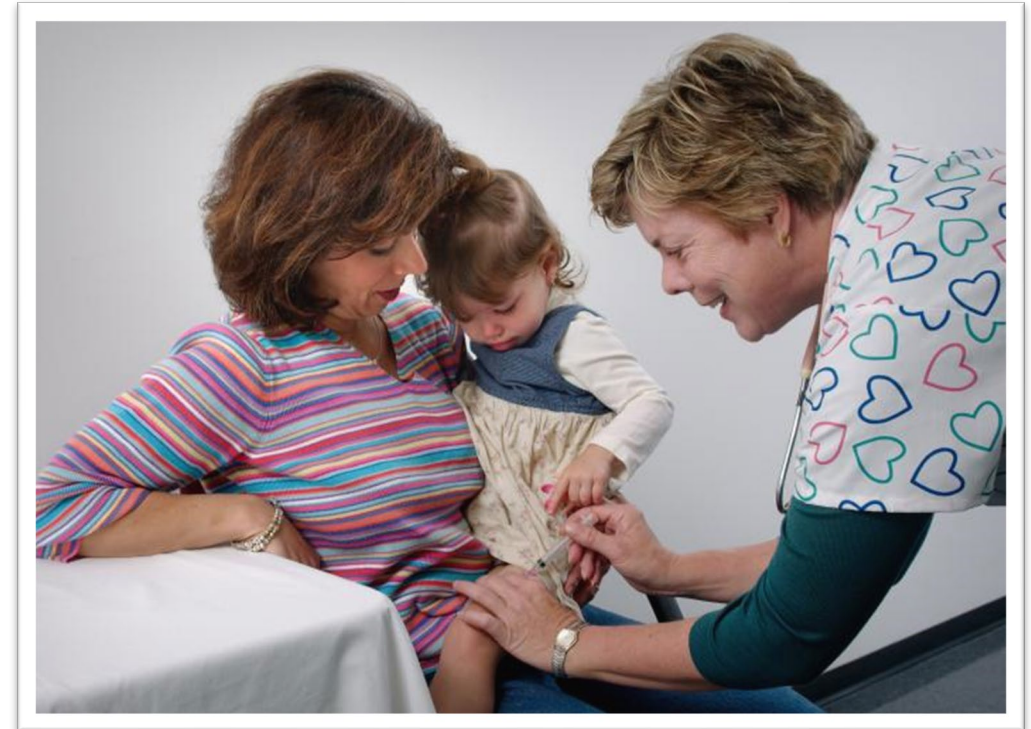
- HBIG and Hepatitis B vaccine administered within 12-24 hours of birth, followed by completion of a 3-dose Hepatitis B vaccine series is **85-95% effective** in preventing acute and chronic HBV infection.
- Hepatitis B vaccine series completion (without HBIG and initiated within 12 hours of birth) is **70-95% effective** in preventing acute and chronic HBV infection.

Why do we give Hep B vaccine to every child at birth before hospital discharge?

- Per ACIP recommendations: For all medically stable infants weighing $\geq 2,000$ grams at birth and born to HBsAg-negative mothers, the first dose of vaccine should be administered within 24 hours of birth
- Errors or delays in testing, reporting, and documenting maternal HBsAg status can and do occur, administering the first dose of hepatitis B vaccine soon after birth to all infants acts as a safety net, reducing the risk for perinatal transmission when maternal HBsAg status is either unknown or incorrectly documented at delivery.

Immune response following Hepatitis B vaccine

- **Anti-HBs** is the only easily measurable correlate of vaccine-induced protection.
- Anti-HBs levels ≥ 10 mIU/mL after vaccination equates to virtually **complete lifetime protection from both acute and chronic HBV infection**.
- Anti-HBs levels decline rapidly in the first year after vaccination, but individuals remain **protected** even when anti-HBs levels are low or undetectable.
- The human body **retains immune memory** and will develop an anti-HBs response after exposure to HBV.



PVST – Post Vaccination Serology Testing

<https://www.cdc.gov/mmwr/volumes/67/rr/pdfs/rr6701-H.pdf> p. 16 of MMWR

Consists of 2 Tests:

- 1. **HBsAg – Hepatitis B surface Antigen**
- 2. **HBsAb – Hepatitis B surface Antibody**

*****Testing should NOT be performed before age nine months to avoid detection of passive anti-HBs from HBIG administered at birth and to maximize the likelihood of detecting late HBV infection.**

****Anti-HBc testing of infants is not recommended because passively acquired maternal anti-HBc might be detected in infants born to HBsAg-positive mothers up to age 24 months**

PVST Results

- PVST Should be performed after completion of the Hepatitis B vaccine series at 9-12 months of age*
 - Should be collected 1-2 months after completion of the Hepatitis B series and no earlier than 9 months of age
- Evaluation of results
 - HBsAg (-) with anti-HBs \geq 10mIU/mL – immune – no further medical management
 - HBsAg (-) with anti-HBs < 10mIU/mL – susceptible – revaccinate and retest 1-2 months after the final dose
 - HBsAg (+) with anti-HBs < 10mIU/mL – infected – refer to specialist for medical management
- What if the HBsAb is negative or equivocal?
 - HBsAg-negative infants with anti-HBs <10 mIU/mL should be re-vaccinated with a single dose of HepB vaccine and receive post vaccination serologic testing 1-2 months later.
 - Infants whose anti-HBs remains <10 mIU/mL following single dose revaccination should receive two additional doses of HepB vaccine, followed by PVST 1-2 months after the final dose

Based on clinical circumstances or physician 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 (PVST) performed 1-2 months after the final dose of vaccine.

NC EDSS REPORTING

Identification of HBsAg-positive women and their infants

- Electronic Lab feed directly into NC EDSS
- Paper lab reporting
- Provider reporting
 - Educate healthcare providers (OB/GYNs, family practitioners, hospitals, etc.) on the importance of testing **all pregnant women** for **HBsAg** during **each** pregnancy and reporting positive results to the LHD and to the selected birth hospital.
 - Work with delivery hospitals to ensure that protocols are in place to identify infants born to women who are HBsAg (+) or women with unknown HBsAg status. Ensure that they have mechanisms in place to report infant births of HBsAg (+) women and any new positive results to the LHD.

PHB Case Management Guidance

- LHD has 30 days from notification to create pregnant woman's event, do investigation and assign to the State for reporting and case management.
- Very important to establish a relationship with the mother as you will be tracking her through her pregnancy and until infant is 9-12 months of age or older if necessary.
- Provide Control Measures for mother and infant and document in the Clinical Package.
 - Even if mother has been reported before, you should review control measures for both mother and infant and document in the event
- Have a tracking mechanism for you to track when infant will be delivered based on EDD

Guidance of Case Management Cont.

- Pregnancy status should be determined for **ALL** positive HBV lab results received for women of childbearing age (**14-50 years**) and documented in NC EDSS.
- All HBsAg-positive pregnant women should be entered into case management for tracking of their pregnancy.

Case Management Tracking Methods

- Variety of ways to track
- Notify provider, contact, and index case
- Generate a reminder letter or call two weeks before intervention is due.
- Any method is acceptable as long as it assures correct and timely follow-up for testing and/or vaccination.

NC EDSS # (if applicable) _____

HEPATITIS B CASE MANAGEMENT

CHRONIC ___ ACUTE ___ CONTACT ___ INFANT ___

NC EDSS event # of source case (for contacts) _____

NAME _____

Date of birth _____ Race _____ Gender _____ Social Security # _____

Address _____

Phone (work) _____ (cell) _____ (home) _____

Country of birth _____ Arrival in US (date) _____ Primary language _____

History of hepatitis? Y ___ N ___ Unknown ___ Pregnant? ___ EDD _____

Physician's name/address _____

Expected delivery hospital _____

LAB RESULTS:

Test	Date	Result

VACCINATION:

Vaccine	Date Given
HBIG	
Hepatitis B vaccine # 1	
Hepatitis B vaccine # 2	
Hepatitis B vaccine # 3	
2 nd series-Hepatitis B vaccine # 1	
2 nd series-Hepatitis B vaccine # 2	
2 nd series-Hepatitis B vaccine # 3	
Twinrix #1	
Twinrix #2	
Twinrix #3	

CONTACTS:

Name	DOB	Date	Lab test	Result	HBIG	HBV vaccine # 1	HBV vaccine #2	HBV vaccine #3

NOTES:

Tracking Methods

Case File/Tickler System

- One file or sheet for index case and each contact
- Can be color-coded
- Periodic review is required
- Advantage: All information relating to case or contact is on one file/sheet.
- Disadvantage: Must review each case on a regular basis to ensure that all cases, contacts, or providers are notified in a timely manner of required interventions.

NC EDSS Task Feature

- Provides a method in NC EDSS to track or follow-up the interventions needed.
- By creating a task which notes the date an intervention is needed, the CD nurse can assure that interventions are provided at the scheduled dates and times.

NC EDSS Task Function

To create a TASK in NC EDSS:

- Open the specific hepatitis B event.
- Click on the TASK button on the Toolbar.
- On the TASK screen, click on “ADD EVENT TASK.”
- Select the type of task from the dropdown list (usually this is Workload Distribution).
- Select the status of the task (this will be “Pending” when creating the event and “Completed” when the intervention has been completed).
- Select the priority of the task (if necessary) and set a due date for the task (the due date relates to the scheduled intervention).
- Enter a brief description of the task to be done. Add notes to clarify, if needed.
- Select the user who is responsible for completing the task by searching for the NC EDSS username. Click on the username, then click SELECT.
- Click the SAVE button at the bottom of the page.
- The TASK will be displayed on the overall workflow page at the bottom under Task Specific Monitors, OPEN TASKS CREATED BY ME.
- To access the task, click on DETAILS on the right hand side of the workflow.

HBsAg-Positive Pregnant Woman who Has Not Been Reported Before

- LHD has 30 days from notification to investigate and send the event to the State
- Investigate to determine if the event is Acute or Chronic - create an Acute or Chronic event
- Complete the following packages
 - Demographic
 - Clinical
 - Risk History
 - Vaccine Information
- Assign to the State Registrar to report to CDC; the State Registrar will forward the event to PCM for Case Management
- PCM will send back to LHD for tracking until delivery. Submit to PCM when delivered

Lab condition report when a woman has been previously reported

- If a woman has been previously reported, the new lab will create a Lab Condition Report Event.
- If the woman is pregnant, leave the event as a Lab Condition Report, complete the Subsequent Package Report and send the event to PCM.
- Provide Control Measures for mother and infant and document in the Subsequent Package.
 - Even if mother has been reported before, you should review control measures for both mother and infant and document in the event.
- LHD will follow this pregnancy in the Lab Condition Report and when the baby delivers, PCM will send the event to the State Registrar to merge it with the original event.

NC EDSS Documentation – Pregnancy Status

North Carolina Electronic Disease Surveillance System

3. Clinical - [REDACTED] - Hepatitis B - Chronic Carrier (115)

DURING THE SIX MONTHS PRIOR TO POSITIVE HBSAG, HBEAG, OR HBV DNA TEST UNTIL NEGATIVE HBSAG

Is this a Hep B-positive woman who is entering the NC Perinatal Hep B Tracking Program due to pregnancy or an infant birth?

Is this an infant born to a Hep B-positive woman who is entering the NC Perinatal Hep B Tracking Program?

Is / was patient symptomatic?

Date that best reflects the earliest date of illness identification

Illness identification date represents:

Is case management tracking required for this clinical condition? Yes

Is case management tracking complete? No, not completed yet

What is the insurance status of the HBsAg Woman at the start of case management?

Document pregnancy and pregnancy details in the **clinical package** or **Hep B Subsequent Report Package**

Is the patient currently pregnant? Yes

Date pregnancy indicated by the user in NCEDSS

Estimated delivery date

For the current pregnancy, enter date of birth or pregnancy termination and pregnancy outcome

Date of Birth or Pregnancy Termination (Actual delivery date)

Pregnancy outcome

Has the mother received prenatal care?

OB Name

Street address

City

State

Zip code

Phone

Once the event is entered into case-management by state PHB, don't forget to enter insurance information.



Infant's Event

- Create infant's event, link to mother's event and assign both events to PCM within 30 days of birth (**this is a monitoring requirement**)
- Complete the following packages:
 - Demographic
 - Clinical
 - Vaccine Information
- Document that control measures for the infant were given to the mother in the infant's event
 - Hep B vaccine series
 - PVST completed as CDC recommends
- You will follow the infant for at least 9-12 months or until the PVST is complete

NC EDSS Documentation – Infant Linkage to Mother

The screenshot shows a web form titled "Link Events" with the following sections:

- Link Events:** Operation: **Create Linked Event** (dropdown), Disease: **Hepatitis B - Perinatally Acquired(116)** (dropdown), Link Type: **Vertical** (dropdown), Relationship: **Child** (dropdown). Buttons: **Select Person...**, **Reset**.
- Demographics:** First Name, Middle Name, Last Name, Suffix, Maiden/Other Name, Alias, Birth Date (MM/DD/YYYY), Gender, Social Security Number.
- Contact Information:** Address Type: **Home** (dropdown), Street, City, State: **NC** (dropdown), Zip Code, County, Country: **USA** (dropdown), Home Phone, Mobile Phone, Work Phone, Email, Fax.

Buttons at the bottom: **Save**, **Dashboard**, **Help**.

Hepatitis B Perinatal Contact Entry

Children born to Hepatitis B positive mothers should be entered as Hepatitis B, Perinatally Acquired, with a case classification of "contact." To create this event:

- Open the mother's event
- Click on the Linked Events / Contacts icon on the tool bar
- In the Link Events box, Operation choose "**Create Linked Event**"
- For the Disease field choose "**Perinatally Acquired**"
- For Link Type choose "**vertical**."
- For the Relationship field choose "**child**"
- Enter the child's name and other information into fields provided
- Click on "**Save**" - the linked events screen will appear and a linked event will appear for the contact
- Open the child's event by clicking on the blue event id number shown in the linked cases box
- Build required tasks for vaccination and testing information
- Enter the birth information, HBIG treatment, vaccination and testing information as they are completed
- After all vaccinations and testing, report the child "does not meet criteria" unless the child tests positive for Hepatitis B, in which case change the classification to reflect "confirmed" before submitting to the state for reporting

NC EDSS Documentation - Infant

North Carolina Electronic Disease Surveillance System

3. Clinical - [REDACTED] - Hepatitis B - Perinatally Acquired

DURING THE SIX MONTHS PRIOR TO POSITIVE HBSAG TEST UNTIL NEGATIVE HBSAG TEST

What is the infants anti-HBs result?	<input type="text"/>
Is this an infant born to a Hep B-positive woman who is entering the NC Perinatal Hep B Tracking Program?	Yes ▼
What is the infant's post-vaccination HBsAg result?	[REDACTED]
Date of post-vaccination HBsAg result	[REDACTED] <input type="text"/>
What is the infant's post-vaccination anti-HBs result?	[REDACTED]
Date of post-vaccination anti-HBs result	[REDACTED] <input type="text"/>
Is / was patient symptomatic?	<input type="text"/>
Date that best reflects the earliest date of illness identification	MM/DD/YYYY <input type="text"/>
Illness identification date represents:	<input type="text"/>
Is case management tracking required for this clinical condition?	Yes ▼
Is case management tracking complete?	No, not completed yet ▼
What is the insurance status of the infant at birth?	Private ▼

Once State PHB has entered the event into case-management, don't forget to enter the insurance information.



NC EDSS PEP Documentation

State of infant's birth	NC
Infant's country of birth	USA
Was the infants birth weight less than 2000 grams (4.4 pounds)?	No
Biologic mother's race	Black African American Add New
Please specify	African American
Biologic mother's Hispanic ethnicity	No
Was the biologic mother born outside the US?	Unknown
Was the biologic mother confirmed HBsAg positive prior to or at time of delivery?	Yes
Date of HBsAg positive test result	<input type="text"/>
Date of HBsAg positive test result	<input type="text"/>
Date of HBsAg positive test result	<input type="text"/> Add New
Was the biologic mother confirmed HBsAg positive after delivery?	No
Did the patient/contact receive hepatitis B immune globulin (HBIG)?	Yes
Date received	08/18/2018
Was HBIG administered within 12 hours of birth?	Yes
Birth hospital	<input type="text"/>
Hospital contact name	<input type="text"/>
Phone	<input type="text"/>

Vaccine Information	
Has patient / contact ever received vaccine related to this disease?	Yes
Date of Administration: 08/18/2017 Vaccine type	zz_Other
Vaccine type	Hepatitis B vaccine, pediatric or pediatric/adolesc
Date of administration	08/18/2017
Vaccine data imported from NCIR or entered manually?	Manual entry
Year of last dose received	2017
Number of doses received	1
If the patient/contact was under the age of 2, was first dose of vaccine administered within 12 hours of birth?	Yes
Vaccine date unknown	No
Number of vaccines given is 1: Is vaccination series complete?	No
Continue to request vaccine information from NCIR?	Yes
Review required for NCIR information?	No
NCIR vaccine information date	<input type="text"/>

Lab No.	Specimen Date	Specimen Number	Specimen Type	Result	Result Status	Result Value	Test
1	01/23/2017		Whole blood sample	Negative			HBV surface Ag Ser QI ...
1	01/23/2017		Whole blood sample	Positive			HBV surface Ab Ser-aCnc ...

Add Lab Result Update Lab Result Delete Lab Result

Details

Last Update: 04/03/2017
 Updated By: [Redacted]
 Specimen Info
 Specimen Date: 01/23/2017
 Specimen Type: Whole blood sample
 Tests
 Test: HBV surface Ag Ser QI || Hepatitis B virus surface Ag:
 Result: Negative
 Result Date: 01/23/2017
 Tests
 Test: HBV surface Ab Ser-aCnc || Hepatitis B virus surface Ab:
 Result: Positive
 Result Date: 01/23/2017
 Lab Facility
 Lab Facility: [Redacted]
 Ordering Facility
 Ordering Facility (Other): [Redacted]
 Ordering Provider
 Name: [Redacted]
 Address: [Redacted]
 City: [Redacted]
 State: [Redacted]
 Zip: [Redacted]
 Phone / Order Callback Number: [Redacted]

What is the infants anti-HBs result? Positive ▾

Is this an infant born to a Hep B-positive woman who is entering the NC Perinatal Hep B Tracking Program? Yes ▾

What is the infant's post-vaccination HBsAg result? Negative ▾

Date of post-vaccination HBsAg result 01/23/2017

What is the infant's post-vaccination anti-HBs result? Positive ▾

Date of post-vaccination anti-HBs result 01/23/2017

Is / was patient symptomatic? ▾

Date that best reflects the earliest date of illness identification

Illness identification date represents: ▾

Document lab results in both the lab and clinical packages

Lost to Follow-Up/Family Relocated

Lost to Follow-up

- Follow your Policy/Procedure
- At least 3 different attempts should be made to contact the family and/or provider and documented on the dashboard of the event
- Examples: phone call, letter/certified letter, home visit
- Other resources to consider – WIC, Medicaid, NCIR, etc

Family Relocated

- Town/city in NC – notify CD nurse and State Perinatal Hepatitis B Coordinator by phone; change county of residence; then LHD – LHD transfer in NC EDSS.
- Another state – obtain and document forwarding address and submit to State PCM
- Another Country – document which country and submit to State PCM

Parent Non-Compliant with Control Measures

Per the NC Hepatitis B Manual:

It is the responsibility of the Communicable Disease nurse to ensure that control measures have been issued to persons known to be infected with a communicable disease such as hepatitis B. Best practice for issuing control measures would be for the nurse to meet face to face with the client, explain the control measures required by law for hepatitis B infection, review written information with the client about hepatitis B, allow time for the client to ask questions, and then have the client sign a letter which indicates that control measures have been explained (see sample letter in this section). For practical reasons, this cannot always be done. Sometimes it is necessary to issue control measures verbally over the phone to the client or by mailing written control measures and information to the client.

If all attempts have been exhausted, your Health Director may need to consult the local health department's legal counsel for further guidance.

- Document that the health director has been notified on the dashboard of the event and any further steps taken

Perinatal Hep B Monitoring

- Monitoring for Perinatal Hep B events are provided at your Immunization Monitoring visit every 2 years (this has to do with your Agreement Addenda requirements and CDC funding for programs)
 - Work with your Immunization Coordinator to be present at this visit or to get a copy of the report
 - Monitoring consists of 3 measures discussed on the following slides
- LHD's will receive a written report with details of infants that were case managed during the cohort year and any concerns that were found

Division of Public Health

Agreement Addendum

FY 21-22

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Alamance County Health Department
Local Health Department Legal Name

715 Immunization Action Plan
Activity Number and Description

06/01/2021 – 05/31/2022
Service Period

07/01/2021 – 06/30/2022
Payment Period

Women's and Children's Health / Immunization
DPH Section / Branch Name

Misheema Morrissey, (919) 707-5556
misheema.morrissey@dhhs.nc.gov

DPH Program Contact
(name, telephone number with area code, and email)

DPH Program Signature **Date**
(only required for a negotiable agreement addendum)

•Has the LHD started the investigation to determine if the report is an authentic report i.e. Have they started the Subsequent Package Report if they have been previously reported OR has the LHD changed the classification to Chronic/Acute/or Probable

Measure #1

2. Vaccine-Preventable Disease Surveillance

To ensure that vaccine-preventable diseases are identified, monitored, and managed, the Local Health Department shall:

- a. Identify and investigate immediately, upon the receipt of any suspect vaccine-preventable disease or condition, the circumstances surrounding the occurrence of the disease or condition to determine the authenticity of the report;

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Alamance County Health Department
Local Health Department Legal Name

715 Immunization Action Plan
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Payment Period

Women's and Children's Health / Immunization
DPH Section / Branch Name

Misheema Morrissey, (919) 707-5556
misheema.morrissey@dhhs.nc.gov

DPH Program Contact
(name, telephone number with area code, and email)

DPH Program Signature **Date**
(only required for a negotiable agreement addendum)

**CD Agreement
Addendum
gives the
definition of the
reporting
requirements**

Measure #2

- j. Follow the reporting requirements in the *Agreement for Local Health Department Participation* in the North Carolina Electronic Disease Surveillance System (NC EDSS);

**Division of Public Health
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Master
Local Health Department Legal Name

Epidemiology / Communicable Disease Branch
DPH Section / Branch Name

510 General Communicable Disease Control
Activity Number and Description

Vanessa M. Greene, (919) 546-1658
vanessa.greene@dhhs.nc.gov
DPH Program Contact
(name, phone number, and email)

06/01/2021 – 05/31/2022
Service Period

DPH Program Signature **Date**
(only required for a negotiable agreement addendum)

07/01/2021 – 06/30/2022
Payment Period

IV. Performance Measures/Reporting Requirements:

Performance Measure #1: Days taken to complete each investigation and submit to DPH.

Reporting Requirements: Document disease investigations in NC EDSS and reassign disease events to the State Disease Registrar **within 30 days** of notification of a reportable communicable disease or condition. Follow North Carolina Communicable Disease Manual Guidelines for NC EDSS documentation.

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Alamance County Health Department
Local Health Department Legal Name

715 Immunization Action Plan
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07/01/2021 – 06/30/2022
Payment Period

Women's and Children's Health / Immunization
DPH Section / Branch Name

Misheema Morrissey, (919) 707-5556
misheema.morrissey@dhhs.nc.gov

DPH Program Contact
(name, telephone number with area code, and email)

DPH Program Signature **Date**
(only required for a negotiable agreement addendum)

Measure #3

- i. Provide or ensure provision of Perinatal Hepatitis B case-management services following current ACIP and these CDC guidelines:
 - i. All pregnant women are tested for HBsAg during each pregnancy;
 - ii. All infants born to HBsAg-positive women and all infants born to women with unknown HBsAg status receive HBIG and a dose of hepatitis B vaccine within 12 hours of birth;
 - iii. All infants born to HBsAg-positive women complete the hepatitis B vaccine series per the most current ACIP recommended schedule; and
 - iv. All infants receive timely post-vaccination serology testing per CDC guidelines.

i. All pregnant women are tested for HBsAg during each pregnancy

- LHD's will document this in the mother's event
- If the woman has refused or did not receive prenatal care, document it was done at delivery
- If not done at delivery educate hospitals and delivering providers of the ACIP recommendations and NC Law. Document education provided in the event

ii.) All infants born to HBsAg-positive women and all infants born to women with unknown HBsAg status receive HBIG and a dose of hepatitis B vaccine within 12 hours of birth,

- LHD's receive this information from the delivering hospital's notes (time of administration should be documented)
- If the hospital did not provide this – did the LHD do an investigation/education as to what happened and did they verify policy

iii. all infants born to HBsAg-positive women complete the hepatitis B vaccine series per the most current ACIP recommended schedule,

- Routine vaccine schedule: last dose is given 6-18 mos of age, but babies born to Hep B + mothers or unknown status of moms at birth, the last dose must be given at 6 months (Table 3 of current ACIP recs)
- The LHD is responsible for ensuring the vaccine is given per ACIP guidelines.
- The LHD can delegate it to the PCP, but if the PCP refuses or wants to use a different schedule, the LHD must advise the parents to come to the LHD for proper vaccine schedule
- If parents refuse, is it documented; is it documented that the health director was notified and what their decision was

iv. all infants
receive timely
post-vaccination
serology testing
according to CDC
guidelines?

- PVST is only HBsAg and anti-HBs
- PVST cannot be done earlier than 9 months
- ACIP recommends it be done between 9-12 months of age (ensure 1-2 months after last dose)
- If it is parent refusal, is it documented that LHD educated parents and notified the health director

Perinatal Hepatitis B Resources

CDC Perinatal Hepatitis B Website:

<https://www.cdc.gov/hepatitis/hbv/perinataxmtn.htm>

Immunization Action Coalition:

<http://www.immunize.org/protect-newborns/>

<http://www.immunize.org/catg.d/p2130.pdf> (standing order)

CDC Pink Book – Hepatitis B Chapter

<https://www.cdc.gov/vaccines/pubs/pinkbook/hepb.html>

Physicians Guide to Hepatitis B: A Silent Killer

https://med.stanford.edu/content/dam/sm/liver/documents/resources/guides/Final_P-Guide_2020_version3.pdf

North Carolina Hepatitis B Public Health Program Manual*

<http://epi.publichealth.nc.gov/cd/lhds/manuals/hepB/toc.html>

Hep B Moms <https://www.hepbmoms.org/>

Resources Cont.

Prevention of hepatitis B Virus Infection in the United States: Recommendations of the Advisory committee on Immunization Practices January 12, 2018

<https://www.cdc.gov/mmwr/volumes/67/rr/pdfs/rr6701-H.pdf>

Management of Infants Born to Women with hepatitis B Virus Infection for Pediatricians

<https://www.cdc.gov/vaccines/programs/perinatal-hepb/downloads/HepB-Provider-tipsheet-508.pdf>

Immunization Action Coalition

www.immunize.org/standing-orders/

Guidance for Developing Admission Orders in Labor & Delivery and Newborn Units to Prevent Hepatitis B Virus Transmission

The guidelines in this document were developed to help hospitals establish policies and standing orders in their labor and delivery (L&D) and newborn units.

In January 2018, CDC published revised guidance to administer the hepatitis B birth dose within 24 hours of birth to all newborns. This and other updated hepatitis B recommendations are available at www.cdc.gov/mmwr/volumes/67/rr/pdfs/rr6701-H.pdf.

To protect infants from HBV infection, CDC recommends that all delivery hospitals institute standing orders or admission orders, and protocols to ensure healthcare professionals do the following:

1. Administer hepatitis B vaccine to ALL newborns within 24 hours of birth, or at hospital discharge, whichever comes first.
2. Identify all infants born to mothers who are hepatitis B surface antigen (HBsAg) positive or to mothers with unknown HBsAg status. Administer appropriate immunoprophylaxis to these infants.

Admission orders and procedures for women admitted to a birthing facility

For pregnant women who have a HBsAg lab report included in their prenatal records, do the following:

1. Examine a copy of the original laboratory report of the pregnant woman's HBsAg¹ test result to verify that the correct test (i.e., HBsAg) was performed and to verify that the testing date was during this pregnancy not a previous one. Do not rely on a hand-written or transcribed HBsAg test result!
2. Place a copy of the original HBsAg lab report into (1) the pregnant woman's L&D record and (2) the infant's hospital record (or have a link to the mother's HBsAg test result).
3. If the pregnant woman is HBsAg positive, alert the nursery staff that the newborn is high risk and will need postexposure prophylaxis – both hepatitis B immune globulin (HBIG) and hepatitis B vaccine – within 12 hours of birth.
4. Perform a repeat blood test for HBsAg¹ if the pregnant woman was HBsAg negative during a prenatal visit but was at risk for acquiring HBV infection during this pregnancy (e.g., more than one sex partner in the previous 6 months, evaluation or treatment for a sexually transmitted disease, recent or current injection-drug use, or HBsAg-positive sex partner), or had clinical hepatitis since her previous testing.
5. Instruct the laboratory to call L&D and the nursery with the HBsAg test result ASAP.



Saint Paul, Minnesota • 651-647-9009 • www.immunize.org • www.vaccineinformation.org
www.immunize.org/catg.d/p2130.pdf • Item #2130 (3/20)

CONTINUED ON THE NEXT PAGE ►

For pregnant women who do not have an HBsAg lab report on their prenatal record, do the following:

1. Perform HBsAg¹ testing ASAP on women who do not have a copy of an original HBsAg laboratory report from the current pregnancy included in their prenatal record.
2. Instruct the lab to call L&D and the nursery units with the newly obtained HBsAg test result ASAP.

Admission orders and procedures for newborns

Hospital procedures to follow for ALL newborns

1. Review a copy of the mother's original HBsAg¹ lab report to ensure that the correct serologic test was ordered and that it was ordered during this pregnancy.
2. Determine if the newborn needs immediate postexposure prophylaxis within 12 hours of birth. To do this you must know the mother's HBsAg status and the newborn's birth weight. If the newborn weighs less than 2 kg (4.4 lb), see the descriptions below and footnotes 2, 4, 5.
3. Prior to vaccination, give parent a Hepatitis B Vaccine Information Statement (available at www.immunize.org/vis).
4. If an infant is transferred to a higher level of care facility prior to vaccination, inform the receiving facility it is their responsibility to administer the hepatitis B vaccine.

For newborns of HBsAg-negative mothers

1. Administer single-antigen hepatitis B vaccine (0.5 mL, IM) within 24 hours of birth, or at hospital discharge, whichever comes first, to all newborns weighing 2 kg (4.4 lb) or more at birth.²
2. Document the hepatitis B vaccine dose in the newborn's medical record, including the date, time, and site of administration, as well as the vaccine lot number.
3. Give the mother an immunization record card that includes the hepatitis B vaccine series to protect her baby. Remind her to bring the immunization record card with her each time her baby sees a provider.

For newborns of mothers with unknown HBsAg status,⁶ do the following:

1. Administer single-antigen hepatitis B vaccine (0.5 mL, IM) within 12 hours of birth.⁴ Do not wait for test results to return before giving this dose of vaccine.
2. Document the hepatitis B vaccine dose in the newborn's medical record, including date, time, and site of administration, as well as the vaccine lot number.

Give birth to the end of Hep B

Protect newborns - Administer hepatitis B vaccine at birth

The Immunization Action Coalition (IAC) is urging hospitals and birthing centers to meet the national standard of care by providing a universal birth dose of hepatitis B vaccine.



It prevents mother-to-infant transmission
Prevents 70%–95% of transmission to infants born to HBsAg-positive women



It prevents household transmission
Protects infants from infected family members and other caregivers



It provides protection if medical errors occur
Provides a safety net to prevent perinatal transmission when medical errors occur



Guidance for Developing Admission Orders in Labor & Delivery and Newborn Units (continued) page 2 of 2

3. Give the mother an immunization record card that includes the hepatitis B vaccine date. Explain the importance of completing the hepatitis B vaccine series to protect her baby. Remind her to bring the immunization record card with her each time her baby sees a provider.
4. Confirm that the laboratory has received blood for the mother's HBsAg¹ test.
5. Verify when the mother's HBsAg result will be available and that it will be reported to L&D and the newborn unit ASAP.
6. If the nursery does not receive the report of the mother's HBsAg test at the expected time, call the laboratory for the result.
7. If the laboratory test indicates the mother's HBsAg¹ test result is positive, do the following:
 - a. Administer HBIG (0.5 mL, IM) to the newborn ASAP (Hepatitis B vaccine should have been given within 12 hours of birth).
 - b. Document the HBIG dose in the newborn's medical record. There is little benefit in administering HBIG to the newborn if more than 7 days have elapsed since birth.
 - c. Alert the mother's and newborn's physician(s) of the test result.
 - d. Follow the instructions below "For newborns of HBsAg-positive mothers," steps 3–7.
8. If the newborn must be discharged before the mother's HBsAg result is known:
 - a. Document the parents' contact information (e.g., addresses, telephone numbers, emergency contacts) in case further treatment is needed for the infant.
 - b. Obtain the name, address, and phone number of the mother's and the newborn's healthcare providers.
 - c. Notify the mother's and newborn's healthcare providers that the mother's HBsAg test result is pending.

- For newborns of HBsAg-positive mothers**
1. Administer HBIG (0.5 mL, IM) and single-antigen hepatitis B vaccine⁴ (0.5 mL, IM) at separate injection sites within 12 hours of birth.
 2. Document the hepatitis B vaccine and HBIG dose in the newborn's medical record, including the date, time, and site of administration, as well as the vaccine lot number.
 3. Give the mother an immunization record card that includes the hepatitis B vaccination and HBIG dates. Explain the importance of completing the hepatitis B vaccine series to protect her baby. Remind her to bring the record card each time her baby sees a provider.
 4. Notify the local or state health department of the infant's birth and the date and time of administration of HBIG and hepatitis B vaccine doses.
 5. Obtain the name, address, and phone number of the newborn's primary care provider.
 6. Notify the provider of the newborn's birth, the date and time of HBIG and hepatitis B vaccine doses administered, and the importance of additional on-time vaccination as well as postvaccination testing of the infant for both HBsAg and antibody to HBsAg (anti-HBs) after completion of the hepatitis B vaccine series to assess the hepatitis B status of the infant following vaccination.
 7. Provide advice to the mother. Tell her the following:
 - a. That she may breast-feed her infant upon delivery, even before hepatitis B vaccine and HBIG are given;
 - b. That it is critically important for the protection of her baby's health that the baby receive the full hepatitis B vaccine series on the recommended schedule;
 - c. That blood tests (HBsAg and antibody to hepatitis B surface antigen [anti-HBs]) need to be drawn from the baby 1–2 months after completion of the 3- or 4-dose hepatitis B vaccine series and also no earlier than 9–12 months of age to determine if the child developed a protective immune response to vaccination or needs additional management;
 - d. About modes of 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 a candidate for antiviral treatment.

FOOTNOTES

1. Be sure the correct test for HBsAg (hepatitis B surface antigen) was ordered. The HBsAg test should not be confused with other hepatitis B serologic tests, including antibody to HBsAg (anti-HBs or HBsAb) and antibody to hepatitis B core antigen (anti-HBc or HBcAb).
2. Infants weighing less than 2 kg (4.4 lb) at birth and whose mothers are documented to be HBsAg-negative should receive the first dose of vaccine 1 month after birth or at hospital discharge, whichever comes first. The mother's HBsAg test result must be part of the infant's medical record.
3. Federal law requires that you give parents a Hepatitis B Vaccine Information Statement (VIS) before vaccine administration. To obtain a VIS, download from the IAC website at www.immunize.org/vis.
4. An infant weighing less than 2 kg (4.4 lb) whose mother's HBsAg status is unknown should receive HBIG and hepatitis B vaccine within 12 hours of birth. Do not save the hepatitis B vaccine dose as the first dose in the vaccine series. Administer the full hepatitis B vaccine series at ages 1–2 months.
5. An infant weighing less than 2 kg (4.4 lb) whose mother's HBsAg status is unknown should receive the first dose of hepatitis B vaccine and HBIG within 12 hours of birth. Do not count the hepatitis B vaccine dose as the first dose in the vaccine series. Administer the full hepatitis B vaccine series at ages 1–2 months.
6. If it is not possible to determine the mother's HBsAg status (e.g., when a parent or parent-in-law could not be contacted) or when an infant is born to a mother whose HBsAg status is unknown, the vaccine series should be completed according to a recommended schedule for infants born to HBsAg-positive mothers. The final dose in the series should not be administered before age 24 weeks (24 days). These infants should receive seronegativity testing at ages 9–12 months, and revaccination if necessary.
7. The optimal timing for serologic testing to assess a vaccine response generally is 1–2 months after the final dose of the HepB vaccine series. Results of tests for HBsAg can be tentatively positive for 1–12 days after vaccination. Serologic testing should be performed no earlier than age 3 months to avoid detection of passive anti-HBs from hepatitis B immune globulin administered at birth and to maximize the likelihood of detecting late HBV infection (see "Update: Shared national framework for postvaccination serologic testing of infants born to hepatitis B-infected mothers," MMWR, 2015; 64: 1113–20 www.cdc.gov/mmwr/pdf/wk/mm6403.pdf).

► For "Sample Text for Developing Admission Orders in Newborn Units for the Hepatitis B Birth Dose," visit www.immunize.org/catg.d/p2131.pdf.

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www.immunize.org/catg.d/p2130.pdf • Item #2130 (3/20)

Hepatitis B:

What Hospitals Need to Do to Protect Newborns

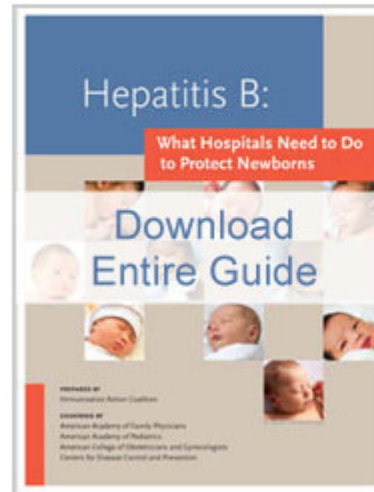


PREPARED BY
Immunization Action Coalition

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

ALL IMAGES: ISTOCKPHOTO.COM

Purchase or Download Birth Dose Guide



Hepatitis B: What Hospitals Need to Do to Protect Newborns

Purchase spiral-bound copy of entire book: 85 pages

Download entire book: 85 pages, 6.24 MB PDF (updated July 2016)

"...The resources compiled by the IAC and being shared as part of this new initiative with all hospitals and birthing centers in the new resource, Hepatitis B: What Hospitals Need to Know to Protect Newborns, are important evidence-based tools and will complement other efforts to increase the proportion of hospitals and birthing centers that routinely administer the birth dose of the HBV vaccine across our nation, resulting in further reductions of new hepatitis B infections in infants..." - read HHS statement

Dr. Howard K. Koh
Assistant Secretary for Health
U.S. Department of Health and Human Service

<https://www.immunize.org/protect-newborns/guide/>

New Vaccines

- Updated 2023-2024 COVID vaccine
- PCV 20
- Menveo one-vial
- RSVmAb
- RSV

Updated 2023-2024 COVID vaccine

Interim Clinical Considerations

** only give the recommended dosage even if there is more liquid in the single dose vial (Moderna Announcement)

- 6 mos – 4 yr – may need multiple doses
- 5yr and older – give one dose of updated 23-24 COVID vaccine
- Different recommendations for people who are moderately to severely immunocompromised

PCV 20 (replacing PCV 13)

ACIP Recommendations for PCV20 in Children

- ACIP recommended use of PCV20 as an option to PCV15 for: routine vaccination of all children aged 2–23 months; catch-up vaccination for healthy children aged 24–59 months who have not received age-appropriate doses; and children aged 24–71 months with certain underlying medical conditions at increased risk for pneumococcal disease who have not received age-appropriate doses.
- ACIP Recommendations for PCV20 in 19 yrs and Older
- *ACIP recommendations specify the use of either PCV20 alone or PCV15 in series with PPSV23 for all adults aged ≥65 years and for adults aged 19–64 years with certain underlying medical conditions or other risk factors who have not received a PCV or whose vaccination history is unknown. In addition, ACIP recommends use of either a single dose of PCV20 or ≥1 dose of PPSV23 for adults who have started their pneumococcal vaccine series with PCV13 but have not received all recommended PPSV23 doses. Shared clinical decision-making is recommended regarding use of a supplemental PCV20 dose for adults aged ≥65 years who have completed their recommended vaccine series with both PCV13 and PPSV23.*

Menveo one-vial

- approved for use in individuals 10 years through 55 years of age – DOES NOT REQUIRE RECONSTITUTION
- two-vial presentation is indicated for use in individuals ages 2 months through 55 years, providers are encouraged to begin limiting use to children ages 2 months through 2 years at increased risk of meningococcal disease as this is the only product available for this age group
- Two-vial is only available in limited quantities

RSVmAb (Beyfortus)

- For infants less than 8 mos and infants and children 8-19 mos who are at increased risk for severe RSV disease before the start of the RSV season
- There are interim recommendations due to the shortage of product

RSV Vaccine

- There are 2 products for adults
 - Arexvy (GSK)
 - Abrysvo (Pfizer)
- On June 21, 2023, ACIP recommended that adults aged ≥ 60 years may receive a single dose of RSV vaccine, using shared clinical decision-making.
- On September 22, 2023, ACIP and CDC recommended maternal Pfizer (Abrysvo) vaccination in pregnant persons as a one-time dose at 32 weeks and zero days'–36 weeks and 6 days' gestation using seasonal administration (meaning September–January in most of the continental United States) for prevention of RSV-associated LRTI in infants aged < 6 months.

Contact Information

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