Perinatal Hepatitis B

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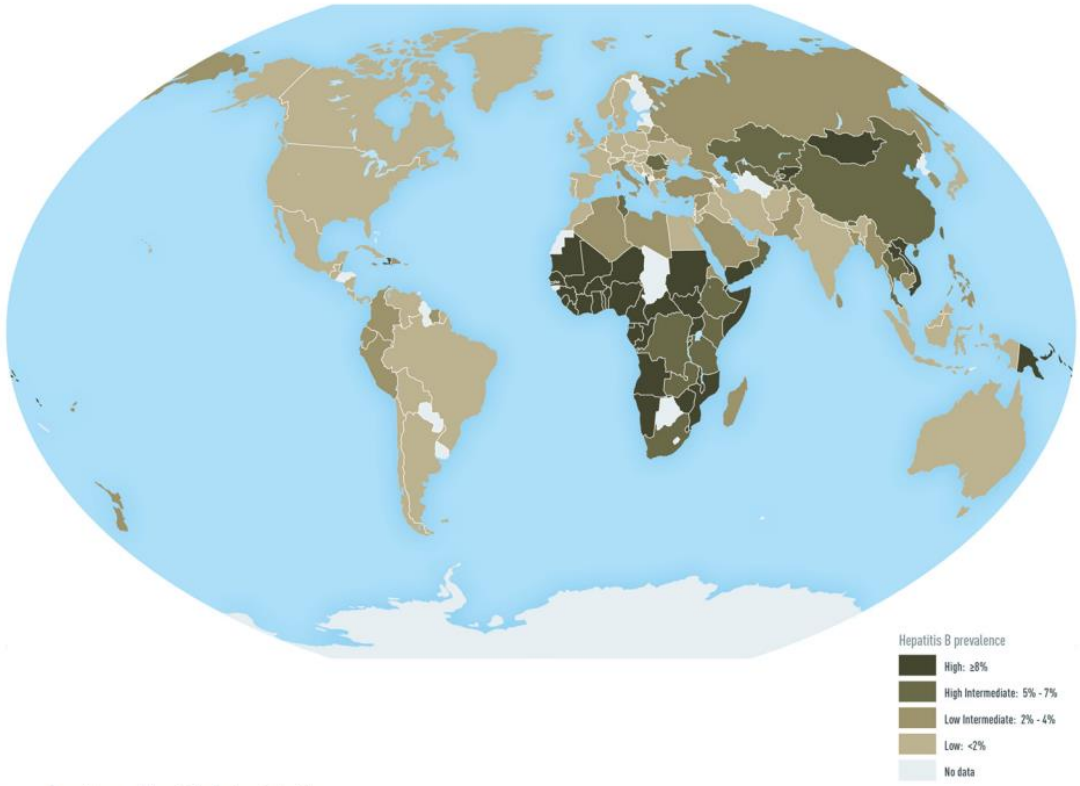
NC IMMUNIZATION BRANCH

What is hepatitis B?

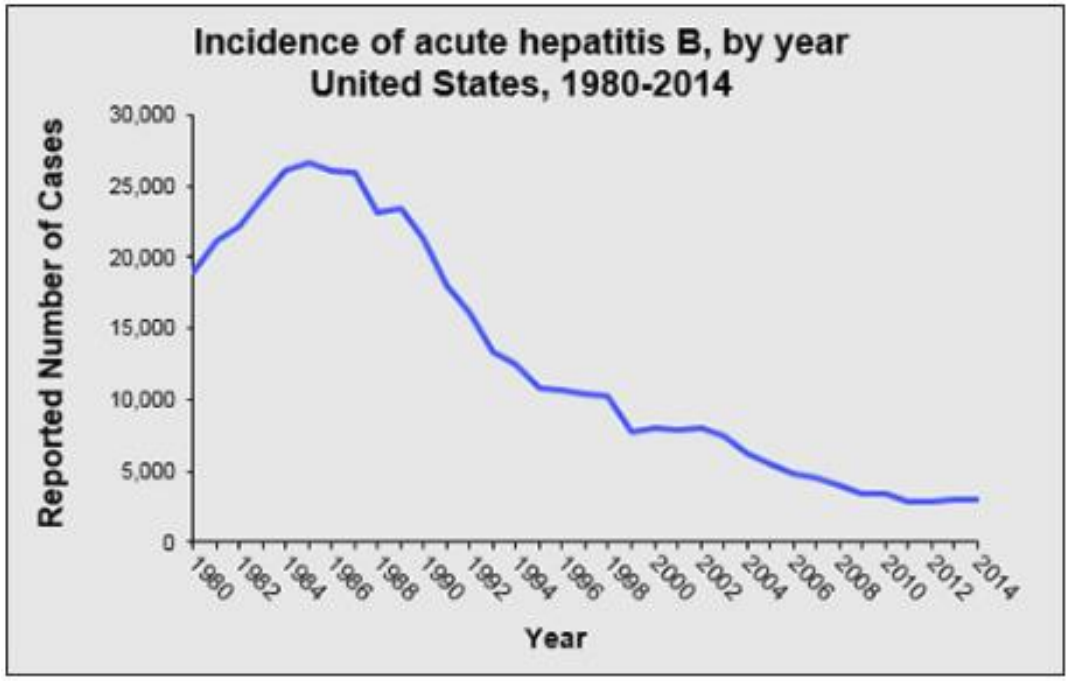


MAP 3-4. **Prevalence of hepatitis B virus infection**
[1] Disease data source: Schweitzer A, Horn J, Mikolajczyk R, Krause G, Ott J. Estimations of worldwide prevalence of chronic hepatitis B virus infection: a systematic review of data published between 1965 and 2013. www.thelancet.com. 2015.Vol 386.

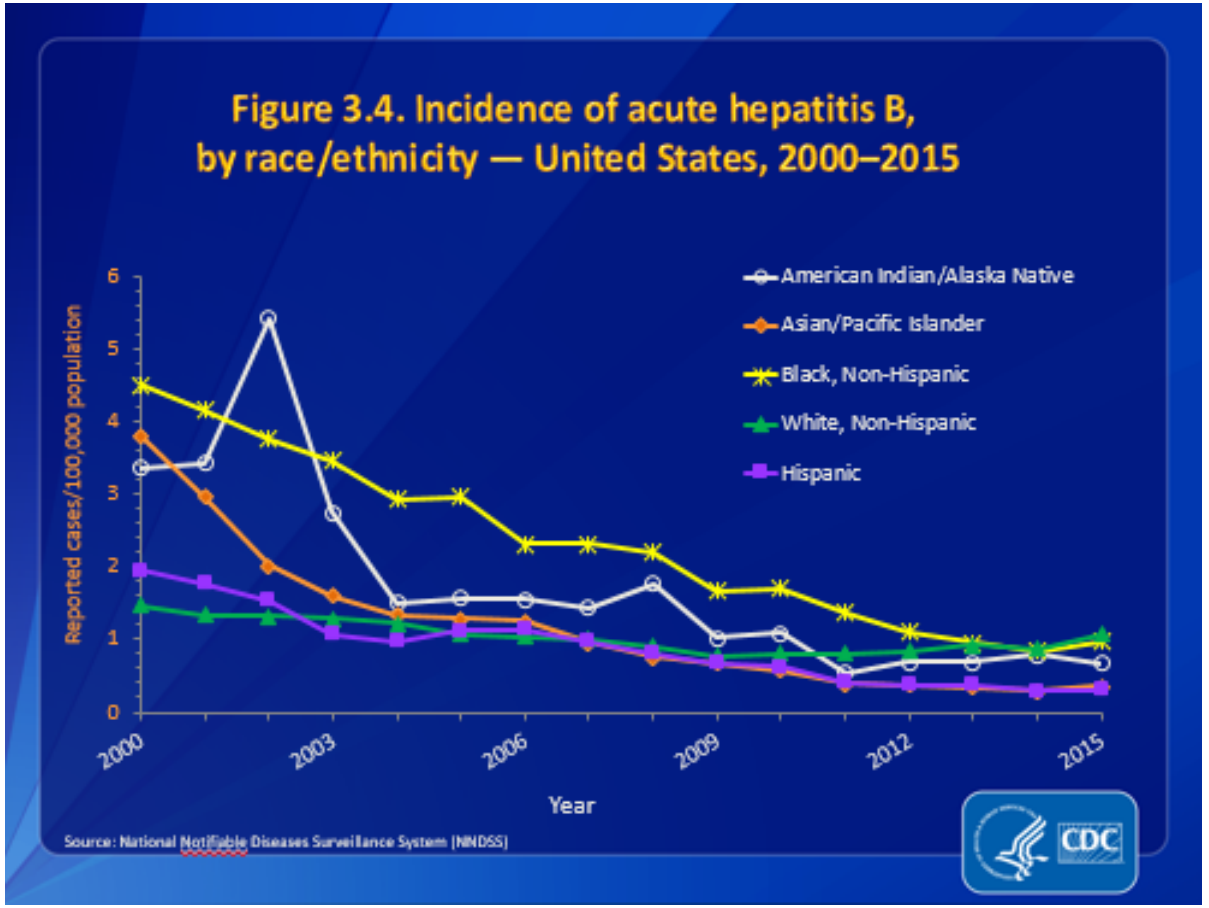
- Liver infection caused by the **hepatitis B virus (HBV)**
- HBV is typically transmitted by **blood, sexual contact, or vertically (mother to child)**
- May cause **acute or chronic hepatitis**
- Known as a silent killer. Many chronically infected persons are **asymptomatic.**
- HBV is **resilient** and can remain infectious on surfaces for more than 7 days at room temperature
- HBV is **50-100 times more infectious than HIV**
- HBV **prevalence rates vary greatly throughout the world**.
- According to the WHO, an estimated **257 million people** worldwide are living with hepatitis B infection.

Hepatitis B in the United States

- CDC estimates that ~19,200 cases of acute HBV occurred in the United States in 2014
- An estimated 850,000-2.2 million persons in the U.S. suffer from chronic HBV.
- The rate of new HBV infections has declined by ~82% since 1991, when a national strategy to eliminate HBV infection was implemented in the U.S.. The decline has been greatest among children born since 1991, when routine vaccination of children was first recommended.



Foreign-born persons and HBV prevalence in the United States



What is *perinatal* Hepatitis B?

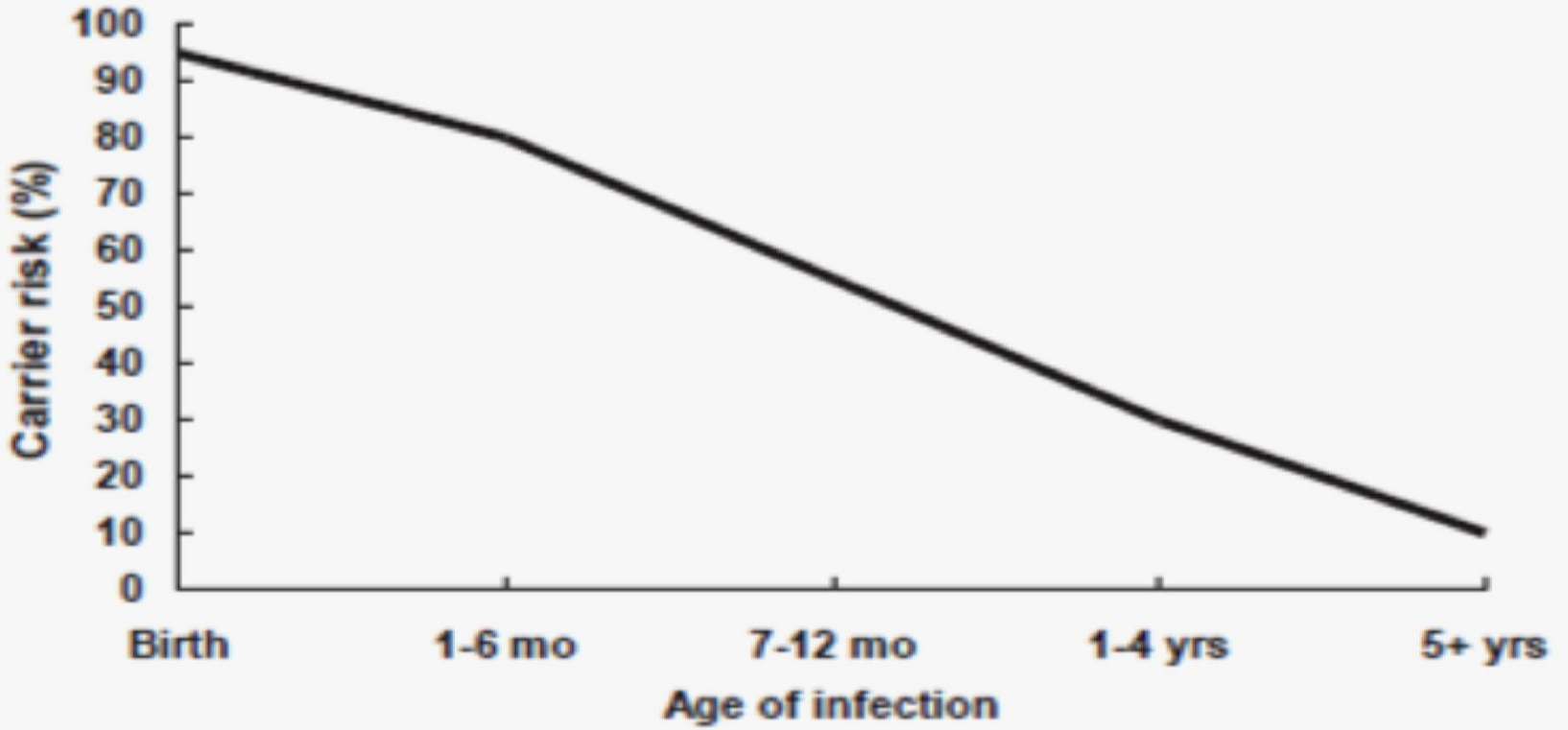
Vertical (mother to child) transmission

Newborns are extremely **vulnerable**. Approximately **90%** of children who are infected at birth or during the first year of life will become chronically infected; 6-10% of newly infected older children and adults become chronically infected.

An estimated **800** U.S. newborns are still becoming chronically infected with HBV each year from exposure at birth.

Each year in the U.S., more than 24,000 infants are born to mothers who are chronically infected with HBV.

Risk of Chronic HBV Carriage by Age of Infection



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.

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

Perinatal Hepatitis B Prevention Program Case Management Components

1. Test all 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 case management program

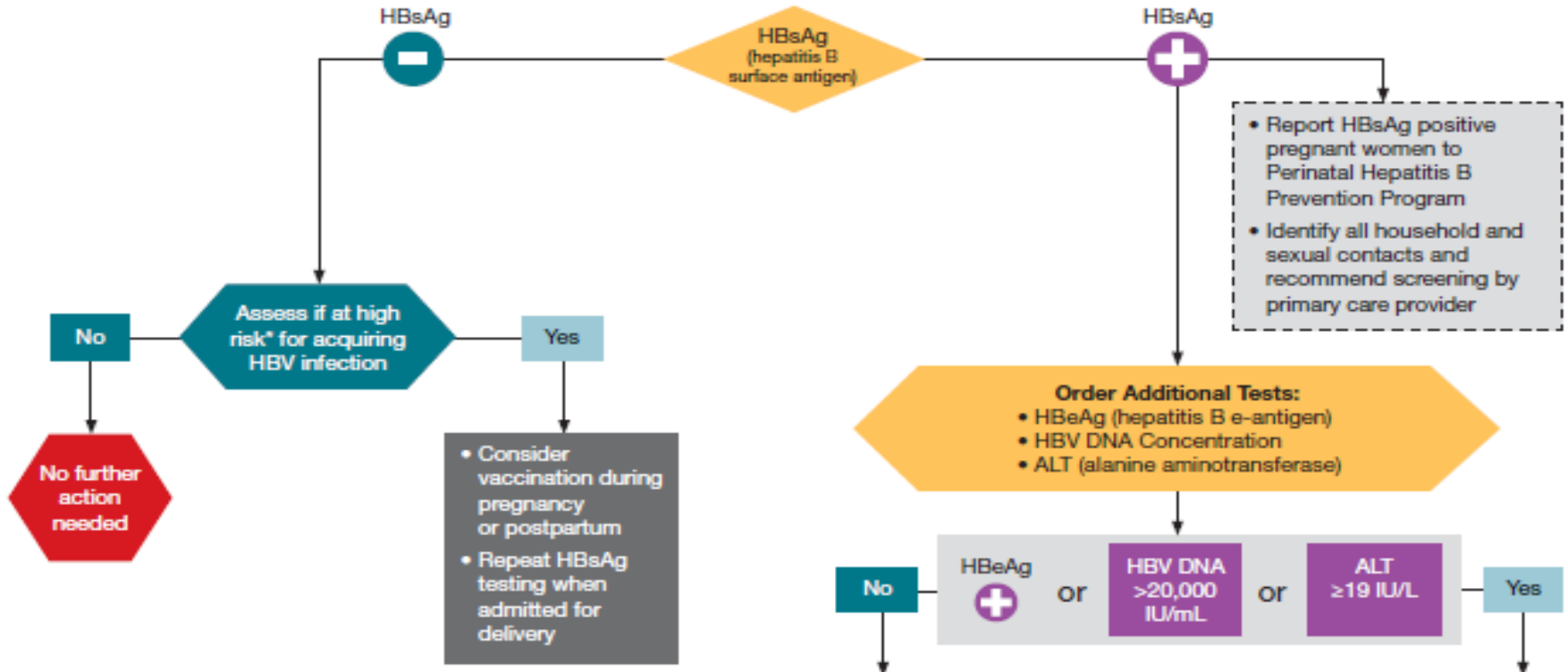
Four focus areas of Perinatal HBV Case-Management

1	Identification of HBsAg-positive women and their infants
2	Post-exposure prophylaxis at birth
3	Hepatitis B Vaccine series completion
4	Post-vaccination Serological Testing (PVST)

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.

Screening and Referral Algorithm for Hepatitis B Virus (HBV) Infection among Pregnant Women



*High risk for HBV infection includes: household or sexual contacts of HBsAg-positive persons; injection drug use; more than one sex partner during the past six months; evaluation or treatment for a sexually transmitted disease; HIV infection, chronic liver disease, or end-stage renal disease; and international travel to regions with HBsAg prevalence of ≥2%.

Adapted with permission from the Hepatitis B Foundation. Original publication: Apuzzio J, Block J, Cullison S, et al. Chronic Hepatitis B in pregnancy: A workshop consensus statement on screening, evaluation, and management, part 2. The Female Patient. 2012; 37[5]:30-34

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

The American College of Obstetricians and Gynecologists
WOMEN'S HEALTH CARE PHYSICIANS

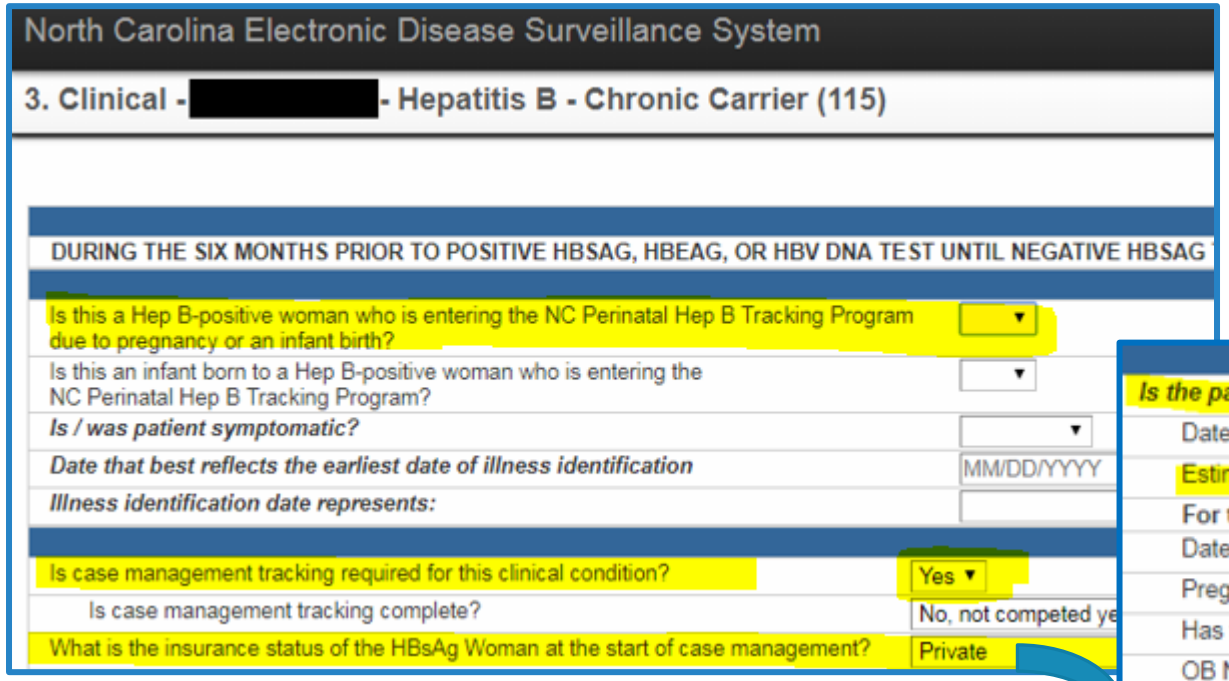
www.cdc.gov/hepatitis

March 2015

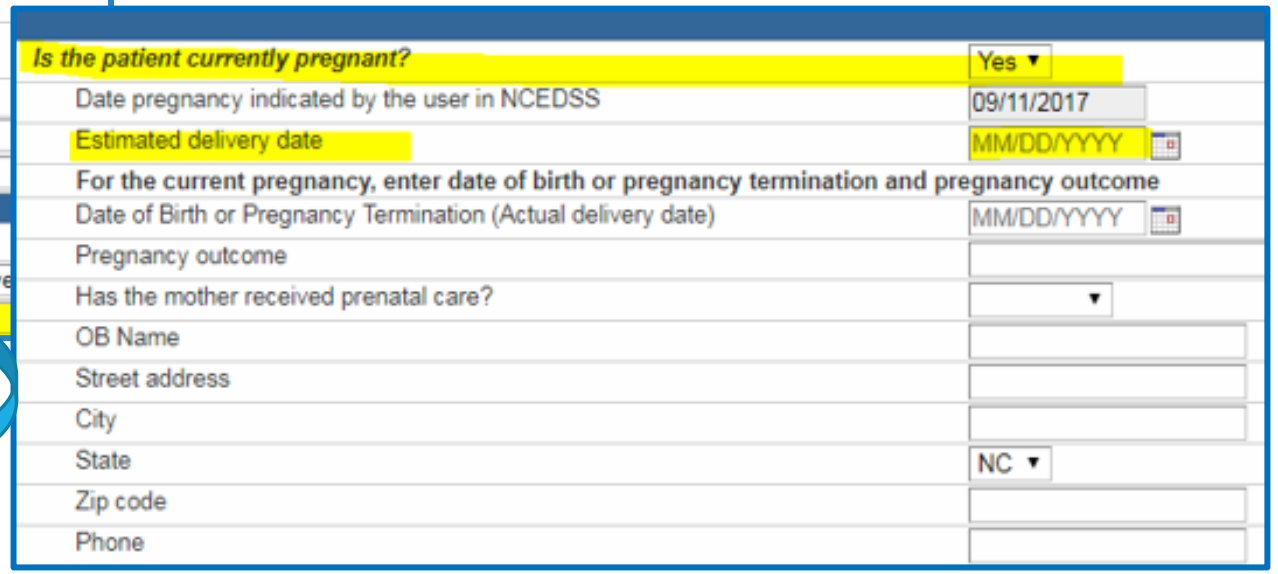
NC EDSS Documentation

- 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.
- Infants born to HBsAg-positive women are **required to be reported to NC EDSS within 30 calendar days of birth** and linked to the mother's event.

NC EDSS Documentation – Pregnancy Status

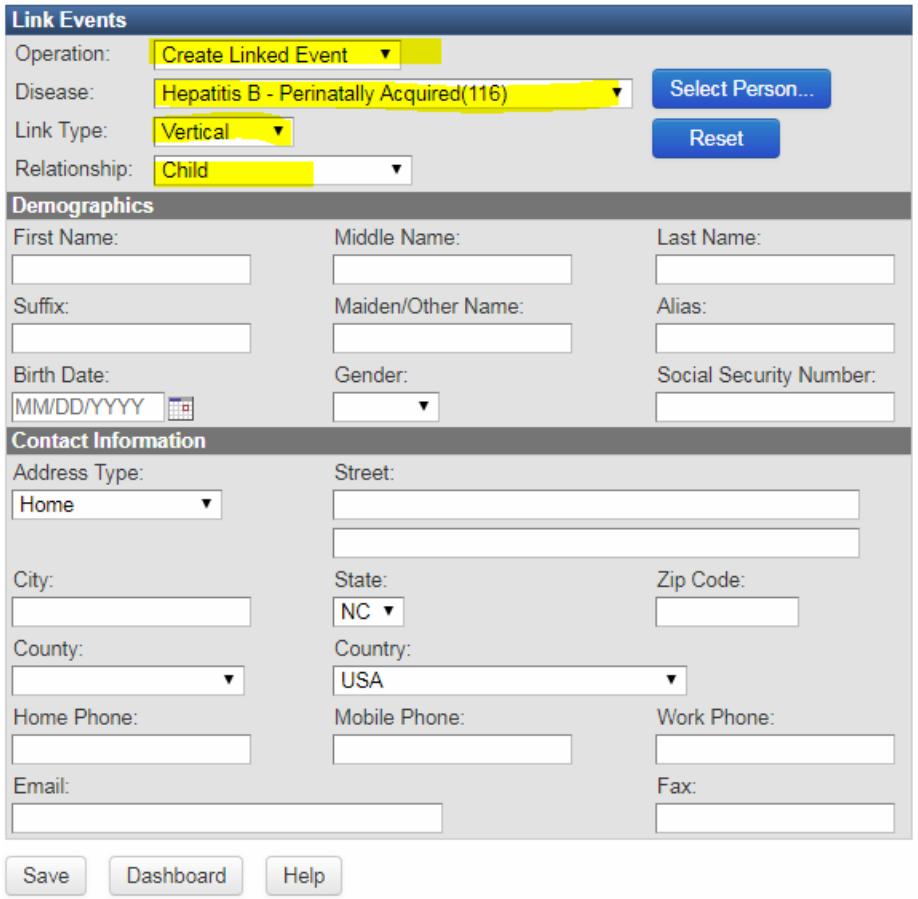


Document pregnancy and pregnancy details in the **clinical package** or **Hep B Subsequent Report Package**



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

NC EDSS Documentation – Infant Linkage to Mother

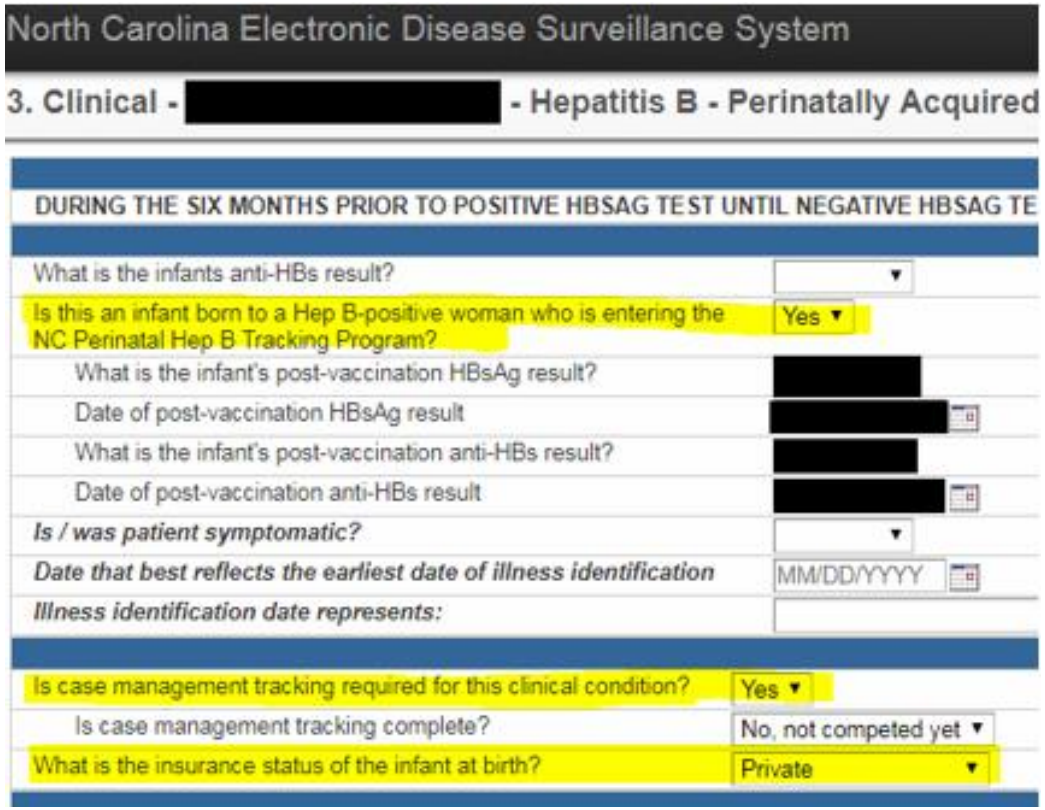


Hepatitis B Perinatal Contact Entry

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

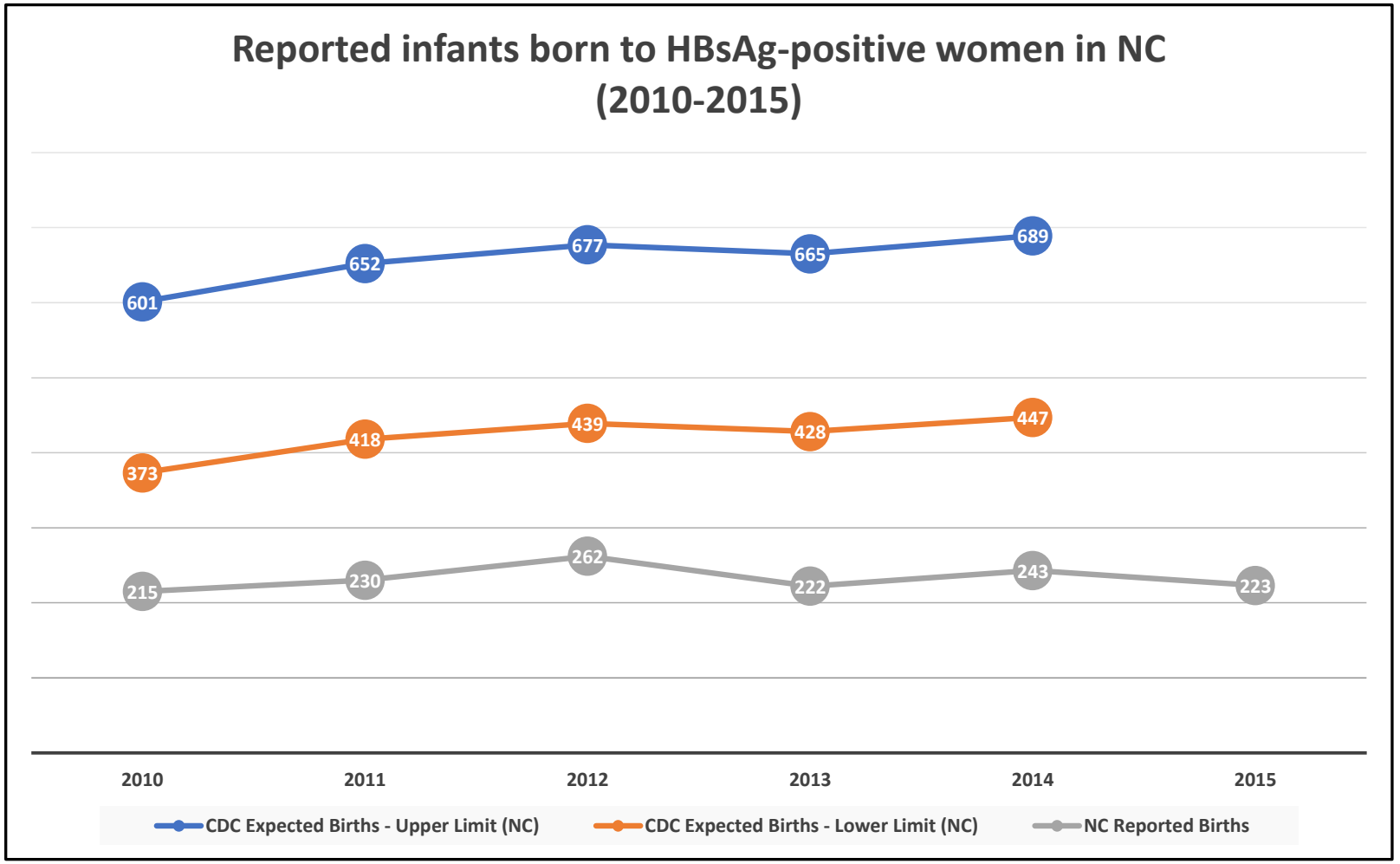
3. Clinical - [redacted] - Hepatitis B - Perinatally Acquired

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

What is the infants anti-HBs result?	
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]
What is the infant's post-vaccination anti-HBs result?	[redacted]
Date of post-vaccination anti-HBs result	[redacted]
Is / was patient symptomatic?	
Date that best reflects the earliest date of illness identification	MM/DD/YYYY
Illness identification date represents:	
Is case management tracking required for this clinical condition?	Yes
Is case management tracking complete?	No, not competed yet
What is the insurance status of the infant at birth?	Private

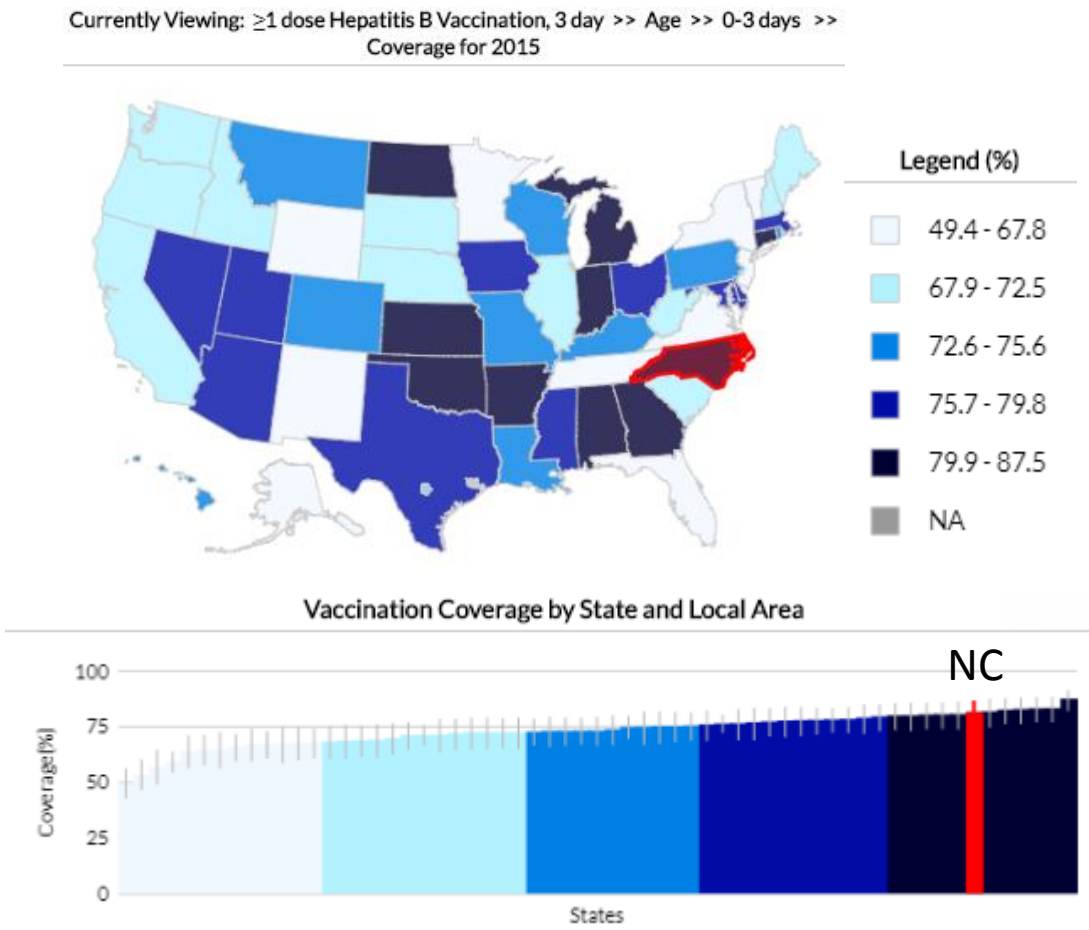
Once State PHB has entered the event into case-management, don't forget to enter the insurance information.

Infants identified in North Carolina (2010-2015)



Post-exposure prophylaxis (PEP) at birth

- Hepatitis B immune globulin (HBIG) **and** hepatitis B vaccine vaccine within 12 hours of birth
- PEP of newborns born to chronically infected mothers is **85-95% effective** when administered **within 12 hours of birth** (and followed by completion of the HBV series).
- Hepatitis B vaccine alone starting at birth will prevent transmission of HBV in 70-95% of infants born to chronically infected mothers (when followed by completion of the HBV series).
- 2015 NIS data shows that **~81.3%** of children in NC received the HBV vaccine within 3 days of life.

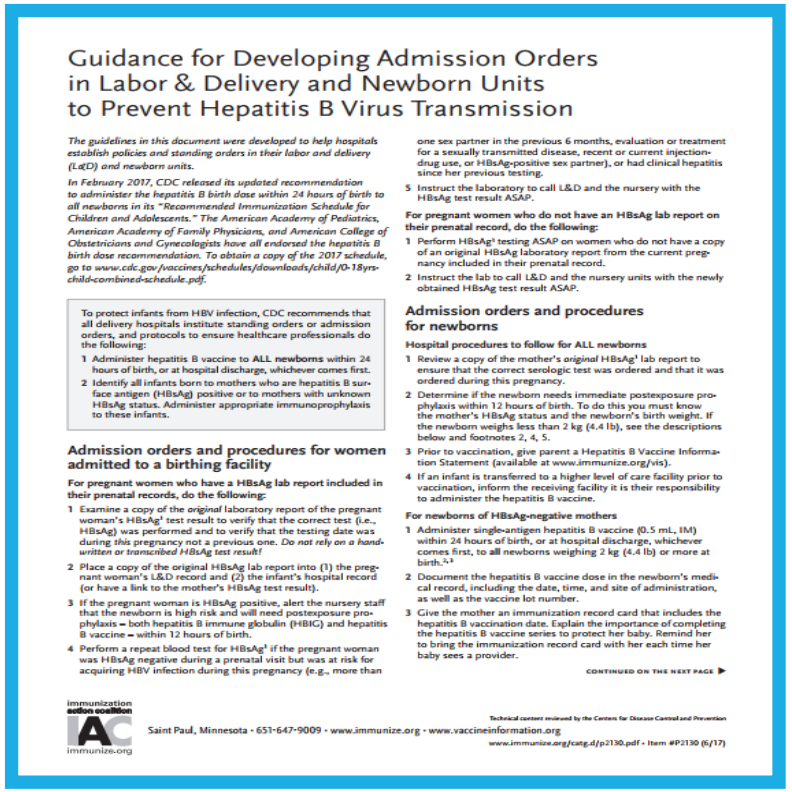


LHD's role with local birthing hospitals

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.
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.**

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 February 2017, CDC released its updated recommendation to administer the hepatitis B birth dose within 24 hours of birth to all newborns in its "Recommended Immunization Schedule for Children and Adolescents." The American Academy of Pediatrics, American Academy of Family Physicians, and American College of Obstetricians and Gynecologists have all endorsed the hepatitis B birth dose recommendation. To obtain a copy of the 2017 schedule, go to www.cdc.gov/vaccines/schedules/downloads/child/0-18yrs-child-combined-schedule.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 HBsAg[1] 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 HBsAg[1] 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.

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

1 Perform HBsAg[1] 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

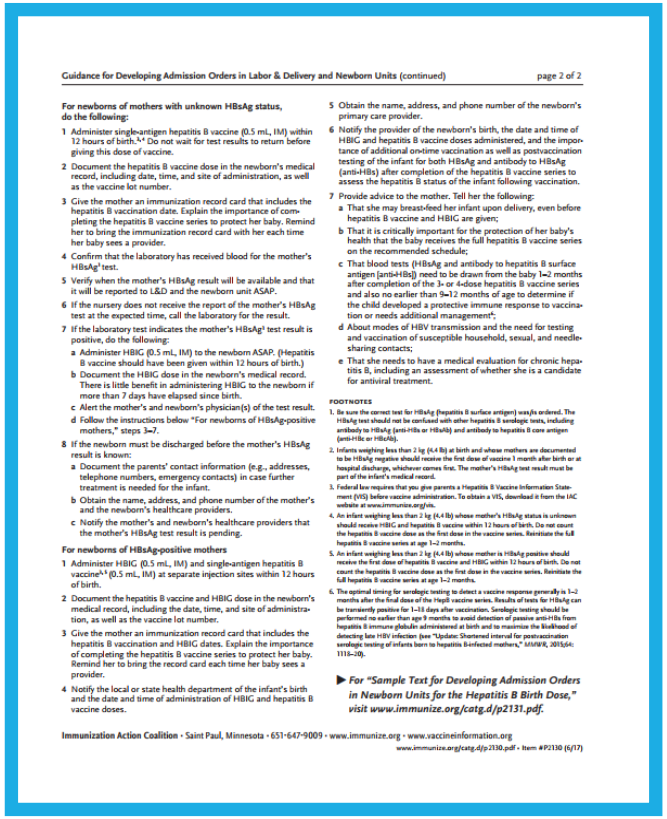
1 Review a copy of the mother's *original* HBsAg[1] lab report to ensure that the correct serologic test was ordered and that it was ordered during this pregnancy.
2 Determine if the newborn needs immediate postexposure prophylaxis within 12 hours of birth. To do this you must know the mother's HBsAg 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.[2,3]
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 vaccination 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.

CONTINUED ON THE NEXT PAGE ▶

immunization action coalition
IAC
immunize.org
Saint Paul, Minnesota • 651-647-9009 • www.immunize.org • www.vaccineinformation.org
Technical content reviewed by the Centers for Disease Control and Prevention
www.immunize.org/catg.d/p2130.pdf • Item #P2130 (6/17)



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

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

1 Administer single-antigen hepatitis B vaccine (0.5 mL, IM) within 12 hours of birth.[2,4] 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.
3 Give the mother an immunization record card that includes the hepatitis B vaccination 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 HBsAg[1] 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 HBsAg[1] 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

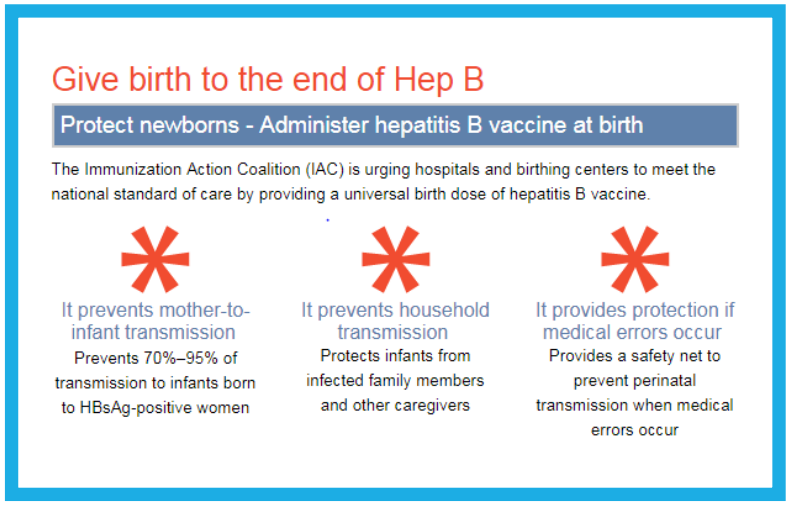
1 Administer HBIG (0.5 mL, IM) and single-antigen hepatitis B vaccine[2,3] (0.5 mL, IM) at separate injection sites within 12 hours of birth.
2 Document the hepatitis B vaccine and HBIG dose in the newborn's medical record, including the date, time, and site of administration, as well as the vaccine 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 receives 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[6];
  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.

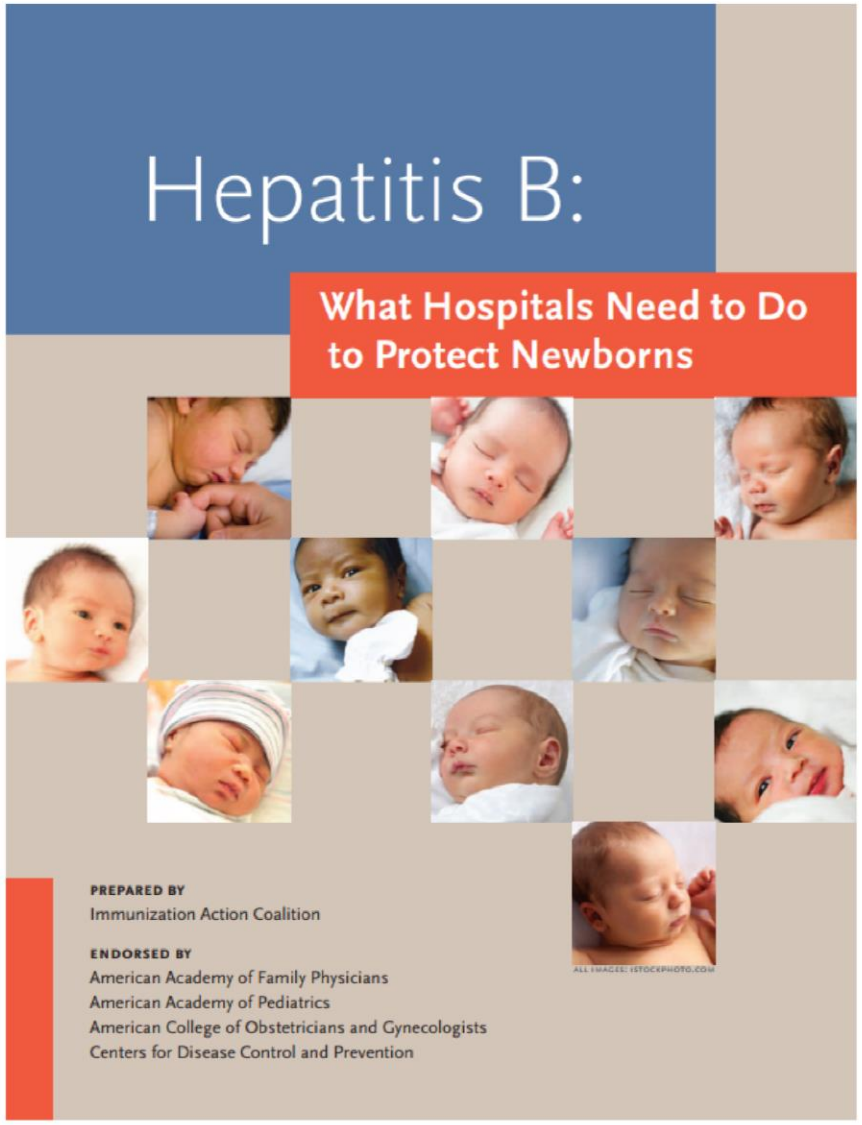
FOOTNOTES

1. Be sure the correct test for HBsAg (hepatitis B surface antigen) was/is 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 it 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 count the hepatitis B vaccine dose as the first dose in the vaccine series. Reinitiate the full hepatitis B vaccine series at age 1–2 months.
5. An infant weighing less than 2 kg (4.4 lb) whose mother is HBsAg positive 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. Reinitiate the full hepatitis B vaccine series at age 1–2 months.
6. The optimal timing for serologic testing to detect a vaccine response generally is 1–2 months after the final dose of the Hepb vaccine series. Results of tests for HBsAg can be transiently positive for 1–13 days after vaccination. Serologic testing should be performed no earlier than age 9 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: Shortened interval for postvaccination serologic testing of infants born to hepatitis B–infected mothers," *MMWR*, 2015;64: 1118–20).

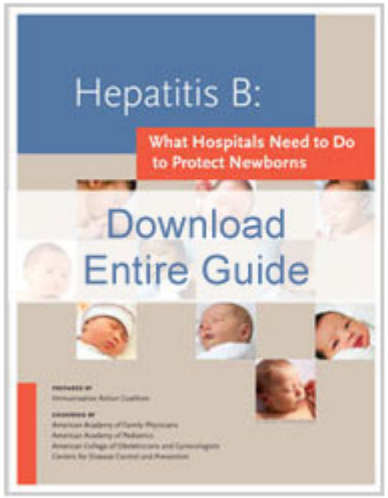
▶ *For "Sample Text for Developing Admission Orders in Newborn Units for the Hepatitis B Birth Dose," visit www.immunize.org/catg.d/p2131.pdf.*

Immunization Action Coalition • Saint Paul, Minnesota • 651-647-9009 • www.immunize.org • www.vaccineinformation.org
www.immunize.org/catg.d/p2130.pdf • Item #P2130 (6/17)





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

We have a limited number of these books available **for free** at the NC Immunization Branch Central Office. Please let us know if you are interested in receiving a copy for one or more of the birthing hospitals in your jurisdiction.

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	1. Administer Hepatitis B vaccine within 12 hours 2. Draw mother's blood 3. If mother is HBsAg(+), administer HBIG as soon as possible, but no later than 7 days after birth	1. Administer Hepatitis B vaccine within 12 hours of birth 2. Draw mother's blood 3. If results are not received within 12 hours, administer HBIG within 12 hours of birth. *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.
Positive	Administer Hepatitis B vaccine **and** HBIG within 12 hours of birth	Administer Hepatitis B vaccine **and** HBIG within 12 hours of birth *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.

NC EDSS PEP Documentation

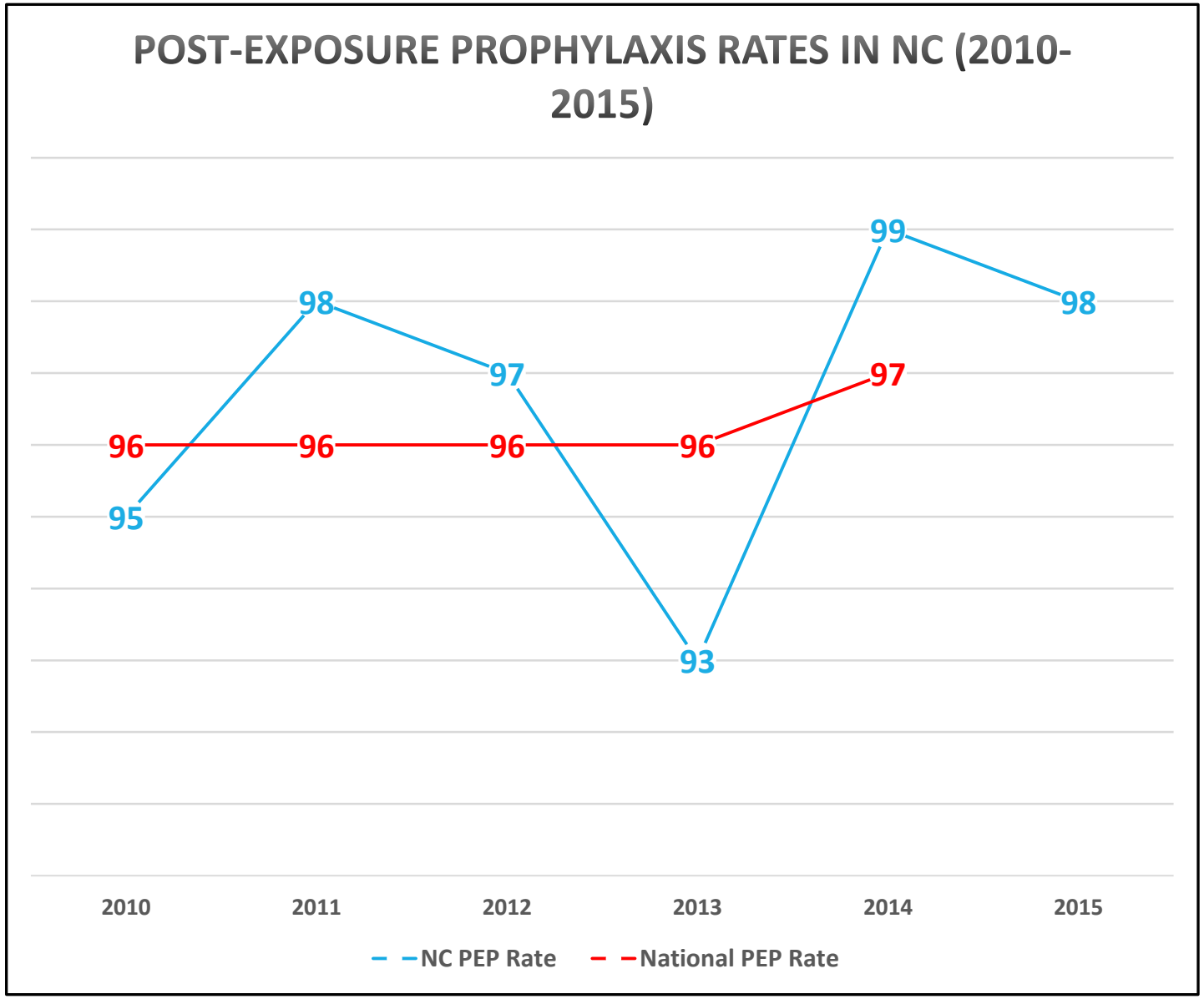
State of infant's birth	NC
Infant's country of birth	USA
Was the infants birth weight less than 2000 grams (4.4 pounds)?	No
Biologic mother's race	Black African American Add New
Please specify	African American
Biologic mother's Hispanic ethnicity	No
Was the biologic mother born outside the US?	Unknown
Was the biologic mother confirmed HBsAg positive prior to or at time of delivery?	Yes
Date of HBsAg positive test result	[redacted]
Date of HBsAg positive test result	[redacted]
Date of HBsAg positive test result	[redacted] 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	[redacted]
Hospital contact name	
Phone	

Vaccine Informat

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	

PEP Rates in NC 2010-2015

*PEP consists of hepatitis B vaccine and HBIG within 1 calendar day of birth



Hepatitis B Vaccine Series Completion

Vaccine	Birth	1 mo	2 mos	4 mos	6 mos	9 mos	12 mos	15 mos	18 mos
Hepatitis B[1] (HepB)	1st dose	←——2nd dose——→			←————————3rd dose————————→				

Dose 1

Within 12 hours of birth

(must be single antigen Hepatitis B vaccine)

Dose 2

Age 1-2 months

(min. interval: 4 wks. from dose 1)

Dose 3

Age 6 months

(min. interval: 8 wks. from dose 2 and 16 wks. from dose 1.)

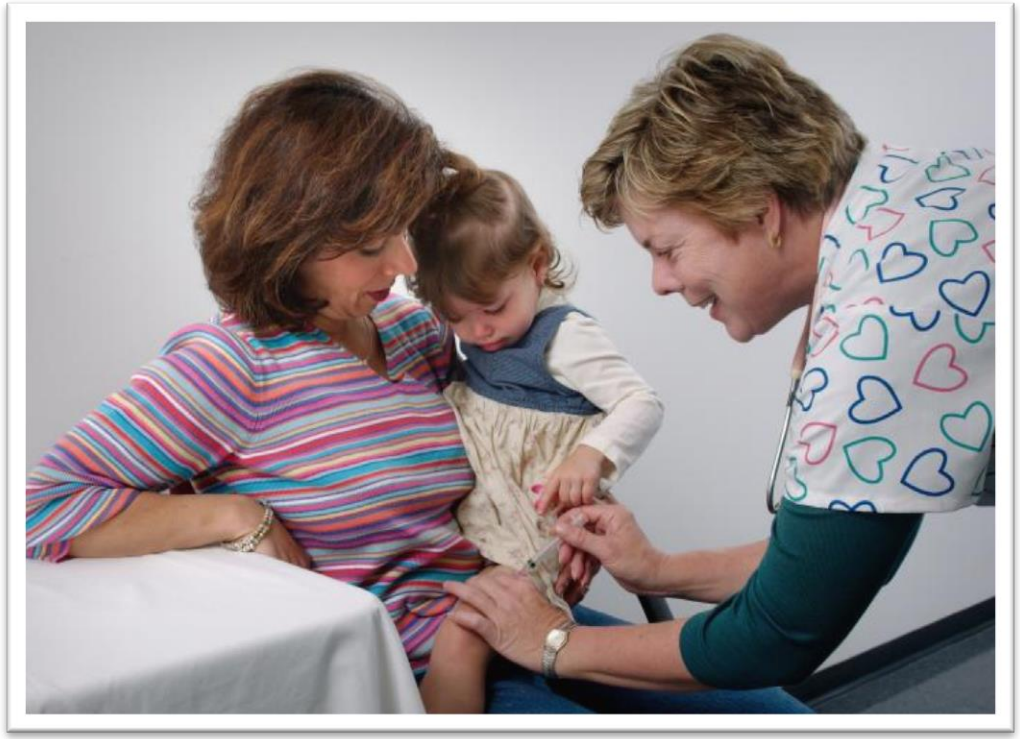
Effectiveness of HBV 3-dose series

- 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.

Immune response following Hepatitis B vaccine

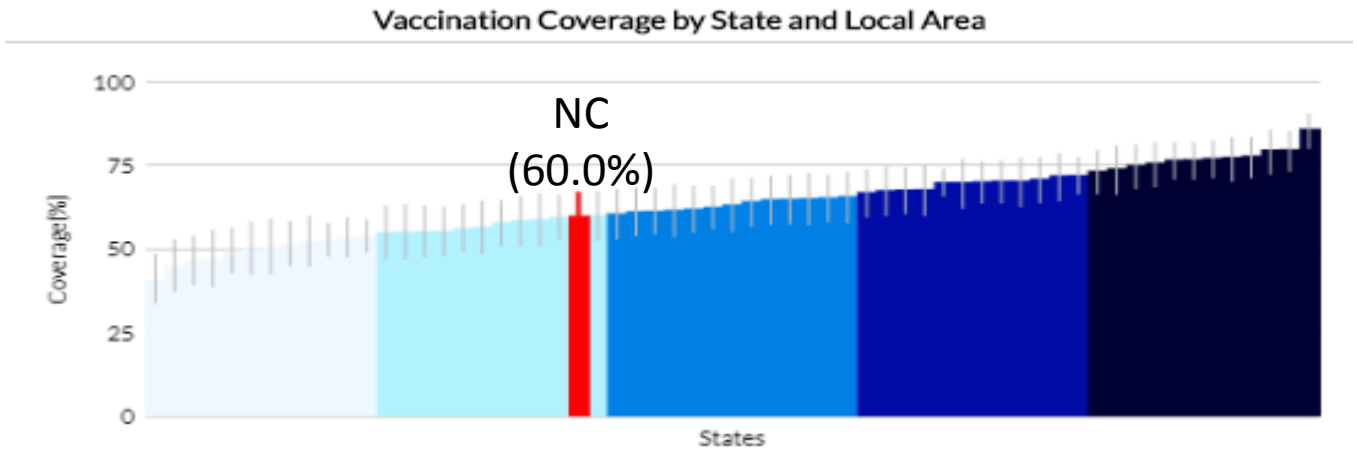
- **Anti-HBs** is the only easily measurable correlate of vaccine-induced protection.
- Anti-HBs levels ≥10 mIU/mL after vaccination equates to virtually **complete lifetime protection from both acute and chronic HBV infection.**
- Anti-HBs levels decline rapidly in the first year after vaccination, 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.

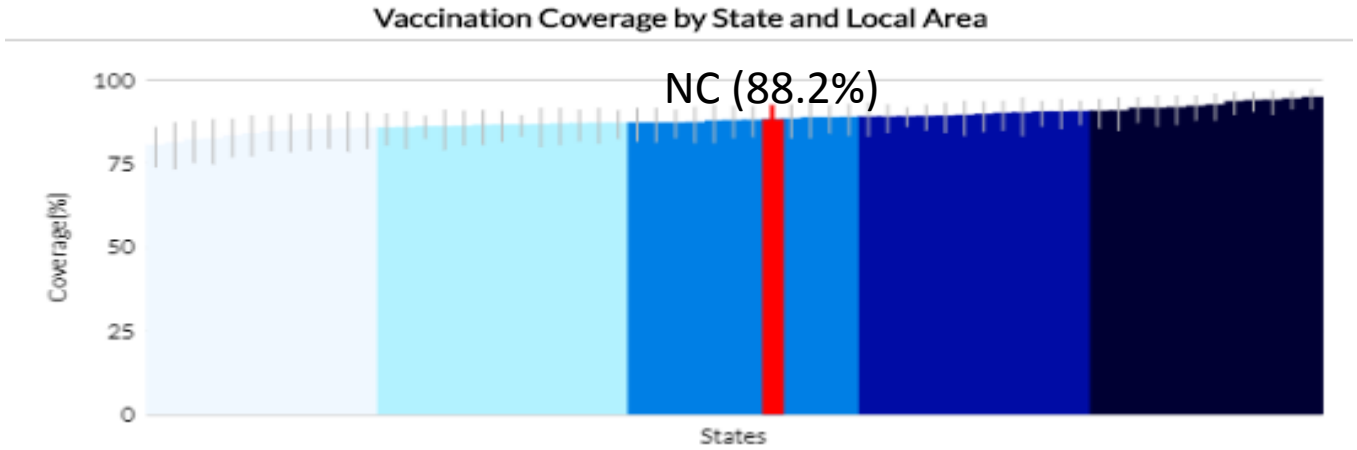


Vaccine Documentation in NC EDSS

Vaccine Informatic	
Has patient / contact ever received vaccine related to this disease?	Yes
Vaccine type ⊟	Hepatitis B vaccine, NOS
Date of administration	01/02/2016
Vaccine data imported from NCIR or entered manually?	Manual entry
Year of last dose received	2016
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
Date of Administration: 02/26/2016 Vaccine type ⊞	Hepatitis B vaccine, NOS
Date of Administration: 05/02/2016 Vaccine type ⊞	Hepatitis B vaccine, NOS
Date of Administration: 07/01/2016 Vaccine type ⊞	Hepatitis B vaccine, NOS
Number of vaccines given is 4: Is vaccination series complete?	No
Continue to request vaccine information from NCIR?	Yes
Review required for NCIR information?	No
NCIR vaccine information date	

HBV Series Completion in NC





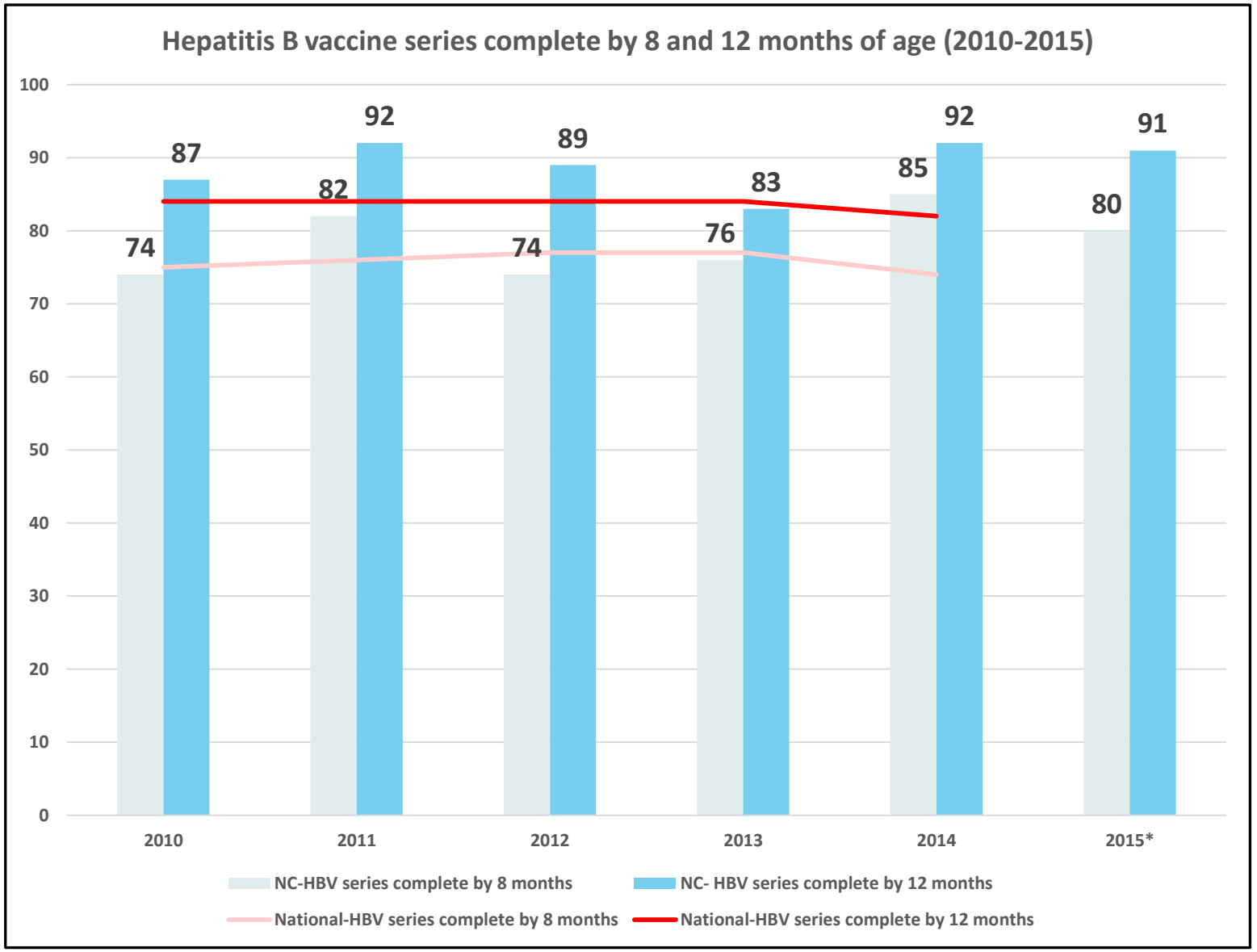
According to 2015 NIS results:

- Only **60%** of the 19-35 month old children sampled in NC completed the HBV series **by 7 months of age.**

- **88.2%** of the 19-35 month old children sampled in NC completed the HBV series by **13 months of age.**

Hepatitis B Vaccine Series Complete by 8 and 12 months of age (2010-2015)

*data based on infants case-managed through the NC PHBPP
**data based on infants that received PEP within 1 calendar day of birth



*2015 data is considered preliminary and is subject to change.

Post-vaccination serological testing (PVST)

- Consists of hepatitis B surface antigen (HBsAg) and hepatitis B surface antibody (anti-HBs)
- Should be performed after completion of the Hepatitis B vaccine series (preferably at 9-12 months of age)*
- PVST 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
- Revaccination*

  Infants born to HBsAg-positive mothers. 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 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.

*new recommendation

Quick Test Results

Result	Interpretation
HBsAg (+) anti-HBs (-)	Chronic HBV infection*
HBsAg (-) anti-HBs (+)	Immune to HBV
HBsAg (-) anti-HBs (-)	Unprotected; needs vaccination
HBsAg (+) anti-HBs (+) (rare)	Chronic HBV infection*

*If HBsAg remains positive for 6 months or in the absence of IgM anti-HBc

Event Data | Lab Results | Concerns | Persons | Tasks | Event Properties | Event History

Labs

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 Ql || ...
1	01/23/2017		Whole blood sample	Positive			HBV surface Ab Ser-aCnc |...

Add Lab Result | Update Lab Result | Delete Lab Result

Details

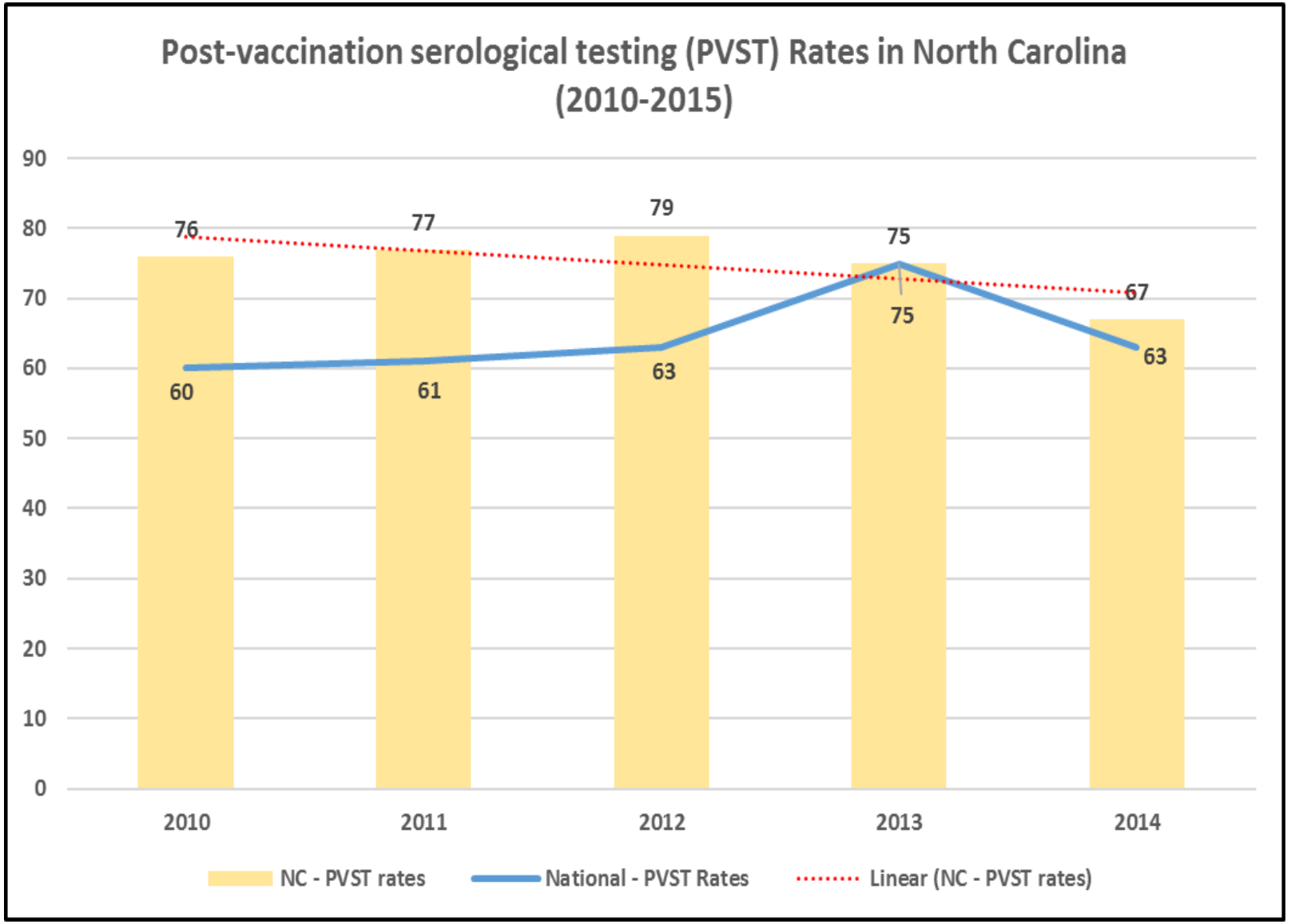
Last Update:	04/03/2017
Updated By:	[redacted]
Specimen Info	
Specimen Date:	01/23/2017
Specimen Type:	Whole blood sample
Tests	
Test:	HBV surface Ag Ser Ql || Hepatitis B virus surface Ag:
Result:	Negative
Result Date:	01/23/2017
Tests	
Test:	HBV surface Ab Ser-aCnc || Hepatitis B virus surface Ab: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

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

Post-vaccination Serological Testing Rates in North Carolina (2010-2015)

*data based on infants case-managed through the NC PHBPP
**data based on infants that received PEP within 1 calendar day of birth



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.

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 # (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	
2nd series-Hepatitis B vaccine # 1	
2nd series-Hepatitis B vaccine # 2	
2nd 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

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.

Lost to Follow-Up/Family Relocated

Lost to Follow-up

- Policy/Procedure
- At least 3 different attempts should be made to contact the family and/or provider
- 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

LHD Monitoring – PHB Assessment

NORTH CAROLINA IMMUNIZATION PROGRAM
2017 LOCAL HEALTH DEPARTMENT MONITORING VISIT
PERINATAL HEPATITIS B ASSESSMENT

Local Health Department:

Perinatal Hepatitis B Surveillance Summary:

Indicator	2015	2016
Total Number of infants reported from 1/1/2015 through 12/31/2016		
Received PEP (HBIG and HBV) within 12 hours of birth		
Documentation in NCEDSS (required within 30 days of birth)		
HBV series completed by 8 months of age		
Post-vaccination serological testing (PVST) completed *(recommended by 9-12 months and 1-2 months after the final HBV dose)*		

Comments:

General Perinatal Hepatitis B Reminders:

- Continue to educate providers (OBGYNs, family practitioners, hospitals, etc.) on the importance of testing pregnant women for HBsAg. Be *proactive* and attempt to identify infants at risk *before* they are born.
- Continue to work with your local hospitals to ensure that they are administering proper PEP (HBIG and HB-1) within 12 hours of birth to infants whose mothers are known to be HBsAg-positive or have an unknown HBsAg status.
- Please continue to document all infants (born to HBsAg-positive women) in NCEDSS within 30 days of birth and link to the mother's event. Documenting infants within 30 days is crucial because it allows the state perinatal Hep B coordinators to also monitor these infants and ensure that they are receiving the appropriate treatment and not falling behind schedule.
- Please continue to follow minimum or recommended intervals for the hepatitis B vaccine series since this is a high risk group. Following the ACIP schedule allows for timely PVST to determine if an infant is immune, susceptible or infected. If found to be susceptible, this gives the provider time to revaccinate early and retest with the hopes of preventing a chronic infection. All HBV doses must be documented in NCEDSS within the vaccine package.
- Continue to work closely with providers to ensure that PVST recommendations are followed and that parents understand the importance of testing. Extensive effort needs to be made to educate parents and to attempt to bring infants in for testing on time (either at the LHD or the provider's office). Be proactive with providers and notify them before the infant is due for testing instead of when they're overdue.
- Continue to educate providers on the appropriate serological markers needed for PVST. Infants must be tested for BOTH HBsAg and anti-HBs. Testing for one serological marker or the other and not both is considered "indeterminate", which results in the infant needing to be retested.
- Remember to follow the new PVST guidelines for completing PVST by **9-12 months** (and 1-2 months after receipt of the final Hep B dose) instead of the previously recommended 9-18 months. Please refer to the MMWR article (Vol. 64/No. 39/October 9, 2015) titled "Update: Shortened Interval for Post-Vaccination Serologic Testing of Infants Born to Hepatitis B-Infected Mothers".
- Please exhaust all possible resources (WIC, Medicaid, certified letters, phone calls, home visits, etc.) to track an infant prior to considering them as lost to follow-up.
- Please continue to update NCEDSS regularly and feel free to call us with any questions.

NC Perinatal Hepatitis B Coordinator Contact Information:

- Mary Stanley, RN:
  919-707-5573
  mary.stanley@dhhs.nc.gov
- Jenny Myers, MPH:
  919-707-5599
  jenny.myers@dhhs.nc.gov

Division of Public Health
Agreement Addendum
FY 17-18

Page 1 of 10

Local Health Department Legal Name	Women's and Children's Health / Immunization **DPH Section / Branch Name**
715 Immunization Action Plan **Activity Number and Description**	Gary Walker, (919) 707-5556 gary.walker@dhhs.nc.gov **DPH Program Contact** (name, telephone number with area code, and email)
06/01/2017– 05/31/2018 **Service Period**	**DPH Program Signature** **Date** (only required for a negotiable agreement addendum)

07/01/2017 – 06/30/2018

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.

Division of Public Health
Agreement Addendum
FY 17-18

Master **Local Health Department Legal Name**	Epidemiology/Communicable Disease Branch **DPH Section / Branch Name**
510 General Communicable Disease Control **Activity Number and Description**	Robert Pace, (919) 819-3607 robert.g.pace@dhhs.nc.gov **DPH Program Contact** (name, phone number, and email)
06/01/2017 – 05/31/2018 **Service Period**	**DPH Program Signature** **Date** (only required for a negotiable agreement addendum)
07/01/2017 – 06/30/2018 **Payment Period**	

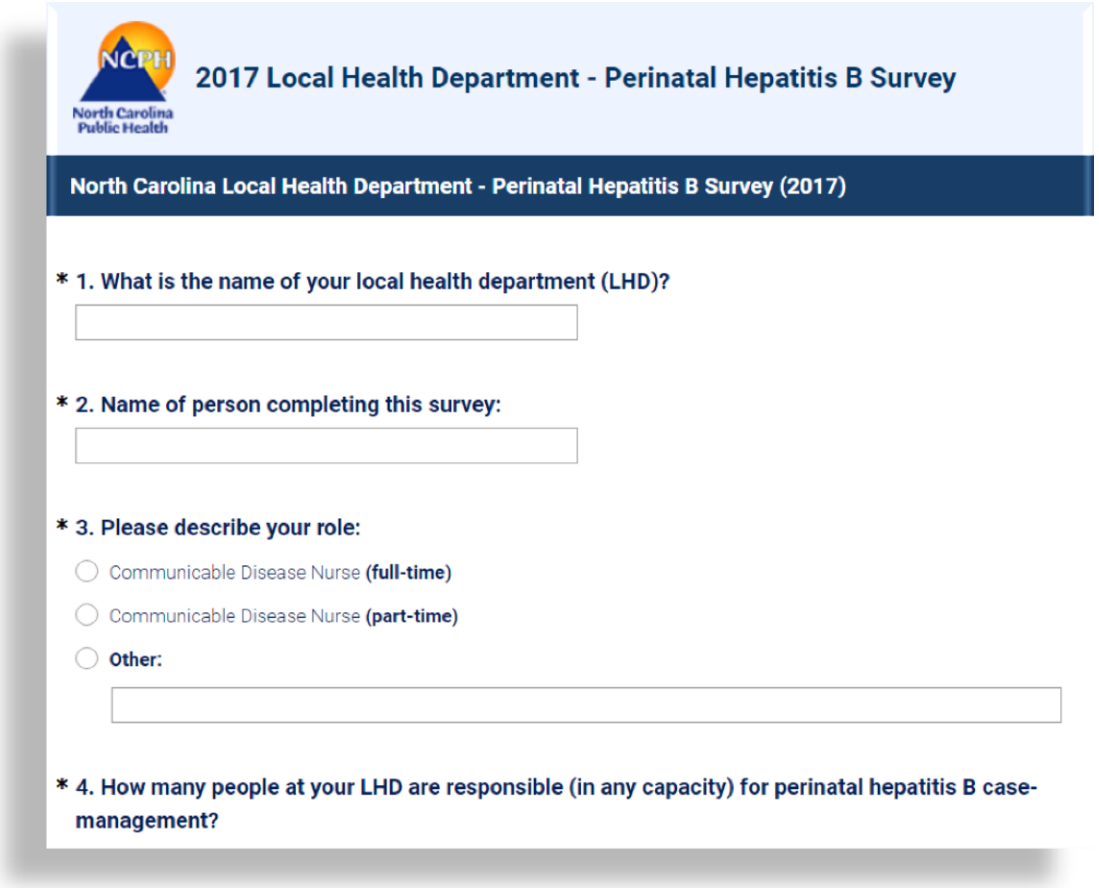
☒ Original Agreement Addendum

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.

LHD Perinatal Hepatitis B Survey



2017 Local Health Department - Perinatal Hepatitis B Survey

North Carolina Local Health Department - Perinatal Hepatitis B Survey (2017)

* 1. What is the name of your local health department (LHD)?

* 2. Name of person completing this survey:

* 3. Please describe your role:

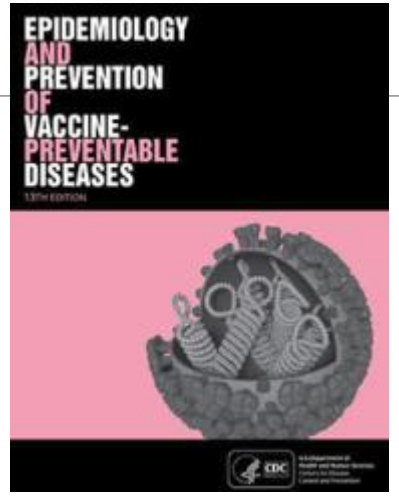
- Communicable Disease Nurse **(full-time)**
- Communicable Disease Nurse **(part-time)**
- **Other:**

* 4. How many people at your LHD are responsible (in any capacity) for perinatal hepatitis B case-management?

We want your input!

Results will be used to identify and address county-specific needs related to perinatal hepatitis b case-management.

Perinatal Hepatitis B Resources



CDC Perinatal Hepatitis B Website:
https://www.cdc.gov/hepatitis/hbv/perinatalxmtn.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 http://med.stanford.edu/yucorps/files/physicians_eng.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/
- VFC Resolution – Hepatitis B https://www.cdc.gov/vaccines/programs/vfc/downloads/resolutions/2017-02-01-hepb.pdf

Contact Information

Mary Stanley, RN

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