

MEMO

TO: Private Providers, Hospitals and
Local Public Health Units

FROM: Abbi Pierce
Perinatal Hepatitis B Coordinator

RE: Pregnancy in a Person Infected with Hepatitis B is a Mandatory Reportable
Condition in North Dakota

DATE: May 1, 2008

The risk of perinatally-transmitted hepatitis B can be substantially reduced through proper screening and administration of vaccine and HBIG to at-risk newborns.

Pregnancy in a person infected with hepatitis B is a mandatory reportable condition in North Dakota. This means that a pregnant woman with any of the following hepatitis B markers **must** be reported to the North Dakota Department of Health (NDDoH):

- HBsAg – hepatitis B surface antigen
- HbeAg - hepatitis B “e” antigen
- Anti-HBc, IgM – IgM antibody to the hepatitis B core antigen
- HBV DNA – viral hepatitis B DNA detection
- Any woman who has chronic hepatitis B and becomes pregnant must be reported to the NDDoH

Each pregnancy in a woman infected with hepatitis B **must** be reported. It is the responsibility, according to North Dakota Century Code (NDCC 23-07-02), of both the physician and the laboratory to report this condition.

A Physician's Prenatal Report of HBsAg-Positive Mother form (SFN 58507) is enclosed. Positive pregnant women can also be reported online at <http://www.ndhealth.gov/Disease/Disease%20Reporting/DiseaseCard.aspx>.

Women with any of the above hepatitis B markers will be tracked throughout their pregnancy by the NDDoH Perinatal Hepatitis B Program. Once the infant is born, the child will also be tracked to ensure proper vaccination and post-vaccination testing.

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Enclosed are informational packets aimed at each type of provider that will be caring for the mother or the infant. They are divided into packets for prenatal care practitioners, delivery hospital/physician, and immunization providers.

Please contact the NDDoH Immunization Program with any questions or concerns at 701.328.3386 or toll-free at 800.472.2180.

Enclosures

cc: Dr. Terry Dwelle, State Health Officer
Dr. Craig Lambrecht, State Medical Officer
Kirby Kruger, Director
Molly Sander, Immunization Program Manager



Protocol for the Prevention of Perinatal Hepatitis B for Health Care Providers

May 2008



Prenatal Care Practitioners

It is important to screen all pregnant women for HBsAg at an early prenatal care visit, even if they have had a previous negative result. If not previously screened or at high risk, the women should be screened at time of admission to the hospital for delivery. Copies of the original laboratory report should be sent to the delivery hospital to minimize errors in transcribing the result into the infant's record.

Enclosed are the following materials:

1. Prenatal Hepatitis B Screening Procedure
2. A Physician's Prenatal Report of HBsAg-Positive Mother form (SFN 58507).
 - Positive pregnant women can also be reported online at <http://www.ndhealth.gov/Disease/Disease%20Reporting/DiseaseCard.aspx>.



Prenatal Hepatitis B Screening Procedure

- Test all pregnant women for HBsAg during an early prenatal visit in each pregnancy, preferably at the same time other routine prenatal laboratory testing is done.
 - Pregnant women should be tested even if they have been previously vaccinated or tested.
- HBsAg testing should be done at the time of admission to the hospital for delivery for women who:
 - were not screened prenatally
 - participate(d) in injection drug use
 - had more than one sex partner in the previous six months
 - had a HBsAg-positive sex partner
 - had an evaluation or treatment for a sexually transmitted diseases
 - have clinical hepatitis
- All laboratories that provide HBsAg testing of pregnant women should use an FDA-licensed or approved HBsAg test and should perform testing according to the manufacturer's labeling, including testing of initially reactive specimens with a licensed neutralizing confirmatory test.
 - When pregnant women are tested for HBsAg at the time of admission for delivery, shortened testing protocols may be used and initially reactive results reported to expedite administration of immunoprophylaxis to infants.
 - Tests for other HBV markers are not necessary for the purpose of maternal screening. However, HBsAg-positive women identified during screening may have HBV-related liver disease and should be evaluated by a healthcare provider.
 - When HBsAg testing of pregnant women is not feasible (i.e., in remote areas without access to a laboratory), all infants should receive hepatitis B vaccine within 12 hours of birth and should complete the hepatitis B vaccine series according to a recommended schedule for infants born to HBsAg-positive mothers.
 - The North Dakota Department of Health (NDDoH) Division of Laboratory Services provides prenatal HBsAg testing and all other appropriate follow-up tests (i.e. sexual contacts, household contacts) at no charge to North Dakota healthcare providers.
 - The NDDoH is not responsible for payment of tests performed at other laboratories.

Reporting Hepatitis B

Hepatitis B is a mandatory reportable condition in North Dakota based on North Dakota Administrative Code 33-06-01 and Statutory Authority NDCC 23-07-01.

- HBsAg-positive results should be reported immediately to the NDDoH Division of Disease Control. Results may be reported by calling 701.328.2378 or toll-free 800.472.2180. Results may also be reported using the Physician's Prenatal Report of HBsAg-Positive Mother form or online at www.ndhealth.gov/Disease/Disease%20Reporting/DiseaseCard.aspx
- Physicians and laboratories are responsible for reporting HBsAg-positive results from private laboratories.
- The NDDoH Division of Laboratory Services reports results directly to the requesting provider and the NDDoH Division of Disease Control.



CONFIDENTIAL

Please complete the information that applies and **FAX to: 701.328.0355 (Confidential Fax Number)**
If you have questions, call: 701.328.3324 or toll-free 800.472.2180.

As of **April 1, 2007**, North Dakota Administrative Rules state that pregnancy in a person infected with hepatitis B is a reportable condition.

| Mother's Information | | | |
|---|--------------|--|---------------------|
| HBsAg(+) Test Date: | | Date of Birth: | |
| Last Name: | | First Name: | |
| Address: | | | |
| City: | | State: | Zip Code: |
| Telephone Number: | | Alternate Telephone Number: | |
| Physician's Name: | | Clinic Name: | |
| Race: <input type="checkbox"/> Asian <input type="checkbox"/> Black or African American <input type="checkbox"/> White <input type="checkbox"/> Other | | Ethnicity: <input type="checkbox"/> Hispanic or Latino <input type="checkbox"/> Not Hispanic or Latino <input type="checkbox"/> Unknown | |
| Mother's Country of Origin: | | Mother's Preferred Language: | Estimated Due Date: |
| Household and/or Sexual Contact Information | | | |
| Name | Relationship | Address | Phone Number |
| | | | |
| | | | |
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N.D. Department of Health
Division of Disease Control
600 East Boulevard Ave. Dept. 301
Bismarck, ND 58505-0200
Telephone Number: 701.328.3324 or toll-free 800.472.2180



NORTH DAKOTA
DEPARTMENT *of* HEALTH

Delivery Hospital/Physician

Delivery hospitals should implement policies, procedures and standing orders to identify infants born to HBsAg-positive mothers, identify infants born to mothers with unknown HBsAg status, and initiate immunization for these infants as well as all other infants born in the facility.

Enclosed are materials to assist in the implementation of these policies, procedures and standing orders:

1. Delivery Hospital/Physician Responsibilities
2. Hepatitis B Sample Standing Orders
3. A Physician's Prenatal Report of HBsAg-Positive Mother form (SFN 58507).
 - Positive pregnant women can also be reported online at <http://www.ndhealth.gov/Disease/Disease%20Reporting/DiseaseCard.aspx>.
4. A flow chart to help determine if an infant needs HBIG in addition to hepatitis B vaccine and guide you through what is needed for each infant.
5. When an infant is born to a HBsAg-positive women, please complete a Hospital Report for Perinatal Hepatitis B (SFN 58464) and fax it to the NDDoH confidential fax at 701.328.0355.



NORTH DAKOTA
DEPARTMENT *of* HEALTH

Delivery Hospital/Physician Responsibilities

Implement policies and procedures to:

- Identify infants born to HBsAg-positive mothers
- Identify infants born to mothers with unknown HBsAg status
- Initiate immunization of these infants and all other infants born in this facility
- Document mothers HBsAg-positive status on electronic birth certificate.
- Document hepatitis B vaccine and HBIG (if needed) given to infants on electronic birth certificate.

Standing orders for:

- Review HBsAg test results at the time of admission for delivery.
 - Flagging the chart of a HBsAg-positive woman prior to admission is preferred.
 - Document HBsAg results in both the labor and delivery record and on the infant's delivery summary sheet.
- Women with no documented HBsAg test results – test as soon as possible after admission for delivery.
- Test women who are at higher risk for hepatitis B exposure at the time of admission for deliver. These women include those who:
 - Participate(d) in injection drug use.
 - Had more than one sex partner in the previous six months.
 - Had a HBsAg-positive sex partner.
 - Had an evaluation or treatment for sexually transmitted diseases.
 - Have clinical hepatitis.
- Identification and management of all infants born to HBsAg-positive mothers.
- Identification and management of all infants born to mothers with unknown HBsAg status.
- Administration of hepatitis B vaccine.
- Documentation in the infant's medical record of:
 - Maternal HBsAg test results.
 - Infant's hepatitis B vaccine administration.
 - Administration of HBIG (if appropriate).

Review mother's chart for HBsAg upon admission

- Flagging the mother's chart prior to admission regarding her HBsAg-positive status is preferred
- Record maternal HBsAg test results on both the labor and delivery record and on the infant's delivery summary sheet.

The hospital is responsible for proper storage and handling of HBIG and hepatitis B vaccine. HBIG and hepatitis B vaccine should be stored between 35 and 46 degrees Fahrenheit (2 and 8 degrees Celsius).

Hepatitis B Sample Standing Orders Based on the CDC Recommendations 2005

Labor & Delivery (L&D):

Review HBsAg laboratory report. Place a copy of the original laboratory report into the L&D record and a copy into baby's delivery record.

If no laboratory report is available, order the test ASAP. Have results called to the nursery as soon as ready.

Alert nursery if the mother is HBsAg-positive or if her hepatitis B status is unknown.

If mother is HBsAg-positive or if unknown status, inform mother of need for immunoprophylaxis of her baby within 12 hours of birth. Inform mother that breastfeeding is OK and encouraged.

Nursery Unit:

Infants born to HBsAg negative mothers

1. Give Hepatitis B (HepB) vaccine (0.5 ml, IM) within 12 hours of birth.
2. Document administration of Hepatitis B vaccine in the infant's medical record.
3. Document that the Vaccine Information Statement was provided to mother in the medical record. Also give the mother her infant's immunization card indicating the date and type of vaccine administered.
4. Preterm infants weighing <2 kg (2,000 gm) should not receive a dose HepB vaccine until they are 1 month old or at hospital discharge. A copy of the original laboratory report indicating that the mother was HBsAg negative should be included in the infant's medical record.
5. If physician chooses not to give the birth dose, **an order must be written** and placed in the infant's chart. A copy of the mother's negative HBsAg laboratory test must also be placed in the infant's chart.

Infants born to HBsAg status unknown mothers

1. Give HepB vaccine (0.5 ml, IM) within 12 hours of birth.
2. If mother's HBsAg status comes back positive, give Hepatitis B Immune Globulin (HBIG 0.5 ml, IM) ASAP. HBIG must be given within 7 days of birth.
3. Document administration of HepB vaccine (and HBIG) in the infant's medical record.
4. If mother's status is still unknown at time of nursery discharge, clearly document how to reach parents and infant's primary care provider in case further treatment is needed.
5. For infants weighing < 2 kg (2,000 gm), whose mother's HBsAg status cannot be determined within 12 hours, give **both** HBIG (0.5 ml, IM) and HepB vaccine (0.5 ml, IM) at separate sites within 12 hours of birth. This birth dose of HepB vaccine will not be counted as the first dose.
6. Document administration of HepB vaccine (and HBIG) in the infant's medical record.

7. Document that the Vaccine Information Statement was provided to mother in the medical record. Also give the mother her infant's immunization card indicating the date and type of vaccine administered.
8. Reassure mother that breastfeeding is OK and encouraged.

Infants born to HBsAg positive mothers

1. Give **both** HBIG (0.5 ml, IM) and HepB vaccine (0.5 ml, IM) at separate sites within 12 hours of birth.
2. For infants weighing < 2 kg (2,000 gm), give **both** HBIG (0.5 ml, IM) and HepB vaccine (0.5 ml, IM) at separate sites within 12 hours of birth. This dose of HepB vaccine will not be counted as the first dose.
3. Document administration of HepB vaccine and HBIG in the infant's medical record.
4. Document that the Vaccine Information Statement was provided to mother in the medical record. Also give the mother her infant's immunization card indicating the date and type of vaccine administered.
5. Reassure mother that breastfeeding is OK and encouraged.
6. Provide educational and written materials to Mother regarding:
 - a. The importance of having her baby complete the HepB vaccination schedule on time
 - b. The importance of post vaccination testing for the infant following the HepB series to assure immunity
 - c. The mother's need for ongoing medical follow-up for her chronic HBV infection
 - d. The importance of testing household members for hepatitis B and then vaccinating if susceptible.
7. Notify the North Dakota Department of Health that mother delivered and infant received post exposure prophylaxis using the Hospital Report for Perinatal Hepatitis B (SFN 58464).
8. Forward copies of medical records to mother's primary care physician.
9. Notify infant's pediatrician of mother's HBsAg positive status.

This policy and procedure shall remain in effect for all patients of the **Name of Hospital** until rescinded or until **Date**.

Medical Director's Signature: _____ Effective
Date: _____

For further information: Immunization Action Coalition www.immunize.org or
Center for Disease Control www.cdc.gov/mmwr/pdf/rr/rr5416.pdf, Recommendation and
Reports 12/23/2005



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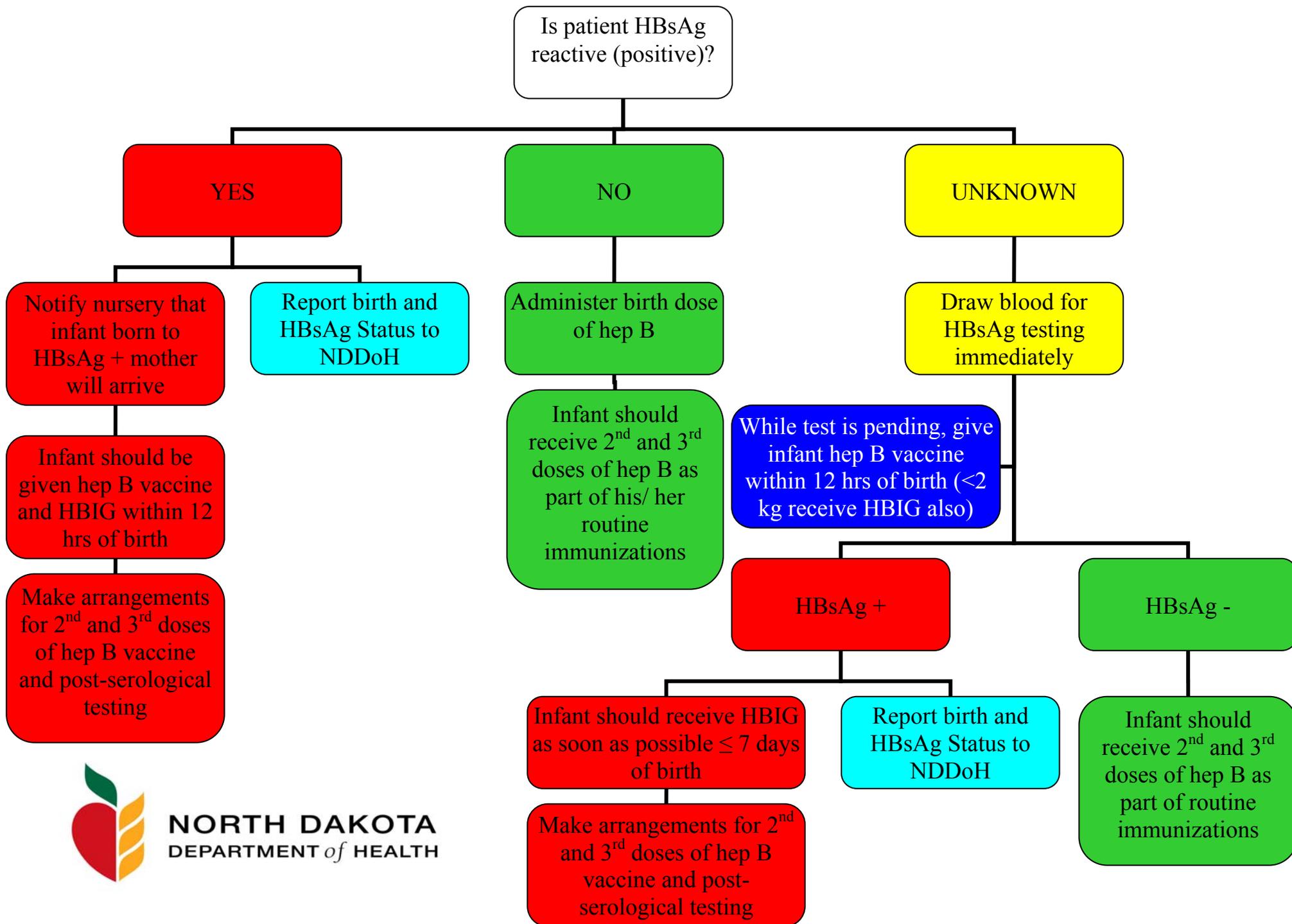
Please complete the information that applies and **FAX to: 701.328.0355 (Confidential Fax Number)**
If you have questions, call: 701.328.3324 or toll-free 800.472.2180.

As of **April 1, 2007**, North Dakota Administrative Rules state that pregnancy in a person infected with hepatitis B is a reportable condition.

| Mother's Information | | | |
|---|--------------|--|---------------------|
| HBsAg(+) Test Date: | | Date of Birth: | |
| Last Name: | | First Name: | |
| Address: | | | |
| City: | | State: | Zip Code: |
| Telephone Number: | | Alternate Telephone Number: | |
| Physician's Name: | | Clinic Name: | |
| Race: <input type="checkbox"/> Asian <input type="checkbox"/> Black or African American <input type="checkbox"/> White <input type="checkbox"/> Other | | Ethnicity: <input type="checkbox"/> Hispanic or Latino <input type="checkbox"/> Not Hispanic or Latino <input type="checkbox"/> Unknown | |
| American Indian or Alaska Native <input type="checkbox"/> Native Hawaiian or other Pacific Islander <input type="checkbox"/> Unknown | | | |
| Mother's Country of Origin: | | Mother's Preferred Language: | Estimated Due Date: |
| Household and/or Sexual Contact Information | | | |
| Name | Relationship | Address | Phone Number |
| | | | |
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N.D. Department of Health
Division of Disease Control
600 East Boulevard Ave. Dept. 301
Bismarck, ND 58505-0200
Telephone Number: 701.328.3324 or toll-free 800.472.2180

When patient is admitted for delivery





Hepatitis B Immunization of Newborns

Infants born to HBsAg-positive mothers

- Alert the nursery if the mother is HBsAg-positive or if the results are unknown.
- Must receive single-antigen hepatitis B vaccine and HBIG (0.5 mL) within 12 hours of birth, administered at different injection sites.
 - If vaccine is not immediately available, the first dose should be given as soon as possible.
 - Subsequent doses should be given as recommended for the specific vaccine.
 - HBIG and hepatitis B vaccination do not interfere with routine childhood vaccinations.
 - Breastfeeding poses no risk of HBV infection for infants who have begun prophylaxis.
 - Infants born to HBsAg-positive women who weigh less than 2 kilograms should also be given post-exposure prophylaxis.
 - The birth dose should not be counted in the required 3-dose schedule; the infant will receive a total of four doses of vaccine.
- Notify the NDDoH immediately after the mother has delivered.
- Make arrangements before the infant leaves the hospital for the second and third doses of hepatitis B vaccine.
 - The physician and mother should determine who will be responsible for ensuring that the additional vaccine doses are given according to recommended schedules.

Infants born to HBsAg-negative mothers

- Must also receive the birth dose of hepatitis B vaccine.
- The maternal HBsAg status and vaccination history must be recorded on the infant's birth certificate, which will be electronically dumped into the North Dakota Immunization Information System (NDIIS).

Infants born to HBsAg-unknown mothers

- Draw mother's blood for testing immediately.
- While test results are pending, the infant should receive hepatitis B vaccine within 12 hours of birth.
 - If the infant weighs < 2,000 grams, HBIG should also be administered
- If the mother is positive, her infant should receive HBIG as soon as possible and within 7 days of birth.
 - This infant should also receive the next two doses of hepatitis B vaccine on schedule and post-serologic testing.
- If the mother is negative, her infant should continue to receive hepatitis B vaccine as part of his or her routine childhood immunization schedule.



HOSPITAL REPORT FOR PERINATAL HEPATITIS B

NORTH DAKOTA DEPARTMENT OF HEALTH

SFN 58464 (Revised 05-2008)

Please complete the information that applies and **FAX to: 701.328.0355 (Confidential Fax Number)**

If questions, call: 701.328.3324 or 800.472.2180

| | | | |
|---|-----------------------------|---|---|
| <u>For Women Known to be HBsAg Positive:</u> | | <u>For Women Whose HBsAg Status is Unknown:</u> | |
| <input type="checkbox"/> Administer hepatitis B immune globulin (HBIG) and hepatitis B vaccine within 12 hours of birth to all infants born to hepatitis B positive mothers. If infant doesn't receive HBIG within 12 hours, it can be administered up to 7 days after birth. | | <input type="checkbox"/> Perform a stat HBsAg screening test for all women admitted for delivery whose hepatitis status is unknown. | |
| <input type="checkbox"/> The North Dakota Department of Health supplies HBIG at no charge to birthing hospitals for infants born to HBsAg-positive mothers. Contact 701.328.3386 for more information or to order HBIG. | | <input type="checkbox"/> While test results are pending, the infant should receive hepatitis B vaccine within 12 hours of birth. If the mother is later found to be positive, her infant should receive the additional protection of HBIG as soon as possible and within 7 days of birth. | |
| Note: Only Report if Mother is HBsAG-positive | | | |
| Name of Hospital: | | City of Hospital: | |
| Date Sent: | | | |
| MOTHER'S INFORMATION | | | |
| Mother's Hospital Record Number: | | | |
| HBsAg(+) Test Date: | | | |
| Last Name: | | First Name: | |
| Address: | | City/State: | |
| Zip Code: | Telephone Number: | | Alternate Telephone No. (i.e., relative): |
| Date of Birth: | Mother's Country of Origin: | | Mother's Preferred Language: |
| Physician's Name: | | Clinic Name: | |
| Race: <input type="checkbox"/> Asian <input type="checkbox"/> Black or African American <input type="checkbox"/> White <input type="checkbox"/> Other | | <input type="checkbox"/> American Indian or Alaska Native <input type="checkbox"/> Native Hawaiian or other Pacific Islander <input type="checkbox"/> Unknown | |
| Ethnicity: <input type="checkbox"/> Hispanic or Latino <input type="checkbox"/> Not Hispanic or Latino <input type="checkbox"/> Unknown | | | |
| INFANT'S INFORMATION | | | |
| Infant's Hospital Record Number: | | | |
| Infant's Last Name: | | Infant's First Name (if known): | |
| Infant's Date of Birth: | | Infant's Birth Weight: | |
| Infant's Sex (please circle): M F | | Infant's Date of HBIG Given: | |
| Infant's Date of Hepatitis B Vaccine Dose 1: | | | |
| **IMPORTANT** | | | |
| Clinic Where Infant Will Receive HBV2: | | | |
| Name of Infant's Physician (include telephone number if known): | | | |

Division of Disease Control
600 East Boulevard Ave., Dept. 301
Bismarck, ND 58505-0200



Infant's Immunization Provider

All infants should receive hepatitis B vaccinations at birth, 2 months of age, and six months of age, but this is especially important in infants born to HBsAg-positive women. Combination vaccines can be used to complete the series. If combination vaccines are used, 4 doses of hepatitis B vaccine may be given. Enclosed is the Immunization Provider Responsibilities

If an infant is born to a HBsAg-positive mother, the infant should be tested for HBsAg and antibody to hepatitis B surface antigen (anti-HBs or HBsAb) after completion of the hepatitis B series, to ensure that he or she has not contracted hepatitis B and is now immune to hepatitis B.

Enclosed are the following materials:

1. Immunization Provider Responsibilities
2. Perinatal Hepatitis B Prevention Checklist (SFN 58460)



Immunization Provider Responsibilities

- Vaccinate the infant at the recommended ages for hepatitis B vaccine.
 - The infant's family should be reminded about the second and third doses of hepatitis B vaccine.
- If infant weighed < 2 kg (<2,000 gm) when birth dose of hepatitis B vaccine was given, do not count this dose as part of the hepatitis B series.
- The provider is also responsible for post-vaccination serologic testing. HBsAg and anti-HBs should be tested.
 - Testing should be done when the infant is 9-18 months of age, one to two months after the child's last dose of hepatitis B vaccine
 - Results should be reported to the Perinatal Hepatitis B Coordinator.
- Test household members and sexual contacts to determine susceptibility to HBV infection, and, if susceptible, administer hepatitis B vaccine.
 - For susceptible sexual contacts of persons with acute HBV infection, a single dose of HBIG (0.06mL/kg) given within 14 days of the last sexual contact is recommended. If the last sexual contact is more than 14 days, hepatitis B vaccination should be initiated, although the amount of protection afforded by postexposure prophylaxis given this late is not known. For sexual partners of persons with chronic HBV infection, postexposure prophylaxis with hepatitis B vaccine alone is recommended. HBIG is not recommended in this situation. Postvaccination anti-HBs antibody testing should be considered for sexual partners of persons with chronic HBV infection.
 - Household contacts of persons with acute HBV infection who have had a blood exposure to the infected person (*e.g.*, sharing a toothbrush or razor) should receive HBIG and begin the vaccine series within 7 days. Routine hepatitis B vaccination should be considered for nonsexual household contacts of the infected person who do not have a blood exposure, especially for children and adolescents.
- Hepatitis B vaccination administered to infants and sexual contacts of HBsAg-positive women should be reported to the NDDoH by entering into the NDIIS or sending in the VAR.



PERINATAL HEPATITIS B PREVENTION CHECKLIST
NORTH DAKOTA DEPARTMENT OF HEALTH
SFN 58460 (Revised 03-2007)

PLEASE PRINT

| | |
|--|------------------------|
| Child's Name: | Child's Date of Birth: |
| Hepatitis B vaccine (HBV) second dose due at 1-2 months of age | |
| Date Given: | |
| HBV third dose due at six months of age | |
| Date Given: | |
| Post vaccination serologic testing drawn at 9-18 months of age (at least 1-2 months after last dose) | |
| Please check: | |
| <input type="checkbox"/> Hepatitis B surface Antigen (HBsAG) | |
| <input type="checkbox"/> Hepatitis B surface Antibody (anti-HBs) | |

Fax this form to: 701.328.0355

If you have any questions, please call:
N. D. Department of Health
Division of Disease Control
600 East Boulevard Ave.
Bismarck, ND 58505-0200
701.328.3324 or toll-free 800.472.2180