



Nevada State Division of Public
and Behavioral Health

Perinatal Hepatitis B Prevention
Policy & Protocols

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PERINATAL HEPATITIS B POLICY STATEMENT

- ◆ The Nevada State Division of Public and Behavioral Health and Nevada’s local Health Authorities are required by Nevada Revised Statute (NRS), Nevada Administrative Code (NAC) and guidelines established by the Centers for Disease Control and Prevention (CDC), to investigate and control the spread of Hepatitis B virus via the vertical and horizontal routes of transmission.

- ◆ In 1984, the Advisory Committee on Immunization Practices (ACIP) recommended that all high-risk pregnant women be screened for hepatitis B. In 1988, ACIP, in consultation with the American College of Obstetrics and Gynecology and the American Academy of Pediatrics, recommended that ALL pregnant women be routinely tested for hepatitis B surface antigen (HBsAg) during an early prenatal visit in EACH pregnancy. In 1991, 35% of HBsAg-positive mothers did not report risk factors for hepatitis B, which confirmed the need for universal testing. The Nevada State Board of Health adopted regulations requiring the testing of all pregnant women for hepatitis B. In 2005, ACIP reinforced the prior recommendation that all pregnant women be tested for HBsAg during each pregnancy.

- ◆ Nevada counties and corresponding local Health Authority:
 - Clark County – Southern Nevada Health District
 - Washoe County – Washoe County Health District
 - Carson City, Douglas and Lyon Counties – Carson City Health and Human Services
 - Elko, White Pine, Eureka, Lander, Humboldt, Pershing, Churchill, Storey, Mineral, Esmerelda, Nye and Lincoln Counties – Nevada State Division of Public and Behavioral Health, Immunization Program.

- ◆ The following protocols are to be utilized by local Health Authority staff, delivery hospital staff, laboratories and providers who work together to prevent perinatal hepatitis B transmission.

CASE IDENTIFICATION PROTOCOL

- ◆ NRS and NAC requires the following:
 - Health care providers, laboratories and medical facilities must report persons having or suspected of having a communicable disease which include hepatitis B (NRS 441A.150).
<http://leg.state.nv.us/NRS/NRS-441A.html#NRS441ASec150>
 - The Health Authority conducts investigations of persons having or suspected of having a communicable disease which includes Hepatitis B (NRS 441A.163, NAC 441A.570).
<http://leg.state.nv.us/NRS/NRS-441A.html#NRS441ASec163>
<http://leg.state.nv.us/NRS/NRS-441A.html#NRS441ASec570>
 - The Health Authority shall have access to medical and laboratory records as requested during the course of the communicable disease investigation. (NRS 441A.165).
<http://leg.state.nv.us/NRS/NRS-441A.html#NRS441ASec165>
 - Pregnant women must be screened during each pregnancy for Hepatitis B Surface Antigen, HBsAg and positive results reported to the Health Authority (NAC 441A.570).
<http://leg.state.nv.us/NAC/NAC-441A.html#NAC441ASec570>

Prenatal Health Care Providers

- ◆ At the time a health care provider attending a pregnant woman orders a blood sample during prenatal care, the provider must also submit a blood sample to be tested for HBsAg. If the HBsAg result is negative early in pregnancy and the woman is engaging in high-risk behaviors, testing should be repeated upon admission to the delivery hospital. Also, if a woman's HBsAg result is negative, and she is engaging in high-risk behaviors, she should be given the hepatitis B vaccine. Pregnancy is not a contraindication to administering the vaccine.
- ◆ Per NRS 439.265 and corresponding regulations, any administered vaccine must be recorded into Nevada WebIZ (immunization registry). People may opt-out of Nevada WebIZ, but the appropriate paperwork for opting out must be completed and submitted to the Nevada State Immunization Program (NSIP). See appendix F for links to NRS.
- ◆ The HBsAg test result should be recorded in the pregnant woman's medical record at or before the time of admission for delivery, and include the date of the blood test. A copy of the original laboratory report should be sent to the delivery hospital prior to delivery.
- ◆ All positive HBsAg test results must be reported to the local Health Authority by the next regular business day and must consist of the following information:
 - communicable disease identified,
 - case's name,
 - case's address,
 - if available, the case's telephone number,
 - health care provider's name,
 - health care provider's address,
 - health care provider's telephone number,
 - and any other requested information made by the local Health Authority.

Delivery Hospitals

- ◆ Assure that the HBsAg test date and test result for every woman admitted for delivery is recorded in the maternal and infant medical records. Ideally, a copy of the original laboratory report should be sent to the delivery hospital prior to delivery. Delivery hospitals must have written policies and standing orders to review and document prenatal HBsAg results on every pregnant woman at admission.
- ◆ Any woman who has not been tested for HBsAg during her pregnancy or whose test result is not available upon time of admission should be immediately tested with the date and time of blood collection recorded in both the maternal and infant medical records. Delivery hospitals must have written policies and standing orders to test those pregnant women who have no documentation of a prenatal HBsAg test.
- ◆ All positive HBsAg test results must be reported to the local Health Authority by the next regular business day and must consist of the following information:
 - specimen collection date
 - laboratory result,
 - the case's name,
 - the case's address,
 - if available, the case's telephone number,
 - the name of the laboratory,
 - address of the laboratory,
 - telephone number of the laboratory,

- the name of the health care provider who ordered the test,
 - the address of the health care provider who ordered the test,
 - the telephone number of the health care provider who ordered the test,
 - and any other requested information made by the local Health Authority.
- ◆ Per NRS 439.265 and corresponding regulations, any administered vaccine must be recorded into Nevada WebIZ (immunization registry). People may opt-out of Nevada WebIZ, but the appropriate paperwork for opting out must be completed and submitted to NSIP. See appendix F for links to NRS.

Clinical Laboratories

- ◆ All HBsAg test results should be reported to the requesting health care provider or delivery hospital as soon as possible.
- ◆ All positive HBsAg test results must be reported to the local Health Authority by the next regular business day and must consist of following information:
- specimen collection date,
 - laboratory result,
 - the case's name,
 - the case's address,
 - if available, the case's telephone number,
 - the name of the laboratory,
 - address of the laboratory,
 - telephone number of the laboratory,
 - the name of the health care provider who ordered the test,
 - the address of the health care provider who ordered the test,
 - the telephone number of the health care provider who ordered the test,
 - and any other requested information made by the local Health Authority.

Hepatitis B Laboratory Tests

- ◆ HBsAg positivity indicates that a person is infectious with either a chronic or acute hepatitis B viral infection. Other 'hepatitis panel' markers may be included with the HBsAg results and should be reported to the local Health Authority even if negative. These other markers aid the clinician and the local Health Authority in determining the status and progress of hepatitis B infection. See Appendix A and B for details on other markers.

Health Insurance Portability and Accountability Act (HIPAA)

- ◆ The HIPAA Privacy Rule has been in effect since April 14, 2003. The intent of HIPAA is to establish national standards for consumer privacy protection and insurance market reform. The Privacy Rule strikes a balance between protecting patient information and allowing traditional public health activities to continue. Disclosure of patient health information without the authorization of the individual is permitted for purposes including but not limited to:
- Disclosures required by law (45 CFR § 164.512(a)) or
 - For "public health activities and purposes." This includes disclosure to "a public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury, or disability, including but not limited to, the reporting of disease, injury, vital events..., and the conduct of public health surveillance,... investigations, and... interventions." (45 CFR § 164.512(b) (i)).

CASE MANAGEMENT PROTOCOL

Funding from the CDC through the Nevada State Immunization Program (NSIP) allows for case management at the local Health Authority level. NSIP staff are available to assist or implement case management duties of Perinatal Hepatitis B cases as requested or needed.

Cases that reside in the following areas will be case managed by the following local Health Authorities:

- Clark County – Southern Nevada Health District
- Washoe County – Washoe County Health District
- Carson City, Douglas and Lyon Counties – Carson City Health and Human Services
- Elko, White Pine, Eureka, Lander, Humboldt, Pershing, Churchill, Storey, Mineral, Esmerelda, Nye and Lincoln Counties – Nevada State Division of Public and Behavioral Health.

RESPONSIBILITIES DURING ANTEPARTUM

- ◆ The local Health Authority receives report from the health care provider, delivery hospital, and/or laboratory.
- ◆ If a female patient is HBsAg positive and of child bearing age (10-55 years old), their pregnancy status will be collected regardless whether it is an acute or a chronic case.
- ◆ Inquire about the following with the health care provider:
 - Pregnancy status and estimated date of confinement (EDC),
 - Client awareness and understanding of the positive result,
 - High risk factors such as IV drug use and multiple sexual partners,
 - Hospital of choice for delivery,
 - Known household/sexual contacts,
 - Other progeny,
 - Other information if needed such as patient's address, telephone number, age, date of birth, and occupation.
- ◆ Notify the hospital of choice for delivery and inform them of the case and the EDC. Notification of the hospital staff should be done at about 2 months prior to the EDC.
- ◆ Contact the case and inquire about, educate and/or reinforce the following:
 - Assure they are aware of the positive HBsAg result.
 - Knowledge of hepatitis B, which includes transmission, risk factors, and prevention methods (see Appendix D for specific education topics).
 - Confirm hospital of choice for delivery.
 - Describe the Perinatal Hepatitis B Prevention Program in detail which would include the following:
 - Explain that the delivery hospital will be notified of the positive HBsAg status,

- The importance of infant receiving HBIG and the first dose of hepatitis B vaccine immunoprophylaxis within 12 hours of delivery ,the hepatitis B series vaccination schedule and the importance of on-time completion,
 - The timing and purpose of post-vaccination testing.
 - Country of birth.
 - Household/sexual contact information and need for their testing and vaccination if applicable. (Some test positive themselves or already show immunity.)
 - Immunizations particularly Hepatitis A vaccine.
- ◆ For women newly identified as HBsAg-positive, repeat HBsAg testing should be performed 6 months after initial testing. Women who remain HBsAg-positive for 6 months or more are chronic carriers and should be referred to a specialist for evaluation and follow-up.
 - ◆ For women who are HBsAg positive and retest as HBsAg negative either in one pregnancy or subsequent pregnancies, further diagnostics should be performed particularly HBcAb and HBV DNA (PCR).
 - ◆ Check case and contacts within the following systems as needed:
 - NEDSS/NETSS,
 - Nevada WebIZ,
 - TriSano,
 - NOMADS.

RESPONSIBILITIES AT TIME OF ADMISSION AND DELIVERY

- ◆ Upon admission, the mother’s original HBsAg laboratory report (or a copy of the original) should be reviewed and a copy of the test result shall be placed onto (1) the labor and delivery record and (2) the infant’s delivery record. It is important to examine a copy of the original laboratory report and not rely on the handwritten prenatal record due to the possibility of transcription error, misinterpretation of the test results, or misordering of the test. Delivery hospitals must have written policies and standing orders to review and document prenatal HBsAg results on every pregnant woman at admission.
- ◆ If the HBsAg result is not available, the labor and delivery unit should order an HBsAg test as soon as possible. Hospitals are to have HBsAg testing available with results available as soon as possible and preferably within 12 hours. The laboratory should be instructed to call the nursery with the result as soon as they are available. Delivery hospitals must have written policies and standing orders to test those pregnant women who have no documentation of a prenatal HBsAg test.
- ◆ **The mother is HBsAg-positive and the infant is any weight:**
 - Delivery hospitals must have written policies and standing orders to immunoprophylax within 12 hours of delivery infants born to HBsAg positive women using hepatitis B vaccine and Hepatitis B Immune Globulin (HBIG).
 - Provide the mother with a Vaccine Information Statement (VIS) prior to administration of the hepatitis B vaccine.
 - Administer both HBIG and hepatitis B vaccine in separate theighs within 12 hours of birth.
 - Discuss the importance of receiving all follow-up doses of hepatitis B vaccine on time.
 - Discuss the importance of post-vaccination testing for the infant following the hepatitis B series to assure immunity.

- Discuss the mother's need for ongoing medical follow-up and possible treatment of chronic hepatitis B viral infection.
- Discuss the importance of testing household, sexual, and needle-sharing contacts for hepatitis B viral infection, then vaccinating if susceptible.
- Notify the local Health Authority case manager and/or the NSIP that the infant was born and has received the appropriate immunoprophylaxis (include the date and time of administration, manufacturer, lot numbers and expiration dates for both HBIG and hepatitis B vaccine).
- Obtain contact information of the infant's primary caregiver and notify them of the birth, the administration of HBIG and hepatitis B vaccine, and the importance of timely completion of the series as well as post-vaccination testing.
- An immunization record card noting the hepatitis B vaccine and HBIG administration date, time and brand must be given to all mothers and entered into Nevada WebIZ. The infant's hospital record should indicate the date and time of hepatitis B vaccine and HBIG administration and must always be forwarded to the infant's primary care provider.
- All premature infants born to HBsAg-positive mothers (regardless of birth weight) should receive immunoprophylaxis with hepatitis B vaccine and HBIG within 12 hours of birth.

◆ **The mother's HBsAg status is unknown and the infant weight is less than (<) 2000 grams:**

- Delivery hospitals must have written policies and standing orders to immunoprophylax within 12 hours of delivery infants born to women whose HBsAg status is unknown using hepatitis B vaccine and Hepatitis B Immune Globulin (HBIG).
- Immediately test the mother for HBsAg and request the laboratory to immediately report the results.
- Infant should be given hepatitis B vaccine and HBIG within 12 hours of birth. Do not wait for the maternal HBsAg test results before giving the vaccine and HBIG.
- Provide the mother with a Vaccine Information Statement (VIS) prior to administration of the hepatitis B vaccine.
- If the maternal HBsAg result is negative, an additional dose of hepatitis B vaccine should be administered at 1 month of age or prior to hospital discharge if medically stable. This will be counted as dose 1 of the hepatitis B vaccination series.
- The birth dose of hepatitis B vaccine should not count toward the completion of the 3-dose series in infants weighing less than 2000 grams at birth.
- An immunization record card noting the hepatitis B vaccine and/or HBIG administration date, time and brand must be given to all mothers and entered into Nevada WebIZ. The infant's hospital record should indicate the date and time of hepatitis B vaccine and HBIG administration and must always be forwarded to the infant's primary care provider.

◆ **The mother's HBsAg status is unknown and the infant weight is greater than or equal to (≥) 2000 grams:**

- Delivery hospitals must have written policies and standing orders to immunoprophylax within 12 hours of delivery infants born to women whose HBsAg status is unknown using hepatitis B vaccine and Hepatitis B Immune Globulin (HBIG).
- Immediately test the mother for HBsAg and request the laboratory to immediately report the results.
- Infant should be given hepatitis B vaccine within 12 hours of birth. Do not wait for the maternal HBsAg test results before giving the vaccine. Provide the mother with a Vaccine Information Statement (VIS) prior to administration of the hepatitis B vaccine.
- If the maternal HBsAg result is positive, administer HBIG to the infant immediately but no later than 7 days from delivery.
- If the maternal HBsAg result remains unknown at the time of discharge administer HBIG to the infant prior to discharge.
- An immunization record card noting the hepatitis B vaccine and/or HBIG administration date, time and brand must be given to all mothers and entered into Nevada WebIZ. The infant's hospital record should

indicate the date and time of hepatitis B vaccine and HBIG administration and must always be forwarded to the infant's primary care provider.

- ◆ **The mother's HBsAg status is negative and the infant weight is greater than or equal to (≥) 2000 grams**
 - Delivery hospitals must have written policies and standing orders to vaccinate prior to discharge infants born to HBsAg negative women using hepatitis B vaccine.
 - Administer hepatitis B vaccine within 24 hours of delivery. See appendix E for more information on the hepatitis B birth dose.

◆ **Rules of Thumb**

- All infants of positive mothers – administer hepatitis B vaccine and HBIG within 12 hours of delivery.
- Unknown mothers with <2000 gram infants – immediate administer hepatitis B vaccine and HBIG within 12 hours.
- Unknown mothers with ≥2000 gram infants – immediate administer hepatitis B vaccine and HBIG if results are not available at discharge.

RESPONSIBILITIES DURING THE POST-NATAL PERIOD

Perinatal Hepatitis B Coordinators must establish contact with the infant's primary care physician after delivery and are responsible for conducting follow-up vaccination and testing if the infant does not have a primary care physician.

Hepatitis B Vaccine Series Completion

Dose	Enerix-B® or Recombivax HB® (HepB)	Pediarix® (DTaP-HepB-IPV)
1	Birth*	Birth (only use single antigen vaccine)*
2	1-2 months	2 months
3	6 months	4 months
4	NA	6 months

* Both single-antigen hepatitis B vaccine (0.5mL) and hepatitis B immune globulin (HBIG) (0.5mL) should be given within 12 hours of birth. HBIG and hepatitis B vaccine should be administered intramuscularly at different sites.

◆ **Combination Vaccines**

After single-antigen hepatitis B vaccine is given at birth, an additional 3 doses of a hepatitis B-containing combination vaccines can be given to complete the series, starting at 6 weeks of age for those whom none of the antigens are contraindicated.

- Pediarix®: The combination DTaP-hepatitis B-inactivated poliovirus vaccine.
- Pediarix® is NOT to be given at birth. Pediarix® is licensed for use as a 3-dose series beginning at 6 weeks to 7 years of age. This vaccine may be used when none of the antigens are contraindicated and only as a primary series.

- ◆ For infants who weigh less than 2000 grams at birth and the mother is HBsAg positive or unknown status, administer hepatitis B vaccine and HBIG within 12 hours of birth. The birth dose of hepatitis B vaccine should not be counted as part of the 3-dose hepatitis B vaccine series. Three (3) additional doses of hepatitis B vaccine should be administered beginning at chronological age of 1 month.

- ◆ The final hepatitis B dose for the series should be given after 24 weeks of age.

- ◆ **Routes and Sites of Administration** - Hepatitis B vaccine should be administered only in the anterolateral thigh muscle of neonates and infants. When hepatitis B vaccine is administered to infants simultaneously with other vaccines, separate sites in the anterolateral thigh should be used for the multiple injections with injections separated by 1-2 inches to avoid overlap in local reactions. Separate injection sites (separate thighs) must be used when administering hepatitis B vaccine and HBIG at the same time. Hepatitis B vaccine administered by any route or site other than intramuscularly in the anterolateral thigh or deltoid muscle should **not** be counted as valid and should be repeated, unless serologic testing indicates that an adequate response has been achieved.
- ◆ **Simultaneous Administration of Other Vaccines** - Hepatitis B vaccine may be given simultaneously and at any interval with all other childhood vaccines. When hepatitis B vaccine has been administered simultaneously with other vaccines, no interference with the antibody response of the other vaccines has been demonstrated.
- ◆ **Interrupted Schedules** - In any age group, when the hepatitis B vaccine schedule is interrupted, the vaccine series does not need to be restarted. If the hepatitis B vaccine series is interrupted after the 1st dose, the 2nd dose should be given as soon as possible, and the 2nd and 3rd doses should be separated by an interval of at least 8 weeks. If only the 3rd dose is delayed, it should be administered as soon as possible. It is not necessary to restart the vaccine series for infants switched from one vaccine brand to another.

Post-Vaccination Testing for Infection and Serologic Response

- ◆ Post-vaccination testing must be completed between 9 and 12 months of age and after 4 weeks after the last hepatitis B vaccine dose. This minimizes the likelihood of detecting passively transferred hepatitis B surface antibody (anti-HBs) from HBIG and maximizes the likelihood of detecting late HBsAg positive infections. Reminding the provider at 8 months and again at 10-11 months may increase the likelihood of test completion.
- ◆ Both HBsAg and quantitative anti-HBs should be ordered for post-vaccination testing. Qualitative anti-HBs results (positive or negative) may not indicate adequate immunity. Refer to appendix C for laboratory codes.
- ◆ **The Immune Infant:** If serology indicates that the infant is HBsAg negative and the quantitative anti-HBs is >10 mIU/mL then immunity is acquired and the case is closed. This occurs most often; up to 95% of infants acquire immunity following proper immunization.
- ◆ **Treatment Failure:** If the post-vaccination serology shows that the infant is HBsAg-positive, this indicates the infant is infected and has a 90% chance of becoming a chronic carrier. This occurs in about 1-3% of cases. These infants should be referred to a medical provider, preferably a pediatric gastroenterologist or pediatric hepatologist for follow-up.
- ◆ **Susceptible:** If the serology shows that the infant did not respond to the 1st vaccination series (HBsAg-negative and anti-HBs <10mIU/mL) the infant should begin another 3 dose vaccination series and repeat serologic testing 1-2 months after the 2nd series is complete. If the infant remains susceptible following a 2nd 3 dose series they are considered a non-responder. Alternatively, a single booster dose of hepatitis B vaccine may be used, followed by serologic testing 1-2 months later. If the serologic testing remains <10mIU/mL, 2 more doses of hepatitis B vaccine must be administered and serologic testing performed 1-2 months after the 3rd dose. The mother should be advised of the appropriate hepatitis B control measures to prevent potential future transmission to this susceptible infant. Some persons who are non-responders following 6 doses may have a low level of antibody that is not detected by routine serologic testing. These people are referred to as “hyporesponders”. Since their status cannot be determined by a blood test, however, they should take precautions as non-responders. See appendix D.

Cases Lost to Follow-up

- ◆ Despite a good tracking system, some cases will be lost to follow-up. Completion rates decrease with each dose of vaccine. Families often move and lose contact with their health care provider. If cases are lost to follow-up during the process of completing the vaccination series and/or post-vaccination testing there are a few of things that can be done to try to find them.
- ◆ You may ask the post office for a forwarding address. A justification form provided by the Postal Service must be completed and a department of health ID will probably be required.
- ◆ Contact the Department of Motor Vehicles. Most driver's license bureaus will allow other state agencies to access their records.
- ◆ Contact Medicaid, Welfare, and or WIC programs—an up-to-date address is required for these services.
- ◆ Contact Food Banks, Shelters and Family Resource Centers
- ◆ Search State of Nevada records including Nevada WebIZ. Many people have contact with the local Health Authority and old records may have a parent's address or other locating information.
- ◆ Contact the case's health care provider and other larger health care providers in the area for a current address.
- ◆ Parole and probation officers may be contacted if the person is in the prison system. The probation/parole officer will usually be persuasive in getting the patient back in for you. If the patient is in violation of parole, the officer will note in the medical section of the file that the patient is being pursued for follow-up.

Reminders and Criteria for Lost to Follow-up

- ◆ Case managers must make contact with the parent(s) and/or the provider if the infant misses a scheduled dose of vaccine or serologic testing.
- ◆ A minimum of 3 attempted contacts by phone, letter or home visit is required. Attempts to contact should continue until 24 months of age and then may be closed if there is no response.
- ◆ A reminder letter should be sent to the parent(s) of the infant prior to each dose of vaccine and prior to serologic testing so they will have a document in hand to remind them.

Missed Appointments

- ◆ Telephone calls – 2 telephone call attempts within 3 days after a missed appointment must be documented.
- ◆ A letter immediately must be sent if telephone calls are unsuccessful.
- ◆ A home visit must be attempted if safety is not a concern.
- ◆ If all are unsuccessful, follow and document the suggestions above to re-acquire contact.
- ◆ Document all attempted and successful contacts in the Perinatal Hepatitis B Module of Nevada WebIZ.

CONTACT MANAGEMENT PROTOCOL

HOUSEHOLD AND SEXUAL CONTACT ASSESSMENT

- ◆ Perinatal Hepatitis B Coordinators must investigate the immunization status for all household and sexual contacts to determine if hepatitis B vaccine or testing is needed. Those with a partially completed hepatitis B vaccination series should complete the vaccine series and then have follow-up serology 1-2 months later. Perinatal Hepatitis B Coordinators must offer hepatitis B vaccination and serologic testing if indicated.
- ◆ The following tests should be completed for household contacts and sexual partners of women who test positive for HBsAg (refer to Appendix A and B for more information):
 - HBsAg: Determines if they are currently infected with the hepatitis B virus,
 - Anti-HBs: Determines if they have protection against the hepatitis B virus,
 - Anti-HBc: Determines if they have natural immunity due to a previous hepatitis B viral infection,
 - If all three tests are negative, the contact is susceptible to infection and should receive hepatitis B vaccine.
 - If HBsAg is positive, the patient is infected and should be reported to the local Health Authority and referred for medical follow up.
 - If anti-HBs is positive, they are considered immune and are protected from getting a hepatitis B virus infection.
 - If the Anti-HBc is positive, and the HBsAg is negative, the contact is considered to be immune due to natural infection and no further follow-up is required.
- ◆ All unvaccinated susceptible contacts need to have the hepatitis B vaccination series administered:
 - The 1st dose should be given at the same visit, but after the blood draw.
 - The 2nd dose should be given 1 month after the 1st dose.
 - The 3rd dose should be given 4-6 months after the 1st dose (at least 8 weeks after the 2nd dose and at least 16 weeks after the 1st dose).
- ◆ Test all household and sexual contacts for quantitative anti-HBs 1 to 2 months after the 3rd dose of hepatitis B vaccine is administered.

CONTACT EDUCATION

- ◆ All contacts of hepatitis B-infected individuals should be given both verbal and written information regarding prevention measures to avoid blood and body fluid of hepatitis B infected individuals such as:
 - Using condoms during sexual activity,
 - Never sharing syringes and needles,
 - Avoid sharing chewing gum, toothbrushes, razors, scissors, nail files, etc.
 - See appendix D

PROVIDER EDUCATION PROTOCOL

ENGAGING PROVIDERS AS STAKEHOLDERS

- ◆ Perinatal Hepatitis B Coordinators must identify and engage medical providers and hospitals in their area that have direct access to the target population.

Delivery Hospitals

- ◆ Site visits to delivery hospitals are a high priority for Perinatal Hepatitis B Coordinators. Delivery hospitals are the focus of many case management activities and of standing orders for administration of hepatitis B vaccine at birth. Policies initiated and implemented in hospitals can influence the practices of private physicians.
- ◆ Perinatal Hepatitis B Coordinators should establish and maintain a contact at each delivery hospital in their program jurisdiction. They should visit each hospital at least once per year for refresher trainings and provide information updates, whether formal or informal.
- ◆ Key staff to identify may be:
 - Chief of obstetrics,
 - Chief of pediatrics,
 - Infection control nurse,
 - Quality assurance agent,
 - Medical director of the nursery,
 - Director of the laboratory,
 - Clinical nurse specialist in charge of labor and delivery,
 - Pharmacist.
- ◆ The clinical nurse specialist in charge of labor and delivery is the best contact. Policies that need to be written are usually initiated by the nurse specialist, whose job is to make sure that medical orders, nursing care, and transfer of information from delivery to nursery are coordinated.

Private Practice Physicians

- ◆ Finding creative ways to initiate and maintain relationships with health-care providers is a must. A good way to reach private practice physicians is through work on individual cases. When you visit or contact them to ask for information on cases or other activities offer to send them information or resources on the current recommendations.
- ◆ Many professional health organizations have state or local chapters that meet regularly. This is an effective opportunity to reach multiple private physicians and nurses at once. Some state-level organizations have an education coordinator who sends out information to local chapters and they may distribute perinatal hepatitis B prevention information.
- ◆ Representatives from state and local immunization programs visit private providers' offices on a regular basis to conduct Vaccines for Children (VFC) site visits and immunization record assessment and feedback (AFIX)

sessions. Partnering with these representatives to distribute information and resources on the Perinatal Hepatitis B Prevention Program can be effective.

EDUCATING PROVIDERS

- ◆ Prevention of perinatal hepatitis B virus transmission depends on providers' understanding and implementation of standards of practice for treating pregnant women and their infants. Education and outreach activities should target health care workers in hospitals, prenatal care settings, and pediatric care settings.

Hospital Staff

- ◆ It is critical that the hospital staff understand the importance of policies and procedures needed to prevent perinatal hepatitis B virus transmission. Once they understand the importance of the issue, you can ask them to help monitor and document maternal HBsAg status, provide appropriate immunoprophylaxis to infants born to HBsAg-positive and unknown-status mothers, implement standing orders and document administration of the hepatitis B vaccine birth dose, report births to HBsAg-positive women to the local Health Authority, and ensure that infant vaccination records are given to parents and pediatricians. Policies, procedures and standing orders should include the following:
 - Review the HBsAg status of all pregnant women.
 - Record maternal HBsAg test results on both labor and delivery record and on infant's delivery summary sheet.
 - Perform HBsAg testing as soon as possible on women who do not have a documented HBsAg test result; were at risk for hepatitis B virus infection during 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 previous testing.
 - Administer single-antigen hepatitis B vaccine and HBIG to all infants born to HBsAg-positive mothers ≤ 12 hours after birth and record date and time of administration of hepatitis B vaccine and HBIG in infant's medical record.
 - Provide information regarding hepatitis B to HBsAg-positive mothers, including advice that they may breast feed their infants upon delivery; modes of hepatitis B virus transmission; need for testing and vaccination of their susceptible household, sexual, and needle-sharing contacts; need for substance abuse treatment, if appropriate; and need for medical management and possible treatment for chronic hepatitis B infection.
 - Administer single-antigen hepatitis B vaccine to all infants born to mothers with unknown HBsAg status ≤ 12 hours after birth and record date and time of administration of hepatitis B vaccine on infant's medical record.
 - Administer a dose of single-antigen hepatitis B vaccine in separate thighs to all infants weighing $\geq 2,000$ grams.
 - Ensure that all mothers have been tested for HBsAg prenatally or at the time of admission for delivery, and document test results.
 - Provide infant's immunization record to mother and remind her to take it to the infant's first visit at the pediatric health-care provider.
 - Record all vaccinations into Nevada WebIZ.
- ◆ A potential venue for educating hospital staff is during regular staff meetings for OB/GYNs, pediatricians, midwives, nurse practitioners, and delivery room staff. Be sure to schedule in-service presentations for staff on all shifts, and make your materials and content available to those who cannot attend. Tailor your presentation as much as possible to the hospital's data and needs. Make them fully aware of the Advisory Committee on Immunization Practices (ACIP), American Congress of Obstetricians and Gynecologists (ACOG), American Academy of Pediatrics (AAP), and the American Academy of Family Physicians (AAFP) recommendations and

encourage them to identify key actions that are needed to implement the recommendations. Follow up with the hospital approximately 1 month after your presentation to check on progress.

- ◆ Assist hospitals in implementing written standing orders for critical perinatal hepatitis B prevention activities. The Immunization Action Coalition has developed a document titled, “Guidelines for Standing Orders in Labor & Delivery and Nursery Units to Prevent Hepatitis B Virus Transmission to Newborns,” a useful two-page sheet that hospitals can use to establish standing orders; the document is available at www.immunize.org/catg.d/p2130per.pdf.
- ◆ Stress to hospital staff that 1) an infant born to an HBsAg-positive mother has been exposed to hepatitis B virus, 2) an infant born to a mother with unknown HBsAg status might have been exposed to hepatitis B virus, and 3) postexposure immunoprophylaxis is urgent. Stress that postexposure immunoprophylaxis is not the same as routine vaccination of other children and that timeliness is crucial.
- ◆ Assist hospitals in implementing written standing orders for universal hepatitis B vaccine birth dose. See Appendix E for supporting information on the birth dose.

Obstetric/Gynecologic Providers

- ◆ Obstetric/gynecologic providers play a key role in preventing perinatal transmission of hepatitis B virus. Efforts to educate obstetric/ gynecologic providers should reinforce the following messages:
 - The need for universal screening of pregnant women for HBsAg during an early prenatal visit in each pregnancy, regardless of the woman's hepatitis B vaccination status.
 - The need to refer HBsAg-positive pregnant women to the local Health Authority for case management.
 - The importance of communicating the mother's HBsAg status to all levels of providers (e.g., delivery site, newborn nursery, pediatrician) to ensure that infants born to HBsAg-positive mothers receive appropriate immunoprophylaxis and follow-up.
 - The importance of sending the delivery hospital a copy of the original HBsAg laboratory report (for both HBsAg-positive mothers and HBsAg-negative mothers) along with the mother's other prenatal information.
 - The need for HBsAg-positive women to be provided with or referred for appropriate counseling and medical management of chronic hepatitis B infection.
 - The need to provide information to HBsAg-positive pregnant women about modes of hepatitis B virus transmission, perinatal concerns (e.g., infants born to HBsAg-positive mothers may be breastfed), the importance of post-exposure immunoprophylaxis for the infant beginning at birth, and prevention of hepatitis B virus transmission to contacts.
 - The need to vaccinate pregnant women who are at risk for hepatitis B virus infection during pregnancy and who are not already HBsAg positive (hepatitis B vaccination initiated during pregnancy but not completed by delivery can be completed during postpartum visits).
 - The need for prenatal care education to include information about the rationale and importance of newborn hepatitis B vaccination.

Pediatricians and Family Practitioners

- ◆ Pediatricians and family practitioners must understand the importance of follow-up care for these newborns, particularly the need to administer the remaining doses of hepatitis B vaccine to all infants on time, to conduct post-vaccination serologic testing for infants born to HBsAg-positive women, and to appropriately manage these infants on the basis of serologic test results.

DATA TRACKING PROTOCOL

- ◆ Local Health Authority Perinatal Hepatitis B Coordinators under guidance from the NSIP will begin utilizing the WebIZ Perinatal Hepatitis B Module during 2012. Cases, infants and contacts will be entered into this module at the local and state level. This data will be used to assess the prevalence of perinatal hepatitis B in Nevada, vaccination and serology completion rates, and other data required by the State of Nevada and CDC.
- ◆ NRS 439.265 and corresponding regulations, requires that all immunizations administered in Nevada be entered into Nevada WebIZ. The Perinatal Hepatitis B Module will provide easy access to track immunizations.
- ◆ The HBsAg-positive pregnant woman must be identified as the index case for your tracking system and other records should be organized around this case. The demographic, medical and delivery information will be necessary for your tracking system. The basic information that should be collected on all HBsAg-positive pregnant women includes:
 - Demographic information,
 - Name,
 - Date of birth,
 - Race,
 - Country of birth,
 - If an immigrant, date of arrival in the United States,
 - Primary language spoken,
 - Home and work information,
 - Home address and telephone number,
 - Secondary telephone number,
 - Emergency telephone number,
 - Medical information,
 - Date(s) and type(s) of test(s),
 - Test results,
 - History of past hepatitis B testing,
 - Prenatal care physician's name,
 - Physician's address and telephone number,
 - Expected date of confinement (EDC or due date),
 - Delivery hospital,
 - Date and time of delivery.

- ◆ Sexual, needle-sharing and household contacts to the HBsAg-positive pregnant woman shall be offered initial seroscreening, the hepatitis B vaccine and HBIG, as medically indicated. To ensure that each contact completes this process, it is important to track and maintain active surveillance until all follow-up treatment is complete. This information should include:
 - Demographic information,
 - Contact's name,
 - Date of birth,
 - Race,
 - Primary language,
 - Home and work information,
 - Home address and telephone number,
 - Secondary and telephone number,
 - Emergency telephone number,
 - Medical information,
 - If known to be infected with hepatitis B,
 - Date of screening,
 - Screening results,
 - Date of HBIG,
 - Date of hepatitis B vaccine dose #1,
 - Date of hepatitis B vaccine dose #2,
 - Date of hepatitis B vaccine dose #3,
 - Date and result of post-vaccination serology.

- ◆ The infant's birth initiates the last phase of your tracking system. The infant will remain in your tracking system through at least its first year of life. The following information should be collected:
 - Demographic information,
 - Infant's name,
 - Date and time of birth,
 - Birth weight ,
 - Home information (if different from mothers),
 - Home address and telephone number,
 - Guardian's name (if not mother),
 - Emergency telephone number,
 - Medical information,
 - Date and time of HBIG,
 - Date and time of hepatitis B vaccine dose #1 manufacturer mcg/ml,
 - Date of hepatitis B vaccine dose #2 manufacturer mcg/ml,
 - Date of hepatitis B vaccine dose #3 manufacturer mcg/ml,
 - All other hepatitis vaccine doses including a 4th dose or 2nd series,
 - Date of follow-up serology,
 - Post-vaccination serology test results,
 - Pediatrician or provider of immunization services,
 - Address and telephone number.

APPENDICES

APPENDIX A: HEPATITIS SEROLOGIC TERMINOLOGY

Acronym	Term	Interpretation
HBV	Hepatitis B Virus	Etiologic agent of Hepatitis B
HBsAg	Hepatitis B Surface Antigen	Indicates infection and communicability. HBsAg can be detected as early as 1 or 2 weeks and as late as 11 or 12 weeks after exposure to Hepatitis B virus when sensitive assays are used. Is present in both acute and chronic infections.
Anti-HBs	Antibody to HBsAg	Is a protective, neutralizing antibody. Indicates past infection, convalescence and immunity to Hepatitis B virus. Also present as a result of HBIG administration and/or in response to Hepatitis B vaccine.
Anti-HBc (Total)	Includes Immunoglobulin M (IgM) and Immunoglobulin G (IgG) antibody to Hepatitis B Core antigen	Indicates prior infection at unknown time. Only occurs after a Hepatitis B viral infection, and does not develop in persons whose immunity to Hepatitis B virus is from vaccine. Anti-HBc generally persists for life.

APPENDIX B: INTERPRETING HEPATITIS B TESTING PANELS

Test	Results	Interpretation
HBsAg anti-HBc anti-HBs	Negative Negative Negative	Susceptible
HBsAg anti-HBc anti-HBs	Negative Negative Positive with ≥ 10 mIU/ml	Immune due to vaccination
HBsAg anti-HBc anti-HBs	Negative Positive Positive	Immune due to natural infection
HBsAg anti-HBc IgM anti-HBc anti-HBs	Positive Positive Positive Negative	Acutely infected
HBsAg anti-HBc IgM anti-HBc anti-HBs	Positive Positive Negative Negative	Chronically infected
HBsAg anti-HBc anti-HBs	Negative Positive Negative	Four interpretations possible*

* Four possible interpretations:

- May be recovering from acute hepatitis B virus infection.
- May be distantly immune due to past disease and the test is not sensitive enough to detect a very low level of anti-HBs in serum.
- May be susceptible with a false positive anti-HBc
- May be chronically infected and have an undetectable level of HBsAg present in the serum.

APPENDIX C: LABORATORY TESTING CODES

Test	CPT code	Laboratory Corporation of America	Quest Diagnostics
Hepatitis B surface antigen HBsAg	87340	006510	498
Hepatitis B surface antibody anti-HBs quantitative	86317	006530	8475
Hepatitis B core antibody anti-HBc total	86704	006718	501
Hepatitis B core antibody anti-HBc IgM	86705	016881	4848
Hepatitis Be antigen HBeAg	87350	006619	555

Laboratory codes current as of July 2014

APPENDIX D: ACTIVITIES TO PREVENT THE TRANSMISSION OF HEPATITIS B

- ◆ Take careful blood precautions.
- ◆ Cover all cuts and open sores.
- ◆ Throw away used personal items (such as tissues, sanitary napkins, and tampons) in a sealed plastic bag.
- ◆ Wash your hands well after touching your own blood or body fluids.
- ◆ Wash clothing and linen soiled with blood in detergent and water.
- ◆ Tell all sex partners you have hepatitis B.
- ◆ Use condoms during sexual intercourse and avoid wet kissing unless your partner has had hepatitis B or has been vaccinated against hepatitis B.
- ◆ Though universal precautions should be practiced in all health care settings, tell dentists and doctors that you are hepatitis B positive.
- ◆ Avoid sharing chewing gum, toothbrushes, razors, scissors, nail files or anything that may have come in contact with your blood or body fluids.
- ◆ Never share syringes and needles.
- ◆ Avoid alcohol, drugs, some over the counter medications, and anything that is processed by the liver.
- ◆ Obtain Hepatitis A vaccine as that will also protect the liver in the event that they ever have a future exposure.
- ◆ Avoid donating blood, plasma, body organs, tissue, or sperm.

APPENDIX E: THE IMPORTANCE OF THE HEPATITIS B VACCINE BIRTH DOSE

- ◆ The ACIP, AAP and AAFP recommend that hepatitis B vaccine be administered to *all* infants at birth or prior to hospital discharge. ACIP's most recent recommendation in June, 2005 is that delivery hospitals implement standing orders for administration of hepatitis B vaccination as part of routine medical care of all medically stable infants weighing greater than 2,000 grams (regardless of the mother's HBsAg status).
- ◆ The hepatitis B birth dose serves as a "safety net" so that if a mother was improperly diagnosed as HBsAg-negative, and was indeed positive, the infant is still properly protected at birth. Children born to HBsAg-positive mothers who do not become infected during the perinatal period remain at high risk of infection during early childhood. Lack of vaccination at birth can lead to needless risk of exposure by the infant in several ways.
- ◆ The following medical errors may occur:
 - The mother is HBsAg-negative and the infant does not receive its first dose of hepatitis B vaccine at birth. The infant is later exposed to hepatitis B viral infection postnatally from another family member or caregiver. This occurs in two-thirds of all childhood transmission cases.
 - The woman is tested early in pregnancy and found to be HBsAg-negative. She develops hepatitis B viral infection later in pregnancy but it is not detected, even though it is recommended that high risk women be tested a second time later in pregnancy. (The infection is not detected so the infant does not receive hepatitis B vaccine or HBIG at birth.)
 - A chronically infected pregnant woman is tested but the wrong test, HBsAb (antibody to hepatitis B surface antigen) instead of HBsAg is ordered. This is a common error because the abbreviations for these two tests differ by only one letter. The incorrectly ordered test result is "negative" so her doctor believes her baby does not need immunoprophylaxis.
 - The pregnant woman is tested and found to be HBsAg-positive, but her status is not communicated to the newborn nursery. (The infant receives neither hepatitis B vaccine nor HBIG protection at birth.)
 - The pregnant woman is not tested for HBsAg either prenatally or in the hospital at the time of delivery. (Her infant does not receive hepatitis B vaccine in the hospital even though the vaccine is recommended within 12 hours of birth for infants whose mothers' test results are unknown.)
- ◆ The benefits of administering the first dose of hepatitis B vaccine at birth include:
 - It is the best opportunity to prevent unrecognized perinatal transmission and to prevent transmission within families due to unrecognized chronic hepatitis B viral infection in the household.
 - It places the importance of immunization as an early and visible priority for parents.
 - It is the only vaccine that is reliably immunogenic in the newborn period.
 - Administering the vaccine at birth provides opportunity to immunize during one of the few dependable medical encounters (at the delivery hospital). If a mother had little or no prenatal care and comes into the hospital to deliver, chances are these infants will have less medical care than other infants. Therefore, time of delivery provides a good opportunity to immunize these infants.
 - There is added assurance that an overall immunization series will be completed on time; 96.3% of infants complete the hepatitis B vaccine series if given the first dose by age 7 days. 81.1% will complete the entire vaccine series on time. JAMA. 2000;284(8).
 - Women who do not receive prenatal care are 8 times more likely to be HBsAg positive than women who receive prenatal care. JAMA. 1991 Nov27;266(20)
 - It is the foundation of the overall public health strategy to eliminate hepatitis B viral infection in the United States.

APPENDIX F: RESOURCES

BACKGROUND INFORMATION DOCUMENTS

Centers for Disease Control and Prevention, Epidemiology and Prevention of Vaccine-Preventable Diseases. Atkinson W, Hamborsky J, Wolfe S, eds. 12th ed. Washington DC: Public Health Foundation, 2011.
www.cdc.gov/vaccines/pubs/pinkbook/index.html www.cdc.gov/vaccines/pubs/pinkbook/hepb.html

Manual for the Surveillance of Vaccine-Preventable Diseases (5th Edition, 2011).
www.cdc.gov/vaccines/pubs/surv-manual/chpt04-hepb.html

A comprehensive immunization strategy to eliminate transmission of hepatitis B virus infection in the United States: recommendations of the Advisory Committee on Immunization Practices (ACIP). Part 1: immunization of infants, children, and adolescents. *MMWR* 2005 (RR-16). www.cdc.gov/mmwr/PDF/rr/rr5416.pdf

Centers for Disease Control and Prevention, Vaccine Management: Vaccine Storage and Handling Toolkit. May 2014.
<http://www.cdc.gov/vaccines/recs/storage/toolkit/>

Centers for Disease Control and Prevention, Managing a Hepatitis B Prevention Program
www.cdc.gov/hepatitis/Partners/PeriHepBCoord.htm#

Admission Orders for Labor & Delivery and Newborn Units to Prevent HBV Transmission.
www.immunize.org/catg.d/p2130.pdf

WEBSITES

Nevada State Division of Public and Behavioral Health: http://dphh.nv.gov/Programs/PHBP/Perinatal_Hepatitis-B_Prevention_-_Home/

Centers for Disease Control and Prevention: www.cdc.gov/hepatitis

National Center for Immunizations and Respiratory Diseases (formally the National Immunization Program):
www.cdc.gov/vaccines/

Vaccine schedules: <http://www.cdc.gov/vaccines/schedules/index.html>

Immunization Action Coalition: www.immunize.org

Immunization Nevada: <https://www.immunizenevada.org/>

American Academy of Pediatrics: www2.aap.org/immunization/pediatricians/pdf/refusaltovaccinate.pdf

HIPPA: http://www.cdc.gov/nhsn/faqs/FAQ_HIPPArules.html

STATUTES AND REGULATIONS

NRS 441A <http://leg.state.nv.us/NRS/NRS-441A.html>

NAC 441A <http://leg.state.nv.us/NAC/NAC-441A.html>

NRS 439.265 <http://leg.state.nv.us/NRS/NRS-439.html#NRS439Sec265>