New York State Department of Health

Perinatal Hepatitis B Prevention Program Manual

Last reviewed and updated May 2011

NOTE TO THE READER:

The New York State Department of Health's Perinatal Hepatitis B Prevention Program is a resource for the maintenance of surveillance and control of perinatal hepatitis B infection. The primary goal of the program is to identify all pregnant women infected with hepatitis B and prevent perinatal transmission of the virus by ensuring infants born to infected women receive the recommended prophylactic treatment at birth. This manual is a guidance document for this program.

The guidance provided in this manual is based on current recommendations of the Centers for Disease Control and Prevention (CDC)'s Advisory Committee for Immunization Practices (ACIP). The manual is intended for use by physicians, nurses, administrators, and other medical professionals, particularly hospital obstetrical and neonatal staff, prenatal care providers, pediatric providers, professional organizations involved in perinatal care, and public health staff.

TABLE OF CONTENTS

KEY POINTS FOR PERINATAL HEPATITIS B PREVENTION

The following key points are taken from the updated recommendations of the Advisory Committee on Immunization Practices (ACIP), published on December 23, 2005, and New York State Public Health Law 2500-e *Pregnant women, Testing for Hepatitis B, Follow-up Care*.

Maternal hepatitis B surface antigen (HBsAg) testing:
• All pregnant women should be tested for HBsAg during each pregnancy. • All women who are in a high-risk category (page 5) should be re-tested at the time of admission to the delivery hospital. • New York State Public Health Law 2500-e (Appendix A) mandates HBsAg testing of all pregnant women, reporting of positive HBsAg results, and prophylactic treatment of all infants born to positive HBsAg women.
Reporting and tracking HBsAg-positive women:
• All HBsAg-positive pregnant women should be reported to local or state perinatal hepatitis B prevention programs (page 31) and their infants and any household, sexual and needle sharing contacts should be entered into case-management tracking systems (page 34).
Vaccination of infants at birth (Appendix G) ***If mother is HBsAg-positive:***
• Infants born to mothers who are HBsAg-positive should receive hepatitis B immune globulin (HBIG) and hepatitis B vaccine within 12 hours of birth (page18, 19). • For preterm infants weighing less than 2,000 grams, the initial dose of vaccine should not count toward the three dose vaccine series (page 20).
If mother has unknown HBsAg status:
• Infants born to mothers whose HBsAg status is unknown should receive hepatitis B vaccine within 12 hours of birth (page 19). • The mother should have blood drawn as soon as possible to determine her HBsAg status (page 19). • If the mother is found to be HBsAg-positive the infant should receive HBIG as soon as possible, but no later than seven days after birth (page 19). • Because of the potentially decreased immunogenicity of vaccine in preterm infants weighing less than 2000g, these infants should receive both hepatitis B vaccine and HBIG if the mother's HBsAg status cannot be determined ≤ 12 hours of birth (page 20).
***If mother is HBsAg-negative*:**
• All delivery hospitals should implement standing orders for administration of hepatitis B vaccination as part of routine medical care of all medically stable infants weighing over 2,000 grams (page 18). • Only in rare circumstances, and on a case-by-case basis, may the first dose may be delayed until after hospital discharge (page 20). • Preterm infants weighing less than 2,000 grams should receive the first dose of vaccine 1 month after birth or at hospital discharge (page 20).
Follow up vaccine doses and post-vaccination serology:
• All infants should complete the vaccine series with either single-antigen vaccine or combination vaccine, according to the recommended vaccination schedule (page 48). • Infants born to HBsAg-positive mothers should be tested for HBsAg and antibody to HBsAg after completion of the vaccine series, at 9-18 months (page 51).
Monitor and evaluate program effectiveness:
• Delivery hospital site visits are routinely conducted to evaluate program effectiveness and ensure hospital and provider compliance with perinatal hepatitis B recommendations and NYS Public Health Law 2500-e and accompanying regulations (page 20).

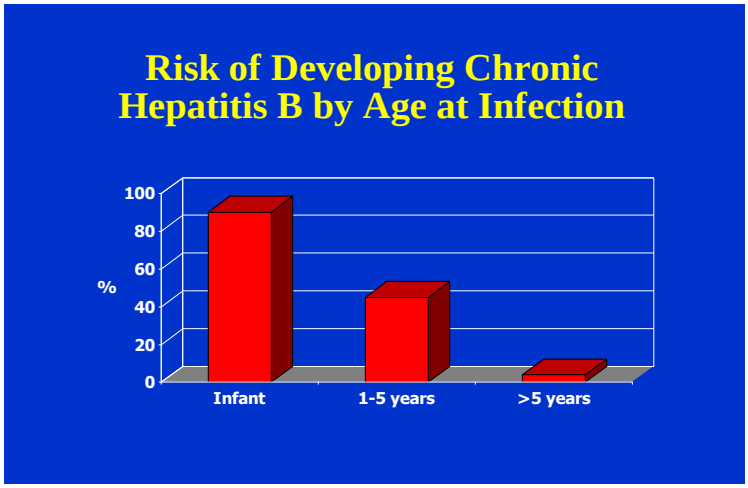
CHAPTER ONE: INTRODUCTION TO PERINATAL HEPATITIS B

BACKGROUND

Hepatitis B virus (HBV) infection is a major cause of acute and chronic hepatitis, cirrhosis of the liver, and primary hepatocellular carcinoma. It is the most prevalent chronic infectious disease in the world, a common cause of morbidity and mortality worldwide, and a major health problem in the United States. In the United States HBV infects about 70,000 people each year and 1.25 million people are chronically infected. Of these chronically infected individuals about 20%-30% acquired their infection in childhood. About 5,000 Americans die each year from hepatitis B and its related complications. One mode of transmission of HBV is perinatal transmission (from mother to infant during birth). The risk of perinatal HBV infection among infants born to mothers already infected with HBV ranges from 10%-85%, depending on the mother's hepatitis B e antigen (HBeAg) status. If the mother is positive for both hepatitis B surface antigen (HBsAg) and HBeAg the risk of perinatal transmission is 70%-90%. If the mother is HBsAg-positive, but HBeAg-negative, the risk of perinatal transmission is <10%. Women who acquire acute HBV during pregnancy are also at risk of transmitting the disease to their infants. If HBV is acquired during the first or second trimester the risk of transmission is low (~ 3%). If a woman has acute HBV during the third trimester the risk to the fetus increases to 78% without vaccine. If a woman is newly infected with HBV at the time of giving birth, virtually all infants will acquire HBV unless vaccine is given.

Most (about 95%) primary infections in adults with normal immune status are self-limited, usually within 2-3 months, with elimination of virus from blood and development of lasting immunity to reinfection. In about 5% of healthy older children and adults, 30% of children <5 years old, and 90% of infants, primary infection develops into chronic infection, with continuing viral replication in the liver and persistent viremia. Though the reasons for this time relationship are not well known, it is theorized that the relative immaturity of the infant's immune system is a factor. An estimated 25% of chronically infected infants will develop chronic liver disease, cirrhosis, or hepatocellular carcinoma and die as young adults.

The Advisory Committee on Immunization Practices (ACIP), American Academy of Pediatrics (AAP), and Centers for Disease Control and Prevention (CDC) recommend identification of women who are HBsAg-positive through screening and prophylaxis of their newborns. Proper prophylaxis and completion of the hepatitis B vaccine series can reduce neonatal infection and the potential sequelae by 95%. New York State Public Health Law mandates that all pregnant women be tested for hepatitis B infection and that all infants born to infected mothers should be given hepatitis B immune globulin (HBIG) and hepatitis B vaccine within 12 hours of birth. The hepatitis B series should be completed by 6 months of age and infants should receive follow-up HBsAg and antibody to hepatitis B surface antigen (anti-HBs) testing at age 9-18 months to determine if immunization was successful.



"Hepatitis B virus is the most common known cause of chronic viremia, with an estimated 350 million chronic carriers worldwide. It is the cause of up to 80% of hapatocellular carcinomas, and is second only to tobacco among known human carcinogens. The World Health Organization estimated that more than 600,000 persons died in 2002 worldwide of hepatitis B-associated acute and chronic liver disease."

Source: Epidemiology and Prevention

The Advisory Committee on Immunization Practices (ACIP), American Academy of Pediatrics (AAP), and Centers for Disease Control and Prevention (CDC) also recommend the routine administration of a birth dose of hepatitis B vaccine. Administering a birth dose to all infants serves as a "safety net" to prevent perinatal infection among infants born to HBsAg positive mothers who are not identified because of errors in maternal HBsAg testing or failures in reporting of test results. The birth dose also provides early protection to infants at risk for infection after the perinatal period. Administration of a birth dose has been associated with higher rates of on-time completion of the hepatitis B vaccine series and in certain populations, improved completion rates for all other infant vaccines. NYSDOH supports these recommendations with the Hepatitis B Universal Birth Dose Program.

EPIDEMIOLOGY

Hepatitis B virus is a small, double-shelled virus in the family Hepadnaviridae. Humans are the only known host for HBV, although some nonhuman primates have been infected in a laboratory. HBV is relatively resilient and, in some instances, has been shown to remain infectious on environmental surfaces for at least a month at room temperature. The risk of HBV infection is 100 times greater than that of HIV infection after blood exposure such as needle stick injury.

Incidence

Reported cases of HBV infection represent only a fraction of cases that actually occur. An estimated 2 billion persons worldwide have been infected with HBV, and more than 350 million persons have chronic, lifelong infection.

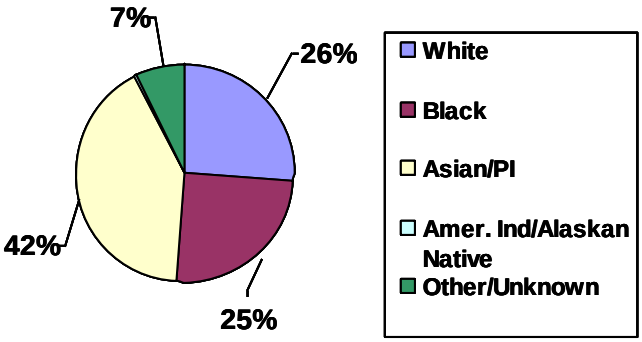
The incidence of reported hepatitis B cases peaked in the United States in the mid 1980s and continues to decline, as vaccine coverage increases. The Centers for Disease Control and Prevention (CDC) estimate approximately 43,000 new infections per year in the United States. In 2008, 73 confirmed acute hepatitis B cases were reported to the New York State Department of Health (NYSDOH) (excluding New York

City (NYC)). An estimated 1.4 million Americans are chronically infected with HBV. Approximately 2,000-4,000 people die from HBV-related disease in the United States each year. Between 2001-2008 approximately 9,000 confirmed chronic hepatitis B cases were reported to the NYSDOH. Additional hepatitis data summaries can be found online at http://www.health.state.ny.us/diseases/communicable/hepatitis, under Surveillance and Reporting.

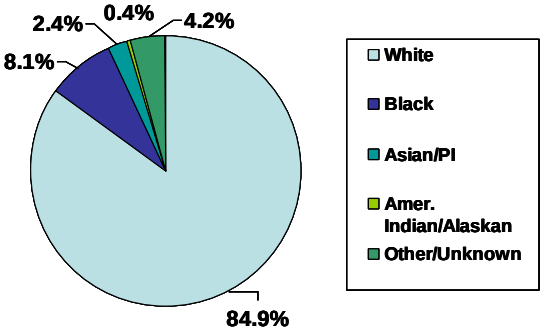
During 1990-2004, overall incidence of reported acute hepatitis B declined 75%, from 8.5 to 2.1 per 100,000 population. The most dramatic declines were among children to whom recommendations for routine infant and adolescent vaccination have applied. . The rates of HBV infection in the United States vary by sex, race, and ethnicity. The rate of acute hepatitis B was higher in men than in women between 1990 and 2002. Males are also much more likely to become chronic carriers than females, and the course in males is more likely to be complicated or fulminant than in females. Of those who progress to hepatocellular carcinoma, 76% are male. In 1990 the incidence rate of acute hepatitis B among persons 19 years and younger by race was highest among Asian/Pacific Islanders (A/PIs) followed by blacks. Whites had the lowest race-specific incidence of hepatitis B in 1990. After the initiation of infant and childhood vaccinations, the rates of hepatitis B have decreased among all groups. From 1990 to 2002, rates decreased 92% among A/PIs, 88% among whites, 88% among blacks, and 84% among American Indians/Alaskan Natives (AI/AN). In 2002, the highest incidence per 100,000 population was seen in A/PIs (0.55) followed by blacks (0.51), AI/AN (0.43) and whites (0.16).

Similar trends in New York State occur with the exception of AI/AN cases, as demonstrated by the two charts shown below. A/PIs make up only 2.4% of the total population of New York State (excluding NYC) but have comprised about 42% of all perinatal hepatitis B cases in the state for the previous 15 years. In this same time period, 25% of perinatal hepatitis B cases occurred in black infants even though blacks comprised only 8% of upstate New York's population.

New York State Perinatal Hepatitis B Cases by Race, 1990-2005



New York State Racial Data 2000 Census (excluding NYC)

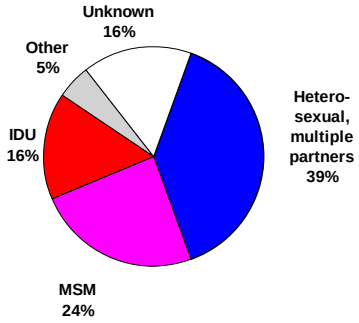


Risk Factors associated with Hepatitis B

Many populations are at high risk of acquiring the disease, including:

- Persons with multiple sex partners;
- Persons diagnosed with a sexually transmitted disease;
- Men who have sex with men;
- Injection drug users;
- Sexual contacts of persons known to be infected;
- Household contact with an infected person;
- Hemodialysis patients;
- Clients in institutions for the developmentally disabled
- Health care workers; and
- Persons who were born in or whose parent was born in a country with endemic hepatitis B. These countries/areas include:
    - Asia;
    - Pacific Islands;
    - Sub-Saharan Africa;
    - Caribbean;
    - Areas of South America and the Mid East; and
    - Indigenous populations of Alaska, Australia, and New Zealand.

Risk Factors for Hepatitis B



MMWR 2006;55(RR-16):6-7

Modes of Transmission

Hepatitis B virus (HBV) is found in highest concentrations in blood, serum, and wound exudates, and in lower concentrations in semen, vaginal secretions, and saliva. Saliva can be a vehicle of transmission through bites; however, other types of exposure to saliva, including kissing, are unlikely modes of transmission. There appears to be no transmission of HBV via tears, sweat, urine, stool, breast milk, or droplet nuclei. The virus is transmitted through one or more of the following modes:

- **Percutaneous Transmission:** Inoculation via the skin with infected blood or blood products, such as needle-stick injury, shared IV/IM needle use, ear or body piercing, tattooing, acupuncture, inadequate sterilization of medical equipment, contaminated needles and other sharps, such as broken glass contaminated with blood. Other breaks in the skin such as fresh cutaneous scratches, abrasions, burns, or other lesions may also serve as routes for entry.b

- **Permucosal Transmission:** Contamination with infective serum or plasma via mucous membranes such as the eyes, nose, or mouth. This may occur from mouth pipetting, eye splashes, or hand-to-mouth or hand-to-eye direct contact when contaminated with infective blood or serum.

- **Sexual Transmission:** Absorption of HBV into mucosal surfaces through sexual activity. Infection by sexual transmission has been associated with increased number of sex partners, number of years of sexual activity, history of sexually transmitted disease, and receptive anal intercourse among homosexual men. In studies of sexual partners of persons with acute HBV, infection developed in 18% - 30%. Among sex partners of persons with chronic HBV, infection developed in 25% -59%. Recent studies have demonstrated that sexual activity accounts for 61% of HBV transmission in the United States.

- **Perinatal Transmission:** Acquisition of HBV by infant from an infected mother. Ninety-five percent of perinatal transmissions occur during birth. In utero transmission is rare and accounts for about 5% of all infections acquired perinatally. Data indicate that mode of delivery (vaginal versus cesarean) does not affect the risk of perinatal transmission.

- **Horizontal Transmission:** Acquisition of HBV in situations and settings such as shared toothbrushes, razors and combs, or passed child-to-child by biting, shared objects, oozing cuts, etc. The hepatitis B virus can continue to exist on environmental surfaces for up to one month and remain infectious; however, transmission to a person after seven days has not been documented. In follow-up studies of the susceptible household contacts of children with chronic HBV infection, new HBV infections developed in 14% - 60% of contacts. Data from cross-sectional studies also demonstrate that household contacts of HBV-infected persons are more likely to have serologic markers of HBV infection (25% - 30%) than the household contacts of persons not infected with HBV (2% - 8%).

Communicability

All persons who are HBsAg-positive are considered to be infectious. The HBsAg may be present several weeks before the onset of illness and last for several weeks (for those who are acutely infected) or years (for those who are chronically infected). If chronic infection develops, patients will most likely remain HBsAg-positive and infective for their lifetime

CLINICAL COURSE

The clinical course of Hepatitis B infection includes the following stages:

- **Acute hepatitis** is defined as infection (HBsAg-positive) lasting no longer than six months. The acute infection can be symptomatic with jaundice or asymptomatic defined only by the presence of HBsAg. The clinical course may end with complete resolution and recovery or proceed to chronic disease.

- **Chronic hepatitis** is defined as an infection (HBsAg-positive) persisting longer than six months. Chronic infection can either be symptomatic or present without clinical manifestations of infection. Complication includes:
    - Super-infection with Hepatitis delta virus (HDV). HDV is a defective RNA virus that requires the presence of HBV for replication and infectivity. There could be a co-infection with HDV which may present with a more severe acute disease and a higher risk (2%-20%) of developing acute liver failure than those infected with HBV alone. Other complications worsen in the presence of HDV. Progression to cirrhosis is more common in super-infected individuals.
    - Hepatocelluar carcinoma: Persons who are chronically infected have up to 30 times higher risk of developing hepatocellular carcinoma. HDV also increases the risk of cancer development.

- **Fulminant hepatitis** is a term used to describe hepatitis associated with sudden onset of encephalopathy and hepatic failure (usually during the first eight weeks of illness). It occurs in 1% to 2% of HBV infections and has a 63% to 93% mortality rate. Each year about 200 to 300 Americans die of fulminant disease. However, most serious complications are due to chronic HBV infection.

Signs and Symptoms

Clinical signs and symptoms of hepatitis B virus occur more often in adults than in infants or children, who usually have an asymptomatic acute course. However, approximately 50% of adults who have acute infections are asymptomatic.

- **Incubation Period:** The average incubation period is 90 days (range: 60-150 days) from exposure to the onset of jaundice, 60 days (range: 40-90 days) from exposure to onset of abnormal serum alanine aminotransferase (ALT) levels, and 30 days (range: 6-60 days) from exposure to detection of hepatitis B surface antigen (HBsAg).

- **Prodromal or preicteric phase:** The preicteric or prodromal phase lasts from the initial symptoms to the onset of jaundice and usually lasts from 3 to 10 days. It is nonspecific and is characterized by an insidious onset of malaise, anorexia, nausea, vomiting, abdominal pain in the right upper quadrant, fever, headache, myalgias, skin rashes, arthralgia and arthritis, or dark urine, beginning one to two days before the onset of jaundice.

- **Icteric phase:** The icteric phase is variable, but usually lasts from one to three weeks, characterized by jaundice, light or gray stools, hepatic tenderness and hepatomegaly (splenomegaly is less common).

- **Convalescence:** During convalescence, malaise and fatigue may persist for weeks or months, while jaundice, anorexia, and other symptoms disappear.

CHAPTER TWO: PERINATAL HEPATITIS B PREVENTION PROGRAM OBJECTIVES

The New York State Perinatal Hepatitis B Prevention Program was implemented in 1988. It encompasses all 57 counties of New York State exclusive of NYC. New York City has its own, separate program. The NYS program has several important features: 1) it is both a surveillance and control program; 2) it was created using existing data collection systems; 3) it involves both the local and state departments of health; and 4) it uses multiple reporting mechanisms to increase reporting completeness. The surveillance population consists of all pregnant women and their newborn infants. The objectives of the program have evolved with new knowledge on the epidemiology of the disease, but the foundation has proven effective and unchanged. The objectives are:

Ensure that all pregnant women are tested for HBsAg.

- Practitioners must test all pregnant women for HBsAg during each pregnancy, even if they have been previously vaccinated or tested.

- HBsAg testing should be incorporated into standard prenatal testing panels (e.g., blood type, HIV infection, Rh factor, rubella titer, syphilis infection) used by all practitioners caring for pregnant women.

- Delivery hospitals must ensure that all pregnant women presenting to their hospital with unknown HBsAg status are immediately tested for HBsAg.

- Women who were found to be HBsAg-negative early in pregnancy and are in a high-risk category for acquiring HBV must be retested upon admission to the delivery hospital.

Ensure reporting and tracking of HBsAg-positive women.

- All HBsAg-positive pregnant women and all women of childbearing age (women aged 10-55 years) with HBsAg-positive laboratory results must be reported to state/local perinatal hepatitis B prevention programs.

- All HBsAg-positive pregnant women must be entered into case-management tracking systems.

- Reporting of HBsAg test status must be entered on the State Perinatal Data System (electronic birth certificate) and neonatal metabolic screening requests.

Ensure receipt of prenatal HBsAg testing records by maternity hospitals prior to delivery.

- HBsAg test results should be included on all forms (hard copy, electronic) used by practitioners to record and transmit information about care during pregnancy.

- For all pregnant women, a copy of the original laboratory report of HBsAg test results should be transferred from the prenatal care provider to the delivery hospital.

- Practitioners should also document that HBsAg-positive pregnant women have a copy of the original laboratory report, and that patients are informed of their HBsAg test status, educated about the consequences to their newborn, and advised to notify delivery staff.

Ensure identification and management of infants born to HBsAg-positive mothers and infants born to mothers without HBsAg test results in delivery hospitals.

- Delivery hospitals should implement policies and procedures to ensure identification of HBsAg-positive women and initiation of post-exposure immunization of infants born to HBsAg-positive mothers and infants born to mothers not screened for HBsAg prenatally; hospitals should safeguard against errors in maternal HBsAg testing and failures in test reporting. This can be done by having non-patient specific standing orders in place for STAT HBsAg testing of pregnant women who do not have a documented HBsAg test result, specifying "HBsAg test" when ordering the test to avoid confusion with other hepatitis serologic markers, including a copy of the *original* laboratory HBsAg report in the delivery record, and adopting a non-patient specific standing order to give hepatitis B vaccine to all infants, regardless of mother's HBsAg status.

- Delivery hospitals must document the date and time of birth and the date and time of administration of HBIG and hepatitis B vaccine for all infants born to HBsAg-positive mothers.

- Delivery hospitals must document the date and time of birth, date and time of administration of hepatitis B vaccine, and maternal HBsAg test date and results for all infants born to mothers with unknown HBsAg status at the time of delivery. Any infant whose mother's HBsAg test result returns as positive should immediately receive HBIG (preferably within 12 hours of birth and no later than 7 days of age).

- Information on administration of any birth doses (of vaccine or HBIG) must be documented on the infant's electronic birth certificate.

Ensure completion of hepatitis B vaccine series.

- Dose number two should be given at one month of age.

- Dose number three should be given at six months of age.

- Combination vaccines may be used to complete the series (See: Hepatitis B Vaccine Schedules, p. 48).

- Practitioners must document the dates of completion of each dose of the hepatitis B vaccine series for all infants born to HBsAg-positive mothers.

- The infant's immunizations must be entered into the New York State Immunization Information System (NYSIIS) or if the infant resides in New York City then entered into the New York Citywide Immunization Registry (CIR).

Ensure completion of post-vaccination testing.

- Practitioners must document the results of post-vaccination testing after completion of the hepatitis B vaccine series for all infants born to HBsAg-positive mothers. HBsAg and anti-HBs testing should be conducted on these infants at 9-18 months of age.

- If Comvax or Pediarix is used to complete the vaccination series, this testing may be done 1-2 months after the last dose of vaccine is given, but never before nine months of age.

Ensure vaccination of household contacts and sex partners of HBsAg-positive women.

- Household and needle-sharing contacts, and sex partners of HBsAg-positive pregnant women must be identified and counseled. These contacts should be offered serologic testing and, if susceptible to HBV infection, should receive the hepatitis B vaccine series (See: Management of Contacts, page 34).

Ensure program quality, monitoring, and evaluation.

- Annually, each program should review the number of pregnant women found to be HBsAg-positive and the proportion of infants born to HBsAg-positive women who received post-exposure prophylaxis within 12 hours of birth, received their third vaccine dose at 6 months of age, and had post-vaccination serologic testing conducted.

- In New York State, routine delivery hospital site visits are conducted to evaluate compliance with NYS public health law and current recommendations for perinatal hepatitis B prevention.

- Occasionally, medical errors occur that result in an infant not receiving appropriate prophylaxis. When these errors occur, a case investigation is conducted by state DOH staff to identify and document the source of the error. Recognizing that each situation is unique, serious errors may be reported to the Office of Heath Systems Management (OHSM) or Office of Professional Medical Conduct (OPMC).

CHAPTER THREE: NEW YORK STATE PUBLIC HEALTH LAW 2500-e: PERINATAL HEPATITIS B PREVENTION

On May 10, 1990, NYSDOH passed Public Health Law 2500-e (Appendix A) mandating the screening and reporting of HBsAg status for all pregnant women. The primary goals of this law are that:

1) **All** pregnant women are screened during **each** pregnancy; and
2) **All** infants born to HBsAg-positive women are treated with hepatitis B vaccine and hepatitis B immune globulin within 12 hours of birth and complete the vaccine series.

To ensure that these goals are met, NYS Public Health Law 2500-e and Title 10 of the Official Compilation of Codes, Rules and Regulations Subpart 69-3 includes several mandates. The following is a summary of the responsibilities of prenatal health care providers, delivery hospitals, clinical laboratories, pediatricians and family practice physicians, parents, and the state and local health departments to ensure compliance with the NYS public health law and regulations and current perinatal hepatitis B prevention recommendations:

Prenatal Health Care Providers

- At the time a health care provider attending a pregnant woman takes a blood sample to be tested for syphilis (Public Health Law 2308), or at another time when blood is drawn during prenatal care, the provider should also submit a blood sample to be tested for hepatitis B surface antigen (HBsAg).

- The HBsAg test result must 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 lab report should be sent to the delivery hospital prior to delivery.

- All positive HBsAg test results must be reported to the local health department.

Delivery Hospitals

- Assure that the HBsAg test date and test result for every woman admitted for delivery is recorded in both the maternal and infant medical records.

- When any woman who has not been tested for HBsAg during pregnancy or whose test result is not available upon time of admission, a STAT test must be performed, with the date and time of blood collection recorded in both the maternal and infant medical records. 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.

- HBsAg test results for all women must be reported to the NYSDOH on the Newborn Screening Blood Collection Form and all HBsAg-positive test results must be reported to the local health department.

- Data requests from the local health department must be responded to in order to provide information from the maternal and/or infant medical records.

- HBIG and first dose of hepatitis B vaccine must be administered to infants born to HBsAg-positive women within 12 hours of birth and the facility must record date and time of administration in the infant's medical record.

- If the mother's HBsAg test result is not available, the infant must be given the first dose of vaccine within 12 hours of birth. *Do not wait for test results before giving vaccine.* If the mother's test result comes back positive the infant should be given HBIG immediately, but definitely within seven days of birth. If the infant is discharged and the mother's result remains unknown, it must be clearly documented how to reach the parent and the infant's primary care provider and both should be notified that the result is pending. The only exception is when the infant is premature and weighs <2,000 grams. In this case, the infant must be given both hepatitis B vaccine and HBIG within 12 hours of birth if the mother's HBsAg status cannot be determined.

- If the infant is immunized at the hospital, the date and time of immunization, the dose and manufacturer's lot number, the name of the person administering the vaccine, the sites of injection, and the print date of the VIS given must be recorded in the infant's medical record.

Clinical Laboratories

- All STAT HBsAg test results must be reported to the requesting health care provider or delivery hospital as soon as possible.

- Any positive HBsAg test result must be reported to the local health department within 24 hours.

Pediatricians and Family Physicians

- Must ensure follow up doses of vaccine are administered at recommended intervals and post-vaccination serology (HBsAg and antibody to HBsAg) is ordered for all infants born to HBsAg-positive women.

- Must share data with the local health department regarding the dates of follow up doses of hepatitis B vaccine and the date and results of post-vaccination serology.

Parents or Legal Guardians

- The parent or guardian of any child born to a woman with a positive HBsAg test result is responsible for ensuring that the child receives the immunizing doses of hepatitis B immune globulin and hepatitis B vaccine at birth as well as completion of doses two and three on time. The parent should also ensure the child receives follow-up testing at the appropriate time.

- Barring a valid religious exemption, if the parent or guardian of any child born to a mother who is HBsAg-positive is unwilling to have the infant immunized, the health care provider must make a report of suspected child abuse or maltreatment (Section 415 of Social Services Law).

Local Health Departments

- The local health department where the infant resides is responsible for providing case management to ensure completion of the vaccine series and post-vaccination serology for the infant and providing education and follow up for all household, sexual, and needle-sharing contacts of the mother.

- Report all data regarding administration of follow up doses of vaccine and post vaccination serology of the infant to the NYSDOH through the Communicable Disease Electronic Surveillance System (CDESS).

- The following CDESS reports should be monitored **weekly or more frequently** especially in counties with large high-risk populations:
    - Vaccination and Serologies Due in Next 2 Weeks
    - Vaccination and Serologies Overdue
    - HBIG/Dose 1 Not given Within 12 Hours of Birth
    - Infants Requiring Additional Follow-up
    - Infants Tracking Missing Information

- The following CDESS reports should be reviewed **monthly or more frequently:**
    - Premature Serology Testing
    - Infants Lost To Follow-up

State Health Department

- Oversee case management statewide.

- Educate and provide consultation for HBsAg-positive pregnant women and contacts.

- Maintain a statewide database of perinatal hepatitis B cases and provide summary data and reports to the Centers for Disease Control and Prevention.

- Conduct periodic birthing hospital record reviews to ensure compliance with NYS public health law 2500-e, accompanying regulations, and current recommendations, including the administration of the hepatitis B vaccine to all newborns within 12 hours of delivery as the standard of care in NYS.

Healthy People 2020 Objective:

- Attain a 50 percent improvement in number of chronic HBV infection acquired perinatally (less than 2 years of age).
  - Baseline: 1,682 (1995) and 799 (2007)
  - Target: 400

- Increase hepatitis B vaccination coverage levels to at least 95% among children by kindergarten enrollment.

CHAPTER FOUR: PERINATAL HEPATITIS B PREVENTION PROCEDURES

MATERNAL HBsAg SCREENING

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 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. In 2005, ACIP reinforced the prior recommendation that ALL pregnant women be tested for HBsAg during EACH pregnancy. In addition, ACIP recommended that prenatal care providers transfer a copy of the original laboratory report of the pregnant woman's HBsAg test result to the patient's medical record in the delivery hospital.

If the HBsAg result is negative early in pregnancy and the woman is in a high-risk category (See page 6), testing should be repeated upon admission to the delivery hospital. Also, if a woman's HBsAg result is negative, and she is in a high-risk category she should be given the hepatitis B vaccine. Pregnancy is not a contraindication to administering the vaccine. If a woman has not been screened prenatally or the results are unavailable at the time of delivery, HBsAg testing should be immediately done at the time of admission for delivery. This identifies infants born to HBsAg-positive mothers for prompt prophylaxis at birth, and for follow-up vaccination at age 1 month and age 6 months. **NYS Public Health Law 2500-e requires that all pregnant women be tested for hepatitis B infection during each pregnancy.**

Since 1990 there has been a 75% decrease in incidence of acute hepatitis B cases. The rate of disease among children <12 years and adolescents aged 12-19 have declined 94%. Steady decline coincides with implementation of a national strategy to achieve the elimination of HBV including 1) **screening of all pregnant women for HBV infection with provision of postexposure prophylaxis to infants born to infected women**; 2) routine vaccination of all infants and children aged 18 and younger; and 3) vaccination of others at increased risk of acquiring hepatitis B.

Sources: "Acute hepatitis B among children and adolescents—United States, 1990-2002"
"Achievements in public health: hepatitis B vaccination, United States, 1982-2002"

DELIVERY HOSPITAL PROCEDURES (Also See Appendix G)

Labor and Delivery Unit

Upon admission, the mother's original HBsAg lab 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 lab report and not rely on the handwritten prenatal record due to the possibility of transcription error, misinterpretation of the test results, or incorrect ordering of the test.

- **If the mother is HBsAg-negative:** It is strongly recommended that all delivery hospitals implement standing orders to ensure that, except in rare instances, **all** infants weighing ≥ 2000 grams begin the hepatitis B vaccine series within 12 hours of birth or at least prior to hospital discharge. In NYS, state-funded vaccine for all infants (regardless of their insurance coverage) is provided free of charge to hospitals that implement standing orders for the birth dose.

- **If the HBsAg result is unknown or not available:** The labor and delivery unit should order an HBsAg test as soon as possible. Title 10 Rules and Regulations require hospitals to have HBsAg testing available with results available within 48 hours, preferably within 12 hours. The lab should be instructed to call the nursery with the result as soon as they are available.
    - If the mother's HBsAg status is unknown, and the infant is premature and weighs <2,000 grams, HBIG should also be given within 12 hours of birth.
    - If a mother with an unknown HBsAg status is later identified as positive, or her status remains unknown, the infant should receive HBIG as soon as possible, but no later than seven days after birth.

- **If the mother is HBsAg-positive:** The infant's exposure to maternal blood containing hepatitis B virus is the primary source of perinatal infection. Blood, body fluid, and tissue precautions are indicated for a pregnant woman who is HBsAg-positive and her infant.
    - The nursery must be alerted immediately upon the mother's admission.
    - The infant should be immediately bathed with soap and water to remove the mother's body fluids. These infants require immunoprophylaxis within 12 hours of birth with hepatitis B vaccine and, if the mother is HBsAg-positive, immunoprophylaxis of the infant with HBIG is also required.
    - The mother should be notified of the need to give immunoprophylaxis to her infant within 12 hours. The mother should always receive a current Vaccine Information Statement (VIS) prior to administration of the vaccine.
    - All health care workers (HCWs) should follow standard precautions by wearing surgical gloves, gowns, and protective eyeglasses. HCWs should be immunized with hepatitis B vaccine (receive a three-dose series and post-vaccination testing to assure immunity was acquired). Any equipment or items soiled with blood or exudates should be carefully cleaned and handled according to standard precautions.

Nursery Unit

An immunization record card noting the hepatitis B vaccine date and brand must be given to all mothers. The mother should be provided with educational and written materials regarding the importance of having her baby complete the hepatitis B vaccination schedule on time. The infant's hospital record should indicate the date of hepatitis B vaccine administration and must always be forwarded to the infant's primary care provider.

- **If the mother is HBsAg-negative:** Infant should be given hepatitis B vaccine before discharge, preferably within 12 hours of birth (See: Birth Dose, p ??).

- **If the mother's HBsAg status is unknown:** Infant should be given hepatitis B vaccine within 12 hours of birth. *Do not wait for the test results before giving the vaccine.* (For infants weighing <2000 g, see special recommendations on page 20 for preterm infants).
    - Give the mother an immunization record card noting hepatitis B vaccine date and explaining the need for further doses to complete the series.
    - Confirm that the lab has drawn a serum for HBsAg and that it should be reported to the nursery ASAP. If the nursery does not receive the lab results of the mother's HBsAg status at the expected time, the lab should be called for the result.
    - If the mother's test comes back positive, give the infant HBIG (0.05mL, IM) ASAP. These infants should follow protocol for HBsAg-positive mothers.
    - Both the mother's and infant's physicians should be notified of the test result or that the HBsAg result is pending. If the test result remains unknown at the time of discharge, be sure to obtain all contact information in case further treatment is needed. There is little benefit in giving HBIG if >7 days have elapsed since birth.

- **If the mother is HBsAg-positive:** Give both HBIG and hepatitis B vaccine at separate sites within 12 hours of birth.
    - The nursery unit should also provide educational materials on all the following:
        - the importance of receiving <u>all</u> follow-up doses of hepatitis B vaccine on time (See: Vaccine Schedules, page 49);
        - the importance of post-vaccination testing for the infant following the hepatitis B series to assure immunity;
        - the mother's need for ongoing medical follow-up and possible treatment of chronic HBV infection; and
        - the importance of testing household, sexual, and needle-sharing contacts for hepatitis B, then vaccinating if susceptible.
    - Encourage the mother to breastfeed if she wishes to do so, including immediately following delivery, even if the infant has not yet been vaccinated. The mother should be educated on good breastfeeding

practices and nipple care. Breastfeeding should temporarily be discontinued when cracked, bleeding nipples or abscesses occur.
- Notify the local health department that the infant was born and has received the appropriate prophylaxis (include the date and time of administration of both HBIG and 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.

Preterm Infants

- 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.

- Because of the potentially decreasing immunogenicity of vaccine in preterm infants weighing <2,000 grams, these infants should receive both single-antigen hepatitis B vaccine and HBIG if the mother's HBsAg status cannot be determined within 12 hours of birth.

- For premature infants weighing less than 2000 grams whose mother is HBsAg-negative, the vaccine should be administered at one month of age or prior to hospital discharge if medically stable.

- Some studies suggest that decreased seroconversion rates might occur in some premature infants with low birth weights (i.e., <2,000 grams) following administration of hepatitis B vaccine at birth. For this reason, this first dose of vaccine should not count toward the completion of the 3-dose series in infants weighing less than 2000 grams at birth. The series should begin at one month of age, giving the infant a total of four doses.
- When hepatitis B vaccine is used, the full recommended dose should be used. Divided or reduced doses are not acceptable.

HOSPITAL RECORD REVIEW USING LOT QUALITY ASSURANCE (LQA) METHODOLOGY

Lot quality assurance is a type of quality control program that was developed in the manufacturing industry. This same concept has been applied to the NYSDOH Perinatal Hepatitis B Prevention Program to evaluate and ensure compliance with perinatal hepatitis B guidelines as well as public health law and regulations. The methodology of LQA is to sample a "lot", which in this case is a certain number of medical records from a six-month birth cohort. The hospital will have the data department compile a list of births in the specified six month period (in chronological order) pairing the mother's name and chart number with the infant's name and chart number. The hospital will send the list to the New York State Department of Health. The NYSDOH will select

random sample of 65 pairs of mother-infant names and send it back to the hospital so the medical records department can pull the records. These records are reviewed for documentation of the maternal HBsAg test dates and status in BOTH the maternal and infant records. Information collected for LQA includes:

- Information in the Maternal record:
  - HBsAg test date and status (P/N/Unknown)
    - Was a copy of the *original* lab report included?
  - Rubella titer, immune status (Immune/Non-Immune/Unknown), and if vaccinated? (Y/N)
  - Was there documentation of varicella disease? (Y/N/Unknown) or vaccination? (Y/N)
  - Influenza vaccination for current pregnancy given? (Y/N)
  - Was Tdap given? (Y/N)

- Information in the Infant record:
  - Delivery date and time
  - Was the mother screened for HBsAg (Y/N)?
  - Mother's HBsAg test date and status
  - Was the infant vaccinated (Y/N/Refused)?
  - Was the infant vaccinated within 12 hours (Y/N/Unknown)?
  - Was the vaccine information documented completely (Y/N), if not what is missing? (see below for complete documentation information)
  - Was the Newborn Screening Form completed and if so, was it correctly completed (Y/N/correct/incorrect)?

New York State Public Health Law mandates testing, reporting, and recording of maternal HBsAg status. Therefore 100% of records reviewed must contain maternal HBsAg status and test date in both the maternal and infant records. Hospitals that meet 100% compliance and have at least a 90% birthdose rate are awarded a "Certificate of Excellence." The hospital will also be required to share their written policies and procedures regarding perinatal hepatitis B and the educational information packet given to new parents. Following the review, an exit interview is conducted to discuss the results and recommendations. This is followed-up with a written letter to appropriate hospital staff summarizing the results and recommendations.

Advantages of using Lot Quality Assurance Methodology

- A random sample of records is selected and fewer records are pulled and reviewed, therefore this is an efficient and time-saving method.

- The process ensures that hospitals are complying with Public Health Law.

- A good educational opportunity is provided. Hospitals are given updated information and materials, review of public health law, regulations, and the most current recommendations.

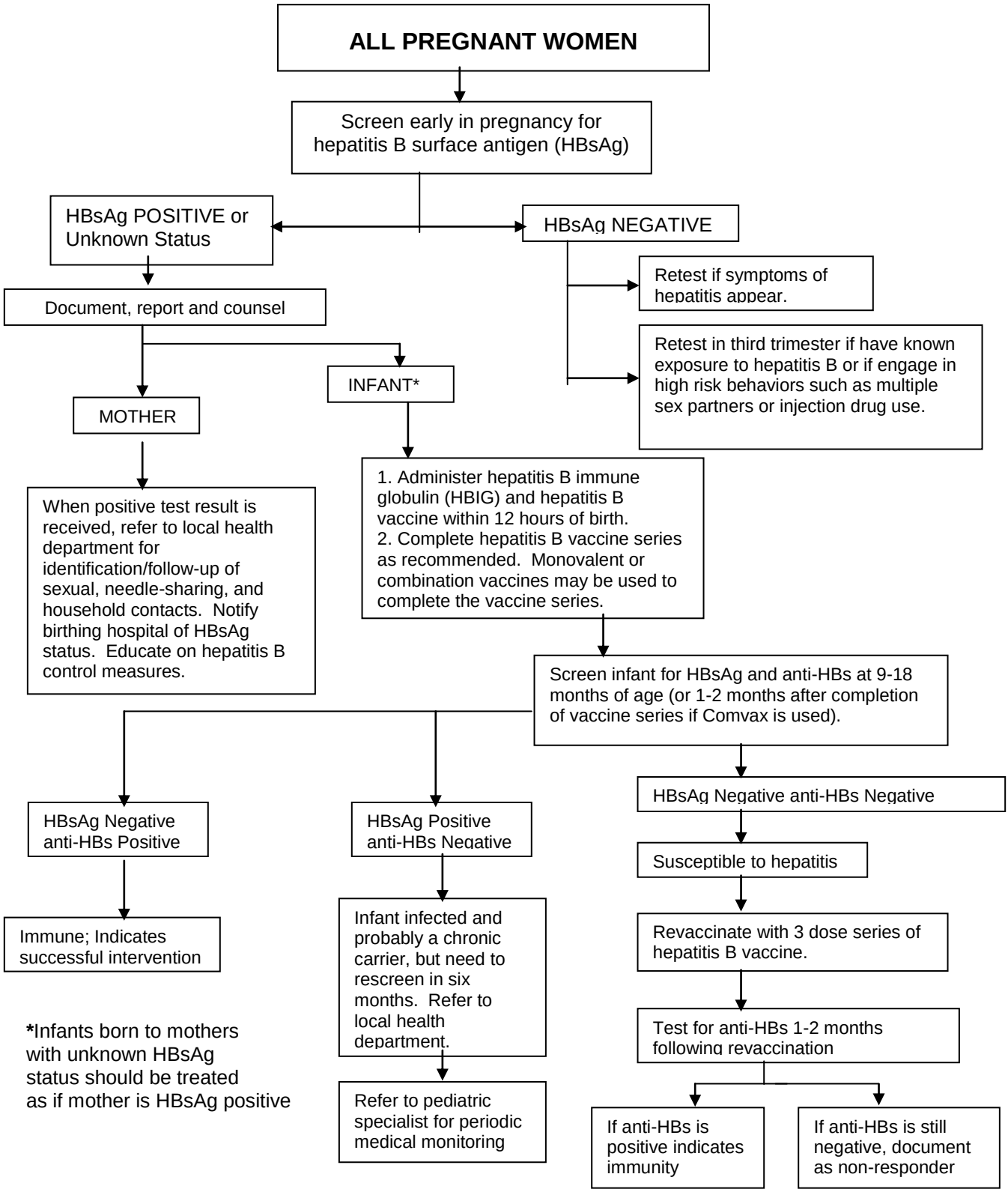
- The review is performed by department of health staff rather than hospital staff. This provides an opportunity for interaction between local health departments and hospitals.

Common Recommendations following Hospital Record Reviews

- Document maternal HBsAg test result and date of test in BOTH the maternal and infant record;
- Include an original copy of HBsAg test results in the maternal and infant record;
- Use “maternal HBsAg” terminology instead of other terms like “hep screen” to minimize the likelihood of ordering the wrong test and hence faulty interpretation;
- Re-test high risk mothers late in pregnancy, or at the time of delivery;
- Promote post-partum administration of Tdap and influenza vaccines if needed;
- Document accurate completion of the Newborn Screening Form by marking maternal status as either positive or negative. It is very rare that there is a valid “unknown” for HBsAg status;
- Identify and address barriers to providing hepatitis birthdose within 12 hours of delivery;
- Provide the most current Vaccine Information Statement (VIS) to the parent/guardian prior to vaccination; and
- Document all vaccines administered at the birthing hospital by including the following:
    - date and time the vaccine was given
    - name of the vaccine and manufacturer
    - lot number of the vaccine
    - dose administered
    - site of injection
    - name of person administering the vaccine
    - print date of the VIS provided to the parent/guardian

Repeated or serious LQA failures will result in notification to the NYSDOH Office of Health Systems Management (OHSM) - Refer to Appendix D - Perinatal Hepatitis B Prevention Program Quality Assurance Guidelines

PREVENTION OF PERINATAL HEPATITIS B TRANSMISSION



CHAPTER FIVE: HEPATITIS B BIRTH DOSE

THE IMPORTANCE OF THE HEPATITIS B BIRTH DOSE

The Advisory Committee on Immunization Practices (ACIP), American Academy of Pediatricians (AAP), American Academy of Family Physicians (AAFP) and the American Congress of Obstetricians and Gynecologists (ACOG) 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 over 2,000 grams (regardless of the mother's HBsAg status). The panel states that exceptions should be rare and considered on a case-by-case basis. Any health care provider who decides to delay the birth dose must document the order to do so, and ensure that a copy of the mother's lab report indicating she was HBsAg-negative during this pregnancy is present in the infant's medical record.

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; in one study, 40% of infants who were not infected perinatally became infected by age 5 years. 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 vaccine at birth. The infant is later exposed to HBV 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 HBV 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 prophylaxis.

- 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 HBV infection in the household.

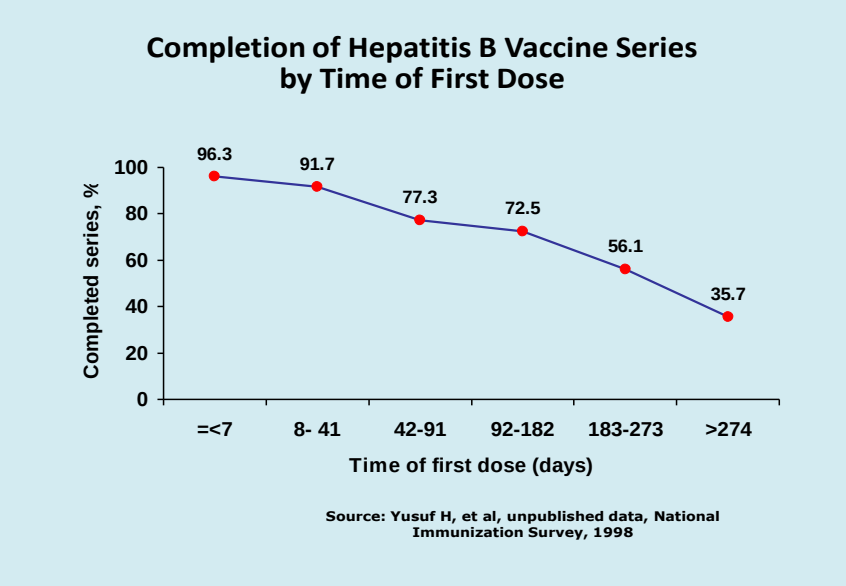
- It places the importance of immunization as an early and visible priority for parents.

- 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 vaccine series if given the first dose by age 7 days, as shown below (Yusef H, et al).

- It is the foundation of the overall public health strategy to eliminate HBV infection in the United States.



"Because screening selected pregnant women for HBsAg has failed to identify a high proportion of HBV-infected mothers, prenatal HBsAg testing of all pregnant women is now recommended. Universal prenatal testing would identify an estimated 22,000 HBsAg-positive women and could prevent at least 6,000 chronic HBV infections annually"

Source: Hepatitis B Virus: A Comprehensive Strategy to Eliminating Transmission in the United States Through Universal Childhood Vaccination: Recommendations of the Immunization Practices Advisory Committee

NEW YORK STATE HEPATITIS B BIRTH DOSE INITIATIVE

The prevention of perinatal hepatitis B remains a vital public health focus in New York State. The Hepatitis B Hospital Birth Dose Initiative was established in October 2003 to remove the cost barrier for hospitals and providers. This new program provided free hepatitis B vaccine to any birthing hospital in New York State that agrees to adopt a universal hepatitis B birth dose policy. After aggressive recruitment efforts in 2008, 100% of birthing hospitals in New York State signed onto the Hepatitis B Hospital Birth Dose Initiative.

However, according to CDC National Immunization Survey (NIS) data the average rate of birth dose administration in New York State remained far lower than the national average. To evaluate for the existence of barriers other than cost to administration of the hepatitis B birth dose, in 2008 an electronic survey was distributed to Medical Directors and Nurse Managers of Newborn Nursery units at all New York State birthing hospitals. Perinatal hepatitis B prevention remains a vital public health focus and the results of this survey will help guide future efforts to achieve optimal coverage and eliminate the perinatal transmission of hepatitis B.

In April 2006, the NYSDOH Commissioner of Health established the state standard of care to be preference for the first dose of hepatitis B vaccine to be administered to all infants within 12 hours of birth. The administration of the first dose of hepatitis B at birth is endorsed by the American Academy of Pediatrics (AAP), American Academy of Family Physicians (AAFP), American College of Obstetricians and Gynecologists (ACOG), and Advisory Committee on Immunization Practices (ACIP).

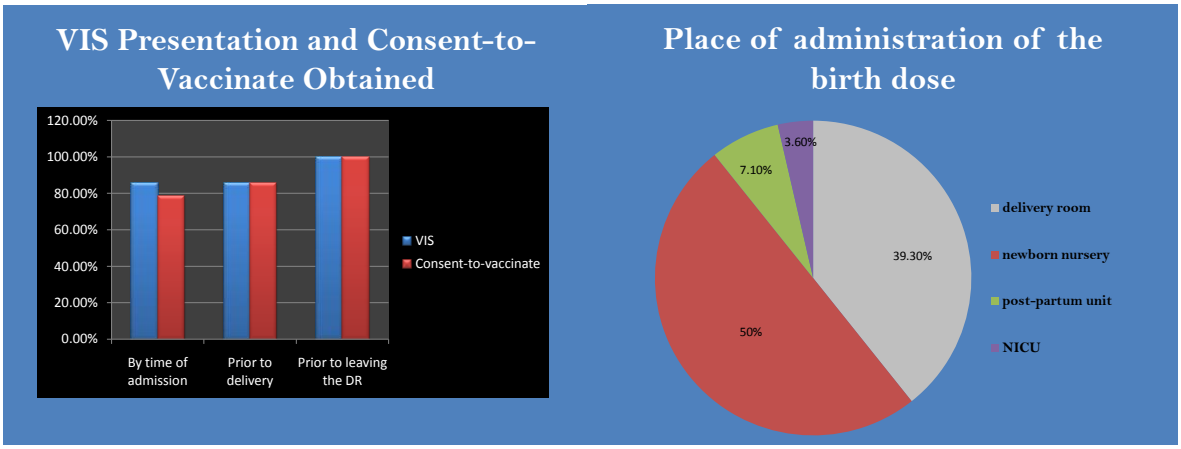
Despite best efforts and 100% enrollment in the Birth Dose Initiative by 2008, the proportion of infants receiving the birth dose in some hospitals in NY remained below the Healthy People 2010 goal of 80%. According to data provided by the New York State Immunization Information System (NYSIIS) the average percent of infants vaccinated in New York State (exclusive of New York City) for 2008 was 70.81% (range 0 to 98.50%; median 79.10%) and increased in 2009 to 75.38% (range 0 to 98.82%; median 83.82%). In most regions of the state, a portion of hospitals with low coverage pulls down the average down for the entire region. Overall, low vaccination coverage is due to both low compliance and Statewide Perinatal Data System (SPDS) reporting errors. Introducing new best practices for birth dose administration can improve the percentage of infants vaccinated and help to reduce the number of infants at risk.

For this purpose, a survey was conducted in 2010 among hospitals with high coverage to investigate practices that promote the high birth dose rates observed in these hospitals. Interviews with hospital maternal/child managers were aimed at identifying common practices that may have led to high coverage rates and with the intent to share best practice recommendations with other facilities. A total of 28 hospitals with rates of 90% and above were identified and contacted. There was 100% completion of the questionnaires.

Important results of the interview survey are as follows:

- **Prenatal/childbirth classes:** A prenatal/childbirth class with information on the hepatitis B birth dose is provided in 84.7% of the hospitals. Therefore, prior to admission to labor and delivery most (75%) pregnant women are aware of the recommendation to vaccinate all infants.

- **VIS and consent to vaccinate:** The Vaccine Information Statement (VIS) is provided and the consent form is signed by the mother prior to leaving the delivery room in all (100%) of the hospitals. In 85.7% of hospitals, the VIS is given and consent obtained prior to birth.



- **Room of administration:** The following rooms are used in administering the birth dose: Delivery room 39.3%, newborn nursery 50%, post-partum unit/ mother's room 7.1 %, and NICU 3.6%. Notable reasons for giving the birth dose in the delivery room and newborn nursery include convenience and better compliance, timeliness of administration as this is done together with the initial newborn assessment and/or the administration of vitamin K and erythromycin ophthalmic ointment. This routine also minimizes the chance of missed opportunity for newborn vaccination.

- **Reasons for parental refusal:** The most common reasons reported for parental refusal of vaccination are preference to receive the vaccine in the pediatrician's office (36%) and cultural or religious beliefs (36%). Other reasons include fear of vaccines in general (21%), preference to discuss with pediatrician (14%), fear of vaccinating the newborn (7%) and lack of understanding of the seriousness of HBV infection (7%).

- **Staff resistance:** Resistance to the administration of the dose is encountered only in 7.1% of the hospitals. In both of these hospitals, the resistance is from private practice pediatricians indicating a desire to vaccinate newborns in their office setting.

- **Staff education:** The respondents indicate that they provide education for both new (100%) and continuing staff (64.3%) about hepatitis B and the rationale for the birth dose. Staff education is targeted at 100% of the nursing staff and only 57.1% of the new medical staff.

- **Special populations:** 28.6% of the hospitals indicate that they serve populations such as Asian or Pacific Islanders, refugees, Amish or Mennonite, Hispanics and/or migrant workers. Culturally and linguistically appropriate materials were provided for these populations, except for the Amish and Mennonite.

- **Provision of vaccine:** All the respondents indicated that the hospitals order state-funded vaccines free of charge from the NYSDOH through the NYS Birth Dose Initiative. This eliminates cost as a barrier to providing the birth dose.

- **Most important factors:** When asked an open-ended question of what hospital maternal/child managers believed are the most important factors in achieving a high birth dose rate, the responses were as follows (not ranked):
    - Having a knowledgeable and supportive staff, especially the physicians;
    - Timely parental education, especially in prenatal classes;
    - Ease and consistency of procedures (the hepatitis B vaccination being part of the newborn routine);
    - Availability of vaccine at no cost (as stated above);
    - Early administration of the vaccine, either in the delivery room or during the admission process in the newborn nursery:
    - Making the hepatitis B vaccine birth dose a part of the preprinted newborn admission orders; and
    - Having a policy for universal hepatitis B vaccination of all newborns regardless of mother's HBsAg status.

- **NYSDOH assistance:** Additional assistance from the NYSDOH was requested from 84.7% of the hospitals in the form of trainings or workshop, webinars, educational materials (pamphlets, posters, videos etc.), and culturally sensitive material for the Amish population.

BEST PRACTICE RECOMMENDATIONS

Based on these results and previous studies the following recommendations are suggested:

Education and Training

- Staff education efforts should be focused on all maternity and newborn staff, including medical students, interns, residents, nursing and clerical staff.

- Parental education regarding the benefits of the birth dose should be provided early in prenatal/childbirth classes to ensure that they have prior knowledge of these upon admission to labor and delivery units. This information should include vaccine safety information with emphasis on the hepatitis B vaccine in particular.

- Culturally sensitive and linguistically appropriate materials should be provided and made available to specific populations, such as Amish, Mennonite and Native American mothers.

Hospital Policies and Procedures

- The VIS should be presented **and** consent to vaccinate obtained from the mother prior to entering the delivery room whenever possible.

- The hepatitis B birth dose should be administered either in the delivery room or on admission to the newborn nursery.

- Ensure pediatricians and private pediatric providers are on-board with the hospital's universal birth dose policy since parents rely on the pediatrician's recommendation and support for vaccination

- In the case of parental refusal to vaccinate:
    - The pediatrician should be informed to discuss the possible consequences of this decision.
    - The reason for parental refusal should be documented in the infant's record.

Additional Recommendations

- The role of cultural and religious beliefs on the decision to vaccinate needs to be studied further for future planning of intervention measures.

- Educational materials such as brochures, videos and webinars should be made available to hospital staff, parents and specific populations. Suggested topics include vaccine safety and importance of the hepatitis B birth dose.

CHAPTER SIX: PERINATAL HEPATITIS B CASE MANAGEMENT SYSTEM

CASE REPORTING

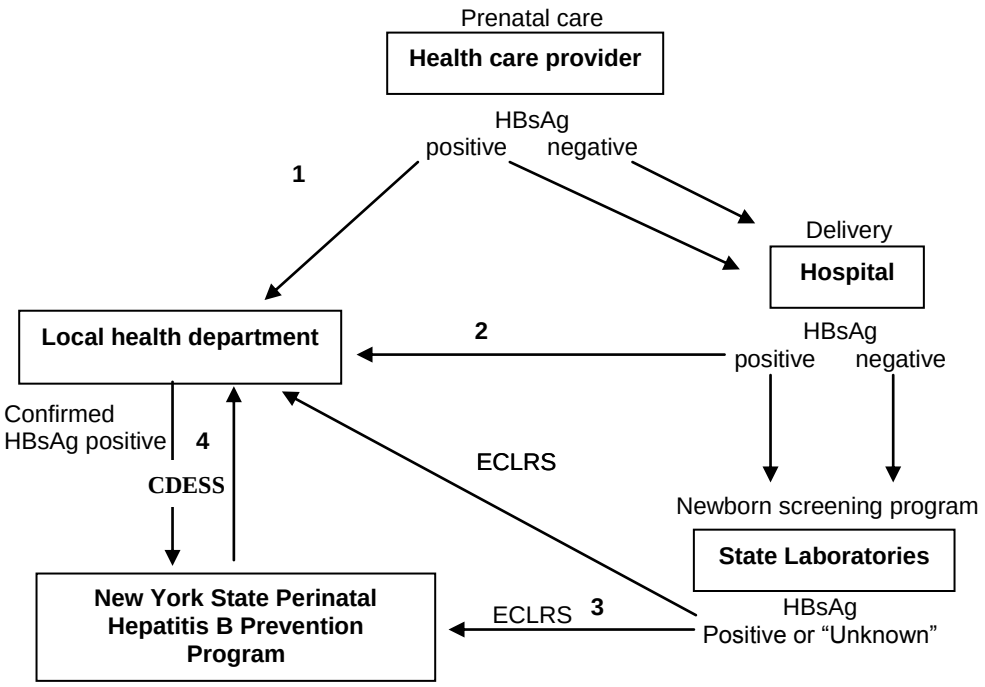
The Perinatal Hepatitis B Prevention Program reports cases through multiple surveillance mechanisms. Hepatitis B is a reportable disease in New York State. Reporting of suspected or confirmed communicable diseases is mandated under the New York State Sanitary Code and Public Health Law (PHL) [PHL § 2102, 10 NYCRR § 2.10, 2.12]. The primary responsibility for reporting rests with the physician. However, persons in charge of laboratories, schools, nursing homes/hospitals and state institutions or other locations providing health services are also required to report hepatitis B. The required information under PHL 2102 includes:

- patient's name, date of birth, and sex;
- patients address and county of residence;
- type and source of specimen;
- date collected;
- test result;
- date of final report; and
- Physician's name, address, and telephone number.

Public Health Law makes surveillance of reportable diseases possible and permits identification of trends and outbreaks. It also increases the likelihood of complete reporting. A mother's HBsAg status is reported in the following ways:

1) Test results indicating HBsAg positivity are reportable to local health departments (LHDs) by laboratories and physicians under existing notifiable disease reporting laws. Prenatal health care providers report to the mother's county of residence health department via Communicable Disease Confidential Case Report (DOH-389). Health care providers must notify the woman's birthing hospital of her HBsAg status at least two weeks prior to her expected date of confinement (due date). Reporting may be done by mail, FAX, or electronically.
2) Labor and delivery hospitals report to a) the mother's county of residence health department via telephone and DOH-389 and b) the State Health Department Laboratory via the Newborn Screening Blood Collection Form (DOH-1514).
3) Diagnostic laboratories report to County and State Health Departments via Electronic Clinical Laboratory Reporting System (ECLRS).
4) Local health departments report to NYSDOH via the Communicable Disease Electronic Surveillance System (CDESS).

Multiple Reporting Sources in New York State
Perinatal Hepatitis B Prevention Program



Reporting and 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:

1. disclosures required by law (45 CFR § 164.512(a)) or
2. 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)).

In New York State there is a mandate for reporting of maternal HBsAg status and hepatitis B is a notifiable disease. Therefore, HIPAA is not a hindrance to review of patient records and reporting of hepatitis B.

CASE MANAGEMENT

The local health department (LHD) receives all HBsAg positive test results through ECLRS. Upon receipt of the test results, the LHD must determine if the case is a female of child-bearing age. The LHD should then investigate to determine whether this woman is pregnant. If this is a pregnant woman, the LHD will contact the prenatal health care provider to confirm the HBsAg status of the pregnant woman and obtain the date of serology. Next, the LHD will contact the delivery hospital to alert the staff of the positive HBsAg mom's due date to ensure that HBIG and hepatitis B vaccine is administered to the infant within 12 hours of birth. A copy of the mother's prenatal record should be forwarded to the delivery hospital by the prenatal healthcare provider, indicating the hepatitis B surface antigen-positive results. According to recent ACIP recommendations (June 2005), a copy of the *original* lab report should be sent to the birthing hospital instead of relying on the handwritten prenatal record so that the possibility of transcription error and/or misinterpretation of test results can be prevented.

The LHD should contact the HBsAg-positive woman to provide information and education. The pregnant woman should become familiar with hepatitis B infection and the importance of timely vaccination for her newborn. A home visit is preferable because advice given face-to-face is more likely to be followed. Both verbal and written control measures on prevention of the transmission of hepatitis B should be provided. In addition, all household, sexual, and needle-sharing contacts exposed to the HBsAg-positive pregnant woman should be identified and counseled. Contacts should be tested for hepatitis B and, if found to be susceptible, vaccinated. The LHD should provide the testing and vaccine to all uninsured or underinsured contacts. The LHD perinatal hepatitis B coordinator is responsible to documenting all counseling, testing and vaccination of susceptible contacts in CDESS.

For women newly identified as HBsAg-positive, repeat HBsAg testing should be performed six months after initial testing to confirm diagnosis of hepatitis B. Women who remain HBsAg-positive for six months or more are chronic carriers and need regular medical monitoring. These women should see a gastroenterologist or liver specialist every six months, even if asymptomatic. Most people do not require treatment. Treatment is only indicated if liver problems develop or liver function tests are elevated above normal. Treatment is recommended depending on a number of factors including: patient's age, the severity of liver disease, likelihood of response, and potential adverse events and complications.

Five therapeutic agents have been approved by the Food and Drug Administration (FDA) for treatment of chronic hepatitis B: interferon alpha, lamivudine, adefovir, entecavir, and pegasys interferon alpha. The aims of treatment are to achieve sustained suppression of HBV replication and remission of liver disease. These medications are effective in up to 40% of people. These medications should not be used by pregnant women. No medications have been approved for use in acute

hepatitis B infection; treatment for these individuals is supportive. Individuals diagnosed with hepatitis B infection should be referred to their primary care provider and a gastroenterologist for disease management.

MANAGEMENT OF CONTACTS

Household, Sexual, and Needle-Sharing Contacts

All sexual, needle-sharing, and household contacts of persons with hepatitis B are at high risk of acquiring the disease. Case investigation shall be performed to determine exposed household, sexual, and needle-sharing contacts. If the date of infection is unknown, identify sexual and needle-sharing contacts during the previous six months.

- All contacts of hepatitis B-infected individuals should be given both verbal and written information regarding control measures, such as the need to:
    - 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 unless your partner has had hepatitis B or has been vaccinated against hepatitis B.
    - Tell dentists and doctors that you are hepatitis B positive so that they can use extra precaution.
    - Advise sexual partners and family members to see their doctors about screening and vaccination for hepatitis B.
    - 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.
    - Never donate blood, plasma, body organs, tissue, or sperm.

- Those who have been exposed to the index case (the HBsAg-positive mother) should be tested for the presence of both HBsAg and anti-HBs. Serologic testing and hepatitis B vaccine (if necessary) are provided by the LHD to those contacts that cannot afford these services.

- When the laboratory tests of household, sexual, and needle-sharing contacts indicate the presence of HBV (HBsAg-positive), hepatitis B control measures apply. These individuals should be referred to their private medical doctor for disease management.

- Contacts whose laboratory data indicates the absence of both hepatitis B infection and immunity (HBsAg-negative, anti-HBc IgM-negative and anti-HBs-negative) are susceptible to infection and should be vaccinated with hepatitis B vaccine (See: Post-exposure prophylaxis, p 35). Control measures should be emphasized until the HBIG and hepatitis B vaccine series have been completed.

- Household, sexual, and needle-sharing contacts should be entered into CDESS under mother's Core screen. From "Core" go to "Supplement," then "See Pregnancy History" and "Contact." The LHD should follow household contacts on CDESS until the completion of the hepatitis B vaccine series. Instruct asymptomatic contacts to immediately report any symptoms of hepatitis to their LHD and to seek care from a medical doctor.

- Symptomatic contacts should be considered cases and managed with the appropriate follow-up with a medical doctor.

The Infant

The purpose of maternal screening and intervention is to prevent the development of hepatitis B infection among infants born to mothers who are hepatitis B surface antigen (HBsAg) positive. Because these infants are at high risk of becoming chronic carriers of the disease, prevention is of great importance. The infant should be tracked on CDESS to ensure timely completion of the vaccine series and serology (See: Hepatitis B Vaccine Schedules, page 48-49). Parents should be advised to strictly adhere to the hepatitis B vaccine schedule to prevent hepatitis B infection in their infants. CDESS tracking of infants should continue through completion of follow-up anti-HBs and HBsAg testing at age 9-18 months. Post-vaccination testing may have three different results each requiring different follow-up procedures.

- **The immune infant**: If serology indicates that immunity was acquired (anti-HBs positive), the case is closed. This is the most common result and up to 95% of infants acquire immunity following proper immunizations alone.

- **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 first vaccination series (HBsAg-negative and anti-HBs negative) the infant should receive another three dose vaccination series and repeat serologic testing 1-2 months after the second series is complete. Alternatively, a single booster dose of hepatitis B vaccine may be used, followed by serologic testing 1-2 months later. If the infant remains susceptible following a second three dose series they are considered a non-responder. The mother should be advised of the appropriate hepatitis B control measures to prevent potential future transmission to this susceptible infant.

Post-Exposure Prophylaxis

- Post-exposure immunoprophylaxis is recommended for perinatal prevention, unvaccinated persons with occupational exposure to blood or body fluids that

contain blood, for sexual and household contacts of persons with acute hepatitis B and chronic HBV infection, and for victims of sexual assault.

- When post-exposure prophylaxis is indicated, it should be administered as soon as possible after exposure (preferably within 24 hours, especially for occupational exposures).

- Hepatitis B vaccine can be administered simultaneously with HBIG, if indicated, at a separate site.

- The minimum interval after exposure during which post-exposure prophylaxis is effective is unlikely to exceed 7 days for perinatal and needlestick exposures and 14 days for sexual exposures.

Recommendations for post-exposure prophylaxis after percutaneous or permucosal exposure to HBV

Vaccination and antibody Status of exposed person*		TREATMENT		
		Source HBsAg** Positive	Source HBsAg** Negative	Source Unknown or not available for testing
Unvaccinated		HBIG^{o} X 1 and initiate HB vaccine series	Initiate HB vaccine series	Initiate HB vaccine series
Previously Vaccinated	Known Responder[1]	No treatment	No treatment	No treatment
	Known Nonresponder[2]	HBIG X 1 and initiate revaccination or HBIG X 2[3]	No treatment	If known high risk source, treat as if source were HBsAg positive.
	Antibody response unknown	Test exposed person for anti-HBs[a] – If adequate[1], no treatment is necessary – If inadequate[2], administer HBIG X 1 and vaccine booster	No treatment	Test exposed person for anti-HBs – If adequate[1], no treatment is necessary – If inadequate[2], administer HBIG X 1 and vaccine booster and recheck titer in 1-2 months

* Persons who have previously been infected with HBV are immune to reinfections and do not require post exposure prophylaxis

** Hepatitis B surface antigen

^{o} Hepatitis B immune globulin, administered intramuscularly. Dosage varies with age. Infants less than 12 months of age should receive .05 ml dose; adults and children older than 12 months should receive .06 ml/kg dose.

[1] A responder is a person with adequate levels of serum antibody to HBsAg (i.e. anti HBs≥10mIU/mL)

[2] A nonresponder is a person with inadequate response to vaccination (i.e. serum anti HBs<10mIU/mL)

[3] The option of giving one dose of HBIG and reinitiating the vaccine series is preferred for nonresponders who have not completed a second 3-dose vaccine series. For persons who previously completed a second vaccine series but failed to respond, two doses of HBIG are preferred.

[a] Antibody to HBsAg.

TRACKING SYSTEM

The local health department (LHD) will identify hepatitis B surface antigen (HBsAg) positive women during pregnancy and track the women, infants, and other contacts through their course(s) of vaccines and follow-up testing. The LHD perinatal hepatitis B coordinator has the primary responsibility for case management, tracking and reporting information in CDESS. Follow-up of the infant will be reported in CDESS in the Perinatal Hepatitis B Infant Summary. This data will be used to assess the prevalence of perinatal hepatitis B in NYS, vaccination and serology completion rates, and other data required by the Centers for Disease Control and Prevention.

The average time required to complete follow-up of a perinatal hepatitis B case is 12-18 months. This length of time is unusual in public health and presents unique challenges. The LHD Perinatal Hepatitis B Coordinator will have long periods of time between contacts with the patients and will need to be reminded of upcoming patient needs. To manage this lengthy and complicated case process for perinatal hepatitis B, it is important to establish a tracking system that will enable you to develop a schedule for subsequent telephone or letter contacts—to remind the mother to have her infant vaccinated or to remind the physician that the infant needs vaccination or testing. The person performing tracking should coordinate tracking efforts with the maternity nurses and immunization personnel. If the patient prefers to receive follow-up with a private health care provider (HCP), the LHD should notify the HCP when immunization or testing is due and to return information requests to the county when they are complete.

Although there is more than one way to organize your tracking system, the CDESS HepB Perinatal Infant Reports are a valuable resource (see Appendix C). However, certain basic elements are necessary to ensure that all information is tracked. These include the following:

1) The HBsAg-Positive Pregnant Woman

The HBsAg-positive pregnant woman should be identified as the index case for your tracking system and other records should be organized around this case. She is the reason you provide screening and preventive care to the infant and contacts. 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 immigrant, date of arrival in the United States
- primary language spoken

Home and work information
- home address and telephone number
- work address and 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

2) The Contacts (sexual, needle-sharing, household)

Sexual, needle-sharing and household contacts that have been exposed to the HBsAg-positive pregnant woman shall be offered testing, 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
- work address and telephone number
- emergency telephone number

Medical information
- date of screening
- screening results
- if known to be infected with hepatitis B
- if indicated:
    - date of HBIG
    - dates of hepatitis B vaccine doses to complete 3-dose immunization series
    - date and result of post-vaccination serology, including HBsAg and Anti-HBs

- dates of hepatitis B vaccine doses to complete a second 3-dose series if serology after first series indicate non-reactivity (negative HBsAg and Anti-HBs)

3) The Infant

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

Home information (if different from mother's)

- 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
- date of follow-up serology
- post-vaccination serology test results
- primary care provider of immunization services
- address and telephone number of provider

Cases Lost to Follow-up

Despite a good tracking system, some cases will be lost to follow-up, and as a result, 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 couple of things that can be done to try to find them.

- Access the New York State Immunization Information System (NYSIIS) to determine if the child has a new address listed.

- 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 and WIC programs—an up-to-date address is required for these services.

- Search local health department records. Many people have contact with the health department 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 county 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.

- Another interview of the index case or contacts may be helpful to clarify or obtain further information on how to contact the person.

- When all avenues of locating a case have been exhausted, update the CDESS Perinatal Hepatitis B Infant Summary under the "Lost to Follow-up Information" section.

CHAPTER SEVEN: HEPATITIS B VACCINATION AND PROPHYLAXIS

PROPHYLAXIS AGAINST HEPATITIS B VIRUS INFECTION

Two types of products are available for prophylaxis against HBV infection. Hepatitis B vaccine, which provides long-term protection against HBV infection, is recommended for pre-exposure and post-exposure prophylaxis. HBIG provides temporary protection (i.e., three to six months) and is indicated only in certain post-exposure settings.

Hepatitis B Immune Globulin (HBIG)

HBIG is prepared by cold ethanol fractionation of plasma from selected donors with high titer of antibody against HBsAg (anti-HBs). In the United States, HBIG has an anti-HBs titer of at least 1:100,000 by radioimmunoassay. The human plasma from which HBIG is prepared is screened for HBsAg, antibodies to HIV and HCV and for HCV RNA. In addition, the process used to manufacture HBIG inactivates viruses (e.g., HBV, HCV, and HIV) from the final product. There is no evidence that HIV can be transmitted by HBIG. HBIG does not contain thimerosal. It is used for passive immunization for accidental (percutaneous, mucous membrane) exposure, sexual exposure to an HBsAg-positive person, perinatal exposure of an infant, or household exposure of an infant less than age 12 months to a primary caregiver with hepatitis B.

All candidates for HBIG are, by definition, in a high-risk category and should therefore be considered for hepatitis B vaccine as well.

Immune globulin (IG) is prepared by cold ethanol fractionation of pooled plasma; it contains low titers of anti-HBs. Because titers are relatively low, there is no valid current use for IG against HBV disease, unless HBIG is unavailable.

Hepatitis B Vaccine

Two types of hepatitis B vaccine have been licensed in the United States. The first, which was manufactured from the plasma of chronically infected people, is no longer produced in the United States. Vaccines currently available in the U.S. are produced by using recombinant DNA technology.

The recombinant vaccines are produced by using HBsAg synthesized by *Saccharomyces cerevisiae* (common bakers' yeast), into which a plasmid containing the gene for HBsAg has been inserted. Purified HBsAg is obtained by lysing the yeast cells and separating HBsAg from the yeast components using biochemical and biophysical techniques. Hepatitis B vaccines are packaged to contain more than 95% HBsAg protein (5-40mcg/ml) after absorption to aluminum hydroxide (0.5 mg/ml). HBV infection cannot result from use of the recombinant vaccine, since no potentially infectious viral DNA or complete viral particles are produced in the recombinant system. Since early 2000 hepatitis B vaccines produced for distribution in the U.S. do not

contain thimerosal as a preservative, although one contains a trace amount of mercury (<0.5 mcg/dose) from the manufacturing process.

HEPATITIS B VACCINE USAGE

During 1993-2000, the national coverage rate for hepatitis B vaccine among children aged 19-35 months increased from 16% to 90%, and the coverage rate for U.S. adolescents aged 13-15 years increased from near zero to 67%.

Pre-Exposure Prophylaxis

The vaccination schedule most often used for adults and children has been three intramuscular injections, with the second and third administered one and six months, respectively, after the first.

- The minimum interval between the first and second dose is four weeks.
- The minimum interval between the second and third dose is eight weeks.
- The third dose should be separated from the first by at least four months and should not be given to an infant before six months of age.

HBIG is not indicated for pre-exposure prophylaxis. Each vaccine has been evaluated to determine the age-specific dose at which an optimum antibody response is achieved. The recommended dose varies by product and the recipient's age. These recommendations are indicated in the product information included in each vial of vaccine (See: Recommended Dosages, page 48).

Routes and Sites of Administration

The recommended series of three intramuscular doses of hepatitis B vaccine induces a protective antibody response (anti-HBs ≥10 milli-international units [mIU]/mL) in >90 percent of healthy adults and in >95 percent of infants, children and adolescents. Hepatitis B vaccine should be administered only in the deltoid muscle of adults and children or in the anterolateral thigh muscle of neonates and infants; the immune response of the vaccine for adults is substantially lower when injections are administered in the buttocks. 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" to avoid overlap in local reactions. Separate injection sites should also be used when administering HBIG and hepatitis B vaccine 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.

Hepatitis B and Breastfeeding
Although HBsAg can be detected in breast milk, there is no evidence that HBV can be transmitted by breastfeeding. Breastfeeding is acceptable and encouraged, even if the mother is HBsAg-positive. Among infants receiving post-exposure prophylaxis to prevent perinatal HBV infection, there is no increased risk of infection among breastfed infants. Immunization of the baby at birth should protect the infant from modes of postnatal HBV transmission, including possible exposure to HBV from cracked or bleeding nipples during breastfeeding. To prevent cracked and bleeding nipples, all mothers who breastfeed should be instructed on proper nipple care.

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 series is interrupted after the first dose, the second dose should be given as soon as possible, and the second and third doses should be separated by an interval of at least 8 weeks. If only the third 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.

Booster Doses
For children and adults whose immune status is normal, booster doses of vaccine are not recommended, nor is serologic testing to assess antibody levels necessary after vaccination. For hemodialysis patients, vaccine-induced protection may be less complete and may persist only as long as antibody levels are ≥10 mIU/mL. For these patients, the need for booster doses should be assessed by annual antibody testing, and a booster dose should be administered when antibody levels decline to <10 mIU/mL. Additionally, for immunosuppressed patients, including those undergoing hemodialysis, higher vaccine dosage or more than three doses per series are required. A special formulation of one vaccine is now available for such persons (Recombivax HB, 40 ug/mL). For HIV-infected persons and other immunocompromised persons (e.g., hematopoietic stem cell transplant recipients) the need for booster doses has not been determined. Annual anti-HBs testing and booster doses when anti-HBs levels decline to <10 mIU/mL should be considered in persons with an ongoing high risk of exposure.

Adverse Reactions Following Vaccination
Hepatitis B vaccine has been shown to be safe when administered to both adults and children. Over 4 million people have been vaccinated in the United States, and at least 750 million people have received hepatitis B vaccine worldwide.

Pain at the injection site (3%-29%) and mild systemic complaints such as fatigue, headache and irritability are adverse side effects reported in 11%-17% of adults and 0-20% of children receiving the vaccine. Low grade fever (> 37.7º C/99.9º F) has been reported in 1% of adults and 0.4%-6.4% of children. In placebo-controlled studies, however, these side effects were reported no more frequently among vaccinees than among people receiving a placebo. Among children receiving both hepatitis B vaccine

and DTaP vaccine, these mild side effects have been observed no more frequently than among children receiving DTaP vaccine alone. Serious systemic adverse events and allergic reactions are rarely reported following hepatitis B vaccination.

There is no evidence that administration of hepatitis B vaccine at or shortly after birth increases the number of febrile episodes, evaluation for sepsis, or allergic or neurologic events in the newborn period. Multiple sclerosis (MS) has been reported after hepatitis B vaccination among adults but no causal relationship has been shown. In fact, recent large population-based studies have shown there is no association between receipt of hepatitis B vaccine and either the development of multiple sclerosis or exacerbation of the course of multiple sclerosis in persons already diagnosed with the disease. Any presumed risk of adverse events possibly associated with hepatitis B vaccination must be balanced against the expected risk of acute and chronic liver disease associated with the current five percent lifetime risk of HBV infection in the United States. It is estimated that, for each U.S. birth cohort, 2,000-5,000 people will die from HBV-related liver disease.

As hepatitis B vaccine has been introduced for routine vaccination of infants, surveillance for vaccine-associated adverse events has continued to be an important part of the program even though the vaccine has been proven very safe. The safety of hepatitis B vaccine will continue to be assessed through ongoing monitoring of data from the Vaccine Adverse Events Reporting System (VAERS) and other surveillance systems. All adverse events suspected to be associated with hepatitis B vaccination should be reported to VAERS. Report forms and assistance are available by calling 1-800-822-7967 or at http://vaers.hhs.gov/index .

Contraindications and Precautions

Hepatitis B vaccine is contraindicated for persons with a history of hypersensitivity to yeast or any vaccine component. Serious allergic reaction to a prior dose of hepatitis B vaccine or a vaccine component is a contraindication to further doses of vaccine. Such allergic reactions are rare.

People with moderate to severe acute illness should not be vaccinated until their condition improves. However, minor illnesses, such as upper respiratory infections are not a contraindication to vaccination.

No specific study about the safety of the vaccine in pregnant women has been performed. However, more than 30 years of experience with inadvertent administration to pregnant women have not identified vaccine safety issues for either the woman or the fetus. Because the vaccine only contains particles that do not cause HBV infection, there should be no risk. In contrast, if a pregnant woman acquires HBV infection, it may cause severe disease in the mother and chronic infection in the newborn baby. Therefore, pregnant women who are identified as being at risk for HBV infection during pregnancy (e.g., having more than one sex partner during the previous 6 months, been evaluated or treated for an STD, recent or current injection drug use, or having had an

HBsAg-positive sex partner) should be vaccinated during the pregnancy. Consult with the patient's physician before administering any vaccine.

Hepatitis B vaccine does not contain live virus, so it may be used in people with immunodeficiency. However, response to the vaccine in immunosuppressed people may be suboptimal.

There is no apparent risk of adverse effects to developing fetuses when hepatitis B vaccine is administered to pregnant women. The vaccine contains noninfectious HBsAg particles and should cause no risk to the fetus. HBV infection affecting a pregnant woman may result in severe disease for the mother and chronic infection for the newborn. Therefore, neither pregnancy nor lactation should be considered a contraindication to vaccination of women. However, consult with the patient's physician before administering any vaccine to a pregnant woman. If hepatitis B vaccine is given during pregnancy, HBsAg serologic testing should be done one to two months (21 days minimum) after administration to avoid transient HBsAg positivity.

Vaccine Efficacy

When HBV vaccine and HBIG are administered within 24 hours of birth, they are 85%-95% effective in preventing HBV infection and development of the chronic carrier state in the infant. Administration of hepatitis B vaccine in a 3 or 4 dose schedule, without HBIG, beginning within 12 hours of birth has been demonstrated to prevent 70%-95% of perinatal HBV infections.

After three intramuscular doses of hepatitis B vaccines more than 95% of infants, children, and adolescents (from birth to 19 years of age) develop adequate antibody responses. Among adults, the three-dose vaccine series administered intramuscularly at 0, 1, and 6 months produces a protective antibody response in approximately 30%-55% of healthy adults <40 years of age after the first dose, 75% after the second dose, and >90% after the third dose. However, there is an age-specific decline in immunogenicity. After age 40 years, approximately 90% of recipients respond to a three-dose series, and by 60 years only 75% of those vaccinated develop protective antibody titers. If a protective antibody response develops after three doses of vaccination, vaccine recipients are virtually 100% protected against clinical illness.

Non-responders: Revaccination

Age over 40 years, male gender, obesity, smoking, and chronic illness have been independently associated with nonresponse to hepatitis B vaccine. When people who do not respond to the primary vaccine series are revaccinated, 30%-50% produce an adequate antibody response after three additional doses and 15%-25% after one additional dose. A study of infants born to HBsAg-positive mothers who did not respond to a primary vaccine series indicated that all those not infected with HBV responded satisfactorily to a repeat 3-dose revaccination series. Therefore, revaccination with three additional doses is recommended for people who do not respond to vaccination initially. Fewer than 5% of people who have the entire series repeated (e.g., a total of

six doses given) fail to develop detectable anti-HBs antibody (<10mIU/ml). In this case, if a measurable immune response cannot be achieved, the non-responder should be counseled regarding the risks of exposure and availability of HBIG for any known or probable parenteral exposure to HBsAg-positive blood. Some persons who are anti-HBs negative 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.

HEPATITIS B VACCINE FORMULATIONS

Single-antigen vaccines are produced by two manufacturers in the United States (see charts on pages 48 -49 for doses):

- **Recombivax HB**® is produced by Merck and Company Vaccine Division. Recombivax HB is available in both pediatric and adult formulations and both are approved for use in any age group. Recombivax HB is unique in that it is approved for a 2-dose schedule (two 10 mcg doses separated by 4-6 months) in adolescents aged 11-15 years.

- **Engerix-B**® is produced by GlaxoSmithKline Pharmaceuticals. Engerix-B is available in both pediatric and adult formulations. However, the pediatric form is approved for use only in children and adolescents <20 years of age. The adult formulation is not approved for use in infants and children, but may be used in both adolescents (11-19 years) and adults.

Only single-antigen vaccines should be used for birth doses to infants.

Two combination vaccines have been licensed for use in infants and one for use in adults:

- **Comvax**® is produced by Merck and Company Vaccine Division. Comvax consists of Hepatitis B vaccine combined with Haemophilus influenzae type b (Hib). Each dose contains 7.5 micrograms of Hib vaccine and 5 micrograms of hepatitis B surface antigen (the same dose as Recombivax). The immunogenicity of the combination vaccine is equivalent to that of the individual antigens administered at separate sites. Comvax may be given at 2, 4, and 12-15 months of age. It must not be administered to infants younger than 6 weeks of age and, therefore, cannot be used for birth doses. Comvax is licensed for use in infants and children six weeks thru four years of age.

- **Pediarix**® is produced by GlaxoSmithKline Pharmaceuticals. Pediarix is a pentavalent (5 component) vaccine containing DTaP (diphtheria, tetanus, acellular pertussis), Hepatitis B, and IPV (inactivated polio) vaccines. Pediarix is licensed for use in children six weeks thru six years. The efficacy is similar to the monovalent vaccine for HBV. Pediarix may be given at 2, 4, and 6 months of

age. Once again, the minimum age for the first dose is 6 weeks and this vaccine may not be used for the birth dose.

- **Twinrix**® is produced by GlaxoSmithKline Pharmaceuticals. Twinrix consists of a combination of hepatitis B (20 mcg) and hepatitis A (720 EL.U.). Twinrix was approved by the FDA in 2001 and is licensed for use in persons 18 years and older. It can be used in persons with indications for both hepatitis A and hepatitis B vaccines. The vaccine is administered as a three-dose series at 0, 1, and 6 months. The first and second dose must be separated by one month, the second and third dose by five months, and the first and third dose by at least six months. Because Twinrix contains the same component of hepatitis B as the single-antigen vaccine, they are interchangeable. However, because a smaller (pediatric) dosage of hepatitis A vaccine is used, those who require hepatitis A vaccination must receive all three doses of Twinrix to be adequately vaccinated.

When the infant receives the birth dose (which must be single-antigen vaccine) and combination vaccine is desired to complete the series, a total of four doses may be given. This schedule has been shown to be safe in clinical trials and is endorsed by the ACIP.

When one or two doses of a vaccine produced by one manufacturer are followed by subsequent doses from a different manufacturer, the immune response has been shown to be comparable with that resulting from a full course of vaccination with vaccine from the same manufacturer.

RECOMMENDED DOSAGES OF HEPATITIS B VACCINES

Single-antigen Hepatitis B Vaccines				
Vaccine	**Age Group**	**Dose**	**Volume**	**# Doses**
Engerix-B	0-19 years	10 µg	0.5 ml	3
	20 years and older	20 µg	1.0 ml	3
	Adult hemodialysis and predialysis patients	40 µg	2.0 ml	3 or more
Recombivax HB	0-19 years	5 µg	0.5 ml	3
	11 thru 15 yrs.	10 µg	1.0 ml	2
	20 years and older	10 µg	1.0 ml	3
	Adult hemodialysis and predialysis patients	40 µg	1.0 ml	3 or more
Combination Hepatitis B Vaccines				
Vaccine	**Age Group**	**Antigens Used**	**Volume**	**# Doses**
Comvax	6 weeks thru 4 yrs.	Recombivax HB 5 µg combined with PedvaxHib	0.5 ml	3
Pediarix	6 weeks thru 6 yrs.	Engerix-B 10 µg, Infanrix (DTaP), and IPV	0.5 ml	3
Twinrix	18 years and older	Engerix-B 20 µg combined with Havrix	1.0 ml	3

HEPATITIS B VACCINE SCHEDULES

Infants Born to HBsAg-positive Women[1]

Single-antigen vaccine		Single-antigen + combination vaccine	
Dose	**Age**	**Dose**	**Age**
1	Birth (within12 hours)	1	Birth (within 12 hours) (single only)
HBIG	Birth (within 12 hours)	HBIG	Birth (within 12 hours) (single only)
2	1-2 months	2	2 months (single or combined)
3	6 months	3	4 months (single or combined)
		4	6 months (PEDIARIX) or 12-15 months (COMVAX)

Infants Born to HBsAg-negative Women

Single-antigen vaccine		Single-antigen + combination vaccine		Combination without birth dose[1]	
Dose	**Age**	**Dose**	**Age**	**Dose**	**Age**
1	Birth (before discharge)	1	Birth (before discharge) (single only)	1	2 months (single or combined)
2	1-4 months	2	2 months (single or combined)	2	4 months (single or combined)
3	6-18 months	3	4 months (single or combined)	3	6 months (PEDIARIX) or 12-15 months (COMVAX)
		4	6 months (PEDIARIX) or 12-15 months (COMVAX)		

[1] ACIP recommends that all infants be given their first dose of vaccine at birth or before discharge from the hospital.

Infants Born to Mother with unknown HBsAg[2]

Single-antigen vaccine		Single-antigen + combination vaccine	
Dose	**Age**	**Dose**	**Age**
1	Birth (within 12 hours)	1	Birth (within 12 hours) (single only)
2	1-2 months	2	2 months (single or combined)
3	6 months	3	4 months (single or combined)
		4	6 months (PEDIARIX) or 12-15 months (COMVAX)

[2] If the mother is found to be HBsAg-positive, the infant should receive HBIG (0.5 mL) as soon as possible and up to 7 days of age.

NOTE: The earliest age at which the last dose of hepatitis B vaccine can be administered is 164 days (6 months) of age. This applies to all infants, regardless of the mother's HBsAg status.

Children (1-10 years)

This age group can be vaccinated according to any of the following schedules:

- 0, 1, 6 months
- 0, 2, 4 months

Selection of a vaccine schedule should consider the need to optimize compliance with vaccination.

Adolescents (11-19 years)

This age group can be vaccinated according to any of the following schedules:

- 0, 1, 6 months
- 0, 1, 4 months
- 0, 2, 4 months
- 0, 12, 24 months

The two-dose schedule of RECOMBIVAX HB (adult) for adolescents 11-15 years of age should be administered at 0 and 4-6 months. Adolescents who are older than 15 years of age when scheduled to receive the second dose should be switched to a three-dose series, with doses 2 and 3 consisting of the pediatric formulation administered on an appropriate schedule.

Selection of a vaccine schedule should consider the need to optimize compliance with vaccination. In consideration of NYS school entry vaccination requirements for 7th graders, either a two-dose series or the 0, 1, 6 schedule is preferred.

Adults

This age group can be vaccinated according to any of the following schedules:

- 0, 1, 6 months
- 0, 1, 4 months
- 0, 2, 4 months
- 0, 1, 2, 12 months (for persons, such as travelers, who require rapid protection)
- TWINRIX should be administered at 0, 1, 6 months

Vaccine Storage and Handling

Hepatitis B vaccines and HBIG should be stored refrigerated at 2°-8°C (35°-46°F), but not frozen. Freezing destroys the potency of the vaccine. The temperature should be monitored at least twice a day and recorded in a temperature log. The refrigerator should be full size, not dorm-style, to ensure a more constant temperature. Be sure the door is left closed at all times and always have a backup plan for keeping the vaccines at the appropriate temperature in case of power outages. There should be a sign placed above the outlet in which the refrigerator is plugged instructing cleaning staff and others to never unplug. For more information on vaccine storage and handling or copies of temperature logs see the New York State Department of Health website http://www.health.state.ny.us/prevention/immunization/supply_storage.htm .

If the vaccine is stored in single-dose vials it should be administered shortly after withdrawal from the vial. If it is stored in manufacturer-filled syringes, it should be administered shortly after the needle is attached to the syringe. For HBIG, the vial should be vigorously shaken before withdrawal and use. It may be used until the vial is outdated, as long as it is not contaminated.

CHAPTER EIGHT: HEPATITIS B SEROLOGY

SEROLOGIC TESTING

Pre-Vaccination Testing for Susceptibility

Susceptibility testing is not indicated prior to immunization of children or most adolescents because of the low rate of HBV infection and the relatively low cost of vaccine. In general, screening is usually not cost-effective for groups with a low expected prevalence of HBV serologic markers such as health professionals in their training years. Screening is usually cost-effective, and should be considered, in groups with a high risk of HBV infection (HBV markers prevalence >20%), such as men who have sex with men (MSM), injection drug users, Alaskan natives, Pacific Islanders, children of immigrants from endemic countries (see: Risk Factors, pg. 6), and family members of HBsAg carriers. The decision for testing should be based on whether the costs of testing balance the costs of vaccine saved by not vaccinating people who are already infected.

Post-Vaccination Testing for Serologic Response

Testing for immunity following vaccination is not recommended routinely, but should be considered for persons whose subsequent management depends on knowing their immune status, such as dialysis patients and staff, HIV-infected and other immunocompromised individuals, sex partners of HBsAg-positive individuals, and persons in whom a suboptimal response may be anticipated, such as those who have received vaccine in the buttock. People at occupational risk who may have exposures from injuries with sharp instruments should also have post-vaccination testing because knowledge of their antibody response will aid in determining appropriate post-exposure prophylaxis. When necessary, post-vaccination testing should be performed from one to two months after completion of the vaccine series.

Testing after hepatitis B vaccine series of infants born to HBsAg-positive mothers should be performed at 9-18 months of age. Post-vaccination testing should never be done before 9 months of age. This minimizes the likelihood of detecting passively transferred anti-HBs from HBIG and maximizes the likelihood of detecting late HBsAg-positive infections. The only exception to this timing is if Comvax is used because the last dose is not given until 12-15 months of age. Post-vaccination testing may be performed 1-2 months after the last dose of vaccine is given when using Comvax.

Both HBsAg and anti-HBs should be ordered for post-vaccination testing. Sometimes a physician may also order anti-HBc, however this is not generally recommended for routine post-vaccination testing of high-risk infants because passively acquired maternal anti-HBc might be detected in infants born to HBV-infected mothers up to age 24 months.

Interpreting the results becomes "blurred" when anti-HBc is also ordered for a high-risk infant. If anti-HBc is also tested the results may be interpreted as follows:

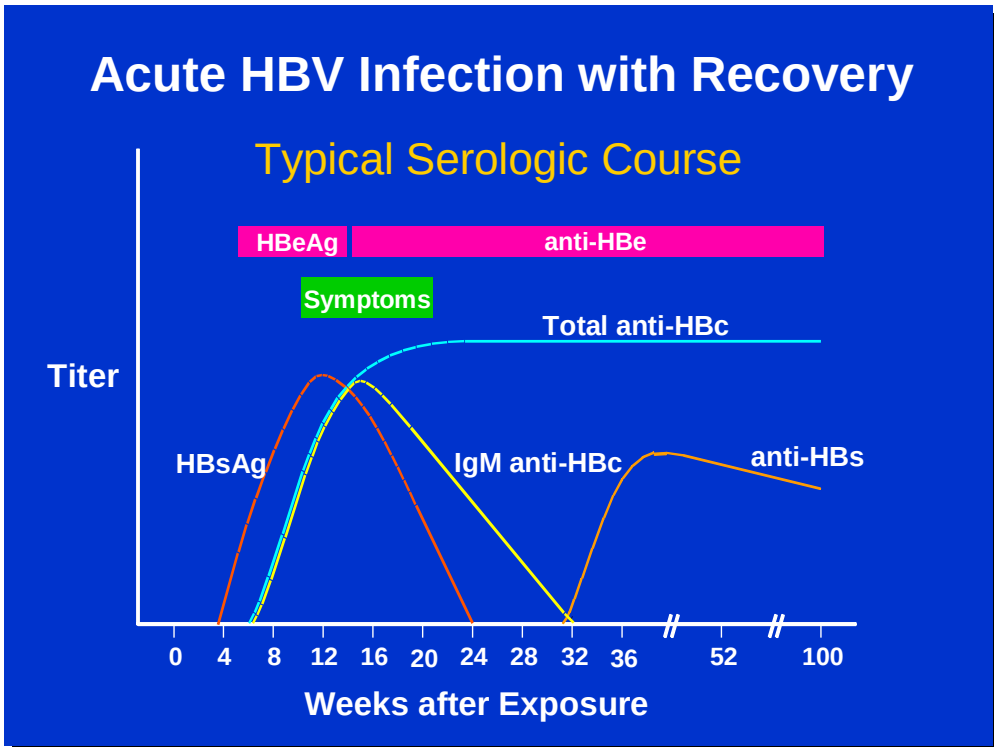
- **HBsAg negative, anti-HBs positive, and anti-HBc positive:** In adults, this usually means immune due to natural infection, however for infants born to HBsAg-positive mothers, if serology was done earlier than the recommended timeframe, then core antibody may be positive due to transfer of maternal antibody still being present in the infant's blood. Anti-HBs may also be positive because of being passively transferred from HBIG. Either interpretation should be followed with retesting for all three markers a few months later to clarify the infant's hepatitis B status.

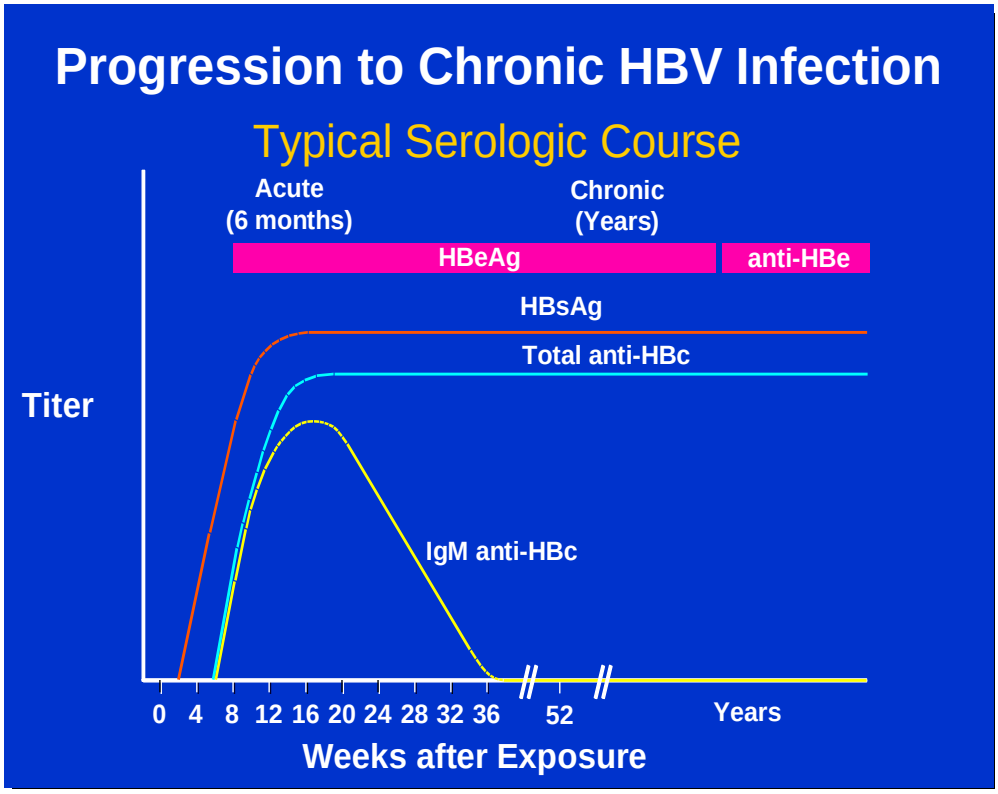
- **HBsAg negative, anti-HBs negative, and anti-HBc positive:** Several interpretations are possible, however for infants born to HBsAg-positive mothers, regardless of the interpretation, reimmunization is recommended followed by repeat serologic testing.

TIME SEQUENCE OF SEROLOGIC MARKERS

When one becomes infected with hepatitis B, first the HBsAg and HBeAg become positive, about one to three weeks after exposure and four to five weeks before jaundice appears. The ALT levels increase about one to two weeks before jaundice. These elevations persist for one to three months and decrease as clinical improvement progresses. The appearance of anti-HBc and anti-HBe is a favorable prognostic sign. HBcAg, although present, is not detectable by any currently readily available practical test. However, anti-HBc is detectable at onset of jaundice, initially as IgM, indicating acute or early convalescent hepatitis B infection. Both anti-HBs and anti-HBc persist for many years. With chronic infection, HBsAg persists for many years and possibly a lifetime. HBeAg may persist as well; more likely if the infection was symptomatic. Chronic infection is more likely in cases where symptoms were mild or absent than in cases with significant clinical disease. For further clarification on the distinct time sequences for acute and chronic infections, see the charts below.

Following vaccination, HBsAg remains present in the blood for two to three weeks. Anti-HBs should be detectable within one month of receiving the vaccine. For this reason, when post-serologic testing is indicated (for adults), it should be performed one to two months following completion of the vaccine series.


Acute HBV Infection with Recovery
Typical Serologic Course
HBeAg
anti-HBe
Symptoms
Total anti-HBc
Titer
HBsAg
IgM anti-HBc
anti-HBs
0 4 8 12 16 20 24 28 32 36 52 100
Weeks after Exposure


Progression to Chronic HBV Infection
Typical Serologic Course
Acute
(6 months)
Chronic
(Years)
HBeAg
anti-HBe
HBsAg
Total anti-HBc
Titer
IgM anti-HBc
0 4 8 12 16 20 24 28 32 36 52
Years
Weeks after Exposure

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 HBV 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. Also present as a result of HBIG administration and/ or in response to Hepatitis B vaccine.
Anti- HBc (Total)	Includes IgM and IgG antibody to Hepatitis B Core antigen	Indicates prior infection at unknown time. Only occurs after HBV infection, and does not develop in persons whose immunity to HBV is from vaccine. Anti-HBc generally persists for life.
IgM anti-HBc	IgM class antibody to HBcAG	Appears in persons with acute disease about the time of illness onset and indicates recent infection with HBV. Is the best serologic marker of acute HBV infection. Detectable up to 4-6 months.
HBeAg	Hepatitis B e antigen	Useful marker of contagiousness. Correlates strongly with the number of infective HBV particles in the serum and is associated with a high risk of infectivity.
Anti-HBe	Antibody to HBeAg	May be seen in active or past disease; In persons with chronic HBV suggests lower viral titer and low degree of infectivity.

INTERPRETING HEPATITIS B TESTING PANELS

Tests	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:

1. May be recovering from acute HBV infection.
2. 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.
3. May be susceptible with a false positive anti-HBc.
4. May be chronically infected and have an undetectable level of HBsAg present in the serum.

REFERENCES

1. Boot H. J., Hahne S., Cremer J., Wong A., Boland G., van Loon A. M. Persistent and transient hepatitis B virus (HBV) infections in children born to HBV-infected mothers despite active and passive vaccination. *Journal of Viral Hepatology 2009; doi:10.1111/j.1365-2893.2009.01247.x*
2. Cooper A, Yusuf H, Rodewald L, Malik T, Pollard R, et al. Attitudes, Practices, and Preferences of Pediatricians Regarding Initiation of Hepatitis B Immunization at Birth. Pediatrics. 2001; 108 (6): e98.
3. Corrarino, Jane. Perinatal Hepatitis B: Update and Recommendations. The American Journal of Maternal/Child Nursing. September 1998.
4. Fisher G., Wang S., Ahring S., Fowler K., Hainline S., Chinglong M., Jacques-Carroll L., Bell Beth, Williams I. An Investigation of Perinatal Hepatitis B Virus Infections among a High Risk Population. *The Delivery Hospital as a Safety Net*. *Pediatric Infectious Disease Journal* 2009;28: 593–597
5. Giraudon I., Permalloo N, Nixon G, Charlett A., Sandra Cohuet S, Mandal S, Ramsay M, Patel B.C, Maguire H. Factors associated with incomplete vaccination of babies at risk of perinatal hepatitis B transmission: A London study in 2006. *Vaccine 27 (2009) 2016–2022*
6. Ikeda RM, Birkhead GS, Flynn MK, Thompson SF, Morse DL. Use of Multiple Reporting Sources for Perinatal Hepatitis B Surveillance and Follow-up. American Journal of Epidemiology. 1995; 142:765-70.
7. Lok A, McMahon B. American Association for the Study of Liver Diseases (AASLD) Practice Guidelines: Chronic Hepatitis B. *Hepatology* 2009; 50(3)661-662.
8. Mieli-Vergani, G. Congenital, Perinatal, and Neonatal Infections. Hepatitis B. New York: Churchill Livingstone. 1992.
9. Olshen Kharbandam E., Stockwell M.S., Fox S.W., Rickert V.I.Text4Health: A Qualitative Evaluation of Parental Readiness for Text Message Immunization Reminders. *Am J Public Health*. 2009; 99:2176–2178
10. Poland G, Jacobson R. Prevention of Hepatitis B with the Hepatitis B Vaccine. *New England Journal of Medicin*e 2004; 351:2832-8.
11. Wasley A., Kruszon-Moran D., Kuhnert W., Simard E.D., Lyn Finelli L., McQuillan G., Bell B. The Prevalence of Hepatitis B Virus Infection in the United States in the Era of Vaccination. *The Journal of Infectious Diseases* 2010; 202 (2):000–000
12. Willis B.C, Wortley P, Wang S.A, Jacques-Carroll L., Fan Zhang F. Gaps in Hospital Policies and Practices to Prevent Perinatal Transmission of Hepatitis B Virus. *Pediatrics* 2010;125(4);704-711
13. Centers for Disease Control and Prevention. Epidemiology and Prevention of Vaccine-Preventable Diseases. Atkinson W, Wolfe S, Hamborsky J, McIntyre L, eds. 11th ed. Washington DC: Public Health Foundation, 2009. http://www.cdc.gov/vaccines/pubs/pinkbook/
14. Centers for Disease Control and Prevention. General recommendations on immunization: Recommendations of the Advisory Committee on Immunization

Practices and the American Academy of Family Physicians. MMWR 2006:55 (No. RR-15). http://www.cdc.gov/mmwr/PDF/rr/rr5515.pdf
15. Centers for Disease Control and Prevention. A Comprehensive Strategy for Eliminating Transmission in the United States: Recommendations of the Immunization Practices Advisory Committee (ACIP) Part: Immunization of infants, children and adolescents. MMWR 2005; 54 (No. RR-16); 1-32. http://www.cdc.gov/mmwr/PDF/rr/rr5416.pdf
16. Centers for Disease Control and Prevention. A Comprehensive Immunization Strategy to Eliminate Transmission in the United States: Recommendations of the Advisory Committee of Immunization Practices (ACIP). Part 2: Immnization of adults. MMWR 2006; 55(No. RR- 16): 1-25. http://www.cdc.gov/mmwr/PDF/rr/rr5516.pdf
17. Centers for Disease Control and Prevention. Summary of Notifiable Diseases—United States, 2007. MMWR 2009; 56(53); 1-84. http://www.cdc.gov/mmwr/mmwr_nd/
18. http://www.aasld.org/practiceguidelines/Pages/PracticeGuidelinesAlpha.aspx
19. Centers for Disease Control and Prevention. Healthy People 2010: Immunization and Infectious Diseases. Volume 1; January 2001. http://www.cdc.gov/nchs/data/hp2000/hp2k01-acc.pdf
20. Centers for Disease Control and Prevention. Vaccine storage and handling toolkit. *National center for immunization and respiratory disease*. http://www2a.cdc.gov/vaccines/ed/shtoolkit/
21. Centers for Disease Control and Prevention. Vaccine Management: Recommendations for Storage and Handling of Selected Biologicals. April 2009. http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/C/storage-handling.pdf
22. Centers for Disease Control and Prevention. Managing a Hepatitis B Prevention Program: A guide to life as a program coordinator. September 1996.
23. Immunization Action Coalition. Vaccinate Women. Volume 3, Number 1; June 2008. http://www.immunize.org/vw/vw0608.pdf
24. NYSDOH Center for Community Health and Wadsworth Center. Laboratory Reporting of Communicable Diseases, 2004. http://www.wadsworth.org/labcert/regaffairs/clinical/commdiseaseguide.pdf

Websites:
Centers for Disease Control and Prevention: www.cdc.gov/hepatitis
National Center for Immunization and Respiratory Diseases: www.cdc.gov/vaccines
Immunization Action Coalition: www.immunize.org
Healthy People 2020: www.healthypeople.gov
Parents of Kids with Infectious Diseases: www.pkids.org
HIPPA: www.cdc.gov/nip/policies/hippa
HepB Moms: http://hepbmoms.org/

Appendix A

Public Health Law 2500-e

LAWS OF NEW YORK, 1990
CHAPTER 4

AN ACT to amend the public health law, in relation to the health screening of pregnant women and infants became a law February 9, 1990, with the approval of the Governor. Passed by a majority vote, three-fifths being present.

THE PEOPLE OF THE STATE OF NEW YORK, REPRESENTED IN SENATE AND ASSEMBLY, DO ENACT AS FOLLOWS:

Section 1. The public health law is amended by adding a new section 2500-e to read as follows:
§ 2500-e. Pregnant women, blood test for hepatitis B; follow-up care.

1. At the time that a blood sample is taken to be tested for syphilis pursuant to section twenty-three hundred eight of this chapter, every physician or other authorized practitioner attending a pregnant woman in the state shall, in addition, submit or cause to be submitted such sample to an approved laboratory for a standard serological test for hepatitis B surface antigen.
2. The term "approved laboratory" means a laboratory approved for the purpose as herein provided by the department, or in the city of New York by the department of health of such city.
3. A standard serological test for hepatitis B surface antigen is one recognized as such by the department or in the city of New York by the department of health of such city.
4. The physician or other authorized practitioner attending a pregnant woman shall record the hepatitis B surface antigen test results prominently in the pregnant woman's medical record at or before the time of hospital admission for delivery.
5. If, at the time of hospital admission for delivery, hepatitis B surface antigen test results are not available, the hospital shall arrange immediate testing of the mother with results available within twenty-four hours, or as soon thereafter as practicable, but in no event longer than forty-eight hours.
6. It shall be the duty of the administrative officer or other person in charge of each institution caring for infants twenty-eight days of age or less to report the hepatitis B surface antigen test results of all mothers of newborn children to the department in such a manner as may be required by the commissioner.
7. If the mother of a newborn infant has tested positive for hepatitis B surface antigen, the physician or other authorized practitioner attending the infant shall offer or cause to be offered immunizing doses of hepatitis B vaccine and hepatitis B immune globulin to the newborn within twelve hours of birth or whenever the infant is stable physiologically and immunizing doses of hepatitis B vaccine and follow-up vaccine in accordance with the schedule specified by the commissioner. If the mother's hepatitis B surface antigen test results were

unavailable when the mother was admitted to a hospital for delivery, the physician or other authorized practitioner attending the infant shall offer or cause to be offered immunizing doses of hepatitis B vaccine and hepatitis B immune globulin for the newborn immediately upon receiving results showing that the mother has tested positive for hepatitis B surface antigen and offer immunizing doses of hepatitis B vaccine and follow-up vaccine in accordance with the schedule specified by the commissioner.

8. The parent or guardian of any child born to a mother positive for hepatitis B surface antigen shall have administered to such child immunizing doses of hepatitis B immune globulin at birth and hepatitis B vaccine as well as follow-up hepatitis B vaccine in accordance with the schedule specified by the commissioner.
9. If the parent or guardian of such child is unable to pay for the services of a private physician or other authorized practitioner, such person shall present such child to the health officer of the county in which the child resides, who shall then administer the follow-up hepatitis B vaccine without charge.
10. If any licensed physician or nurse practitioner certifies that a follow-up dose of hepatitis B vaccine may be detrimental to a child's health, the requirements of this section shall be inapplicable until such immunization is found no longer to be detrimental to such child's health.
11. The provision of this section relating to immunization shall not apply in the case of any newborn infant whose parent or guardian holds genuine and sincere religious beliefs which prohibit immunization and who notifies the person charged with administering such immunization of the religious objection thereto.
12. The commissioner of health shall promulgate such rules and regulations as are necessary to carry out the requirements of this section.

S 2. This act shall take effect on the ninetieth day after it shall have become a law.

The legislature of the STATE OF NEW YORK SS: (JURAT PLACEHOLDER)

Pursuant to the authority vested in us by section 70-b of the Public Officers Law, we hereby jointly certify that this slip copy of this session law was printed under our direction, and, in accordance with such section is entitled to be read into evidence.

RALPH J. MARINO
TEMPORARY PRESIDENT OF THE SENATE

MELVIN H. MILLER
SPEAKER OF THE ASSEMBLY

Appendix B

Public Health Law, Title 10 Regulation Subpart 69-3

Pursuant to the authority vested in the Commissioner of Health by Section 2500-e of the **Public Health Law, Title 10 of the Official Compilation of Codes, Rules, and Regulations** of the State of New York is hereby amended by adding a new Subpart to be effective upon publication of a notice of adoption, to read as follows:

Subpart 69-3
Pregnant women, Testing for hepatitis B, follow-up care.

Section
69-3.1 Definitions.
69-3.2 Responsibilities of health care providers attending pregnant women.
69-3.3 Responsibilities of health care facilities.
69-3.4 Responsibilities of clinical laboratories.
69-3.5 Responsibilities of health care providers attending newborn children of women with a positive HBsAg test result.
69-3.6 Responsibilities of health care providers providing follow-up care for newborn children of women with a positive HBsAg test result.
69-3.7 Responsibilities of the parent or legal guardian.
69-3.8 Responsibilities of the local health officer.
69-3.9 Medical exemptions from immunization.
69-3.10 Religious exemptions from immunization.
69-3.11 Failure to obtain required immunization.

69-3.1 Definitions.
(a) Health care provider means a physician or other health care professional licensed to practice in New York State.

(b) Health care facility means a facility in New York State where children are born including those facilities licensed pursuant to Article 28 of the Public Health Law.

(c) Clinical laboratory means a laboratory which possesses a permit to test for hepatitis B surface antigen (HBsAg) issued under Article 5, Title 5 of the Public Health Law.

(d) Hepatitis B surface antigen (HBsAg) test means a test which has been approved for in vitro diagnostic use by the United States Food and Drug Administration.

(e) Satisfactory specimen means a specimen received by a clinical laboratory in a condition suitable for testing.

69-3.2 Responsibilities of health care providers attending pregnant women. At the time a health care provider attending a pregnant woman takes a blood sample to be tested

for syphilis (see Section 2803 of the Public Health Law) or at another time when blood is drawn during prenatal care, the provider shall:

(a) submit or cause to be submitted to a clinical laboratory from such a woman, a blood sample to be tested for HBsAg;

(b) record the HBsAg test result, including the date of specimen collection, prominently in the pregnant woman's medical record at or before the time of admission to a health care facility for delivery; and

(c) report all positive HBsAg test results to the local health officer in accordance with Section 2.10 of this Title.

69-3.3 Responsibilities of health care facilities.

(a) The health care facility shall assure that the HBsAg test result for every woman admitted for delivery is recorded in the newborn child's medical record.

(b) When a woman who has not been tested for HBsAg during pregnancy is admitted for delivery or if a woman's HBsAg test result is not available at the time of admission for delivery, the health care facility shall:

(1) submit immediately a satisfactory blood specimen from such a woman to a clinical laboratory that will test it for HBsAg and make the test result available within twenty-four hours of admission, or as soon thereafter as practicable, but in no event longer than forty-eight hours of admission. Blood specimens submitted for testing must be marked clearly as "mother/delivery" in order to facilitate reporting of test results; and

(2) record the date and time of the blood collection and the HBsAg test results of such specimens in the medical records of the woman and her newborn child or children.

(c) Report the HBsAg test results for all women with newborn children to the State Department of Health on the Newborn Screening Blood Collection Form and report all positive HBsAg test results for women with newborn children within twenty-four hours of receipt to the local health officer in accordance with Section 2.10 of this Title.

(d) Respond to inquiries from the local health officer to provide pertinent information from the medical records of pregnant women with positive HBsAg test results and their newborn children regarding diagnosis and therapy of hepatitis B provided within the health care facility.

(e) In the case of the inter-facility transfer of a newborn child, the transferring facility shall provide written notification to accompany the child to the receiving hospital indicating:

(1) the HBsAg test result for the child's mother, or

(2) that the HBsAg test result is pending, in which case the test result should be transmitted when it becomes available immediately by telephone and in writing to the receiving hospital, or

(3) that the HBsAg test result is unknown and a blood sample has not been submitted for testing, in which case this testing shall be the responsibility of the facility where the child's mother is located or of her health care provider if she is not within a health care facility.

69-3.4 Responsibilities of clinical laboratories. Clinical laboratories shall:

(a) report immediately any initially reactive HBsAg test result from a blood specimen marked "mother/delivery" to the requesting health care provider or health care facility; and

(b) report any positive HBsAg test result to the local health officer within twenty-four hours (see Section 2102 of the Public Health Law).

69-3.5 Responsibilities of the health care providers attending newborn children of women with a positive HBsAg test result.

(a) Health care providers attending newborn children of a woman with a positive HBsAg test result shall offer or cause to be offered immunizing doses of hepatitis B vaccine and hepatitis B immune globulin for each such newborn child within twelve hours of birth unless a licensed physician or health care practitioner practicing under the supervision of a licensed physician determines that the child is not physiologically stable to permit immunization. In such cases the hepatitis B vaccine and hepatitis B immune globulin shall be administered when the child becomes physiologically stable to permit immunization.

(b) Health care providers attending newborn children of a pregnant woman admitted for delivery without a HBsAg test result available shall offer or cause to be offered immunizing doses of hepatitis B vaccine and hepatitis B immune globulin for each such newborn child immediately upon receiving a blood test result showing that the woman has a positive HBsAg test.

(c) If a woman's HBsAg test result is not available and her newborn child is to be discharged from the health care facility or 48 hours has elapsed since birth and if, in the health care provider's medical judgment the mother has a reasonable likelihood of being positive for HBsAg, the provider shall offer or cause to be offered for such a newborn child, immunizing doses of hepatitis B vaccine and hepatitis B immune globulin.

(d) After administering hepatitis B vaccine or hepatitis B immune globulin to a newborn

child, the health care provider shall record in the child's medical record the date and time of immunization and the dosage, the manufacturer's lot number and the sites of injection for hepatitis B vaccine and hepatitis B immune globulin and shall provide the woman with a certificate of immunization for her child stating the immunizing agents administered and the dates of administration.

69-3.6 Responsibilities of health care providers providing follow-up care for newborn children of women with a positive HBsAg test result. Health care providers providing follow-up care for newborn children of women with a positive HBsAg test result shall arrange for follow-up immunizing doses of hepatitis B vaccine to be administered one and six months or one, two and twelve months after the first dose.

69-3.7 Responsibilities of the parent or legal guardian. The parent or guardian of any child born to a woman with a positive HBsAg test result shall have administered to such child immunizing doses of hepatitis B immune globulin and hepatitis B vaccine at birth as well as follow-up doses of hepatitis B vaccine.

69-3.8 Responsibilities of the local health officer.

(a) If the parent or legal guardian of a child requiring hepatitis B immunization pursuant to this Subpart is unable to pay for the services of a private physician or other authorized practitioner to administer the follow-up doses of hepatitis B vaccine, such person shall present such child to the health officer of the county in which the child resides, who shall then administer the follow-up hepatitis B vaccine without charge.

(b) The local health officer shall make a report within 30 days of initiation of follow-up and within 30 days of the completion of follow-up to the Commissioner of Health for each newborn child of a HBsAg-positive woman. Such report shall include verification of the woman's HBsAg test result and details of the child's follow-up care.

69-3.9 Medical exemption from immunization. If any licensed physician or health care practitioner practicing under the supervision of a licensed physician certifies that a follow-up dose of hepatitis B vaccine may be detrimental to a child's health, the requirements of this Subpart regarding follow-up immunizations shall be inapplicable until such immunization is found no longer to be detrimental to such child's health. The nature and duration of the medical exemption must be stated in the child's medical record.

69-3.10 Religious exemption from immunization. The provisions of this Subpart regarding immunizations shall not apply in the case of any child whose parent or legal guardian holds genuine and sincere religious beliefs which prohibit immunization and who notifies the person charged with administering such immunization of the religious objection hereto. The health care provider attending the child shall document the religious objection exemption in the child's medical record, including a statement signed by the parents or legal guardian stating that they hold genuine and sincere religious

beliefs which prohibit immunization and that they acknowledge that they have been informed about the risk to the child's health by withholding hepatitis B immunization.

69-3.11 Failure to obtain required immunization. Barring a valid medical contraindication or religious exemption from hepatitis B immunization, if the parent or legal guardian of a child born to a woman with a positive HBsAg test result is unwilling to have the infant immunized, the health care provider attending the child, or the local health officer if vaccine is to be administered under section 3.8 of this Subpart, shall make a report of suspected child abuse or maltreatment (See Section 415 of the Social Services Law).

Appendix C

Guidelines for Perinatal Hepatitis B Infant Tracking on the Communicable Diseases Electronic Surveillance System (CDESS)

This guidance is intended to clarify responsibilities for monitoring perinatal hepatitis B reports in CDESS. County and state perinatal hepatitis B coordinator roles and recommendations for reviewing specific reports are covered. However, this guidance is not intended to replace the "Perinatal Hepatitis B User Guide" available on the CDESS for instructions on how to access CDESS perinatal hepatitis B reports.

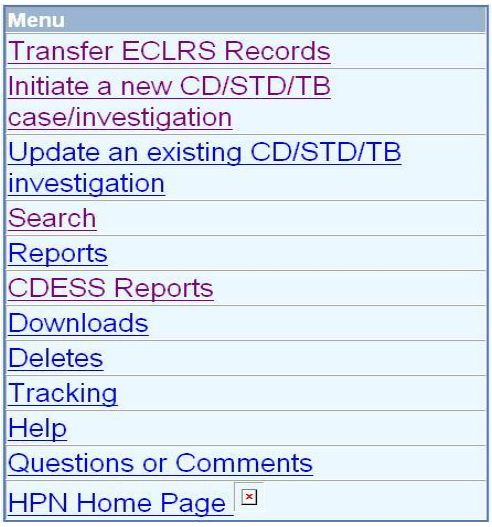
LHD Perinatal Hepatitis Coordinator

Transfer Electronic Clinical Laboratory Reporting System (ECLRS) Records
At a minimum of once a week, the LHD Perinatal Hepatitis Coordinator or designee must access the *Transfer ECLRS Records* from the CDESS main menu. If the county has a perinatal hepatitis B record listed in the *Summary of ECLRS Reports Available For Transfer To CDESS* (Screen Shot 1), then either a case investigation or case dismissal must be completed **within 30 days**.

Screen Shot 1

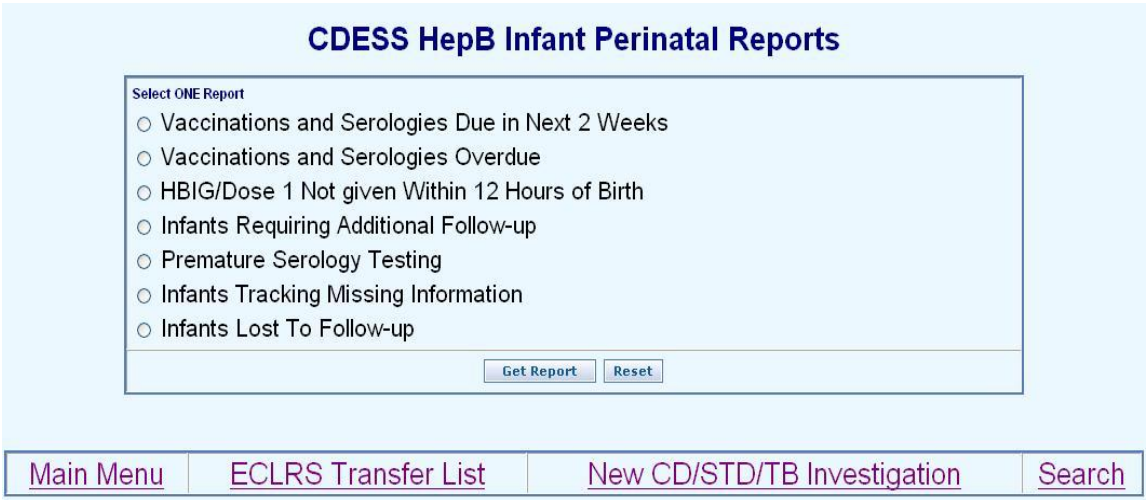
Accessing Perinatal Hepatitis B Reports
There are currently 7 perinatal hepatitis B reports available in CDESS. Additional reporting options will be available at a future date. There are two report options accessible from the CDESS Main Menu. Select the *CDESS Reports* option to find the perinatal hepatitis b reports. (Screen Shot 2)

Screen Shot 2



The perinatal hepatitis B reports are accessed from the *HepB Infant Perinatal Reports* link. Click on the link that displays the CDESS *HepB Infant Perinatal Reports* screen (Screen shot 3).

Screen Shot 3



Monitoring Perinatal Hepatitis B Reports

The following reports should be reviewed **weekly or more frequently** especially in counties with large high-risk populations:

- Vaccination and Serologies Due in Next 2 Weeks
- Vaccination and Serologies Overdue
- HBIG/Dose 1 Not given Within 12 Hours of Birth*
- Infants Requiring Additional Follow-up
- Infants Tracking Missing Information

The following reports should be reviewed **monthly or more frequently:**

- Premature Serology Testing
- Infants Lost To Follow-up

Notification of Missing Information

In the past, the NYSDOH Division of Epidemiology Statistical Unit sent monthly reports to the LHD perinatal hepatitis coordinators. The LHD perinatal hepatitis coordinator would forward the reports to contact hospitals or private providers directly to obtain missing information. This process is no longer necessary.

The following reports may be batched and sent to hospitals on a **weekly or more frequent** basis.

- Infants Requiring Additional Follow-up
- Infants Tracking Missing Information

Private provider offices should be contacted as soon as possible after reviewing CDESS Reports of missing information.

NYSDOH Regional Office Perinatal Hepatitis Coordinator

The role of the regional office Perinatal Hepatitis Coordinator is to provide technical assistance to the county and to monitor county perinatal hepatitis B reports for delays and errors. The regional coordinators will provide support with follow-up actions as outlined in the Perinatal Hepatitis Guidelines.

The following reports should be reviewed **weekly:**

- Summary of ECLRS Records Available for Transfer To CDESS
- HBIG/Dose 1 Not given Within 12 Hours of Birth*
- Infants Requiring Additional Follow-up

The following reports should be reviewed **monthly** and reviewed with the county if the frequency within a county increases:

- Vaccination and Serologies Overdue
- Infants Lost To Follow-up
- Infants Tracking Missing Information

NYSDOH Perinatal Hepatitis Coordinator

The NYSDOH Perinatal Hepatitis Coordinator will be responsible for CDC and NYSDOH quarterly and annual perinatal hepatitis B reports with assistance from the Division of Epidemiology Statistical Unit. The state perinatal hepatitis coordinator will provide technical assistance and support with follow-up as outlined in the Perinatal Hepatitis Guidelines.

In addition, the following reports will be reviewed **weekly**:

- Summary of ECLRS Records Available for Transfer To CDESS
- Vaccination and Serologies Overdue
- HBIG/Dose 1 Not given Within 12 Hours of Birth*

The following reports will be reviewed **monthly**:

- Vaccination and Serologies Overdue
- Infants Requiring Additional Follow-up
- Infants Tracking Missing Information

*Regional and central offices must be notified immediately if an infant born to a mother with a positive HBs Ag or unknown serology did not receive appropriate post exposure prophylaxis within 12 hours of birth.

Appendix D

LOT QUALITY ASSURANCE (LQA) METHODOLOGY AND PROTOCOLS
A Method to Evaluate Perinatal Hepatitis B Prevention Program Compliance

Introduction and Background

The New York State Department of Health (NYSDOH) Perinatal Hepatitis B Prevention Program conducts on-going statewide evaluation of Hepatitis B prevention activities in upstate New York (excluding New York City) birthing hospitals on a rotating basis every 2-3 years. The review is conducted by staff from the state and local health departments authorized to have access to the confidential information related to hepatitis B viral infection, a reportable disease in New York State. During the visits a record review is conducted and hospital staff are updated on current perinatal hepatitis B recommendations and other immunization related issues.

The method used to do the record review is called Lot Quality Assurance or LQA. This is a type of quality control methodology that was developed in the manufacturing industry. A sampling is done on a lot; in this case the lot is a certain number of medical records from a six month birth cohort. The records are examined for the presence of a certain number of "deficiencies," thereby giving the reviewer an indication of the overall quality of the product. An example of a deficiency for this review would be failure to properly record the mother's HBsAg status defined as test result **and** date in the maternal **and** infant record. Since NYS has a public health law mandating maternal HBsAg testing and recording of maternal HBsAg status in both the maternal and infants records, our review standard requires that 100% of the records must contain this required documentation.

Advantages of LQA hospital record reviews:

- Review is done on a small sample
  - ✓ Takes a minimal amount of time
  - ✓ Requires only a few records to be pulled and reviewed
- Review is conducted by state and local health department staff
  - ✓ Minimal hospital staff is required other than medical records department staff

Advantages for the hospital:

- Hospital quality improvement (in some instances, LQA is the only systematic review of perinatal hepatitis B activities for the hospital)
  - ✓ Establishes a baseline
  - ✓ Ensures public health law compliance
  - ✓ Provides the opportunity to improve hospital/provider recording and reporting
  - ✓ Provides important interface to improve communication and referral process between hospital staff and local health department
- Education benefits
  - ✓ Opportunity to share updated information and materials
  - ✓ Review of current perinatal hepatitis B recommendations

Regional Planning of LQA Visits

Each year, regional immunization program representatives should plan and determine which hospitals to target for LQAs within their region. The goal is to conduct reviews every year in each region representative of at least 30% of the region's annual birth population. Both large and small hospitals should be targeted and rotated so that each hospital is reviewed approximately every 3 years. Hospitals for which there are technical or quality concerns (i.e. high number of unknowns on newborn screening forms, medical errors, etc.) should be prioritized for a visit. Consult with perinatal hepatitis B coordinators at the local health departments (LHDs) regarding any concerns they may have with hospitals in their county.

If a hospital was unsuccessful in their review, schedule a re-visit LQA. You may utilize the LQA Scheduling Algorithm (page 4 of this document) to determine when the next LQA should be scheduled. Alternatively, you may choose to perform a repeat LQA in 6 to 12 months from the date of the current unsuccessful LQA.

Before the LQA Visit

1. Invite appropriate LHD staff from the county where the hospital is located in to participate in the LQA visit. Plan for at least 3-4 reviewers, including LHD staff, to participate in the visit. Establish who is to take the lead with the hospital (LHD or the regional DOH staff). Lead staff should bring adequate copies of the LQA tally sheet for use by all reviewers.
2. Contact the appropriate hospital staff approximately one month prior to the visit to explain the purpose of the LQA visit and to set up a date to conduct the LQA visit. The hospital should be offered written information about the LQA process.
3. Request that the hospital compile a list of all births, in chronological order, for a 6 month period of time that begins approximately 6-9 months prior to the LQA date.
4. Perform a random digit selection of 65 record pairs from the list provided by the hospital. Co-CASA can be used for the random selection.
5. Request that the hospital pulls the record pairs (infant and maternal records) for the 65 selected births prior to the LQA review date. For a more efficient record review, request that the records are paired (maternal/infant) for your visit.
6. Request that the hospital provide you with a copy of their policies and procedures regarding perinatal hepatitis B, as well as a copy of their information packet for new parents including immunization information. To expedite the process, you may wish to ask that this information be sent to you prior to the visit.

During the LQA Visit

1. On the day of the review, a brief entrance interview should be conducted with appropriate hospital staff (i.e. infection control nurse, maternity nurse manager, quality assurance nurse). At this meeting, review the purpose of the LQA and ask the staff to show you where you might find the information on the maternal and infant records. This will help expedite your record review.
2. Conduct the record review. Using the chronological list of the 65 births, select any 31 out of the 65 chart pairs, since they are already randomized. Review a minimum of 31

chart pairs for documentation of both maternal HBsAg status as defined by the test result **and** date on the maternal record **and** the infant record. If less than 31 paired charts are reviewed, then a pattern cannot be established and the LQA is incomplete. Throughout the review process it is helpful to take notes, recording any issues encountered while examining the records.

If all 31 chart pairs have maternal HBsAg status (test result and date) recorded in both mother and infant records:

- STOP- your review is completed and the hospital passed

If 1-3 of the 31 charts (maternal **or** infant) do **not** have maternal HBsAg status (test result **or** date) recorded:

- Continue to review the remaining 34 records, even though this is a failure, until a total of 4 charts do **not** have maternal HBsAg status (test result **or** date) recorded
- STOP – your review is completed and the hospital failed

If 4 or more of the 31 charts (maternal **or** infant) do **not** have maternal HBsAg status (test result **or** date) recorded:

- STOP- your review is completed and the hospital failed

The following data is reviewed in each record review:
Maternal Records

- Maternal HBsAg test date and result
- Presence of original lab report in maternal chart
- Maternal rubella titer test history and MMR vaccination prior to hospital discharge if negative or equivocal
- Maternal varicella titer result and varicella vaccination prior to hospital discharge if negative or equivocal
- Maternal influenza vaccination during pregnancy or prior to hospital discharge
- Tdap vaccination prior to hospital discharge (if not previously given)

Infant Records

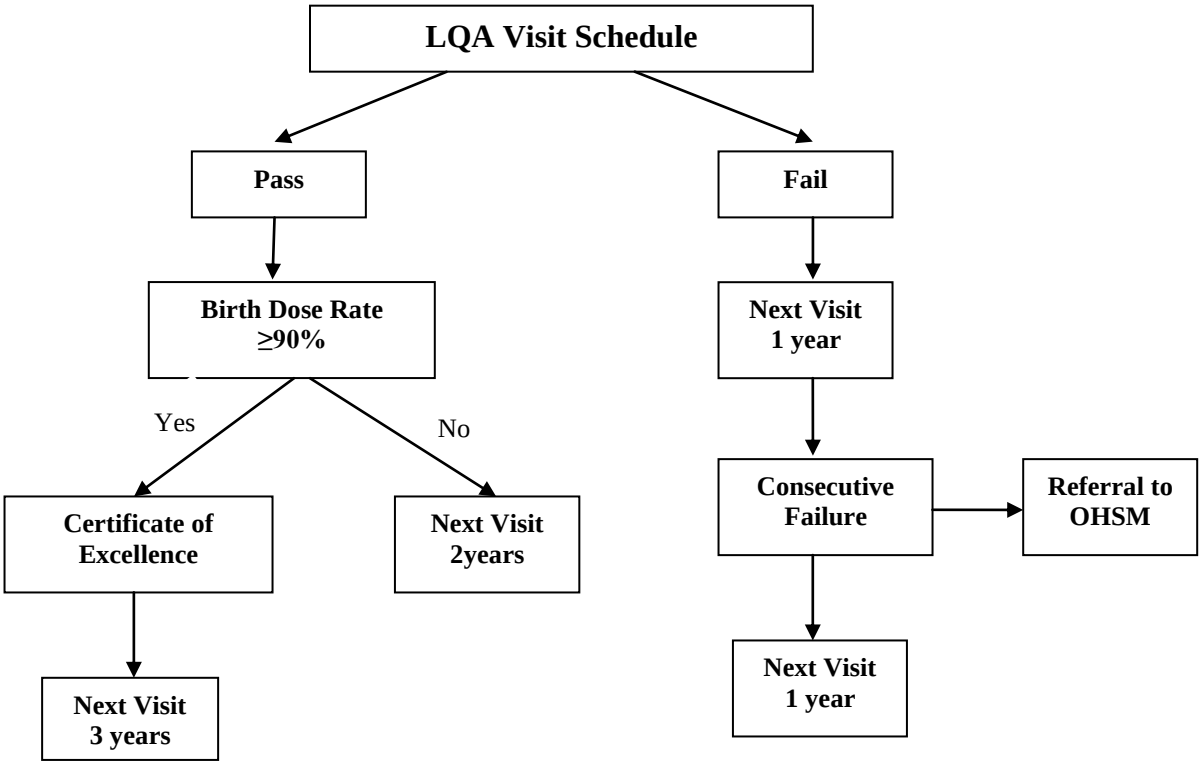
- Delivery date and time
- Maternal HBsAg test date and result
- Record of hepatitis B vaccine administered within 12 hours of birth
- Record of HBIG if mother is HBsAg positive
- If vaccinated, assess completeness of documentation

3. Immediately following the review, an exit interview should be conducted with appropriate hospital staff to review findings and recommendations. Determine to whom any follow-up correspondence should be directed. At the exit interview, lead staff should be advised of link to NYSDOH Perinatal Hepatitis B website at http://www.nyhealth.gov/diseases/communicable/hepatitis/perinatal.htm and provide copies of the following materials to hospital staff:

- Non patient-specific standing order and protocol guidelines
- NYS Public Health Law 2500-e
- Comprehensive Immunization Strategy to Eliminate Transmission of Hepatitis B Virus Infection in the United States (MMWR December 23, 2005/Vol.54/N.RR-16)
- Other relevant resources (i.e. birth dose information, most current childhood immunization schedule, VIS for hepatitis, MMR, varicella, Tdap etc.)

After the LQA Visit

1. Following the visit, promptly follow-up with a written letter reviewing all of your findings and recommendations.
2. Forward copies of all data collected and the follow up letter addressed to the hospital and to the NYSDOH central office, c/o Lynn Pollock.
3. If a hospital passes their LQA and has at least a 90% birthdose rate, complete the form entitled "Request for Certificate of Excellence" and submit it electronically to the NYSDOH central office, c/o Lynn Pollock.
4. If a hospital fails their LQA in two consecutive years, then the Office of Health Systems Management (OHSM) is notified for follow-up corrective actions.



Appendix E

NEW YORK STATE DEPARTMENT OF HEALTH
Bureau of Communicable Disease Control
Immunization Program

Perinatal Hepatitis B Household Contact Follow-up

Name of Index Patient (HBsAg+ Woman) _____ Date ____/____/____
LAST NAME FIRST NAME MIDDLE INITIAL

Street Address _____ City _____ State _____ Zip _____

Infant Name _____ DOB ____/____/____ **COUNTY** _____

Household Contact Name Don't Include Index Patient or Newborn Infant	**Sex** (circle one)	**DOB**	**Pre-Vaccine Serologic Test Results**				**Date of Vaccine Doses**			**Post Vaccine Serologic Test Results**			
			Date	**Anti-HBc** (+ or -)	**HBsAg** (+ or -)	**Anti-HBs** (+ or -)	**#1**	**#2**	**#3**	**Date**	**Anti-HBc** (+ or -)	**HBsAg** (+ or -)	**Anti-HBs** (+ or -)
1. _____	M F	__/__/__	__/__/__	____	____	____	__/__/__	__/__/__	__/__/__	__/__/__	____	____	____
2. _____	M F	__/__/__	__/__/__	____	____	____	__/__/__	__/__/__	__/__/__	__/__/__	____	____	____
3. _____	M F	__/__/__	__/__/__	____	____	____	__/__/__	__/__/__	__/__/__	__/__/__	____	____	____
4. _____	M F	__/__/__	__/__/__	____	____	____	__/__/__	__/__/__	__/__/__	__/__/__	____	____	____
5. _____	M F	__/__/__	__/__/__	____	____	____	__/__/__	__/__/__	__/__/__	__/__/__	____	____	____
6. _____	M F	__/__/__	__/__/__	____	____	____	__/__/__	__/__/__	__/__/__	__/__/__	____	____	____
7. _____	M F	__/__/__	__/__/__	____	____	____	__/__/__	__/__/__	__/__/__	__/__/__	____	____	____
8. _____	M F	__/__/__	__/__/__	____	____	____	__/__/__	__/__/__	__/__/__	__/__/__	____	____	____

Comments

DOH-3385 (3/02)

REPORT INFANT'S FOLLOW-UP ON DOH-2621

Appendix F

Labor & Delivery and Nursery Unit Guidelines to Prevent Hepatitis B Virus Transmission

Hepatitis B vaccine should be given to all newborns prior to discharge from the newborn nursery. That's the recommendation of the Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices, the American Academy of Pediatrics, the American Academy of Family Physicians, and the American College of Obstetricians and Gynecologists.
The following guidelines are CDC reviewed. Feel free to use them to help your hospital establish standing orders for preventing perinatal hepatitis B virus (HBV) transmission in your Labor & Delivery and Nursery Units.

Labor & Delivery Unit Guidelines

1. Upon admission, review the mother's HBsAg* lab report and place a copy of the test result onto (1) the labor and delivery record and (2) the infant's delivery record. You must examine a copy of the *original* lab report and not rely on the handwritten prenatal record due to the possibility of transcription error, misinterpretation of test results, or misordering of the test.
2. If the HBsAg result is not available, order the test ASAP.* Instruct the lab to call the nursery with the result ASAP.
3. Alert the nursery if the mother is HBsAg positive or if the mother's HBsAg result is unknown. These infants require immunoprophylaxis within 12 hours of birth with HepB vaccine. If the mother is HBsAg positive, give the infant HBIG as well.
4. If the woman's HBsAg test result is positive or unknown at the time of admission, notify her of the need to give immunoprophylaxis to her infant within 12 hours of birth.

Nursery Unit Guidelines

Infants born to HBsAg-negative mothers

1. Give HepB vaccine (0.5 mL, IM) before discharge from the nursery.§
2. Give the mother an immunization record card that includes the HepB vaccination date. Remind the mother to bring this personal record card with her each time she brings her baby to the doctor or clinic.
3. Instruct the mother about the importance of her baby's completing the entire HepB vaccination series.
4. Make sure that the infant's hospital record clearly indicates the date of HepB vaccine administration and that the hospital record is *always* forwarded to the infant's primary care provider.

Infants born to mothers with unknown HBsAg status

1. Give HepB vaccine (0.5 mL, IM) within 12 hours of birth.§ *Do not wait for test results before giving vaccine*. (For infants weighing <2kg, see special recommendations in item 6 of this section.)
2. Give the mother an immunization record card noting HepB vaccine date and explain the need for further doses to complete the series.
3. Confirm that the lab has drawn a serum specimen from the mother for an HBsAg test, and verify when the result will be available and that it will be reported to the nursery ASAP. If the nursery does not receive the report at the expected time, call the lab for the result.
4. If the mother's HBsAg report comes back positive:
a. Give HBIG (0.5 mL, IM) to the infant ASAP and alert the mother's and infant's physician(s) of the test result. There is little benefit in giving HBIG if >7 days have elapsed since birth.
b. Follow instructions in the section **Infants born to HBsAg-positive mothers.**

5. If infant must be discharged before the HBsAg result is known:
a. Clearly document how to reach the parents (addresses, telephone numbers, emergency contacts) as well as the infant's primary care provider, in case further treatment is needed.
b. Notify the mother's and infant's doctor(s) that the HBsAg result is pending.
6. For infants weighing <2 kg, administer HepB vaccine *and* HBIG within 12 hours of birth. Do not count this as the first dose. Then initiate the full HepB vaccine series at 1–2 mos. of age.

Infants born to HBsAg-positive mothers

1. Give HBIG (0.5 mL, IM) and HepB vaccine (0.5 mL, IM) at separate sites within 12 hours of birth.§ (For infants weighing <2 kg, see special recommendations in item 7 of this section.)
2. Give the mother an immunization record card that includes the dates of the HepB vaccine and HBIG, and instruct her to bring this personal record card with her each time her baby sees a provider.
3. Encourage mothers inclined to breastfeed to do so, including immediately after delivery, even if the infant has not yet been vaccinated.
4. Provide the mother with educational and written materials regarding
a. the importance of having her baby complete the HepB vaccination schedule on time (1–2 and 6 mos. for monovalent vaccine; 2, 4, and 12–15 mos. for Comvax; or 2, 4, and 6 mos. for Pediarix);
b. the importance of postvaccination 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; and
d. the importance of testing household members for hepatitis B and then vaccinating if susceptible.
5. Notify your local or state health department that the infant has been born and has received postexposure prophylaxis (include dates of receipt of HBIG and HepB vaccine).
6. Obtain the name, address, and phone number of the infant's primary care clinic and doctor. Notify them of the infant's birth, the receipt of postexposure prophylaxis, and the importance of additional onetime vaccination and postvaccination testing.
7. For infants weighing <2 kg, administer HepB vaccine and HBIG within 12 hours of birth. Do not count this dose as the first dose. Then initiate the full HepB vaccine series at 1.2 mos. of age.

*Be sure you order the correct test-**hepatitis B surface antigen (HBsAg)**.for your patient. Do not confuse this test result with any of the following tests:
1. Anti-HBs or HBsAb = antibody to hepatitis B surface antigen
2. Anti-HBc or HBcAb = antibody to hepatitis B core antigen

Be sure you include a copy of the original lab report with the labor and delivery record and that a copy is placed in the newborn's chart.

§Federal law requires that you give parents a HepB Vaccine Information Statement (VIS) **prior** to vaccine administration. To obtain VISs, download them from IAC's website at: www.immunize.org/vis or call the CDC-Info Contact Center at (800) 232-4636 [(800) CDC-INFO] or call your state health department.

Appendix G

Procedures for HBsAg-Positive and Unknown Mothers and Newborns
Non-Patient Specific Standing Order for the Hepatitis B Birth Dose[1]

POLICY STATEMENT:

The Advisory Committee on Immunization Practices (ACIP), American Academy of Pediatrics (AAP), and Centers for Disease Control and Prevention (CDC) recommend identification of women who are HBsAg-positive through screening and prophylaxis of their newborns. Proper prophylaxis and completion of the hepatitis B vaccine series can reduce neonatal infection and the potential sequelae by 95%. New York State Public Health Law (NYSPHL) 2500-e mandates that all pregnant women be tested for hepatitis B infection and that all newborns born to infected mothers must be given hepatitis B immune globulin (HBIG) and hepatitis B vaccine within 12 hours of birth. NYSPHL 2500-e mandates that pregnant women who have not been tested or whose test results are unknown be tested immediately (STAT) after admission. Until the test result is known, the woman is assumed to be HBsAg-positive.

EQUIPMENT/SUPPLIES:

- Hepatitis B Vaccine Information Statement
- Screening and consent form
- Hepatitis B Vaccine (RECOMBIVAX HB or Engerix-B) Intramuscular, Dose: 0.5 mL.
- Hepatitis B immune globulin (HBIG) Intramuscular, Dose: 0.5 mL
- Syringes with ⅝" (22-25 gauge) needles

COMPETENCY REQUIRED: Current CPR certification[1]

PROCEDURES:

Vaccination of newborns at birth ***If mother is HBsAg-positive:***
• Newborns born to mothers who are HBsAg-positive must receive hepatitis B immune globulin (HBIG) and hepatitis B vaccine within 12 hours of birth. • For newborns weighing less than 2,000 grams, the initial dose of vaccine does not count toward the three dose vaccine series.
If mother has unknown HBsAg status:
• Newborns born to mothers whose HBsAg status is unknown must receive hepatitis B vaccine within 12 hours of birth. • The mother must have blood drawn as soon as possible to determine her HBsAg status. • If the mother is found to be HBsAg-positive the newborn must receive HBIG as soon as possible, but no later than seven days after birth. • Because of the potentially decreased immunogenicity of vaccine in newborns weighing less than 2000g, these newborns must receive both hepatitis B vaccine and HBIG if the mother's HBsAg status cannot be determined ≤ 12 hours of birth.[2]

For HBsAg positive mother upon admission to labor and delivery

1. Examine a copy of the original laboratory report of the pregnant woman's hepatitis B surface antigen (HBsAg) test result to verify that the correct test was performed and to verify that the testing date was during this pregnancy and not a previous one.

a. Place a copy of the original HBsAg laboratory report into the pregnant woman's medical record and the newborn's medical record.
b. HBsAg test results, including date, must be in **both** maternal and newborn medical records[3].

2. Provide the mother with a Vaccine Information Statement (VIS) upon admission to labor and delivery or before vaccine administration and ensure the VIS date is accurate.[4]

3. Obtain written consent for vaccination from the mother upon admission to the hospital preferably before the mother enters the delivery room.

4. Obtain the name, address, and phone number of the newborn's primary care provider.
   a. Notify the pediatric provider of the mother's test result
   b. Obtain an order for HBIG [5]
   c. There is little benefit in giving HBIG if more than 7 days have elapsed since birth

5. Provide counsel to the mother. Tell her the following:
   a. That she may breast-feed her newborn upon delivery, even before hepatitis B vaccine and HBIG are given
   b. That it is critical for her newborn to complete the full hepatitis B vaccine series on the recommended schedule
   c. That after completion of at least 3 doses of the hepatitis B vaccine series, blood will need to be drawn from the newborn at 9 months of age (usually done at a well-child visit) to determine if the newborn developed a protective immune response to vaccination or needs additional management
   d. About modes of hepatitis B virus (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 eligible for antiviral treatment if not already done

6. In accordance with NYSPHL 2500-e, if the mother refuses vaccination of the newborn after counseling, then contact Child Protective Services (CPS) and the county health department where the mother resides as soon as possible. Post exposure prophylaxis is significantly reduced the longer vaccine administration is delayed.

For newborn of HBsAg positive mother

1. Administer single-antigen hepatitis B vaccine (0.5 mL, IM) preferably in the delivery room and within 12 hours of birth.

2. Per medical order, administer HBIG (0.5mL, IM) at separate site from vaccine within 12 hours of birth preferably in the delivery room.[5]

3. Document the HBIG and hepatitis B vaccine doses in the newborn's medical record and include date, time, site of administration, and manufacturer lot number.

4. Give the mother an immunization record card that includes the hepatitis B vaccination and HBIG dates.
   a. Explain the need for the complete hepatitis B vaccine series to protect her newborn.

   b. Remind her to bring the card with her each time her child sees a provider.

5. Notify the county health department where the mother resides within 24 hours of the newborn's birth and provide the date and time of administration of HBIG and hepatitis B vaccine doses.

6. Indicate the mother's HBsAg status on the NYSDOH Newborn Screening Blood Collection Form as Pos. (positive).

7. Indicate the HBV vaccine administration on the Statewide Perinatal Data System (SPDS).[7]

8. In accordance with NYSPHL 2500-e, if the mother refuses vaccination of the newborn after counseling, then CPS and the county health department where the mother resides must be contacted within 24 hours.

For mother with unknown HBsAg status upon admission to labor and delivery

1. NYSPHL 2500-e requires that when any woman who has not been tested for HBsAg during pregnancy or whose test result is not available upon time of admission
   a. STAT test must be performed, with the date and time of blood collection recorded in both the maternal and newborn medical records.
   b. Contact the laboratory to confirm receipt of blood sample and need for STAT results.

2. Provide the mother with a Vaccine Information Statement (VIS) upon admission to labor and deliverable or before vaccine administration and ensure the VIS date is accurate.[4]

3. Obtain written consent for vaccination from the mother upon admission to the hospital preferably before the mother enters the delivery room.

4. In accordance with NYSPHL 2500-e, if the mother refuses vaccination of the newborn after counseling and test results are not available within 24-48 hours, then CPS and the county health department where the mother resides must be contacted. *Forty-eight (48) hours is the maximum time for vaccination of a newborn when the mother's test results are pending.* Post exposure prophylaxis is significantly reduced the longer vaccine administration is delayed.

For newborn of mother with unknown HBsAg status

1. If the mother's HBsAg test result is not available, administer single-antigen hepatitis B vaccine (0.5mL, IM) within 12 hours of birth. *Do not wait for test results before giving vaccine.*
2. Give the mother an immunization record card that includes the hepatitis B vaccination date.
   a. Explain the need for the complete hepatitis B vaccine series to protect her newborn.
   b. Remind her to bring the card with her each time her child sees a provider.
3. If the mother's result remains unknown at the time of newborn discharge or transfer to another facility:
   a. Notify the parents, the newborn's primary care provider and the county health department where the mother resides that the result is pending since there is little benefit in giving HBIG if more than 7 days have elapsed since birth
   b. The only exception is when the newborn weighs less than 2,000g. In this case, the newborn must be given both hepatitis B vaccine and HBIG within 12 hours of birth if the mother's HBsAg status cannot be determined

c. Document contact information for the parents (e.g., addresses, telephone numbers, and emergency contacts) in case further treatment is needed

4. If the mother's test result comes back positive, obtain order and administer HBIG (0.5mL, IM) to the newborn immediately, but definitely within seven days of birth.[5] (See #3a above.)

5. Indicate the mother's HBsAg status on the NYSDOH Newborn Screening Blood Collection Form as either Pos. (positive) or Neg. (negative). Indicate status as Unk. (unknown) only if mother's test results are not available on newborn discharge.

6. Indicate the hepatitis B vaccine administration and HBIG if given on the Statewide Perinatal Data System (SPDS).[6]

REFERENCES

[1] NYS Nurse Practice Act (Education Law Article 139 §6909) authorizes the administration of non-patient specific orders for certain immunizations, anti-anaphylactic agents, and HIV and tuberculosis tests across all service delivery systems. A registered professional nurse may execute a non-patient specific regimen prescribed or ordered by a licensed physician or certified nurse practitioner, pursuant to regulations promulgated by the Commissioner of Education. www.op.nysed.gov/prof/nurse/immunguide.htm

[2] NYSPHL 2500-e states if an infant of HBsAg positive mother is medically unstable, the infant's health care provider may defer vaccine and HBIG until the infant is medically stable.

[3] NYSPHL 2500-e mandates that all newborns born to HBsAg-positive women are treated with hepatitis B vaccine and HBIG within 12 hours of birth and with the complete vaccine series. Title 10 Subpart 69-3.3 requires health care facilities to screen and report HBsAg status for all pregnant women, record tests results in newborn medical records, respond to inquiries from local health officers, and provide written documents to accompany newborns transferring between facilities.

[4] 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 or call your county health department.

[5] The NYS Nurse Practice Act (Education Law Article 139 §6909) does not authorize the administration of HBIG without a patient specific order.

[6] This information is automatically transferred to the NYS Immunization Information System (NYSIIS) as required by NYSPHL 2168.

_____ From___/___/___to___/___/___

Authorizing Physician or Nurse Practitioner Effective Dates

Appendix H

Procedures for HBsAg-Negative Mothers and Newborns
Non-Patient Specific Standing Order Universal Hepatitis B Birth Dose[1]

POLICY STATEMENT:

In 2005, the Advisory Committee on Immunization Practices (ACIP), American Academy of Pediatricians (AAP) and American Academy of Family Physicians (AAFP) recommended that hepatitis B vaccine be administered to all newborns within 12 hours of birth referred to as the universal hepatitis B birth dose. 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 newborn is still properly protected at birth.

EQUIPMENT/SUPPLIES:

- Hepatitis B Vaccine Information Statement
- Screening and consent form
- Hepatitis B Vaccine (RECOMBIVAX HB or Engerix-B) Intramuscular, Dose: 0.5 mL.
- Syringe with ⅝" (22-25 gauge) needle

COMPETENCY REQUIRED: Current CPR certification[1]

PROCEDURES:

For HBsAg negative mothers upon admission to labor and delivery

7. Examine a copy of the original laboratory report of the pregnant woman's hepatitis B surface antigen (HBsAg) test result to verify that the correct test was performed and to verify that the testing date was during this pregnancy and not a previous one.
    a. Place a copy of the original HBsAg laboratory report into the pregnant woman's medical record and the newborn's medical record. HBsAg test results, including date, must be in **both** maternal and newborn medical records.[2]
    b. If pregnant woman indicates hepatitis B risk behavior, then repeat HBsAg test on admission.[3]
    c. If the HBsAg test result is not available see "Procedures for HBsAg-Positive and Unknown Mothers and Newborns".

8. Provide the mother with a Vaccine Information Statement (VIS) upon admission to labor and deliverable or before vaccine administration and ensure the VIS date is accurate.[4]

9. Obtain written consent for vaccination from the mother upon admission to the hospital preferably before the mother enters the delivery room.

For newborns of HBsAg negative mothers

1. Administer single-antigen hepatitis B vaccine (0.5 mL, IM) preferably in the delivery room and within 12 hours of birth but always before hospital discharge to all newborns weighing 2000 grams or more at birth. [5]

2. Document the hepatitis B vaccine dose in the newborn's medical record, including date, time, site of administration, and manufacturer lot number.

3. Give the mother an immunization record card that includes the hepatitis B vaccination date.
    a. Explain the need for the complete hepatitis B vaccine series to protect her newborn.
    b. Remind the mother to bring the card with her each time her child sees a provider.

4. If the mother refuses the hepatitis B vaccine, then document the reason on the screening and consent form. [6]

5. Indicate the mother's HBsAg status on the NYSDOH Newborn Screening Blood Collection Form as Neg. (negative). It is rare to have Unk. (unknown) status.

6. Indicate the hepatitis B vaccine administration on the Statewide Perinatal Data System (SPDS). [7]

REFERENCES

[1] NYS Nurse Practice Act (Education Law Article 139 §6909) authorizes the administration of non-patient specific orders for certain immunizations, anti-anaphylactic agents, and HIV and tuberculosis tests across all service delivery systems. A registered professional nurse may execute a non-patient specific regimen prescribed or ordered by a licensed physician or certified nurse practitioner, pursuant to regulations promulgated by the Commissioner of Education. www.op.nysed.gov/prof/nurse/immunguide.htm

[2] NYSPHL 2500-e mandates that all newborns born to HBsAg-positive women are treated with hepatitis B vaccine and HBIG within 12 hours of birth. Title 10 Subpart 69-3.3 requires health care facilities to screen and report HBsAg status for all pregnant women, record tests results in newborn medical records, respond to inquiries from local health officers, and provide written documents to accompany newborns transferring between facilities

[3] Perform a repeat blood test for HBsAg if the pregnant woman was HBsAg negative during a prenatal visit but was at risk for acquiring HBV infection during this pregnancy (e.g., not in a long-term, mutually monogamous relationship; had an HBsAg-positive sex partner; had evaluation or treatment for a sexually transmitted disease; currently uses or recently used injection drugs).

[4] 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 or call your county health department.

[5] Newborns weighing less than 2000g 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.

[6] Exceptions to administering the birth dose of hepatitis B vaccine are allowed only in the case of HBsAg-negative status of the mother. If a birth dose is not administered, a copy of the mother's negative HBsAg test result from the current pregnancy must be placed in the newborn's medical record and the attending physician must write a specific order directing staff not to administer the birth dose in the hospital. Newborns who do not receive the first dose of hepatitis B vaccine before hospital discharge should receive the first dose no later than age 2 months.

[7] This information is automatically transferred to the NYS Immunization Information System (NYSIIS) as required by NYSPHL 2168.

_____ From___/___/___to___/___/___

Authorizing Physician or Nurse Practitioner — Effective Dates

Appendix I

Sample Hepatitis B Consent/Refusal Form
Hepatitis B Birth Dose Vaccination

The Advisory Committee on Immunization Practices (ACIP) and the American Academy of Pediatrics (AAP) recommend that a birth dose of hepatitis B vaccine be administered to all infants born in the United States. The New York State Department of Health has established that this hepatitis B vaccine birth dose be given within 12 hours of birth as the standard of care in New York State. As with all childhood immunizations, a parental consent is necessary. Also, the Hepatitis B Vaccine Information Statement (VIS) must be provided to the parent prior to vaccination and the publication date of the VIS must be documented.
Publication date of VIS provided to parent: __July 18, 2007_

☐ Verbal consent obtained RN signature: _____ **OR**

☐ I give consent for my infant _____ to be given a birth dose of hepatitis B vaccine. I have received the Hepatitis B Vaccine Information Statement and understand the risks and benefits of my child receiving the vaccine.

Parent Signature: _____ Date: _____
Witness Signature: _____ Date: _____

Hepatitis B Vaccine 0.5 ml dose
Date of administration: _____ Time: _____ Site: _____
Manufacturer/Vaccine Trade Name: _____
Lot #: _____ Expiration Date: _____
Administered by: _____

☐ I understand the risks of hepatitis B and refuse to have my child receive the hepatitis B vaccine. My child's physician will receive a copy of this form.

Reason for refusing vaccination: _____
Parent Signature: _____
Witness Signature: _____

Appendix J

NEW YORK STATE DEPARTMENT OF HEALTH
Bureau of Communicable Disease Control

Perinatal Hepatitis B Prevention Program: Supplemental Confidential Case Report

INSTRUCTIONS ON BACK

Source of Case Identification **Newborn Screening Number** _____
☐ Newborn Screening ☐ Local Referral If Local Referral ☐ prenatal ☐ postnatal

Demographic Information

Mother's Name_____ Date of Birth ☐☐☐☐☐☐
last first maiden name

Address_____ County _____ Zip Code ☐☐☐☐☐

Home Phone (☐☐☐) ☐☐☐-☐☐☐☐ Work Phone (☐☐☐) ☐☐☐-☐☐☐☐

Infant's Name_____ Date of Birth ☐☐☐☐☐☐ Time of Birth ☐☐☐ am pm
last first middle initial

Race
1 ☐ White 2 ☐ Black 3 ☐ Asian/Pacific Islander 4 ☐ American Indian/Alaskan Native 5 ☐ Other _____ 9 ☐ Unk

Ethnicity
1 ☐ Hispanic 2 ☐ Non-Hispanic 9 ☐ Unk

Insurance (this pregnancy) (check all that apply)
1 ☐ Private 2 ☐ PCAP 3 ☐ Medicaid 4 ☐ None (self-pay) 8 ☐ Other _____ 9 ☐ Unk

Mother's History EDC (due date) ☐☐☐☐☐☐ gravida _____ para _____
Delivery Hospital _____

HBsAg test result (during this pregnancy)	1 ☐ Pos	2 ☐ Neg		Date ☐☐☐☐☐☐
HBeAg test result	1 ☐ Pos	2 ☐ Neg	9 ☐ Not done	Date ☐☐☐☐☐☐
Known Acute Hep B	1 ☐ Yes	2 ☐ No		Date of Diagnosis ☐☐☐☐☐☐
Known chronic carrier	1 ☐ Yes	2 ☐ No		Date of Diagnosis ☐☐☐☐☐☐

Mother's Risk Factor(s)

Asian/Pacific Islander/ Alaskan descent	1 ☐ Yes	2 ☐ No	9 ☐ Unk	Haitian or sub-Saharan African native	1 ☐ Yes	2 ☐ No	9 ☐ Unk
History of:				History of:			
hepatitis B	1 ☐ Yes	2 ☐ No	9 ☐ Unk	use of percutaneous (IV) illicit drugs	1 ☐ Yes	2 ☐ No	9 ☐ Unk
acute/chronic liver disease	1 ☐ Yes	2 ☐ No	9 ☐ Unk	sexual contact with hep B carriers	1 ☐ Yes	2 ☐ No	9 ☐ Unk
hemodialysis worker/patient	1 ☐ Yes	2 ☐ No	9 ☐ Unk	sexual contact with IV drug user	1 ☐ Yes	2 ☐ No	9 ☐ Unk
worker/resident in institution for mentally retarded	1 ☐ Yes	2 ☐ No	9 ☐ Unk	frequent occupational blood exposure	1 ☐ Yes	2 ☐ No	9 ☐ Unk
multiple blood transfusions	1 ☐ Yes	2 ☐ No	9 ☐ Unk	If yes, 1 ☐ Nurse 2 ☐ MD 3 ☐ Laboratory			
multiple episodes of STD	1 ☐ Yes	2 ☐ No	9 ☐ Unk	4 ☐ Dental 5 ☐ Other 9 ☐ Unknown			
Ever rejected as a blood donor	1 ☐ Yes	2 ☐ No	9 ☐ Unk				

Infant's Vaccination Record (see back for codes)

	Date	Time	Vaccine Type	Lot #	Hospital/Clinic/MD Name
HBIG Vaccine	☐☐☐☐☐☐	_____ am/pm	_____	_____	_____
Dose #1	☐☐☐☐☐☐	_____ am/pm	_____	_____	_____

	Date	Age of Child	Vaccine Type	Lot #	Hospital/Clinic/MD Name
Dose #2	☐☐☐☐☐☐	_____	_____	_____	_____
Dose #3	☐☐☐☐☐☐	_____	_____	_____	_____
Dose #4	☐☐☐☐☐☐	_____	_____	_____	_____
Dose #5	☐☐☐☐☐☐	_____	_____	_____	_____
Dose #6	☐☐☐☐☐☐	_____	_____	_____	_____

Infant's Serology **Lab Name** _____

Anti-HBs	Date ☐☐☐☐☐☐	1 ☐ Pos	2 ☐ Neg	3 ☐ Not done	**Repeat Serology** Anti-HBs	Date ☐☐☐☐☐☐	1 ☐ Pos 2 ☐ Neg 3 ☐ Not done
HBsAg	Date ☐☐☐☐☐☐	1 ☐ Pos	2 ☐ Neg	3 ☐ Not done	HBsAg	Date ☐☐☐☐☐☐	1 ☐ Pos 2 ☐ Neg 3 ☐ Not done

Lost to follow-up Date ☐☐☐☐☐☐ 1 ☐ Can't locate 2 ☐ Parent Refuses Follow-up 3 ☐ Physician Refuses Follow-up
4 ☐ Other, specify _____ 5 ☐ Moved to: _____

White - State Health Department when 2nd vaccine dose complete. Yellow - State Health Department when 3rd vaccine dose complete. Pink - State Health Department when serology (1 year) complete. Goldenrod - County Health Department.
DOH-2621 (3/02)

[5] Newborns weighing less than 2000g 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.