CHAPTER 1. CASE IDENTIFICATION AND MANAGEMENT

Chapter 1. Case Identification and Management

By the end of this chapter, you will be able to:

- Identify components of case management programs to prevent perinatal HBV infections
- Discuss methods to identify HBsAg-positive pregnant women
- Describe case management for infants born to HBsAg-positive mothers and infants born to mothers with unknown HBsAg status
- Explain the policies, procedures, laws, and regulations to prevent perinatal HBV infection for prenatal care providers, delivery hospitals, and pediatric care providers
- Describe program data management

Identification and management of HBsAg-positive mothers and their infants are vital components of robust perinatal hepatitis B prevention programs. Use of comprehensive case management techniques, including employment of staff specifically for identification and tracking of HBsAg-positive mothers and their infants, use of a computer-based tracking system, and use of reminder letters for patients and their health-care providers, has been demonstrated to maximize timely delivery of immunoprophylaxis and completion of the hepatitis B vaccine series.

Identification of pregnant women who do not have documented HBsAg test results at the time of delivery, as well as appropriate management of these women and their infants, is also a vital component of perinatal hepatitis B prevention. Pregnant women who do not receive prenatal care account for a disproportionate number of births to HBsAg-positive mothers because of the higher prevalence of HBsAg among those women than among women who receive prenatal care. Case management of pregnant women with unknown HBsAg status at the time of delivery and their infants requires implementation of policies and procedures in delivery hospitals, availability of HBsAg testing in delivery hospitals with rapid turnaround of test results, mechanisms to ensure that all pregnant or delivering women are tested for HBsAg before hospital discharge, and communication between delivery staff, nursery staff, laboratory staff, and pediatric care providers.

According to ACIP recommendations, states and localities should establish case management programs (Box 1.1), including appropriate policies, procedures, laws, and regulations, to ensure that

- all pregnant women are tested for HBsAg during each pregnancy, and
- infants born to HBsAg-positive women and infants born to women with unknown HBsAg status receive recommended case management.

BOX 1.1. Components of Case Management Programs to Prevent Perinatal Hepatitis B Virus (HBV) infection

Test all pregnant women for hepatitis B surface antigen (HBsAg)

- Health-care providers should test all pregnant women for HBsAg during each pregnancy.
- HBsAg testing should be incorporated into standard prenatal testing panels (e.g., blood type, HIV infection, Rh factor, rubella antibody titer, syphilis infection) used by all practitioners caring for pregnant women.
- Women who test negative for HBsAg but have risk factors (>1 sex partner in past 6 months, evaluation or treatment for an STD, recent or current injection-drug use, HBsAg-positive sex partner) should be vaccinated against hepatitis B and should be retested in the third trimester.
- Delivery hospitals should ensure that all pregnant or delivering women have been tested for HBsAg before hospital discharge.
- Reporting of maternal HBsAg test status should be included on hospital-based electronic birth certificates or newborn metabolic screening results.

Report and track HBsAg-positive women

- All HBsAg-positive test results for pregnant women and women of childbearing age should be reported to state or local perinatal hepatitis B prevention programs.
- Case data for HBsAg-positive pregnant women should be entered into case management tracking systems.

Provide prenatal HBsAg testing records to delivery hospitals

- HBsAg test results should be included on all forms (hard copy and 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.
- Health-care providers should document that HBsAg-positive pregnant women have received a copy of the original laboratory report, that a copy of the original laboratory report has been transferred from the prenatal care provider to the delivery hospital, and that patients have been informed of their HBsAg test result and advised to notify delivery staff.

Identify and manage infants born to HBsAg-positive mothers

- Delivery hospitals should implement policies and procedures to ensure identification and initiation of postexposure immunization of infants born to HBsAg-positive mothers.
- Delivery hospitals should document the date and time of birth and the date and time of administration of hepatitis B immune globulin (HBIG) and hepatitis B vaccine for all infants born to HBsAg-positive mothers and provide this information to both the parent and the pediatrician.

Identify and manage infants born to mothers without HBsAg test results

- Delivery hospitals should implement policies and procedures to ensure identification of and initiation of postexposure vaccination of infants born to mothers with unknown HBsAg status at delivery.
- Delivery hospitals should document the date and time of birth, date and time of administration of hepatitis B vaccine, and maternal HBsAg test results for all infants born to mothers with unknown HBsAg status at time the of delivery.

Complete the hepatitis B vaccine series

- Pediatric care providers should document the dates of administration of all doses of the hepatitis B vaccine series for all infants born to HBsAg-positive mothers.

Complete post-vaccination testing

- Pediatric care providers should document the results of testing for HBsAg and anti-HBs after completion of the hepatitis B vaccine series for all infants born to HBsAg-positive mothers.
- HBsAg-positive test results in infants should be reported to CDC via the National Notifiable Diseases Surveillance System.

Monitor and evaluate the case management program

- Annually, each program should track
  - the number of HBsAg-positive pregnant women
  - the number of infants born to HBsAg-positive pregnant women
  - the proportion of infants born to HBsAg-positive mothers receiving postexposure immunoprophylaxis within 12 hours of birth, on-time completion of the vaccination series, and post-vaccination serologic testing for HBsAg and anti-HBs
  - the number of delivering mothers with unknown HBsAg status
  - the proportion of infants born to mothers with unknown HBsAg status receiving hepatitis B vaccine within 12 hours of birth
- Programs should determine reasons for
  - >10% difference between expected and identified number of HBsAg-positive pregnant women
  - <90% completion rates for administration of HBIG and hepatitis B vaccine within 12 hours of birth, on-time completion of the vaccination series, and post-vaccination testing for infants born to HBsAg-positive mothers
  - <90% completion rates for administration of hepatitis B vaccine within 12 hours of birth for infants born to mothers with unknown HBsAg status

Source: CDC. A comprehensive immunization strategy to eliminate transmission of hepatitis B virus infection in the United States: recommendations of the Advisory Committee on Immunization Practices (ACIP). Part 1: immunization of infants, children, and adolescents. *MMWR* 2005 (RR-16).

CASE IDENTIFICATION, MANAGEMENT, AND TRACKING BY HEALTH DEPARTMENTS

Typically, case management, from identification of an HBsAg-positive pregnant woman through follow-up of her infant, can take up to two years. Such a lengthy process is unusual in public health and presents unique challenges, particularly because most case workers will have long periods of time between contacts with patients. This section outlines key steps for each phase of the process.

Case Identification

Identification of HBsAg-positive pregnant women by the state health department occurs primarily through reporting by laboratories and prenatal care providers. Typically, the state or local health department receives HBsAg-positive test results, reviews the results to identify all women of childbearing age, and then investigates to determine the pregnancy status of each HBsAg-positive woman. In addition, because approximately 5% of pregnant women do not receive prenatal care before delivery, it is important for perinatal hepatitis B prevention programs to work with delivery hospitals and delivery hospital laboratories to ensure that all pregnant women with unknown HBsAg status at the time of delivery are identified and tested and that those with HBsAg-positive results are reported to the health department.

Despite overall improvements in HBsAg screening of pregnant women and reporting of test results to health departments, a large number of HBsAg-positive mothers are not being identified in time to ensure necessary case management for these mothers and their infants. Perinatal

hepatitis B prevention programs can use the following mechanisms to improve case identification:

- Maintain a list of all laboratories that perform prenatal HBsAg testing (including delivery hospital laboratories) and confirm that positive HBsAg test results are being reported to the health department. A laboratory evaluation form and worksheet are provided in Appendix B.
- Periodically remind prenatal care providers and delivery hospitals to report all HBsAg-positive women to the health department.
- Ensure that the state health department and local health departments have clear protocols for reviewing HBsAg-positive test results to identify women of childbearing age and to determine the pregnancy status of each of these women.
- Ensure that HBsAg testing is incorporated into standard prenatal testing panels used by prenatal care providers.
- Work with delivery hospitals to ensure that all pregnant or delivering women have been tested for HBsAg before hospital discharge.
- Work to establish appropriate policies, procedures, laws, and regulations to ensure that all pregnant women are tested for HBsAg during each pregnancy. A CDC review of applicable laws conducted in 2005 found that 24 states had a law for prenatal HBsAg screening.
- Work to establish reporting of maternal HBsAg test status on hospital-based electronic birth certificates or neonatal metabolic screening requests, and work with delivery hospitals to ensure maternal HBsAg status is accurately documented. As of 2006, 24 perinatal hepatitis B prevention programs reported that maternal HBsAg test results were included on either newborn metabolic screening cards or electronic birth certificates.
- Work to establish linkages between state chronic hepatitis B registries and reporting mechanisms for HBsAg-positive pregnant women. For example, at least one state has built an interface between the state chronic hepatitis B registry and the state birth database to cross-reference the mothers of new infants with known HBsAg-positive women. This interface has helped identify additional perinatal hepatitis B cases.

Guidance on evaluating the completeness of HBsAg test result reporting is provided in Chapter 2.

Case Initiation

When an HBsAg-positive woman is identified during her pregnancy, perinatal hepatitis B prevention program staff should do the following:

- Contact the prenatal care provider to confirm HBsAg test results, date of testing, expected date of delivery, and expected delivery hospital.
- Notify the delivery hospital of the HBsAg-positive woman planning to deliver at the facility.
- Contact the HBsAg-positive woman to provide information and education about hepatitis B, including the importance of immunoprophylaxis for her infant, ways to prevent transmission, perinatal concerns (e.g., infants born to HBsAg-positive mothers may be breastfed), substance abuse treatment (if appropriate), and the need for the mother to receive evaluation and medical management for chronic hepatitis B.
- Identify sex partners and household and needle-sharing contacts of the mother and manage them according to current recommendations.

Case Management at the Time of Delivery

- Before the expected delivery date, remind the mother and delivery hospital of the importance of postexposure immunoprophylaxis for the infant at birth.
- Shortly after the expected delivery date, contact the delivery hospital for information about HBIG and hepatitis B vaccine administration (date of delivery, date and time of administration) if the hospital has not reported this information.
- After the delivery date, notify the pediatric care provider of the infant's birth and ensure that the provider is aware of guidelines for postexposure immunoprophylaxis and follow-up testing for the infant.
- When an HBsAg-positive mother who was *not* identified prenatally is identified in the hospital at or after delivery, perinatal hepatitis B prevention program staff should contact the HBsAg-positive woman as soon as possible to provide information and education about hepatitis B (including the importance of immunoprophylaxis of infant, ways to prevent transmission, perinatal concerns [e.g., infants born to HBsAg-positive mothers may be breastfed], information about substance abuse treatment (if appropriate), and the need for the mother to receive evaluation and medical management for chronic hepatitis B). In addition, sex partners and household and needle-sharing contacts of the mother should be identified and managed according to current recommendations.

Case Management Completion

- Remind pediatric care providers and parents when an infant is due for a dose of hepatitis B vaccine or post-vaccination serologic testing. A reminder and recall system is important for all infants born to HBsAg-positive mothers, especially for those with risk factors associated with under-immunization including poverty, minority status, birth to a first-generation immigrant mother from a part of the world where HBV infection is endemic, lack of prenatal care, or residence in a medically underserved urban or rural area. For those with risk factors, a reminder and recall approach might provide not only a linkage to all immunization services but also a connection to a pediatric care provider. Reminder and recall approaches work best if parents are notified before vaccination visits are due (reminder) and immediately after scheduled visits are missed (recall). These might take the form of a postcard addressed by the parent and filed by the provider or health department to be mailed at a certain date. Or, providers might use a computer system that automatically makes a phone call.
- Verify the date of administration of each dose of hepatitis B vaccine with the pediatric provider or immunization information system.
- Verify anti-HBs and HBsAg test results of infants with the pediatric provider, and discuss follow-up of the infant on the basis of these results.
  - HBsAg negative infants with anti-HBs levels of ≥10 mIU/mL are protected and need no further medical management.
  - HBsAg negative infants with anti-HBs levels of <10 mIU/mL should be revaccinated with a second 3-dose series and retested 1–2 months after the final dose.
  - Infants who are HBsAg positive should be referred for medical evaluation and management of chronic hepatitis B.

Patients Lost to Follow-Up

In the 9–18 months necessary to complete the newborn's management, some patients will move without communicating their new contact information. To find patients, coordinators might use the following sources:

- Perinatal hepatitis B prevention programs might be able to search state WIC and Medicaid databases for updated demographic information on some perinatal hepatitis B patients lost to follow-up.
- Updated demographic information on an infant might be available from an immunization information system.
- Sometimes, finding the patient can be difficult. Before you give up, however, try a little detective work. See Box 1.2 for ideas.

Box 1.2. Finding Patients Lost To Follow-Up

- Call telephone information (411) to see if you can locate the lost contact.
- Use Internet search engines (e.g., Google) and the white pages to search for contact information.
- Try old telephone numbers. Relatives/friends with information on the patient might still be reached at those numbers.
- Look in directories that list occupants of each house in the city. Most sexually transmitted disease (STD) programs have such directories.
- Transpose the digits in telephone numbers and addresses. Poor handwriting and mistakes can lead you astray. Rearrange the numbers in the address (e.g., change 5132 Any Street to 3152), and try these addresses.
- Try "Street" instead of "Avenue."
- Ask the neighbors. One neighbor might keep track of the comings and goings of the people in the neighborhood. You might find someone who knows where the patient works or knows a friend of the patient.
- Ask the mail carrier; s/he cannot give you addresses, by law, but might confirm whether the patient still lives at the address or suggest similar street names to try.
- Ask the post office for a forwarding address. You will have to complete a justification form provided by the Postal Service and show your health department identification. Check with your STD case managers on local procedures.
- Search health department records. Old records might contain a parent's address or other locating information.
- Ask other state and local agencies and programs, including the Department of Motor Vehicles, Medicaid and WIC programs, the Department of Child and Family Services, and parole and probation offices for contact information. Clients might have greater incentives to maintain contact with such agencies and will keep their contact information current.

Case Management to Improve Identification of Infants Born to Women of Unknown Status

Perinatal hepatitis B coordinators should also work with delivery hospitals to implement protocols and procedures to ensure that

- pregnant women who were not screened prenatally are identified and tested as soon as possible after admission for delivery;
- infants born to women without documentation of HBsAg test results receive the first dose of hepatitis B vaccine within 12 hours of birth;
- all pregnant or delivering women are tested for HBsAg before hospital discharge; and

- pediatric care providers are contacted to provide follow-up for infants whose mothers have unknown HBsAg status at the time of hospital discharge, including review of maternal HBsAg test results and appropriate management of infants on the basis of those test results.

Data Tracking and Management

Successful case management requires effective data tracking and management. An effective system is one that allows the program to both manage cases and evaluate success of the program. Some states have successfully integrated their case management data system with another statewide electronic system, such as an immunization information system or disease reporting system.

The state of Florida has successfully integrated its perinatal case management into the state's disease reporting system, Merlin. Case management in Florida is conducted at the local level. Using the disease reporting system to manage perinatal cases enables local case managers to enter perinatal hepatitis B case data into Merlin and transfer case data electronically to the state. The system also generates reminders on cases in need of follow-up.

Any data management system needs to be able to index files according to the last name of either the mother or the infant. The following functions can simplify case management:

- Patient and provider reminder and recall
- Ability to generate letters
- Ability to run reports
- Ability to summarize data at the program level
- Case manager reminders (tickler file)

To optimize case management and enhance program evaluation, you should consider collecting the following data elements in your data management system:

<u>Mother</u>
Name
Contact information
Emergency contact
Insurance status
OB/GYN contact information
Liver disease specialist contact information
Date of first appointment with liver disease specialist
Date of birth
Race/ethnicity
Primary language spoken
Country of birth
Estimated due date
Number of previous deliveries
Prenatal care provider contact information
HBV testing results (HBsAg, HBeAg, HBV DNA level) and dates specimens were obtained

Infant
Name
Date/time of birth
Birth weight
Gestational age
Delivery hospital
Pediatrician contact information
HBIG administration (date, time, brand, dose)
1st dose of hepatitis B vaccine (date, time, brand, dose)
Subsequent doses of hepatitis B vaccine (date, brand, dose)
Post-vaccination testing results (HBsAg, anti-HBs level) and date specimen obtained
Reason(s) for loss to follow-up (if applicable)

Sex partners and household and needle-sharing contacts of mother
Pre-vaccination testing results (susceptible/not susceptible) and date specimen obtained
Hepatitis B vaccine doses (date, brand, dose)

POLICIES, PROCEDURES, AND PRACTICES FOR PRENATAL CARE, DELIVERY HOSPITAL, AND PEDIATRIC CARE SETTINGS

One of your main responsibilities as the coordinator of your state's perinatal hepatitis B prevention program is to foster practices conducive to effective case management. Effective implementation of perinatal hepatitis B prevention requires that appropriate policies and procedures are established in prenatal care settings, delivery hospitals, and pediatric care settings. By engaging your stakeholders in your overall prevention effort (see Chapter 3) and by providing education and training to obstetric, hospital, nursery, and pediatric care providers (see Chapter 4), you can assist in the development and implementation of these policies. This section outlines the critical components of such policies in each of the different settings.

Prenatal Care Provider Policies and Procedures

Established relationships with prenatal care providers enable you to encourage providers to screen their patients and report positive HBsAg test results to the health department so that you can begin a file for the mother and her infant. A first step in securing active participation from prenatal care providers is to help them develop written policies and procedures for their practices. The primary activity to promote among prenatal care practitioners is to ***test ALL pregnant women for HBsAg during each pregnancy.*** Prenatal care providers should test every woman for HBsAg during an early prenatal visit (e.g., in the first trimester), even if a woman has been previously vaccinated or tested.

In addition, prenatal care settings should incorporate each of the following actions into their policies and protocols:

For a pregnant woman with a *positive* HBsAg test result

- Report the positive test result to the health department.
- Provide a copy of the original laboratory report indicating the pregnant woman's HBsAg status to the hospital where the delivery is planned and to the health-care provider who will care for the newborn.
- Attach an alert notice or sticker to the woman's medical record to remind the delivery hospital/nursery that the infant will need hepatitis B vaccine and HBIG at birth.
- Educate the mother about the need for immunoprophylaxis of her infant at birth, and obtain consent for immunoprophylaxis before delivery. Consider printing additional reminder notices for mothers about the importance of immunoprophylaxis for infants and attaching the notices to the inside front or back cover of the medical record.
- Advise the mother that all household, sexual, and needle-sharing contacts should be tested for HBV infection and vaccinated if susceptible.
- Provide information to the mother about hepatitis B, including modes of transmission, prenatal concerns (e.g., infants born to HBsAg-positive mothers may be breastfed), medical evaluation and possible treatment of chronic hepatitis B, and substance abuse treatment (if appropriate).
- Refer the mother to a medical specialist for evaluation of chronic hepatitis B.

For a pregnant woman with a *negative* HBsAg test result

- Provide a copy of the original laboratory report indicating the pregnant woman's HBsAg status to the hospital where the delivery is planned and to the health-care provider who will care for the newborn.
- Include information in prenatal care education about the rationale for and importance of newborn hepatitis B vaccination for all infants.
- Administer the hepatitis B vaccine series if the patient has a risk factor for HBV infection during pregnancy (e.g., injection-drug use, more than one sex partner in the previous 6 months or an HBsAg-positive sex partner, evaluation or treatment for a sexually-transmitted disease [STD]).
- Repeat HBsAg testing upon admission to labor and delivery for HBsAg-negative women who are at risk for HBV infection during pregnancy or who have had clinical hepatitis since previous testing.

Delivery Hospital Policies and Procedures

In a perfect world, every woman would receive prenatal health care, including testing for HBsAg, throughout her pregnancy from the same provider. Unfortunately, this is not always the case. As a result, you must be prepared to identify mothers at risk of transmitting HBV to their infants at multiple points throughout a pregnancy, including at the time of delivery. A partnership with the staff of the delivery hospitals in your area is needed to support development of policies and procedures to prevent perinatal HBV transmission, including:

- ***identification of infants born to HBsAg-positive mothers and infants born to mothers with unknown HBsAg status, and***
- ***initiation of immunization for these infants.***

In addition, delivery hospitals should enroll in the federally funded Vaccines for Children (VFC) program to obtain free hepatitis B vaccine for administration of the birth dose to eligible newborns (i.e., Medicaid eligible, American Indian or Alaska Native, underinsured if served at a Rural Health Center or Federally Qualified Health Center, or uninsured).

Delivery hospital policies and procedures to prevent perinatal HBV transmission are needed in both the labor and delivery department and the newborn nursery and should include the following ***standing orders***:

- For all pregnant women, review of HBsAg test results at the time of admission for delivery
- For women who do not have a documented HBsAg test result, HBsAg testing as soon as possible after admission for delivery
- Identification and management of all infants born to HBsAg-positive mothers, including provision of postexposure immunoprophylaxis
- Identification and management of all infants born to mothers with unknown HBsAg status
- For all infants, documentation on the infant's medical record of maternal HBsAg test results, infant hepatitis B vaccine administration, and administration of HBIG (if appropriate)

The Immunization Action Coalition has developed a document entitled *Guidelines for Standing Orders in Labor & Delivery and Nursery Units to Prevent Hepatitis B Virus Transmission to Newborns*, a useful two-page sheet that hospitals can use to establish standing orders; the document is available at http://www.immunize.org/catg.d/p2130per.pdf. Additional elements of delivery hospital policies and procedures to prevent perinatal HBV transmission are listed in Box 1.3, below.

In addition to policies and procedures to prevent perinatal HBV transmission, ***all delivery hospitals should implement standing orders for administration of hepatitis B vaccination before hospital discharge as part of routine medical care*** of all medically stable infants weighing ≥2,000 grams at birth.

On a case-by-case basis and only in rare circumstances, the first dose may be delayed until after hospital discharge for an infant who weighs at least 2,000 grams and whose mother is HBsAg negative. When such a decision is made, a physician's order to withhold the birth dose and a copy of the original laboratory report indicating that the mother was HBsAg negative during this pregnancy should be placed in the infant's medical record. For infants who do not receive a first dose before hospital discharge, the first dose should be administered no later than age 2 months.

Situations in which the birth dose *should not be delayed* include any high-risk sexual or drug-using practices of the infant's mother during pregnancy (e.g., more than one sex partner during the previous 6 months or an HBsAg-positive sex partner, evaluation or treatment for an STD, or recent or current injection-drug use) and expected poor compliance with follow-up to initiate the vaccine series.

Box 1.3. Delivery Hospital Policies and Procedures to Prevent Perinatal HBV Transmission

At time of admission for delivery

- Review hepatitis B surface antigen (HBsAg) status of all pregnant women.
- Record maternal HBsAg test results on both labor and delivery record and on infant's delivery summary sheet.
- Perform HBsAg testing as soon as possible on women who
  - — do not have a documented HBsAg test result;
  - — were at risk for HBV infection during pregnancy (e.g., more than one sex partner in the previous 6 months, evaluation or treatment for a sexually transmitted disease, recent or current injection-drug use, or HBsAg-positive sex partner); or
  - — had clinical hepatitis since previous testing.

After delivery

HBsAg-positive mothers and their infants

- Administer single-antigen hepatitis B vaccine and hepatitis B immune globulin (HBIG) to all infants born to HBsAg-positive mothers $\leq$12 hours after birth and record date and time of administration of HBIG and hepatitis B vaccine in infant's medical record.
- Provide information regarding hepatitis B to HBsAg-positive mothers, including
  - — advice that they may breast feed their infants upon delivery;
  - — modes of HBV transmission;
  - — need for vaccination of their susceptible household, sexual, and needle-sharing contacts;
  - — need for substance abuse treatment, if appropriate; and
  - — need for medical management and possible treatment for chronic hepatitis B.

Mothers with unknown HBsAg status and their infants

- Administer single-antigen hepatitis B vaccine (without HBIG) to all infants born to mothers with unknown HBsAg status $\leq$12 hours after birth and record date and time of administration of hepatitis B vaccine on infant's medical record.
- Alert infant's pediatric health-care provider if an infant is discharged before the mother's HBsAg test result is available; if the mother is determined to be HBsAg positive, HBIG should be administered to the infant as soon as possible, but no later than age 7 days.

All mothers and their infants

- Administer a dose of single-antigen hepatitis B vaccine to all infants weighing $\geq$2,000 g.
- Ensure that all mothers have been tested for HBsAg prenatally or at the time of admission for delivery, and document test results.

At time infant is discharged

- Provide infant's immunization record to mother and remind her to take it to the infant's first visit to pediatric health-care provider.

Source: CDC. A comprehensive immunization strategy to eliminate transmission of hepatitis B virus infection in the United States: recommendations of the Advisory Committee on Immunization Practices (ACIP). Part 1: immunization of infants, children, and adolescents. *MMWR* 2005 (RR-16).

Pediatric Care Provider Practices

Pediatric care providers should establish practices for ***ensuring appropriate follow-up of infants born to HBsAg-positive mothers and infants born to mothers with unknown HBsAg status at the time of delivery.*** These practices should include the following:

- For all infants, complete the hepatitis B vaccine series according to a recommended vaccination schedule, and document the date of administration of each dose of the vaccine series.
- Identify and manage infants born to mothers who did not have a documented HBsAg test at the time of delivery. This requires obtaining maternal HBsAg test results from the delivery hospital laboratory and providing appropriate management on the basis of those results:
  - If the mother is found to be HBsAg positive, her infant should receive HBIG as soon as possible but no later than age 7 days, and the vaccine series should be completed according to a schedule for infants born to HBsAg-positive mothers.
  - If the mother is found to be HBsAg negative, the vaccine series should be completed according to a recommended schedule for infants born to HBsAg-negative mothers.
- For preterm infants weighing <2,000 grams at birth, the initial vaccine dose (birth dose) should not be counted as part of the vaccine series because of the potentially reduced immunogenicity of hepatitis B vaccine in these infants. Three additional doses of vaccine (for a total of four doses) should be administered beginning when the infant reaches the chronological age of 1 month.
- For infants born to HBsAg-positive mothers, perform post-vaccination testing for anti-HBs and HBsAg after completion of the vaccine series, at 9–18 months of age (generally at the next well-child visit after administration of the final dose). Testing should not be performed before age 9 months. Test results should be managed as follows:
  - HBsAg-negative infants with anti-HBs concentrations of ≥10 mIU/mL are protected and need no further medical management.
  - HBsAg-negative infants with anti-HBs concentrations of <10 mIU/mL should be revaccinated with a second three-dose series and retested 1–2 months after the last dose of vaccine.
  - Infants who are HBsAg positive should receive appropriate follow-up and should be reported to the health department.

LAWS AND REGULATIONS

Laws and regulations concerning perinatal hepatitis B screening, reporting, and case management vary by state. Some states legislate public health practice, whereas others give regulatory power to the state health agency. The content and effect of the resulting laws and regulations vary as well. As a perinatal hepatitis B prevention coordinator, you must not only be knowledgeable about applicable laws and regulations, but should also be prepared to educate relevant health-care providers and laboratory staff about their implications. Furthermore, you might consider reviewing current state laws to determine whether they should be expanded or improved.

Many states have found that the best way to ensure that HBsAg screening and reporting becomes a standard practice is to enact screening and reporting laws. Most states have enacted laws requiring HBsAg screening of all pregnant women and have made positive HBsAg status in pregnant woman a reportable condition for the health-care provider and laboratory. Some states have legislated case management of infants born to HBsAg-positive mothers. In some cases, the law specifies that hepatitis B immune globulin (HBIG) and the first dose of hepatitis B vaccine should be provided to the infant within 12 hours of birth. Information about state perinatal hepatitis B reporting requirements is available at http://www.cste.org/nndsssurvey/2004nndss/nndss2005.asp. A basic overview of hepatitis B prevention mandates is provided at http://www.immunize.org/laws/hepb.htm.

Creating a law does not ensure that every case will be reported to you, but it does provide a legitimate basis for you to seek that information from health-care providers and laboratories. Placing the minimum activities required of health-care providers and hospitals into statute not only provides a basis for legal action but also provides motivation for hospitals and health-care providers to think about their own perinatal hepatitis B prevention policies. Unfortunately, legislating perinatal hepatitis B prevention policy does not automatically change the practices of health-care providers, hospitals, and laboratories. Ensuring true change and improvement in the program requires proper education of everyone involved in the screening, identification, and case management of HBsAg-positive women and their infants.

Laws and regulations can affect a perinatal hepatitis B prevention program in at least two ways. First, they can establish requirements that must be met by the public and by health-care professionals (e.g., laws that govern screening, reporting, or immunization). Second, some laws set restrictions on how a perinatal hepatitis B prevention program can operate. For example, laws can affect how your program transfers information about a patient's immunization history. The legal status of patient information in your state will influence how this complex issue is handled. It is imperative that you are familiar with your state’s laws and regulations as they relate to your work.

State laws and regulations also protect the confidentiality of medical information. In some states, immunization information is considered part of the medical record and cannot be shared without consent. In other states, this is not the case. Many states also have laws authorizing an immunization information system, and some states have laws that specifically address the exchange of immunization information.

The Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule is a federal regulation that governs the use and disclosure of individually identifiable health-care information by providers and other entities covered by the rule. The Privacy Rule permits providers to disclose patient health information to public health professionals without the authorization of the individual. Additional information is available from the Office for Civil Rights website at http://www.hhs.gov/ocr/hipaa.