CHAPTER FOUR

CASE IDENTIFICATION AND INFORMATION TRANSFER
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Reporting Sources

One of the most difficult challenges for a perinatal hepatitis B prevention program is obtaining reports of HBsAg-positive pregnant women. To have a successful reporting system, a prevention program should have several overlapping sources of information to identify cases. Three main reporting sources are laboratories, prenatal care providers, and delivery hospitals.

Laboratory Reports

There are several advantages to using laboratory reports as a source of cases.

- Laboratory reporting is more consistent and reliable than provider reporting and is often automatic;
- Reporting by labs can be made a condition of licensure, but non-laboratory reporting sources require constant reminders and education;
- Because testing is usually done early in the pregnancy, program staff have a long time before the birth of the infant to educate the mother, inform the hospital, and identify and inform a pediatrician;
- By receiving reports early in the pregnancy, the program staff can begin vaccination of susceptible household and sexual contacts sooner. Later reporting means that the contacts have continuous exposure throughout the pregnancy.

The following are some examples of problems encountered using laboratory reporting as a source of perinatal cases:

- Sometimes the age and sex identifiers are omitted;
- Prenatal obstetric providers may not order appropriate tests;
- Some women are tested in one state but give birth in another;
- Laboratory reports do not always indicate pregnancy status, although it is sometimes implied;
- Some providers do not test at all, test only for members of perceived high-risk groups, or do not test women who were identified as a carrier in a previous pregnancy.

Having alternate reporting sources is a good way to compensate for deficiencies or periodic problems that may occur in laboratory reporting.

Provider Reports

A second possible reporting source is the prenatal provider (physician, nurse practitioner, certified midwife, etc.). Provider reporting alone should not be used to identify HBsAg-positive pregnant women. A physician can report an HBsAg-positive woman in the following ways:

- Calling program staff;
- Faxing *Physician’s Prenatal Report of HBsAg-Positive Mother* (Stock # EF11-11014) to the program. This form is available on page 33 and online at [www.texasperinatalhepb.org](http://www.texasperinatalhepb.org)
- Mailing or faxing the information to the program.

If a provider is reluctant to share medical information due to confidentiality issues, explain Section 164.512(b) of the federal Health Insurance Portability and Accountability Act (HIPAA) of 1996 (See Chapter 3) and Texas Health and Safety Code that gives DSHS authority to conduct disease investigation and gather medical information. Information is available at [www.legis.state.tx.us](http://www.legis.state.tx.us).
Health-care providers have refused access by public health officials to patient records for immunization assessment and surveillance purposes due to confusion about the intent and implementation of HIPAA. HIPAA allows for all providers, hospitals and laboratories to report HBsAg-positive women to local health agencies without the authorization of the individual. This includes the HBsAg status of the pregnant woman, serologic and vaccine information on the newborn and household and sexual contact.

Every opportunity to speak with providers is a chance to educate them on the importance of reporting. When possible, program staff should establish contact with identified providers and offer information on the Perinatal Hepatitis B Prevention Program, educational materials, and assistance with establishing policies and procedures for screening pregnant women for HBsAg. Provider education and assistance can be accomplished using a variety of methods:

- Perinatal Hepatitis B Prevention Program Provider brochure (Stock # E59-12547) available at: [www.texasperinatalhepb.org](http://www.texasperinatalhepb.org);
- Program materials and letters containing information about the prevention program can be mailed to the physician's office (Refer to attached Manual CD Rom);
- A visit to the physician’s office can be scheduled;
- Presentations can be given during grand rounds or during other in-services to office staff.
Physician’s Prenatal Report of HBsAg-positive Mother

MOTHER’S INFORMATION:
Name: ________________________________

DOB: __/__/____
Address: _______________________________________

Phone number: (_____)____________________

Mother’s preferred language: _______________________

Gravida: ______ Para: ______

PRENATAL CARE PROVIDER INFORMATION:
Name: ________________________________

Address: _______________________________________

Phone number: (_____)____________________

PLANNED DELIVERY HOSPITAL INFORMATION:
Name: ________________________________

Phone number: (_____)____________________

EDC: _______________________________________

MOTHER’S TEST RESULTS:
Date(s) of Result: _______________________

☐ HBsAg Result: _______________________
☐ anti-HBc Result: _______________________
☐ anti-HBc IgM Result: _______________________
☐ anti-HBs Result: _______________________
☐ HBeAg Result: _______________________

INFANT INFORMATION:
Name: ________________________________

Infant DOB: __/__/____
Time of birth: _______________________

Post-birth Vaccination Information:

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>HBIG</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date</td>
<td></td>
</tr>
<tr>
<td>Time</td>
<td></td>
</tr>
<tr>
<td>Formulation</td>
<td></td>
</tr>
<tr>
<td>Dose</td>
<td></td>
</tr>
<tr>
<td>Manufacturer</td>
<td></td>
</tr>
<tr>
<td>Lot #</td>
<td></td>
</tr>
</tbody>
</table>

INFANT CARE PROVIDER INFORMATION:
Provider’s Name: ________________________________

Provider’s Address: _______________________________________

Provider’s Phone number: ________________________________

REPORTED BY:
Name: ________________________________
Phone Number: (_____)____________________
Hospital Reports

Perinatal prevention programs also use hospital reports to identify infants born to HBsAg-positive women. In order to use the hospital as a reporting source, it will be necessary to educate individuals who are responsible for determining a pregnant woman's HBsAg status and administering HBIG and HB vaccine to the newborn. The program must target hospital in-service training presentations to staff physicians, labor and delivery nursing staff, newborn nursery staff, pharmacy staff, and infection control staff. When possible, program assistance should be offered to develop hospital policies and procedures regarding screening and treatment standards (see Checklist for Hospital Perinatal Hepatitis B Policies and Protocol for Identification of Women Admitted for Delivery on page 38 and at www.immunize.org/catg.d/p2130per.pdf).

Perinatal Hepatitis B Prevention Program staff should encourage reporting by making the process as easy as possible, and by helping each hospital identify what works best for that particular facility (for example, reporting by nursing staff or by infection control staff). Hospital staff designated to identify and report cases should either call in a case report or complete and mail or fax in the case report form: Hospital Delivery Report of HBsAg-positive Mother (Stock #E F11-1101 5). This form is available on page 35 and at www.texasperinatalhepb.org. Program staff are responsible for completing the paperwork on cases that are called in by hospitals.

Information Transfer

The figure below illustrates the information that must be transferred for a perinatal hepatitis B prevention program to succeed.

Figure 4. Flow of Information
Hospital Delivery Report of HBsAg-positive Mother

REPORTING FACILITY INFORMATION:
Name and Address:

Phone: ( )

MOTHER’S INFORMATION:
Name:

DOB: __/__/____
Address:

Phone: ( )
Mother’s preferred language:

Gravida: _______Para: _______

PROVIDER INFORMATION:
Name:

Address:

Phone: ( )

MOTHER’S TEST RESULTS
Date(s) of Result: ______________________

☐ HBsAg Result:
☐ anti-HBc Result:
☐ anti-HBc IgM Result:
☐ anti-HBs Result:
☐ HBeAg Result:

INFANT’S INFORMATION:
Name:

DOB: __/__/____
Time of birth: ______________________

Post-birth Vaccination Information:

<table>
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<tr>
<th>Date</th>
<th>Vaccine B</th>
<th>HBIG</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time</td>
<td>Formulation</td>
<td>Dose</td>
</tr>
</tbody>
</table>

PROVIDER INFORMATION:
Name:

Address:

Phone: ( )

REPORTED BY:
Name:
Location:
Role of the Hospital

Prevention and eventually elimination of perinatal and childhood HBV transmission in the United States is possible, but it requires coordinated efforts of three groups: providers of prenatal, obstetrical, neonatal, and pediatric care; hospitals; and health departments.

Hospitals and obstetrical providers are mandated to screen all pregnant women prenatally and at delivery for each pregnancy and report HBsAg-positive pregnant women to the health department. They should document maternal HBsAg results with dates of testing in all infant medical records.

Once an infant is born to an HBsAg-positive woman, hospitals and neonatal care providers should provide post-exposure prophylaxis (PEP) by administering hepatitis B vaccine and hepatitis B immune globulin (HBIG) to infants within 12 hours of birth. After the infant is discharged from the hospital, pediatric care providers should complete the hepatitis B vaccine series according to the recommended schedule and perform post-vaccination testing for both antibody to HBsAg (known as anti-HBs) and for HBsAg after completion of the vaccine series.

When an infant is born to a woman of unknown HBsAg status, the hospitals and obstetrical care providers are responsible for performing HBsAg testing of the mother. If the mother is HBsAg-positive, this must be reported to the health department. Hospitals and neonatal care providers are responsible for providing post-exposure prophylaxis to infants born to mothers of unknown HBsAg status by giving hepatitis B vaccine within 12 hrs of birth. If the mother is subsequently identified as HBsAg positive, the infant should also be given HBIG no later than seven days after birth.

The ACIP recommends that hospitals should enroll in their state’s Vaccines for Children (VFC) Program so that free vaccine can be obtained for all infants who qualify. If your hospital is not enrolled in the Texas Vaccines for Children (TVFC) Program, please contact TVFC Program at (800) 252-9152 or visit the website for more information at www.immunizeTexas.com.

Hospitals must consider developing written policies to ensure the screening of pregnant women whose HBsAg status is unknown in order to manage their infants appropriately. These policies should include standing orders for the following key elements of a prenatal program:

- Review the maternal HBsAg status;
- Test all mothers for HBsAg at delivery;
- Provide the first dose of hepatitis B vaccine to all infants before hospital discharge regardless of mother’s HBsAg status;
- Provide immunoprophylaxis to infants of HBsAg-positive mothers;
- Provide immunoprophylaxis to any infant whose mother’s HBsAg status is unknown.
The Importance of the Hepatitis B Birth Dose

In a statement in December 2005, the Advisory Committee on Immunization Practices (ACIP), American Academy of Pediatrics (AAP) and American Academy of Family Physicians (AAFP) recommended that hepatitis B vaccine be administered to all infants at birth or prior to hospital discharge. They also recommended 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 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 to the infant. Guidelines for standing orders in labor & delivery and nursery units to prevent hepatitis B virus transmission to newborns are listed at www.immunize.org/catg.d/p2130per.pdf.
Guidelines for Standing Orders in Labor & Delivery and Nursery Units to Prevent Hepatitis B Virus Transmission to Newborns

To obtain the Centers for Disease Control and Prevention (CDC) recommendations for preventing hepatitis B in infants, children, and adolescents, visit CDC's website at www.cdc.gov/mmwr/PDF/mm5416.pdf.

In December 2005, the Centers for Disease Control and Prevention (CDC) published updated recommendations of the Advisory Committee on Immunization Practices (ACIP) for prevention of hepatitis B virus (HBV) infections in infants, children, and adolescents. The American Academy of Pediatrics, American Academy of Family Physicians, and American College of Obstetricians and Gynecologists have endorsed these recommendations. To obtain a copy, go to www.cdc.gov/mmwr/PDF/mm5416.pdf.

CDC recommends that all delivery hospitals institute standing orders to ensure:

- Administration of hepatitis B vaccine to all medically stable newborns weighing at least 2 kg (4.4 lb) at birth before discharge from the nursery.
- Identification of infants born to hepatitis B surface antigen (HBsAg)-positive mothers and infants born to mothers with unknown HBsAg status and administration of appropriate immunoprophylaxis to these infants.

The guidance below has been developed to help your hospital establish standing orders in the labor and delivery and nursery units and has been reviewed by CDC staff for consistency with ACIP recommendations.

**Labor and Delivery (L&D)**

Upon admission, review the HBsAg status of all pregnant women. You must review a copy of the mother's original laboratory report to verify that the correct test was performed during this pregnancy and to verify the test date. Do not rely on a transcribed test result.

**For women with a documented HBsAg test result**

- Place a copy of the original laboratory report of the mother’s HBsAg test result into (1) the mother’s L&D record and (2) the infant’s medical record.
- If the mother is HBsAg positive, alert the nursery staff.
- If the mother is HBsAg negative and is at risk for HBV infection during this pregnancy (e.g., had more than one sex partner in the previous 6 months; had an HBsAg-positive sex partner; had evaluation or treatment for a sexually transmitted disease; currently uses or recently used injection drug), perform a repeat test for HBsAg. If HBsAg is positive, instruct the laboratory to call L&D and the nursery with the HBsAg test result ASAP.

**For women without a documented HBsAg test result**

- Perform HBsAg testing ASAP on women who do not have a documented HBsAg test result from the current pregnancy.
- Instruct the lab to call L&D and the nursery with the HBsAg test result ASAP.

**Nursery**

For all newborns:

- Review a copy of the mother’s original HBsAg test report. Provide appropriate management based on (1) the mother’s HBsAg status and (2) the infant’s birth weight. Manage those who weigh less than 2 kg differently from those who weigh 2 kg or more (see below and footnotes 2, 5, 6).
- Ensure that a copy of the original maternal HBsAg laboratory report is in the infant’s medical record.

**For infants born to HBsAg-negative mothers**

- Administer single-antigen hepatitis B vaccine (0.5 mL, IM) before discharge to all infants weighing at least 2 kg at birth.1,2,4 Document the hepatitis B vaccine dose appropriately in the infant’s medical record, including date and time of administration.
- Give the mother an immunization record card that includes the hepatitis B vaccination date, and explain the need for a complete hepatitis B vaccine series to fully protect her baby. Remind the mother to bring the card with her each time her baby sees a provider.

**For infants born to mothers with unknown HBsAg status**

- Administer single-antigen hepatitis B vaccine (0.5 mL, IM) within 12 hours of birth.3,5 Do not wait for test results to return before giving this dose of vaccine! Document the hepatitis B vaccine dose appropriately.
- Give the mother an immunization record card that includes the hepatitis B vaccination date. Explain the need for further doses to fully protect her baby. Remind the mother to bring the card with her each time her baby sees a provider.
- Confirm that the laboratory has received serum for the mother’s HBsAg test. Verify when the HBsAg result will be available and that it will be reported to L&D and the nursery ASAP. If the nursery does not receive the report at the expected time, call the laboratory for the result.
- If the mother’s HBsAg test result comes back positive:
  - Administer hepatitis B immune globulin (HBIG 0.5 mL, IM) to the infant ASAP. Document the HBIG dose appropriately in the infant’s medical record. There is little benefit in giving HBIG if more than 7 days have elapsed since birth.
  - Alert the mother’s and infant’s physician(s) of the test result.
  - Follow the instructions below for infants born to HBsAg-positive mothers.
- If the infant must be discharged before the HBsAg result is known:
  - Document contact information for the parents (e.g., addresses, (continued on next page))
telephone numbers, emergency contacts) in case further treatment is needed.
• Obtain the name, address, and phone number of the mother’s and the infant’s healthcare provider.
• Notify the mother’s and the infant’s healthcare provider that the mother’s HBsAg test result is pending.

For infants born to HBsAg-positive mothers
• Administer HBIG (0.5 mL, IM) and single-antigen hepatitis B vaccine (0.5 mL, IM) at separate injection sites within 12 hours of birth. Document the hepatitis B vaccine and HBIG doses appropriately in the infant’s medical record, including date and time of administration.
• Give the mother an immunization record card that includes the date of the hepatitis B vaccine and HBIG doses, and explain the need for further doses of hepatitis B vaccine to fully protect her baby. Remind the mother to bring the card with her each time her baby sees a provider.
• Notify the local or state health department of the infant’s birth and the date and time of administration of HBIG and hepatitis B vaccine doses.
• Obtain the name, address, and phone number of the infant’s primary care provider. Notify the provider of the infant’s birth, the date and time of HBIG and hepatitis B vaccine doses administered, and the importance of additional on-time vaccination and postvaccination testing of the infant for HBsAg and antibody to HBsAg after completion of the hepatitis B vaccine series.
• Provide advice to the mother. Tell her:
• About the importance of her infant completing the full hepatitis B vaccine series on schedule
• About modes of HBV transmission and the need for vaccination of her susceptible household, sexual, and needle-sharing contacts
• That she may breast-feed her infant upon delivery, even before hepatitis B vaccine and HBIG are given
• That blood will need to be drawn from the infant after completion of the hepatitis B vaccine series at age 9–18 months to determine if the infant needs further management
• That she needs to have a medical evaluation for chronic hepatitis B, including an assessment of whether she is eligible for antiviral treatment

Footnotes
1. Be sure the correct test for HBsAg (hepatitis B surface antigen) was done. The HBsAg test should not be confused with other hepatitis B serologic tests, including antibody to HBsAg (anti-HBs) or HBsAb and antibody to hepatitis B core antigen (anti-HBc or HBCAb).
2. Infants weighing less than 2 kg whose mothers are documented to be HBsAg negative should receive the first dose of vaccine 1 month after birth or at hospital discharge. The mother’s HBsAg status must be part of the infant’s medical record.
3. Federal law requires that you give parents a Hepatitis B Vaccine Information Statement (VIS) before vaccine administration. To obtain a VIS, download from the IAC website at www.immunize.org or call your state health department.
4. Exceptions to giving the birth dose of hepatitis B vaccine are allowed on a case-by-case basis and only in rare circumstances. 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 infant’s medical record and the attending physician must write a specific order directing staff not to administer the birth dose in the hospital.
5. An infant weighing less than 2 kg whose mother’s HBsAg status is unknown should receive HBIG and hepatitis B vaccine within 12 hours of birth. Do not count the hepatitis B vaccine dose as the first dose in the vaccine series. Reinitialize the full hepatitis B vaccine series at age 1–2 months.
6. An infant weighing less than 2 kg whose mother is HBsAg positive should receive the first dose of hepatitis B vaccine and HBIG within 12 hours of birth. Do not count the hepatitis B vaccine dose as the first dose in the vaccine series. Reinitialize the full hepatitis B vaccine series at age 1–2 months.

To access a CDC web page that includes a text version of the recommendations, a “Dear Colleague” letter that explains details of the recommendations, an archived net conference, brochures, slide sets, and more, go to: www.cdc.gov/ncll/dod/diseases/hepatitis/b/acip.htm