

# Chapter 1

## Program Background and Introduction



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# Background

The Texas Department of State Health Services (DSHS) Perinatal Hepatitis B Prevention Program (PHBPP) was first implemented in 1991 in Harris, Tarrant, and Dallas counties as well as the cities of Houston and San Antonio. In 2001, the program was expanded to provide services to the entire state.

Although vaccine prevention and awareness has steadily increased since the start of the program, it was estimated in 2013 by the National Health and Nutrition Examination Survey (NHANES) that 1,038 to 1,483\* infants were born to HBsAg-positive women in Texas. However, only 562\* infants were identified as being born to HBsAg-positive women.

In 2013, a total of 3,050 cases of acute hepatitis B were reported nationwide to the Centers for Disease Control and Prevention (CDC); the highest rate was amongst 30 - 39 year olds. From 2003 - 2011, rates of acute hepatitis B declined among all age groups. From 2011 - 2013 rates of acute hepatitis B increased among both the 30 - 39 year old and 40 - 49 year old age groups but remain steady amongst the other age groups.

Perinatal transmission of the hepatitis B virus (HBV) is highly efficient and usually occurs from blood exposures during labor and delivery. Although in utero transmission is rare, it does account for less than two percent of perinatal infections in most studies. Every year, more than 24,000 infants are born to women chronically infected with hepatitis B. Without timely post-exposure prophylaxis (PEP) at birth, approximately 10,000 of these infants would become chronically infected themselves, while 2,500 would die of liver failure or liver cancer as early as age 10.

Transmission to these high-risk babies could be prevented 85 - 95 percent of the time by providing appropriate PEP within 12 hours of birth, as described in this manual. Although perinatal hepatitis B has been nationally notifiable since 1995, reported cases have not been reliable for monitoring purposes.

Less than five percent of the HBV infections that occur among children are reported as cases of acute hepatitis B to the CDC because these infections in infants and children rarely produce signs or symptoms of disease until complications arise. Infants infected during their first year of life have an 80 - 90 percent chance of developing a chronic HBV infection compared to only 30 -50 percent of children infected after the first year of life, but before age six. Alternatively, less than five percent of otherwise healthy adults who become infected during adulthood will develop a chronic infection. Prior to routine PEP of infants and children, cases occurring in children accounted for a disproportionate amount of the disease burden due to chronic infection.

According to the 2014 National Immunization Survey (NIS), 86.5 percent of Texas children aged 19 - 35 months, have three or more doses of hepatitis B vaccine. The 2014 NIS results also show that 77.4 percent of children in Texas received the first dose of hepatitis B vaccine between birth and three days of age.

\*Numbers are not inclusive of City of Houston and City of San Antonio.

Screening of all pregnant women for hepatitis B has been recommended since 1991 by the American College of Obstetricians and Gynecologists (ACOG), the American Academy of Pediatrics (AAP), and the Advisory Committee on Immunization Practices (ACIP). On June 18, 1999, Governor George W. Bush signed legislation requiring pregnant women in Texas to be screened for HBV infection at their first prenatal examination and at delivery for each pregnancy. This law became effective September 1, 1999, and applies to the provider who attends to a pregnant woman during gestation and/or at delivery of her infant.

Under Texas law, both acute and chronic cases of hepatitis B in a pregnant woman are conditions that must be reported to the DSHS. The Texas Health & Safety Code Title 2, Chapter 81 authorizes LHDs to conduct disease investigations and gather all pertinent medical information.

## Key Elements of the Perinatal Hepatitis B Prevention Program (PHBPP)

The DSHS Immunization Branch PHBPP has several important features including, but not limited to: surveillance, case management, promotion of the universal birth dose and collaboration between DSHS HSR offices, LHDs, medical providers, and laboratories. The ten objectives of the program are listed below. All case management and reporting forms can be found online at [www.texasperinatalhepb.org](http://www.texasperinatalhepb.org).

### 1) Ensure that all pregnant women are tested for hepatitis B surface antigen.

- According to Texas law, providers must screen pregnant women for hepatitis B infection at the first prenatal examination (regardless of trimester) and upon delivery, or as soon as feasibly possible thereafter.
- The CDC recommends the HBsAg as the preferred test for screening for HBV infection during pregnancy.
- HBsAg testing should be incorporated into standard prenatal testing panels used by all providers caring for pregnant women. It is recommended that the hepatitis B serologic marker (HBsAg) and reason for testing (pregnancy) be specified when submitting these specimens to the laboratory.
- Providers should notify all HBsAg-positive pregnant women of their positive status as soon as possible and give them a copy of the original laboratory result.
- Providers should provide education to all HBsAg-positive pregnant women regarding the potential risks to their unborn child and what measures can be taken in an effort to protect the child from transmission (HBIG, hepatitis B vaccine series, PVST). The patient should also be informed that the DSHS HSR or LHD will be contacting them for case management.
- Delivery hospitals should determine if a pregnant woman presenting to their hospital was screened for HBsAg prenatally and document those results in both the mother and infant's medical records.
- Delivery hospitals must draw blood to screen for HBV infection upon delivery, regardless of the result obtained at the prenatal examination.

- Delivery hospitals should safeguard against errors in maternal HBsAg testing and failures in test reporting. This can be done by:
  - Maintaining standing orders for immediate HBsAg testing of all pregnant women.
  - Ordering admission lab tests that specify to draw “HBsAg” – this will help to avoid confusion with other hepatitis serologic markers.
  - Including a copy of the original HBsAg laboratory report in the delivery record.

## **2) Ensure reporting and tracking of HBsAg-positive women.**

- All HBsAg-positive pregnant women must be reported to the DSHS Immunization Branch PHBPP for case management of the mother and infant(s).
- Reporting can be accomplished by reporting directly to the appropriate DSHS HSR or LHD.

## **3) Ensure that delivery facilities / hospitals receive all prenatal HBsAg lab reports prior to delivery.**

- HBsAg test results should be included on all forms (hard copy and electronic) used by providers to record and transmit information about care during pregnancy.
- For all pregnant women, a copy of the original HBsAg laboratory result should be transferred from the prenatal care provider to the delivery hospital with the mother’s medical records.
- Providers caring for HBsAg-positive pregnant women should remind delivery staff (doctors, midwives, nurses) of HBsAg-positive status during a client’s pregnancy to ensure that the baby receives all necessary care upon delivery, using the above methods.

## **4) Ensure identification and management of infants born to HBsAg-positive mothers. (Please refer to Chapter 4 on PEP guidelines.)**

- Delivery facilities / hospitals should implement policies and procedures to ensure proper identification of HBsAg-positive pregnant women and their infants. Please refer to Appendix E for examples.
- All infants born to HBsAg-positive women require the administration of PEP within 12 hours of birth. Delivery facilities / hospitals should document all required information. Please refer to number 5 under Key Elements for reporting information.
- Document proper health information on infant’s birth certificate (hepatitis B infection during pregnancy).
- If an HBsAg-positive mother refuses PEP for her newborn, providers must ensure that the mother is informed and educated about her status and the potential consequences to her newborn(s) and the option to receive PEP up to seven days after delivery.
- Document in the infant’s medical record the mother’s signed declination / against medical advice (AMA) form (facility specific) against the medically-recommended treatment of her infant(s) and all education provided regarding hepatitis B and the potential consequences to her newborn.

## 5) Ensure reporting of infants born to HBsAg-positive mothers.

- Infants born to HBsAg-positive mothers must be reported within one day by completing the Hospital / Provider Report form and sending it to either their DSHS HSR or LHD.
- Delivery facilities / hospitals must report all of the information mentioned above in number 4 - Key Elements regarding birth, HBIG, and hepatitis B vaccine on the appropriate forms.
- Delivery facilities / hospitals should document the following information on the Hospital / Provider Report form:
  - maternal HBsAg status (and other serology) at time of delivery
  - provider (doctor/clinic)
  - date and time of birth
  - birth weight
  - HBIG and hepatitis B vaccine administration
    - date and time
    - lot number
    - manufacturer\*
    - formulation / brand name (i.e., Engerix-B<sup>®</sup>, Recombivax HB<sup>®</sup>, HepaGam HB<sup>®</sup>, HyperHEP B<sup>®</sup>, Nabi-HB<sup>®</sup>, etc.)

\* A chart with formulations and manufacturers of HBIG can be found in Chapter 4, postexposure prophylaxis (PEP).

## 6) Ensure identification and management of infants born to mothers of unknown HBsAg status. (Please refer to Chapter 4 on PEP guidelines.)

- Delivery facilities / hospitals should implement policies and procedures to ensure prompt identification and appropriate PEP administration to infants born to women of unknown HBsAg status.
- An infant whose mother's HBsAg test result comes back positive should immediately receive HBIG.
- Document proper health information on infant's birth certificate (i.e., hepatitis B during pregnancy).

## 7) Ensure timely completion of the hepatitis B vaccine series for all infants born to HBsAg-positive mothers. (Please refer to Chapter 4 for use of combination vaccines.)

- Dose one should be given within 12 hours of birth, but ideally no later than hospital discharge.
- Dose two should be given at one month of age, but no later than two months of age.
- Dose three should be given at six months of age:
  - Must be at least eight weeks after dose two
  - At least 16 weeks after dose one

- Combination vaccines may be used to complete the series, giving the infant a total of four doses of hepatitis B vaccine.
- Providers should document the date, lot number, and name / manufacturer for each dose of the hepatitis B vaccine administered to the infant.
- If the child was not already registered for the Texas Immunization Registry (ImmTrac), at birth, parental consent should be obtained and the vaccination history of infants should be entered into ImmTrac as soon as possible after each visit.

**8) Ensure timely completion of PVST for all infants born to HBsAg-positive women.**

- To determine infant outcomes after appropriate PEP, PVST should be performed on all infants born to HBsAg-positive women once:
  - the infant has completed a full hepatitis B vaccine series;
  - the infant is at least nine months of age; and
  - at least one month has passed since the infant received the final dose of a hepatitis B containing vaccine.
- Providers should order:
  - HBsAg; and
  - Anti-HBs
- Providers should document the infant's PVST and report results (positive or negative) to their DSHS HSR or LHD.

**9) Ensure vaccination of household contacts ≤ 24 months of age. (Please refer to Chapter 9 for case management of household contacts.)**

- Household contacts 24 months of age and younger must be identified and a case management record initiated within 15 days of notification.
- These contacts must be offered serologic testing (HBsAg and anti-HBs) and, if susceptible to HBV infection, initiate the hepatitis B vaccine series. If needed, both the testing and vaccine are provided free of charge through the PHBPP for all contacts ≤ 24 months of age. Please refer to Chapter 9 for additional information.
- Records for contacts ≤ 24 months of age are closed upon hepatitis B vaccine series completion and PVST results. Revaccination may be needed before the case can be closed.
- All contacts > 24 months of age, and sexual partners to the HBsAg-positive mother, should be referred to a health care provider for health care evaluation.

**10) Ensure program quality, monitoring, and evaluation.**

- Within the quarterly report time frames, each DSHS HSR and LHD should report the following to the DSHS Immunization Branch PHBPP as part of their grant activity report:
  - number of HBsAg-positive pregnant women identified;
  - number of HBsAg-positive pregnant women referred for medical follow up;

- number of infants born to HBsAg-positive women; and
- number of susceptible household contacts that are  $\leq$  24 months of age.

**Note:** For comprehensive information regarding grant activities, please visit <http://www.dshs.state.tx.us/immunize/providers.shtm>.

- If any of the below occur, an Investigational Report form should be completed to determine the cause:
  - Missed maternal screening during pregnancy and / or at delivery;
  - Infant does not receive the appropriate PEP within 12 hours of birth;
  - Child misses any of the hepatitis B vaccine doses; or
  - PVST is not done as required.
- Once the case manager has identified problems on the Investigational Report form, training will be provided by the DSHS HSR or LHD in an attempt to correct any identified error(s).