California Perinatal Hepatitis B Prevention Program

California Department of Public Health
Perinatal Hepatitis B Prevention Program
COORDINATOR HANDBOOK

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Note to the Reader

The following materials are intended to be used by local perinatal hepatitis B (HBV) prevention coordinators and other health department staff who provide follow up for HBV-infected pregnant women and their infants. The guidance provided in this manual is based on current recommendations of the CDC and the ACIP.

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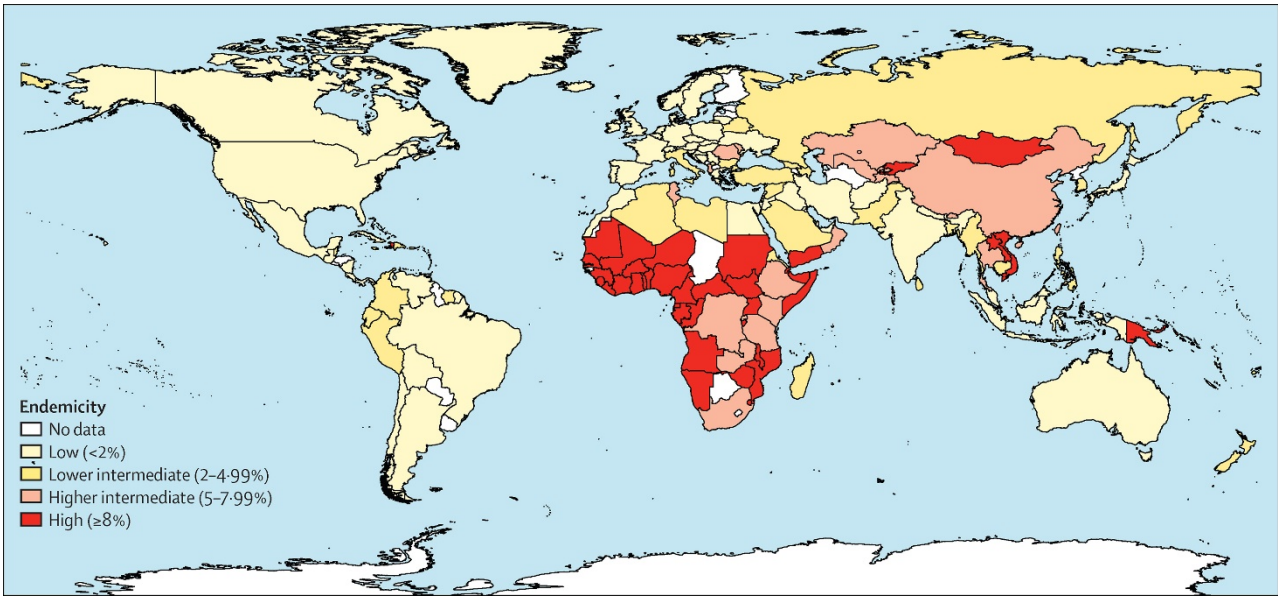
Chapter One: Introduction to Perinatal Hepatitis B

Background

Hepatitis B is a serious liver disease caused by the hepatitis B virus (HBV). HBV is highly infectious and can range in severity from a mild illness lasting a few weeks to a serious, lifelong illness. Although many people recover and develop natural immunity to HBV after acute (initial) infection, others, including infants infected at birth, become chronic (lifelong) carriers. Chronic HBV infection can lead to severe complications, including liver damage, cirrhosis and hepatocellular carcinoma (liver cancer) later in life. Hepatitis B prevalence is highest in sub-Saharan Africa and East Asia, where between 5–10% of the adult population is chronically infected (Figure). Worldwide it is estimated there are 350 million people with chronic HBV infection and about 620,000 people die each year from hepatitis B associated acute and chronic liver disease.[1]

Figure: Prevalence of Chronic HBV by country



Aparna Schweitzer, Johannes Horn, Rafael T Mikolajczyk, Gérard Krause, Jördis J Ott, Estimations of worldwide prevalence of chronic hepatitis B virus infection: a systematic review of data published between 1965 and 2013, The Lancet, Volume 386, Issue 10003, 2015, Pages 1546-1555, ISSN 0140-6736

HBV can be spread through contact with blood and certain body fluids of people infected with HBV, including semen, vaginal secretions, and saliva. Also, transmission of HBV can occur when the virus is passed from an infected mother to her infant during birth (perinatally). Perinatal HBV transmission

[1] Centers for Disease Control and Prevention, National Center for HIV/AIDS, Viral Hepatitis, STD, and TB, PreventionDivision of Viral Hepatitis,

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is a serious public health problem because approximately 70-95% of infants who are born to infected mothers become chronically infected if they don't receive prophylaxis.[2]

Fortunately, it is possible to prevent perinatal HBV infection. Once it is determined that a pregnant woman is infected with HBV, it is recommended that her exposed infant receive immunoprophylaxis, consisting of hepatitis B immune globulin (HBIG) and the first dose of hepatitis B vaccine, within the first 12 hours of life. When followed by completion of a three-dose hepatitis B vaccine series, development of disease is prevented in 85-95% of infants born to infected mothers.[3]

Another important intervention to prevent perinatal HBV infection is antiviral therapy during the third trimester of pregnancy. Antiviral treatment is recommended for all HBsAg positive pregnant women who have an HBV viral load greater than 200,000 IU/ml.[4] Antiviral treatment for HBV, in conjunction with HBIG and hepatitis B vaccine series, can further reduce the risk of perinatal HBV infection among infants whose mother's had high HBV DNA levels during pregnancy.

In 1989, infection with HBV became a reportable condition under Title 17 of the California Code of Regulations (Appendix B).[5] Additionally, the California Health and Safety Code prenatal hepatitis B screening law became effective in 1991 and requires that all pregnant women be serologically screened for hepatitis B surface antigen (HBsAg) (Appendix B).[6] This law, supported by the American College of Obstetricians and Gynecologists (ACOG) and the American Academy of Pediatrics (AAP), was designed to identify pregnant women who are infected with hepatitis B.

A comprehensive strategy to eliminate HBV transmission was first recommended by the Advisory Committee on Immunization Practices (ACIP) in 1991, and later updated in 2005 and 2018.[7] In California, an essential part of implementing this strategy was the establishment of the California Perinatal Hepatitis B Prevention Program (CA PHPP) by the California Department of Public Health (CDPH) in 1991.

Approximately 2,000-2,500 pregnant women infected with HBV are identified and enrolled in the CA PHPP each year. More detailed information can be found on the Immunization Branch website and selecting the appropriate Vaccine-Preventable Disease Summary.

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[2] Wong, VC, Ip HM, Reesink HW, et al. Prevention of the HBsAg carrier state in newborn infants of mothers who are chronic carriers of HBsAg and HBeAg by administration of hepatitis-B vaccine and hepatitis-B immunoglobulin: double-blind randomized placebo-controlled study. Lancet 1984;1(8383):921-6.
[3] Schillie S, Vellozzi C, Reingold A, et al. Prevention of Hepatitis B Virus Infection in the United States: Recommendations of the Advisroy Committee on Immunization Practices. MMWR Recomm Rep 2018;67(No. RR-1):1-31. DOI: http://dx.doi.org/10.15585/mmwr.rr6701a1
[4] Terrault NA, Bzowej NH, Chang K-M, et al. AASLD guidelines for treatment of chronic hepatitis B. *Hepatol Baltim Md*. 2016;63(1):261-283. doi:10.1002/hep.28156
[5] California Code of Regulations (CCR), Title 17, § 2500, § 2593, §2641-2643, and §2800-2812.
[6] California Health and Safety (H&S) Code § 125050-125119.5.
[7] Ibid

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Program Objectives:

The objective of the program is to prevent transmission of HBV by ensuring the following:

- Prenatal testing of pregnant women for HBV to identify infected mothers.
- Prophylaxis and vaccination of infants born to HBV-positive women.
- Post-vaccination serologic testing for the infants at 9 through 12 months of age to confirm immunity; and
- Serologic screening and vaccination of susceptible household contacts.

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Chapter Two: Identifying HBV-infected Pregnant Women

Screening

Perinatal HBV prevention starts with screening all women for HBsAg during pregnancy. California Health and Safety Code[8] (§125080 and §125085) states:

> *"As early as possible during prenatal care the person engaged in the prenatal care of a pregnant woman or attending the woman at the time of delivery shall obtain a blood specimen and submit it to a licensed or approved laboratory to determine the presence of hepatitis B surface antigen."*

California law does not require a prenatal care provider to retest a pregnant woman if the woman is already known to be HBV-infected and is under the care of a medical professional, but her HBsAg status must be documented in her prenatal medical record (H&S Code §125090 (d)) and reported to the local health department. The ACIP recommends that prenatal providers screen ***all*** women with ***each*** pregnancy, even if the provider knows she has been vaccinated or if she was previously identified as HBsAg positive.[3] When this testing is done, it ensures that the LHD receives a laboratory report for an HBV-infected woman with each pregnancy and that the infant is identified for timely prophylaxis.

If a woman's HBsAg status is unknown at the time of labor and delivery, the person engaged in the woman's prenatal care or attending the woman at delivery is legally required to order an HBsAg test "by a method that will ensure earliest possible results" (H & S Code § 125090 (d)). The ACIP guidelines also recommend that providers repeat the HBsAg test at the time of labor if the woman originally tests negative for HBsAg but is at high-risk for acquiring HBV in the last six months of the pregnancy (more than 1 sex partner, an HBsAg-positive sex partner, injection drug use, or recent evaluation or treatment for an STD).

Since some pregnant women do not receive prenatal care before delivery, it is essential to work with birth hospitals to ensure that all pregnant women who have an unknown or undocumented HBsAg status are tested at the time of admission for delivery.

For those HBV-infected women who DO receive prenatal care but are not reported to the LHJ prior to delivery, LHJs should conduct additional follow-up to determine if HBsAg testing was performed and, if so, determine why reporting did not occur earlier.

[8] California Health and Safety (H&S) Code § 125050-125119.5.

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HBV Positive Laboratory Reports

The LHD may receive reports of HBV-infected pregnant women from laboratories, prenatal care providers, or birth hospitals. Coordinators should establish relationships with all of their reporting sources to ensure that they receive reports for ALL pregnant women who are infected with HBV. The coordinator can facilitate reporting by hospitals and providers by providing them with the appropriate Quicksheets (see Appendix D).

> Laboratories are **required** to report both acute and chronic hepatitis B cases within one working day to the health department where the ordering physician is located (Title 17 CCR § 2505). California H&S Code (§125085 (B), 125090) requires laboratories to report positive HBsAg results to the local health officer. Health care providers are required to report HBsAg positive pregnant women to the LHD where the case resides (Title 17, CCR § 2500 (b)).

Electronic Laboratory Reporting

In jurisdictions using CalREDIE, the California Reportable Disease Information Exchange, electronic laboratory reports are received from laboratories and healthcare facilities statewide.

For new HBV laboratory reports received through ELR in CalREDIE, the report will be automatically imported as a suspect Chronic Hepatitis B case (process status = entered) but remain open for LHJs to review. If an HBV laboratory report is received for a previously reported Chronic Hepatitis B case, the new laboratory report will be appended to the existing record. Some laboratories may continue to submit paper-based laboratory reports so jurisdictions may need to review both electronic and paper reports. Additional information on electronic laboratory reporting can be found on the CalREDIE Help web page.

Identification of HBV-Infected Pregnant Women

Health department staff must review all reports of HBV-infected individuals to identify women who are of childbearing age (i.e., 14 to 45 yrs.) and then contact the physician's office to determine if any of these women are pregnant. If an HBsAg test is ordered as part of a prenatal panel from one of the major labs, specific CPT codes could be used to identify pregnant women (http://www.cdc.gov/hepatitis/hbv/pdfs/prenatalhbsagtesting.pdf). In jurisdictions using CalREDIE, some electronic laboratory results may indicate the patient is pregnant using the "Relevant Clinical Information" field.

All pregnant persons who test positive for HBsAg are also recommended to receive HBV DNA testing. However, some patients may have HBeAg or HBV DNA testing only and no corresponding

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HBsAg test result. These patients should be treated as infected and follow-up should proceed as with an HBsAg positive report, unless additional follow-up finds otherwise.

In absence of any other information, the LHJ can also streamline the process of identifying which infected women are pregnant by prioritizing lab tests ordered by prenatal care providers. However, all laboratory reports should be reviewed to determine pregnancy status. Coordinators should become familiar with the names of local medical providers who deliver infants, including those in family practice.

Improving identification of HBV-infected pregnant women
Despite screening and reporting laws and regulations, some HBV-infected women are not identified and some births to HBV-infected women are not reported to the health department. Perinatal HBV prevention programs and LHDs can use the following mechanisms to improve case identification:

- Periodically remind prenatal care providers and delivery hospitals to report all HBV-positive pregnant women to the health department. Provide them with a reporting form they can fax to the health department.

- Establish clear health department protocols to review HBV-positive test results to identify women of childbearing age and to determine their pregnancy status.

- Work with birth hospitals to ensure that all pregnant or delivering women have been tested for HBV before hospital discharge, and that results are reported to the LHD.

- Maintain a list of all laboratories in your jurisdiction that perform prenatal HBV testing (including birth hospital laboratories) and confirm that positive HBV test results are being reported to the health department through electronic laboratory reporting (for specific questions regarding electronic laboratory reporting, please contact CalREDIEHelp@cdph.ca.gov).

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Chapter Three: Hepatitis B Vaccination and Post-exposure Prophylaxis

Infants born to women who are acutely or chronically infected with HBV are at high risk of developing chronic HBV infection. When hepatitis B vaccine and HBIG are administered within 24 hours of birth, followed by completion of a 3-dose series of hepatitis B vaccine, PEP is 85%-95% effective in preventing acute and chronic HBV infection. HBIG and hepatitis B vaccine should be administered intramuscularly at separate anatomical sites in the anterolateral thigh, and only single antigen hepatitis B vaccine should be used. HBIG and vaccine are recommended to be given as soon as possible, or within 12 hours of birth, but may be given up to 7 days after birth.

Two types of products are available for prophylaxis against HBV infection.

1. **Hepatitis B vaccine**, which provides long-term protection against HBV infection, is recommended for pre-exposure and post-exposure prophylaxis.

2. **Hepatitis B Immune Globulin (HBIG)** is a product that contains antibodies to hepatitis B. It provides temporary protection (i.e., three to six months) and is used as passive immunization for discrete, identifiable percutaneous or mucosal exposures and for perinatal exposure.

Hepatitis B Vaccine

Hepatitis B vaccines currently licensed in the U.S. are produced by using recombinant DNA technology. HBV infection cannot result from use of the recombinant vaccine, as 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. have not contained thimerosal as a preservative, although Engerix-B contains a trace of thimerosal as residual from the manufacturing process. Single antigen hepatitis B vaccine is currently produced by three manufacturers in the United States, Merck (Recombivax HB), GlaxoSmithKline Pharmaceuticals (Engerix-B), and Dynavax Technologies Corporation (Hepislav-B). Recombivax HB and Engerix-B are available in both pediatric and adult formulations, while Heplisav -B is available in an adult formulation only. Additionally, only Recombivax HB is approved for the two-dose schedule for adolescents aged 11-15 years. Both the pediatric and adult formulations of Recombivax HB are approved for use in any age group. The pediatric form of Engerix-B is approved for children and adolescents less than 20 years of age but not for adults. The adult formulation of Engerix-B is approved for adolescents 11-19 years of age but not for infants and children. The adult formulation of Heplisav -B is approved for adults 18 years of age and older. In general, the brands of age-appropriate hepatitis B vaccines are interchangeable within an immunization series.

Hepatitis B Immune Globulin (HBIG)

HBIG is prepared from plasma from selected donors with high titer of antibody against HBsAg (anti-HBs). The human plasma from which HBIG is prepared is screened for HBsAg, antibodies to HIV and

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HCV and for HCV RNA. In addition, the process used to manufacture HBIG inactivates viruses (e.g., HBV, HCV, HIV) from the final product. There is no evidence that HIV can be transmitted by HBIG. HBIG does not contain thimerosal. HBIG given at birth does not interfere with other vaccines given at 2 months of age.

Birth Hospital - Policies, Procedures, and Standing Orders

Policies and procedures for the nursery and labor and delivery units to prevent perinatal HBV transmission must ensure:

- Identification of infants born to HBsAg-positive mothers and infants born to mothers with unknown HBsAg status
- Initiation of immunoprophylaxis for these infants.

These policies should include the following ***standing orders***:

- Review HBsAg test results of all pregnant women at the time of admission for delivery
- For women who do not have a documented HBsAg test result, perform the test as soon as possible after admission for delivery
- Identify and manage all infants born to HBsAg-positive mothers, including the provision of post exposure immunoprophylaxis
- For infants born to mothers with unknown HBsAg status, administer hepatitis B vaccine within 12 hours of birth
- For all infants, document in the infant's medical record the maternal HBsAg test results, infant hepatitis B vaccine administration, and administration of HBIG (if applicable)

In addition to policies and procedures to prevent perinatal hepatitis B transmission, ***all birth hospitals should implement standing orders for administration of hepatitis B vaccination within 24 hours of birth as part of routine medical care*** of all medically stable infants weighing ≥2,000 grams at birth.

The Immunization Action Coalition has developed a document that hospitals can use to establish standing orders entitled *Guidelines for Standing Orders in Labor & Delivery and Nursery Units to Prevent Hepatitis B Virus Transmission to Newborns.*

For mothers who do not have a documented HBsAg test at the time of delivery, maternal HBsAg test results should be obtained from the delivery hospital laboratory as soon as possible, and appropriate management provided on the basis of those results. While awaiting test results, infants should receive the first dose of HepB vaccine (without HBIG) within 12 hours of birth. Test results should be managed as follows:

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- 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. Work with the hospital, pediatric provider and mother to case manage the infant.

- 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.

Recommended Dosages of Hepatitis B Vaccines

Single-antigen Hepatitis B Vaccines (to be used for the birth dose)				
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 years	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
Heplisav-B	18 years and older	20 µg	0.5 ml	2
Combination Hepatitis B Vaccines (not to be used for the birth dose)				
Vaccine	**Age Group**	**Antigens Used**	**Volume**	**# Doses**
Pediarix	6 weeks thru 6 years.	10 mcg recombinant HBsAg plus DTaP, IPV (Engerix-B + Infanrix + IPV)	0.5 ml	3
Twinrix	18 years and older	20mcg recombinant HBsAg plus inactivated hepatitis A virus (Engerix-B + Havrix)	1.0 ml	3
Vaxelis	6 weeks thru 4 years.	10mcg recombinant HBsAg plus DTaP, IPV, Hib (Pentacel + Recombivax HB)	0.5 ml	3

For additional information on hepatitis B vaccination uses and contraindications see the Epidemiology and Prevention of Vaccine-Preventable Diseases (Pink Book) Chapter on Hepatitis B.

Post-Exposure Prophylaxis (PEP) Errors

A PEP error occurs when either HBIG or hepatitis B vaccine is given after 12 hours of birth. Failure to provide PEP within this time frame increases the infant's risk of acquiring hepatitis B infection. If this occurs, coordinators must contact the birth hospital and gather additional information about the nature of the PEP error, why it occurred, and how the hospital will prevent similar events moving forward. Additionally, for each PEP error, coordinators must complete the PEP Error Form found on the CDPH PHPP website and submit it to CDPH PHPP within 5 business days.

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Pediatric Care Provider - Policies and 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 (see Appendix A), and document the date of administration of each dose of the vaccine series.
- Vaccine providers are encouraged to use the California Immunization Registry (CAIR) or their local immunization registry to document vaccination.
- The final dose in the series should not be administered before age 24 weeks (164 days).
- Although not indicated in the manufacturer's package labeling, Pediarix may be used for infants aged ≥6 weeks born to HBsAg-positive mothers to complete the vaccine series after receipt of a birth dose of single-antigen HepB vaccine and HBIG.
- For preterm infants weighing <2,000 grams at birth, the initial vaccine 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 complete vaccination schedule, see Appendix A). The final dose in the series should not be administered before age 24 weeks (164 days).

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Chapter Four: Post-Vaccination Serologic Testing

Post-vaccination serologic testing (PVST) helps identify infants born to HBV-infected women who do not have an adequate immune response to an initial hepatitis B vaccine series and might require additional vaccination. PVST also enables early identification of HBV-infected infants. CDC recommends that infants born to HBV-infected women receive PVST consisting of a **quantitative hepatitis B surface antigen (HBsAg) test** and an **antibody to hepatitis B surface antigen (anti-HBs) test** at age 9-12 months (or 1–2 months after the final dose of the vaccine series, if the series is delayed). To avoid a false negative anti-HBs test, clinicians should ensure that they select a quantitative anti-HBs test when performing PVST.

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 an additional dose of hepatitis B vaccine and retested 1-2 months after that dose is administered. If the infant's anti-HBs concentration is still <10 mIU/mL, the infant should receive the additional two doses to make up a second three-dose vaccine series. After administering the remaining doses of the second three dose vaccine series at the appropriate intervals, retest 1-2 months after the third dose of vaccine.

- Infants who are HBsAg positive should be referred to a specialist for appropriate medical follow-up and should be reported to the health department.

Common reasons for less-than-optimal PVST testing among infants are that providers often order (1) either an HBsAg test OR an anti-HBs test, but not both, or (2) a hepatitis panel containing tests extraneous to recommended testing of these infants but missing an anti-HBs test (e.g. anti-HBc total) (3) PVST is performed too early. CDC has recently issued a memo titled Post-Vaccination Serologic Testing (PVST) Panels for Infants Born to Hepatitis B Virus (HBV) Infected Women that requests that commercial laboratories create a PVST panel to address this problem.

If cost of post vaccination serologic testing or lack of insurance is a barrier for the mother, please contact CDPH PHPP.

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Chapter Five: Practical Guidance for Case Management

Case management of HBsAg positive mothers and their infants is one of the core functions of a perinatal hepatitis B prevention program. While the CA PHPP had previously been split into 'funded' and 'unfunded' counties, all counties are now 'funded' and expected to complete this core public health activity. This section outlines key steps for each phase of the process.

When an HBsAg-positive woman is identified during her pregnancy, LHD staff should do the following:

1. Contact the Prenatal Care Provider

Contact the mother's prenatal care provider by phone, fax, or email to ensure that the prenatal care provider is aware of the patient's test results and can interpret them. If results are discrepant or additional testing is needed provide technical assistance on additional testing.

Actions to be taken:

- Provide a copy of the Prenatal Provider Quicksheet (Appendix D):
- Ask the doctor to place an alert in the patient's prenatal record so the birth hospital is aware of the patient's HBV status. Also remind the doctor that the **original** laboratory result should be submitted to the birth hospital.
- Obtain the following patient information:
  - ✓ Expected date of delivery (EDD),
  - ✓ Expected delivery hospital,
  - ✓ Contact information for the patient,
  - ✓ Language spoken,
  - ✓ Whether the patient is aware of her hepatitis B status,
  - ✓ Risk factors for noncompliance or becoming lost to follow-up.
- Ask the doctor to notify you if the patient changes healthcare providers or does not plan to follow ACIP recommendations for prophylaxis of their infant after birth.

2. Contact the HBsAg Positive Pregnant Woman

Contact the pregnant woman to ensure that they are aware of their diagnosis and provide information about the Perinatal Hepatitis B Prevention Program.

Obtain the following information:

- Planned birth hospital
- Planned pediatrician (if already provided)
- Information on household contacts

Provide the following information:

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- The type and timing of immunoprophylaxis the infant will need at birth, the complete HBV vaccine series, and post-vaccination serology
- Ways to prevent HBV transmission (including risks to sexual or household contacts)
- Breastfeeding is safe
- The need for evaluation and medical management of the pregnant woman's HBV infection

- **Some women may require frequent reminders and repetition of information in order to get their infants vaccinated on schedule and to complete post-vaccination serologic testing. Other cases can be managed primarily by the medical care providers and will require minimal health department intervention. Discretion must be used by the LHJ in determining how to case manage each patient.**

When this has been completed, submit the first page of the Confidential HBsAg+ Case/Household Management Report Form to CDPH PHPP.

3. Follow-up of Household, Sexual, or Needle-Sharing Contacts

All unvaccinated sexual, needle-sharing, and household contacts of persons with HBV are at high risk of acquiring the disease.

Household Definition
A household is defined as all persons residing at the primary residence of the HBsAg-positive woman for whom a case is opened, but may also include close or sexual contacts outside of this residence. The primary residence is that address where the woman spends the majority of her time. If a woman lives at or maintains two separate addresses, the LHD should follow individuals from both addresses. Data on all household and close contacts followed, regardless of their residence, should be included on page 6 of the Confidential HBsAg+ Case/Household Management Form.

Actions to be taken:

- Testing for infection or susceptibility is recommended for household, sexual, and needle-sharing contacts of HBsAg-positive persons. The preferred testing is HBsAg and anti-HBs. However, anti-HBs testing should be interpreted in combination with documented vaccination status.
- If your local public health laboratory cannot perform this testing, provide information on free or low fee services for serologic testing and hepatitis B vaccination to contacts who do not have access to health care.
- Susceptible persons should complete the HBV vaccine series.
- Contacts found to be infected with HBV should be referred to a medical provider for disease management and should be reported to CDPH.
- Household, sexual, and needle-sharing contacts can be tracked using page 7 of the Confidential HBsAg+ Case/Household Management Form.

*Persons who were vaccinated in other countries should be considered fully vaccinated if they have written documentation of ≥3 doses of vaccine administered at minimum intervals, including the third

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dose at ≥24 weeks after the first dose. Persons who are susceptible should complete the age-appropriate vaccine series. Persons who are not fully vaccinated should complete the vaccine series.

4. Contact the Birth Hospital Labor and Delivery Unit of the HBsAg Positive Pregnant Woman

- Contact the hospital to inform them that a mother infected with HBV plans to deliver at their facility, her healthcare provider's information, and her EDD. Fax a copy of the original laboratory report to the hospital, and inform the patient's health care provider
- Ensure that the labor and delivery unit staff understand PEP recommendations for the infant. Provide a copy of the Labor and Delivery Quicksheet (see Appendix D).
- Inform the hospital that the LHJ must be notified as soon as possible
  - ✓ After the birth of the infant, report the time of infant birth and time of receipt of PEP.
  - ✓ If the mother refuses PEP for the infant
- If the birth hospital has not reported the birth within 1 week of the EDD, follow up to determine the status of the mother and infant.
- If you were unable to collect information on the infant's prenatal care provider, request this information from the hospital

5. Contact the Infant's Healthcare Provider

- Upon initial contact with the provider, discuss the recommendations for PEP, HBV vaccination series, and PVST with the infants' pediatric provider. Ensure that the healthcare provider receives the guidelines outlined in the Pediatric Provider Quicksheet (see Appendix D).
- Ask the infant's healthcare provider to contact the LHJ immediately if
  - ✓ The mother refuses PEP or vaccination,
  - ✓ The infant is not receiving timely or regular care,
  - ✓ The infant is transferred to another provider,
  - ✓ The family has difficulty in completing PVST.

- Contact the infant's healthcare provider when the infant is 9 months of age to ensure the infant has received 3 doses of HBV vaccine and remind the provider to complete PVST, preferably by 12 months.

- PVST should be comprised of BOTH HBsAg AND **quantitative** anti-HBsserologic tests.

- Report results of PVST to CDPH; if an infant meets the CSTE case definition for perinatal hepatitis B, report this infant to CDPH through CalREDIE or using the CDPH Perinatal Hepatitis B Case Report Form.

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Chapter Six: Frequently Asked Questions

1. What if the other has discrepant HBsAg results?

Sometimes, women may have been screened for HBsAg multiple times during pregnancy, sometimes with discrepant results. When this happens consider the following:

- Whether the positive HBsAg result was a test that reflexed to confirmation.
- The mother's potential risk factors for chronic HBV and whether markers for acute HBV should be considered in additional testing recommendations (assess risk factors such as multiple sex partners or injecting drug use, for example).
- Repeat/additional testing, such as repeat HBsAg with addition of total anti-HBc, IgM anti-HBc, and HBV DNA.
    - ✓ If the repeat/additional testing indicates the patient is total anti-HBc negative and HBsAg negative then the mother is unlikely to be infected
    - ✓ If the patient has a known history of HBsAg positivity but additional testing results in total anti-HBc positive and HBsAg negative markers, please be aware that the patient could have occult HBV infection. Additional testing of the mother should be considered, and PEP for the infant should be given, if appropriate.
    - ✓ If after additional testing questions still remain about the mother's HBV status, PEP should be provided to the infant.
- The above is general guidance but each specific situation can vary. Please contact CDPH to discuss specific testing recommendations.

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2. What does it mean if the mother is HBsAg Negative, but HBV DNA is Detected?

While only HBsAg testing during pregnancy is required sometimes clinicians will order additional tests, such as HBV DNA. We have received reports of mothers with detectable HBV DNA and non-detectable HBsAg. Although mothers with these results would not technically meet the chronic HBV case definition for a confirmed case, we recommend follow up and case management since these results could indicate active infection.

Typically we would recommend:

- Working with the provider to obtain repeat testing, or referring to a gastroenterologist to determine likelihood of infection
- If infection cannot be ruled out, we recommend PEP for the infant.

A note on interpretation of DNA testing:
Commercial laboratories offer two types of testing for HBV DNA levels – qualitative and quantitative. Qualitative test results are reported as either 'detected' or 'not-detected' with the reference range being 'not-detected'. However, quantitative tests can be more difficult to interpret. For example, the reference range for the Quest HBV DNA quantitative test is <20 IU/ml. Unlike other tests where we might interpret this as a "negative" with an HBV DNA quantitative test this may mean it is positive but below the level of detection or that it is not detected, or a negative result. For clinical purposes, HBV DNA PCR qualitative may be used for diagnosis, while HBV DNA quantitative PCR is used to monitor disease progression in a previously diagnosed person. For questions about interpreting HBV DNA results, please contact CDPH or the performing laboratory.

3. What if the birth hospital fails to provide PEP to an infant?

Birth hospitals are responsible for administering hepatitis B postexposure immunoprophylaxis (PEP) to all infants born to mothers who are infected with HBV. The failure of a hospital to provide PEP is reportable to the Joint Commission as a **sentinel event.** The Joint Commission defines a sentinel event as "an unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof." Failure to provide PEP increases the infant's risk of acquiring HBV infection which can lead to fulminant or chronic hepatitis, and early death. A sentinel event may be reported by the hospital, the infant's physician, the health department, a parent, or the media, and must be reported within 12 months of the infant's birth.

If the coordinator learns of such an occurrence, they should do the following:

- Complete an investigation by interviewing the hospital nurse manager, infection control practitioner, and requesting all relevant medical records to determine the source of the error.
- Complete a PEP Error Form and submit to CDPH within five business days.
- Ensure that education/corrective action is taken to prevent any future occurrence.
- When warranted, some cases may be reported to CDPH Licensing and Certification.

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4. What happens if the parent refused PEP for their infant?

Parents of an infant whose mother has HBV infection should be informed of the importance of PEP as a **medical treatment** to prevent HBV infection and its consequences. **If a parent is refusing PEP for their infant, contact CDPH PHPP as soon as possible**. Attempt to work through the pediatrician or OB/GYN if a parent is refusing PEP for their infant. However, if parents continue to refuse PEP for their infant after receiving this information, parents should be informed that refusal of PEP may be considered medical neglect and will be reported to Child Protective Services under CA Welfare and Institutions Code, Section 300(b) and California Penal Code, Section 11165.2. If the infant is still hospitalized, the hospital or pediatrician should report the situation to Child Protective Services (CPS) and may be able to obtain an emergency court order to administer PEP. If the infant has been discharged, the pediatrician or coordinator may make a report to CPS.

5. What happens if post vaccination serologic testing is completed too early (e.g. prior to nine months of age or less than one month after 3rd dose of vaccine)?

PVST should not be performed before 9 months of age or less than 4 weeks after the final dose of hepatitis B vaccine. Testing prior to 9 months of age may result in a false negative HBsAg result because of a prolonged incubation time in those who have received HBIG. Additionally, the presence of maternal antibodies may lead to falsely positive anti-HBs due to passive anti-HBs from HBIG administered at birth. Testing completed less than 4 weeks after HBV vaccination may result in falsely positive HBsAg. If PVST is completed before 9 months of age or less than 4 weeks after vaccination, testing should be repeated.

If the infant is at least 9 months of age, the PVST should be done approximately 1-2 months after the 3rd or final dose of vaccine. Anti-HBs levels decline rapidly in the first year after vaccination and may be undetectable by 5 years. Despite declines in detectable antibodies, most individuals who initially responded to a vaccine series remain protected against HBV infection. Please see the following MMWR for more information: Update: Shortened Interval for Postvaccination Serologic Testing of Infants Born to Hepatitis B-Infected Mothers (cdc.gov)

6. How do I interpret post vaccination serologic testing that shows a positive HBsAg and a positive anti-HBs result?

It is possible for an infected person to be both HBsAg and anti-HBs positive. As long as timing of the testing was appropriate and does not need to be repeated, these infants should be reported as infected, referred to a gastroenterologist, and reported to CDPH PHPP. If it is later determined that the infant is not infected, the case status of the infant can be changed.

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7. What happens if the infant has completed two rounds of vaccination and is still anti-HBs negative?

If an infant is still anti-HBs 'negative' after two rounds of PVST, first check the laboratory result to determine if testing was quantitative or qualitative. Depending on the laboratory, qualitative anti-HBs tests may have a higher cut-off value than is considered protective (e.g. 12.9 mIU/mL versus 10 mIU/mL). If the test performed was qualitative and the cut-off was above 10 mIU/mL, ask the physician to re-order a quantitative test. To avoid this with future cases always make providers aware that they should be ordering a **quantitative** anti-HBs test as part of PVST.

Unfortunately, there are no additional recommendations for vaccination of infants who are susceptible after two rounds of vaccination. If the infant remains susceptible after a second vaccine series, the family should be counseled on precautions to prevent HBV infection and on medical follow up for the infant. If the child experience symptoms of HBV infection in the future they should be referred for testing.

8. How do I determine whether a mother/infant are lost to follow up?

Despite a good tracking system, some cases will be lost to follow-up. The coordinator must first determine if a case is truly lost to follow up, and then determine the reason for being lost to follow-up. If it is believed that a mother/infant is lost to follow-up take the following steps:

If you believe the contact information you have is correct, make a good faith effort to contact the mother by several different communication modes. This includes:

- Making 3 phone calls to each phone number of mother/guardian and if applicable, father. Sending text messages in addition to phone calls may also be helpful if the LHD has a policy that allows text messaging.
- Sending 2 letters or e-mails to mother/guardian and if applicable, father.
- Making 1 home visit to mother/guardian (maybe skipped due to COVID-19/safety concerns).

If you believe the contact information you have is incorrect:

- Check with the infant's healthcare provider to determine if the infant moved to another practice.
- Check the California Immunization Registry (CAIR) to identify whether the infant has a new healthcare provider.
- Check CalREDIE for any updates to the mother's address, if available.
- Conduct a DMV search.
- The social services department of the LHD (if the patient was receiving WIC assistance) may have up to date locating information for patients.
- Parole and probation offices may be contacted if the person is in the prison system.
- Google.com or other internet/social media sites

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If mother is determined to have moved to another California county or out of state, follow the 'CDPH PHPP Transfer Protocol' in the CDPH PHPP Handbook. If no new information is received OR the mother cannot be reached after these steps, the case can be closed as lost to follow-up

9. What if an infant was <2,000 grams at birth and is still <2,000 grams at one month of age?

For preterm infants weighing <2,000 g, 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; additional doses of vaccine (for a total of 4 doses) should be administered beginning when the infant reaches age 1 month. Even if the infant is still less than 2,000 grams at 1 month and single antigen vaccine is being used, proceed with the 1 month dose. Such infants will receive a total of 4 doses of HepB vaccine.

10. What if the mother is planning to give birth with a midwife?

Some midwives are licensed to provided PEP. If the midwife is unable to administer PEP at the time of the birth, prior arrangements can be made with a local emergency department to receive PEP within 12 hours of birth. Contact the midwife and ensure that they are aware that PEP needs to be provided to the infant and request a plan for how PEP will be administered.

11. What if the infant is safely surrendered or placed in foster care, and the mother's HBsAg status will never be known?

Beginning in 2018, the ACIP recommends that infants for whom maternal HBsAg status is not known, and will never be known, should receive post-exposure prophylaxis and complete the hepatitis B vaccine series and PVST as though the mother was HBsAg positive.

12. What if a child comes in for PVST and an extended period (e.g., more than six months) has elapsed since the child received the final dose of hepatitis B vaccine?

If the vaccine series has been completed on schedule, PVST should ideally occur at 9-12 months of age. However, testing that is performed at 13-18 months of age is still valid, but there may be a higher occurrence of falsely negative anti-HBs results. During the COVID-19 pandemic, CDC released guidance stating that if PVST is delayed more than six months after completion of the hepatitis B vaccine series, the provider should consider administering a "booster" dose of single antigen hepatitis B vaccine and then ordering PVST 1-2 months after the "booster" dose. The full guidance on vaccine recommendations during the COVID-19 pandemic can be found here.

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Chapter Seven: Data Management

Who Should be Reported to the Perinatal Hepatitis B Program?

A case in the California Perinatal Hepatitis B Prevention Program is defined as an HBsAg-positive woman who is either pregnant or has just recently delivered an infant.

Pregnant women who are HBsAg-positive should be reported to the CDPH PHPP but should also be reported as an HBV infection, either acute or chronic as appropriate, in CalREDIE if not previously reported. The CDC case definitions for hepatitis B are listed below.

Chronic HBV Infection

Confirmed: a case that meets laboratory criteria for diagnosis of either

- IgM anti-HBc negative **AND** a positive result on one of the following tests: HBsAg, HBeAg, or hepatitis B virus DNA (including qualitative, quantitative and genotype testing), **OR**
- HBsAg positive or HBV DNA positive (including qualitative, quantitative and genotype testing) or HBeAg positive two times at least 6 months apart (Any combination of these tests performed 6 months apart is acceptable)

Probable: A person with a single HBsAg positive or HBV DNA positive (including qualitative, quantitative and genotype testing) or HBeAg positive lab result and does not meet the case definition for acute hepatitis B.

Acute HBV Infection

Confirmed: An acute illness with a discrete onset of any sign or symptom* consistent with acute viral hepatitis (e.g., fever, headache, malaise, anorexia, nausea, vomiting, diarrhea, and abdominal pain), and either

- Jaundice **OR**
- Elevated serum alanine aminotransferase (ALT) levels > 100 IU/mL **AND**
- Meets the laboratory confirmation for diagnosis of either
- HBsAg positive **AND**
- Immunoglobulin M (IgM) antibody to hepatitis B core antigen (IgM anti-HBc) positive (if done)

**A documented negative hepatitis B surface antigen (HBsAg) laboratory test result within 6 months prior to a positive test (either HBsAg, hepatitis B "e" antigen (HBeAg), or hepatitis B virus nucleic acid testing (HBV NAT) including genotype) result does not require an acute clinical presentation to meet the surveillance case definition.*

Infants who are found to be infected when PVST is completed should be reported in CalREDIE as a perinatal HBV case.

Perinatal HBV Infection

Confirmed: Child born in the US to a HBV-infected mother **AND**

- Positive for HBsAg at ≥ 1 month of age and ≤ 24 months of age **OR**
- Positive for HBeAg or HBV DNA ≥9 months of age and ≤ 24 months of age.

Probable: Child born in the US **AND**

- Positive for HBsAg at ≥ 1 month of age and ≤ 24 months of age **OR**

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- Positive for HBeAg or HBV DNA ≥9 months of age and ≤ 24 months of age **BUT**
- Whose mother's hepatitis B status is unknown (i.e. epidemiologic linkage not present).

Confidentiality
Documentation and reporting of HBsAg-positive status is required under Section 2500 of the California Code of Regulations (California Health and Safety Code; see Appendix B). The reporting of all other information and data in the case/household management report form is voluntary. However, the CA PHPP requests this information for the purposes of monitoring perinatal hepatitis B prevention and to further document and describe the extent of the HBV burden in the state. Information provided may be transferred between LHDs for the purposes of case/household follow-up. The records maintained for this program are confidential insofar as the identity of the individual patient is concerned and shall be used solely for the purposes of improving program effectiveness and to prevent further spread of HBV. Any information published from these reports shall be restricted to statistical compilations relating to risk profiles, immunization histories or other epidemiologic data on HBV which do not identify individual cases by name. Case/household management reports will be maintained in locked file cabinets. Access to computerized data files is restricted to only those individuals who have authorization from the State Perinatal Hepatitis B Prevention Program.

When to Report
A photocopy (or electronic copy) of the case/household management report should be submitted to the CDPH PHPP for each case/household on three separate occasions:

1. When the case is "opened" with the mother's information
2. When the case form has been "updated", meaning infant is born and information is available regarding PEP status and/or vaccination history.
3. When the case is "closed" with the complete infant and household contact information.

1. Opening a Case

A newly opened case should be submitted to the CDPH as soon as possible (i.e., after a case/household identification number has been assigned to a confirmed case and the information on the "MOTHER" form has been completed).

- Fax a copy of Page 1 of the case/household management report to: (510) 620-3949 or send via secure email to the CDPH PHPP Coordinator.

2. Updates/Revisions

- Once an infant has been born to an HBV positive mother, an updated form with the relevant infant information should be submitted to CDPH PHPP via fax or secure email
- If there are changes to information originally obtained during the case/household follow-up period (e.g., demographic information, new dates/results, etc.), these changes should also be submitted to CDPH PHPP. Make any changes by crossing out the old information and writing in the revised information, and mark "Update" at the top of Page 1.

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3. Closing a Case

- A case is closed after every effort has been made to follow up with an HBsAg-positive woman, her infant(s), and her household contacts. Examples of various scenarios in which a case might be closed are described below:
    - The infant has received HBIG, all three to four hepatitis B vaccine doses and post vaccination serologic testing and has been found to be immune. Every household contact has been screened and referred for appropriate follow-up.
    - The infant has received HBIG, all three to four hepatitis B vaccine doses and post vaccination serologic testing and has been found to be immune. Every effort has been made to screen the household contacts, but they have been lost to follow-up.
    - A case/household management report has been initiated for a pregnant woman known to be positive for HBsAg, but her pregnancy results in a miscarriage. Her household contacts have been screened and referred for appropriate follow-up.
    - A case/household management report has been initiated for a pregnant woman known to be positive for HBsAg, but she and her infant have been closed a lost to follow-up, despite all attempts to contact/locate them.

- When a case is closed, regardless of the reason it is closed, a copy of the completed case/household management report should be sent to the CDPH PHPP. “Closed” should be marked on the top of Page 1. Page 6, the optional worksheet, does not need to be submitted. Make sure the case identification numbers on each of the three pages are identical and that the closing date has been entered in Question 20 of the Page 1.

Transfers

When a case/household moves, all of the information necessary for case management (e.g., forwarding address and phone number, lab results, immunization histories, etc.) should be forwarded to the new jurisdiction to ensure proper follow-up.

Intrastate transfers – Between California Jurisdictions

- If a case transfers from one jurisdiction to another within California, the county from which the case is moving is responsible for transferring the case **directly** to the receiving California jurisdiction.
- The jurisdiction to which the case is transferred is responsible for continuing case/household management, closing the case, and submitting the case/household management report to CDPH PHPP
- The Perinatal Hepatitis B Prevention Program In-State Case Transfer Form (Appendix C) should be included during this transfer process.
- The case should retain its original identification number. However, the transfer county will assign the case a second “transfer county” identification number, using the prescribed 9-digit format.
- Should a case transfer more than twice during case follow-up, additional transfer county identification numbers should be written on the case/household management report under the first transfer number.

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Interstate transfers- Between U.S. States

- If a case transfers out of California but to another U.S. state, the county of origin should close the case and submit the appropriate case management information to the CDPH PHPP. CDPH will then send the case to the receiving state's PHPP coordinator.
- Any known forwarding address and all information about mother/infant and contacts should be included so that the CDPH PHPP can pass on the information to the appropriate coordinator.
- The Perinatal Hepatitis B Prevention Program Out-of-State Case Transfer Form (Appendix C) should also be included during this transfer process.
- The LHD should make every effort to provide the woman and her household with the information they will need to give to their new providers.

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Chapter 8: Instructions for Completing Confidential HBsAg+ Case/Household Management Report

Instructions for Page 1: MOTHER

Case/Household Identification No. __-__-__-___ (county of origin)
County mm yy

- All of the spaces in this field must be filled in. Leave no blanks.
- Insert your 2-digit county/jurisdiction in the first two spaces marked “county.”
- The second two spaces, labeled ‘mm,’ represent the month in which the case is opened (i.e., the month the HBsAg-positive report was received, the case report initiated and follow-up begun).
- The spaces labeled ‘yy’ represent the year in which the case is opened.
- The last three spaces in the field represent the chronological order in which cases are opened during each month. Most counties/jurisdictions will open somewhere between one (001) and 50 (050) cases each month, though some may open more.

Examples:
01-08-18-003: This number indicates that the case was opened in Alameda County (code 01), in August (08), 2018 (18), and that it was the third (003) case opened during the month of August.

36-02-20-020: This number indicates that the case was opened in San Bernardino County (code 36) in February (02), 2020 (20), and that it was the twentieth (020) case opened during the month of February.

☐ New Report ☐Update ☐False Positive ☐Final Report/Closed

☐ Transfer (specify TO and FROM below)

To: (county/state) _____ From: (county/state) _____ Date: _____

If this case transferred from another county, what was that county’s ID Number__-__-__-___
Co mm yy

- Check the appropriate box(es)
  - ✓ New Report: The first report submitted to the state
  - ✓ Update: Additional information on a mother, infant or household for a case already opened
  - ✓ False Positive: Confirmatory testing shows the mother is not infected with HBV
  - ✓ Final Report/Closed: The infant has completed PVST or the case has been lost to follow-up. This is the final report submitted to the state
  - ✓ Transfer (specify TO and FROM below): The mother and/or infant have moved outside of your jurisdiction and a new address is available

- If the case has been transferred, please check the box marked "Transfer". Also list the county or state of origin, the receiving county or state, and the date the transfer was completed.

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- When a case is transferred from one county to another, it must be assigned a new household identification number by the receiving county. The numbering process should be exactly the same for the transfer county as it is for the county of origin (i.e., the month and year used in the nine-digit identification number should be the month and year that the transfer was received, the case opened, and follow-up began).

1. County: _____

- Write in the name of your county or health jurisdiction.

2. Date county initiated report ___/___/_____
mm dd yyyy

- The date entered here (in MM/DD/YYYY format) should correspond to the date that the HBsAg-positive test result was reported to the local hepatitis B program, the case number was assigned, and follow-up begun (the month and year should coincide with the case identification number).

3. SSN ___-__-____

- If possible, attain the mother's social security number and enter it correctly. This is a key identifier for assuring that there are no record duplications. If the woman does not have a social security number, leave the entry blank.

4. Name _____ _____ __
Last First MI

- Enter mother's last name, first name and middle initial

5. Date of Mother's Birth ___/___/_____
mm dd yyyy

- Enter the date of mother's birth in the MM/DD/YYYY format. If the month or day is a single-digit number, be sure to enter a "0" in the first field (e.g., 04 for April). If the month, day, or year of birth is unknown, leave the field blank. Do not enter "00" or "99" for any part of the birth date.

6. Mother's Age When Screened ___

- Enter the mother's age at the time she was screened for HBsAg. Do not leave this field blank if the mother's date of birth is unknown.

7. EDD___/___/_____
mm dd yyyy

- Enter the mother's estimated date of delivery (EDD) in the MM/DD/YYYY format.

8. City _____ 9. Zip _____

- Enter the city and zip code in which the mother primarily resides.

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10. Pregnancy Outcome 1☐ Live Birth(s), number: _____ 3☐ Miscarriage/Abortion
2☐ Fetal Death(s), number: _____ 9☐ Unknown

- This question should not be completed until after the pregnancy has ended.
- If the current pregnancy resulted in a live birth, check the appropriate box and enter the number of live births into space provided.
- If the current pregnancy resulted in a fetal death, check the appropriate box and enter the number of fetal deaths into space provided.
    - A fetal death is defined by the National Center for Health Statistics as "Death before the complete expulsion or extraction from its mother of a product of conception, irrespective of the duration of pregnancy; the death is indicated by the fact that after such separation, the fetus does not breathe or show any other evidence of life, such as beating of the heart, pulsation of the umbilical cord, or definite movement of voluntary muscles." However, for the purposes of this program, fetal deaths should be differentiated from miscarriages or abortions by virtue of the fact that they occur after five months (twenty weeks) gestation.
- If the current pregnancy resulted in a miscarriage or abortion occurs, check the appropriate box. Under this program, any fetal death occurring prior to 20 weeks gestation will be considered a miscarriage or abortion.
    - If a miscarriage/abortion occurs and the box has been appropriately checked, the form is complete, and no further information is required. At this point, please send the report to CDPH PHPP.
- These fields are not mutually exclusive. If a pregnancy results in one live birth and one fetal death, then both boxes should be marked and the numbers provided appropriately.

11. Is this the first case/household management report submitted to CA Perinatal Hepatitis B Program on this mother?

1☐ Yes 2☐ No (include previous ID number: __-__-__-___) **9☐ Unknown**

- This question will let the CDPH PHPP know if there was a hepatitis B case/household management record on this woman from a previous pregnancy.
- Check "no" only if it is known that this case was previously reported to CDPH PHPP. A report of HBsAg-positivity on a CMR or a report to other Department of Public Health agencies is not equivalent to submission of a report to the Perinatal Hepatitis B Prevention Program.

13. Source of HBsAg+ report

1☐ Laboratory 2☐ Prenatal care Provider 3☐ Delivery hospital
9☐ Unknown 4☐ Other (Specify): _____

- Select the source of the HBsAg-positive report to the health department that is most current and from which you initiated your follow-up. "Laboratory" refers to any laboratory (even if hospital-

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based or health department-based). “Prenatal Provider” refers to the clinician or practice caring for the woman during her pregnancy, including hospital-based clinics, community clinics, etc. “Delivery hospital” refers to reports received from anyone at a delivery hospital (the nursery, infection control nurse, etc.) except the laboratory concerning a mother and infant who are currently hospitalized or have been hospitalized in the past 7 days. If none of these categories apply, check “Other” and specify.

14. Is Mom a known Chronic Hepatitis B Carrier?

1☐ Yes 2☐ No 9☐ Unknown

- Check “yes,” “no,” or “unknown.” If “Yes,” confirm the mother has been entered in CalREDIE as “Hepatitis B, Chronic”.

15. Is Mom currently taking anti-viral medication for Hepatitis B?

1☐ Yes 2☐ No 9☐ Unknown

- Check “yes,” “no,” or “unknown.”
- Recently, data have shown that women with high HBV viral loads are at higher risk of transmitting the virus to their infant, despite appropriate post exposure prophylaxis and vaccination. Therefore, anti-viral therapy during pregnancy may be recommended for those women with a viral load > 200,000 IU/mL in order to reduce the risk of transmission.

15. Diagnostic tests (If repeat tests were done on different dates, they may be included in the Comments)

	Positive	*Negative*	*Unknown*	*Date of test (MM/DD/YYYY)*	*Comments*
a. HBsAg	☐	☐	☐	____/____/_____	
b. anti-HBc	☐	☐	☐	____/____/_____	
c. HBeAg	☐	☐	☐	____/____/_____	
d. anti-HBe	☐	☐	☐	____/____/_____	
e. Other: _____	☐	☐	☐	____/____/_____	
f. HBV DNA (describe results)_____				____/____/_____	

- Check the appropriate boxes to indicate which laboratory tests have been done to confirm HBV positive status. Pregnant women are recommended to be screened for HBsAg during each pregnancy. Don’t forget to indicate both the test date and the test result.
- For a description of each laboratory marker, can be found in CDC’s Interpretation of Hepatitis B Serologic Test Results (Appendix A)

16a. Planned delivery hospital?

Name: _____
City: _____

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- Provide the name and city of the case's anticipated delivery hospital. This question pertains specifically to mothers identified as HBsAg+ before their infants are born. If the hospital has not yet been determined, please write "Unknown".

16b. Prenatal Care Provider?

MD Name: _____
Clinic Name: _____
City: _____**Phone:**_____
Mother's MRN: _____

- Provide the physician name, clinic name, clinic city, and phone number of the mother's prenatal care provider, and the mother's medical record number.

17. Country of mother's birth

1☐ U.S.A. 2☐ Other (Specify): _____ 9☐ Unknown

- Check the box marked "unknown" only if absolutely no information about a mother's birth country is available. If the mother was not born in the United States, check the box marked "Other" and write in the country of her birth when it is available on the specification line. If the mother was not born in the United States but her country of birth is unknown, check the box for "Other" but leave the specification line blank.

18a. **Race: (Check all that apply)**
- ☐ White
- ☐ Black
- ☐ Amer. Indian/ Alaskan Native
- ☐ Other/Unspecified

18b. **Ethnicity:**
- ☐ Hispanic
- ☐ Non-Hispanic
- ☐ Unknown

Asian (check all that apply)
- ☐ Chinese
- ☐ Japanese
- ☐ Korean
- ☐ Filipino
- ☐ Asian Indian
- ☐ Cambodian (non-Hmong)
- ☐ Thai
- ☐ Laotian (non-Hmong)
- ☐ Vietnamese (non-Hmong)
- ☐ Hmong
- ☐ Mien
- ☐ Other Asian: _____

Pacific Islander (check all that apply)
- ☐ Guamanian
- ☐ Samoan
- ☐ Native Hawaiian
- ☐ Tongan
- ☐ Other Pacific Islander: _____

18a. Race:

- Answer both the race and ethnicity questions. Select "White" for women who identify as White/Caucasian; select "Black" for women who identify as Black/African American; select "Amer. Indian/Alaskan Native" for women who identify as American Indian or Alaskan Native.
- For women who identify as Asian or Pacific Islander, check the primary ethnic group with which they identify on the bottom of the report form. If the Asian or Pacific Islander ethnicity is unknown, check the box marked "Other Asian" or "Other Pacific Islander" and write "Unknown" in the space provided.
- Be sure to record the mother's ethnic origin and not the ethnicity that is associated with the country from which she immigrated. For example, a woman of Chinese descent who is born in Vietnam is ethnically Chinese.

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18b. Ethnicity:

- A person may be coded as Hispanic, regardless of his/her race, if his/her ethnicity is of Hispanic origin, such as Mexican/Mexican-American/Latino/Chicano, Puerto Rican, Cuban, Central/South American or other specified Spanish/Hispanic.

19. Initial submit date: ___/___/_____
mm dd yyyy

- Enter the date this form was initially submitted to CDPH in MM/DD/YYYY format. The date entered for the initial report submission should be a date within one month of the date the report is initiated.

20. Close date: ___/___/_____
mm dd yyyy

- Enter the date this case was closed in MM/DD/YYYY format. The close date should be the date that the case management form is completed and submitted to the CDPH. A case can only be closed if the infant has completed PVST, or has been lost to follow up, despite all attempts to locate them.

Person completing form_____ Date: _____

Agency: _____Phone: _____

- Enter the name of the local health department investigator completing the form, the date the form was completed, the public health agency at which they work, and the best phone number to call should any questions arise.

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Instructions for Pages 2-3: INFANT

☐New Report ☐Update ☐False Positive ☐Final Report/Closed

☐ Transfer (specify TO and FROM below)

To: (county/state) _____ From: (county/state) _____ Date: _____

If this case transferred from another county, what was that county's ID Number__-__-__-___

- These fields should be identical to what is written on Page 1. Make sure that the identification number on Page 2 is identical to the identification numbers for the Page 1 and Page 3. If there is a transfer identification number, make sure that it also is identical to the transfer identification numbers on the other two pages of the report form.

Birth Information:

3. Source of payment for delivery?

1☐ Medi-Cal **4☐ Self-pay**
2☐ Other/Govt. 3rd party payer **5☐ Low income: ____**
3☐ Private 3rd party payer **9☐ Other/Unk: _____**

- Indicate the source of hospital payment/insurance status at delivery.
- "Other/Govt. 3rd party payer" refers to programs similar to Medi-Cal, such as Medicare, CHDP, CCS or other forms of government subsidy that directly cover the delivery. "Private 3rd party" refers only to private insurers. "Low income" refers to public sector clients that are not eligible for Medi-Cal but still too low-income to pay for their care.

4. Delivery hospital:

Name: _____City: _____

- Write the name and the city of the actual delivery hospital in the appropriate fields. This may or may not be the same facility as the planned delivery hospital listed on page 1.

5. Pediatric Care Provider?

MD Name: _____
Clinic Name: _____
City: _____Phone:_____
Infant's MRN: _____Case ID:_____

- Provide the physician name, clinic name, clinic city, and phone number for the infant's pediatrician. Please provide the infant's medical record number and the infant's case ID number (if the infant is a Northern California Kaiser Permanente patient).

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Infant Information:

Infant #____

- Number each infant born during this pregnancy (live births only). If only one live infant is born, enter '1'. If two or more live infants are born, attach an additional page for each infant, assign the same case/household ID number on this form, number each infant accordingly (1, 2, 3 etc.) and complete the infant section only.
- This field should correspond with the number of live births recorded in field 4a.

6. Name: _____ _____ ___ 7a. Birth date:__/__/____
Last First MI mm dd yyyy

8. Sex: 1☐Male 2☐Female 7b. Time of Birth (military): __:__ (hh:mm)

- Provide the last name, first name, middle initial, date of birth, time of birth, and sex for each live infant in fields 6-8.
- Birth date should be recorded in MM/DD/YYYY format.
- Time of birth should be in military format.

Immunization Record:

- There is solid clinical evidence that the timing of the administration of hepatitis B immune globulin (HBIG) and vaccine doses is important in ensuring immunity to HBV infection. As recommended by the ACIP, HBIG and the first dose of vaccine should be given within 12 hours of the infant's birth.[7] Only single antigen vaccine should be given as the birth dose of hepatitis B vaccine.
- For those women whose HBsAg status is unknown, or for whom test results are pending, the infant should receive the first dose of hepatitis B vaccine within 12 hours of birth. 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.
- If the infant weighs <2,000 grams and the mother's status is unknown at 12 hours of age, HBIG should also be.

9. HBIG
a. ☐ Not given
b. ☐ Given
c. Date when given ____/____/_____ __:__ (hh:mm)
mm dd yyyy
d. If date/time not available, age in hours, when given _____

- If no HBIG was given, check box 9a. If HBIG was given, regardless of date/time, check box 9b.
- If HBIG was given, enter the date and time HBIG was given in field 9c. Time should be in military format.
- If the date and time of HBIG administration is not available, please enter the infant's age (in hours) at the time HBIG was given in field 9d.

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10. Hep B Vac1

a. ☐ Not given
b. ☐ Given
c. Date when given ____/____/_____ __:__ (hh:mm)
mm dd yyyy
d. If date/time not available, age in hours, when given _____

- If no Hep B Vac 1 was given, check box 10a. If Hep B Vac 1 was given, regardless of date/time, check box 10b.
- If Hep B Vac 1 was given, enter the date and time Hep B Vac 1 was given in field 10c. Time should be in military format.
- If the date and time of Hep B Vac 1 administration is not available, please enter the infant's age (in hours) at the time Hep B Vac 1 was given in field 10d.

11. Hep B Vac2 a. Date when given ____/____/_____
mm dd yyyy

b. Type of vaccine (if known): _____

12. Hep B Vac3 a. Date when given ____/____/_____
mm dd yyyy

b. Type of vaccine (if known): _____

13. Hep B Vac4 a. Date when given ____/____/_____
(If applicable) mm dd yyyy

b. Type of vaccine (if known): _____

- Enter the dates that the second, third and fourth (if applicable) doses of the hepatitis B vaccine were given. If the exact date is not known, please elaborate in the General Comments section on page 3.
- Infants may be given four doses of hepatitis B vaccine if a combination vaccine schedule is being followed, or if the infant weighed <2,000 grams at birth.
- If a fifth dose is given, please write the date the vaccine was given in the space below question 13.

Post-Vaccination Follow-up Serology Record:

- All infants born to HBsAg-positive women should receive PVST , ideally at 9-12 months of age, and 1-2 months after having received their last dose of hepatitis B vaccine (if the series is delayed). Infant should not be tested before 9 months of age and should be tested for both HBsAg and hepatitis B surface antibody (anti-HBs).
- If HBsAg is not present and anti-HBs is present (≥10 mL if quantitative test, or reactive if qualitative test), the infant can be considered immune.
- If neither HBsAg nor anti-HBs are present, the infant cannot be considered immune and should receive an additional dose of hepatitis B vaccine and retested for both HBsAg and anti-HBs 1-2 months after the dose of vaccine. If the infant remains susceptible after

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testing, administer the remaining doses of the second three dose vaccine series and retest 1-2 months after the third dose of vaccine. (questions 17-19).

- If HBsAg is present and anti-HBs is not present, the infant can be considered infected and should be reported to CDPH as a case of perinatal hepatitis B infection via CalREDIE or the Perinatal Hepatitis B Case Report Form. The infant should also be referred to a specialist for follow-up care.

14. a. HBsAg test done? 1☐Yes 2☐No 9☐Unk

If 'Yes': b. Date done ____/____/_____
mm dd yyyy

c. Result: 1☐Pos 2☐Neg 9☐Unk

15. a. Anti-HBs test done? 1☐Yes 2☐No 9☐Unk

If 'Yes': b. Date done ____/____/_____
mm dd yyyy

c. Result: 1☐Pos 2☐Neg 9☐Unk

- If post-vaccine testing for HBsAg has been done, check "Yes" (14a) and enter the date of the test in MM/DD/YYYY format (14b) and the result of the test (14c).

- If post-vaccine testing for anti-HBs has been done, check "Yes" (15a) and enter the date of the test in MM/DD/YYYY format (15b) and the result of the test (15c).

16. Reasons PVST was not completed (select all that apply):

- ☐ **Compliance problem with physician/hospital**
- ☐ **Funding problem (i.e, lack of insurance, incomplete reimbursement)***
- ☐ **Social circumstances/Access to Care**
- ☐ **Parent declined PVST**
- ☐ **Parent concern over blood draw**
- ☐ **Other (specify):_____**

- If the infant did not receive post vaccination serologic testing at the time the case was closed, please check one of the following boxes. If more space is required, please include additional information in the General Comments box on page 3. See below for specific explanations:

☐ **Compliance problem with physician/hospital**
  - If the physician refuses to order PVST, or refuses to order it at the appropriate time, check this box.

☐ **Funding problem (i.e, lack of insurance, incomplete reimbursement)***
  - If the parent does not complete PVST for their child due to the cost of the test, getting reimbursed, or lacking the necessary insurance, check this box.

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- If cost or payment of the test is an issue, please contact CDPH PHPP

☐ **Social circumstances/Access to Care**
- If the parent does not complete PVST for their child due to a specific social hardship (aside from cost), check this box.

☐ **Parent declined PVST**
- If the parent refuses PVST for their child due to their personal beliefs, or if they do not find the testing to be necessary for their child, check this box.

☐ **Parent concern over blood draw**
- If the parent refuses PVST for their child due to concern about the blood draw necessary to complete the test, check this box. Please note, this is different that refusing testing due to personal beliefs (see above).

☐ **Other (specify):**
- If the parent refuses or does not complete PVST for any reason other than reasons listed above, check this box and specify the reason in the space provided.

Second Series Immunization and Repeat Post-Vaccination Serology Record:

17. a. If 'Neg', did infant receive a 2nd series of vaccine?

1☐ Yes 2☐ No 9☐ Unk

b. Hep B Vac1 ____/____/_____
mm dd yyyy

c. Hep B Vac2 ____/____/_____
mm dd yyyy

d. Hep B Vac3 ____/____/_____
mm dd yyyy

- If the infant is found to be positive for anti-HBs (i.e., found to be immune) after completion of the hepatitis B vaccine series, disregard this section (questions 17-19).
- If the infant is found to be negative for both HBsAg and anti-HBs (i.e., found to still be susceptible), indicate if the infant received an additional dose of hepatitis B vaccine or the entire 2nd three dose vaccine series
- If the infant received one or more doses of hepatitis B vaccine in the 2nd series, enter the dates the doses of vaccine were given in MM/DD/YYYY format (17b-d).

18. a. Was HBsAg test done after completion of 2nd series?

1☐Yes 2☐No 9☐Unk

b. Date done ____/____/_____
mm dd yyyy

c. Result:1☐Pos 2☐Neg 9☐Unk

19. a. Was Anti-HBs test done after 2nd series?

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1☐Yes 2☐No 9☐Unk

b. Date done ____/____/_____
mm dd yyyy

c. Result:1☐Pos 2☐Neg 9☐Unk

- If the infant receives part or all of the 2nd series of hepatitis B vaccine and is serologically tested for HBsAg, check "Yes" (18a) and enter the date of the test in MM/DD/YYYY format (18b) and the result of the test (18c).
- If the infant receives part or all of the 2nd series of hepatitis B vaccine and is serologically tested for anti-HBs, check "Yes" (19a) and enter the date of the test in MM/DD/YYYY format (19b) and the result of the test (19c).
- If the infant is still susceptible after two rounds of post vaccination serologic testing, please refer to the "Frequently Asked Questions" section of the Coordinator Handbook.

Lost to Follow-up (for mother and infant):

20a. When was the mother/infant lost to follow-up?

☐ Before infant was born ☐ During vaccination series ☐ Before PVST completed

Date of Last Contact: __/__/___ (approximate) ☐ Never Contacted

- If the case becomes lost to follow-up, please check the appropriate box in 20a, and proceed to question 20b.
- Specify at what point in case management the case was lost to follow up and specify the date of last contact.
- If the infant was lost to follow-up before PVST was complete, please make sure you answer question 16 on page 2.

20b. Check all reasons mother and infant were lost to follow-up (check all that apply)
- This section should be completed for those mothers and infants that are lost to follow-up.
- Before a case is closed as lost to follow-up, please make sure the appropriate steps have been taken (listed on page 18).

☐ **Infant could never be located due to incorrect contact information**
- Check this box if the infant could not be located because the address, phone number, or other contact information provided was not correct and all attempts to find correct contact information (i.e. Accurint) have failed.

☐ **Infant moved out of the state:**
- If the infant moved out of the state, check this box and enter the date the case moved in the space provided.

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- If it is determined that the case moved out of CA, please complete the Out-of-State Transfer Form, and send to CDPH PHPP as soon as possible.

☐ **Infant moved out of the country**

- If the infant moved out of the country, check this box and enter the date the case moved, and the destination country in the fields provided.
- Often there are situations where a woman will travel to the U.S. to deliver the infant, and then return back to her home country with the baby. Follow-up on these infants is time-consuming and often infeasible. This field will help track these scenarios.

☐ **Compliance problem with family (i.e. uncooperative, refused PEP**

- If the mother/household was contacted but refuses to participate or be compliant with the Perinatal Hepatitis B Prevention Program, check this box. Please contact the CDPH PHPP if infant does not receive PEP at birth.

Was case reported to Child Protective Services?

1☐ Yes 2☐ No 9☐ Unknown

- Check “yes,” “no,” or “unknown.”
- A case can be reported to Child Protective Services if the parent refuses post exposure prophylaxis for the infant, preventing the administration of PEP or resulting in a delay in PEP administration. If you have any questions about a specific case that might warrant CPS involvement, please contact the CDPH PHPP for further assistance.

☐ **Infant died – date of death: _____, time of death (if available) _____**

cause of death: _____

- “Infant died,” refers to any death that is not considered a fetal death (i.e., stillbirth), miscarriage, or abortion. This typically applies in circumstances where the infant dies following birth. Sometimes, HBIG and one or more doses of the hepatitis B vaccine will have been given. Please specify the date and time of death (if available), as well as the cause of death

☐ **Other (specify): _____**

- If the infant is lost to follow-up for other reasons that are not listed here, please check this box and specify in the space given. If additional space is required, please use the General Comments box.

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Instructions for Page 6: HOUSEHOLD CONTACTS

1. Case/Household Identification No. /_/_/-/_/_/-/_/_/-/_/_/_/

2. All Household Contacts

- The first section of this page concerns summary data for all household contacts of each HBsAg-positive woman identified through the Perinatal Hepatitis B Prevention Program.
- While you will need additional information for case follow-up (see page 6: Optional Worksheet for Case/Household Management), CDPH PHPP collects only the consolidated data on page 5.
- Enter the immunization status of each household contact found during follow-up for this case only. For instance, if an HBsAg-positive woman is enrolled in the Perinatal Hepatitis B Prevention Program twice, for two separate pregnancies, and a household contact was seroscreened and consequently immunized during follow-up for her first pregnancy (3d, 3h and 3i), that same household contact would be documented as previously immunized (3c) for the second pregnancy.

a. ___Total number of household contacts identified (a = b+c+d+j+k)

- Enter the total number of adults and children **(excluding the newborn)** who are part of the HBsAg-positive woman's primary household or are a sexual contact. If the woman lives at more than one address, it is up to the program to decide which (i.e., how many) of her household contacts should be followed. The number entered in Field 2a should reflect all those contacts for whom information will be collected.
- **The total number of household contacts identified (2a) should equal the sum of 2b, 2c, 2d, 2j and 2k.**

b. ___Number already known to be chronically infected or immune due to prior infection of Hepatitis B

- Enter the number of household contacts who have previously (i.e., prior to the opening of the current case) been screened for HBV and have a history of HBV infection, who are assumed positive for HBV markers and for whom screening is not recommended. The individuals included in the total entered in this field should not be counted again in Field 2d, "Number seroscreened for Hep B markers."

c. ___Number previously immunized

- Enter the number of household contacts who have a record of having already completed the hepatitis B immunization series prior to the opening of the current case, and who are assumed to be immune from HBV.
- Persons in the middle of completing the vaccine series who need additional dose(s) of vaccine (without screening) should not be included in this field as previously immunized, but should be included in the total entered for Field 2j "Number vaccinated without screening."
- The individuals included in 2c should not be counted again in Field 2d, "Number seroscreened for Hep B markers."

d. ___ Number seroscreened for Hep B markers

e. ___ Of those seroscreened, number age ≤ 5 years

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f . ___ Of those seroscreened, number age ≥ 6 years

g. ___ Of those seroscreened, number found to be already infected or immune

h. ___ Of those seroscreened, number found to be susceptible (i.e., negative for hepatitis B markers)

i. ___ Of those found to be susceptible, number vaccinated

- Enter the number of household contacts who had a laboratory test done during the follow-up for the current case to determine their HBV status in Field 2d.
- The age category (2e or 2f) and test result (2g or 2h) should also be documented for each household contact included in Field 2d.
- Enter the number of contacts who were seroscreened and found to be susceptible, and were subsequently vaccinated, in Field 2i.
- The number of contacts seroscreened for HBV markers (2d) should equal the sum of 2e and 2f and the sum of 2g and 2h.

j. ___Number vaccinated without screening

- Enter the number of household contacts who are either: (1) not screened but considered susceptible (i.e., followed up for immunization during the follow-up of this current case); or (2) completing the vaccine series during the follow-up of this current case. The age and immunization information for each of these susceptible household contacts should also be documented in the grid for question 3, “Household Contacts Receiving Immunization (List in any order),” as described below.

k. ___Number lost to follow-up

- Enter the number of household contacts who, during the follow-up of the current case, are either: (1) never located; (2) not screened; or (3) are eligible to receive immunization without screening, but are not immunized for whatever reason (e.g., refuse to be immunized).

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3. HOUSEHOLD CONTACTS RECEIVING IMMUNIZATION (List in any order)

Please enter the codes in () into the spaces below.

	a. Name (optional)	b. Age 0-5 yrs (1) 6-21 yrs (2) ≥ 22 yrs (3)	c. Hep B Vac Dose #1 Given? Yes (1); No (2); Unk (9)	d. Hep B Vac Dose #2 Given? Yes (1); No (2); Unk (9)	e. Hep B Vac Dose #3 Given? Yes (1); No(2); Unk (9)
Contact 1					
Contact 2					
Contact 3					
Contact 4					
Contact 5					
Contact 6					

- Only the information for all household contacts included in Fields 2i (Of those found to be susceptible, number vaccinated) and 2j (Number vaccinated without screening) should be recorded in this grid.
- The primary purpose of this section is to determine the relative success in completing the 3-dose hepatitis B immunization series for household contacts who receive screening and are determined to be susceptible, who receive no screening but are assumed to be susceptible, or who have started the vaccine series elsewhere and need additional doses.
- Enter the information for Fields 3a–3e for each household contact receiving immunization.

3a. Name (optional)

- The name of each household contact receiving immunization does not need to be listed. Please make sure, however, that each household contact's summary immunization information appearing on this page can be tied to working documents.

3b. Age [when screened]: 0-5 yrs (1); 6-21 yrs (2); ≥ 21 yrs (3)

- Enter the household contact's age at the time that they are screened and identified as susceptible (i.e., in need of immunization), or, if no screening is done, their age at the time of first immunization.
    - If a household contact is age 0 to 5 years, enter a number "1" in Field 3b.
    - If a household contact is age 6 to 21 years, enter a number "2" in Field 3b.
    - If a household contact is age 22 years or older, enter a number "3" in Field 3b.

3c–3e. Hep B Vac Dose #1, #2, #3 Given? Yes (1); No (2); Unk (9)

- Indicate whether or not each household contact needing vaccine (i.e., screened and known to be susceptible), received vaccine without screening, or needed to finish the vaccine series)

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received the first, second, and/or third doses. Enter a “1” for Yes, a “2” for No, or a “9” for Unknown.

- Specific dates of administration are **not** required for the purposes of this case/household management report.
- If a household contact needing immunization received any part of the vaccine series in another jurisdiction, a “1” (Yes) should be checked in the box for the appropriate dose. For instance, if a household contact receives only the third dose of the vaccine through the Perinatal Hepatitis B Prevention Program but has documentation that doses 1 and 2 were received elsewhere, a “1” would be entered for doses one and two.
- If a household contact receiving immunization moves out of the jurisdiction or is lost to follow-up, enter “9” (Unk) for any remaining doses not yet given.

4. Lost to Follow-Up

If any of the household contacts listed above does not complete the 3-dose series, check all of the reasons that apply.

a. ☐ Contact(s) located but later lost to follow-up
b. ☐ Contact(s) found to be already infected or immune after series was started
c. ☐ Contact(s) moved to another county within the state for follow-up and don’t know whether vaccination series was completed or not
d. ☐ Contact(s) moved out of the state
e. ☐ Contact(s) moved out of the country
f. ☐ Contact(s) died
g. ☐ Compliance problem with family
h. ☐ Other (specify):_____

- This section applies only to those individuals who are listed in the grid for question #3, above. Complete this section if any one of the susceptible or assumed susceptible household contacts does not complete the 3-dose immunization series.
- More than one reason may be checked.

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Instructions for Post Exposure Prophylaxis (PEP) Error Form

A PEP error has occurred when an infant born to an HBsAg positive mother does not receive HBIG and/or HBV vaccine at all OR within the recommended time frame (within 12 hours of birth). ***If a PEP error occurs, please complete the following form and fax to (510) 620-3949 within 5 business days***

☐ New Report **County: _____** **PHPP ID Number __-__-__-___**
☐ Update

- For a newly reported error in PEP administration, check the New Report box. If you are submitting a revision to a previously reported form, check the Update box.
- List your county or jurisdiction name in the County field
- Include the PHPP ID Number were indicated. This should match the ID assigned to both the mother and the infant.

MOTHER'S Name: **MOTHER'S date of birth**

_____ ___/___/_____
Last First MI mm dd yyyy

INFANT'S Name: **INFANT'S date of birth Time of birth**

_____ ___/___/_____ ____:____
Last First MI mm dd yyyy (Military Time: hh:mm)

Sex: 1☐Male 2☐Female

- Include the mother's name and date of birth as they appear on page 1 of the case management form
- Include the infant's name, date of birth, time of birth, and sex as they appear on page 2 of the case management form.

Hospital Name:_____ **Phone:** _____ **Fax:**_____

HBIG ☐ Not given ☐ Given **Hep B Vac1** ☐ Not given ☐ Given

Date and time when given ___ ___ _____ ____ ____ **Date and time when given** ___ ___ ____ ____ ____
mm dd yyyy (military, hh:mm) mm dd yyyy (military, hh:mm)

If date/time not available, age in hrs when given ____ **If date/time not available, age in hrs when given** ____

- List the name of the birth hospital as well as their phone and fax numbers.

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- Include the infant's HBIG and Hepatitis B Vaccine information as written on page 2 of the case management form. This includes the date and time that HBIG and/or vaccine were given, as well as the infant's age. If HBIG or Hepatitis B Vaccine were not given, check the appropriate box.

Reasons for error (check all that apply)

It is the responsibility of the local health department to contact the birth hospital where the PEP error occurred and identify the cause of the PEP error. If appropriate, the local health department should request that the hospital develop a corrective action plan describing how to avoid similar errors in the future. Please contact CDPH PHPP if you have any questions about PEP errors.

After completing the appropriate follow-up, please check all the boxes that describe the cause of the PEP error. Reasons are grouped by category, as described below:

HBsAg testing

☐ **Mother's status was not known at the time of admission**
- ☐ **Hospital did not test mother**
- ☐ **Hospital tested mother but the results were delayed**

☐ **Mother's HBsAg status was misinterpreted**
- ☐ **By a clinician at the hospital**
- ☐ **By the treating provider who provided incorrect information to the hospital**

☐ **Original lab result was not available in the hospital record**
- ☐ **Mother's HBsAg result was communicated verbally to the hospital**
- ☐ **Mother's HBsAg result was communicated in writing to the hospital**

☐ **Mother had multiple HBsAg tests and hospital only had documentation of a negative test**

☐ **Hospital did not assess mother's HBsAg status**

This collection of check boxes refers to errors related the miscommunication or misinterpretation of the mother's HBV status or prenatal lab result. When one of these scenarios occurs, the hospital must provide education to the appropriate staff or departments to ensure that the mother's HBV labs are available in a timely manner and are correctly interpreted by and communicated the appropriate personnel.

PEP Availability

☐ **Pharmacy was closed/delay in the pharmacy**
☐ **Pharmacy did not have HBIG in stock**
☐ **Pharmacy did not have HBV vaccine in stock**

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This section refers specifically to the availability of PEP. If one of these scenarios occurs, inform the hospital to work with their pharmacy to ensure that HBIG and HBV vaccine are available when requested.

Compliance

☐ **Parent refused PEP for infant**
☐ **Physician did not provide PEP for the infant**
☐ **Parent did not present child to care for PEP (e.g. in the event of a home birth where the infant might receive PEP in an ED or other planned facility)**

This section refers to scenarios where PEP is not given to the infant by either the parents or the treating provider. If the parents are refusing PEP despite the mother's positive HBV test result, or the provider is refusing to administer PEP, please report this error to CDPH PHPP as soon as you can so that we can assist you in determining next steps.

Patient Care

☐ **Staff miscommunication or poor recordkeeping of administration/receipt of PEP**
☐ **Short-staffed; patient census high, could not provide PEP within time frame**
☐ **Change of shift**

This section includes errors that are related to the care that the patient is receiving at the birth hospital. Unlike the section relating the mother's HBV status, this section focuses on the birth hospital staff and the actions or protocols followed during delivery. Examples of these types of scenarios include: "the nurses changed shifts and failed to inform the next shift that PEP was needed" or "a nurses' strike at the hospital delayed the administration of PEP". When one of these scenarios occurs, the hospital should provide education to the staff to prevent a similar mistake in the future.

Infant Medical Reason

☐ **Infant medical emergency**
☐ **Physician or other clinical refused to provide PEP to infant because of infant's medical condition**

This section refers medical scenarios that might result in a delay in PEP administration.

☐ **Other (if so, please specify) _____**

If the cause of the PEP error is determined to be something other than the boxes included above, please select the "Other" option and explain the circumstances surrounding the PEP error. Page 2 of the PEP Error Form contains addition space in which you can describe the nature of the error.

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Please describe why the PEP error occurred in as much detail as possible. Attach any lab reports and relevant medical records available for this mother and infant, as well as any corrective action plans developed by the birthing facility.

Regardless of the reason for the PEP error, please provide additional information on page 2 on the PEP Error Form. Please be as specific as possible.