

California Perinatal Hepatitis B Prevention Program Reporting Manual



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Revised January 2008

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California Perinatal Hepatitis B Prevention Program

Hepatitis B is a serious liver disease caused by the hepatitis B virus (HBV) that occurs worldwide among people of all ages. HBV is a highly infectious virus that can result in severe illness, liver damage, cirrhosis and increased risk for hepatocellular carcinoma. Each year, more than 250,000 persons worldwide die of hepatitis B-associated acute and chronic liver disease.

HBV can be spread through contact with blood and certain body fluids of people infected with HBV, such as blood products, semen, vaginal secretions, and saliva. Pregnant women who are infected with HBV can transmit the disease to their babies perinatally. Perinatal hepatitis B virus transmission is a serious public health problem because approximately 70-90% of infants who are born to hepatitis B surface antigen (HBsAg) positive and hepatitis B e antigen (HBeAg) positive women and do not receive prophylaxis become chronically infected.¹ Up to 90% of these infected babies will develop chronic hepatitis B, which can lead to liver failure or liver cancer later in life.

Fortunately, it is possible to prevent perinatal HBV infection. Once it is determined that a pregnant woman is infected with HBV, the exposed baby can receive hepatitis B immune globulin and be vaccinated with one dose of hepatitis B vaccine at birth. Two to three additional doses of the hepatitis B vaccine will also need to be given to the baby by 6 to 15 months of age, depending on the formulation that is used.

A comprehensive strategy to eliminate hepatitis B virus transmission was first recommended by the Advisory Committee on Immunization Practices (ACIP) in 1991 and updated in 2005.² The Centers for Disease Control and Prevention (CDC) estimate that between four and five thousand infants are born each year in California to HBsAg-positive women.³ The California Perinatal Hepatitis B Prevention Program (CA PHPP) was established by the California Department of Public Health (CDPH) in 1991 and currently operates in 24 local health department jurisdictions.

In 1989, infection with hepatitis B became a reportable condition under Title 17 of the California Code of Regulations (Appendix B).⁴ 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 HBsAg (Appendix C).⁵ This law, supported by the American College of Obstetrician and Gynecologist (ACOG) and the American Association of Pediatrics (AAP), was designed to identify pregnant women who are infected with hepatitis B. Together with the screening and reporting laws and the recommendation for routine hepatitis B vaccination for all infants, the Perinatal Hepatitis B Prevention Program is designed to reduce the perinatal transmission of HBV to infants and prevent transmission of HBV to high risk household contacts.

¹ 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.

² Centers for Disease Control and Prevention. A comprehensive immunization strategy to eliminate transmission of hepatitis B virus infection in the United States: recommendations of the Advisory Committee on Immunization Practices (ACIP); Part 1: Immunization of Infants, Children and Adolescents. *MMWR* 2005;54 (No. RR-16).

³ Okada K, Kamiyama I, Inomata M, Imai M, Miyakawa Y. e antigen and anti-e in the serum of asymptomatic carrier mothers as indicators of positive and negative transmission of hepatitis B virus to their infants. *N Engl J Med* 1976;294:746-9.

⁴ California Code of Regulations. Title 17 Section 2500.

⁵ California Health and Safety Code. Section 125050-125119.5.

The goals of the CA PHPP include:

- 1) Prenatal testing of pregnant women for HBsAg to identify carrier mothers;
- 2) Appropriate immunoprophylaxis for infants born to these mothers and post-vaccination serology testing;
- 3) Outreach and education for birth hospitals, prenatal care providers and pediatricians and
- 4) Referrals for serologic tests and immunizations for susceptible household contacts.

In order to identify hepatitis B carrier women and ensure that their infants and household contacts are appropriately immunized, a multi-system approach must be employed. The local health department should work together with clinical laboratories, private physicians, other health professionals and delivery hospitals to ensure timely reporting of HBsAg-positive test results to facilitate follow-up for carrier mothers and their families.

Once a case is enrolled in the program, the local health department should work together with parents, private providers and delivery hospitals to ensure that all infants born to HBsAg-positive mothers receive timely and appropriate immunizations and post-vaccination serology testing to confirm immunity. The local health department should also ensure that the household contacts are being referred for serological screening and immunizations if they are susceptible to the disease. Outreach and culturally appropriate health education materials should be used to reinforce the importance of preventing perinatal hepatitis B transmission.

The Confidential HBsAg+ Case/Household Management Report (CDPH 8546) or an electronic file equivalent should be submitted to the State program (Appendix A). The State Perinatal Hepatitis B Prevention Program maintains and regularly updates a state-wide database of HBsAg-infected mothers and their infants. Program analyses and reports are routinely generated to provide feedback to the individual local programs and CDC.

Approximately 3,000 pregnant women infected with hepatitis B are identified and enrolled in the CA PHPP each year. More detailed information on demographics of these enrolled women, case management outcomes and number of women and infants enrolled by county are available on the California Immunization Branch website at:

http://www.dhs.ca.gov/ps/dcdc/izgroup/diseasesbrowse/Vaccine-Preventable_Diseases_Report_SIRE.htm

Reporting Guidelines for the Perinatal Hepatitis B Program

Case Definition

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. When a local health department is notified of an HBsAg-positive woman, the health department should confirm that the case has been reported on a Confidential Morbidity Report (CMR) form. The CMR should read "HBsAg-positive Prenatal Screen." Pregnant women who are HBsAg-positive typically meet the CDC case definition for chronic HBV infection. The CDC case definitions for hepatitis B are listed below.

Chronic HBV Infection

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

- 1) IgM antibodies to hepatitis B core antigen (anti-HBc) negative AND a positive result on one of the following tests: HBsAg, HBeAg or HBV DNA
OR
- 2) HBsAg positive or HBV DNA positive two times at least 6 months apart

Probable: a case with a single HBsAg positive or HBeAg positive lab result when no IgM anti-HBc results are available

Acute HBV Infection

Confirmed: a case that meets the clinical case definition of acute illness with

- 1) Discrete onset of symptoms
AND
- 2) Jaundice or elevated serum aminotransferase levels

AND meets the laboratory confirmation for diagnosis of either

- 1) Immunoglobulin M (IgM) antibody to hepatitis B core antigen (anti-HBc) positive
OR
- 2) HBsAg positive IgM anti-HAV negative (if done)

Perinatal HBV Infection

HBsAg positivity in any infant aged >1-24 months who was born in the United States or in U.S. territories to an HBsAg-positive mother

Household Definition

A household is defined as all persons residing at the primary residence of the HBsAg-positive woman on 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 local health department should follow individuals from both addresses. Data on all household and close contacts followed, regardless of their residence, should be included on the case/household management form.

Confidential Case/Household Management Report

The Case/Household management report form is located in Appendix A. A fill-in electronic version is also available from the Division of Communicable Disease Control Forms website and upon request from the CA PHPP.

Page 1 (Data on the Mother): This section includes descriptive questions regarding the mother's health status, race/ethnicity, source of payment for medical services, etc.

Page 2 (Data on the Infant): This section includes questions pertaining primarily to the infant's hepatitis B immunization record.

Page 3 (Data on Household Contacts): This section includes questions pertaining to the screening and immunization of household contacts.

Page 4 (Worksheet): This page is provided for local health departments' use in following up with the case and household contacts. It is not necessary to submit the worksheet to the state.

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 the 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 local health departments 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 hepatitis B. Any information published from these reports shall be restricted to statistical compilations relating to risk profiles, immunization histories or other epidemiologic data on hepatitis B 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 State Perinatal Hepatitis B Prevention Program for each case/household on two separate occasions:

- (1) When the case is “opened” with the mother’s information; and
- (2) When the case is “closed” with the infant and household contact information.

Opening a Case

- A newly opened case should be submitted to the State Perinatal Hepatitis B Prevention Program 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).
- Send a copy of Page 1 (MOTHER) only of the case/household management report to:

Perinatal Hepatitis B Prevention Program
California Department of Public Health
Immunization Branch
850 Marina Bay Parkway, Building P, 2nd Floor
Richmond, CA 94804

OR

Fax: (510) 620-3949
Attention: Perinatal Hepatitis B Prevention Program

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:
 - a) The infant has received HBIG, all three hepatitis B vaccine doses and has been post-vaccine serology tested and found to be immune. Every household contact has been screened and referred for appropriate follow-up.
 - b) The infant has received HBIG, all three hepatitis B vaccine doses and has been post-vaccine serology tested and found to be immune. Every effort has been made to screen the household contacts, but they have been lost to follow-up.
 - c) 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.
 - d) A case/household management report has been initiated for a pregnant woman known to be positive for HBsAg, but she has moved and is lost to follow-up.

- If a county chooses, it may close a case after the infant receives HBIG and all 3 hepatitis B vaccine doses. Additional information about post-vaccine serology (PVS) testing and household contact follow-up should be sent to the State as an “Update” (see more information below).
- When a case is closed, regardless of the reason it is closed, a copy of the entire case/household management report (Pages 1-3: MOTHER, INFANT(S), and ALL HOUSEHOLD CONTACTS) should be sent in to the State Perinatal Hepatitis B Prevention Program. The box “Close” should be marked on the top of Page 1 (MOTHER). Page 4, 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 Field 21 of the MOTHER form.

New Closes

- Sometimes a case will be submitted for the first time to the State Perinatal Hepatitis B Prevention Program as a closed case. The following situations are two common examples of when this might occur:
 - a) A case has been identified, but the woman moves out of the country before the case has been submitted to the State Perinatal Hepatitis B Prevention Program.
 - b) A case was submitted but the State Perinatal Hepatitis B Prevention Program has no record of it, so the case is not “opened” in the state database.
- For new closes, send in the report forms as if closing the case, and mark both “New Report” and “Close” on the top of Page 1 (MOTHER).

Updates/Revisions

- There are often changes to information originally obtained during the case/household follow-up period (e.g. demographic information, post-vaccination serology test dates and results, etc.). These changes should be submitted to the State Perinatal Hepatitis B Prevention Program so that the state database may be updated accordingly.
- Make any changes by crossing out the old information and writing in the revised information. Mark any submitted revision as an “Update” at the top of Page 1 (MOTHER).

Transfers

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

Intrastate transfers – Between jurisdictions **with** Perinatal Hepatitis B Programs

- If a case transfers from one jurisdiction with a perinatal hepatitis B prevention program to another, the county to which the case has transferred is responsible for continuing case/household management, closing the case, and submitting the case/household management report to the State Perinatal Hepatitis B Prevention Program.
- The Perinatal Hepatitis B Prevention Program In-State Case Transfer Form (Appendix D) may be used 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.
- The county of origin may inform the State Perinatal Hepatitis B Prevention Program of the transfer and submit a copy of the form marked “In-State Transfer” on the top of Page 1 (MOTHER), but should not submit the closing paperwork for the case.
- 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.

Intrastate transfers – To jurisdictions **without** a Perinatal Hepatitis B Program

- If a case transfers to a jurisdiction in California that does not have a perinatal hepatitis B prevention program, the county of origin should close the case and submit the appropriate paperwork to the State Perinatal Hepatitis B Prevention Program with the boxes “In-State Transfer” and “Close” marked on the top of Page 1 (MOTHER). Any known forwarding address or information should be written on the form so that the State Perinatal Hepatitis B Prevention Program can pass on the information to the appropriate contacts.
- The Perinatal Hepatitis B Prevention Program In-State Case Transfer Form (Appendix D) may be used during this transfer process.
- The local health department should make every effort to provide the woman and her household with the information they will need should they change providers upon moving.

Interstate transfers

- If a case transfers out of the state of California, the county of origin should close the case and submit the appropriate paperwork to the State Perinatal Hepatitis B Prevention Program with the boxes “Out-of-State Transfer” and “Close” marked on the top of Page 1 (MOTHER). Any known forwarding address and all information about mother/infant and contacts should be written on the form so that the State Perinatal Hepatitis B Prevention Program can pass on the information to the appropriate contacts.
- The Perinatal Hepatitis B Prevention Program Out-of-State Case Transfer Form (Appendix D) may be used during this transfer process.
- The local health department should make every effort to provide the woman and her household with the information they will need to give to their new providers.

**Confidential HBsAg+ Case/Household Management Report
Instructions for Page 1:
MOTHER**

New Report **Update** **In-State Transfer** **Out-of-State Transfer** **Close**

- 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
- In-State Transfer: A case transferred to and from a county within the state
- Out-of-State Transfer: A case transferred to or from another state
- Close: The final report submitted to the state

1. 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 code (see Appendix E) in the first two spaces marked "county." A list of all health jurisdiction codes can be found at the end of this instruction booklet.
- 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.

Examples:

01-08-02-003: This number indicates that the case was opened in Alameda County (code 01), in August (08), 2002 (02), and that it was the third (003) case opened during the month of August.

36-02-02-020: This number indicates that the case was opened in San Bernardino County (code 36) in February (02), 2002 (02), and that it was the twentieth (020) case opened during the month of February.

2. County: _____

- Write in the name of your county or health jurisdiction. For intrastate transfer cases, the original county/jurisdiction that was entered on this line should be lined-out in red and the new or transfer county written in red above it.

3. Case/Household Identification No. /_/_/_-/_/_-/_/_-/_/_/_/ (transfer county)

County mm yy

- When a case is transferred from one contract county into another, it must be assigned a transfer case/household identification number. The county to which the case has transferred should enter its own identification number in the transfer county field, while the original identification number remains in its designated field. 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 seven-digit identification number should be the month and year that the transfer was received, the case opened, and follow-up began).

Example:

1. Case/Household Identification No. 30-01-02-014 (county of origin)

3. Case/Household Identification No. 48-06-02-008 (transfer county)

This case was originally opened in Orange County (code 30) in January 2002. However, the second identification number indicates that the case was transferred to Solano County (code 48) in June 2002. Solano will now be the jurisdiction responsible for following up with and closing the case. Orange County does not close the case to the state, as the case is still being actively followed in Solano, the transfer county.

has left the hospital, including hospital-based or community-based clinics. "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.

14a. Was HBsAg+ known before this pregnancy?

1 Yes 2 No 9 Unknown

- Check "yes," "no," or "unknown." If "Yes," proceed to 14b. Otherwise, leave 14b blank.

14b. If "Yes" (to 14a), was this discovered with a previous pregnancy?

1 Yes 2 No 9 Unk

- Check "yes," "no," or "unknown."

15a. When was HBsAg+ test done?

1 Pre-pregnancy 2 At delivery

3 During pregnancy 9 Other/Unk

- If the test was done pre-pregnancy, check the appropriate box. If the test was done within 24 hours of an infant's birth, check the box labeled "At delivery." This implies either just before or just after the baby was born. Check "During pregnancy" if appropriate, and proceed to 14b.

15b. If "During pregnancy" (in 15a), enter month of pregnancy ____

- If the test was done sometime during this pregnancy, and the month is known, enter the appropriate single-digit number in the box (i.e., 1,2,...9, indicating month of pregnancy). If a woman happens to deliver in her 10th month of pregnancy, enter a "9" in the space provided. If the test was done during pregnancy and only the approximate time of the test is known, estimate as follows: If the test was done sometime during the first trimester, enter "2". This represents the second month or the midpoint of the first trimester. If the test was done sometime during the second trimester, enter "5", the midpoint of the second trimester. If the test was done sometime during the third semester (but before labor and delivery), enter "8", indicating the midpoint of the third trimester. If the answer to this question is unknown, leave it blank.

16. Planned 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: _____

- This question pertains specifically to mothers identified as HBsAg+ before their infants are born. "Other/Govt. 3rd party payer" refers to programs like Medi-Cal, such as Medicare, CHDP, CCS or other forms of government subsidy that directly covers 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.

17. Planned delivery hospital?

1 Public hospital

3 Outside of hospital

2 Private hospital

9 Unknown

- This question pertains specifically to mothers identified as HBsAg+ before their infants are born. A public hospital is defined as a publicly supported and/or managed hospital that provides services to public sector patients for obstetric services.

18a. 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. Proceed to 18b only if "Other" or "Unknown" is checked.

18b. If mother born outside of U.S.A., is she a refugee? 1 Yes 2 No 9 Unk

- Answer this question only if the mother is known to have been born outside the United States and you have checked "other" in the previous question.

19a. Ethnicity:

1 Hispanic 2 Non-Hispanic 9 Unknown

19b. Race:

1 White 2 Black 3 Amer. Indian/Alaskan Native
4 Asian 5 Pacific Islander 6 Other/Unspecified

- Answer both the race and ethnicity questions. Enter "White" for White/Caucasian; enter "Black" for Black/African American; enter "Amer. Indian/Alaskan Native" for American Indian or Alaskan Native. For mothers who are Asian or Pacific Islanders, enter "Asian" or "Pacific Islander" and 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, leave the field blank and write "Unknown" in the margin of the form.
- 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.
- A person may be coded as Hispanic, regardless of his/her race, if his/her ethnicity is of Spanish origin, such as Mexican/Mexican-American/Latino/Chicano, Puerto Rican, Cuban, Central/South American or other specified Spanish/Hispanic.

20. Initial submit date: / /
mm dd yyyy

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

21. Close date: / /
mm dd yyyy

- Enter the date this case was closed in MMDDYYYY format. The close date should be the date that Pages 1, 2, and 3 (all pages should be submitted, whether completed or not) of the case/household management form for a closed case are submitted to the State.

6. Name: _____
Last First MI

7. Birth date: ____/____/____
mm dd yyyy

8. Sex: 1 Male 2 Female

- Enter the information for each live birth that occurred during this pregnancy. Birth date should be recorded in MMDDYYYY 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 hepatitis B. As prescribed by the Advisory Committee on Immunization Practices (ACIP), HBIG and the first dose of vaccine should be given within twelve hours of the infant's birth. For infants receiving monovalent hepatitis B vaccine, the second dose should be given at 1-2 month of age and the third dose at six months of age. Please see Appendix F for information on combination immunization schedules and schedules for low-birth-weight infants.
- 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 not later than seven days of age. If the mother's status is unknown and the infant weighs <2,000 grams, HBIG should be administered with hepatitis B vaccine within 12 hours of birth.

9. HBIG a. Not given
b. Age when given (hours) _____
c. Date when given ____/____/____
mm dd yyyy

- If no HBIG was given, check box 9a.
- If HBIG was given, enter the age of the infant in hours that HBIG was given (9b) and the date HBIG was given (9c) in MMDDYYYY format.

10. Hep B Vac1 a. Not given
b. Age when given (hours) _____
c. Date when given ____/____/____
mm dd yyyy

- If no doses of hepatitis B vaccine were given, check box 10a and record the reason that no doses of vaccine were given at the bottom of the page in field 19.
- If the first dose of hepatitis B vaccine was given, enter the age of the infant in hours that the first dose of the hepatitis B vaccine was given if less than or equal to twenty-four hours after the infant's birth (10b) and/or the date the first dose was given if more than twenty-four hours after birth (10c). If the first dose of hepatitis B vaccine was given at greater than 24 hours after birth, only the date the vaccine was given should be completed (10c) in MMDDYYYY format.

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

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

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

- Enter the dates that the second, third and fourth doses of the hepatitis B vaccine were given. If the exact date is not known, estimate if at all possible (e.g. the fifteenth of the month). If the date of vaccine administration is completely unknown, leave the field blank (Do not enter "00/00/00" or "99/99/99") and write "Date Unknown" in the margin.

- Infants may be given four doses of hepatitis B vaccine if a combination vaccine schedule is being followed. Please see Appendix F for information on combination immunization schedules.

Post-Vaccination Follow-up Serology Record:

- All infants born to HBsAg-positive women should be tested 1-2 months after having received their third dose of hepatitis B vaccine, but not before 9 months of age. Infants 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 protected.
- If neither HBsAg nor anti-HBs are present, the infant cannot be considered protected and should receive a second hepatitis B vaccine series.
- If HBsAg is present and anti-HBs is not present, the infant can be considered infected and should be reported as a case of Perinatal Hepatitis B Infection.
- For more information on interpreting hepatitis B lab tests, see Appendix G.

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 MMDDYYYY 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 MMDDYYYY format (15b) and the result of the test (15c).

Second Series Immunization and Repeat Post-Vaccination Serology Record:

16. 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 16-18).
- If the infant is found to be negative for anti-HBs (i.e. found not to be immune), indicate if the infant received a 2nd series of vaccine.
- 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 MMDDYYYY format (16b-d).

17. 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

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

1 Yes 2 No 9 Unk

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

c. Result: 1 Pos 2 Neg 9 Unk

- If the infant completes the 2nd series of hepatitis B vaccine and is post-vaccine tested for HBsAg, check “Yes” (17a) and enter the date of the test in MMDDYYYY format (17b) and the result of the test (17c).
- If the infant completes the 2nd series of hepatitis B vaccine and is post-vaccine tested for anti-HBs, check “Yes” (18a) and enter the date of the test in MMDDYYYY format (18b) and the result of the test (18c).

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

- a. Infant completed Hep B series but was lost before serology testing was completed
- b. Infant diagnosed with acute Hep B before vaccine series was completed
- c. Infant could never be located
- d. Located mother/household but later lost to follow-up
- e. Infant moved or transferred to another county within the state for follow-up and don't know whether vaccination series was completed or not
- f. Infant moved out of the state
new address: _____
- g. Infant moved out of the country
- h. Compliance problem with family
- i. Infant died
- j. Other (specify): _____

- This section should be completed for those mothers and infants that are lost to follow-up
- If the infant does not complete the hepatitis B vaccine series or post-vaccination serology testing, check all of the reasons that apply.

a. Infant completed Hep B series but was lost before serology testing was completed

- If the infant completed the entire hepatitis B vaccine series but was lost to follow-up before post-vaccine serology was completed, check field 19a.

b. Infant diagnosed with acute Hep B before vaccine series was completed

- If the infant was diagnosed with acute hepatitis B before the vaccine series was completed, check field 19b and submit a CDC Perinatal Hepatitis B case report form.

c. Infant could never be located

- If the mother/infant could never be located, check field 19c.

d. Located mother/household but later lost to follow-up

- If the mother/household was initially contacted but then later lost to follow-up, check field 19d.

e. Infant moved or transferred to another county within the state for follow-up and don't know whether vaccination series was completed or not

- If the infant/mother was enrolled but then moved or transferred to another county within California (that may or may not have a Perinatal Hepatitis B Prevention Program), and vaccine or post-vaccine serology information was not received, check field 19e.

f. Infant moved out of the state

- If the infant moved out of the state, check field 19f and enter the new address in the space provided.

g. Infant moved out of the country

- If the infant moved out of the country, check field 19g.
- Often there are situations where a woman will travel to the U.S.A. to deliver the infant, then return back to her home country with the baby. Follow-up on these infants is time-consuming and often infeasible. Checking field 19g will help track these scenarios.

h. Compliance problem with family

- If the mother/household was contacted but refuses to participate or be compliant with the Perinatal Hepatitis B Prevention Program, check field 19h.

i. Infant died

- Field 19i, "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 some time after the first twenty-four hours of life, and usually after HBIG and one dose of the hepatitis B vaccine have been given.

j. Other (specify): _____

- If the infant is lost to follow-up for other reasons that are not enumerated here, please check field 19j and specify in the space given.

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

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

- Enter the number of household contacts who have a laboratory test done during the follow-up for the current case to determine their hepatitis B status in Field 3d.
- The age category (3e or 3f) and test result (3g or 3h) should also be documented for each household contact included in this field.
- Enter the number of contacts who were seroscreened, found to be susceptible and were vaccinated in Field 3i.
- The total number of contacts seroscreened for Hep B markers (3d) should equal the sum of 3e and 3f and the sum of 3g and 3h.

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 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 4, "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 for 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).

4. 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) ≥ 21 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 3i (Of those found to be susceptible, number vaccinated) and 3j (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 4a–4e for each household contact receiving immunization.

4a. 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.

4b. 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 4b.
 - If a household contact is age 6 to 21 years, enter a number “2” in Field 4b.
 - If a household contact is age 21 years or older, enter a number “3” in Field 4b.

4c–4e. 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, receiving vaccine without screening, or needing to finish the vaccine series) 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.

5. 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 #4, 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.

Appendix A
Confidential HBsAg+ Case/Household Management Report Form

INFANT(S)

1. **Case/Household Identification No.** _____ - _____ - _____ - _____ (county of origin)
County mm yy

2. **Case/Household Identification No.** _____ - _____ - _____ - _____ (transfer county)
County mm yy

3. **This pregnancy resulted in a: (Check all that apply)**

- a. Live birth → Number of live infant(s) born (1,2 etc): _____
- b. Fetal death → Number of fetal deaths: _____
- c. Miscarriage or abortion → (check box if 'yes')

4. **Actual source of payment for delivery?**

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

5. **Actual delivery hospital?**

- 1 Public hospital
- 2 Private hospital
- 3 Outside of hospital
- 9 Unknown

Infant # ____ If only one live infant, enter "1". If two or more live infants, attach 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.

6. **Name:** _____
Last First MI

7. **Birth date:** ____/____/____
mm dd yyyy

8. **Sex:** 1 Male 2 Female

Immunization Record:

- 9. **HBIG**
 - a. Not given
 - b. Age when given (hours) _____
 - c. Date when given ____/____/____
mm dd yyyy
- 10. **Hep B Vac1**
 - a. Not given
 - b. Age when given (hours) _____
 - c. Date when given ____/____/____
mm dd yyyy
- 11. **Hep B Vac2** Date when given ____/____/____
mm dd yyyy
- 12. **Hep B Vac3** Date when given ____/____/____
mm dd yyyy
- 13. **Hep B Vac4** Date when given ____/____/____
(If applicable) mm dd yyyy

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

19. If infant does not complete the Hep B vaccine series or post-vaccination serology testing, check all of the reasons that apply.
- a. Infant completed Hep B series but was lost before serology testing was completed
 - b. Infant diagnosed with acute Hep B before vaccine series was completed
 - c. Infant could never be located
 - d. Located mother/household but later lost to follow-up
 - e. Infant moved or transferred to another county within the state for follow-up and don't know whether vaccination series was completed or not
 - f. Infant moved out of the state
new address: _____

 - g. Infant moved out of the country
 - h. Compliance problem with family
 - i. Infant died
 - j. Other (specify): _____

Post-Vaccination Follow-up Serology Record:

- 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

Second Series Immunization and Repeat Post-Vaccination Serology Record:

- 16. 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
- 17. a. **Was HBsAg test done after 2nd series?**
1 Yes 2 No 9 Unk
b. Date done ____/____/____
mm dd yyyy
c. Result: 1 Pos 2 Neg 9 Unk
- 18. a. **Was Anti-HBs test done after 2nd series?**
1 Yes 2 No 9 Unk
b. Date done ____/____/____
mm dd yyyy
c. Result: 1 Pos 2 Neg 9 Unk

CONTACTS

1. **Case/Household Identification No.** ____ - ____ - ____ - ____ (county of origin)
County mm yy

2. **Case/Household Identification No.** ____ - ____ - ____ - ____ (transfer county)
County mm yy

3. All Household Contacts

- a. ____ Total number of household contacts identified (a = b+c+d+j+k)
- b. ____ Number already known to be chronically infected or immune due to prior infection of Hep B
- c. ____ Number previously immunized
- d. ____
 ____ Of those seroscreened, number age ≤ 5 years
- 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 Hep B markers)
 i. ____ Of those found to be susceptible, number vaccinated
- j. ____ Number vaccinated without screening
- k. ____ Number lost to follow-up

4. Household Contacts Receiving Immunization (list in any order)

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

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

5. 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): _____

1 Case/Household Identification No. ____ - ____ - ____ (county of origin)
County mm yy

2 Case/Household Identification No. ____ - ____ - ____ (transfer county)
County mm yy

Optional worksheet (Do not send to State)

Name _____

Household address(es)/phone(s) _____

Translator needed? YES NO Mother's language _____

Staff person assigned to case/household _____ Delivery hospital _____

Provider type _____ Provider type _____

Physician name _____ Physician name _____

Clinic address(es) _____ Clinic address(es) _____

Phone(s) _____ Phone(s) _____

Infant(s) Dates Doses Due/Given=

Due
Given

Name(s)	Date of Birth	HBIG/Vac #1	Vac #2	Vac #3	Vac 4	PVS*
1.						
2.						

*Post Vaccination Serology Testing

Household Contacts Dates Doses Due/Given=

Due
Given

Name(s)	DOB	Sex	Date Referred	Serology Results	Vac #1	Vac #2	Vac #3	Notes
1.								
2.								
3.								
4.								
5.								
6.								

Appendix B
California Code of Regulations, Title 17, Sections 2500 and 2505

**Title 17, California Code of Regulations (CCR) §2500, §2593, §2641-2643, and §2800-2812
Reportable Diseases and Conditions***

§ 2500. REPORTING TO THE LOCAL HEALTH AUTHORITY.

- **§ 2500(b)** It shall be the duty of every health care provider, knowing of or in attendance on a case or suspected case of any of the disease or conditions listed below, to report to the local health officer for the jurisdiction where the patient resides. Where no health care provider is in attendance, any individual having knowledge of a person who is suspected to be suffering from one of the diseases or conditions listed below may make such a report to the local health officer for the jurisdiction where the patient resides.
- **§ 2500(c)** The administrator of each health facility, clinic, or other setting where more than one health care provider may know of a case, a suspected case or an outbreak of disease within the facility shall establish and be responsible for administrative procedures to assure that report are made to the local officer.
- **§ 2500(a)(14)** "Health care provider" means a physician and surgeon, a veterinarian, a podiatrist, a nurse practitioner, a physician assistant, a registered nurse, a nurse midwife, a school nurse, an infection control practitioner, a medical examiner, a coroner, or a dentist.

URGENCY REPORTING REQUIREMENTS [17 CCR §2500(h)(i)]

- ☎ = Report immediately by telephone (designated by a ♦ in regulations).
- † = Report immediately by telephone when two or more cases or suspected cases of foodborne disease from separate households are suspected to have the same source of illness (designated by a ● in regulations.)
- FAX ☎ ☒ = Report by FAX, telephone, or mail within one working day of identification (designated by a + in regulations).
- = All other diseases/conditions should be reported by FAX, telephone, or mail within seven calendar days of identification.

REPORTABLE COMMUNICABLE DISEASES §2500(j)(1), §2641-2643

	Acquired Immune Deficiency Syndrome (AIDS) (HIV infection only: see "Human Immunodeficiency Virus")				
FAX ☎ ☒	Amebiasis	☎ ☒	Pelvic Inflammatory Disease (PID)		
☎	Anthrax	☎ ☒	Pertussis (Whooping Cough)		
☎	Avian Influenza (human)	☎ ☒	Plague, Human or Animal		
FAX ☎ ☒	Babesiosis	☎ ☒	Poliomyelitis, Paralytic		
☎	Botulism (Infant, Foodborne, Wound)	☎ ☒	Psittacosis		
☎	Brucellosis	☎ ☒	Q Fever		
FAX ☎ ☒	Campylobacteriosis	☎ ☒	Rabies, Human or Animal		
	Chancroid	☎ ☒	Relapsing Fever		
FAX ☎ ☒	Chickenpox (only hospitalizations and deaths)		Rheumatic Fever, Acute		
	Chlamydial Infections, including Lymphogranulom Venereum (LGV)		Rocky Mountain Spotted Fever		
☎	Cholera		Rubella (German Measles)		
☎	Ciguatera Fish Poisoning	FAX ☎ ☒	Rubella Syndrome, Congenital		
	Coccidioidomycosis	☎	Salmonellosis (Other than Typhoid Fever)		
FAX ☎ ☒	Colorado Tick Fever	☎	Scombroid Fish Poisoning		
FAX ☎ ☒	Conjunctivitis, Acute Infectious of the Newborn, Specify Etiology	☎	Severe Acute Respiratory Syndrome (SARS)		
	Creutzfeldt-Jakob Disease (CJD) and other Transmissible Spongiform Encephalopathies (TSE)	FAX ☎ ☒	Shiga toxin (detected in feces)		
FAX ☎ ☒	Cryptosporidiosis		Shigellosis		
	Cysticercosis or Taeniasis	FAX ☎ ☒	Smallpox (Variola)		
☎	Dengue	FAX ☎ ☒	Streptococcal Infections (Outbreaks of Any Type and Individual Cases in Food Handlers and Dairy Workers Only)		
☎	Diarrhea of the Newborn, Outbreak	FAX ☎ ☒	Syphilis		
☎	Diphtheria		Tetanus		
☎	Domoic Acid Poisoning (Amnesic Shellfish Poisoning)		Toxic Shock Syndrome		
FAX ☎ ☒	Encephalitis, Specify Etiology: Viral, Bacterial, Fungal, Parasitic	FAX ☎ ☒	Toxoplasmosis		
	<i>Escherichia coli</i> : shiga toxin producing (STEC) including <i>E. coli</i> O157	FAX ☎ ☒	Trichinosis		
FAX ☎ ☒	Foodborne Disease		Tuberculosis		
	Giardiasis	FAX ☎ ☒	Tularemia		
	Gonococcal Infections	FAX ☎ ☒	Typhoid Fever, Cases and Carriers		
FAX ☎ ☒	<i>Haemophilus influenzae</i> invasive disease (report an incident less than 15 years of age)	FAX ☎ ☒	Typhus Fever		
☎	Hantavirus Infections		<i>Vibrio</i> Infections		
☎	Hemolytic Uremic Syndrome	☎	Viral Hemorrhagic Fevers (e.g., Crimean-Congo, Ebola, Lassa, and Marburg viruses)		
	Hepatitis, Viral	FAX ☎ ☒	Water-Associated Disease (e.g., Swimmer's Itch or Hot Tub Rash)		
FAX ☎ ☒	Hepatitis A	FAX ☎ ☒	West Nile Virus (WNV) Infection		
	Hepatitis B (specify acute case or chronic)	☎	Yellow Fever		
	Hepatitis C (specify acute case or chronic)	☎	Yersiniosis		
	Hepatitis D (Delta)				
	Hepatitis, other, acute				
	Human Immunodeficiency Virus (HIV) (§2641-2643)				
	Influenza deaths (report an incident of less than 18 years of age)				
	Kawasaki Syndrome (Mucocutaneous Lymph Node Syndrome)				
	Legionellosis				
	Leprosy (Hansen Disease)				
	Leptospirosis				
FAX ☎ ☒	Listeriosis				
	Lyme Disease				
FAX ☎ ☒	Malaria				
FAX ☎ ☒	Measles (Rubeola)				
FAX ☎ ☒	Meningitis, Specify Etiology: Viral, Bacterial, Fungal, Parasitic				
☎	Meningococcal Infections				
	Mumps				
☎	Paralytic Shellfish Poisoning				

**REPORTABLE NONCOMMUNICABLE DISEASES AND
CONDITIONS §2800-2812 and §2593(b)**

Disorders Characterized by Lapses of Consciousness (§2800-2812)
Pesticide-related illness or injury (known or suspected cases)**
Cancer, including benign and borderline brain tumors (except (1) basal and squamous skin cancer unless occurring on genitalia, and (2) carcinoma in-situ and CIN III of the cervix) (§2593)***

LOCALLY REPORTABLE DISEASES

Some local health jurisdictions require reporting of additional diseases. Please check with your local health department.

* Health care providers are required to report those diseases mandated by Title 17, California Code of Regulations (CCR). Failure to report is a misdemeanor (Health and Safety Code§ 120295) and is a citable offense under the Medical Board of California Citation and Fine Program (Title 16, CCR, §1364.10 and 1364.11).

** Failure to report is a citable offense and subject to civil penalty (§250) (Health and Safety Code §105200).

*** The Confidential Physician Cancer Reporting Form may also be used. See Physician Reporting Requirements for Cancer Reporting in CA at: www.ccrca.org.

Title 17, California Code of Regulations (CCR), Section 2505
REPORTABLE CONDITIONS: NOTIFICATION BY LABORATORIES

(edited date: 08/13/2007)

California Code of Regulations, Title 17, Section 2505 requires laboratories to report laboratory testing results suggestive of the following diseases of public health importance to the local health department:

List (e)(1)	List (e)(2)
Anthrax Botulism Brucellosis <i>Burkholderia mallei</i> and <i>pseudomallei</i> Plague , animal or human Smallpox (Variola) Tularemia Viral hemorrhagic fever agents (e.g., Crimean-Congo, Ebola, Lassa and Marburg viruses)	Acid-fast bacilli <i>Borrelia burgdorferi</i> Chlamydial infections, including Lymphogranuloma Venereum Cryptosporidiosis <i>Cyclospora cayetenensis</i> Diphtheria Encephalitis, arboviral <i>Escherichia coli</i> STEC, including O157:H7 infection Gonorrhea <i>Hemophilus influenzae</i> (from sterile site in patient <15 years old) Hepatitis A, acute infection , by IgM antibody test or positive viral antigen test Hepatitis B, acute infection , by IgM anti-HBc antibody test Hepatitis B surface antigen positivity (specify gender of case) Hepatitis C (see instructions below) <i>Legionella pneumophila</i> <i>Listeria monocytogenes</i> Malaria Measles (Rubeola), acute infection , by IgM antibody test or positive viral antigen test <i>Mycobacterium tuberculosis</i> (see instructions below) <i>Neisseria meningitidis</i> (from sterile site) Rabies , animal or human Rubella <i>Salmonella</i> species, including <i>S. typhi</i> (Section 2612 – see below) Shiga toxin (in feces) Syphilis <i>Vibrio</i> species infections West Nile virus infection

WHEN TO REPORT

These laboratory findings are reportable to the local health officer of the health jurisdiction where the health care provider who first submitted the specimen is located within one (1) hour (List (e)(1) diseases) or within one (1) working day (List (e)(2) diseases) from the time that the laboratory notifies that health care provider or other person authorized to receive the report. If the laboratory that makes the positive finding received the specimen from another laboratory, the laboratory making the positive finding shall notify the local health officer of the jurisdiction in which the health care provider is located within the time specified above from the time the laboratory notifies the referring laboratory that submitted the specimen. If the laboratory is an out-of-state laboratory, the California laboratory that receives a report of such findings shall notify the local health officer in the same way as if the finding had been made by the California laboratory.

HOW TO REPORT

Laboratory reports must be made in writing and give the following information:

- the date the specimen was obtained,
- the patient identification number,
- the specimen accession number or other unique specimen identifier,
- the laboratory findings for the test performed,
- the date that any positive laboratory findings were identified,
- the name, gender, address, telephone number (if known), and age or date of birth of the patient,
- the name, address, and telephone number of the health care provider who ordered the test.

The notification for **List (e)(1) diseases** shall be reported by telephone within **one (1) hour**, followed by a written report submitted by electronic facsimile transmission or electronic mail within **one (1) working day**, to the local health officer in the jurisdiction where the health care provider who submitted the specimen is located. The notification for **List (e)(2) diseases** shall be submitted by courier, mail, electronic facsimile transmission or electronic mail within **one (1) working day** to the local health officer in the jurisdiction where the health care provider who submitted the specimen is located. Whenever the specimen, or an isolate there from, is transferred between laboratories, a test requisition with the above patient and submitter information shall accompany the specimen. The laboratory that first receives a specimen shall be responsible for obtaining the patient and submitter information at the time the specimen is received by that laboratory.

ADDITIONAL REPORTING REQUIREMENTS

ANTHRAX, AVIAN INFLUENZA, BOTULISM, BRUCELLOSIS, GLANDERS, MELIOIDOSIS, PLAGUE, SMALLPOX, TULAREMIA, and VIRAL HEMORRHAGIC FEVERS

Whenever a laboratory **receives a specimen** for the laboratory diagnosis of a suspected human case of one of these diseases, such laboratory shall **communicate immediately by telephone** with the Microbial Diseases Laboratory (or, for Avian Influenza, Smallpox or Viral Hemorrhagic Fevers, with the Viral and Rickettsial Disease Laboratory) of the Department of Public Health for instruction.

TUBERCULOSIS

Any laboratory that isolates *Mycobacterium tuberculosis* from a patient specimen must submit a culture to the local public health laboratory for the local health jurisdiction in which the health care provider's office is located as soon as available from the primary isolate on which a diagnosis of tuberculosis was established.

The information listed under "HOW TO REPORT" above must be submitted with the culture.

Unless drug susceptibility testing has been performed by the clinical laboratory on a strain obtained from the same patient within the previous three months or the health care provider who submitted the specimen for laboratory examination informs the laboratory that such drug susceptibility testing has been performed by another laboratory on a culture obtained from that patient within the previous three months, the clinical laboratory must do the following:

- Perform or refer for drug susceptibility testing on at least one isolate from each patient from whom *Mycobacterium tuberculosis* was isolated,
- Report the results of drug susceptibility testing to the local health officer of the city or county where the submitting physician's office is located within **one (1) working day** from the time the health care provider or other authorized person who submitted the specimen is notified, and
- If the drug susceptibility testing determines the culture to be resistant to at least isoniazid and rifampin, in addition, submit one culture or subculture from each patient from whom multidrug-resistant *Mycobacterium tuberculosis* was isolated to the local public health laboratory (as described above).

Whenever a clinical laboratory finds that a specimen from a patient with known or suspected tuberculosis tests positive for acid fast bacillus (AFB) staining and the patient has not had a culture which identifies that acid fast organism within the past 30 days, the clinical laboratory shall culture and identify the acid fast bacteria or refer a subculture to another laboratory for those purposes.

MALARIA

Any clinical laboratory that makes a finding of malaria parasites in the blood film of a patient shall immediately submit one or more such blood film slides for confirmation to the local public health laboratory for the local health jurisdiction where the health care provider is located. When requested, all blood films will be returned to the submitter.

HEPATITIS C

Any laboratory with a positive hepatitis C virus (HCV) test that meets the CDC laboratory criteria for diagnosis of HCV infection in a California resident shall report the positive test to the local health officer.

The following test results are reportable:

- (1) All HCV positive recombinant immunoblot assay (RIBA) tests;
- (2) All HCV RNA positive tests [e.g., nucleic acid tests (NAT)];
- (3) All HCV genotype reports; and
- (4) Anti-HCV reactive by a screening test (e.g., enzyme immunoassay [EIA] or chemiluminescence immunoassay [CIA] with either:
 - (A) The exact signal-to-cut-off (s/co) ratio or index value; or
 - (B) A comment that indicates whether or not the screening test s/co ratio or index value is predictive of a true positive as determined for the particular assay as defined by the CDC in the case definition for "laboratory criteria for diagnosis" of Hepatitis C virus infection, past or present. The url for the s/co ratios that meet the CDC case definition is: http://www.cdc.gov/ncidod/diseases/hepatitis/c/sc_ratios.htm.

If a laboratory chooses to report a reactive anti-HCV screening test (e.g., EIA or CIA test) with a s/co or index value that is lower than required to meet the CDC case definitions AND does not report the exact s/co or index value (i.e., the laboratory report is positive without a specific s/co or index value reported), then the laboratory report must include a comment to indicate the s/co or index value is low and that supplemental testing (e.g. RIBA or NAT) is recommended by the CDC.

SALMONELLA

California Code of Regulations, Title 17, Section 2612 requires that a culture of the organisms on which a diagnosis of salmonellosis is established must be submitted to the local public health laboratory and then to the State's Microbial Diseases Laboratory for definitive identification.

All laboratory notifications are acquired in confidence. The confidentiality of patient information is always protected.

Appendix C
California Health and Safety Code, Section 125085-12590

Maternal HBsAg Screening Law

California Health and Safety Code Section 125085-12590

125085: As early as possible during prenatal care, a blood specimen obtained pursuant to Section 125080 shall be submitted to a clinical laboratory licensed by the department or to an approved public health laboratory for a test **to determine the presence of hepatitis B surface antigen** and the human immunodeficiency virus (HIV), and the **results shall be reported to** both of the following:

(A) The physician and surgeon or other person engaged in the prenatal care of the women or attending the woman at the time of delivery who ordered the test, and who shall subsequently inform the woman tested.

(B) A positive test result shall be reported to the local health officer, with the information required and within the timeframes established by the department, pursuant to Chapter 4 (commencing with Section 2500) of Title 17 of the California Code of Regulations.

125090. (d) If, during the final prenatal care standard medical tests, the medical records of the pregnant woman do not document a test for rhesus (Rh) blood type, a test for hepatitis B, or a test for HIV, the physician and surgeon or other person engaged in the prenatal care of the woman or attending the woman **at the time of labor or delivery** shall obtain a blood specimen from the woman for the test that has not been documented. . . . **The blood shall be tested by a method that will ensure the earliest possible results**, and the results shall be reported to both of the following: (1) The physician and surgeon or other person engaged in the prenatal care of the woman or attending the woman at the time of delivery. (2) The woman tested.

(e) After the results of the tests done pursuant to this section and Section 125085 have been received, the physician and surgeon or other person engaged in the prenatal care of the pregnant woman or attending the woman at the time of labor, delivery, or postpartum care at the time the results are received shall ensure that the woman receives information and counseling, as appropriate, to explain the results and the implications for the mother's and infant's health, including any followup care that is indicated.

Appendix D
Case Transfer Forms for
In-State and Out-of-State



Perinatal Hepatitis B Prevention Program

In-State Case Transfer Form

This form is for case transfers within California.

County of Transfer Information: _____
Name of County

Name of Coordinator _____

E-mail _____ Phone (_____) _____

Fax (_____) _____

Date of Transfer _____ / _____ / _____

Case Transfer ID number _____
co mm yy

County of Origin Information: _____
Name of County

Name of Coordinator _____

E-mail _____ Phone (_____) _____

Fax (_____) _____

Name of Mother _____ Name of Infant _____

New Contact information _____

Date of Transfer _____ / _____ / _____

Case ID Number _____
co mm yy

The State Perinatal Hepatitis B Program HAS HAS NOT been notified of this transfer

- Instructions:**
- This form is for case transfers within the state.
 - Both counties (County of Transfer and County of Origin) should keep a copy of this transfer form in their respective records.
 - For County of Transfer - Send completed form to County of Origin to acknowledge receipt of transfer.
 - For County of Origin - If form has not been received within 2 weeks from date of transfer, then follow-up with the coordinator in the County of Transfer.



Perinatal Hepatitis B Prevention Program

Out-of-State Case Transfer Form

This form is for case transfers out of California.

State of Transfer Information: _____
Name of State

Name of Coordinator _____

E-mail _____ Phone (_____) _____

Fax (_____) _____

Date of Transfer ____ / ____ / ____

California County of Origin Information: _____
Name of County

Name of Coordinator _____

E-mail _____ Phone (_____) _____

Fax (_____) _____

Name of Mother _____ Name of Infant _____

New Contact information _____

Date of Transfer ____ / ____ / ____

Case ID Number _____
co mm yy

Instructions:

- This form is for case transfers out of California.
- The County of Origin should keep a copy of this transfer form in their record.
- Send completed form to the state Perinatal Hepatitis B Prevention Program.

Appendix E
California County/Jurisdiction Codes

California County/Jurisdiction Codes

<u>Code</u>	<u>County/Jurisdiction</u>	<u>Code</u>	<u>County/Jurisdiction</u>
01	Alameda	32	Plumas
02	Alpine	33	Riverside
03	Amador	34	Sacramento
04	Butte	35	San Benito
05	Calaveras	36	San Bernardino
06	Colusa	37	San Diego
07	Contra Costa	38	San Francisco
08	Del Norte	39	San Joaquin
09	El Dorado	40	San Luis Obispo
10	Fresno	41	San Mateo
11	Glenn	42	Santa Barbara
12	Humboldt	43	Santa Clara
13	Imperial	44	Santa Cruz
14	Inyo	45	Shasta
15	Kern	46	Sierra
16	Kings	47	Siskiyou
17	Lake	48	Solano
18	Lassen	49	Sonoma
19	Los Angeles	50	Stanislaus
20	Madera	51	Sutter
21	Marin	52	Tehama
22	Mariposa	53	Trinity
23	Mendocino	54	Tulare
24	Merced	55	Tuolumne
25	Modoc	56	Ventura
26	Mono	57	Yolo
27	Monterey	58	Yuba
28	Napa	59	Berkeley City
29	Nevada	60	Long Beach City
30	Orange	61	Pasadena City
31	Placer		

Appendix F
Hepatitis B Immunization Schedules for
Infants ≥ 2000 gm and
Preterm Infants < 2000 gm

**Hepatitis B Vaccine Schedules for Newborn Infants \geq 2000 gm
by Maternal Hepatitis B Surface Antigen (HBsAg) Status^o**

MATERNAL HBsAg STATUS	SINGLE ANTIGEN VACCINE		SINGLE ANTIGEN + COMBINATION VACCINE	
	DOSE	AGE	DOSE	AGE
POSITIVE	Vac1 Hep B vaccine and Hepatitis B immune globulin (HBIG)	Within 12 hrs of birth	Vac1 Hep B vaccine and HBIG*	Within 12 hrs of birth
	Vac2 Hep B vaccine	1-2 months	Vac2 Combination vaccine	2 months
	Vac3 Hep B vaccine	6 months ^o	Vac3 Combination vaccine	4 months
			Vac4 Combination vaccine	6 months (Pediarix) or 12-15 months (Comvax)
	Serology testing for HBsAg and anti-HBs	9 months	Serology testing for HBsAg and anti-HBs	9 months or 1-2 months after 4 th Comvax dose*
UNKNOWN	1 Hep B vaccine within 12 hrs of birth			
	HBIG, if test result is positive within 7 days of birth			
	Test mother for HBsAg immediately. If positive, continue series as above [↑] . If negative, continue series as below [↓] .			
NEGATIVE	Vac1 Hep B vaccine [√]	Before discharge	Vac1 Hep B vaccine* [√]	Before discharge
	Vac2 Hep B vaccine	1-2 months	Vac2 Combination vaccine	2 months
	Vac3 Hep B vaccine ^o	6-18 months	Vac3 Combination vaccine	4 months
			Vac4 Combination vaccine ^o	6 months (Pediarix) or 12-15 months (Comvax) ^o

^o From Recommendations of the Advisory Committee on Immunization Practices (ACIP), 12/05. www.cdc.gov/ncidod/diseases/hepatitis/b/acip.htm

* Combination vaccines should not be given before 6 weeks of age.

^o The final dose in the series should not be given before age 24 weeks.

* PVS testing of infants receiving the Comvax series may be done at 9 months and after the 3rd vaccine dose.

[√] On a case-by-case basis, the first dose of hepatitis vaccine may be delayed until after hospital discharge for an infant who weighs \geq 2000 gm and whose mother is HBsAg negative, but only if the physician's order and the mother's original HBsAg lab report are documented in the infant's medical record.

**Hepatitis B Vaccine Schedules for Preterm Infants Weighing < 2000 gm
by Maternal Hepatitis B Surface Antigen (HBsAg) Status^o**

MATERNAL HBsAg STATUS	RECOMMENDATION	
	DOSE	AGE
POSITIVE	Hep B vaccine & Hepatitis B immune globulin (HBIG) ⁺	≤ 12 hours
	Vac1 Hep B vaccine*	1 month
	Vac2 Hep B vaccine	2-4 months
	Vac3 Hep B vaccine ^o	6-7 months (Pediarix or monovalent vaccine) 12-15 months (Comvax)
	Serology testing	9 months or 1-2 months after Vac 3. Do not test before 9 months of age or ≤ 4 weeks of the most recent vaccine dose.
UNKNOWN	Hep B vaccine & HBIG ⁺	≤ 12 hours of birth
	Test mother for HBsAg immediately: If positive, continue series as above↑ If negative, continue series as below↓	
NEGATIVE	Vac1 Hep B vaccine	At 1 month, or at hospital discharge*
	Vac2 Hep B vaccine	2-4 months
	Vac3 Hep B vaccine	6-18 months ^o

^o From “A Comprehensive Immunization Strategy to Eliminate Transmission of Hepatitis B Virus Infection in the United States: Recommendations of the Advisory Committee on Immunization Practices (ACIP) Part I: Immunization of Infants, Children, and Adolescents,” <http://www.cdc.gov/ncidod/diseases/hepatitis/b/acip.htm>
CDC version of Table 4 is available at <http://www.cdc.gov/hepatitis/hbv/pdfs/correctedtable4.pdf>

⁺ Do not count the birth dose as part of the vaccine series.

* Single-antigen vaccine should be used for doses administered before 6 weeks (42 days) of age. Either single or combination vaccine may be used for doses administered at ≥ 6 weeks of age.

^o The final dose in the vaccine series should not be given before 24 weeks of age (164 days).

Appendix G
Immunization Action Coalition (IAC) Resources

Hepatitis B Facts: Testing and Vaccination

— Who should be vaccinated? —

The following persons should receive routine hepatitis B vaccination according to the Centers for Disease Control and Prevention (CDC):

Routine vaccination:

- All newborns at birth prior to hospital discharge
- All children and teens ages 0 through 18 years
- All persons who wish to be protected from hepatitis B virus (HBV) infection. CDC states it is not necessary for the patient to disclose a risk factor in order to receive hepatitis B vaccine.

Persons who are at risk for sexual exposure:

- Sexually active persons who are not in long-term mutually monogamous relationships
- Sex partners of HBsAg-positive persons
- Persons seeking evaluation or treatment for an STD
- Men who have sex with men

Persons at risk for infection by percutaneous or mucosal exposure to blood:

- Current or recent injection-drug users
- Household contacts of HBsAg-positive persons
- Residents and staff of facilities for developmentally challenged persons
- Healthcare and public safety workers with reasonably anticipated risk for exposure to blood or blood-contaminated body fluids
- Persons with end-stage renal disease and those receiving dialysis.

Others:

- Travelers to areas with moderate or high rates of HBV infection
- Persons with chronic (life-long) liver disease
- Persons with HIV infection

All refugees, immigrants, and adoptees from countries with moderate or high rates of HBV infection should be screened. Adults should discuss their need or desire for hepatitis B vaccination with their healthcare providers.

— Hepatitis B lab nomenclature —

HBsAg: *Hepatitis B surface antigen* is a marker of infectivity. Its presence indicates either acute or chronic HBV infection.

anti-HBs: *Antibody to hepatitis B surface antigen* is a marker of immunity. Its presence indicates an immune response to HBV infection, an immune response to vaccination, or the presence of passively acquired antibody. (It is also known as **HBsAb**, but this abbreviation is best avoided since it is often confused with abbreviations such as HBsAg.)

anti-HBc (total): *Antibody to hepatitis B core antigen* is a nonspecific marker of acute, chronic, or resolved HBV infection. It is *not* a marker of vaccine-induced immunity. It may be used in prevaccination testing to determine previous exposure to HBV infection. (It is also known as **HBcAb**, but this abbreviation is best avoided since it is often confused with other abbreviations.)

IgM anti-HBc: *IgM antibody subclass of anti-HBc*. Positivity indicates recent infection with HBV (within the past 6 mos). Its presence indicates acute infection.

HBeAg: *Hepatitis B “e” antigen* is a marker of a high degree of HBV infectivity, and it correlates with a high level of HBV replication. It is primarily used to help determine the clinical management of patients with chronic HBV infection.

Anti-HBe: *Antibody to hepatitis B “e” antigen* may be present in an infected or immune person. In persons with chronic HBV infection, its presence suggests a low viral titer and a low degree of infectivity.

HBV-DNA: *HBV Deoxyribonucleic acid* is a marker of viral replication. It correlates well with infectivity. It is used to assess and monitor the treatment of patients with chronic HBV infection.

— Screening before vaccination —

Serologic testing prior to vaccination may be undertaken based on your assessment of your patient’s level of risk and your or your patient’s need for definitive information (see information in the left column). If you decide to test, draw the blood first, and then give the first dose of vaccine at the same office visit. Vaccination can then be continued, if needed, based on the results of the tests. If you are not sure who needs hepatitis B screening, consult your state or local health department.

Tests	Results	Interpretation	Vaccinate?
HBsAg anti-HBc anti-HBs	negative negative negative	susceptible	vaccinate if indicated
HBsAg anti-HBc anti-HBs	negative negative positive with $\geq 10\text{mIU/mL}^*$	immune due to vaccination	no vaccination necessary
HBsAg anti-HBc anti-HBs	negative positive positive	immune due to natural infection	no vaccination necessary
HBsAg anti-HBc IgM anti-HBc anti-HBs	positive positive positive negative	acutely infected	no vaccination necessary
HBsAg anti-HBc IgM anti-HBc anti-HBs	positive positive negative negative	chronically infected	no vaccination necessary (may need treatment)
HBsAg anti-HBc anti-HBs	negative positive negative	four interpretations possible [†]	use clinical judgment

*Postvaccination testing, when it is recommended, should be performed 1–2 months after the last dose of vaccine. Infants born to HBsAg-positive mothers should be tested 3–9 months after the last dose of vaccine.

- [†]1. May be recovering from acute HBV infection
 2. May be distantly immune, but the test may not be sensitive enough to detect a very low level of anti-HBs in serum
 3. May be susceptible with a false positive anti-HBc
 4. May be chronically infected and have an undetectable level of HBsAg present in the serum

— Managing chronic HBV infection —

When you identify a patient who is chronically infected with HBV, make sure you consult a specialist knowledgeable in the treatment of liver disease so your patient’s care is optimized. Chronically infected persons need medical evaluation every 6–12 months to assess the status of their liver health and their need for antiviral therapy, as well as to screen for liver cancer. Persons with HBV infection should also be educated about their disease and how to protect others.

Household members and sex partners should be tested for HBV infection and given the first dose of hepatitis B vaccine at the same visit. (Vaccinating a person who has already been infected will do no harm). If testing indicates HBV susceptibility, complete the hepatitis B vaccination series. If testing indicates HBV infection, consultation and further care with a physician knowledgeable about chronic hepatitis B is needed.

Give the birth dose . . .

Hepatitis B vaccine at birth saves lives!

By **Deborah L. Wexler, MD**, Executive Director, Immunization Action Coalition

On Dec. 23, 2005, CDC issued new recommendations on hepatitis B vaccination that were published in the MMWR. The recommendations strongly support the birth dose of hepatitis B vaccine for every newborn prior to hospital discharge and also recommend the use of standing orders for giving the birth dose. Copies of original maternal hepatitis B lab reports are also recommended (instead of transcribed test results). According to the new recommendations, the birth dose should only be withheld in "rare circumstances," and if doing so, physicians should write an order **not** to give the dose, and a copy of the mother's original HBsAg-negative lab report must be on the infant's chart. The American Academy of Pediatrics, American Academy of Family Physicians, and American College of Obstetricians and Gynecologists endorse these new recommendations.

The Immunization Action Coalition (IAC) urges all health professionals and hospitals to protect all infants from hepatitis B virus (HBV) infection by administering the first dose of hepatitis B vaccine to every infant at birth and no later than hospital discharge.

Approximately 19,000 women with chronic hepatitis B virus infection give birth in the U.S. each year. Up to 95% of perinatal infections can be prevented by postexposure prophylaxis given within 12 hours of birth. Tragically, many babies are exposed to HBV at birth but do not receive appropriate postexposure prophylaxis.

The primary advantage of giving the first dose at birth is that IT SAVES LIVES.

Why is such a policy necessary? Following are some of the ways infants who are not vaccinated at birth can become infected:

- The pregnant woman is tested and found to be hepatitis B surface antigen (HBsAg) positive, but her status is not communicated to the newborn nursery. The infant receives neither hepatitis B vaccine nor HBIG protection at birth.
- A chronically infected pregnant woman is tested with the wrong test. For example, antibody to hepatitis B surface antigen is sometimes ordered in error instead of HBsAg. This can happen because some laboratories use the improper and confusing abbreviation HBsAb instead of anti-HBs. This misordering of a test is relatively common since the two abbreviations (HBsAg and HBsAb) differ by only one letter. However, when her incorrectly ordered test comes back "negative," the woman may have actually been HBsAg positive and her infant would not receive appropriate postexposure prophylaxis.
- The pregnant woman is HBsAg positive, but her test results are misinterpreted or mistranscribed into her prenatal record or her infant's chart. Her infant does not receive HBIG or hepatitis B vaccine.
- The pregnant woman is not tested for HBsAg ei-

ther prenatally or in the hospital at the time of delivery. Women in this group have a higher likelihood of being HBsAg-positive (in one study, women who didn't receive prenatal care were 8 times more likely to be HBsAg positive than women who received such care). Her infant does not receive hepatitis B vaccine in the hospital, even though it is recommended within 12 hours of birth for infants whose mothers' test results are unknown.

- The woman is tested in early pregnancy for HBsAg and is found to be negative. She develops HBV infection later in pregnancy, but it is not detected, even though it is recommended by CDC that high-risk women be retested later in pregnancy. Because the infection is not clinically detected by her health care provider, her infant does not receive hepatitis B vaccine or HBIG at birth.
- The mother is HBsAg negative, but the infant is exposed to HBV postnatally from another family member or caregiver. This occurs in two-thirds of the cases of childhood transmission.

While there are certain advantages to giving the first dose at a later well-baby visit, these are advantages of administrative convenience. The primary advantage of giving the first dose at birth is that it saves lives.

In 2001 and 2002, IAC surveyed hepatitis coordinators at every state health department as well as at city and county CDC projects to express their views about providing hepatitis B vaccine in the hospital. Their responses contained many examples of children who were unprotected or inadequately protected because health professionals failed to order or misordered the hepatitis B blood test or misinterpreted, mistranscribed, or miscommunicated the test results of the children's mothers.

These state coordinators' reports tell us that no matter how well healthcare providers think they are doing with HBsAg screening of all pregnant women, serious mistakes continue to occur; children are unnecessarily being exposed without the benefit of postexposure prophylaxis, and at least

To obtain the CDC recommendations (12/23/05) for hepatitis B immunization of infants, children, and adolescents, go to: www.cdc.gov/mmwr/pdf/rr/rr5416.pdf.

For more information on the importance of giving the birth dose, and results from IAC's survey of state hepatitis B coordinators, go to: www.immunize.org/birthdose.

one baby has died. In order to overcome these failures, all 50 state hepatitis B coordinators overwhelmingly endorse providing a birth dose.

To maximally protect every newborn, ACIP recommends we vaccinate *all* infants (regardless of the mother's HBsAg status) prior to hospital discharge with Engerix-B[®] or Recombivax HB[®]. Providers who wish to complete the series using hepatitis B-containing combination vaccines (Comvax[®], Pediarix[®]), may do so by giving three additional doses. Giving a total of four doses of hepatitis B vaccine to infants is acceptable to CDC, AAP, AAFP, and these vaccine doses are covered under the Vaccines for Children (VFC) program.

All 50 state hepatitis B coordinators overwhelmingly endorse providing a birth dose.

Hepatitis B vaccine is a highly effective vaccine. Studies have shown that infants of the most highly infectious mothers (women who are both HBsAg and HBeAg positive) who receive postexposure prophylaxis with hepatitis B vaccine alone (without HBIG) at birth are protected in up to 95% of cases, essentially the same level of protection afforded by administering hepatitis B vaccine in addition to HBIG. Even higher rates of protection with postexposure prophylaxis have been demonstrated in infants born to less infectious mothers (those who are HBsAg positive and HBeAg negative).

Please read the hepatitis coordinators' survey results (see the web address box above), including descriptions of their experiences with failures of the current system—failures that largely will be prevented by administering hepatitis B vaccine to infants before they go home from the hospital.

Your support for providing a birth dose of hepatitis B vaccine to infants while still in the hospital will protect and save lives that are now being put at risk. ♦

www.immunize.org/catg.d/p2125.pdf • Item #P2125 (5/06)

Guidelines for Standing Orders in Labor & Delivery & Nursery Units to Prevent Hepatitis B Virus (HBV) Transmission to Newborns

To obtain the Centers for Disease Control and Prevention (CDC) recommendations for preventing hepatitis B in infants and children, visit CDC's website at www.cdc.gov/mmwr/PDF/rr/rr5416.pdf

In December 2005, the Centers for Disease Control and Prevention (CDC) published new recommendations of the Advisory Committee on Immunization Practices (ACIP) for prevention of hepatitis B virus (HBV) infections in infants and children. The American Academy of Pediatrics, American Academy of Family Physicians, and American College of Obstetricians and Gynecologists have endorsed these recommendations. To obtain a copy, go to www.cdc.gov/mmwr/PDF/rr/rr5416.pdf.

The guidelines below were developed to help all hospitals establish standing orders and protocols in their labor and delivery and nursery units. The content has been reviewed by CDC staff for consistency with CDC recommendations.

To protect all infants, CDC recommends that all delivery hospitals **institute standing orders and protocols** to ensure healthcare professionals do the following:

- Administer hepatitis B vaccine to all newborns who weigh at least 2 kg (4.4 lb) before discharge from the nursery.
- Identify all infants born to mothers who are hepatitis B surface antigen (HBsAg) positive or to mothers with unknown HBsAg status. Administer appropriate immunoprophylaxis to all these infants.

Labor and Delivery (L&D) Procedures

Upon admission, review the HBsAg¹ status of all pregnant women. Be sure to review a copy of the mother's *original* laboratory report to verify that the correct test was performed during this pregnancy and to verify the test date. Do not rely on a transcribed test result!

For women with a documented HBsAg lab report

- Place a copy of the *original* laboratory report of the mother's HBsAg¹ test result into (1) the mother's L&D record and (2) the infant's medical record.
- If the mother is HBsAg positive, alert the nursery staff.
- If the mother is HBsAg negative during a prenatal visit but was at risk for acquiring HBV infection during this pregnancy (e.g., not in a long-term, mutually monogamous relationship; had an HBsAg-positive sex partner; had evaluation or treatment for a sexually transmitted disease; currently uses or recently used injection drugs), perform a repeat test for HBsAg.¹ Instruct the laboratory to call L&D and the nursery with the HBsAg test result ASAP.

For women without a documented HBsAg lab report

- Perform HBsAg¹ testing ASAP on women who do not have a documented HBsAg test result from the current pregnancy.
- Instruct the lab to call L&D and the nursery with the newly obtained HBsAg test result ASAP.

Nursery Procedures

Procedures to follow for ALL newborns

1. Review a copy of the mother's *original* HBsAg¹ lab report to ensure test was ordered and interpreted accurately.
2. Provide appropriate management based on (1) the mother's HBsAg status and (2) the infant's birth weight. Manage infants who weigh less than 2 kg differently from those who weigh 2 kg or more. See descriptions below and footnotes 2, 5, 6.
3. Give the mother an immunization record card that includes the hepatitis B vaccination date. Explain the need for the complete hepatitis B vaccine series to protect her baby. Remind her to bring the card with her each time her baby sees a provider.

For infants born to HBsAg-negative mothers

Administer single-antigen hepatitis B vaccine (0.5 mL, IM) before discharge to all infants weighing at least 2 kg at birth.^{2,3,4} Document the hepatitis B vaccine dose in the infant's medical record, including date, time, site of administration, and lot number.

For infants born to mothers with unknown HBsAg status

Administer single-antigen hepatitis B vaccine (0.5 mL, IM) within 12 hours of birth.^{3,5} Do not wait for test results to return before giving this dose of vaccine. Document the hepatitis B vaccine dose appropriately.

- Confirm that the laboratory has received serum for the mother's HBsAg¹ test. Verify when the HBsAg result will be available and that it will be reported to L&D and the nursery ASAP. If the nursery does not receive the report at the expected time, call the laboratory for the result.
- If the mother's HBsAg¹ test result is positive, do the following:
 - Administer hepatitis B immune globulin (HBIG 0.5 mL, IM) to the infant ASAP. Document the HBIG dose appropriately in the infant's medical record. There is little benefit in giving HBIG if more than 7 days have elapsed since birth.
 - Alert the mother's and infant's physician(s) of the test result.
 - Follow the instructions below for infants born to HBsAg-positive mothers.
- If the infant must be discharged before the HBsAg result is known:
 - Document contact information for the parents (e.g., addresses, telephone numbers, emergency contacts) in case further treatment is needed.
 - Obtain the name, address, and phone number of the mother's

(continued on next page)

and the infant's healthcare providers.

- Notify the mother's and the infant's healthcare providers that the mother's HBsAg test result is pending.

For infants born to HBsAg-positive mothers

- Administer HBIG (0.5 mL, IM) and single-antigen hepatitis B vaccine^{3, 6} (0.5 mL, IM) at separate injection sites within 12 hours of birth. Document the hepatitis B vaccine and HBIG doses appropriately in the infant's medical record.
- Notify the local or state health department of the infant's birth and the date and time of administration of HBIG and hepatitis B vaccine doses.
- Obtain the name, address, and phone number of the infant's primary care provider. Notify the provider of the infant's birth, the date and time of HBIG and hepatitis B vaccine doses administered, and the importance of additional on-time vaccination and postvaccination testing of the infant for HBsAg and antibody to HBsAg after completion of the hepatitis B vaccine series.
- Provide advice to the mother. Tell her
 - That she may breast-feed her infant upon delivery, even before hepatitis B vaccine and HBIG are given
 - About the importance of her infant completing the full hepatitis B vaccine series on schedule
 - That blood will need to be drawn from the infant after completion of the hepatitis B vaccine series at age 9–18 months to determine if the infant needs further management
 - About modes of HBV transmission and the need for testing and vaccination of susceptible household, sexual, and needle-sharing contacts
 - That she needs to have a medical evaluation for chronic hepatitis B, including an assessment of whether she is eligible for antiviral treatment.

Footnotes

1. Be sure the correct test for HBsAg (hepatitis B surface antigen) was/is ordered. The HBsAg test should not be confused with other hepatitis B serologic tests, including antibody to HBsAg (anti-HBs or HBsAb) and antibody to hepatitis B core antigen (anti-HBc or HBcAb).
2. Infants weighing less than 2 kg whose mothers are documented to be HBsAg negative should receive the first dose of vaccine 1 month after birth or at hospital discharge. The mother's HBsAg status must be part of the infant's medical record.
3. Federal law requires that you give parents a Hepatitis B Vaccine Information Statement (VIS) before vaccine administration. To obtain a VIS, download it from the IAC website at www.immunize.org/vis or call your state health department.
4. Exceptions to giving the birth dose of hepatitis B vaccine are allowed on a case-by-case basis and only in rare circumstances. If a birth dose is not administered, a copy of the mother's negative HBsAg test result from the current pregnancy must be placed in the infant's medical record and the attending physician must write a specific order directing staff not to administer the birth dose in the hospital. Infants who don't receive the first dose of hepatitis B vaccine before hospital discharge should receive the first dose no later than age 2 months.
5. An infant weighing less than 2 kg whose mother's HBsAg status is unknown should receive HBIG and hepatitis B vaccine within 12 hours of birth. Do not count the hepatitis B vaccine dose as the first dose in the vaccine series. Reinitiate the full hepatitis B vaccine series at age 1–2 months.
6. An infant weighing less than 2 kg whose mother is HBsAg positive should receive the first dose of hepatitis B vaccine and HBIG within 12 hours of birth. Do not count the hepatitis B vaccine dose as the first dose in the vaccine series. Reinitiate the full hepatitis B vaccine series at age 1–2 months.

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