

Appendix A

Vaccine Schedule



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Give the Birth Dose...

Hepatitis B Vaccine at Birth Saves Lives!

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In December 2005, CDC issued updated recommendations on hepatitis B vaccination for infants. The recommendations strongly support (1) giving the hepatitis B vaccine birth dose to every newborn prior to hospital discharge and (2) using standardized admission orders for administering the birth dose. In addition, it is recommended that a copy of the original maternal hepatitis B lab report be sent to the hospital—not a transcribed result. The recommendations also state that the hepatitis B vaccine birth dose may be delayed until after hospital discharge only “in rare circumstances.” When doing so, a physician’s order to withhold the birth dose and a copy of the original lab report indicating that the mother was HBsAg negative during this pregnancy should be placed in the infant’s medical record. The most recent CDC estimates indicate only 70% of newborns receive the hepatitis B vaccine birth dose by 3 days of age. Clearly, there is much work left to do to fully protect newborns.

Leading health organizations – CDC, AAP, AAFP, and ACOG – recommend that all hospitals and healthcare professionals protect newborns from hepatitis B virus (HBV) infection by administering the first dose of hepatitis B vaccine to every baby at birth, no later than hospital discharge.

Approximately 24,000 women with chronic HBV infection give birth in the U.S. each year, and many do not know they are infected. Up to 95% of perinatal infections can be prevented by post-exposure prophylaxis given within 12 hours of birth. Tragically, many babies are exposed to HBV at birth and do not receive appropriate postexposure prophylaxis. Infants infected at birth have a 90% chance of becoming chronically infected with HBV. Chronic HBV infection in infants leads to liver cancer, cirrhosis, and liver failure in up to 25% of these infants when they become adults.

Why is a universal birth dose policy necessary in hospitals?

Following are some of the ways newborns can be infected if they do not receive a dose of hepatitis B vaccine, ideally within 12 hours of birth:

- The pregnant woman is tested and found to be hepatitis B surface antigen (HBsAg) positive, but her “infected” status is not communicated to the newborn nursery. The infant receives neither hepatitis B vaccine nor hepatitis B immune globulin (HBIG) protection at birth.

Healthcare professionals:

Urge your patients to protect their newborns with hepatitis B vaccine before hospital discharge.

Your recommendation to vaccinate is a strong patient motivator!

The birth dose saves lives!

To obtain CDC’s recommendations for hepatitis B immunization of infants, children, and adolescents, visit www.cdc.gov/mmwr/pdf/rr/rr5416.pdf.



- A chronically infected pregnant woman receives the wrong test. For example, antibody to hepatitis B surface antigen (antiHBs) is ordered in error, instead of HBsAg. This can happen because some labs use the 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 actually be 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. As a result, her infant does not receive HBIG or hepatitis B vaccine.

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Technical content reviewed by the Centers for Disease Control and Prevention

www.immunize.org/catg.d/p2125.pdf • Item #P2125 (2/14)



- The pregnant woman is not tested for HBsAg either prenatally or in the hospital at the time of delivery. In one study, women who didn't receive prenatal care were eight times more likely to be HBsAg positive than women who received prenatal care. When a woman does not receive prenatal care and is not tested at the time of delivery, her infant is in danger of being infected with HBV at birth – unless he or she is born in a hospital that adheres to a policy of administering hepatitis B vaccine within 12–24 hours of birth to every newborn **without fail**. This provides the greatest effectiveness in preventing HBV infection.
- She develops HBV infection later in pregnancy, but it is not clinically detected. Because her initial HBsAg test result is negative, she is not retested later in pregnancy as CDC recommends for high-risk women, and 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.

In 2001, 2002, and 2008, the Immunization Action Coalition surveyed perinatal hepatitis B coordinators at every state health department, as well as at city and county CDC projects to assess their views about providing hepatitis B vaccine in the hospital. Their responses contained hundreds of reports of newborns who were unprotected or inadequately protected because healthcare professionals failed to order or misordered hepatitis B blood tests or misinterpreted, mistranscribed, or miscommunicated the test results of the children's mothers. (See *States Report Hundreds of Medical Errors in Perinatal Hepatitis B Prevention*, at www.immunize.org/catg.d/p2062.pdf.)

These state coordinators' reports tell us that no matter how well healthcare providers think they are doing in screening all pregnant women for HBsAg, mistakes continue to occur. Newborns are unnecessarily being exposed without the benefit of postexposure prophylaxis. At least one baby has died of fulminant hepatitis B; hundreds have become chronically infected and are doomed to preventable hepatocellular carcinoma or cirrhosis later in life. To overcome these failures, perinatal hepatitis B vaccine coordinators overwhelmingly endorse providing a hepatitis B vaccine birth dose as the first step in developing a safety net to protect all infants from HBV infection, regardless of the circumstances.

To maximally protect every newborn, CDC, AAP, AAFP, and ACOG recommend all infants be vaccinated with a hepatitis B vaccine birth dose prior to hospital discharge. Delaying hepatitis B vaccination until a follow-up office visit will be too late to prevent perinatal HBV transmission.*

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 70%–95% of cases. Please read the hepatitis coordinators' survey results (www.immunize.org/birthdose/birthdose_survey.asp), including descriptions of their experiences with failures of the system – failures that largely will be prevented by administering hepatitis B vaccine to infants before they go home from the hospital, ideally within 12 hours of birth.

Your support for providing a birth dose to newborns while they are still in the hospital will protect and save lives that are now being put at risk.

*For subsequent doses of hepatitis B vaccine in infants, use monovalent hepatitis B vaccine or hepatitis B-containing combination vaccines. If using a hepatitis B-containing combination vaccine, you will be giving 3 more doses of hepatitis B vaccine. Giving a total of 4 doses of hepatitis B vaccine to infants is acceptable practice according to CDC, AAP, and AAFP. These vaccine doses are covered under the Vaccines For Children (VFC) program for VFC-eligible children.

Routine Infant Hepatitis B Vaccine Schedule Using Monovalent Vaccine

Dose	Recommended Age
1	Birth
2	1 - 2 months
3	6 - 18 months*

Both the ACIP and CDC recommend that all children born to women who are HBsAg-positive receive their third and final dose of the hepatitis B vaccine series at six months of age, as long as all minimum intervals (below) are met.

Infant Hepatitis B Vaccine Schedule Using Combination Vaccines

Pediarix® Vaccine Schedule		
Biologic	Dose	Age of Infant
Hepatitis B vaccine - dose 1	0.5 mL	Birth (Monovalent vaccine ONLY)
Hepatitis B vaccine - dose 2	0.5 mL	2 months*
Hepatitis B vaccine - dose 3	0.5 mL	4 months
Hepatitis B vaccine - dose 4	0.5 mL	6 months**

* Not approved for use in infants < 6 weeks of age.

** Final dose of hepatitis B vaccine cannot be administered < 6 months (24 weeks) of age.

Minimum Intervals	
Dose 1 to 2	4 weeks
Dose 2 to 3	8 weeks
Dose 3*	16 weeks after 1 st dose

*Dose three should not be administered before six months (24 weeks) of age.

Postexposure Prophylaxis (PEP) Treatment of Infants

Born to HBsAg – Positive mother		
Biologic	Dose	Age of Infant
HBIG	0.5 mL	Within 12 hours of birth* [±]
Hepatitis B vaccine - dose 1	0.5 mL	Within 12 hours of birth* [±]
Hepatitis B vaccine - dose 2	0.5 mL	1 month
Hepatitis B vaccine - dose 3	0.5 mL	6 months**

* Administer at separate anatomical sites. Preferred site: anterolateral thighs.

** Infant should not receive third dose of hepatitis B vaccine before 6 months (24 weeks) of age.

[±] Regardless of infant's birth weight.

Born to HBsAg – Unknown Status mother		
Biologic	Dose	Age of Infant
HBIG	0.5 mL	< 2,000 g (4.4 lbs.) – within 12 hours of birth*
		> 2,000 g (4.4 lbs.) – ASAP but no later than 7 days if mother is positive
Hepatitis B vaccine - dose 1	0.5 mL	Within 12 hours of birth*
Hepatitis B vaccine - dose 2	0.5 mL	1 to 2 months
Hepatitis B vaccine - dose 3	0.5 mL	6 months**

* Administer at separate anatomical sites. Preferred site: anterolateral thighs.

** Infant should not receive third dose of hepatitis B vaccine before 6 months (24 weeks) of age.

If the mother's HBsAg delivery result comes back negative, the infant does not need to receive HBIG. However, it will not harm the child if HBIG has already been administered.

Vaccination and PEP of Preterm Infants Weighing < 2,000 grams (4.4 pounds)

Born to HBsAg – Positive OR HBsAg - Unknown mothers		
Biologic	Dose	Age of Infant
HBIG	0.5 mL	Within 12 hours of birth*
Hepatitis B vaccine - dose 1	0.5 mL	Within 12 hours of birth* (Do not count birth dose as part of series)
Hepatitis B vaccine - dose 2	0.5 mL	1 month
Hepatitis B vaccine - dose 3	0.5 mL	2 months
Hepatitis B vaccine - dose 4 [±]	0.5 mL	6 months**

* Administer at separate anatomical sites. Preferred site: anterolateral thighs.

** Infant should not receive third dose of hepatitis B vaccine before 6 months (24 weeks) of age.

± All preterm infants weighing < 2,000 g (4.4 lbs.) at birth should reinitiate the series beginning at 1 month of age.