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Addressing the Problem: Practical Tools

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Guidance for Developing Admission Orders in Labor & Delivery and Newborn Units to Prevent Hepatitis B Virus Transmission

The guidelines in this document were developed to help hospitals establish policies and standing orders in their labor and delivery (L&D) and newborn units.

During 2005, the Centers for Disease Control and Prevention (CDC) published updated recommendations of the Advisory Committee on Immunization Practices (ACIP) for prevention of hepatitis B virus (HBV) infections in children which includes the recommendation to administer hepatitis B vaccine to **all newborns before hospital discharge**. The American Academy of Pediatrics, American Academy of Family Physicians, and American College of Obstetricians and Gynecologists have all endorsed the birth dose recommendation. To obtain a copy, go to www.cdc.gov/mmwr/PDF/rr/rr5416.pdf.

Admission Orders and Procedures for Women Admitted to a Birthing Facility

For pregnant women who have a HBsAg lab report included in their prenatal records, do the following:

1. Examine a copy of the *original* laboratory report of the pregnant woman's HBsAg¹ test result to verify that the correct test (i.e., HBsAg) was performed and to verify that the testing date was during *this* pregnancy, not a previous one. *Do not rely on a handwritten or transcribed HBsAg test result!*
2. Place a copy of the original HBsAg lab report into (1) the pregnant woman's L&D record and (2) the infant's hospital record (or have a link to the mother's HBsAg test result).
3. If the pregnant woman is HBsAg positive, alert the nursery staff that the newborn is high risk and will need postexposure prophylaxis – both hepatitis B immune globulin (HBIG) and hepatitis B vaccine – within 12 hours of birth.
4. Perform a repeat blood test for HBsAg¹ if the pregnant woman was HBsAg negative during a

To protect infants from HBV infection, CDC recommends that all delivery hospitals institute standing orders or admission orders and protocols to ensure healthcare professionals do the following:

1. Administer hepatitis B vaccine to **all newborns** before they are discharged from the hospital.
2. 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 these infants.

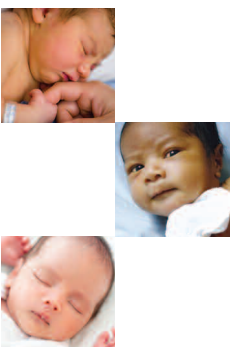
prenatal visit but was at risk for acquiring HBV infection during this pregnancy (e.g., more than one sex partner in the previous 6 months, evaluation or treatment for a sexually transmitted disease, recent or current injection-drug use, or HBsAg-positive sex partner), or had clinical hepatitis since her previous testing.

5. Instruct the laboratory to call L&D and the nursery with the HBsAg test result ASAP.

For pregnant women who do not have a HBsAg lab report on their prenatal record, do the following:

1. Perform HBsAg¹ testing ASAP on women who do not have a copy of an original HBsAg laboratory report from the current pregnancy included in their prenatal record.
2. Instruct the lab to call L&D and the nursery units with the newly obtained HBsAg test result ASAP.

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Admission Orders and Procedures for Newborns

Hospital procedures to follow for ALL newborns

1. Review a copy of the mother's *original* HBsAg¹ lab report to ensure that the correct serologic test was ordered and that it was ordered during this pregnancy.
2. Determine if the newborn needs immediate postexposure prophylaxis within 12 hours of birth. To do this you must know the mother's HBsAg status and the newborn's birth weight. If the newborn weighs less than 2 kg (4.4 lb), see the guidance below and footnotes 2, 5, 6.
3. Prior to vaccination, give parent a Hepatitis B Vaccine Information Statement (available at www.immunize.org/vis).

For newborns of HBsAg-negative mothers

1. Administer single-antigen hepatitis B vaccine (0.5 mL, IM) before hospital discharge to **all** newborns weighing 2 kg (4.4 lb) or more at birth.^{2,3,4}
2. Document the hepatitis B vaccine dose in the newborn's medical record, including the date, time, and site of administration, as well as the vaccine lot number.
3. Give the mother an immunization record card that includes the hepatitis B vaccination date. Explain the importance of completing the hepatitis B vaccine series to protect her baby. Remind her to bring the immunization record card with her each time her baby sees a provider.

For newborns of mothers with unknown HBsAg status, do the following:

1. 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.
2. Document the hepatitis B vaccine dose in the newborn's medical record, including date, time, and site of administration, as well as the vaccine lot number.

3. Give the mother an immunization record card that includes the hepatitis B vaccination date. Explain the importance of completing the hepatitis B vaccine series to protect her baby. Remind her to bring the immunization record card with her each time her baby sees a provider.
4. Confirm that the laboratory has received blood for the mother's HBsAg¹ test.
5. Verify when the mother's HBsAg result will be available and that it will be reported to L&D and the newborn unit ASAP.
6. If the nursery does not receive the report of the mother's HBsAg test at the expected time, call the laboratory for the result.
7. If the laboratory test indicates the mother's HBsAg¹ test result is positive, do the following:
 - a. Administer HBIG (0.5 mL, IM) to the newborn ASAP. (Hepatitis B vaccine should have been given within 12 hours of birth.)
 - b. Document the HBIG dose in the newborn's medical record. There is little benefit in administering HBIG to the newborn if more than 7 days have elapsed since birth.
 - c. Alert the mother's and newborn's physician(s) of the test result.
 - d. Follow the instructions below "For newborns of HBsAg-positive mothers," steps 3–7.
8. If the newborn must be discharged before the mother's HBsAg result is known:
 - a. Document the parents' contact information (e.g., addresses, telephone numbers, emergency contacts) in case further treatment is needed for the infant.
 - b. Obtain the name, address, and phone number of the mother's and the newborn's health-care providers.
 - c. Notify the mother's and newborn's healthcare providers that the mother's HBsAg test result is pending.

For newborns of HBsAg-positive mothers

1. 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.

2. Document the hepatitis B vaccine and HBIG dose in the newborn's medical record, including the date, time, and site of administration, as well as the vaccine lot number.
3. Give the mother an immunization record card that includes the hepatitis B vaccination and HBIG dates. Explain the importance of completing the hepatitis B vaccine series to protect her baby. Remind her to bring the immunization record card with her each time her baby sees a provider.
4. 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.
5. Obtain the name, address, and phone number of the newborn's primary care provider.
6. Notify the provider of the newborn's birth, the date and time of HBIG and hepatitis B vaccine doses administered, and the importance of additional on-time vaccination as well as post-vaccination testing of the infant for both HBsAg and antibody to HBsAg (anti-HBs) after completion of the hepatitis B vaccine series to assess the hepatitis B status of the infant following vaccination.
7. Provide advice to mother. Tell her the following:
 - a. That she may breast-feed her infant upon delivery, even before hepatitis B vaccine and HBIG are given;
 - b. That it is critically important for the protection of her baby's health that the baby receives the full hepatitis B vaccine series on the recommended schedule;
 - c. That blood tests (HBsAg and antibody to hepatitis B surface antigen [anti-HBs]) need to be drawn from the baby 1–2 months after completion of the 3- or 4-dose hepatitis B vaccine series and also no earlier than 9–12 months of age to determine if the child developed a protective immune response to vaccination or needs additional management⁷;
 - d. About modes of HBV transmission and the need for testing and vaccination of susceptible household, sexual, and needle-sharing contacts;

- e. That she needs to have a medical evaluation for chronic hepatitis B, including an assessment of whether she is a candidate 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) or antibody to hepatitis B core antigen (anti-HBc or HBcAb).
2. Infants weighing less than 2 kg (4.4 lb) at birth and whose mothers are documented to be HBsAg negative should receive the first dose of vaccine 1 month after birth or at hospital discharge, whichever comes first. The mother's HBsAg test result 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.
4. According to the CDC recommendations, exceptions to administering the birth dose of hepatitis B vaccine are allowed on a case-by-case basis and only in rare circumstances. If the hepatitis B vaccine birth dose is not administered, a copy of the mother's negative HBsAg test result from the current pregnancy must be placed in the newborn'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 do not 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 (4.4 lb) 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 (4.4 lb) 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.
7. The optimal timing for serologic testing to detect a vaccine response generally is 1–2 months after the final dose of the HepB vaccine series. Results of tests for HBsAg can be transiently positive for 1–18 days after vaccination. Serologic testing should be performed no earlier than age 9 months to avoid detection of passive anti-HBs from hepatitis B immune globulin administered at birth and to maximize the likelihood of detecting late HBV infection (see "Update: Shortened interval for postvaccination serologic testing of infants born to hepatitis B-infected mothers," *MMWR*, 2015;64:1118–20).

Sample Text for Developing Admission Orders in Newborn Units for the Hepatitis B Vaccine Birth Dose

Routine orders for all newborns

1. Review a copy of the mother's original lab report to ensure that the correct serologic test (HBsAg) was ordered and that it was ordered during this pregnancy. Perform a repeat HBsAg blood test on the pregnant woman (mother) if she was HBsAg negative during a prenatal visit but was at risk for acquiring HBV infection during this pregnancy (e.g., more than one sex partner in the previous 6 months, evaluation or treatment for a sexually transmitted disease, recent or current injection-drug use, or HBsAg-positive sex partner), or had clinical hepatitis since her previous testing.
2. Determine if the newborn is high risk and needs immediate postexposure prophylaxis within 12 hours of birth. The infant is high risk if the mother's HBsAg status is positive or unknown.

For routine newborn hepatitis B vaccination: the mother is HBsAg negative

1. Administer single-antigen hepatitis B vaccine, pediatric, 0.5 mL, intramuscular (IM), in anterolateral thigh no later than hospital discharge. Prior to vaccination, give parent a Hepatitis B Vaccine Information Statement and obtain verbal consent to vaccinate. Give parent a record of the vaccination. If parent is unwilling to give consent, notify physician ASAP. Document vaccine administration or vaccine refusal in hospital record.

For highest-risk infants: the mother is HBsAg positive

1. Administer Hepatitis B Immune Globulin (HBIG), 0.5 mL, IM, in anterolateral thigh in the delivery room or ASAP within 12 hours of birth. Document HBIG administration in hospital record. Give parent a record of the HBIG dose.
2. At same time and in opposite anterolateral thigh, administer single-antigen hepatitis B vaccine, pediatric, 0.5 mL, IM, ASAP within 12 hours of birth. Document vaccine administration in hospital record. Give parent a record of the vaccination.
3. Prior to administering both HBIG and hepatitis B vaccine, give parent a Hepatitis B Vaccine Information Statement and obtain verbal consent to vaccinate. If parent is unwilling to give consent, notify physician ASAP. Consider notifying Child Protective Services if parent continues to refuse despite discussion with physician.
4. Notify local or state health department of the infant's birth and the date and time of administration of HBIG and hepatitis B vaccine doses.
5. Obtain the name, address, and phone number of the newborn's primary care provider.
6. Notify primary care provider of newborn's birth, the date and time that HBIG and hepatitis B vaccine doses were administered, and the importance of additional on-time vaccination (infants weighing less than 2 kg [4.4 lbs] will require 4 doses of vaccine as the first dose does not "count") and post-vaccination testing of the infant for HBsAg and antiHBs (antibody to HBsAg) 1–2 months after completion of the hepatitis B vaccine series and no earlier than when the infant is 9–12 months of age.

NOTE: The optimal timing for serologic testing to detect a vaccine response generally is 1–2 months after the final dose of the HepB vaccine series. Results of tests for HBsAg can be transiently positive for 1–18 days after vaccination. Serologic testing should be performed no earlier

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than age 9 months to avoid detection of passive anti-HBs from hepatitis B immune globulin administered at birth and to maximize the likelihood of detecting late HBV infection.

7. Provide advice to the mother. Tell her the following:
 - a. She may breast-feed her infant upon delivery, even before hepatitis B vaccine and HBIG are given;
 - b. It is critical for her infant to complete the full hepatitis B vaccine series on the recommended schedule;
 - c. Blood tests (HBsAg and anti-HBs) will need to be obtained from the infant 1–2 months after completion of the hepatitis B vaccine series (at 9–12 months of age) to determine if the infant developed a protective immune response to vaccination or needs additional management;
 - d. About modes of HBV transmission and the need for testing and vaccination of susceptible household, sexual, and needle-sharing contacts;
 - e. She and other infected contacts need to have medical evaluations for chronic hepatitis B, including assessments to determine if they are candidates for antiviral treatment.

For high-risk infants: the mother’s HBsAg status is unknown

1. Administer single-antigen hepatitis B vaccine (0.5 mL, IM) within 12 hours of birth. For infants weighing less than 2 kg (4.4 lbs) at birth, also administer hepatitis B immune globulin (HBIG 0.5 mL, IM) within 12 hours. Do not wait for test results to return before giving this dose of vaccine (and HBIG for infants weighing less than 2 kg [4.4 lb]). Document vaccine administration in the hospital record. Give the parent a record of the vaccination.
2. Confirm that the laboratory has received blood for the mother’s HBsAg test.
3. Verify when the mother’s HBsAg result will be available and that it will be reported to the newborn unit ASAP.
4. If the laboratory test indicates the mother’s HBsAg test result is positive, do the following:
 - a. Administer HBIG, 0.5 mL, IM, ASAP, to the newborn weighing 2 kg (4.4 lb) or more. (Those weighing less than 2 kg [4.4 lb] at birth should have already received HBIG.) (Hepatitis B vaccine should have been given within 12 hours of birth to all infants of mothers with unknown HBsAg status.)
 - b. Follow steps 4–7 of previous section (see “For highest-risk infants: the mother is HBsAg positive”).

REFERENCES

1. *A Comprehensive Immunization Strategy to Eliminate Transmission of Hepatitis B Virus Infection in the United States*. Part 1: Immunization of Infants, Children and Adolescents. *MMWR*, December 23, 2005, Vol. 54(RR-16):1–39. A complete copy of this reference is available on pages 41–74 of this booklet.
2. CDC. Update: Shortened interval for postvaccination serologic testing of infants born to hepatitis B-infected mothers, *MMWR*, 2015;64:1118–20 at www.cdc.gov/mmwr/pdf/wk/mm6439.pdf

For additional detailed information about text that you might incorporate into newborn admission orders, including orders for premature infants, refer to *Guidance for Developing Admission Orders in Labor & Delivery and Newborn Units to Prevent Hepatitis B Virus Transmission* available on pages 23–25 of this booklet.

About Hepatitis B Vaccine Information Statements

VACCINE INFORMATION STATEMENT

Hepatitis B Vaccine

What You Need to Know

Many Vaccine Information Statements are available in Spanish and other languages. See www.immunize.org/viis.
Hojas de Información Sobre Vacunas están disponibles en Español y en muchos otros idiomas. Véase <http://www.immunize.org/viis>.

1 What is hepatitis B?

Hepatitis B is a serious infection that affects the liver. It is caused by the hepatitis B virus.

- In 2009, about 38,000 people became infected with hepatitis B.
- Each year about 2,000 to 4,000 people die in the United States from cirrhosis or liver cancer caused by hepatitis B.

Hepatitis B can cause:

Acute (short-term) illness. This can lead to:

- loss of appetite
- diarrhea and vomiting
- tiredness
- jaundice (yellow skin or eyes)
- pain in muscles, joints, and stomach

Acute illness, with symptoms, is more common among adults. Children who become infected usually do not have symptoms.

Chronic (long-term) infection. Some people go on to develop chronic hepatitis B infection. Most of them do not have symptoms, but the infection is still very serious, and can lead to:

- liver damage (cirrhosis)
- liver cancer
- death

Chronic infection is more common among infants and children than among adults. People who are chronically infected can spread hepatitis B virus to others, even if they don't look or feel sick. Up to 1.4 million people in the United States may have chronic hepatitis B infection.

Hepatitis B virus is easily spread through contact with the blood or other body fluids of an infected person. People can also be infected from contact with a contaminated object, where the virus can live for up to 7 days.

- A baby whose mother is infected can be infected at birth;
- Children, adolescents, and adults can become infected by:
 - contact with blood and body fluids through breaks in the skin such as bites, cuts, or sores;
 - contact with objects that have blood or body fluids on them such as toothbrushes, razors, or monitoring and treatment devices for diabetes;
 - having unprotected sex with an infected person;
 - sharing needles when injecting drugs;
 - being stuck with a used needle.

2 Hepatitis B vaccine: Why get vaccinated?

Hepatitis B vaccine can prevent hepatitis B, and the serious consequences of hepatitis B infection, including liver cancer and cirrhosis.

Hepatitis B vaccine may be given by itself or in the same shot with other vaccines.

Routine hepatitis B vaccination was recommended for some U.S. adults and children beginning in 1982, and for all children in 1991. Since 1990, new hepatitis B infections among children and adolescents have dropped by more than 95% – and by 75% in other age groups.

Vaccination gives long-term protection from hepatitis B infection, possibly lifelong.

3 Who should get hepatitis B vaccine and when?

Children and Adolescents

- Babies normally get 3 doses of hepatitis B vaccine:

1st Dose:	Birth
2nd Dose:	1-2 months of age
3rd Dose:	6-18 months of age

Some babies might get 4 doses, for example, if a combination vaccine containing hepatitis B is used. (This is a single shot containing several vaccines.) The extra dose is not harmful.

- Anyone through 18 years of age who didn't get the vaccine when they were younger should also be vaccinated.

Adults

- All unvaccinated adults at risk for hepatitis B infection should be vaccinated. This includes:
 - sex partners of people infected with hepatitis B,
 - men who have sex with men,
 - people who inject street drugs,
 - people with more than one sex partner,
 - people with chronic liver or kidney disease,
 - people under 60 years of age with diabetes,
 - people with jobs that expose them to human blood or other body fluids,

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

English- and Spanish-language versions of the hepatitis B Vaccine Information Statement (VIS) are available on the next four pages. VISs are information sheets developed by the Centers for Disease Control and Prevention to inform vaccine recipients – or their parents or legal representatives – about the benefits and risks of vaccines.

Federal law requires that hepatitis B VISs, and other VISs, be handed out before the vaccine is administered. English- and Spanish-language hepatitis B VISs are shown on the following pages.

- ▶ For more information about how to use VISs, visit www.immunize.org/viis.
- ▶ For hepatitis B VISs in many languages, visit www.immunize.org/viis/viis_hepatitis_b.asp.

Severe problems are extremely rare. Severe allergic reactions are believed to occur about once in 1.1 million doses.

A vaccine, like any medicine, could cause a serious reaction. But the risk of a vaccine causing serious harm, or death, is extremely small. More than 100 million people in the United States have been vaccinated with hepatitis B vaccine.

6 What if there is a moderate or severe reaction?

What should I look for?

- Any unusual condition, such as a high fever or unusual behavior. Signs of a serious allergic reaction can include difficulty breathing, hoarseness or wheezing, hives, paleness, weakness, a fast heart beat or dizziness.

What should I do?

- Call a doctor, or get the person to a doctor right away.
- Tell your doctor what happened, the date and time it happened, and when the vaccination was given.
- Ask your doctor, nurse, or health department to report the reaction by filing a Vaccine Adverse Event Reporting System (VAERS) form. Or you can file this report through the VAERS web site at www.vaers.hhs.gov, or by calling 1-800-822-7967.

VAERS does not provide medical advice.

7 The National Vaccine Injury Compensation Program

The National Vaccine Injury Compensation Program (VICP) was created in 1986.

Persons who believe they may have been injured by a vaccine can learn about the program and about filing a claim by calling 1-800-338-2382 or visiting the VICP website at www.hrsa.gov/vaccinecompensation.

8 How can I learn more?

- Ask your doctor They can give you the vaccine package insert or suggest other sources of information.
- Call your local or state health department.
- Contact the Centers for Disease Control and Prevention (CDC):
 - Call 1-800-232-4636 (1-800-CDC-INFO) or
 - Visit CDC's website at www.cdc.gov/vaccines

Vaccine Information Statement (Interim)
Hepatitis B Vaccine

2/2/2012
42 U.S.C. § 300aa-26

4 Who should not get hepatitis B vaccine?

- Anyone with a life-threatening allergy to yeast, or to any other component of the vaccine, should not get hepatitis B vaccine. Tell your doctor if you have any severe allergies.
- Anyone who has had a life-threatening allergic reaction to a previous dose of hepatitis B vaccine should not get another dose.
- Anyone who is moderately or severely ill when a dose of vaccine is scheduled should probably wait until they recover before getting the vaccine.

Your doctor can give you more information about these precautions.

Note: You might be asked to wait 28 days before donating blood after getting hepatitis B vaccine. This is because the screening test could mistake vaccine in the bloodstream (which is not infectious) for hepatitis B infection.

5 What are the risks from hepatitis B vaccine?

Hepatitis B is a very safe vaccine. Most people do not have any problems with it.

The vaccine contains non-infectious material, and cannot cause hepatitis B infection.

Some mild problems have been reported:

- Soreness where the shot was given (up to about 1 person in 4).
- Temperature of 99.9°F or higher (up to about 1 person in 15).



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Hepatitis B Vaccine

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Chronic infection is more common among infants and children than among adults. People who are chronically infected can spread hepatitis B virus to others, even if they don't look or feel sick. Up to 1.4 million people in the United States may have chronic hepatitis B infection.

Hepatitis B virus is easily spread through contact with the blood or other body fluids of an infected person. People can also be infected from contact with a contaminated object, where the virus can live for up to 7 days.

- A baby whose mother is infected can be infected at birth;
- Children, adolescents, and adults can become infected by:
 - contact with blood and body fluids through breaks in the skin such as bites, cuts, or sores;
 - contact with objects that have blood or body fluids on them such as toothbrushes, razors, or monitoring and treatment devices for diabetes;
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3rd Dose:	6-18 months of age

Some babies might get 4 doses, for example, if a combination vaccine containing hepatitis B is used. (This is a single shot containing several vaccines.) The extra dose is not harmful.

- Anyone through 18 years of age who didn't get the vaccine when they were younger should also be vaccinated.

Adults

- All unvaccinated adults at risk for hepatitis B infection should be vaccinated. This includes:
 - sex partners of people infected with hepatitis B,
 - men who have sex with men,
 - people who inject street drugs,
 - people with more than one sex partner,
 - people with chronic liver or kidney disease,
 - people under 60 years of age with diabetes,
 - people with jobs that expose them to human blood or other body fluids,



- household contacts of people infected with hepatitis B,
 - residents and staff in institutions for the developmentally disabled,
 - kidney dialysis patients,
 - people who travel to countries where hepatitis B is common,
 - people with HIV infection.
- Other people may be encouraged by their doctor to get hepatitis B vaccine; for example, adults 60 and older with diabetes. Anyone else who wants to be protected from hepatitis B infection may get the vaccine.
 - Pregnant women who are at risk for one of the reasons stated above should be vaccinated. Other pregnant women who want protection may be vaccinated.

Adults getting hepatitis B vaccine should get 3 doses — with the second dose given 4 weeks after the first and the third dose 5 months after the second. Your doctor can tell you about other dosing schedules that might be used in certain circumstances.

4 Who should not get hepatitis B vaccine?

- Anyone with a life-threatening allergy to yeast, or to any other component of the vaccine, should not get hepatitis B vaccine. Tell your doctor if you have any severe allergies.
- Anyone who has had a life-threatening allergic reaction to a previous dose of hepatitis B vaccine should not get another dose.
- Anyone who is moderately or severely ill when a dose of vaccine is scheduled should probably wait until they recover before getting the vaccine.

Your doctor can give you more information about these precautions.

Note: You might be asked to wait 28 days before donating blood after getting hepatitis B vaccine. This is because the screening test could mistake vaccine in the bloodstream (which is not infectious) for hepatitis B infection.

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Hepatitis B is a very safe vaccine. Most people do not have any problems with it.

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- Temperature of 99.9°F or higher (up to about 1 person in 15).

Severe problems are extremely rare. Severe allergic reactions are believed to occur about once in 1.1 million doses.

A vaccine, like any medicine, could cause a serious reaction. But the risk of a vaccine causing serious harm, or death, is extremely small. More than 100 million people in the United States have been vaccinated with hepatitis B vaccine.

6 What if there is a moderate or severe reaction?

What should I look for?

- Any unusual condition, such as a high fever or unusual behavior. Signs of a serious allergic reaction can include difficulty breathing, hoarseness or wheezing, hives, paleness, weakness, a fast heart beat or dizziness.

What should I do?

- **Call** a doctor, or get the person to a doctor right away.
- **Tell** your doctor what happened, the date and time it happened, and when the vaccination was given.
- **Ask** your doctor, nurse, or health department to report the reaction by filing a Vaccine Adverse Event Reporting System (VAERS) form. Or you can file this report through the VAERS web site at www.vaers.hhs.gov, or by calling **1-800-822-7967**.

VAERS does not provide medical advice.

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- Call your local or state health department.
- Contact the Centers for Disease Control and Prevention (CDC):
 - Call **1-800-232-4636 (1-800-CDC-INFO)** or
 - Visit CDC's website at www.cdc.gov/vaccines

Vaccine Information Statement (Interim)
Hepatitis B Vaccine

2/2/2012

42 U.S.C. § 300aa-26

Vacuna contra la hepatitis B

Lo que usted necesita saber

Muchas de las declaraciones informativas sobre vacunas están disponibles en español y otros idiomas. Consulte www.immunize.org/vis.
Las hojas de información sobre vacunas están disponibles en español y en muchos otros idiomas. Visite <http://www.immunize.org/vis>.

1 ¿Qué es la hepatitis B?

La hepatitis B es una infección grave que afecta al hígado y que es causada por el virus de la hepatitis B.

- En 2009, alrededor de 38,000 personas se infectaron con hepatitis B.
- Cada año entre 2,000 y 4,000 personas mueren en los Estados Unidos de cirrosis o cáncer hepático causado por hepatitis B.

La hepatitis B puede causar:

Enfermedad aguda (a corto plazo). Esto puede dar lugar a:

- pérdida del apetito
- cansancio
- dolor en los músculos, en las articulaciones y en el estómago
- diarrea y vómitos
- ictericia (coloración amarilla de la piel o los ojos)

La enfermedad aguda, con síntomas, es más común entre los adultos. Los niños que se infectan con frecuencia no presentan síntomas.

Infección crónica (a largo plazo). Algunas personas llegan a desarrollar infección crónica de hepatitis B.

La mayoría de ellas no tienen síntomas, pero aún así la infección es muy grave y puede resultar en:

- daño hepático (cirrosis)
- cáncer hepático
- muerte

La infección crónica es más común entre bebés y niños que entre adultos. Las personas que tienen una infección crónica pueden contagiar el virus de la hepatitis B a otras personas, incluso aunque no se vean o no se sientan enfermas. Hasta 1.4 millones de personas en los Estados Unidos pueden tener una infección crónica de hepatitis B.

El virus de la hepatitis B se puede diseminar fácilmente a través de contacto con la sangre o con otros fluidos corporales de una persona infectada. Las personas también se pueden infectar por medio del contacto con un objeto contaminado, en donde el virus puede vivir hasta 7 días.

- Un bebé cuya madre esté infectada puede contagiarse al nacer;
- Los niños, adolescentes y adultos se pueden infectar por:
 - contacto con sangre y fluidos corporales a través de cortadas en la piel como mordidas, cortes o úlceras;
 - contacto con objetos que tengan sangre o fluidos corporales en ellos como cepillos de dientes, navajas de rasurar, o dispositivos de monitoreo y tratamiento para la diabetes;
 - tener relaciones sexuales sin protección con una persona infectada;
 - compartir agujas al inyectarse drogas;
 - pincharse con una aguja usada.

2 Vacuna contra la hepatitis B: ¿Por qué es necesario vacunarse?

La vacuna contra la hepatitis B puede prevenir la hepatitis B y las graves consecuencias de la infección por hepatitis B, incluyendo el cáncer hepático y la cirrosis.

La vacuna contra la hepatitis B puede administrarse sola o con otras vacunas en la misma inyección.

La recomendación de la aplicación rutinaria de la vacuna contra la hepatitis B para algunos adultos y niños en los EE. UU. comenzó en 1982, y para todos los niños en 1991. Desde 1990, las infecciones nuevas por hepatitis B entre niños y adolescentes han disminuido en más del 95%, y en 75% en otros grupos de edad.

La vacuna ofrece protección a largo plazo contra la infección por hepatitis B, posiblemente de por vida.

3 ¿Quién debe vacunarse contra la hepatitis B y cuándo?

Niños y adolescentes

- Los bebés normalmente reciben 3 dosis de la vacuna contra la hepatitis B:

1	^a dosis:	Nacimiento
2	^a dosis:	1-2 meses de edad
3	^a dosis:	6-18 meses de edad

Algunos bebés podrían recibir 4 dosis, por ejemplo, si se utiliza una vacuna combinada que contenga la de hepatitis B (esta es una sola inyección que contiene varias vacunas). La dosis adicional no es perjudicial.

- Cualquier persona hasta los 18 años de edad que no haya recibido la vacuna cuando era más joven también debe vacunarse.

Adultos

- Todos los adultos que no estén vacunados y estén en riesgo de una infección por hepatitis B deben vacunarse. Esto incluye a:
 - parejas sexuales de personas infectadas con hepatitis B,
 - hombres que tienen relaciones sexuales con hombres,
 - personas que se inyectan drogas ilegales,
 - personas con más de una pareja sexual,
 - personas con una enfermedad hepática o renal crónica,
 - personas menores de 60 años de edad con diabetes,
 - personas cuya actividad laboral las expongan a sangre humana o a otros fluidos corporales,
 - integrantes del hogar de personas infectadas con hepatitis B,
 - residentes y miembros del personal en instituciones para discapacidades relacionadas a problemas de desarrollo,



- pacientes con diálisis renal,
 - personas que viajan a países en donde la hepatitis B es común,
 - personas con infección por VIH.
- Otras personas pueden ser alentadas por sus médicos para aplicarse la vacuna contra la hepatitis B; por ejemplo, los adultos de 60 años y mayores que padecen de diabetes. Cualquier otra persona que quiera estar protegida contra la infección por hepatitis B puede aplicarse la vacuna.
 - Las mujeres embarazadas que estén en riesgo por una de las razones antes mencionadas deben vacunarse. Otras mujeres embarazadas que quieran protección pueden vacunarse.

Los adultos que se vacunen contra la hepatitis B deben ponerse 3 dosis, con la segunda dosis administrada 4 semanas después de la primera y la tercera dosis 5 meses después de la segunda. Su médico puede hablarle de otros esquemas de administración que podrían emplearse en ciertas circunstancias.

4 ¿Quién no debe aplicarse la vacuna contra la hepatitis B?

- Cualquier persona con alergia a la levadura que pueda poner en peligro la vida o que sea alérgica a cualquier otro componente de la vacuna, no debe ponerse la vacuna contra la hepatitis B. Informe a su médico si ha tenido alguna alergia severa.
- Cualquier persona que haya tenido una reacción alérgica que pueda poner en peligro la vida a una dosis anterior de la vacuna contra la hepatitis B no debe aplicarse otra dosis.
- Cualquier persona con una enfermedad moderada o severa en el momento de aplicarse una dosis de la vacuna probablemente deba esperar hasta que esté recuperada antes de aplicarse la vacuna.

Su médico puede ofrecerle más información acerca de estas precauciones.

Nota: tal vez le pidan que espere 28 días antes de donar sangre después de aplicarse la vacuna contra la hepatitis B. Esto se debe a que la prueba de detección podría confundir la vacuna en el torrente sanguíneo (que no es infecciosa) con la infección por hepatitis B.

5 ¿Cuáles son los riesgos de la vacuna contra la hepatitis B?

La vacuna contra la hepatitis B es muy segura. La mayoría de las personas no tienen problemas con ella.

La vacuna contiene material no infeccioso y no puede causar una infección por hepatitis B.

Se han reportado algunos problemas leves:

- Dolor en el lugar donde se aplicó la inyección (hasta 1 de cada 4 personas).
- Temperatura de 37.7 °C (99.9 °F) o superior (hasta 1 de cada 15 personas).

Los problemas severos son extremadamente raros. Se cree que las reacciones alérgicas severas ocurren aproximadamente una vez en 1.1 millones de dosis.

Una vacuna, como cualquier medicamento, puede provocar una reacción grave. Sin embargo, el riesgo de que la vacuna ocasione un daño grave, o la muerte, es extremadamente pequeño. Más de 100 millones de personas en los Estados Unidos han sido vacunadas contra la hepatitis B.

6 ¿Qué hago si ocurre una reacción moderada o severa?

¿De qué debo estar pendiente?

- De todo signo inusual, como fiebre alta o comportamiento inusual. Los signos de una reacción alérgica grave pueden incluir dificultad para respirar, ronquera o jadeo, urticaria, palidez, debilidad, pulso acelerado o mareos.

¿Qué debo hacer?

- **Llame** a un médico o lleve a la persona al médico de inmediato.
- **Dígale** al médico lo que ocurrió, la fecha y la hora en la que ocurrió, y cuándo le pusieron la vacuna.
- **Pida** al médico, al personal de enfermería o al departamento de salud que reporten la reacción presentando un formulario del Sistema de reporte de eventos adversos derivados de las vacunas (Vaccine Adverse Event Reporting System, VAERS). O puede presentar este reporte a través del sitio web de VAERS: www.vaers.hhs.gov o llamando al **1-800-822-7967**.

El VAERS no ofrece consejos médicos.

7 Programa Nacional de Compensación por Lesiones ocasionadas por Vacunas

En 1986 se creó el Programa Nacional de Compensación por Lesiones Ocasionadas por Vacunas (National Vaccine Injury Compensation Program, VICP).

Las personas que consideren que pueden haber tenido lesiones ocasionadas por una vacuna pueden informarse sobre el programa y sobre cómo presentar una reclamación llamando al **1-800-338-2382** o visitando el sitio web del VICP en: www.hrsa.gov/vaccinecompensation.

8 ¿Dónde puedo obtener más información?

- Consulte a su médico, él puede proporcionarle el folleto informativo de la vacuna o sugerirle otras fuentes de información.
- Llame al departamento de salud local o estatal.
- Comuníquese con los Centros para el Control y la Prevención de Enfermedades (Centers for Disease Control and Prevention, CDC):
 - Llame al **1-800-232-4636 (1-800-CDC-INFO)** o
 - Visite el sitio web de los CDC en www.cdc.gov/vaccines

Vaccine Information Statement (Interim)
Hepatitis B Vaccine

2/2/2012

Spanish

42 U.S.C. § 300aa-26

Translation provided by the Immunization Action Coalition

About the Parent Handout *Hepatitis B Shots Are Recommended for All New Babies*

Hepatitis B Shots Are Recommended for All New Babies

What is hepatitis B and why do I need to protect my baby now?

Hepatitis B is a serious disease caused by the hepatitis B virus. The virus can enter the bloodstream, attack the liver, and cause serious damage. When babies get infected, the virus usually remains in the body for a lifetime (this is called chronic hepatitis B). About 1 out of 4 infected babies will die of liver failure or liver cancer as adults. Hepatitis B is a deadly disease – but it's preventable with vaccination.

How is hepatitis B virus spread?

Anyone can become infected with hepatitis B virus at anytime during their lives. Hepatitis B virus is spread by contact with an infected person's blood or certain body fluids. For example, babies can get hepatitis B virus from their infected mothers at birth, and children can get it if they live with or are cared for by an infected person, or even if they share personal care items (e.g., toothbrush) with an infected person.

Currently, about 1 out of 20 people in the United States have been infected with the hepatitis B virus.

How many people have hepatitis B?

In the United States, tens of thousands of people get infected with the hepatitis B virus each year. About one million people in the U.S. are already infected. Every year, about 3,000 Americans die from liver failure or liver cancer caused by hepatitis B. Worldwide, 350 million people are infected.



Hepatitis B is preventable! Make sure your baby gets vaccinated in the hospital at birth.

It is impossible to know if a person is infected with the hepatitis B virus by looking at them. Most people have no symptoms, do not feel sick, and don't know they are infected.

As a result, they can spread the virus to others without knowing it. The only way to know if a person is infected is with a blood test.



Hepatitis B vaccine helps protect your baby's future!

Is there a cure for hepatitis B?

No. Although there are several medicines to help people who have life-long hepatitis B virus infection, there is no medicine that "cures" it. The good news is that hepatitis B can be prevented by vaccination.

Who recommends that all babies get hepatitis B vaccination at birth?

Medical groups such as the American Academy of Pediatrics, the American Academy of Family Physicians, the American College of Obstetricians and Gynecologists, and the Centers for Disease Control and Prevention recommend that every baby get hepatitis B vaccine at birth, before leaving the hospital. These are the same groups that recommend babies get vaccinated against whooping cough (pertussis), measles, tetanus, polio, and other serious diseases.

Why does my baby need a hepatitis B shot at birth?

It is important to vaccinate babies at birth so they will be protected as early as possible from any exposure to the hepatitis B virus. Babies and young children are not able to fight off hepatitis B virus infection as well as older people. A baby who gets

Hospital staff who need to explain to parents why a dose of hepatitis B vaccine is given at birth may find the educational handout on the next two pages helpful. Easy-to-read Q&As explain how the virus is spread, how serious hepatitis B infection is, and why the first dose of vaccine at is given at birth.

▶ Double-sided, tri-fold versions of this handout are available in Spanish, Arabic, Chinese, French, Korean, Turkish, and Vietnamese at www.immunize.org/handouts/hepatitis-b-vaccines.asp.

infected with the hepatitis B virus during the first five years of life has a 15% to 25% risk for premature death from liver disease, including liver failure or liver cancer. Hepatitis B vaccine is your baby's "insurance policy" against being infected with the hepatitis B virus.

Experts recommend vaccination against hepatitis B as a routine part of a newborn's hospital care, just like checking the baby's hearing.

How could my baby come in contact with the hepatitis B virus?

In many cases, the hepatitis B virus passes from mother to baby during birth when the mother does not know she is infected. In other cases, the virus is spread to the baby during close contact with an infected family member, caregiver, or friend. Most people who are infected with hepatitis B do not feel sick and have no idea they carry this virus. They are surprised when they are told they are infected. Many people have no idea how they became infected with the virus in the first place. To protect your baby from infection with the hepatitis B virus, make sure your baby receives the first dose of hepatitis B vaccine before leaving the hospital.

Everyone needs vaccinations! If you can't afford a visit to the doctor, call your local health department.

Won't my baby just recover from hepatitis B?

Babies are not able to fight off hepatitis B as well as adults. About 9 out of 10 babies who get infected in the first year of life will stay infected for life.

How many doses of hepatitis B vaccine will my baby receive?

The basic series is 3 or 4 doses. The first dose should be given in the hospital (at birth), the second dose 1–2 months later, and the third dose at age 6 months or later. Because many healthcare providers choose to use certain combination vaccines during well baby check-ups, some infants will receive 4 doses of hepatitis B vaccine. Either alternative is considered routine and acceptable.

How effective is hepatitis B vaccine?

Very effective. More than 95% of infants, children, and adolescents develop immunity to the hepatitis B virus after 3 doses of properly spaced vaccine.

Is hepatitis B vaccine safe?

Yes. Hepatitis B vaccine has been shown to be very safe when given to people of all ages. More than one billion hepatitis B shots have been given worldwide. In the United States, more than 120 million people, including infants, children, and adults have received hepatitis B vaccine. The most common side effects from hepatitis B vaccine are soreness at the injection site or slight fever. Serious side effects are rare.

Some parents worry that their baby's immune system is immature and cannot handle vaccination at such a young age. Actually, as soon as they are born, babies start effectively dealing with trillions of bacteria and viruses. The challenge to their immune systems from vaccines is tiny compared to the everyday challenges from living!

Why does my baby need so many vaccinations?

It's true that little babies get lots of shots, which can cause temporary discomfort. The good news is that more vaccines mean more protection from serious diseases than in the past. Like hepatitis B, many of these diseases such as rotavirus, whooping cough, and meningitis can result in severe illness, hospitalization, and even death.

Make sure your baby gets all his or her vaccines at the recommended ages. It's the safest and surest way to protect children from deadly infectious diseases. Your baby is counting on you!



If you have questions about vaccines, contact your healthcare provider, your local health department, or call the CDC-INFO Contact Center at 800-232-4636.

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www.immunize.org/protect-newborns



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www.immunize.org/protect-newborns

Childhood Immunization Record Cards

An immunization record should be given to a parent every time their child receives a vaccine, including at birth. Parents should receive a printout or other record of the vaccinations administered to their infant before the infant leaves the hospital.

Official immunization record cards can be obtained from many state health departments free of charge.

- ▶ Phone numbers of state immunization programs are listed online at www.immunize.org/coordinators.
- ▶ Childhood immunization record cards (see image below) are also available for purchase from the Immunization Action Coalition at www.immunize.org/shop/record-cards.asp. Sample record cards are available upon request.

Vaccine	Type of vaccine	Date given mo/day/yr	Healthcare professional or clinic	Date next dose due
Hepatitis B (HepB, Hib-HepB, DTaP-HepB-IPV, HepA-HepB)				
Diphtheria, Tetanus, Pertussis (DTaP, DTP, DT, Td, Tdap, DTaP-HepB-IPV, DTaP-IPV/Hib, DTaP-IPV, DTaP/Hib)				
Other				

CHILD & TEEN IMMUNIZATION RECORD
 Always carry this record with you and have your healthcare professional or clinic keep it up to date.

Last name: _____ First name: _____ M.I.: _____
 Birthdate: (mo) [] - (day) [] - (yr) []

Patient Number: _____

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Medical notes (e.g., allergies, vaccine reactions):

Healthcare provider: List the month/yr for each vaccination given. Record the generic abbreviation (e.g., PCV13, DTaP-HepB-IPV) or the trade name. For combination vaccines, fill in a row for each separate antigen in the combination.

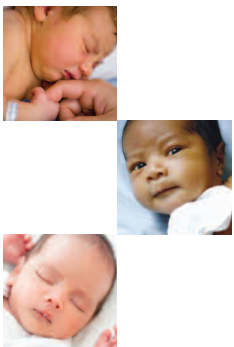
Form #1000

To learn more about vaccines, visit www.immunize.org or www.vaccineinformation.org

Last name		First name		M.I.	Birthdate (mo) (day) (yr)
Vaccine	Type of vaccine	Date given mo/day/yr	Healthcare professional or clinic	Date next dose due	
H. influenzae type b (Hib, Hib-HepB, DTaP-IPV/Hib, DTaP/Hib)					
Polio (IPV, OPV, DTaP-HepB-IPV, DTaP-IPV/Hib, DTaP-IPV)					
Pneumococcal (PCV7, PCV13, PPSV23)					
Rotavirus (RV5 [RotaTeq], RV1 [Rotarix], RV [unknown])					

Vaccine	Type of vaccine	Date given mo/day/yr	Healthcare professional or clinic	Date next dose due
Measles, Mumps, Rubella (MMR, MMRV)				
Varicella (VAR, MMRV)				
Hepatitis A (HepA, HepA-HepB)				
If combo				
Meningococcal (MCV4, MPSV4)				
Human papillomavirus (HPV4 [Gardasil], HPV2 [Cervarix])				
Influenza (TIV, LAIV)				

Get vaccinated against influenza each year to protect yourself and others around you.



Hepatitis B: What Hospitals Need to Do to Protect Newborns