

# 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

## Hepatitis B:

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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](http://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.

# Hepatitis B Vaccine

## What You Need to Know

Many Vaccine Information Statements are available in Spanish and other languages.  
See [www.immunize.org/vis](http://www.immunize.org/vis).

Hojas de Información Sobre Vacunas están disponibles en Español y en muchos otros idiomas. Visite <http://www.immunize.org/vis>

### 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,



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- 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.

#### 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).

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.

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#### 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](http://www.vaers.hhs.gov), or by calling **1-800-822-7967**.

*VAERS does not provide medical advice.*

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#### 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](http://www.hrsa.gov/vaccinecompensation).

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#### 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](http://www.cdc.gov/vaccines)

Vaccine Information Statement (Interim)  
**Hepatitis B Vaccine**

2/2/2012

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# 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](http://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](http://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](http://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](http://www.cdc.gov/vaccines)

Vaccine Information Statement (Interim)

## Hepatitis B Vaccine

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Spanish

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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](http://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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# 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



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](http://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](http://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](http://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				

To learn more about vaccines, visit [www.immunize.org](http://www.immunize.org) or [www.vaccineinformation.org](http://www.vaccineinformation.org)

**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: \_\_\_\_\_  
Printed by Immunization Action Coalition, Saint Paul, MN  
[www.immunize.org](http://www.immunize.org) • [www.vaccineinformation.org](http://www.vaccineinformation.org)

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

Healthcare provider: List the mo/day/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 #10100

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

# 4

## Obtaining Support: Helpful Contacts

- ▶ **Your State or Local Perinatal Hepatitis B Coordinator  
Can Help Implement the Hepatitis B Birth Dose**
- ▶ **How the Vaccines For Children (VFC) Program  
Can Help Your Hospital**



# Your State or Local Perinatal Hepatitis B Coordinator Can Help Implement the Hepatitis B Birth Dose

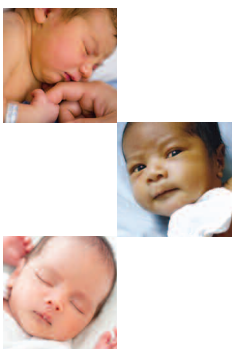
Every state, territory, and some large city health departments have a perinatal hepatitis B coordinator. This coordinator works with birthing hospitals and healthcare providers to help ensure all newborns are protected against hepatitis B virus (HBV) infection.

Perinatal hepatitis B coordinators can assist hospitals in numerous ways. Your coordinator can

- help you develop model standing orders and policies to assist with implementation or continuation of universal hepatitis B vaccine birth dose practices,
- assist your facility in learning about the VFC program and determining if your facility could receive hepatitis B vaccine at no cost for eligible children,

- facilitate case management of babies born to HBsAg-positive women to help ensure that babies receive the CDC-recommended follow-up medical care, and
- answer any questions you have about implementing or enhancing your hospital's hepatitis B prevention policies to protect newborns.

State and large city coordinators' names and phone numbers can be found on the Centers for Disease Control and Prevention's website at [www.cdc.gov/vaccines/vpd-vac/hepb/perinatal-contacts.htm](http://www.cdc.gov/vaccines/vpd-vac/hepb/perinatal-contacts.htm).



# How the Vaccines For Children (VFC) Program Can Help Your Hospital

Vaccines For Children (VFC) is a federal entitlement program that provides vaccines at no cost to eligible children. To qualify for VFC, children must be 18 years of age or younger and meet at least one of the following criteria:

- Medicaid-eligible (or covered)
  - American Indian or Alaska Native
  - Uninsured
  - Underinsured (i.e., has insurance but it does not cover the cost of vaccine) and receiving services at a federally qualified health center or rural health clinic
- The VFC program helps hospitals by providing vaccines at no cost for their

VFC-eligible patients. Hepatitis B vaccine for newborns is covered under the VFC program along with all routinely recommended vaccines for children and teens.

There is no charge for a hospital to become a VFC provider.

All states, territories, and the District of Columbia have VFC coordinators who can answer questions about enrolling in the program. To find contact information for your area's VFC coordinator, visit the Centers for Disease Control and Prevention website at [www.cdc.gov/vaccines/programs/vfc/contacts-state.html](http://www.cdc.gov/vaccines/programs/vfc/contacts-state.html).



Hepatitis B:

**What Hospitals Need to Do to Protect Newborns**

# 5

## Appendix: Authoritative Resources

- ▶ A Comprehensive Immunization Strategy to Eliminate Transmission of Hepatitis B Virus Infection in the United States. *MMWR*, December 23, 2005, Vol. 54 (RR16): 1–33
- ▶ Gaps in Hospital Policies and Practices to Prevent Perinatal Transmission of Hepatitis B Virus. *Pediatrics*, April 2010, Vol. 125(4):704–711
- ▶ Additional Resources





# MMWR<sup>TM</sup>

## Morbidity and Mortality Weekly Report

Recommendations and Reports

December 23, 2005 / Vol. 54 / No. RR-16

### 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 WITH ERRATA CORRECTIONS

This document incorporates the errata published by CDC in *MMWR* on February 17, 2006, and December 7, 2007. Corrections have been made to text and tables appearing on pages numbered (at the top) 2, 8, 9, 27, 28, and 29 of this document.

The original report is available online at [www.cdc.gov/mmwr/pdf/rr/rr5416.pdf](http://www.cdc.gov/mmwr/pdf/rr/rr5416.pdf).

#### YELLOW HIGHLIGHTING ADDED TO ORIGINAL ARTICLE

Certain information in this document has been highlighted in yellow, because it provides precise guidance for administration of hepatitis B vaccine to all newborns at birth, *prior to hospital discharge*.

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# 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

Prepared by

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### Summary

*This report is the first of a two-part statement from the Advisory Committee on Immunization Practices (ACIP) that updates the strategy to eliminate hepatitis B virus (HBV) transmission in the United States. The report provides updated recommendations to improve prevention of perinatal and early childhood HBV transmission, including implementation of universal infant vaccination beginning at birth, and to increase vaccine coverage among previously unvaccinated children and adolescents. Strategies to enhance implementation of the recommendations include 1) establishing standing orders for administration of hepatitis B vaccination beginning at birth; 2) instituting delivery hospital policies and procedures and case management programs to improve identification of and administration of immunoprophylaxis to infants born to mothers who are hepatitis B surface antigen (HBsAg) positive and to mothers with unknown HBsAg status at the time of delivery; and 3) implementing vaccination record reviews for all children aged 11–12 years and children and adolescents aged <19 years who were born in countries with intermediate and high levels of HBV endemicity, adopting hepatitis B vaccine requirements for school entry, and integrating hepatitis B vaccination services into settings that serve adolescents. The second part of the ACIP statement, which will include updated recommendations and strategies to increase hepatitis B vaccination of adults, will be published separately.*

### Strategy to Eliminate Hepatitis B Virus Transmission

Hepatitis B virus (HBV) is a bloodborne and sexually transmitted virus. Rates of new infection and acute disease are highest among adults, but chronic infection is more likely to occur in persons infected as infants or young children. Before hepatitis B vaccination programs became routine in the United States, an estimated 30%–40% of chronic infections are believed to have resulted from perinatal or early childhood transmission, even though <10% of reported cases of hepatitis B occurred in children aged <10 years (1). Chronically infected persons are at increased lifetime risk for cirrhosis and hepatocellular carcinoma (HCC) and also serve as the main reservoir for continued HBV transmission.

Hepatitis B vaccination is the most effective measure to prevent HBV infection and its consequences. Since they were first issued in 1982, recommendations for hepatitis B vaccination have evolved into a comprehensive strategy to eliminate HBV transmission in the United States (2–6) (Box 1). A primary focus of this strategy is universal vaccination of infants to prevent early childhood HBV infection and to eventually protect adolescents and adults from infection. Other components include routine screening of all pregnant women for hepatitis B surface antigen (HBsAg) and postexposure immunoprophylaxis of infants born to HBsAg-positive women, vaccination of children and adolescents who were not previously vaccinated, and vaccination of unvaccinated adults at increased risk for infection.

To date, the immunization strategy has been implemented with considerable success. Recent estimates indicate that >95% of pregnant women are tested for HBsAg, and case management has been effective in ensuring high levels of initiation and completion of postexposure immunoprophylaxis among identified infants born to HBsAg-positive women (7). Hepatitis B vaccine has been successfully integrated into the childhood vaccine schedule, and infant vaccine coverage levels are now equivalent to those of other vaccines in the childhood schedule. During 1990–2004, incidence of acute hepatitis B

The material in this report originated in the National Center for Infectious Diseases, Rima F. Khabbaz, MD, Director, Division of Viral Hepatitis, John W. Ward, MD, Director; and the National Immunization Program, Anne Schuchat, MD, Director, Immunization Services Division, Lance E. Rodewald, MD, Director.

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**BOX 1. Immunization strategy to eliminate transmission of hepatitis B virus (HBV) infection in the United States**

- Universal vaccination of infants beginning at birth
- Prevention of perinatal HBV infection through
  - routine screening of all pregnant women for hepatitis B surface antigen (HBsAg), and
  - immunoprophylaxis of infants born to HBsAg-positive women and infants born to women with unknown HBsAg status
- Routine vaccination of previously unvaccinated children and adolescents
- Vaccination of previously unvaccinated adults at increased risk for infection

in the United States declined 75%. The greatest decline (94%) occurred among children and adolescents, coincident with an increase in hepatitis B vaccine coverage. As of 2004, among U.S. children aged 19–35 months, >92% had been fully vaccinated with 3 doses of hepatitis B vaccine (8). This success can be attributed in part to the established infrastructure for vaccine delivery to children and to federal support for perinatal hepatitis B prevention programs.

Vaccine coverage among adolescents has also increased substantially. Preliminary data demonstrate that 50%–60% of adolescents aged 13–15 years have records indicating vaccination (with 3 doses) against hepatitis B (CDC, unpublished data, 2003). As of November 2005, a total of 34 states require vaccination for middle-school entry (9). Certain programs provide hepatitis B vaccine to youth who engage in behaviors that place them at high risk for HBV infection (i.e., injection-drug use, having more than one sex partner, and male sexual activity with other males), and adolescent hepatitis B vaccination is included as a Health Plan Employer Data Information Set (HEDIS) measure (10).

Despite these successes, challenges remain. Even with improvements in the management of pregnant women, only approximately 50% of expected births to HBsAg-positive women are identified (on the basis of application of racial/ethnic-specific HBsAg prevalence estimates to U.S. natality data) for case management, which maximizes timely delivery of postexposure immunoprophylaxis (11; CDC, unpublished data, 2004). The need for proper management of women without prenatal care, including HBsAg testing at the time of admission for delivery and administration of the first dose of vaccine to infants <12 hours of birth, is underscored by the higher prevalence of HBsAg seropositivity among these women than among women who are screened prenatally (12). Even when maternal HBsAg testing does occur, certain infants of HBsAg-positive mothers do not receive postexposure immuno-

prophylaxis because of testing errors and lapses in reporting of test results (13), and infants of women with unknown HBsAg status at the time of delivery often do not receive a birth dose of vaccine (14). Birth dose coverage in 2004 was only 46% (National Immunization Survey, unpublished data, 2004), and coverage has not returned to levels from before July 1999 (54%), when recommendations were made to temporarily suspend administration of hepatitis B vaccines at birth until vaccines that do not contain thimerosal as a preservative became available (15). Among adolescents, efforts to prevent HBV transmission are hampered by the low rate of health-care visits in this age group compared with that of young children and the frequency of initiation of high-risk behaviors.

To address these remaining challenges and accelerate progress toward elimination of HBV transmission in the United States, the ACIP has updated the hepatitis B immunization recommendations for infants, children, and adolescents and supplemented the recommendations with strategies for implementation. The recommendations and implementation strategies address prevention of perinatal and early childhood transmission and routine vaccination of children and adolescents. A main focus is on universal infant vaccination beginning at birth, which provides a “safety net” for prevention of perinatal infection, prevents early childhood infections, facilitates implementation of universal vaccination recommendations, and prevents infections in adolescents and adults. The second part of the ACIP statement, which includes updated recommendations and implementation strategies to increase hepatitis B vaccination among unvaccinated adults, will be published separately (16).

## Major Updates to the Recommendations

This report provides updated recommendations and approaches to address challenges in implementing the strategy to eliminate HBV transmission in the United States. These include the following measures:

- **Improve prevention of perinatal and early childhood HBV transmission.** Implement delivery hospital policies and procedures, case-management programs, and laws and regulations to improve identification of infants born to HBsAg-positive mothers and to mothers with unknown HBsAg status at the time of delivery, ensure administration of appropriate postexposure immunoprophylaxis to these infants beginning at birth, and administer a birth dose of hepatitis B vaccine to medically stable infants who weigh  $\geq 2,000$  g and who are born to HBsAg-negative mothers.

- **Improve vaccine coverage of children and adolescents who were not previously vaccinated.** Implement immunization record reviews for all children aged 11–12 years and children and adolescents aged <19 years who were born in countries in which HBV endemicity is high or intermediate (Figure 1 and Box 2); adopt hepatitis B vaccine requirements for school entry; and vaccinate all unvaccinated adolescents in settings that provide health-care services to persons in this age group.

## Background

### Clinical Features and Natural History of HBV Infection

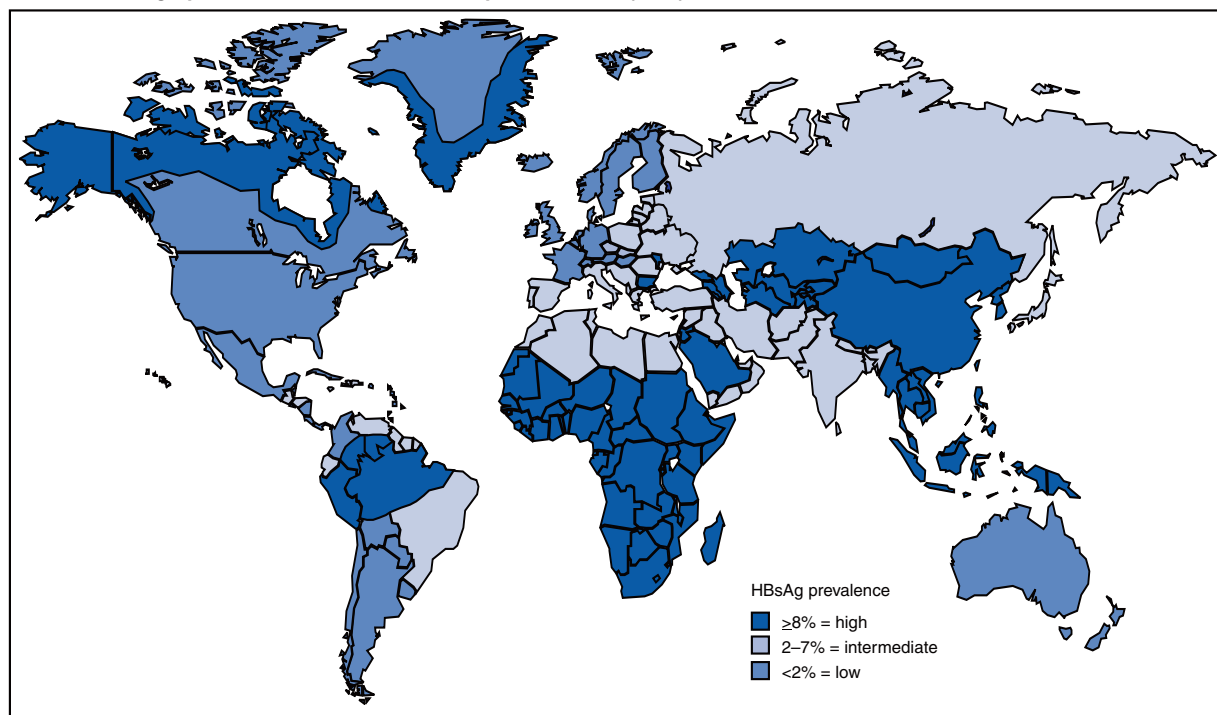
HBV is a 42-nm DNA virus classified in the *Hepadnaviridae* family. The liver is the primary site of HBV replication. After a susceptible person is exposed, the virus enters the liver via the bloodstream; no evidence exists indicating that the virus replicates at mucosal surfaces. HBV infection can produce either asymptomatic or symptomatic infection. The average

incubation period is 90 days (range: 60–150 days) from exposure to onset of jaundice and 60 days (range: 40–90 days) from exposure to onset of abnormal serum alanine aminotransferase (ALT) levels (17,18).

The onset of acute disease is usually insidious. Infants and young children (aged <10 years) are typically asymptomatic (19). When present, clinical symptoms and signs might include anorexia, malaise, nausea, vomiting, abdominal pain, and jaundice. Extrahepatic manifestations of disease (e.g., skin rashes, arthralgias, and arthritis) also can occur (20). The fatality rate among persons with reported acute hepatitis B is 0.5%–1.5%, with highest rates in adults aged >60 years (21).

Although the consequences of acute hepatitis B can be severe, the majority of serious sequelae associated with HBV disease occur in persons who are chronically infected. Persons with chronic infection also serve as the major reservoir for continued HBV transmission. Chronic infection occurs in approximately 90% of infected infants, 30% of infected children aged <5 years, and <5% of infected persons aged ≥5 years, with continuing viral replication in the liver and persistent viremia (19,22–24). Primary infections also become chronic more fre-

FIGURE 1. Geographic distribution of chronic hepatitis B virus (HBV) infection, 2005\*



\* For multiple countries, estimates of prevalence of hepatitis B surface antigen (HBsAg), a marker of chronic HBV infection, are based on limited data and might not reflect current prevalence in countries that have implemented routine childhood hepatitis B vaccination. In addition, HBsAg prevalence rates might vary within countries by subpopulation and locality.

**BOX 2. Geographic areas with intermediate\* and high† hepatitis B virus endemicity**

Africa: all countries  
 South Asia: all countries except Sri Lanka  
 Western Pacific: all countries and territories except Australia and New Zealand  
 Middle East: all countries except Cyprus  
 Eastern Europe: all countries except Hungary  
 Newly Independent States of the former Soviet Union: all countries  
 Western Europe: Greece, Italy, Malta, Portugal, and Spain  
 North America: Alaska Natives and indigenous populations of Northern Canada and Greenland  
 Central America: Belize, Guatemala, Honduras, and Panama  
 South America: Argentina, Bolivia, Brazil, Ecuador, Guyana, Suriname, Venezuela, and the Amazonian areas of Colombia and Peru  
 Caribbean: Antigua and Barbuda, Dominica, Dominican Republic, Grenada, Haiti, Jamaica, Puerto Rico, St. Kitts and Nevis, St. Lucia, St. Vincent and the Grenadines, Trinidad and Tobago, and Turks and Caicos

\* Hepatitis B surface antigen (HBsAg) prevalence of 2%–7%.

† HBsAg prevalence of ≥8%.

quently in immunosuppressed persons (e.g., hemodialysis patients and persons with human immunodeficiency virus [HIV] infection) (23,25,26). On the basis of data from follow-up studies of persons infected with HBV as infants or young children, approximately 25% of those with chronic infection die prematurely from cirrhosis or liver cancer; the majority remain asymptomatic until onset of cirrhosis or end-stage liver disease (27–29).

No specific treatment exists for acute hepatitis B. Persons who have chronic HBV infection require medical evaluation and regular monitoring (30,31). Therapeutic agents approved by the Food and Drug Administration (FDA) for treatment of chronic hepatitis B can achieve sustained suppression of HBV replication and remission of liver disease in certain persons (31). Periodic screening with alpha fetoprotein or imaging studies has been demonstrated to enhance early detection of HCC (31). Chronically infected persons with HCC have been reported to have experienced long-term survival after resection or ablation of small HCCs, and persons who were screened had a substantial survival advantage compared with historic controls (31).

Reinfection or reactivation of latent HBV infection has been reported among certain groups of immunosuppressed persons, including renal transplant recipients, HIV-infected patients, bone marrow transplant recipients, and patients receiving che-

motherapy (32–35). The frequency with which this phenomenon occurs is unknown.

**Interpretation of Serologic Markers of HBV Infection**

The antigens and antibodies associated with HBV infection include HBsAg and antibody to HBsAg (anti-HBs), hepatitis B core antigen (HBcAg) and antibody to HBcAg (anti-HBc), and hepatitis B e antigen (HBeAg) and antibody to HBeAg (anti-HBe). At least one serologic marker is present during the different phases of HBV infection (Table 1) (18,36). Serologic assays are commercially available for all markers except HBcAg because no free HBcAg circulates in blood.

The presence of a confirmed HBsAg result is indicative of ongoing HBV infection. All HBsAg-positive persons should be considered infectious. In newly infected persons, HBsAg is the only serologic marker detected during the first 3–5 weeks after infection, and it persists for variable periods at very low levels. The average time from exposure to detection of HBsAg is 30 days (range: 6–60 days) (17,18). Highly sensitive single-

**TABLE 1. Typical interpretation of serologic test results for hepatitis B virus infection**

HBsAg*	Serologic marker			Interpretation
	Total anti-HBc†	IgM <sup>§</sup> anti-HBc	Anti-HBs <sup>¶</sup>	
–**	–	–	–	Never infected
+††§§	–	–	–	Early acute infection; transient (up to 18 days) after vaccination
+	+	+	–	Acute infection
–	+	+	–	Acute resolving infection
–	+	–	+	Recovered from past infection and immune
+	+	–	–	Chronic infection
–	+	–	–	False positive (i.e., susceptible); past infection; "low-level" chronic infection; ¶¶ passive transfer to infant born to HBsAg-positive mother
–	–	–	+	Immune if concentration is ≥10 mIU/mL; *** passive transfer after hepatitis B immune globulin administration

\* Hepatitis B surface antigen.

† Antibody to hepatitis B core antigen.

§ Immunoglobulin M.

¶ Antibody to HBsAg.

\*\* Negative test result.

†† Positive test result.

§§ To ensure that an HBsAg-positive test result is not a false positive, samples with repeatedly reactive HBsAg results should be tested with a licensed (and, if appropriate, neutralizing confirmatory) test.

¶¶ Persons positive for only anti-HBc are unlikely to be infectious except under circumstances in which they are the source for direct percutaneous exposure of susceptible recipients to large quantities of virus (e.g., blood transfusion or organ transplant).

\*\*\* Milli-International Units per milliliter.



sample nucleic acid tests can detect HBV DNA in the serum of an infected person 10–20 days before detection of HBsAg (37). Transient HBsAg positivity has been reported for up to 18 days after vaccination and is clinically insignificant (38,39).

Anti-HBc appears at the onset of symptoms or liver test abnormalities in acute HBV infection and persists for life. Acute or recently acquired infection can be distinguished by the presence of the IgM class of anti-HBc, which is detected at the onset of acute hepatitis B and persists for up to 6 months if the disease resolves. In patients who develop chronic hepatitis B, IgM anti-HBc can persist at low levels during viral replication and can result in positive tests for IgM anti-HBc (40). In addition, false-positive IgM anti-HBc test results can occur. Because the positive predictive value is low in asymptomatic persons, for diagnosis of acute hepatitis B, testing for IgM anti-HBc should be limited to persons with clinical evidence of acute hepatitis or an epidemiologic link to a case.

In persons who recover from HBV infection, HBsAg is eliminated from the blood, usually within 3–4 months, and anti-HBs develops during convalescence. The presence of anti-HBs typically indicates immunity from HBV infection. Infection or immunization with one genotype of HBV confers immunity to all genotypes. In addition, anti-HBs can be detected for several months after hepatitis B immune globulin (HBIG) administration. The majority of persons who recover from natural infection will be positive for both anti-HBs and anti-HBc, whereas persons who respond to hepatitis B vaccine have only anti-HBs. In persons who become chronically infected, HBsAg and anti-HBc persist, typically for life. HBsAg will become undetectable in approximately 0.5%–2% of chronically infected persons yearly, and anti-HBs will occur in the majority of these persons (41–44).

In certain persons, the only HBV serologic marker detected in serum is anti-HBc. Isolated anti-HBc can occur after HBV infection among persons who have recovered but whose anti-HBs levels have waned or among persons in whom anti-HBs failed to occur. Persons in the latter category include those with circulating HBsAg levels not detectable by commercial assays. These persons are unlikely to be infectious except under circumstances in which they are the source for direct percutaneous exposure of susceptible recipients to substantial quantities of virus (e.g., through blood transfusion or following liver transplantation) (45). HBV DNA has been detected in the blood of <5% of persons with isolated anti-HBc (46). Typically, the frequency of isolated anti-HBc relates directly to the prevalence of HBV infection in the population. In populations with a high prevalence of HBV infection, isolated anti-HBc likely indicates previous infection, with loss of anti-HBs. For persons in populations with a low prevalence of HBV

infection, an isolated anti-HBc result often represents a false-positive reaction. The majority of these persons have a primary anti-HBs response after a 3-dose series of hepatitis B vaccine (47,48). Infants who are born to HBsAg-positive mothers and who do not become infected might have detectable anti-HBc for  $\leq 24$  months after birth from passively transferred maternal antibody.

HBeAg can be detected in the serum of persons with acute or chronic HBV infection. The presence of HBeAg correlates with viral replication and high levels of virus (i.e., high infectivity) (49,50). Anti-HBe correlates with the loss of replicating virus and with lower levels of virus, although reversion to HBeAg positivity has been observed (44).

## Epidemiology of HBV Infection

### Transmission

HBV is transmitted by percutaneous (i.e., puncture through the skin) or mucosal (i.e., direct contact with mucous membranes) exposure to infectious blood or to body fluids that contain blood. All HBsAg-positive persons are infectious, but those who are also HBeAg positive are more infectious because their blood contains high titers of HBV (typically  $10^7$ – $10^9$  virions/mL) (49,50). Although HBsAg has been detected in multiple body fluids, only serum, semen, and saliva have been demonstrated to be infectious (51,52). HBV is comparatively stable in the environment and remains viable for  $\geq 7$  days on environmental surfaces at room temperature (53). HBV at concentrations of  $10^2$ – $10^3$  virions/mL can be present on environmental surfaces in the absence of any visible blood and still cause transmission (53,54).

For infants and children, the two primary sources of HBV infection are perinatal transmission from infected mothers and horizontal transmission from infected household contacts. Adolescents are at risk for HBV infection primarily through high-risk sexual activity (i.e., sex with more than one partner and male sexual activity with other males) and injection-drug use (21). Transmission of HBV via transfusion of blood and plasma-derived products is rare because of donor screening for HBsAg and viral inactivation procedures.

For a newborn infant whose mother is positive for both HBsAg and HBeAg, the risk for chronic HBV infection is 70%–90% by age 6 months in the absence of postexposure immunoprophylaxis (55–57). For infants of women who are HBsAg positive but HBeAg negative, the risk for chronic infection is <10% in the absence of postexposure immunoprophylaxis (58–60). Rare cases of fulminant hepatitis B among perinatally infected infants also have been reported (61,62). Studies suggest that breastfeeding by an HBsAg-

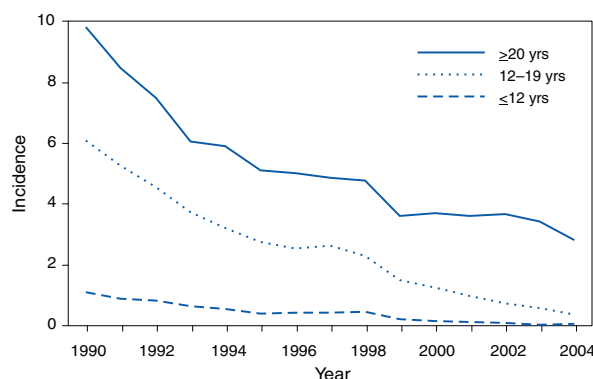
positive mother does not increase the risk for acquisition of HBV infection in the infant (63).

Children who are not infected at birth remain at risk from long-term interpersonal contact with their infected mothers. In one study, 38% of infants who were born to HBsAg-positive mothers and who were not infected perinatally became infected by age 4 years (64). In addition, children living with any chronically infected persons are at risk for becoming infected through percutaneous or mucosal exposures to blood or infectious body fluids (e.g., sharing a toothbrush, contact with exudates from dermatologic lesions, contact with HBsAg-contaminated surfaces). HBV transmission rates to susceptible household contacts of chronically infected persons have varied (range: 14%–60%) (65,66). High rates of infection also have been reported among unvaccinated long-term residents of institutions for the mentally handicapped (67,68), and, in rare instances, person-to-person transmission has been reported in child care settings (69,70).

### Incidence

During 1990–2004, overall incidence of reported acute hepatitis B declined 75%, from 8.5 to 2.1 per 100,000 population. The most dramatic declines occurred in the cohort of children to whom recommendations for routine infant and adolescent vaccination have applied. Incidence among children aged <12 years and adolescents aged 12–19 years declined 94%, from 1.1 to 0.36 and 6.1 to 2.8 per 100,000 population, respectively (Figure 2). Since implementation of routine childhood immunization, an estimated 6,800 perinatal infections and an additional 18,700 infections during the first 10 years of life have been prevented annually in the United States (71).

**FIGURE 2. Reported acute hepatitis B incidence,\* by age group and year — United States, 1990–2004**



\* Per 100,000 population.

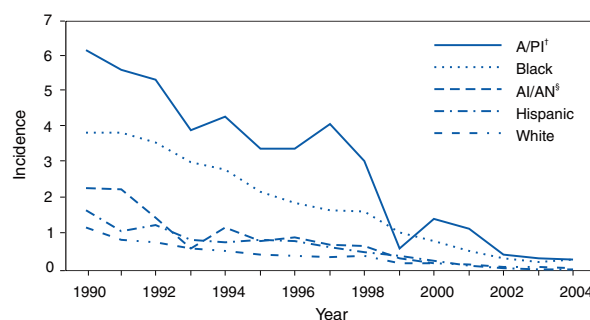
Although infections in infants and children aged <10 years represented <10% of all HBV infections before implementation of childhood immunization programs, childhood infections resulted in an estimated 30%–40% of the chronic HBV infections among persons who acquired their infections in the United States (1). In two population-based studies conducted among Asian/Pacific Islander children who were born in the United States before perinatal hepatitis B prevention programs were widely implemented, 61%–66% of the chronic HBV infections occurred in children born to HBsAg-negative mothers (72,73). A substantial proportion of these chronic infections would not have been prevented by a selective program of identification and immunization of only infants born to HBsAg-positive mothers.

In addition to declines in incidence among all age groups, racial disparities in hepatitis B incidence among children have been substantially reduced (Figure 3). The reduction of the disparity between Asian/Pacific Islander and other children is consistent with recent observations noting a decline in seroprevalence of HBV infection after successful implementation of routine hepatitis B vaccination among Asians who have recently immigrated to the United States (74,75). However, as hepatitis B incidence has declined among U.S.-born children, unvaccinated foreign-born children account for a high proportion of infections. During 2001–2002, of 19 children born after 1991 in whom acute hepatitis B had been verified, eight (42%) were foreign born (76).

### Prevalence

In the U.S. population, the overall age-adjusted prevalence of HBV infection (including persons with chronic infection and those with previous infection) was 4.9% in the third

**FIGURE 3. Reported acute hepatitis B incidence\* among persons aged <19 years, by race/ethnicity and year — United States, 1990–2004**



\* Per 100,000 population.

† Asian/Pacific Islander.

‡ American Indian/Alaska Native.

National Health and Nutrition Examination Survey (NHANES III, 1988–1994) (77). Foreign-born persons (particularly Asian/Pacific Islanders) who have emigrated from countries in which HBV is endemic (Figure 1 and Box 2) contribute disproportionately to the burden of chronic HBV infection in the United States. The prevalence of chronic HBV infection among foreign-born persons immigrating to the United States from Central and Southeast Asia, the Middle East, and Africa varies (range: 5%–15%) and reflects the patterns of HBV infection in the countries and regions of origin for these persons. During 1994–2003, approximately 40,000 immigrants with chronic HBV infection were admitted annually to the United States for permanent residence (78; CDC, unpublished data, 2005).

## Prophylaxis Against HBV Infection

### Hepatitis B Vaccine

HBsAg is the antigen used for hepatitis B vaccination (79,80). Vaccine antigen can be purified from the plasma of persons with chronic HBV infection or produced by recombinant DNA technology. Vaccines available in the United States use recombinant DNA technology to express HBsAg in yeast, which is then purified from the cells by biochemical and biophysical separation techniques (81,82). Hepatitis B vaccines licensed in the United States are formulated to contain 10–40 µg of HBsAg protein/mL. Since March 2000, hepatitis B vaccines produced for distribution in the United States do not contain thimerosal as a preservative or contain only a trace amount (<1.0 mcg mercury/mL) from the manufacturing process (83,84).

Hepatitis B vaccine is available as a single-antigen formulation and also in fixed combination with other vaccines. Two single-antigen vaccines are available in the United States: Recombivax HB® (Merck & Co., Inc., Whitehouse Station, New Jersey) and Engerix-B® (GlaxoSmithKline Biologicals, Rixensart, Belgium). Of the three licensed combination vaccines, one (Twinrix® [GlaxoSmithKline Biologicals, Rixensart, Belgium]) is used for vaccination of adults, and two (Comvax® [Merck & Co., Inc., Whitehouse Station, New Jersey] and Pediarix® [GlaxoSmithKline Biologicals, Rixensart, Belgium]) are used for vaccination of infants and young children. Twinrix contains recombinant HBsAg and inactivated hepatitis A virus. Comvax contains recombinant HBsAg and *Haemophilus influenzae* type b (Hib) polyribosylribitol phosphate conjugated to *Neisseria meningitidis* outer membrane protein complex. Pediarix contains recombinant HBsAg, diphtheria and tetanus toxoids and acellular pertussis adsorbed (DTaP), and inactivated poliovirus (IPV).

### HBIG

HBIG provides passively acquired anti-HBs and temporary protection (i.e., 3–6 months) when administered in standard doses. HBIG is typically used as an adjunct to hepatitis B vaccine for postexposure immunoprophylaxis to prevent HBV infection. HBIG administered alone is the primary means of protection after an HBV exposure for nonresponders to hepatitis B vaccination.

HBIG is prepared from the plasma of donors with high concentrations of anti-HBs. The plasma is screened to eliminate donors who are positive for HBsAg, antibodies to HIV and hepatitis C virus (HCV), and HCV RNA. In addition, proper manufacturing techniques for HBIG inactivate viruses (e.g., HBV, HCV, and HIV) from the final product (85,86). No evidence exists that HBV, HCV, or HIV ever has been transmitted by HBIG commercially available in the United States. HBIG that is commercially available in the United States does not contain thimerosal.

## Vaccination Schedules and Results of Vaccination

### Preexposure Vaccination

#### Infants and Children

Primary vaccination consists of ≥3 intramuscular doses of hepatitis B vaccine (Table 2). Vaccine schedules for infants and children (Tables 3–5) are determined on the basis of immunogenicity data and the need to integrate hepatitis B vaccine into a harmonized childhood vaccination schedule. Although not all possible schedules for each product have been evaluated in clinical trials, available licensed formulations for both single-antigen vaccines produce high (>95%) levels of seroprotection among infants and children when administered in multiple schedules (87–91).

The immunogenicity of the combined hepatitis B-Hib conjugate vaccine (Comvax) and the combined hepatitis B-DTaP-IPV vaccine (Pediarix) is equivalent to that of their individual antigens administered separately. However, these vaccines cannot be administered to infants aged <6 weeks; only single-antigen hepatitis B vaccine may be used for the birth dose. Use of 4-dose hepatitis B vaccine schedules, including schedules with a birth dose, has not increased vaccine reactogenicity (92,93). Anti-HBs responses after a 3-dose series of hepatitis B-containing combination vaccines among infants who were previously vaccinated at birth with single-antigen hepatitis B vaccine are comparable to those observed after a 3-dose series of combination vaccine without a birth dose (93).

TABLE 2. Recommended doses of currently licensed formulations of hepatitis B vaccine, by age group and vaccine type

Age group	Single-antigen vaccine				Combination vaccine					
	Recombivax HB		Engerix-B		Comvax*		Pediarix†		Twinrix§	
	Dose (µg) <sup>¶</sup>	Volume (mL)	Dose (µg) <sup>¶</sup>	Volume (mL)	Dose (µg) <sup>¶</sup>	Volume (mL)	Dose (µg) <sup>¶</sup>	Volume (mL)	Dose (µg) <sup>¶</sup>	Volume (mL)
Infants (<1 yr)	5	0.5	10	0.5	5	0.5	10	0.5	NA**	NA
Children (1–10 yrs)	5	0.5	10	0.5	5*	0.5	10†	0.5	NA	NA
Adolescents										
11–15 yrs	10 <sup>††</sup>	1.0	NA	NA	NA	NA	NA	NA	NA	NA
11–19 yrs	5	0.5	10	0.5	NA	NA	NA	NA	NA	NA
Adults (≥20 yrs)	10	1.0	20	1.0	NA	NA	NA	NA	20 <sup>§</sup>	1.0
<b>Hemodialysis patients and other immunocompromised persons</b>										
<20 yrs <sup>§§</sup>	5	0.5	10	0.5	NA	NA	NA	NA	NA	NA
≥20 yrs	40 <sup>¶¶</sup>	1.0	40***	2.0	NA	NA	NA	NA	NA	NA

\* Combined hepatitis B–*Haemophilus influenzae* type b conjugate vaccine. This vaccine cannot be administered at birth, before age 6 weeks, or after age 71 months.

† Combined hepatitis B–diphtheria, tetanus, and acellular pertussis-inactivated poliovirus vaccine. This vaccine cannot be administered at birth, before age 6 weeks, or at age ≥7 years.

§ Combined hepatitis A and hepatitis B vaccine. This vaccine is recommended for persons aged ≥18 years who are at increased risk for both hepatitis B virus and hepatitis A virus infections.

¶ Recombinant hepatitis B surface antigen protein dose.

\*\* Not applicable.

†† Adult formulation administered on a 2-dose schedule.

§§ Higher doses might be more immunogenic, but no specific recommendations have been made.

¶¶ Dialysis formulation administered on a 3-dose schedule at age 0, 1, and 6 months.

\*\*\* Two 1.0-mL doses administered at one site, on a 4-dose schedule at age 0, 1, 2, and 6 months.

## Birth Dose

Hepatitis B vaccine can be administered soon after birth with only minimal decrease in immunogenicity, compared with administration at older ages, and no decrease in protective efficacy (87). Administration of a birth dose of hepatitis B vaccine is required for effective postexposure immunoprophylaxis to prevent perinatal HBV infection. Although infants who require postexposure immunoprophylaxis should be identified by maternal HBsAg testing, administering a birth dose to infants even without HBIG serves as a “safety net” to prevent perinatal infection among infants born to HBsAg-positive mothers who are not identified because of errors in maternal HBsAg testing or failures in reporting of test results (13). The birth dose also provides early protection to infants at risk for infection after the perinatal period. Administration of a birth dose has been associated with higher rates of on-time completion of the hepatitis B vaccine series (15,94). In certain populations, the birth dose has been associated with improved completion rates for all other infant vaccines (95), although findings have not been consistent (15,94).

## Adolescents

Recommended vaccination schedules for adolescents balance available immunogenicity data with the need to achieve compliance with vaccination in this age group (Tables 2 and 5). Both licensed single-antigen hepatitis B vaccines administered intramuscularly at 0, 1, and 6 months produce a >95%

sero-protection rate in adolescents. Equivalent seroprotection rates are achieved among adolescents vaccinated at 0, 1–2, and 4 months and 0, 12, and 24 months. The adult (10 µg) dose of Recombivax-HB administered in a 2-dose schedule to children and adolescents aged 11–15 years at 0 and 4–6 months produces antibody levels equivalent to those obtained with the 5-µg dose administered on a 3-dose schedule (96,97). However, no data on long-term antibody persistence or protection are available for 2-dose schedules. No combination vaccines containing hepatitis B vaccine antigen are approved for use in adolescents aged 11–17 years.

## Nonstandard Vaccine Schedules

No apparent effect on immunogenicity has been documented when minimum spacing of doses is not achieved precisely. Increasing the interval between the first 2 doses has little effect on immunogenicity or final antibody concentration (98–100). The third dose confers the maximum level of seroprotection but acts primarily as a booster and appears to provide optimal long-term protection (101). Longer intervals between the last 2 doses result in higher final antibody levels but might increase the risk for acquisition of HBV infection among persons who have a delayed response to vaccination. No differences in immunogenicity have been observed when 1 or 2 doses of hepatitis B vaccine produced by one manufacturer are followed by doses from a different manufacturer (102).

**TABLE 3. Hepatitis B vaccine schedules for newborn infants, by maternal hepatitis B surface antigen (HBsAg) status\***

Maternal HBsAg status	Single-antigen vaccine		Single antigen + combination vaccine	
	Dose	Age	Dose	Age
<b>Positive</b>	1†	Birth (≤12 hrs)	1†	Birth (≤12 hrs)
	HBIG‡	Birth (≤12 hrs)	HBIG	Birth (≤12 hrs)
	2	1–2 mos	2	2 mos
	3¶	6 mos	3	4 mos
			4¶	6 mos (Pediarix) or 12–15 mos (Comvax)
<b>Unknown**</b>	1†	Birth (≤12 hrs)	1†	Birth (≤12 hrs)
	2	1–2 mos	2	2 mos
	3¶	6 mos	3	4 mos
			4¶	6 mos (Pediarix) or 12–15 mos (Comvax)
<b>Negative</b>	1†,††	Birth (before discharge)	1†,††	Birth (before discharge)
	2	1–2 mos	2	2 mos
	3¶	6–18 mos	3	4 mos
			4¶	6 mos (Pediarix) or 12–15 mos (Comvax)

\* See Table 4 for vaccine schedules for preterm infants weighing <2,000 g.

† Recombivax HB or Engerix-B should be used for the birth dose. Comvax and Pediarix cannot be administered at birth or before age 6 weeks.

‡ Hepatitis B immune globulin (0.5 mL) administered intramuscularly in a separate site from vaccine.

¶ The final dose in the vaccine series should not be administered before age 24 weeks (164 days).

\*\* Mothers should have blood drawn and tested for HBsAg as soon as possible after admission for delivery; if the mother is found to be HBsAg positive, the infant should receive HBIG as soon as possible but no later than age 7 days.

†† On a case-by-case basis and only in rare circumstances, the first dose may be delayed until after hospital discharge for an infant who weighs ≥2,000 g and whose mother is HBsAg negative, but only if a physician's order to withhold the birth dose and a copy of the mother's original HBsAg-negative laboratory report are documented in the infant's medical record.

**TABLE 4  
Hepatitis B Immunization Management of Preterm Infants Weighing <2,000 g, by Maternal Hepatitis B Surface Antigen (HBsAg) Status**

Maternal HBsAg status	Recommendation
<b>Positive</b>	<ul style="list-style-type: none"> <li>Administer HBIG* + single-antigen hepatitis B vaccine within 12 hrs of birth.</li> <li>Do not count the birth dose as part of the vaccine series.</li> <li>Administer 3 additional hepatitis B vaccine doses with               <ul style="list-style-type: none"> <li>single-antigen vaccine at ages 1, 2–3, and 6 mos, or</li> <li>hepatitis B-containing combination vaccine at ages 2, 4, and 6 mos (Pediarix) or 2, 4, and 12–15 mos (Comvax).†</li> </ul> </li> <li>Test for HBsAg and antibody to HBsAg 1–2 mos after completion of ≥3 doses of a licensed hepatitis B vaccine series (i.e., at age 9–18 mos, generally at the next well-child visit). Testing should not be performed before age 9 mos nor within 4 wks of the most recent vaccine dose.</li> </ul>
<b>Unknown</b>	<ul style="list-style-type: none"> <li>Administer HBIG + single-antigen hepatitis B vaccine within 12 hrs of birth.</li> <li>Test mother for HBsAg.</li> <li>Do not count the birth dose as part of the vaccine series.</li> <li>Administer 3 additional hepatitis B vaccine doses with               <ul style="list-style-type: none"> <li>single-antigen vaccine at ages 1, 2–3, and 6 mos, or</li> <li>hepatitis B-containing combination vaccine at ages 2, 4, and 6 mos (Pediarix) or 2, 4, and 12–15 mos (Comvax).†</li> </ul> </li> </ul>
<b>Negative</b>	<ul style="list-style-type: none"> <li>Delay first dose of hepatitis B vaccine until age 1 mo or hospital discharge.</li> <li>Complete the hepatitis B vaccine series with               <ul style="list-style-type: none"> <li>single-antigen vaccine at ages 2 mos and 6–18 mos, or</li> <li>hepatitis B-containing combination vaccine at ages 2, 4, and 6 mos (Pediarix) or 2, 4, and 12–15 mos (Comvax).†</li> </ul> </li> </ul>

\* Hepatitis B immune globulin.

† The final dose in the vaccine series should not be administered before age 24 weeks (164 days).

## Response to Revaccination

A study of infants born to HBsAg-positive mothers who did not respond to a primary vaccine series indicated that all those not infected with HBV responded satisfactorily to a repeat 3-dose revaccination series (103). No data suggest that children who have no detectable antibody after 6 doses of vaccine would benefit from additional doses.

## Groups Requiring Different Vaccination Doses or Schedules

**Preterm infants.** Preterm infants weighing <2,000 g at birth have a decreased response to hepatitis B vaccine administered before age 1 month (104–106). By age 1 month, medically stable preterm infants, regardless of initial birth weight or gestational age, have a response to vaccination that is comparable to that of full-term infants (107–110).

**Hemodialysis patients and other immunocompromised persons.** Although data concerning the response of pediatric hemodialysis patients to vaccination with standard pediatric doses are lacking, protective levels of antibody occur in 75%–97% of those who receive higher dosages (20-μg) on either the 3- or the 4-dose schedule (111–114). Humoral response to hepatitis B vaccination is also reduced in other children and adolescents who are immunocompromised (e.g., hematopoietic stem cell transplant recipients, patients undergoing chemotherapy, and HIV-infected persons) (115–119). Modified dosing regimens, including a doubling of the standard antigen dose or administration of additional doses, might increase response rates (120). However, data on response to these alternative vaccination schedules are limited (121).

## Immune Memory

Anti-HBs is the only easily measurable correlate of vaccine-induced protection. Immunocompetent persons who achieve anti-HBs concentrations ≥10 mIU/mL after preexposure vaccination have virtually complete protection against both acute disease and chronic infection even if anti HBs concentrations subsequently decline to <10 mIU/mL (122–125). Although immunogenicity is lower among immunocompromised persons, those who achieve and maintain a protective antibody response before exposure to HBV have a high level of protection from infection.

After primary immunization with hepatitis B vaccine, anti-HBs concentrations decline rapidly within the first



**TABLE 5. Hepatitis B vaccine schedules for children, adolescents, and adults\***

Age	Schedule
Children (1–10 yrs)	0, 1, and 6 mos <sup>†</sup> 0, 2, and 4 mos <sup>†</sup> 0, 1, 2, and 12 mos <sup>†§</sup>
Adolescents (11–19 yrs)	0, 1, and 6 mos <sup>†</sup> 0, 1, and 4 mos <sup>†</sup> 0, 2, and 4 mos <sup>†</sup> 0, 12, and 24 mos <sup>†</sup> 0 and 4–6 mos <sup>†**</sup> 0, 1, 2, and 12 mos <sup>†¶</sup>
Adults (≥20 yrs)	0, 1, and 6 mos <sup>**††</sup> 0, 1, and 4 mos <sup>**</sup> 0, 2, and 4 mos <sup>**</sup> 0, 1, 2, and 12 mos <sup>¶**</sup>

\* Children, adolescents, and adults may be vaccinated according to any of the schedules indicated, except as noted. Selection of a schedule should consider the need to optimize compliance with vaccination.

<sup>†</sup> Pediatric/adolescent formulation.

<sup>¶</sup> A 2-dose schedule of Recombivax-HB adult formulation (10 µg) is licensed for adolescents aged 11–15 years. When scheduled to receive the second dose, adolescents aged >15 years should be switched to a 3-dose series, with doses 2 and 3 consisting of the pediatric formulation administered on an appropriate schedule.

<sup>§</sup> A 4-dose schedule of Engerix B is licensed for all age groups.

<sup>\*\*</sup> Adult formulation.

<sup>††</sup> Twinrix may be administered to persons aged ≥18 years at 0, 1, and 6 months.

year and more slowly thereafter. Among children who respond to a primary vaccine series with antibody levels ≥10 mIU/mL, 15%–50% have low or undetectable concentrations of anti-HBs (anti-HBs loss) 5–15 years after vaccination (126–130). The persistence of detectable anti-HBs after vaccination, in the absence of exposure to HBV, depends on the level of post-vaccination antibody concentration.

Despite declines in anti-HBs to <10 mIU/mL, nearly all vaccinated persons are still protected against HBV infection. The mechanism for continued vaccine-induced protection is thought to be the preservation of immune memory through selective expansion and differentiation of clones of antigen-specific B and T lymphocytes (131). Persistence of vaccine-induced immune memory among persons who responded to a primary childhood vaccine series 13–23 years earlier but then had levels of anti-HBs below 10 mIU/mL has been demonstrated by an anamnestic increase in anti-HBs levels in 67%–76% of these persons 2–4 weeks after administration of an additional vaccine dose (132,133). Although direct measurement of immune memory is not yet possible, these data indicate that a high proportion of vaccine recipients retain immune memory and would develop an anti-HBs response upon exposure to HBV.

Studies of cohorts of immunocompetent persons vaccinated as children or infants also indicate that, despite anti-HBs loss years after immunization, nearly all vaccinated persons who

respond to a primary series remain protected from HBV infection. No clinical cases of hepatitis B have been observed in follow-up studies conducted 15–20 years after vaccination among immunocompetent vaccinated persons with antibody levels ≥10 mIU/mL. Certain studies have documented breakthrough infections (detected by the presence of anti-HBc or HBV DNA) in a limited percentage of vaccinated persons (130,131), but these infections are usually transient and asymptomatic; chronic infections have been documented only rarely (134). Breakthrough infections resulting in chronic infection have been observed only among vaccinated infants born to HBsAg-positive women.

Limited data are available on the duration of immune memory after hepatitis B vaccination in immunocompromised persons (e.g., HIV-infected patients, dialysis patients, patients undergoing chemotherapy, or hematopoietic stem cell transplant patients). No clinically important HBV infections have been documented among immunocompromised persons who maintain protective levels of anti-HBs. In studies of long-term protection among HIV-infected persons, breakthrough infections occurring after a decline in anti-HBs concentrations to <10 mIU/mL have been transient and asymptomatic (135). However, among hemodialysis patients who respond to the vaccine, clinically significant HBV infection has been documented in persons who have not maintained anti-HBs concentrations of ≥10 mIU/mL (136).

## Postexposure Prophylaxis

Both passive-active postexposure prophylaxis (PEP) with HBIG and hepatitis B vaccine and active PEP with hepatitis B vaccine alone have been demonstrated to be highly effective in preventing transmission after exposure to HBV (137–140). HBIG alone has also been demonstrated to be effective in preventing HBV transmission (141–144), but with the availability of hepatitis B vaccine, HBIG typically is used as an adjunct to vaccination.

The major determinant of the effectiveness of PEP is early administration of the initial dose of vaccine. The effectiveness of PEP diminishes the longer it is initiated after exposure (17,145,146). Studies are limited on the maximum interval after exposure during which PEP is effective, but the interval is unlikely to exceed 7 days for perinatal (147) and needlestick (140–142) exposures and 14 days for sexual exposures (122, 138,139,143,144).

No data are available on the efficacy of HBsAg-containing combination vaccines when used to complete the vaccine series for PEP, but the efficacy of combination vaccines is expected to be similar to that of single-antigen vaccines because the HBsAg component induces a comparable anti-HBs response.