

HEPATITIS B VACCINATION

The first hepatitis B vaccine became commercially available in the United States in 1982. In 1986, a hepatitis B vaccine produced by recombinant DNA technology was licensed and a second recombinant-type hepatitis B vaccine was licensed in 1989. The two recombinant DNA vaccines (Recombivax HB and Engerix-B) are the only hepatitis B vaccine preparations currently used in the United States. (There are additional products licensed in the United States that contain these vaccines in combination with other vaccines.)

Who should get this vaccine?

Hepatitis B vaccine (usually a three-dose series) is recommended for all children 0-18 years of age. It is recommended for infants beginning at birth in the hospital. All older children who did not get all the recommended doses of hepatitis B vaccine as an infant should complete their vaccine series as soon as possible. Most states require hepatitis B vaccine for school entry. Adolescents who are just starting their series will need two or three doses, depending on their age and the brand of vaccine used. Adults at increased risk of acquiring HBV infection should also be vaccinated. In addition, the vaccine can be given to any person who desires protection from hepatitis B.

Who is at increased risk of HBV infection?

- Healthcare workers and public safety workers with reasonably anticipated risk for exposure to blood or blood-contaminated body fluids.
- Men who have sex with men.
- Sexually active people who are not in long-term, mutually monogamous relationships.
- People seeking evaluation or treatment for a sexually transmitted disease.
- Current or recent injection drug users.
- Inmates of long-term correctional facilities.
- People with end-stage kidney disease, including pre-dialysis, hemodialysis, peritoneal dialysis and home dialysis patients.
- Staff and residents of institutions or group homes for the developmentally challenged.
- Household members and sex partners of people with chronic HBV infection.
- Susceptible (non-infected and non-vaccinated) people from United States populations known to previously or currently have high rates of childhood HBV infection, including Alaska Natives, Pacific Islanders, and immigrants or refugees from countries with intermediate or high rates of chronic HBV infection.
- International travelers to regions with high or intermediate rates of HBV infection.

Who recommends this vaccine?

The Centers for Disease Control and Prevention (CDC), the American Academy of Pediatrics (AAP), the American Academy of Family Physicians (AAFP), the American College of Physicians (ACP), and American College of Obstetricians and Gynecologists (ACOG) recommend this vaccine.

Is hepatitis B vaccine safe?

Yes. Hepatitis B vaccines have been demonstrated to be safe when administered to infants, children, adolescents and adults. Since 1982, more than an estimated 70 million adolescents and adults and more than 50 million infants and children have received at least one dose of hepatitis B vaccine in the United States. Serious reactions are rare and the majority of children who receive this vaccine have no side effects.

What side effects have been reported with this vaccine?

Of those children experiencing a side effect, most will have only a very mild reaction, such as soreness at the injection site (fewer than one-out-of-three children) or low-grade fever. Adults are slightly more likely to experience such mild symptoms. Serious allergic reactions following hepatitis B vaccination are rare.

How effective is this vaccine?

After three properly administered doses of vaccine, at least nine out of ten healthy young adults and more than nine out of ten infants, children and adolescents develop protective antibodies and subsequent immunity to HBV infection.

Why is this vaccine recommended for all babies when most of them won't be exposed to HBV for many years, if then?

There are four reasons for recommending that all infants receive hepatitis B vaccine, starting at birth. First, people have a very high risk for developing chronic hepatitis B virus (HBV) infection if they become infected at birth or during childhood, with an increased risk of dying prematurely from liver cancer or cirrhosis. Second, HBV infection in infants and young children usually produces no symptoms, so these individuals can spread the infection to others without knowing it. Third, most early childhood spread of HBV occurs in households where a person has chronic HBV infection but the spread of HBV has also been recognized in daycare centers and schools. Fourth, long-term protection following infant vaccination is expected to last for decades and will ultimately protect against acquiring infection at any age.

Who should NOT receive hepatitis B vaccine?

People who had a serious allergic reaction to one dose of hepatitis B vaccine should not have another dose of hepatitis B vaccine. People with a history of hypersensitivity to yeast should not receive this vaccine. People with a moderate or severe acute illness should postpone receiving the vaccine until their condition is improved.

Can the hepatitis B vaccine be given during pregnancy?

Yes.

Should persons be tested for immunity to hepatitis B before being vaccinated?

Blood testing before vaccination is not recommended for the routine vaccination of infants, children and adolescents. However, children born in countries where HBV is moderate or highly endemic should be tested to be sure they are not already infected. Testing can be done at the same visit when the first dose of hepatitis B vaccine is given. Vaccinating a person already immune to or infected with HBV will not help or harm the person. The main reason for testing people at increased risk for HBV is to determine if they are infected in order to refer them for medical care.

Should persons be tested for immunity to hepatitis B after being vaccinated?

Testing after vaccination is not recommended routinely. Testing after vaccination is recommended only for people whose medical care depends on knowledge of their response to the vaccine. This includes infants born to HBV-infected mothers; healthcare and public safety workers at risk of continued exposure to blood on the job; immune-compromised people (e.g., people with AIDS or on hemodialysis); and sex and needle-sharing partners of people with chronic HBV infection.

When should postvaccination testing be done?

If indicated, testing should be performed one-to-two months after administration of the last dose of the vaccine series by using a method that allows determination of a protective level of anti-HBs (≥ 10 mIU/mL). Persons determined to have anti-HBs levels of < 10 mIU/mL after the primary vaccine series should be revaccinated with a three dose series, followed by anti-HBs testing one-to-two months after the third dose. Persons who do not respond to revaccination should be tested for HBsAg. If HbsAg-positive, the person should receive appropriate management; if HbsAg-negative, the person should be considered susceptible to HBV infection and counseled concerning precautions to prevent HBV infection and the need for HBIG post-exposure prophylaxis (PEP) for any known exposure.

For infants born to HBsAg-positive mothers, post-vaccination testing should be performed one-to-two months after completion of ≥ 3 doses of a licensed hepatitis B vaccine series (i.e., at age 9–18 months, generally at the next well-child visit). To avoid detection of anti-HBs from hepatitis B immune globulin administered during infancy and to maximize detection of late HBV infection, testing should not be performed before age 9 months nor within four weeks of the most recent vaccine dose.

If there is an interruption between doses of hepatitis B vaccine, does the vaccine series need to be restarted?

No, the series does not need to be restarted.

- If the vaccine series was interrupted after the first dose, the second dose should be administered as soon as possible.
- The second and third doses should be separated by an interval of at least eight weeks.
- If only the third dose is delayed, it should be administered as soon as possible.

Is it harmful to administer an extra dose(s) of hepatitis A or hepatitis B vaccine or to repeat the entire vaccine series if documentation of vaccination history is unavailable?

No. If necessary, administering extra doses of hepatitis A or hepatitis B vaccine is not harmful.

Can hepatitis B vaccine be administered concurrently with other vaccines?

Yes. When hepatitis B vaccine has been administered at the same time as other vaccines, no interference with the antibody response of the other vaccines has been demonstrated. Separate body sites and syringes should be used for simultaneous administration of injectable vaccines.

How long does hepatitis B vaccine protection last?

Studies indicate that immunologic memory remains intact for at least 20 years among healthy vaccinated individuals who initiated hepatitis B vaccination >6 months of age. The vaccine confers long-term protection against clinical illness and chronic hepatitis B virus infection. Cellular immunity appears to persist even though antibody levels might become low or decline below detectable levels.

Are booster doses of hepatitis B vaccine recommended?

Booster doses of hepatitis B vaccine are recommended only in certain circumstances:

- For **hemodialysis patients**, the need for booster doses should be assessed by annual testing for antibody to hepatitis B surface antigen (anti-HBs). A booster dose should be administered when anti-HBs levels decline to <10 mIU/mL.
- For **other immunocompromised persons** (e.g., HIV-infected persons, hematopoietic stem-cell transplant recipients, and persons receiving chemotherapy), the need for booster doses has not been determined. When anti-HBs levels decline to <10 mIU/mL, annual anti-HBs testing and booster doses should be considered for those with an ongoing risk for exposure.

For persons with normal immune status who have been vaccinated, booster doses are not recommended.

When should persons be vaccinated before traveling to endemic areas?

Ideally, vaccination should begin six months before overseas travel so the full vaccine series can be completed before departure. Because some protection is provided by one or two doses, the vaccine series should be initiated, if indicated, even if it cannot be completed before departure. Optimal protection, however, is not conferred until after the final vaccine dose is received. Recently the Food and Drug Administration approved an accelerated vaccine schedule to be used for those traveling to endemic areas at short notice and facing imminent exposure or for emergency responders to disaster areas. An accelerated vaccination schedule with Twinrix® (combined hepatitis A and hepatitis B vaccine) also can be used (doses at 0, 7, and 21–30 days). In this situation, a booster dose should be given at 12 months to promote long-term immunity. For children and adults with normal immune status who received the recommended vaccine series, pre-travel booster doses are not recommended. Serologic testing to assess antibody levels is not necessary for most fully vaccinated people.

Hepatitis B Vaccination Schedules (CDC)

Child and Adolescent & Adult

- <https://www.cdc.gov/vaccines/schedules/hcp/index.html>

Vaccine Questions:

<http://www.immunize.org/catg.d/p4030.pdf>

Criteria for NCIP Vaccine Usage

https://immunize.nc.gov/providers/ncip/pdf/ncip_coverage_criteria_4_25_19_final.pdf