

HEPATITIS B

The Importance of the Hepatitis B Vaccine

Since 1982, a hepatitis B vaccine has been available to prevent hepatitis B virus infection. Today, the vaccine is made using recombinant DNA technology and contains only a portion of the outer protein coat of the virus, called the hepatitis B surface antigen.

The vaccine is a very safe and effective immunization against a viral infection that can lead to liver inflammation, cirrhosis and liver cancer. About 4 millions adults and children have been immunized against the infection in the United States alone.

The vaccine is given in a series of three intramuscular doses; the second vaccine is administered 30 days after the first, and the third application is administered six months after the first injection. More than 95 percent of children and adolescents and more than 90 percent of young, healthy adults develop adequate antibodies to the recommended series of three doses.

Who Should Be Vaccinated?

The National Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP) recommends hepatitis B vaccination for everyone 18 years of age and younger and for adults over 18 years of age who are at risk of infection through household or sexual contact with infected individuals or who engage in high-risk sexual activity or injecting drug use.

Other adults who should be vaccinated include men who have sex with men, persons at occupational risk of infection, hemodialysis patients and clients and staff of institutions for the developmentally disabled. Others who may be at risk are children of individuals from countries where hepatitis B infection is endemic.

The hepatitis B vaccine has been recommended as a routine infant vaccination since 1991 and as a routine adolescent vaccination since 1995. In the United States, each state has differing vaccination requirements, but most require hepatitis B vaccination in students entering public schools.

Hepatitis B vaccination is recommended for all infants and should be incorporated into

vaccination schedules for children. The National Centers for Disease Control and Prevention (CDC) strongly recommends that all infants receive their first vaccination within 12 hours of birth.

According to CDC guidelines, newborn babies whose mothers either are infected with the hepatitis B virus or have not been tested should get their first shot within 12 hours of birth, the second shot at one to two months of age and the third shot at six months of age.

Other babies can get their first shot between birth and two months of age, the second at one to four months of age and the third at six to 18 months of age.

Babies born to infected mothers should also receive hepatitis B immune globulin (HBIG) within 12 hours of birth.

These babies should be tested for HBV when they are nine to 15 months of age to make sure the vaccine was effective in preventing infection.

Because the highest level of hepatitis B surface antibodies are achieved when the last two doses of vaccine are spaced at least four months apart, schedules that achieve this spacing are recommended. However, schedules with two-month intervals between doses, which conform to schedules for other childhood vaccines, have been shown to produce a good antibody response and may be appropriate in populations in which it is difficult to ensure that infants will be brought back for all their vaccinations.

The development of combination vaccines containing the hepatitis B antigen may lead to other schedules that will allow optimal use of combined antigens.

More than 500 million persons have received the vaccine worldwide. The most common side effects from hepatitis B vaccination are pain at the injection site and mild to moderate fever.

How Effective Is the Hepatitis B Vaccine?

In normal circumstances, testing to make sure the vaccine has produced a suitable level of antibodies is usually not recommended. Testing for immunity is recommended only for:

- Healthcare workers who risk exposure to blood or body fluids in their workplace
- Infants born to hepatitis B surface antigen (HBsAg)-positive mothers to ensure

ongoing protection

- Immunocompromised persons, including dialysis patients and AIDS patients
- Sex partners of HBsAg-positive persons to ensure adequate protection

When necessary, post-vaccination testing should be performed from one to two months after completion of the vaccine series.

When people who do not respond to the primary vaccine series are revaccinated, CDC estimates that 15 to 25 percent produce an adequate antibody response after one additional dose and 30 to 50 percent respond adequately after three additional doses. Therefore, revaccination with one or more additional doses should be considered for persons who do not respond to vaccination initially.

What Happens If the Vaccine Doesn't Work?

The vast majority of people respond to the vaccine and develop adequate levels of antibodies to the hepatitis B surface antigen (the antibody concentration is 10 or greater mIU/mL).

Those who do not are called nonresponders and should be evaluated to determine whether they are chronically infected. If they are not chronically infected, CDC recommends they be revaccinated a second time with the full three-dose series.

For How Long Are People Protected by the Vaccine?

The duration of vaccine-induced immunity has been studied long-term only in plasma-derived hepatitis B vaccines, because they have the longest clinical use. Researchers expect the currently used recombinant vaccines to show similar trends.

Among young adults who initially responded to a three-dose vaccine series, loss of detectable antibody and possible vaccine protection has ranged from 13 to 60 percent after nine years of follow-up, according to CDC.

Long-term studies of healthy adults and children indicate that “immunologic” memory remains intact for at least 15 years and confers protection against chronic HBV infection, even though antibody levels may become low or decline below detectable levels.

In these studies, no episodes of clinical hepatitis were reported. In general, follow-up studies of children vaccinated at birth to prevent perinatal (mother-to-child) hepatitis B

virus infection have shown that a continued high level of protection against chronic infection persists for at least five years.

While the exact duration of protection that vaccines confer against the hepatitis B virus is inconclusive, most physicians say boosters are not needed for more than a decade after initial vaccination.

Currently, CDC does not recommend periodic boosters or testing to determine immune response. CDC is continuing to study whether children who were immunized at birth will require boosters later in life.

Years after immunization, people may have a low number of hepatitis B antibodies or “titers” circulating in their bodies. But despite that low number, their immune system retains “immune memory” for years.

“Long-term follow-up of vaccine recipients indicates that immune memory persists for at least 12 years. Additional doses of vaccine elicit a prompt anamnestic rise in antibody titers among vaccine responders, indicating that immunologic memory is preserved, even if antibody concentrations fall below 10 mIU/mL,” wrote Dr. Harold Margolis of the CDC in *Archives of Internal Medicine*.

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