About Hepatitis B Vaccine Information Statements

VACCINE INFORMATION STATEMENT

Hepatitis B Vaccine

What You Need to Know

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
 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

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 contami-nated object, where the virus can live for up to 7 days. • A baby whose mother is infected can be infected at

- ct with blood and body fluids through breaks in
- contact with blood and body futures unreaged 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.

Hepatitis B vaccine: Why get vaccinated?

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.

Who should get hepatitis B vaccine and when?

Children and Adolescents

· Babies normally get 3 doses of hepatitis B vaccine: 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.

- All unvaccinated adults at risk for henatitis 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 chronic liver or kidney disease,
 people with chronic liver or kidney disease,
 people under 60 years of age with diabetes,
 people with obstate expose them to human blood or
 other body fluids,



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

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

- For more information about how to use VISs, visit www.immunize.org/vis.
- For hepatitis B VISs in many languages, visit www.immunize.org/vis/vis_hepatitis_b.asp.
- household contacts of people infected with hepatitis B. residents and staff in institutions for the developmentally disabled,
- tany disabled, kidney dialysis patients, people who travel to countries where hepatitis B is common,
- common, people with HIV infection.
- Other people may be encouraged by their doctor to get repatitis 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.

Who should not get hepatitis B vaccine?

- · Anyone with a life-threatening allergy to yeast, or to 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 screening test could mistake vaccine in the blood (which is not infectious) for hepatitis B infection

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
- · Temperature of 99.9°F or higher (up to about 1 person

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

out the risk of a vaccine causing serious of death, is extremely small. More than 100 million people in the United States have been vaccinated whepatitis B vaccine.

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 re difficulty breathing, hoarseness or wheezing, hives, paleness, weakness, a fast heart beat or dizziness.

What should I do?

- what should 1 do?

 Call a doctor, or get the person to a doctor right away.

 Tell your doctor what happened, the date and time it happened, and when the vaccination was given.

 Ask your doctor, nurse, or health department to report the reaction by filing a Vaccine Adverse Event Reporting System (VAERS) form. Or you can file this report through the VAERS web site at www.vaers.hhs.gov, or by calling 1-800-822-7967.

VAERS does not provide medical advice

The National Vaccine Injury Compensation Program

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

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

8 How can I learn more?

- Ask your doctor They can give you the vaccine package insert or suggest other sources of information. Call your local or state health department. Contact the Centers for Disease Control and Prevention (CDC):

 Call 1-800-232-4636 (1-800-CDC-INFO) or
- Visit CDC's website at www.cdc.gov/vaccines

Vaccine Information Statement (Interim) Hepatitis B Vaccine

2/2/2012

42 U.S.C. § 300aa-26



28