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
- 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.

Many Vaccine Information Statements are available in Spanish and other languages. See www.immunize.org/vis

Hojas de Informacián Sobre Vacunas están disponibles en Español y en muchos otros idiomas. Visite www.immunize.org/vis

2 Hepatitis B vaccine: Why get vaccinated?

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

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

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

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

3

Who should get hepatitis B vaccine and when?

Children and adolescents

- Babies normally get 3 doses of hepatitis B vaccine:
 1st Dose: Birth
 - 2nd Dose: 1-2 months of age

3rd Dose: 6-18 months of age

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

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

Adults

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



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

- 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.

6 What if there is a serious reaction?

What should I look for?

• Look for anything that concerns you, such as signs of a severe allergic reaction, very high fever, or behavior changes.

Signs of a severe allergic reaction can include hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, and weakness. These would start a few minutes to a few hours after the vaccination.

What should I do?

- If you think it is a severe allergic reaction or other emergency that can't wait, call 9-1-1 or get the person to the nearest hospital. Otherwise, call your doctor.
- Afterward, the reaction should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your doctor might file this report, or you can do it yourself through the VAERS web site at **www.vaers.hhs.gov**, or by calling **1-800-822-7967**.

VAERS is only for reporting reactions. They do not give medical advice.

The National Vaccine Injury Compensation Program

The National Vaccine Injury Compensation Program (VICP) is a federal program that was created to compensate people who may have been injured by certain vaccines.

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.

7

- 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



42 U.S.C. § 300aa-26

2/2/2012