VACCINE INFORMATION STATEMENT

Hepatitis B Vaccine

What You Need to Know

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 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.

Hepatitis B vaccine: Why get 2 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: Rinth
 - 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,



- 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 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, or by calling 1-800-822-7967.

VAERS does not provide medical advice.

7

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