



Immunizations prevent disease and keep your child, your family, and the community healthy. Keeping up with your child's shots is the best way to keep him or her safe and could save your child's life. Many parents have questions or concerns about vaccines. Kaiser Permanente has carefully reviewed the research on individual vaccines – both the benefits and risks. We want you to have the facts. Studies show that the health benefits from vaccines are significant, while the risks are very small.

Facts about Vaccinations

Are shots (vaccinations) safe?

Yes. Medical experts are constantly reviewing the safety and effectiveness of vaccines. Immunizations protect your child against vaccine-preventable diseases. The effects of these diseases can range from mild to life-threatening for a child who does not get vaccinated.

What about side effects?

Some children will have mild reactions to vaccines, such as a sore arm, mild swelling at the site of the shot, or fussiness. Other children have no side effects at all. A low fever or mild rash may also develop, especially a few weeks after receiving the vaccine for measles, mumps, and rubella (MMR). Acetaminophen drops may soothe your child's discomfort and fever. Keep in mind that the risks of having mild side effects from the shots are minimal compared to the risk of getting seriously ill from the disease.

Are vaccinations just for babies and young children?

Adolescents need to keep up with their vaccinations too. If your teen hasn't received all three hepatitis B shots, make an appointment today. Also, the tetanus vaccine your child received when he/she was young wears off over time. It is important for all pre-teens and teens to get a booster shot to remain protected against both tetanus and whooping cough (Tdap). They should also receive the meningococcal vaccine.

If my child has a cold, can she still get her shots?

Yes. If your child has a mild illness (cold, cough, low-grade fever), she can safely be vaccinated.

I have heard that vaccination causes autism. Is this true?

No. Research shows that shots do not cause autism. While autism is a serious and growing concern, and some people

have claimed there is a link, vaccines are not the cause. Hundreds of studies have looked for evidence that any vaccine or combination of vaccines causes autism. No links have been found. If you are concerned about autism, or have any questions about vaccines, let's discuss them. We want to be sure you have the facts.

Is there still mercury in the vaccines?

No, all vaccines currently being given to children under 3 years old are FDA-approved, preservative-free vaccines, containing no mercury. The only frequently used vaccine which now contains detectable amounts of mercury in the form of the preservative known as thimerosal is the flu shot for adults and older children. Studies have shown no connection between thimerosal and autism.

What about spacing out shots over time?

There is no benefit to splitting up the vaccines. Not following the vaccination schedule could mean your child is not protected against certain diseases. Splitting up vaccines may mean more shots later. Your child's immune system can easily respond to multiple vaccines.

What are the risks if I don't have my child immunized?

Your child may be at greater risk of catching one of the vaccine-preventable diseases. Every time a parent decides to skip an immunization, it puts their child and others at risk of getting a disease that could be dangerous or even deadly.

Protect your child from serious diseases. Keep up with all recommended immunizations.	
Hepatitis A (HAV)	Protects against the Hepatitis A virus. This vaccination should be given to all children starting at age 1 year, and to children ages 2 to 18 who have not been previously vaccinated.
Hepatitis B (HBV)	Protects against Hepatitis B, which causes liver disease. This vaccine must be given 3 times, usually between birth and 2 years. California law requires that all children get the HBV vaccine before 7th grade.
Rotavirus	Protects against rotavirus, which causes severe diarrhea in babies and toddlers. This vaccine is given 3 times during your child's first 6 months.
Diphtheria Tetanus Pertussis (DTaP)	Protects against diphtheria, tetanus (lockjaw), and pertussis (whooping cough). This shot is given 5 times between birth and 6 years, with a booster shot at 11 to 12 years of age.
Measles, Mumps, Rubella (MMR)	Protects against measles (rubeola), mumps, and rubella (German measles). MMR is given twice before your child is 6 years old.
Pneumococcal	Protects against some brain, blood, lung and ear infections. This vaccine is given 4 times during your child's first 18 months. Your child may also need a booster dose between ages 2 and 5.
Influenza (Flu)	Protects against common strains of flu. All children 6 months to 18 years old should receive a yearly flu vaccination. Children with certain chronic illnesses are especially vulnerable to serious complications from influenza.
Haemophilus Influenzae Type B (HiB)	Protects against a major cause of spinal meningitis. The HiB vaccine is usually given at 2, 4, 6 and 12 to 18 months of age. HiB must be given 4 times during your child's first 18 months.
Polio (IPV)	Protects against polio. This vaccine must be given 4 times during the first 6 years of your child's life.
Varicella Zoster (Chickenpox)	Children who have never had chickenpox should get 2 doses of the vaccine: one at 12 to 18 months, and another booster dose before kindergarten. The varicella vaccine is required before a child can enter school or child care. Anyone 13 and older needs 2 doses at least one month apart. If your child has not had chickenpox or the varicella vaccine, schedule this shot as soon as possible.
Meningococcal	Protects against meningitis, an infection of the fluid around the brain and spinal cord, and sometimes of the blood. Pre-teens should receive a single shot during their 11 to 12-year old well check visit. Teens entering high school and college should also get the vaccine, if not done already.
Human Papillomavirus (HPV)	This vaccine protects against the types of HPV that most commonly cause cervical cancer and genital warts. This vaccine is recommended for 11 and 12-year old girls. Girls should get 3 doses of this vaccine well before their first sexual contact, when they could be exposed to HPV. If your teenage daughter missed getting the vaccine when she was 11 or 12, ask about getting it now.

Stay on top of your child's immunizations online.

Information about your child's immunizations appears on the printed registration slip you receive at every office visit. You can also find your child's shot record online. Go to your pediatrician's home page at kp.org/mydoctor and click on "View your Preventive Services."

Once you sign up to use our "Act for a Family Member" feature, you can check to see what immunizations your child needs. You can also print a detailed shot record for school or camp, if needed.

If your child is due for shots, you can send your pediatrician a secure email. We can also discuss what shots your child needs at your next visit.

Other resources

- kp.org/mydoctor
- kp.org/actforfamily
- aap.org/immunization
- immunize.org

This information is not intended to diagnose health problems or to take the place of medical advice or care you receive from your physician or other health care professional. If you have persistent health problems, or if you have additional questions, please consult with your doctor.

© 2003, The Permanente Medical Group, Inc. All rights reserved. Regional Health Education.

HEPATITIS A VACCINE

WHAT YOU NEED TO KNOW

1 What is hepatitis A?

Hepatitis A is a serious liver disease caused by the hepatitis A virus (HAV). HAV is found in the stool of persons with hepatitis A. It is usually spread by close personal contact and sometimes by eating food or drinking water containing HAV.

Hepatitis A can cause:

- mild “flu-like” illness
- jaundice (yellow skin or eyes)
- severe stomach pains and diarrhea

People with hepatitis A often have to be hospitalized (up to about 1 person in 5).

Sometimes, people die as a result of hepatitis A (about 3-5 deaths per 1,000 cases).

A person who has hepatitis A can easily pass the disease to others within the same household.

Hepatitis A vaccine can prevent hepatitis A.

2 Who should get hepatitis A vaccine and when?

WHO?

Some people should be routinely vaccinated with hepatitis A vaccine:

- All children 1 year (12 through 23 months) of age.
- Persons 1 year of age and older traveling to or working in countries with high or intermediate prevalence of hepatitis A, such as those located in Central or South America, Mexico, Asia (except Japan), Africa, and eastern Europe. For more information see www.cdc.gov/travel.
- Children and adolescents through 18 years of age who live in states or communities where

routine vaccination has been implemented because of high disease incidence.

- Men who have sex with men.
- Persons who use street drugs.
- Persons with chronic liver disease.
- Persons who are treated with clotting factor concentrates.
- Persons who work with HAV-infected primates or who work with HAV in research laboratories.

Other people might get hepatitis A vaccine in special situations:

- Hepatitis A vaccine might be recommended for children or adolescents in communities where outbreaks of hepatitis A are occurring.

Hepatitis A vaccine is not licensed for children younger than 1 year of age.

WHEN?

For children, the first dose should be given at 12-23 months of age. Children who are not vaccinated by 2 years of age can be vaccinated at later visits.

For travelers, the vaccine series should be started at least one month before traveling to provide the best protection.

Persons who get the vaccine less than one month before traveling can also get a shot called immune globulin (IG). IG gives immediate, temporary protection.

For others, the hepatitis A vaccine series may be started whenever a person is at risk of infection.

Two doses of the vaccine are needed for lasting protection. These doses should be given at least 6 months apart.

Hepatitis A vaccine may be given at the same time as other vaccines.

3

Some people should not get hepatitis A vaccine or should wait

- Anyone who has ever had a severe (life-threatening) **allergic reaction to a previous dose** of hepatitis A vaccine should not get another dose.
- Anyone who has a severe (life threatening) **allergy to any vaccine component** should not get the vaccine. Tell your doctor if you have any severe allergies. All hepatitis A vaccines contain alum and some hepatitis A vaccines contain 2-phenoxyethanol.
- Anyone who is **moderately or severely ill** at the time the shot is scheduled should probably wait until they recover. Ask your doctor or nurse. People with a **mild illness** can usually get the vaccine.
- Tell your doctor if you are **pregnant**. The safety of hepatitis A vaccine for pregnant women has not been determined. But there is no evidence that it is harmful to either pregnant women or their unborn babies. The risk, if any, is thought to be very low.

4

What are the risks from hepatitis A vaccine?

A vaccine, like any medicine, could possibly cause serious problems, such as severe allergic reactions. The risk of hepatitis A vaccine causing serious harm, or death, is extremely small.

Getting hepatitis A vaccine is much safer than getting the disease.

Mild problems

- soreness where the shot was given (*about 1 out of 2 adults, and up to 1 out of 6 children*)
- headache (*about 1 out of 6 adults and 1 out of 25 children*)
- loss of appetite (*about 1 out of 12 children*)
- tiredness (*about 1 out of 14 adults*)

If these problems occur, they usually last 1 or 2 days.

Severe problems

- serious allergic reaction, within a few minutes to a few hours of the shot (*very rare*)

5

What if there is a moderate or severe reaction?

What should I look for?

- Any unusual condition, such as a high fever or behavior changes. 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.

6

The National Vaccine Injury Compensation Program

In the event that you or your child has a serious reaction to a vaccine, a federal program has been created to help pay for the care of those who have been harmed.

For details about the National Vaccine Injury Compensation Program, call 1-800-338-2382 or visit their website at www.hrsa.gov/vaccinecompensation.

7

How can I learn more?

- Ask your doctor or nurse. 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)**
 - Visit CDC websites at: www.cdc.gov/hepatitis or www.cdc.gov/nip



DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION
NATIONAL IMMUNIZATION PROGRAM

HEPATITIS B VACCINE

WHAT YOU NEED TO KNOW

1 What is hepatitis B?

Hepatitis B is a serious disease that affects the liver. It is caused by the hepatitis B virus (HBV). HBV 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 is more common among adults.

Children who become infected usually do not have acute illness.

Chronic (long-term) infection. Some people go on to develop chronic HBV infection. This can be very serious, and often leads to:

- liver damage (cirrhosis)
- liver cancer
- death

Chronic infection is more common among infants and children than among adults. People who are infected can spread HBV to others, even if they don't appear sick.

-
- In 2005, about 51,000 people became infected with hepatitis B.
 - About 1.25 million people in the United States have chronic HBV infection.
 - Each year about 3,000 to 5,000 people die from cirrhosis or liver cancer caused by HBV.

Hepatitis B virus is spread through contact with the blood or other body fluids of an infected person. A person can become infected by:

- contact with a mother's blood and body fluids at the time of birth;
- contact with blood and body fluids through breaks in the skin such as bites, cuts, or sores;
- contact with objects that could have blood or body fluids on them such as toothbrushes or razors;
- having unprotected sex with an infected person;
- sharing needles when injecting drugs;
- being stuck with a used needle on the job.

2 Hepatitis B vaccine: Why get vaccinated?

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

Routine hepatitis B vaccination of U.S. children began in 1991. Since then, the reported incidence of acute hepatitis B among children and adolescents has dropped by more than 95% – and by 75% in all age groups.

Hepatitis B vaccine is made from a part of the hepatitis B virus. It cannot cause HBV infection.

Hepatitis B vaccine is usually given as a **series of 3 or 4 shots**. This vaccine series gives long-term protection from HBV infection, possibly lifelong.

3 Who should get hepatitis B vaccine and when?

Children and Adolescents

- All children should get their first dose of hepatitis B vaccine **at birth** and should have completed the vaccine series by 6-18 months of age.
- Children and adolescents through 18 years of age who did not get the vaccine when they were younger should also be vaccinated.

Adults

- All unvaccinated adults **at risk for HBV infection** should be vaccinated. This includes:
 - sex partners of people infected with HBV,
 - 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 with jobs that expose them to human blood,
 - household contacts of people infected with HBV,
 - 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.

- Anyone else who wants to be protected from HBV infection may be vaccinated.

4 Who should NOT get hepatitis B vaccine?

- Anyone with a life-threatening allergy to **baker's yeast**, or to **any other component of the vaccine**, should not get hepatitis B vaccine. Tell your provider 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 provider can give you more information about these precautions.

Pregnant women who need protection from HBV infection may be vaccinated.

5 Hepatitis B vaccine risks

Hepatitis B is a very safe vaccine. Most people do not have any problems with it.

The following **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 have gotten hepatitis B vaccine in the United States.

6 What if there is a moderate or severe reaction?

What should I look for?

- Any unusual condition, such as a high fever or behavior changes. 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

In the event that you or your child has a serious reaction to a vaccine, a federal program has been created to help pay for the care of those who have been harmed.

For details about the National Vaccine Injury Compensation Program, call 1-800-338-2382 or visit their website at www.hrsa.gov/vaccinecompensation.

8 How can I learn more?

- Ask your doctor or nurse. 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)**
 - Visit CDC websites at:
 - www.cdc.gov/ncidod/diseases/hepatitis
 - www.cdc.gov/vaccines
 - www.cdc.gov/travel



DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION

Vaccine Information Statement (Interim)
Hepatitis B (7/18/07) 42 U.S.C. § 300aa-26

ROTAVIRUS VACCINE

WHAT YOU NEED TO KNOW

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

1 What is rotavirus?

Rotavirus is a virus that causes severe diarrhea, mostly in babies and young children. It is often accompanied by vomiting and fever.

Rotavirus is not the only cause of severe diarrhea, but it is one of the most serious. Before rotavirus vaccine was used, rotavirus was responsible for:

- more than 400,000 doctor visits,
- more than 200,000 emergency room visits,
- 55,000 to 70,000 hospitalizations, and
- 20-60 deaths

in the United States each year.

Almost all children in the U.S. are infected with rotavirus before their 5th birthday.

Children are most likely to get rotavirus diarrhea between November and May, depending on the part of the country.

Your baby can become infected by being around other children who have rotavirus diarrhea.

2 Rotavirus vaccine

Better hygiene and sanitation have not reduced rotavirus diarrhea very much in the United States. The best way to protect your baby is with rotavirus vaccine.

Rotavirus vaccine is an oral (swallowed) vaccine, not a shot.

Rotavirus vaccine will not prevent diarrhea or vomiting caused by other germs, but it is very good at preventing diarrhea and vomiting caused by rotavirus. Most babies who get the vaccine will not get rotavirus diarrhea at all, and almost all of them will be protected from severe rotavirus diarrhea.

Babies who get the vaccine are also much less likely to be hospitalized or to see a doctor because of rotavirus diarrhea.

A virus (or parts of the virus) called porcine circovirus is in both rotavirus vaccines. This virus is not known to infect people and there is no known safety risk. For more information, see www.fda.gov.

3 Who should get rotavirus vaccine and when?

There are two brands of rotavirus vaccine. A baby should get either 2 or 3 doses, depending on which brand is used.

The doses are recommended at these ages:

First Dose: 2 months of age

Second Dose: 4 months of age

Third Dose: 6 months of age (if needed)

The first dose may be given as early as 6 weeks of age, and should be given by age 14 weeks 6 days. The last dose should be given by 8 months of age.

Rotavirus vaccine may be given at the same time as other childhood vaccines.

Babies who get the vaccine may be fed normally afterward.

4 Some people should not get rotavirus vaccine or should wait.

- A baby who has had a severe (life-threatening) allergic reaction to a dose of rotavirus vaccine should not get another dose. A baby who has a severe (life-threatening) allergy to any component of rotavirus vaccine should not get the vaccine. Tell your doctor if your baby has any severe allergies that you know of, including a severe allergy to latex.
- Babies who are moderately or severely ill at the time the vaccination is scheduled should probably wait until they recover. This includes babies who have moderate or severe diarrhea or vomiting. Ask your doctor or nurse. Babies with mild illnesses should usually get the vaccine.

- Check with your doctor if your baby’s immune system is weakened because of:
 - HIV/AIDS, or any other disease that affects the immune system
 - treatment with drugs such as long-term steroids
 - cancer, or cancer treatment with x-rays or drugs

In the late 1990s a different type of rotavirus vaccine was used. This vaccine was found to be associated with a common type of bowel obstruction called “intussusception,” and it was taken off the market.

The new rotavirus vaccines have not been associated with intussusception.

However, babies who have had intussusception, from any cause, are at higher risk for getting it again. If your baby has ever had intussusception, discuss this with your doctor.

5 What are the risks from rotavirus vaccine?

A vaccine, like any medicine, could possibly cause serious problems, such as severe allergic reactions. The risk of any vaccine causing serious harm, or death, is extremely small.

Most babies who get rotavirus vaccine do not have any problems with it.

Mild problems

Babies may be slightly more likely to be irritable, or to have mild, temporary diarrhea or vomiting after getting a dose of rotavirus vaccine than babies who did not get the vaccine.

Rotavirus vaccine does not appear to cause any serious side effects.

If rare reactions occur with any new product, they may not be identified until thousands, or millions, of people have used it. Like all vaccines, rotavirus vaccine will continue to be monitored for unusual or severe problems.

6 What if there is a moderate or severe reaction?

What should I look for?

Any unusual condition, such as a severe allergic reaction or a high fever. If a severe allergic reaction occurred, it would be within a few minutes

to an hour after the vaccination. Signs of a serious allergic reaction can include difficulty breathing, weakness, hoarseness or wheezing, a fast heart beat, hives, dizziness, paleness, or swelling of the throat.

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 provider to report the reaction by filing a Vaccine Adverse Event Reporting System (VAERS) form. Or you can file this report through the VAERS website 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 may file a claim with VICP by calling **1-800-338-2382** or by visiting their website at www.hrsa.gov/vaccinecompensation.

8 How can I learn more?

- Ask your health care provider. 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)
 - Visit CDC’s National Immunization Program website at: www.cdc.gov/vaccines



U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION

DIPHTHERIA TETANUS & PERTUSSIS VACCINES

WHAT YOU NEED TO KNOW

1 Why get vaccinated?

Diphtheria, tetanus, and pertussis are serious diseases caused by bacteria. Diphtheria and pertussis are spread from person to person. Tetanus enters the body through cuts or wounds.

DIPHTHERIA causes a thick covering in the back of the throat.

- It can lead to breathing problems, paralysis, heart failure, and even death.

TETANUS (Lockjaw) causes painful tightening of the muscles, usually all over the body.

- It can lead to “locking” of the jaw so the victim cannot open his mouth or swallow. Tetanus leads to death in up to 2 out of 10 cases.

PERTUSSIS (Whooping Cough) causes coughing spells so bad that it is hard for infants to eat, drink, or breathe. These spells can last for weeks.

- It can lead to pneumonia, seizures (jerking and staring spells), brain damage, and death.

Diphtheria, tetanus, and pertussis vaccine (DTaP) can help prevent these diseases. Most children who are vaccinated with DTaP will be protected throughout childhood. Many more children would get these diseases if we stopped vaccinating.

DTaP is a safer version of an older vaccine called DTP. DTP is no longer used in the United States.

2 Who should get DTaP vaccine and when?

Children should get 5 doses of DTaP vaccine, one dose at each of the following ages:

- ✓ 2 months
- ✓ 4 months
- ✓ 6 months
- ✓ 15-18 months
- ✓ 4-6 years

DTaP may be given at the same time as other vaccines.

3

Some children should not get DTaP vaccine or should wait

- Children with minor illnesses, such as a cold, may be vaccinated. But children who are moderately or severely ill should usually wait until they recover before getting DTaP vaccine.
- Any child who had a life-threatening allergic reaction after a dose of DTaP should not get another dose.
- Any child who suffered a brain or nervous system disease within 7 days after a dose of DTaP should not get another dose.
- Talk with your doctor if your child:
 - had a seizure or collapsed after a dose of DTaP,
 - cried non-stop for 3 hours or more after a dose of DTaP,
 - had a fever over 105°F after a dose of DTaP.

Ask your health care provider for more information. Some of these children should not get another dose of pertussis vaccine, but may get a vaccine without pertussis, called **DT**.

4

Older children and adults

DTaP is not licensed for adolescents, adults, or children 7 years of age and older.

But older people still need protection. A vaccine called **Tdap** is similar to DTaP. A single dose of Tdap is recommended for people 11 through 64 years of age. Another vaccine, called **Td**, protects against tetanus and diphtheria, but not pertussis. It is recommended every 10 years. There are separate Vaccine Information Statements for these vaccines.

5 What are the risks from DTaP vaccine?

Getting diphtheria, tetanus, or pertussis disease is much riskier than getting DTaP vaccine.

However, a vaccine, like any medicine, is capable of causing serious problems, such as severe allergic reactions. The risk of DTaP vaccine causing serious harm, or death, is extremely small.

Mild Problems (Common)

- Fever (up to about 1 child in 4)
- Redness or swelling where the shot was given (up to about 1 child in 4)
- Soreness or tenderness where the shot was given (up to about 1 child in 4)

These problems occur more often after the 4th and 5th doses of the DTaP series than after earlier doses. Sometimes the 4th or 5th dose of DTaP vaccine is followed by swelling of the entire arm or leg in which the shot was given, lasting 1-7 days (up to about 1 child in 30).

Other mild problems include:

- Fussiness (up to about 1 child in 3)
- Tiredness or poor appetite (up to about 1 child in 10)
- Vomiting (up to about 1 child in 50)

These problems generally occur 1-3 days after the shot.

Moderate Problems (Uncommon)

- Seizure (jerking or staring) (about 1 child out of 14,000)
- Non-stop crying, for 3 hours or more (up to about 1 child out of 1,000)
- High fever, over 105°F (about 1 child out of 16,000)

Severe Problems (Very Rare)

- Serious allergic reaction (less than 1 out of a million doses)
- Several other severe problems have been reported after DTaP vaccine. These include:
 - Long-term seizures, coma, or lowered consciousness
 - Permanent brain damage.

These are so rare it is hard to tell if they are caused by the vaccine.

Controlling fever is especially important for children who have had seizures, for any reason. It is also important if another family member has had seizures. You can reduce fever and pain by giving your child an *aspirin-free* pain reliever when the shot is given, and for the next 24 hours, following the package instructions.

6 What if there is a moderate or severe reaction?

What should I look for?

Any unusual conditions, such as a serious allergic reaction, high fever or unusual behavior. Serious allergic reactions are extremely rare with any vaccine. If one were to occur, it would most likely be within a few minutes to a few hours after the shot. Signs can include difficulty breathing, hoarseness or wheezing, hives, paleness, weakness, a fast heart beat or dizziness. If a high fever or seizure were to occur, it would usually be within a week after the shot.

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

In the rare event that you or your child has a serious reaction to a vaccine, a federal program has been created to help pay for the care of those who have been harmed.

For details about the National Vaccine Injury Compensation Program, call **1-800-338-2382** or visit the program's website at www.hrsa.gov/vaccinecompensation.

8 How can I learn more?

- Ask your health care provider. They can give you the vaccine package insert or suggest other sources of information.
- Call your local or state health department's immunization program.
- Contact the Centers for Disease Control and Prevention (CDC):
 - Call **1-800-232-4636 (1-800-CDC-INFO)**
 - Visit the National Immunization Program's website at www.cdc.gov/nip



U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Disease Control and Prevention

MEASLES, MUMPS & RUBELLA (MMR) VACCINES

WHAT YOU NEED TO KNOW

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

1 Why get vaccinated?

Measles, mumps, and rubella are serious diseases.

Measles

- Measles virus causes rash, cough, runny nose, eye irritation, and fever.
- It can lead to ear infection, pneumonia, seizures (jerking and staring), brain damage, and death.

Mumps

- Mumps virus causes fever, headache, and swollen glands.
- It can lead to deafness, meningitis (infection of the brain and spinal cord covering), painful swelling of the testicles or ovaries, and, rarely, death.

Rubella (German Measles)

- Rubella virus causes rash, mild fever, and arthritis (mostly in women).
- If a woman gets rubella while she is pregnant, she could have a miscarriage or her baby could be born with serious birth defects.

You or your child could catch these diseases by being around someone who has them. They spread from person to person through the air.

Measles, mumps, and rubella (MMR) vaccine can prevent these diseases.

Most children who get their MMR shots will not get these diseases. Many more children would get them if we stopped vaccinating.

2 Who should get MMR vaccine and when?

Children should get 2 doses of MMR vaccine:

- The first at **12-15 months of age**
- and the second at **4-6 years of age**.

These are the recommended ages. But children can get the second dose at any age, as long as it is at least 28 days after the first dose.

Some **adults** should also get MMR vaccine:

Generally, anyone 18 years of age or older who was born after 1956 should get at least one dose of MMR vaccine,

unless they can show that they have had either the vaccines or the diseases.

Ask your provider for more information.

MMR vaccine may be given at the same time as other vaccines.

Note: A “combination” vaccine called **MMRV**, which contains both MMR and varicella (chickenpox) vaccines, may be given instead of the two individual vaccines to people 12 years of age and younger.

3 Some people should not get MMR vaccine or should wait

- People should not get MMR vaccine who have ever had a life-threatening allergic reaction to gelatin, the antibiotic neomycin, or to a previous dose of MMR vaccine.
- People who are moderately or severely ill at the time the shot is scheduled should usually wait until they recover before getting MMR vaccine.
- Pregnant women should wait to get MMR vaccine until after they have given birth. Women should avoid getting pregnant for 4 weeks after getting MMR vaccine.
- Some people should check with their doctor about whether they should get MMR vaccine, including anyone who:
 - Has HIV/AIDS, or another disease that affects the immune system
 - Is being treated with drugs that affect the immune system, such as steroids, for 2 weeks or longer.
 - Has any kind of cancer
 - Is taking cancer treatment with x-rays or drugs
 - Has ever had a low platelet count (a blood disorder)
- People who recently had a transfusion or were given other blood products should ask their doctor when they may get MMR vaccine

Ask your provider for more information.

4

What are the risks from MMR vaccine?

A vaccine, like any medicine, is capable of causing serious problems, such as severe allergic reactions. The risk of MMR vaccine causing serious harm, or death, is extremely small.

Getting MMR vaccine is much safer than getting any of these three diseases.

Most people who get MMR vaccine do not have any problems with it.

Mild Problems

- Fever (up to 1 person out of 6)
- Mild rash (about 1 person out of 20)
- Swelling of glands in the cheeks or neck (rare)

If these problems occur, it is usually within 7-12 days after the shot. They occur less often after the second dose.

Moderate Problems

- Seizure (jerking or staring) caused by fever (about 1 out of 3,000 doses)
- Temporary pain and stiffness in the joints, mostly in teenage or adult women (up to 1 out of 4)
- Temporary low platelet count, which can cause a bleeding disorder (about 1 out of 30,000 doses)

Severe Problems (Very Rare)

- Serious allergic reaction (less than 1 out of a million doses)
- Several other severe problems have been known to occur after a child gets MMR vaccine. But this happens so rarely, experts cannot be sure whether they are caused by the vaccine or not. These include:
 - Deafness
 - Long-term seizures, coma, or lowered consciousness
 - Permanent brain damage

Note: The first dose of **MMRV** vaccine has been associated with rash and higher rates of fever than MMR and varicella vaccines given separately. Rash has been reported in about 1 person in 20 and fever in about 1 person in 5. Seizures caused by a fever are also reported more often after MMRV. These usually occur 5-12 days after the first dose.

5

What if there is a moderate or severe reaction?

What should I look for?

- Any unusual condition, such as a high fever, weakness, or behavior changes. 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 provider to report the reaction by filing a Vaccine Adverse Event Reporting System (VAERS) form.

Or you can file this report through the VAERS website at www.vaers.hhs.gov, or by calling **1-800-822-7967**.

VAERS does not provide medical advice.

6

The National Vaccine Injury Compensation Program

A federal program has been created to help people who may have been harmed by a vaccine.

For details about the National Vaccine Injury Compensation Program, call **1-800-338-2382** or visit their website at www.hrsa.gov/vaccinecompensation.

7

How can I learn more?

- Ask your provider. 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)**
 - Visit CDC website at: www.cdc.gov/vaccines



DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION

Vaccine Information Statement (Interim)
MMR Vaccine (3/13/08) 42 U.S.C. §300aa-26

PNEUMOCOCCAL CONJUGATE VACCINE

WHAT YOU NEED TO KNOW

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

1 Pneumococcal disease

Infection with *Streptococcus pneumoniae* bacteria can make children very sick.

It causes blood infections, pneumonia, and meningitis, mostly in young children. (Meningitis is an infection of the covering of the brain.) Although pneumococcal meningitis is relatively rare (less than 1 case per 100,000 people each year), it is fatal in about 1 of 10 cases in children.

Pneumococcal meningitis can also lead to other health problems, including deafness and brain damage.

Before routine use of pneumococcal conjugate vaccine, pneumococcal infections caused:

- over 700 cases of meningitis,
- 13,000 blood infections,
- about 5 million ear infections, and
- about 200 deaths

annually in the United States in children under five.

Children younger than 2 years of age are at higher risk for serious disease than older children.

Pneumococcal bacteria are spread from person to person through close contact.

Pneumococcal infections may be hard to treat because some strains of the bacteria have become resistant to the drugs that are used to treat them. This makes **prevention** of pneumococcal infections through vaccination even more important.

2 Pneumococcal conjugate vaccine (PCV13)

There are more than 90 types of pneumococcal bacteria. The new pneumococcal conjugate vaccine (PCV13) protects against 13 of them. These bacteria types are responsible for most severe pneumococcal infections among children. PCV13 replaces a previous conjugate vaccine (PCV7), which protected against 7 pneumococcal types and has been in use since 2000. During that time severe pneumococcal disease dropped by nearly 80% among children under 5.

PCV13 may also prevent some cases of pneumonia and some ear infections. But pneumonia and ear infections have many causes, and PCV13 only works against the types of pneumococcal bacteria targeted by the vaccine.

PCV13 is given to infants and toddlers, to protect them when they are at greatest risk for serious diseases caused by pneumococcal bacteria.

In addition to receiving PCV13, older children with certain chronic illnesses may get a different vaccine called PPSV23. There is a separate Vaccine Information Statement for that vaccine.

3 Who should get PCV13, and when?

Infants and Children Under 2 Years of Age

PCV13 is recommended as a series of **4 doses**, one dose at each of these ages: 2 months, 4 months, 6 months, and 12 through 15 months

Children who miss their shots at these ages should still get the vaccine. The number of doses and the intervals between doses will depend on the child's age. Ask your health care provider for details.

Children who have begun their immunization series with PCV7 should complete the series with PCV13.

Older Children and Adolescents

- Healthy children between their 2nd and 5th birthdays who have not completed the PCV7 or PCV13 series before age 2 years should get 1 dose.
- Children between the 2nd and 6th birthdays with medical conditions such as:
 - sickle cell disease,
 - a damaged spleen or no spleen,
 - cochlear implants,
 - diabetes,
 - HIV/AIDS or other diseases that affect the immune system (such as cancer, or liver disease), or
 - chronic heart or lung disease,or who take medications that affect the immune system, such as immunosuppressive drugs or steroids, should get **1 dose of PCV 13** (if they received 3

doses of PCV7 or PCV13 before age 2 years), or **2 doses of PCV13** (if they have received 2 or fewer doses of PCV7 or PCV13).

A dose of PCV13 may be administered to children and adolescents 6 through 18 years of age who have certain medical conditions, even if they have previously received PCV7 or PPSV23.

Children who have completed the 4-dose series with PCV7: Healthy children who have not yet turned 5, and children with medical conditions who have not yet turned 6, should get one additional dose of PCV13.

Ask your health care provider if you have questions about any of these recommendations.

PCV13 may be given at the same time as other vaccines.

4 Some children should not get PCV13 or should wait

Children should not get PCV13 if they had a serious (life-threatening) allergic reaction to a previous dose of this vaccine, to PCV7, or to any vaccine containing diphtheria toxoid (for example, DTaP).

Children who are known to have a severe allergy to any component of PCV7 or PCV13 should not get PCV13. Tell your health care provider if your child has any severe allergies.

Children with minor illnesses, such as a cold, may be vaccinated. But children who are moderately or severely ill should usually wait until they recover before getting the vaccine.

5 What are the risks from PCV13?

Any medicine, including a vaccine, could possibly cause a serious problem, such as a severe allergic reaction. However, the risk of any vaccine causing serious harm, or death, is extremely small.

In studies, most reactions after PCV13 were mild. They were similar to reactions reported after PCV7, which has been in use since 2000. Reported reactions varied by dose and age, but on average:

- About half of children were drowsy after the shot, had a temporary loss of appetite, or had redness or tenderness where the shot was given.
- About 1 out of 3 had swelling where the shot was given.
- About 1 out of 3 had a mild fever, and about 1 in 20 had a higher fever (over 102.2°F).

- Up to about 8 out of 10 became fussy or irritable.

Life-threatening allergic reactions from vaccines are very rare. If they do occur, it would be within a few minutes to a few hours after the vaccination.

6 What if there is a severe reaction?

What should I look for?

Any unusual condition, such as a high fever or behavior changes. Signs of a severe 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 the doctor what happened, the date and time it happened, and when the vaccination was given.
- Ask your provider to report the reaction by filing a Vaccine Adverse Event Reporting System (VAERS) form.
Or you can file this report through the VAERS website 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 may file a claim with VICP by calling **1-800-338-2382** or visiting their website at www.hrsa.gov/vaccinecompensation.

8 How can I learn more?

- Ask your provider. 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.



DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION



Vaccine Information Statement (Interim)
PCV13 **4/16/2010**

42 U.S.C. §300aa-26

INACTIVATED INFLUENZA VACCINE

WHAT YOU NEED TO KNOW 2010-11

Many Vaccine Information Statements are available in Spanish and other languages. See <http://www.immunize.org/vis>
Hojas de Información Sobre Vacunas están disponibles en Español y en muchos otros idiomas. Visite <http://www.immunize.org/vis>

1 Why get vaccinated?

Influenza (“flu”) is a contagious disease.

It is caused by the influenza virus, which can be spread by coughing, sneezing, or nasal secretions.

Anyone can get influenza, but rates of infection are highest among children. For most people, symptoms last only a few days. They include:

- fever
- sore throat
- chills
- fatigue
- cough
- headache
- muscle aches

Other illnesses can have the same symptoms and are often mistaken for influenza.

Infants, the elderly, pregnant women, and people with certain health conditions – such as heart, lung or kidney disease or a weakened immune system – can get much sicker. Flu can cause high fever and pneumonia, and make existing medical conditions worse. It can cause diarrhea and seizures in children. Each year thousands of people die from seasonal influenza and even more require hospitalization.

By getting vaccinated you can protect yourself from influenza and may also avoid spreading influenza to others.

2 Inactivated influenza vaccine

There are two types of influenza vaccine:

1. **Inactivated** (killed) vaccine, or the “flu shot” is given by injection into the muscle.
2. **Live, attenuated** (weakened) influenza vaccine is sprayed into the nostrils. *This vaccine is described in a separate Vaccine Information Statement.*

A “high-dose” inactivated influenza vaccine is available for people 65 years of age and older. Ask your healthcare provider for more information.

Influenza viruses are always changing, so annual vaccination is recommended. Each year scientists try to match the viruses in the vaccine to those most likely to cause flu that year.

The 2010-2011 vaccine provides protection against A/H1N1 (pandemic) influenza and two other influenza viruses – influenza A/H3N2 and influenza B. It will not prevent illness caused by other viruses.

It takes up to 2 weeks for protection to develop after the shot. Protection lasts about a year.

Some inactivated influenza vaccine contains a preservative called thimerosal. Thimerosal-free influenza vaccine is available. Ask your healthcare provider for more information.

3 Who should get inactivated influenza vaccine and when?

WHO

All people **6 months of age and older** should get flu vaccine.

Vaccination is especially important for people at higher risk of severe influenza and their close contacts, including healthcare personnel and close contacts of children younger than 6 months.

People who got the 2009 H1N1 (pandemic) influenza vaccine, or had pandemic flu in 2009, should still get the 2010-2011 seasonal influenza vaccine.

WHEN

Getting the vaccine as soon as it is available will provide protection if the flu season comes early. You can get the vaccine as long as illness is occurring in your community.

Influenza can occur at any time, but most influenza occurs from November through May. In recent seasons, most infections have occurred in January and February. Getting vaccinated in December, or even later, will still be beneficial in most years.

Adults and older children need one dose of influenza vaccine each year. But some children younger than 9 years of age need two doses to be protected. Ask your healthcare provider.

Influenza vaccine may be given at the same time as other vaccines, including pneumococcal vaccine.

4 Some people should not get inactivated influenza vaccine or should wait

- Tell your healthcare provider if you have any **severe** (life-threatening) allergies. Allergic reactions to influenza vaccine are rare.

- Influenza vaccine virus is grown in eggs. People with a **severe egg allergy** should not get influenza vaccine.
- A severe allergy to any vaccine component is also a reason not to get the vaccine.
- If you ever had a severe reaction after a dose of influenza vaccine, tell your healthcare provider.

- Tell your healthcare provider if you ever had Guillain-Barré Syndrome (a severe paralytic illness, also called GBS). Your provider will help you decide whether the vaccine is recommended for you.
- People who are moderately or severely ill should usually wait until they recover before getting flu vaccine. If you are ill, talk to your healthcare provider about whether to reschedule the vaccination. People with a mild illness can usually get the vaccine.

5 What are the risks from inactivated influenza vaccine?

A vaccine, like any medicine, could possibly cause serious problems, such as severe allergic reactions. The risk of a vaccine causing serious harm, or death, is extremely small.

Serious problems from inactivated influenza vaccine are very rare. The viruses in inactivated influenza vaccine have been killed, so you cannot get influenza from the vaccine.

Mild problems:

- soreness, redness, or swelling where the shot was given
- hoarseness; sore, red or itchy eyes; cough
- fever • aches

If these problems occur, they usually begin soon after the shot and last 1-2 days.

Severe problems:

- Life-threatening allergic reactions from vaccines are very rare. If they do occur, it is usually within a few minutes to a few hours after the shot.
- In 1976, a type of inactivated influenza (swine flu) vaccine was associated with Guillain-Barré Syndrome (GBS). Since then, flu vaccines have not been clearly linked to GBS. However, if there is a risk of GBS from current flu vaccines, it would be no more than 1 or 2 cases per million people vaccinated. This is much lower than the risk of severe influenza, which can be prevented by vaccination.

One brand of inactivated flu vaccine, called Afluria, **should not be given** to children 8 years of age or younger, except in special circumstances. A related vaccine was associated with fevers and fever-related seizures in young children in Australia. Ask your healthcare provider for more information.

The safety of vaccines is always being monitored. For more information, visit:

http://www.cdc.gov/vaccinesafety/Vaccine_Monitoring/Index.html and
http://www.cdc.gov/vaccinesafety/Activities/Activities_Index.html

6 What if there is a severe reaction?

What should I look for?

Any unusual condition, such as a high fever or behavior changes. Signs of a severe 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** the doctor what happened, the date and time it happened, and when the vaccination was given.
- **Ask** your healthcare provider to report the reaction by filing a Vaccine Adverse Event Reporting System (VAERS) form. Or you can file this report through the VAERS website at <http://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.

People 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 <http://www.hrsa.gov/vaccinecompensation>.

8 How can I learn more?

- Ask your healthcare provider. 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 <http://www.cdc.gov/flu>



DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION



Vaccine Information Statement (Interim)
Inactivated Influenza Vaccine (8/10/10) 42 U.S.C. §300aa-26

LIVE, INTRANASAL INFLUENZA VACCINE

WHAT YOU NEED TO KNOW 2010-11

Vaccine Information Statements are available in Spanish and many other languages. See <http://www.immunize.org/vis>
Hojas de Información Sobre Vacunas están disponibles en Español y en muchos otros idiomas. Visite <http://www.immunize.org/vis>

1 Why get vaccinated?

Influenza (“flu”) is a contagious disease.

It is caused by the influenza virus, which can be spread by coughing, sneezing, or nasal secretions.

Anyone can get influenza, but rates of infection are highest among children. For most people, symptoms last only a few days. They include:

- fever
- sore throat
- chills
- fatigue
- cough
- headache
- muscle aches

Other illnesses can have the same symptoms and are often mistaken for influenza.

Infants, the elderly, pregnant women, and people with certain health conditions – such as heart, lung or kidney disease or a weakened immune system – can get much sicker. Influenza can cause high fever and pneumonia, and make existing medical conditions worse. It can cause diarrhea and seizures in children. Each year thousands of people die from seasonal influenza and even more require hospitalization.

By getting vaccinated you can protect yourself from influenza and may also avoid spreading influenza to others.

2 Live, attenuated influenza vaccine - LAIV (nasal spray)

There are two types of influenza vaccine:

1. **Live, attenuated** influenza vaccine (LAIV) contains live but attenuated (weakened) influenza virus. It is sprayed into the nostrils.
2. **Inactivated** (killed) influenza vaccine, or the “flu shot,” is given by injection into the muscle. *This vaccine is described in a separate Vaccine Information Statement.*

Influenza viruses are always changing, so annual vaccination is recommended. Each year scientists try to match the viruses in the vaccine to those most likely to cause flu that year.

The 2010 – 2011 vaccine provides protection against A/H1N1 (pandemic) influenza and two other influenza viruses– influenza A/H3N2 and influenza B. It will not prevent illness caused by other viruses.

It takes up to 2 weeks for protection to develop after the vaccination. Protection lasts about a year.

LAIV does not contain thimerosal or other preservatives.

3 Who can receive LAIV?

LAIV is recommended for healthy people **2 through 49 years of age**, who are not pregnant and do not have certain health conditions (see #4, below).

People who got the 2009 H1N1 (pandemic) influenza vaccine, or had pandemic flu in 2009, should still get the 2010-2011 seasonal influenza vaccine.

4 Some people should not receive LAIV

LAIV is not recommended for everyone. The following people should get the inactivated vaccine (flu shot) instead:

- **Adults 50 years of age and older or children from 6 through 23 months of age.** (Children younger than 6 months should not get either influenza vaccine.)
- Children younger than 5 years with asthma or one or more episodes of wheezing within the past year.
- Pregnant women.
- People who have long-term health problems with:
 - heart disease
 - kidney or liver disease
 - lung disease
 - metabolic disease, such as diabetes
 - asthma
 - anemia, and other blood disorders
- Anyone with certain muscle or nerve disorders (such as seizure disorders or cerebral palsy) that can lead to breathing or swallowing problems.
- Anyone with a weakened immune system.
- Anyone in close contact with someone whose immune system is so weak they require care in a protected environment (such as a bone marrow transplant unit). *Close contacts of other people with a weakened immune system (such as those with HIV) may receive LAIV. Healthcare personnel in neonatal intensive care units or oncology clinics may receive LAIV.*
- Children or adolescents on long-term aspirin treatment.

Tell your healthcare provider if you have any severe (life-threatening) allergies. Allergic reactions to influenza vaccine are rare.

- Influenza vaccine virus is grown in eggs. People with a **severe egg allergy** should not get influenza vaccine.
- A severe allergy to any vaccine component is also a reason not to get the vaccine.
- If you ever had a severe reaction after a dose of influenza vaccine, tell your healthcare provider.

Tell your healthcare provider if you ever had Guillain-Barré Syndrome (a severe paralytic illness, also called GBS). Your provider will help you decide whether the vaccine is recommended for you.

Tell your healthcare provider if you have gotten any other vaccines in the past 4 weeks.

Anyone with a nasal condition serious enough to make breathing difficult, such as a very stuffy nose, should get the flu shot instead.

People who are moderately or severely ill should usually wait until they recover before getting flu vaccine. If you are ill, talk to your healthcare provider about whether to reschedule the vaccination. People with a mild illness can usually get the vaccine.

5 When should I receive influenza vaccine?

Getting the vaccine as soon as it is available will provide protection if the flu season comes early. You can get the vaccine as long as illness is occurring in your community.

Influenza can occur any time, but most influenza occurs from November through May. In recent seasons, most infections have occurred in January and February. Getting vaccinated in December, or even later, will still be beneficial in most years.

Adults and older children need one dose of influenza vaccine each year. But some children younger than 9 years of age need two doses to be protected. Ask your healthcare provider.

Influenza vaccine may be given at the same time as other vaccines.

6 What are the risks from LAIV?

A vaccine, like any medicine, could possibly cause serious problems, such as severe allergic reactions. The risk of a vaccine causing serious harm, or death, is extremely small.

Live influenza vaccine viruses very rarely spread from person to person. Even if they do, they are not likely to cause illness.

LAIV is made from weakened virus and does not cause influenza. The vaccine can cause mild symptoms in people who get it (see below).

Mild problems:

Some children and adolescents 2-17 years of age have reported:

- runny nose, nasal congestion or cough
- fever
- headache and muscle aches
- wheezing
- abdominal pain or occasional vomiting or diarrhea

Some adults 18-49 years of age have reported:

- runny nose or nasal congestion
- sore throat
- cough, chills, tiredness/weakness
- headache

Severe problems:

- Life-threatening allergic reactions from vaccines are very rare. If they do occur, it is usually within a few minutes to a few hours after the vaccination.

- If rare reactions occur with any product, they may not be identified until thousands, or millions, of people have used it. Millions of doses of LAIV have been distributed since it was licensed, and the vaccine has not been associated with any serious problems.

The safety of vaccines is always being monitored. For more information, visit:

http://www.cdc.gov/vaccinesafety/Vaccine_Monitoring/Index.html and

http://www.cdc.gov/vaccinesafety/Activities/Activities_Index.html

7 What if there is a severe reaction?

What should I look for?

Any unusual condition, such as a high fever or behavior changes. Signs of a severe 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** the doctor what happened, the date and time it happened, and when the vaccination was given.
- **Ask** your healthcare provider to report the reaction by filing a Vaccine Adverse Event Reporting System (VAERS) form. Or you can file this report through the VAERS website at <http://www.vaers.hhs.gov>, or by calling **1-800-822-7967**.

VAERS does not provide medical advice.

8 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 <http://www.hrsa.gov/vaccinecompensation>.

9 How can I learn more?

- Ask your healthcare provider. 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 <http://www.cdc.gov/flu>



DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION



Vaccine Information Statement (Interim)
Live, Attenuated Influenza Vaccine (8/10/10) U.S.C. §300aa-26

Haemophilus Influenzae Type b (Hib) Vaccine

WHAT YOU NEED TO KNOW

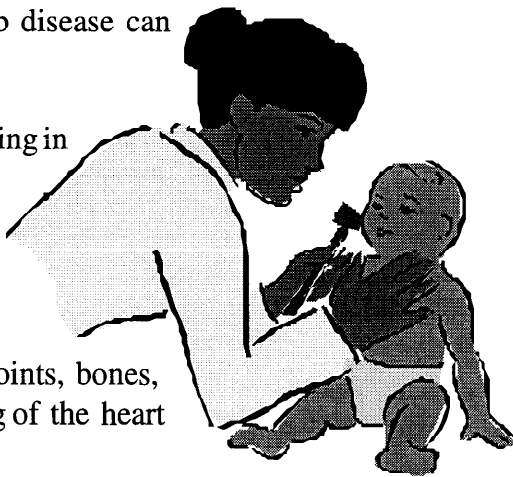
1 What is Hib disease?

Haemophilus influenzae type b (Hib) disease is a serious disease caused by a bacteria. It usually strikes children under 5 years old.

Your child can get Hib disease by being around other children or adults who may have the bacteria and not know it. The germs spread from person to person. If the germs stay in the child's nose and throat, the child probably will not get sick. But sometimes the germs spread into the lungs or the bloodstream, and then Hib can cause serious problems.

Before Hib vaccine, Hib disease was the leading cause of bacterial meningitis among children under 5 years old in the United States. Meningitis is an infection of the brain and spinal cord coverings, which can lead to lasting brain damage and deafness. Hib disease can also cause:

- pneumonia
- severe swelling in the throat, making it hard to breathe
- infections of the blood, joints, bones, and covering of the heart
- death



Before Hib vaccine, about 20,000 children in the United States under 5 years old got severe Hib disease each year and nearly 1,000 people died.

Hib vaccine can prevent Hib disease.

Many more children would get Hib disease if we stopped vaccinating.

2 Who should get Hib vaccine and when?

Children should get Hib vaccine at:

- ✓ 2 months of age
- ✓ 4 months of age
- ✓ 6 months of age*
- ✓ 12-15 months of age

* Depending on what brand of Hib vaccine is used, your child might not need the dose at 6 months of age. Your doctor or nurse will tell you if this dose is needed.

If you miss a dose or get behind schedule, get the next dose as soon as you can. There is no need to start over.

Hib vaccine may be given at the same time as other vaccines.

Older Children and Adults

Children over 5 years old usually do not need Hib vaccine. But some older children or adults with special health conditions should get it. These conditions include sickle cell disease, HIV/AIDS, removal of the spleen, bone marrow transplant, or cancer treatment with drugs. Ask your doctor or nurse for details.

3 Some people should not get Hib vaccine or should wait

- People who have ever had a life-threatening allergic reaction to a previous dose of Hib vaccine should not get another dose.
- Children less than 6 weeks of age should not get Hib vaccine.
- People who are moderately or severely ill at the time the shot is scheduled should usually wait until they recover before getting Hib vaccine.

Ask your doctor or nurse for more information.

4**What are the risks from Hib vaccine?**

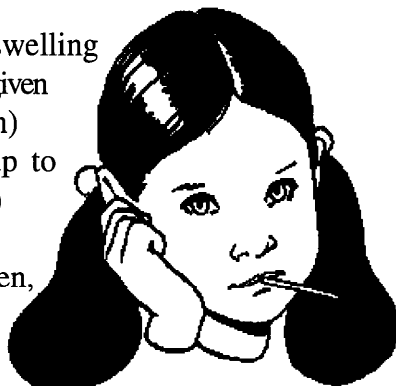
A vaccine, like any medicine, is capable of causing serious problems, such as severe allergic reactions. The risk of Hib vaccine causing serious harm or death is extremely small.

Most people who get Hib vaccine do not have any problems with it.

Mild Problems

- Redness, warmth, or swelling where the shot was given (up to 1/4 of children)
- Fever over 101°F (up to 1 out of 20 children)

If these problems happen, they usually start within a day of vaccination. They may last 2-3 days.

**5****What if there is a moderate or severe reaction?****What should I look for?**

Any unusual condition, such as a serious allergic reaction, high fever or behavior changes. Signs of a serious allergic reaction can include difficulty breathing, hoarseness or wheezing, hives, paleness, weakness, a fast heart beat, or dizziness within a few minutes to a few hours after the shot.

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 file a Vaccine Adverse Event Reporting System (VAERS) form, or call VAERS yourself at **1-800-822-7967**.

6**The National Vaccine Injury Compensation Program**

In the rare event that you or your child has a serious reaction to a vaccine, a federal program has been created to help you pay for the care of those who have been harmed.

For details about the National Vaccine Injury Compensation Program, call **1-800-338-2382** or visit the program's website at <http://www.hrsa.dhhs.gov/bhpr/vicp>

7**How can I learn more?**

- Ask your doctor or nurse. They can give you the vaccine package insert or suggest other sources of information.
- Call your local or state health department's immunization program.
- Contact the Centers for Disease Control and Prevention (CDC):
 - Call **1-800-232-2522** (English)
 - Call **1-800-232-0233** (Español)
 - Visit the National Immunization Program's website at <http://www.cdc.gov/nip>



U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Disease Control and Prevention
National Immunization Program

POLIO VACCINE

WHAT YOU NEED TO KNOW

1 What is polio?

Polio is a disease caused by a virus. It enters a child's (or adult's) body through the mouth. Sometimes it does not cause serious illness. But sometimes it causes *paralysis* (can't move arm or leg). It can kill people who get it, usually by paralyzing the muscles that help them breathe.

Polio used to be very common in the United States. It paralyzed and killed thousands of people a year before we had a vaccine for it.

2 Why get vaccinated?

Inactivated Polio Vaccine (IPV) can prevent polio.

History: A 1916 polio epidemic in the United States killed 6,000 people and paralyzed 27,000 more. In the early 1950's there were more than 20,000 cases of polio each year. **Polio vaccination was begun in 1955.** By 1960 the number of cases had dropped to about 3,000, and by 1979 there were only about 10. The success of polio vaccination in the U.S. and other countries sparked a world-wide effort to eliminate polio.

Today: No wild polio has been reported in the United States for over 20 years. But the disease is still common in some parts of the world. It would only take one case of polio from another country to bring the disease back if we were not protected by vaccine. If the effort to eliminate the disease from the world is successful, some day we won't need polio vaccine. Until then, we need to keep getting our children vaccinated.

Oral Polio Vaccine: No longer recommended

There are two kinds of polio vaccine: **IPV**, which is the shot recommended in the United States today, and a live, oral polio vaccine (**OPV**), which is drops that are swallowed.

Until recently OPV was recommended for most children in the United States. OPV helped us rid the country of polio, and it is still used in many parts of the world.

Both vaccines give immunity to polio, but OPV is better at keeping the disease from spreading to other people. However, for a few people (about one in 2.4 million), OPV actually causes polio. Since the risk of getting polio in the United States is now extremely low, experts believe that using oral polio vaccine is no longer worth the slight risk, except in limited circumstances which your doctor can describe. The polio shot (IPV) does not cause polio. **If you or your child will be getting OPV, ask for a copy of the OPV supplemental Vaccine Information Statement.**

3 Who should get polio vaccine and when?

IPV is a shot, given in the leg or arm, depending on age. Polio vaccine may be given at the same time as other vaccines.

Children

Most people should get polio vaccine when they are children. Children get 4 doses of IPV, at these ages:

- ✓ A dose at 2 months
- ✓ A dose at 4 months
- ✓ A dose at 6-18 months
- ✓ A booster dose at 4-6 years

Adults

Most adults do not need polio vaccine because they were already vaccinated as children. But three groups of adults are at higher risk and *should* consider polio vaccination:

- (1) people traveling to areas of the world where polio is common,
- (2) laboratory workers who might handle polio virus, and
- (3) health care workers treating patients who could have polio.

Adults in these three groups who **have never been vaccinated against polio** should get 3 doses of IPV:

- ✓ The first dose at any time,
- ✓ The second dose 1 to 2 months later,
- ✓ The third dose 6 to 12 months after the second.

Adults in these three groups who **have had 1 or 2 doses** of polio vaccine in the past should get the remaining 1 or 2 doses. It doesn't matter how long it has been since the earlier dose(s).

Adults in these three groups who **have had 3 or more doses** of polio vaccine (either IPV or OPV) in the past may get a booster dose of IPV.

Ask your health care provider for more information.

4

Some people should not get IPV or should wait.

These people should not get IPV:

- Anyone who has ever had a life-threatening allergic reaction to the antibiotics **neomycin**, **streptomycin** or **polymyxin B** should not get the polio shot.
- Anyone who has a severe allergic reaction to a polio shot should not get another one.

These people should wait:

- Anyone who is moderately or severely ill at the time the shot is scheduled should usually wait until they recover before getting polio vaccine. People with minor illnesses, such as a cold, *may* be vaccinated.

Ask your health care provider for more information.

5

What are the risks from IPV?

Some people who get IPV get a sore spot where the shot was given. The vaccine used today has never been known to cause any serious problems, and most people don't have any problems at all with it.

However, a vaccine, like any medicine, could cause serious problems, such as a severe allergic reaction. *The risk of a polio shot causing serious harm, or death, is extremely small.*

6

What if there is a serious reaction?

What should I look for?

Look for any unusual condition, such as a serious allergic reaction, high fever, or unusual behavior.

If a serious allergic reaction occurred, it would happen within a few minutes to a few hours after the shot. Signs of a serious allergic reaction can include difficulty breathing, weakness, hoarseness or wheezing, a fast heart beat, hives, dizziness, paleness, or swelling of the throat

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 file a Vaccine Adverse Event Reporting System (VAERS) form, or call the VAERS toll-free number yourself at **1-800-822-7967**.

Reporting reactions helps experts learn about possible problems with vaccines.

7

The National Vaccine Injury Compensation Program

In the rare event that you or your child has a serious reaction to a vaccine, there is a federal program that can help pay for the care of those who have been harmed.

For details about the National Vaccine Injury Compensation Program, call **1-800-338-2382** or visit the program's website at <http://www.hrsa.gov/bhpr/vicp>

8

How can I learn more?

- Ask your doctor or nurse. They can give you the vaccine package insert or suggest other sources of information.
- Call your local or state health department's immunization program.
- Contact the Centers for Disease Control and Prevention (CDC):
 - Call **1-800-232-2522** (English)
 - Call **1-800-232-0233** (Español)
 - Visit the National Immunization Program's website at <http://www.cdc.gov/nip>



U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Disease Control and Prevention
National Immunization Program

CHICKENPOX VACCINE

WHAT YOU NEED TO KNOW

1 Why get vaccinated?

Chickenpox (also called varicella) is a common childhood disease. It is usually mild, but it can be serious, especially in young infants and adults.

- It causes a rash, itching, fever, and tiredness.
- It can lead to severe skin infection, scars, pneumonia, brain damage, or death.
- The chickenpox virus can be spread from person to person through the air, or by contact with fluid from chickenpox blisters.
- A person who has had chickenpox can get a painful rash called shingles years later.
- Before the vaccine, about 11,000 people were hospitalized for chickenpox each year in the United States.
- Before the vaccine, about 100 people died each year as a result of chickenpox in the United States.

Chickenpox vaccine can prevent chickenpox.

Most people who get chickenpox vaccine will not get chickenpox. But if someone who has been vaccinated does get chickenpox, it is usually very mild. They will have fewer blisters, are less likely to have a fever, and will recover faster.

2 Who should get chickenpox vaccine and when?

Routine

Children who have never had chickenpox should get 2 doses of chickenpox vaccine at these ages:

1st Dose: 12-15 months of age

2nd Dose: 4-6 years of age (may be given earlier, if at least 3 months after the 1st dose)

People 13 years of age and older (who have never had chickenpox or received chickenpox vaccine) should get two doses at least 28 days apart.

Chickenpox

3/13/08

Catch-Up

Anyone who is not fully vaccinated, and never had chickenpox, should receive one or two doses of chickenpox vaccine. The timing of these doses depends on the person's age. Ask your provider.

Chickenpox vaccine may be given at the same time as other vaccines.

Note: A "combination" vaccine called **MMRV**, which contains both chickenpox and MMR vaccines, may be given instead of the two individual vaccines to people 12 years of age and younger.

3 Some people should not get chickenpox vaccine or should wait

- People should not get chickenpox vaccine if they have ever had a life-threatening allergic reaction to a previous dose of chickenpox vaccine or to gelatin or the antibiotic neomycin.
- People who are moderately or severely ill at the time the shot is scheduled should usually wait until they recover before getting chickenpox vaccine.
- Pregnant women should wait to get chickenpox vaccine until after they have given birth. Women should not get pregnant for 1 month after getting chickenpox vaccine.
- Some people should check with their doctor about whether they should get chickenpox vaccine, including anyone who:
 - Has HIV/AIDS or another disease that affects the immune system
 - Is being treated with drugs that affect the immune system, such as steroids, for 2 weeks or longer
 - Has any kind of cancer
 - Is getting cancer treatment with radiation or drugs
- People who recently had a transfusion or were given other blood products should ask their doctor when they may get chickenpox vaccine.

Ask your provider for more information.

4

What are the risks from chickenpox vaccine?

A vaccine, like any medicine, is capable of causing serious problems, such as severe allergic reactions. The risk of chickenpox vaccine causing serious harm, or death, is extremely small.

Getting chickenpox vaccine is much safer than getting chickenpox disease. Most people who get chickenpox vaccine do not have any problems with it. Reactions are usually more likely after the first dose than after the second.

Mild Problems

- Soreness or swelling where the shot was given (about 1 out of 5 children and up to 1 out of 3 adolescents and adults)
- Fever (1 person out of 10, or less)
- Mild rash, up to a month after vaccination (1 person out of 25). It is possible for these people to infect other members of their household, but this is extremely rare.

Moderate Problems

- Seizure (jerking or staring) caused by fever (very rare).

Severe Problems

- Pneumonia (very rare)

Other serious problems, including severe brain reactions and low blood count, have been reported after chickenpox vaccination. These happen so rarely experts cannot tell whether they are caused by the vaccine or not. If they are, it is extremely rare.

Note: The first dose of **MMRV** vaccine has been associated with rash and higher rates of fever than MMR and varicella vaccines given separately. Rash has been reported in about 1 person in 20 and fever in about 1 person in 5. Seizures caused by a fever are also reported more often after MMRV. These usually occur 5-12 days after the first dose.

5

What if there is a moderate or severe reaction?

What should I look for?

- Any unusual condition, such as a high fever, weakness, or behavior changes. 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 provider to report the reaction by filing a Vaccine Adverse Event Reporting System (VAERS) form.

Or you can file this report through the VAERS website at www.vaers.hhs.gov, or by calling **1-800-822-7967**.

VAERS does not provide medical advice.

6

The National Vaccine Injury Compensation Program

A federal program has been created to help people who may have been harmed by a vaccine.

For details about the National Vaccine Injury Compensation Program, call **1-800-338-2382** or visit their website at www.hrsa.gov/vaccinecompensation.

7

How can I learn more?

- Ask your provider. 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)**
 - Visit CDC website at: www.cdc.gov/vaccines



DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION

Vaccine Information Statement (Interim)
Varicella Vaccine (3/13/08) 42 U.S.C. §300aa-26

TETANUS, DIPHTHERIA (Td) or TETANUS, DIPHTHERIA, PERTUSSIS (Tdap) **VACCINE**

WHAT YOU NEED TO KNOW

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

1 Why get vaccinated?

Children 6 years of age and younger are routinely vaccinated against tetanus, diphtheria and pertussis. But older children, adolescents, and adults need protection from these diseases too. Td (Tetanus, Diphtheria) and Tdap (Tetanus, Diphtheria, Pertussis) vaccines provide that protection.

TETANUS (Lockjaw) causes painful muscle spasms, usually all over the body.

- It can lead to tightening of the jaw muscles so the victim cannot open his mouth or swallow. Tetanus kills about 1 out of 5 people who are infected.

DIPHTHERIA causes a thick covering in the back of the throat.

- It can lead to breathing problems, paralysis, heart failure, and even death.

PERTUSSIS (Whooping Cough) causes severe coughing spells, vomiting, and disturbed sleep.

- It can lead to weight loss, incontinence, rib fractures and passing out from violent coughing. Up to 2 in 100 adolescents and 5 in 100 adults with pertussis are hospitalized or have complications, including pneumonia.

These three diseases are all caused by bacteria. Diphtheria and pertussis are spread from person to person. Tetanus enters the body through cuts, scratches, or wounds.

The United States averaged more than 1,300 cases of tetanus and 175,000 cases of diphtheria each year before vaccines. Since vaccines have been available, tetanus cases have fallen by over 96% and diphtheria cases by over 99.9%.

Before 2005, only children younger than 7 years of age could get pertussis vaccine. In 2004 there were more than 8,000 cases of pertussis in the U.S. among adolescents and more than 7,000 cases among adults.

2 Td and Tdap vaccines

- Td vaccine has been used for many years. It protects against tetanus and diphtheria.
- Tdap was licensed in 2005. It is the first vaccine for adolescents and adults that protects against all three diseases.

Note: At this time, Tdap is licensed for only one lifetime dose per person. Td is given every 10 years, and more often if needed.

These vaccines can be used in three ways: 1) as catch-up for people who did not get all their doses of DTaP or DTP when they were children, 2) as a booster dose every 10 years, and 3) for protection against tetanus infection after a wound.

3 Which vaccine, and when?

Routine: Adolescents 11 through 18

- A dose of Tdap is recommended for adolescents who got DTaP or DTP as children and have not yet gotten a booster dose of Td. The preferred age is 11-12.
- Adolescents who have already gotten a booster dose of Td are encouraged to get a dose of Tdap as well, for protection against pertussis. Waiting at least 5 years between Td and Tdap is encouraged, but not required.
- Adolescents who did not get all their scheduled doses of DTaP or DTP as children should complete the series using a combination of Td and Tdap.

Routine: Adults 19 and Older

- All adults should get a booster dose of Td every 10 years. Adults under 65 who have never gotten Tdap should substitute it for the next booster dose.
- Adults under 65 who expect to have close contact with an infant younger than 12 months of age (including women who may become pregnant) should get a dose of Tdap. Waiting at least 2 years since the last dose of Td is suggested, but not required.
- Healthcare workers under 65 who have direct patient contact in hospitals or clinics should get a dose of Tdap. A 2-year interval since the last Td is suggested, but not required.

New mothers who have never gotten Tdap should get a dose as soon as possible after delivery. If vaccination is needed *during* pregnancy, Td is usually preferred over Tdap.

Protection After a Wound

A person who gets a severe cut or burn might need a dose of Td or Tdap to prevent tetanus infection. Tdap may be used for people who have never had a dose. But Td should be used if Tdap is not available, or for:

- anybody who has already had a dose of Tdap,
- children 7 through 9 years of age, or
- adults 65 and older.

Tdap and Td may be given at the same time as other vaccines.

4 Some people should not be vaccinated or should wait

- Anyone who has had a life-threatening allergic reaction after a dose of DTP, DTaP, DT, or Td should not get Td or Tdap.
- Anyone who has a severe allergy to any component of a vaccine should not get that vaccine. Tell your provider if the person getting the vaccine has any severe allergies.

- Anyone who had a coma, or long or multiple seizures within 7 days after a dose of DTP or DTaP should not get Tdap, unless a cause other than the vaccine was found (these people *can* get Td).
- Talk to your provider if the person getting either vaccine:
 - has epilepsy or another nervous system problem,
 - had severe swelling or severe pain after a previous dose of DTP, DTaP, DT, Td, or Tdap vaccine, or
 - has had Guillain Barré Syndrome (GBS).

Anyone who has a moderate or severe illness on the day the shot is scheduled should usually wait until they recover before getting Tdap or Td vaccine. A person with a mild illness or low fever can usually be vaccinated.

5 What are the risks from Tdap and Td vaccines?

With a vaccine (as with any medicine) there is always a small risk of a life-threatening allergic reaction or other serious problem.

Getting tetanus, diphtheria or pertussis would be much more likely to lead to severe problems than getting either vaccine.

Problems reported after Td and Tdap vaccines are listed below.

Mild Problems

(Noticeable, but did not interfere with activities)

Tdap

- Pain (about 3 in 4 adolescents and 2 in 3 adults)
- Redness or swelling (about 1 in 5)
- Mild fever of at least 100.4°F (up to about 1 in 25 adolescents and 1 in 100 adults)
- Headache (about 4 in 10 adolescents and 3 in 10 adults)
- Tiredness (about 1 in 3 adolescents and 1 in 4 adults)
- Nausea, vomiting, diarrhea, stomach ache (up to 1 in 4 adolescents and 1 in 10 adults)
- Chills, body aches, sore joints, rash, swollen glands (uncommon)

Td

- Pain (up to about 8 in 10)
- Redness or swelling (up to about 1 in 3)
- Mild fever (up to about 1 in 15)
- Headache or tiredness (uncommon)

Moderate Problems

(Interfered with activities, but did not require medical attention)

Tdap

- Pain at the injection site (about 1 in 20 adolescents and 1 in 100 adults)
- Redness or swelling (up to about 1 in 16 adolescents and 1 in 25 adults)
- Fever over 102°F (about 1 in 100 adolescents and 1 in 250 adults)
- Headache (1 in 300)
- Nausea, vomiting, diarrhea, stomach ache (up to 3 in 100 adolescents and 1 in 100 adults)

Td

- Fever over 102°F (rare)

Tdap or Td

- Extensive swelling of the arm where the shot was given (up to about 3 in 100).

Severe Problems

(Unable to perform usual activities; required medical attention)

Tdap

- Two adults had nervous system problems after getting the vaccine during clinical trials. These may or may not have been caused by the vaccine. These problems went away on their own and did not cause any permanent harm.

Tdap or Td

- Swelling, severe pain, and redness in the arm where the shot was given (rare).

A severe allergic reaction could occur after any vaccine. They are estimated to occur less than once in a million doses.

6 What if there is a severe reaction?

What should I look for?

Any unusual condition, such as a high fever or behavior changes. Signs of a severe 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 the doctor what happened, the date and time it happened, and when the vaccination was given.
- Ask your provider to report the reaction by filing a Vaccine Adverse Event Reporting System (VAERS) form. Or you can file this report through the VAERS website 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

A federal program exists to help pay for the care of anyone who has a serious reaction to a vaccine.

For details about the National Vaccine Injury Compensation Program, call 1-800-338-2382 or visit their website at www.hrsa.gov/vaccinecompensation.

8 How can I learn more?

- Ask your provider. 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.



DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION

MENINGOCOCCAL VACCINES

WHAT YOU NEED TO KNOW

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

1 What is meningococcal disease?

Meningococcal disease is a serious bacterial illness. It is a leading cause of **bacterial meningitis** in children 2 through 18 years old in the United States. Meningitis is an infection of the fluid surrounding the brain and spinal cord.

Meningococcal disease also causes blood infections.

About 1,000 - 2,600 people get meningococcal disease each year in the U.S. Even when they are treated with antibiotics, 10-15% of these people die. Of those who survive, another 11-19% lose their arms or legs, become deaf, have problems with their nervous systems, become mentally retarded, or suffer seizures or strokes.

Anyone can get meningococcal disease. But it is most common in infants less than one year of age and people with certain medical conditions, such as lack of a spleen. College freshmen who live in dormitories, and teenagers 15-19 have an increased risk of getting meningococcal disease.

Meningococcal infections can be treated with drugs such as penicillin. Still, about 1 out of every ten people who get the disease dies from it, and many others are affected for life. This is why *preventing* the disease through use of meningococcal vaccine is important for people at highest risk.

2 Meningococcal vaccine

There are two kinds of meningococcal vaccine in the U.S.:

- **Meningococcal conjugate vaccine (MCV4)** was licensed in 2005. It is the preferred vaccine for people 2 through 55 years of age.
- **Meningococcal polysaccharide vaccine (MPSV4)** has been available since the 1970s. It may be used if MCV4 is not available, and is the only meningococcal vaccine licensed for people older than 55.

Both vaccines can prevent **4 types** of meningococcal disease, including 2 of the 3 types most common in the United States and a type that causes epidemics in Africa. Meningococcal vaccines cannot prevent all types of the disease. But they do protect many people who might become sick if they didn't get the vaccine.

Both vaccines work well, and protect about 90% of people who get them. MCV4 is expected to give better, longer-lasting protection.

MCV4 should also be better at preventing the disease from spreading from person to person.

3 Who should get meningococcal vaccine and when?

A dose of MCV4 is recommended for children and adolescents 11 through 18 years of age.

This dose is normally given during the routine pre-adolescent immunization visit (at 11-12 years). But those who did not get the vaccine during this visit should get it at the earliest opportunity.

Meningococcal vaccine is also recommended for other people at increased risk for meningococcal disease:

- College freshmen living in dormitories.
- Microbiologists who are routinely exposed to meningococcal bacteria.
- U.S. military recruits.
- Anyone traveling to, or living in, a part of the world where meningococcal disease is common, such as parts of Africa.
- Anyone who has a damaged spleen, or whose spleen has been removed.
- Anyone who has terminal complement component deficiency (an immune system disorder).
- People who might have been exposed to meningitis during an outbreak.

MCV4 is the preferred vaccine for people 2 through 55 years of age in these risk groups. MPSV4 can be used if MCV4 is not available and for adults over 55.

How Many Doses?

People 2 years of age and older should get 1 dose. Sometimes a second dose is recommended for people who remain at high risk. Ask your provider.

MPSV4 may be recommended for children 3 months to 2 years of age under special circumstances. These children should get 2 doses, 3 months apart.

4

Some people should not get meningococcal vaccine or should wait

- Anyone who has ever had a severe (life-threatening) **allergic reaction to a previous dose** of either meningococcal vaccine should not get another dose.
- Anyone who has a severe (life threatening) **allergy to any vaccine component** should not get the vaccine. Tell your provider if you have any severe allergies.
- Anyone who is **moderately or severely ill** at the time the shot is scheduled should probably wait until they recover. Ask your provider. People with a **mild illness** can usually get the vaccine.
- Anyone who has ever had **Guillain-Barré Syndrome** should talk with their provider before getting MCV4.
- Meningococcal vaccines may be given to pregnant women. However, MCV4 is a new vaccine and has not been studied in pregnant women as much as MPSV4 has. It should be used only if clearly needed.
- Meningococcal vaccines may be given at the same time as other vaccines.

5

What are the risks from meningococcal vaccines?

A vaccine, like any medicine, could possibly cause serious problems, such as severe allergic reactions. The risk of meningococcal vaccine causing serious harm, or death, is extremely small.

Mild problems

As many as half the people who get meningococcal vaccines have mild side effects, such as redness or pain where the shot was given.

If these problems occur, they usually last for 1 or 2 days. They are more common after MCV4 than after MPSV4.

A small percentage of people who receive the vaccine develop a fever.

Severe problems

- Serious allergic reactions, within a few minutes to a few hours of the shot, are very rare.
- A serious nervous system disorder called **Guillain-Barré Syndrome** (or GBS) has been reported among some people who received MCV4. This happens so rarely that it is currently not possible to tell if the vaccine might be a factor. Even if it is, the risk is very small.

6

What if there is a moderate or severe reaction?

What should I look for?

- Any unusual condition, such as a high fever, weakness, or behavior changes. 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

A federal program exists to help pay for the care of anyone who has had a rare serious reaction to a vaccine.

For information about the National Vaccine Injury Compensation Program, call **1-800-338-2382** or visit their website at www.hrsa.gov/vaccinecompensation.

8

How can I learn more?

- Ask your doctor or nurse. 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)**
 - Visit CDC's National Immunization Program website at www.cdc.gov/vaccines
 - Visit CDC's meningococcal disease website at www.cdc.gov/ncidod/dbmd/diseaseinfo/meningococcal_g.htm
 - Visit CDC's Travelers' Health website at wwwn.cdc.gov/travel



HPV (HUMAN PAPILLOMAVIRUS) VACCINE

Gardasil®

WHAT YOU NEED TO KNOW

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

1 What is HPV?

Genital human papillomavirus (HPV) is the most common sexually transmitted virus in the United States. More than half of sexually active men and women are infected with HPV at some time in their lives.

About 20 million Americans are currently infected, and about 6 million more get infected each year. HPV is usually spread through sexual contact.

Most HPV infections don't cause any symptoms, and go away on their own. But HPV can cause **cervical cancer** in women. Cervical cancer is the 2nd leading cause of cancer deaths among women around the world. In the United States, about 10,000 women get cervical cancer every year and about 4,000 are expected to die from it.

HPV is also associated with several less common cancers, such as vaginal and vulvar cancers in women and other types of cancer in both men and women. It can also cause genital warts and warts in the throat.

There is no cure for HPV infection, but some of the problems it causes can be treated.

2 HPV vaccine - Why get vaccinated?

HPV vaccine is important because **it can prevent most cases of cervical cancer** in females, if it is given before a person is exposed to the virus.

Protection from HPV vaccine is expected to be long-lasting. But vaccination is not a substitute for cervical cancer screening. Women should still get regular Pap tests.

The vaccine you are getting is one of **two vaccines that can be given to prevent HPV**. It may be given to both males and females. In addition to preventing cervical cancer, it can also prevent **vaginal and vulvar cancer** in females, and **genital warts** in both males and females.

The other vaccine is given to females only, and only for prevention of cervical cancer.

3 Who should get this HPV vaccine and when?

Females: *Routine Vaccination*

- HPV vaccine is recommended for girls **11 or 12 years of age**. It may be given to girls starting at age 9.

Why is HPV vaccine given to girls at this age?

It is important for girls to get HPV vaccine **before** their first sexual contact – because they won't have been exposed to human papillomavirus.

Once a girl or woman has been infected with the virus, the vaccine might not work as well or might not work at all.

Females: *Catch-Up Vaccination*

- The vaccine is also recommended for girls and women **13 through 26 years of age** who did not get all 3 doses when they were younger.

Males

Males **9 through 26 years** of age may get HPV vaccine to prevent genital warts. As with females, it is best to be vaccinated before the first sexual contact.

HPV vaccine is given as a 3-dose series

1st Dose	Now
2nd Dose	1 to 2 months after Dose 1
3rd Dose	6 months after Dose 1

Additional (booster) doses are not recommended.

HPV vaccine may be given at the same time as other vaccines.

4 Some people should not get HPV vaccine or should wait

- Anyone who has ever had a life-threatening allergic reaction to any component of HPV vaccine, or to a previous dose of HPV vaccine, should not get the vaccine. Tell your doctor if the person getting vaccinated has any severe allergies, including an allergy to yeast.

- HPV vaccine is not recommended for **pregnant women**. However, receiving HPV vaccine when pregnant is not a reason to consider terminating the pregnancy. Women who are breast feeding may get the vaccine.

Any woman who learns she was pregnant when she got this HPV vaccine is encouraged to contact the manufacturer's **HPV in pregnancy registry** at 800-986-8999. This will help us learn how pregnant women respond to the vaccine.

- People who are mildly ill when a dose of HPV vaccine is planned can still be vaccinated. People with a **moderate or severe illness** should wait until they are better.

5 What are the risks from this vaccine?

This HPV vaccine has been used in the U.S. and around the world for several years and has been very safe.

However, any medicine could possibly cause a serious problem, such as a severe allergic reaction. The risk of any vaccine causing a serious injury, or death, is extremely small.

Life-threatening allergic reactions from vaccines are very rare. If they do occur, it would be within a few minutes to a few hours after the vaccination.

Several **mild to moderate problems** are known to occur with HPV vaccine. These do not last long and go away on their own.

- Reactions in the arm where the shot was given:
 - Pain (about 8 people in 10)
 - Redness or swelling (about 1 person in 4)
- Fever:
 - Mild (100° F) (about 1 person in 10)
 - Moderate (102° F) (about 1 person in 65)
- Other problems:
 - Headache (about 1 person in 3)
 - Fainting. Brief fainting spells and related symptoms (such as jerking movements) can happen after any medical procedure, including vaccination. **Sitting or lying down for about 15 minutes after a vaccination can help prevent fainting and injuries caused by falls.** Tell your provider if the patient feels dizzy or light-headed, or has vision changes or ringing in the ears.

Like all vaccines, HPV vaccines will continue to be monitored for unusual or severe problems.

6 What if there is a severe reaction?

What should I look for?

Serious allergic reactions including rash; swelling of the hands and feet, face, or lips; and breathing difficulty.

What should I do?

- Call a doctor, or get the person to a doctor right away.
- Tell the doctor what happened, the date and time it happened, and when the vaccination was given.
- Ask your provider to report the reaction by filing a Vaccine Adverse Event Reporting System (VAERS) form. Or you can file this report through the VAERS website at <http://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 may file a claim with VICP by calling 1-800-338-2382 or visiting their website at <http://www.hrsa.gov/vaccinecompensation>.

8 How can I learn more?

- Ask your provider. 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 <http://www.cdc.gov/hpv> and <http://www.cdc.gov/vaccines>



DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION



Vaccine Information Statement (Interim)
Human Papillomavirus (HPV) *Gardasil* 3/30/2010