VACCINE INFORMATION STATEMENT

Your Child's First Vaccines

What You Need to Know

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

Hojas de información sobre vacunas están disponibles en español y en muchos otros idiomas. Visite www.immunize.org/vis

The vaccines covered on this statement are those most likely to be given during the same visits during infancy and early childhood. Other vaccines (including measles, mumps, and rubella; varicella; rotavirus; influenza; and hepatitis A) are also routinely recommended during the first five years of life.

Your child will get these vaccines today:

☐ DTaP ☐ Hib ☐ Hepatitis B ☐ Polio ☐ PCV13

(Provider: Check appropriate boxes.)

1 Why get vaccinated?

Vaccine-preventable diseases are much less common than they used to be, thanks to vaccination. But they have not gone away. Outbreaks of some of these diseases still occur across the United States. **When fewer babies get vaccinated, more babies get sick.**

7 childhood diseases that can be prevented by vaccines:

1. Diphtheria (the 'D' in DTaP vaccine)

- **Signs and symptoms** include a thick coating in the back of the throat that can make it hard to breathe.
- **Diphtheria can lead to** breathing problems, paralysis and heart failure.
  - About 15,000 people died each year in the U.S. from diphtheria before there was a vaccine.

2. Tetanus (the 'T' in DTaP vaccine; also known as Lockjaw)

- **Signs and symptoms** include painful tightening of the muscles, usually all over the body.
- **Tetanus can lead to** stiffness of the jaw that can make it difficult to open the mouth or swallow.
  - Tetanus kills about 1 person out of every 10 who get it.

3. Pertussis (the 'P' in DTaP vaccine, also known as Whooping Cough)

- **Signs and symptoms** include violent coughing spells that can make it hard for a baby to eat, drink, or breathe. These spells can last for several weeks.
- **Pertussis can lead to** pneumonia, seizures, brain damage, or death. Pertussis can be very dangerous in infants.
  - Most pertussis deaths are in babies younger than 3 months of age.

4. Hib (*Haemophilus influenzae* type b)

- **Signs and symptoms** can include fever, headache, stiff neck, cough, and shortness of breath. There might not be any signs or symptoms in mild cases.
- **Hib can lead to** meningitis (infection of the brain and spinal cord coverings); pneumonia; infections of the ears, sinuses, blood, joints, bones, and covering of the heart; brain damage; severe swelling of the throat, making it hard to breathe; and deafness.
  - Children younger than 5 years of age are at greatest risk for Hib disease.

5. Hepatitis B

- **Signs and symptoms** include tiredness, diarrhea and vomiting, jaundice (yellow skin or eyes), and pain in muscles, joints and stomach. But usually there are no signs or symptoms at all.
- **Hepatitis B can lead to** liver damage, and liver cancer. Some people develop chronic (long term) hepatitis B infection. These people might not look or feel sick, but they can infect others.
  - Hepatitis B can cause liver damage and cancer in 1 child out of 4 who are chronically infected.

6. Polio

- **Signs and symptoms** can include flu-like illness, or there may be no signs or symptoms at all.
- **Polio can lead to** permanent paralysis (can't move an arm or leg, or sometimes can't breathe) and death.
  - In the 1950s, polio paralyzed more than 15,000 people every year in the U.S.

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

7. Pneumococcal Disease

- **Signs and symptoms** include fever, chills, cough, and chest pain. In infants, symptoms can also include meningitis, seizures, and sometimes rash.
- **Pneumococcal disease can lead to** meningitis (infection of the brain and spinal cord coverings); infections of the ears, sinuses and blood; pneumonia; deafness; and brain damage.
  - About 1 out of 15 children who get pneumococcal meningitis will die from the infection.

Children usually catch these diseases from other children or adults, who might not even know they are infected. A mother infected with hepatitis B can infect her baby at birth. Tetanus enters the body through a cut or wound; it is not spread from person to person.

Vaccines that protect your baby from these seven diseases:

Vaccine	Number of doses	Recommended ages	Other information
DTaP (Diphtheria, Tetanus, Pertussis)	5	2 months, 4 months, 6 months, 15-18 months, 4-6 years	Some children get a vaccine called DT (Diphtheria & Tetanus) instead of DTaP.
Hepatitis B	3	Birth, 1-2 months, 6-18 months	
Polio	4	2 months, 4 months, 6-18 months, 4-6 years	An additional dose of polio vaccine may be recommended for travel to certain countries.
Hib (*Haemophilus influenzae* type b)	3 or 4	2 months, 4 months, (6 months), 12-15 months	There are several Hib vaccines. With one of them the 6-month dose is not needed.
Pneumococcal (PCV13)	4	2 months, 4 months, 6 months, 12-15 months	Older children with certain health conditions also need this vaccine.

Your healthcare provider might offer some of these vaccines as **combination vaccines**—several vaccines given in the same shot. Combination vaccines are as safe and effective as the individual vaccines, and can mean fewer shots for your baby.

---

2 Some children should not get certain vaccines

Most children can safely get all of these vaccines. But there are some exceptions:

- A child who has a mild cold or other illness on the day vaccinations are scheduled may be vaccinated. A child who is moderately or severely ill on the day of vaccinations might be asked to come back for them at a later date.
- Any child who had a life-threatening allergic reaction after getting a vaccine should not get another dose of that vaccine. ***Tell the person giving the vaccines if your child has ever had a severe reaction after any vaccination.***
- A child who has a severe (life-threatening) allergy to a substance should not get a vaccine that contains that substance. ***Tell the person giving your child the vaccines if your child has any severe allergies that you are aware of.***

Talk to your doctor before your child gets:

- **DTaP vaccine**, if your child ever had any of these reactions after a previous dose of DTaP:
  - A brain or nervous system disease within 7 days,
  - Non-stop crying for 3 hours or more,
  - A seizure or collapse,
  - A fever of over 105°F.
- **PCV13 vaccine**, if your child ever had a severe reaction after a dose of DTaP (or other vaccine containing diphtheria toxoid), or after a dose of PCV7, an earlier pneumococcal vaccine.

3 Risks of a Vaccine Reaction

With any medicine, including vaccines, there is a chance of side effects. These are usually mild and go away on their own. Most vaccine reactions are not serious: tenderness, redness, or swelling where the shot was given; or a mild fever. These happen soon after the shot is given and go away within a day or two. They happen with up to about half of vaccinations, depending on the vaccine.

Serious reactions are also possible but are rare.

Polio, Hepatitis B and **Hib Vaccines** have been associated only with mild reactions.

DTaP and **Pneumococcal** vaccines have also been associated with other problems:

DTaP Vaccine

- **Mild Problems:** Fussiness (up to 1 child in 3); tiredness or loss of appetite (up to 1 child in 10); vomiting (up to 1 child in 50); swelling of the entire arm or leg for 1-7 days (up to 1 child in 30)—usually after the 4th or 5th dose.
- **Moderate Problems:** Seizure (1 child in 14,000); non-stop crying for 3 hours or longer (up to 1 child in 1,000); fever over 105°F (1 child in 16,000).
- **Serious problems:** Long term seizures, coma, lowered consciousness, and permanent brain damage have been reported following DTaP vaccination. These reports are extremely rare.

Pneumococcal Vaccine

- **Mild Problems:** Drowsiness or temporary loss of appetite (about 1 child in 2 or 3); fussiness (about 8 children in 10).
- **Moderate Problems:** Fever over 102.2°F (about 1 child in 20).

After any vaccine:

Any medication can cause a severe allergic reaction. Such reactions from a vaccine are very rare, estimated at about 1 in a million doses, and would happen within a few minutes to a few hours after the vaccination.

As with any medicine, there is a very remote chance of a vaccine causing a serious injury or death.

The safety of vaccines is always being monitored. For more information, visit: **www.cdc.gov/vaccinesafety/**

4 What if there is a serious reaction?

What should I look for?

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

  Signs of a severe allergic reaction can include hives, swelling of the face and throat, and difficulty breathing. In infants, signs of an allergic reaction might also include fever, sleepiness, and disinterest in eating. In older children signs might include a fast heartbeat, dizziness, and weakness. These would usually start a few minutes to a few hours after the vaccination.

What should I do?

- If you think it is a severe allergic reaction or other emergency that can't wait, call 9-1-1 or get the person to the nearest hospital. Otherwise, call your doctor.

  Afterward, the reaction should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your doctor should file this report, or you can do it yourself through the VAERS web site at **www.vaers.hhs.gov**, or by calling **1-800-822-7967**.

VAERS does not give medical advice.

5 The National Vaccine Injury Compensation Program

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

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

6 How can I learn more?

- Ask your healthcare provider. He or she 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 website at **www.cdc.gov/vaccines** or **www.cdc.gov/hepatitis**

Vaccine Information Statement

Multi Pediatric Vaccines

11/05/2015

Office Use Only

42 U.S.C. § 300aa-26

VACCINE INFORMATION STATEMENT

Serogroup B Meningococcal Vaccine (MenB): *What You Need to Know*

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

Hojas de información sobre vacunas están disponibles en español y en muchos otros idiomas. Visite www.immunize.org/vis

1 Why get vaccinated?

Meningococcal disease is a serious illness caused by a type of bacteria called *Neisseria meningitidis*. It can lead to meningitis (infection of the lining of the brain and spinal cord) and bacteremia or septicemia (infections of the blood). Meningococcal disease often strikes without warning—even people who are otherwise healthy.

Meningococcal disease can spread from person to person through close contact (coughing or kissing) or lengthy contact, especially among people living in the same household.

There are at least 12 types of *Neisseria meningitidis*, called "serogroups." Serogroups A, B, C, W, and Y cause most meningococcal disease.

Anyone can get meningococcal disease but certain people are at increased risk, including:

- Infants less than one year old
- Adolescents and young adults 16 through 23 years old
- People with certain medical conditions that affect the immune system
- Microbiologists who routinely work with isolates of *N. meningitidis*
- People at risk because of an outbreak in their community

Even when it is treated, meningococcal disease kills 10 to 15 infected people out of 100. And of those who survive, about 10 to 20 out of every 100 will suffer disabilities such as hearing loss, brain damage, amputations, nervous system problems, or severe scars from skin grafts.

Serogroup B meningococcal (MenB) vaccine can help prevent meningococcal disease caused by serogroup B. Other meningococcal vaccines are recommended to help protect against serogroups A, C, W, and Y.

2 Serogroup B Meningococcal Vaccines

Two serogroup B meningococcal vaccines have been licensed by the Food and Drug Administration.

These vaccines are recommended routinely for people 10 years or older who are at increased risk for serogroup B meningococcal infections, including:

- People at risk because of a serogroup B meningococcal disease outbreak
- Anyone whose spleen is damaged or has been removed
- Anyone with a rare immune system condition called "persistent complement component deficiency"
- Anyone taking a drug called eculizumab (also called Soliris®)
- Microbiologists who routinely work with *N. meningitidis* isolates

These vaccines may also be given to anyone 16 through 23 years old to provide short term protection against most strains of serogroup B meningococcal disease; 16 through 18 years are the preferred ages for vaccination.

The recommended schedule depends on which vaccine you get:

- Bexsero® is given as **2 doses**, at least 1 month apart.
  or
- Trumenba® is given as **3 doses**, with the second dose 2 months after the first and the third dose 6 months after the first.

The same vaccine must be used for all doses.

3 Some people should not get these vaccines

Tell the person who is giving you the vaccine:

- **If you have any severe, life-threatening allergies.** If you have ever had a life-threatening allergic reaction after a previous dose of serogroup B meningococcal vaccine, or if you have a severe allergy to any part of this vaccine, you should not get the vaccine. *Tell your healthcare provider if you have any severe allergies that you know of, including a severe allergy to latex.* He or she can tell you about the vaccine's ingredients.
- **If you are pregnant or breastfeeding.** There is not very much information about the potential risks of this vaccine for a pregnant woman or breastfeeding mother. It should be used during pregnancy only if clearly needed.
- **If you are not feeling well.** It is usually okay to get this vaccine when you have a mild illness, but you might be advised to come back when you feel better.

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

4 Risks of a vaccine reaction

With any medicine, including vaccines, there is a chance of reactions. These are usually mild and go away on their own within a few days, but serious reactions are also possible.

More than half of the people who get serogroup B meningococcal vaccine have **mild problems** following vaccination. These reactions can last up to 3 to 7 days, and include:

- Soreness, redness, or swelling where the shot was given
- Tiredness or fatigue
- Headache
- Muscle or joint pain
- Fever or chills
- Nausea or diarrhea

Problems that could happen after any injected vaccine:

- People sometimes faint after a medical procedure, including vaccination. Sitting or lying down for about 15 minutes can help prevent fainting, and injuries caused by a fall. Tell your doctor if you feel dizzy, or have vision changes or ringing in the ears.
- Some people get severe pain in the shoulder and have difficulty moving the arm where a shot was given. This happens very rarely.
- Any medication can cause a severe allergic reaction. Such reactions from a vaccine are very rare, estimated at about 1 in a million doses, and would happen within a few minutes to a few hours after the vaccination.

As with any medicine, there is a very remote chance of a vaccine causing a serious injury or death.

The safety of vaccines is always being monitored. For more information, visit: **www.cdc.gov/vaccinesafety/**

5 What if there is a serious reaction?

What should I look for?

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

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

What should I do?

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

VAERS does not give medical advice.

6 The National Vaccine Injury Compensation Program

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

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

7 How can I learn more?

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

VACCINE INFORMATION STATEMENT

Rotavirus Vaccine

What You Need to Know

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

Hojas de información sobre vacunas están disponibles en español y en muchos otros idiomas. Visite www.immunize.org/vis

1 Why get vaccinated?

Rotavirus is a virus that causes diarrhea, mostly in babies and young children. The diarrhea can be severe, and lead to dehydration. Vomiting and fever are also common in babies with rotavirus.

Before rotavirus vaccine, rotavirus disease was a common and serious health problem for children in the United States. Almost all children in the United States had at least one rotavirus infection before their 5th birthday.

Every year before the vaccine was available:

- more than 400,000 young children had to see a doctor for illness caused by rotavirus,
- more than 200,000 had to go to the emergency room,
- 55,000 to 70,000 had to be hospitalized, and
- 20 to 60 died.

Since the introduction of the rotavirus vaccine, hospitalizations and emergency visits for rotavirus have dropped dramatically.

2 Rotavirus vaccine

Two brands of rotavirus vaccine are available. Your baby will get either 2 or 3 doses, depending on which vaccine is used.

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)

Your child must get the first dose of rotavirus vaccine before 15 weeks of age, and the last by age 8 months. Rotavirus vaccine may safely be given at the same time as other vaccines.

Almost all babies who get rotavirus vaccine will be protected from severe rotavirus diarrhea. And most of these babies will not get rotavirus diarrhea at all.

The vaccine will not prevent diarrhea or vomiting caused by other germs.

Another virus called porcine circovirus (or parts of it) can be found in both rotavirus vaccines. This is not a virus that infects people, and there is no known safety risk. For more information, see **www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm205547.htm**.

3 Some babies should not get this vaccine

A baby who has had a life-threatening allergic reaction to a dose of rotavirus vaccine should not get another dose. A baby who has a severe allergy to any part 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 with "severe combined immunodeficiency" (SCID) should not get rotavirus vaccine.

Babies who have had a type of bowel blockage called "intussusception" should not get rotavirus vaccine.

Babies who are mildly ill can get the vaccine. Babies who are moderately or severely ill should wait until they recover. This includes babies with moderate or severe diarrhea or vomiting.

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 steroids
- cancer, or cancer treatment with x-rays or drugs

4 Risks of a vaccine reaction

With a vaccine, like any medicine, there is a chance of side effects. These are usually mild and go away on their own. Serious side effects are also possible but are rare.

Most babies who get rotavirus vaccine do not have any problems with it. But some problems have been associated with rotavirus vaccine:

Mild problems following rotavirus vaccine:

- Babies might become irritable, or have mild, temporary diarrhea or vomiting after getting a dose of rotavirus vaccine.

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

Serious problems following rotavirus vaccine:

- Intussusception is a type of bowel blockage that is treated in a hospital, and could require surgery. It happens "naturally" in some babies every year in the United States, and usually there is no known reason for it.

  There is also a small risk of intussusception from rotavirus vaccination, usually within a week after the 1st or 2nd vaccine dose. This additional risk is estimated to range from about 1 in 20,000 to 1 in 100,000 US infants who get rotavirus vaccine. Your doctor can give you more information.

Problems that could happen after any vaccine:

- Any medication can cause a severe allergic reaction. Such reactions from a vaccine are very rare, estimated at fewer than 1 in a million doses, and usually happen within a few minutes to a few hours after the vaccination.

As with any medicine, there is a very remote chance of a vaccine causing a serious injury or death.

The safety of vaccines is always being monitored. For more information, visit: **www.cdc.gov/vaccinesafety/**

5 What if there is a serious problem?

What should I look for?

For **intussusception**, look for signs of stomach pain along with severe crying. Early on, these episodes could last just a few minutes and come and go several times in an hour. Babies might pull their legs up to their chest.

Your baby might also vomit several times or have blood in the stool, or could appear weak or very irritable. These signs would usually happen during the first week after the 1st or 2nd dose of rotavirus vaccine, but look for them any time after vaccination.

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

Signs of a **severe allergic reaction** can include hives, swelling of the face and throat, difficulty breathing, or unusual sleepiness. These would usually start a few minutes to a few hours after the vaccination.

What should I do?

If you think it is **intussusception**, call a doctor right away. If you can't reach your doctor, take your baby to a hospital. Tell them when your baby got the rotavirus vaccine.

If you think it is a **severe allergic reaction** or other emergency that can't wait, call 9-1-1 or get your baby to the nearest hospital.

Otherwise, call your doctor.

Afterward, the reaction should be reported to the "Vaccine Adverse Event Reporting System" (VAERS). Your doctor might file this report, or you can do it yourself through the VAERS web site at **www.vaers.hhs.gov**, or by calling **1-800-822-7967**.

VAERS does not give medical advice.

6 The National Vaccine Injury Compensation Program

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

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

7 How can I learn more?

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

Vaccine Information Statement

Rotavirus Vaccine

04/15/2015

42 U.S.C. § 300aa-26

Office Use Only

VACCINE INFORMATION STATEMENT

Hepatitis A Vaccine

What You Need to Know

Many Vaccine Information Statements are available in Spanish and other languages. See 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 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 people with hepatitis A.

It is usually spread by close personal contact and sometimes by eating food or drinking water containing HAV. A person who has hepatitis A can easily pass the disease to others within the same household.

Hepatitis A can cause:

- "flu-like" illness
- jaundice (yellow skin or eyes, dark urine)
- severe stomach pains and diarrhea (children)

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

Adults with hepatitis A are often too ill to work for up to a month.

Sometimes, people die as a result of hepatitis A (about 3-6 deaths per 1,000 cases).

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 between their first and second birthdays (12 through 23 months of age).
- Anyone 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 2 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.
- People who use street drugs.
- People with chronic liver disease.
- People who are treated with clotting factor concentrates.
- People who work with HAV-infected primates or who work with HAV in research laboratories.
- Members of households planning to adopt a child, or care for a newly arriving adopted child, from a country where hepatitis A is common.

Other people might get hepatitis A vaccine in certain situations (ask your doctor for more details):

- Unvaccinated children or adolescents in communities where outbreaks of hepatitis A are occurring.
- Unvaccinated people who have been exposed to hepatitis A virus.
- Anyone 1 year of age or older who wants protection from hepatitis A.

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 through 23 months of age. Children who are not vaccinated by 2 years of age can be vaccinated at later visits.

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

For travelers, it is best to start the vaccine series at least one month before traveling. (Some protection may still result if the vaccine is given on or closer to the travel date.)

Some people who cannot get the vaccine before traveling, or for whom the vaccine might not be effective, can get a shot called immune globulin (IG). IG gives immediate, temporary protection.

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.

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

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,** including a severe allergy to latex. 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. People with a mild illness can usually get the vaccine.
- Tell your doctor if you are pregnant. Because hepatitis A vaccine is inactivated (killed), the risk to a pregnant woman or her unborn baby is believed to be very low. But your doctor can weigh any theoretical risk from the vaccine against the need for protection.

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 after 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 unusual behavior. Signs of a serious allergic reaction can include difficulty breathing, hoarseness or wheezing, hives, paleness, weakness, a fast heart beat or dizziness.

What should I do?

- **Call** a doctor, or get the person to a doctor right away.
- **Tell** your doctor what happened, the date and time it happened, and when the vaccination was given.
- **Ask** your doctor, nurse, or health department to report the reaction by filing a Vaccine Adverse Event Reporting System (VAERS) form. Or you can file this report through the VAERS web site at **www.vaers.hhs.gov**, or by calling **1-800-822-7967.**

VAERS does not provide medical advice.

6 The National Vaccine Injury Compensation Program

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

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

7 How can I learn more?

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

Vaccine Information Statement (Interim)

Hepatitis A Vaccine

10/25/2011

42 U.S.C. § 300aa-26

VACCINE INFORMATION STATEMENT

Chickenpox Vaccine

What You Need to Know

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

Hojas de información sobre vacunas están disponibles en español y en muchos otros idiomas. Visite www.immunize.org/vis

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.

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 doctor.

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 doctor for more information.

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

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 serious reaction?

What should I look for?

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

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

What should I do?

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

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

6 The National Vaccine Injury Compensation Program

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

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

7 How can I learn more?

- Ask your doctor.
- Call your local or state health department.
- Contact the Centers for Disease Control and Prevention (CDC):
  - Call **1-800-232-4636 (1-800-CDC-INFO)** or
  - Visit CDC's website at **www.cdc.gov/vaccines**

Vaccine Information Statement (Interim)

Varicella Vaccine

3/13/2008

Office Use Only

42 U.S.C. § 300aa-26

VACCINE INFORMATION STATEMENT

MMR Vaccine

(Measles, Mumps and Rubella)

What You Need to Know

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

Hojas de información sobre vacunas están disponibles en español y en muchos otros idiomas. Visite www.immunize.org/vis

1 Why get vaccinated?

Measles, mumps, and rubella are serious diseases. Before vaccines they were very common, especially among children.

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, muscle pain, loss of appetite, 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 sterility.

Rubella (German Measles)

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

These diseases spread from person to person through the air. You can easily catch them by being around someone who is already infected.

Measles, mumps, and rubella (MMR) vaccine can protect children (and adults) from all three of these diseases.

Thanks to successful vaccination programs these diseases are much less common in the U.S. than they used to be. But if we stopped vaccinating they would return.

2 Who should get MMR vaccine and when?

Children should get 2 doses of MMR vaccine:

- **First Dose**: 12–15 months of age
- **Second Dose**: 4–6 years of age (may be given earlier, if at least 28 days after the 1st dose)

Some infants younger than 12 months should get a dose of MMR if they are traveling out of the country. (This dose will not count toward their routine series.)

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 either been vaccinated or had all three diseases.

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

Children between 1 and 12 years of age can get a "combination" vaccine called MMRV, which contains both MMR and varicella (chickenpox) vaccines. There is a separate Vaccine Information Statement for MMRV.

3 Some people should not get MMR vaccine or should wait.

- Anyone who has ever had a life-threatening allergic reaction to the antibiotic neomycin, or any other component of MMR vaccine, should not get the vaccine. Tell your doctor if you have any severe allergies.
- Anyone who had a life-threatening allergic reaction to a previous dose of MMR or MMRV vaccine should not get another dose.
- Some people who are sick at the time the shot is scheduled may be advised to wait until they recover before getting MMR vaccine.
- Pregnant women should not get MMR vaccine. Pregnant women who need the vaccine should wait until after giving birth. Women should avoid getting pregnant for 4 weeks after vaccination with MMR vaccine.

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

- Tell your doctor if the person getting the vaccine:
  - Has HIV/AIDS, or another disease that affects the immune system
  - Is being treated with drugs that affect the immune system, such as steroids
  - Has any kind of cancer
  - Is being treated for cancer with radiation or drugs
  - Has ever had a low platelet count (a blood disorder)
  - Has gotten another vaccine within the past 4 weeks
  - Has recently had a transfusion or received other blood products

Any of these might be a reason to not get the vaccine, or delay vaccination until later.

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 measles, mumps or rubella.

Most people who get MMR vaccine do not have any serious 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 (about 1 person out of 75)

If these problems occur, it is usually within 6-14 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 reported after a child gets MMR vaccine, including:
  - Deafness
  - Long-term seizures, coma, or lowered consciousness
  - Permanent brain damage

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

5 What if there is a serious reaction?

What should I look for?

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

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

What should I do?

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

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

6 The National Vaccine Injury Compensation Program

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

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

7 How can I learn more?

- Ask your doctor.
- Call your local or state health department.
- Contact the Centers for Disease Control and Prevention (CDC):
  - Call **1-800-232-4636** (**1-800-CDC-INFO**) or
  - Visit CDC's website at **www.cdc.gov/vaccines**

Vaccine Information Statement (Interim)
MMR Vaccine

4/20/2012

42 U.S.C. § 300aa-26

Office Use Only

VACCINE INFORMATION STATEMENT

HPV (Human Papillomavirus) Vaccine—Gardasil®-9: *What You Need to Know*

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

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

1 Why get vaccinated?

Gardasil-9 prevents human papillomavirus (HPV) types that cause many cancers, including:

- **cervical cancer** in females,
- **vaginal and vulvar cancers** in females,
- **anal cancer** in females and males,
- **throat cancer** in females and males, and
- **penile cancer** in males.

In addition, Gardasil-9 prevents HPV types that cause **genital warts** in both females and males.

In the U.S., about 12,000 women get cervical cancer every year, and about 4,000 women die from it. Gardasil-9 can prevent most of these cases of cervical cancer.

Vaccination is not a substitute for cervical cancer screening. This vaccine does not protect against all HPV types that can cause cervical cancer. Women should still get regular Pap tests.

HPV infection usually comes from sexual contact, and most people will become infected at some point in their life. About 14 million Americans, including teens, get infected every year. Most infections will go away and not cause serious problems. But thousands of women and men get cancer and diseases from HPV.

2 HPV vaccine

Gardasil-9 is an FDA-approved HPV vaccine. It is recommended for both males and females. It is routinely given at 11 or 12 years of age, but it may be given beginning at age 9 years through age 26 years.

Three doses of Gardasil-9 are recommended with the second dose given 1–2 months after the first dose and the third dose given 6 months after the first dose.

3 Some people should not get this vaccine

- Anyone who has had a severe, life-threatening allergic reaction to a dose of HPV vaccine should not get another dose.
- Anyone who has a severe (life threatening) allergy to any component of HPV vaccine should not get the vaccine.

  Tell your doctor if you have any severe allergies that you know of, including a severe allergy to yeast.
- HPV vaccine is not recommended for pregnant women. If you learn that you were pregnant when you were vaccinated, there is no reason to expect any problems for you or your baby. Any woman who learns she was pregnant when she got Gardasil-9 vaccine is encouraged to contact the manufacturer's registry for HPV vaccination during pregnancy at 1-800-986-8999. Women who are breastfeeding may be vaccinated.
- If you have a mild illness, such as a cold, you can probably get the vaccine today. If you are moderately or severely ill, you should probably wait until you recover. Your doctor can advise you.

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

4 Risks of a vaccine reaction

With any medicine, including vaccines, there is a chance of side effects. These are usually mild and go away on their own, but serious reactions are also possible.

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

Mild or moderate problems following Gardasil-9:

- Reactions in the arm where the shot was given:
  - Soreness (about 9 people in 10)
  - Redness or swelling (about 1 person in 3)
- 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)

Problems that could happen after any injected vaccine:

- People sometimes faint after a medical procedure, including vaccination. Sitting or lying down for about 15 minutes can help prevent fainting, and injuries caused by a fall. Tell your doctor if you feel dizzy, or have vision changes or ringing in the ears.
- Some people get severe pain in the shoulder and have difficulty moving the arm where a shot was given. This happens very rarely.
- Any medication can cause a severe allergic reaction. Such reactions from a vaccine are very rare, estimated at about 1 in a million doses, and would happen within a few minutes to a few hours after the vaccination.

As with any medicine, there is a very remote chance of a vaccine causing a serious injury or death.

The safety of vaccines is always being monitored. For more information, visit: **www.cdc.gov/vaccinesafety/**.

5 What if there is a serious reaction?

What should I look for?

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

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

What should I do?

If you think it is a **severe allergic reaction** or other emergency that can't wait, call 9-1-1 or get to the nearest hospital. Otherwise, call your doctor.

Afterward, the reaction should be reported to the "Vaccine Adverse Event Reporting System" (VAERS). Your doctor might file this report, or you can do it yourself through the VAERS web site at **www.vaers.hhs.gov**, or by calling **1-800-822-7967**.

VAERS does not give medical advice.

6 The National Vaccine Injury Compensation Program

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

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

7 How can I learn more?

- Ask your health care provider. He or she 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/hpv**

Vaccine Information Statement
HPV Vaccine (Gardasil-9)

03/31/2016

42 U.S.C. § 300aa-26

Office Use Only

VACCINE INFORMATION STATEMENT

Tdap Vaccine

What You Need to Know

(Tetanus, Diphtheria and Pertussis)

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

Hojas de información sobre vacunas están disponibles en español y en muchos otros idiomas. Visite www.immunize.org/vis

1 Why get vaccinated?

Tetanus, diphtheria and **pertussis** are very serious diseases. Tdap vaccine can protect us from these diseases. And, Tdap vaccine given to pregnant women can protect newborn babies against pertussis..

TETANUS (Lockjaw) is rare in the United States today. It causes painful muscle tightening and stiffness, usually all over the body.

- It can lead to tightening of muscles in the head and neck so you can't open your mouth, swallow, or sometimes even breathe. Tetanus kills about 1 out of 10 people who are infected even after receiving the best medical care.

DIPHTHERIA is also rare in the United States today. It can cause a thick coating to form in the back of the throat.

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

PERTUSSIS (Whooping Cough) causes severe coughing spells, which can cause difficulty breathing, vomiting and disturbed sleep.

- It can also lead to weight loss, incontinence, and rib fractures. Up to 2 in 100 adolescents and 5 in 100 adults with pertussis are hospitalized or have complications, which could include pneumonia or death.

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

Before vaccines, as many as 200,000 cases of diphtheria, 200,000 cases of pertussis, and hundreds of cases of tetanus, were reported in the United States each year. Since vaccination began, reports of cases for tetanus and diphtheria have dropped by about 99% and for pertussis by about 80%.

2 Tdap vaccine

Tdap vaccine can protect adolescents and adults from tetanus, diphtheria, and pertussis. One dose of Tdap is routinely given at age 11 or 12. People who did *not* get Tdap at that age should get it as soon as possible.

Tdap is especially important for healthcare professionals and anyone having close contact with a baby younger than 12 months.

Pregnant women should get a dose of Tdap during **every pregnancy**, to protect the newborn from pertussis. Infants are most at risk for severe, life-threatening complications from pertussis.

Another vaccine, called Td, protects against tetanus and diphtheria, but not pertussis. A Td booster should be given every 10 years. Tdap may be given as one of these boosters if you have never gotten Tdap before. Tdap may also be given after a severe cut or burn to prevent tetanus infection.

Your doctor or the person giving you the vaccine can give you more information.

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

3 Some people should not get this vaccine

- A person who has ever had a life-threatening allergic reaction after a previous dose of any diphtheria, tetanus or pertussis containing vaccine, OR has a severe allergy to any part of this vaccine, should not get Tdap vaccine. Tell the person giving the vaccine about any severe allergies.
- Anyone who had coma or long repeated seizures within 7 days after a childhood dose of DTP or DTaP, or a previous dose of Tdap, should not get Tdap, unless a cause other than the vaccine was found. They can still get Td.
- Talk to your doctor if you:
  - have seizures or another nervous system problem,
  - had severe pain or swelling after any vaccine containing diphtheria, tetanus or pertussis,
  - ever had a condition called Guillain-Barré Syndrome (GBS),
  - aren't feeling well on the day the shot is scheduled.

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

4 Risks

With any medicine, including vaccines, there is a chance of side effects. These are usually mild and go away on their own. Serious reactions are also possible but are rare.

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

Mild problems following Tdap
(Did not interfere with activities)

- Pain where the shot was given (about 3 in 4 adolescents or 2 in 3 adults)
- Redness or swelling where the shot was given (about 1 person in 5)
- Mild fever of at least 100.4°F (up to about 1 in 25 adolescents or 1 in 100 adults)
- Headache (about 3 or 4 people in 10)
- Tiredness (about 1 person in 3 or 4)
- Nausea, vomiting, diarrhea, stomach ache (up to 1 in 4 adolescents or 1 in 10 adults)
- Chills, sore joints (about 1 person in 10)
- Body aches (about 1 person in 3 or 4)
- Rash, swollen glands (uncommon)

Moderate problems following Tdap
(Interfered with activities, but did not require medical attention)

- Pain where the shot was given (up to 1 in 5 or 6)
- Redness or swelling where the shot was given (up to about 1 in 16 adolescents or 1 in 12 adults)
- Fever over 102°F (about 1 in 100 adolescents or 1 in 250 adults)
- Headache (about 1 in 7 adolescents or 1 in 10 adults)
- Nausea, vomiting, diarrhea, stomach ache (up to 1 or 3 people in 100)
- Swelling of the entire arm where the shot was given (up to about 1 in 500).

Severe problems following Tdap
(Unable to perform usual activities; required medical attention)

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

Problems that could happen after any vaccine:

- People sometimes faint after a medical procedure, including vaccination. Sitting or lying down for about 15 minutes can help prevent fainting, and injuries caused by a fall. Tell your doctor if you feel dizzy, or have vision changes or ringing in the ears.
- Some people get severe pain in the shoulder and have difficulty moving the arm where a shot was given. This happens very rarely.
- Any medication can cause a severe allergic reaction. Such reactions from a vaccine are very rare, estimated at fewer than 1 in a million doses, and would happen within a few minutes to a few hours after the vaccination.

As with any medicine, there is a very remote chance of a vaccine causing a serious injury or death.

The safety of vaccines is always being monitored. For more information, visit: **www.cdc.gov/vaccinesafety/**

5 What if there is a serious problem?

What should I look for?

- Look for anything that concerns you, such as signs of a severe allergic reaction, very high fever, or unusual behavior.
- Signs of a severe allergic reaction can include hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, and weakness. These would usually start a few minutes to a few hours after the vaccination.

What should I do?

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

VAERS does not give medical advice.

6 The National Vaccine Injury Compensation Program

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

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

7 How can I learn more?

- Ask your doctor. He or she can give you the vaccine package insert or suggest other sources of information.
- Call your local or state health department.
- Contact the Centers for Disease Control and Prevention (CDC):
  - Call **1-800-232-4636** (**1-800-CDC-INFO**) or
  - Visit CDC's website at **www.cdc.gov/vaccines**

Vaccine Information Statement
Tdap Vaccine

2/24/2015

42 U.S.C. § 300aa-26

Office Use Only

VACCINE INFORMATION STATEMENT

Pneumococcal Polysaccharide Vaccine

What You Need to Know

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

Hojas de información sobre vacunas están disponibles en español y en muchos otros idiomas. Visite www.immunize.org/vis

1 Why get vaccinated?

Vaccination can protect older adults (and some children and younger adults) from **pneumococcal disease**.

Pneumococcal disease is caused by bacteria that can spread from person to person through close contact. It can cause ear infections, and it can also lead to more serious infections of the:

- Lungs (pneumonia),
- Blood (bacteremia), and
- Covering of the brain and spinal cord (meningitis). Meningitis can cause deafness and brain damage, and it can be fatal.

Anyone can get pneumococcal disease, but children under 2 years of age, people with certain medical conditions, adults over 65 years of age, and cigarette smokers are at the highest risk.

About 18,000 older adults die each year from pneumococcal disease in the United States.

Treatment of pneumococcal infections with penicillin and other drugs used to be more effective. But some strains of the disease have become resistant to these drugs. This makes prevention of the disease, through vaccination, even more important.

2 Pneumococcal polysaccharide vaccine (PPSV23)

Pneumococcal polysaccharide vaccine (PPSV23) protects against 23 types of pneumococcal bacteria. It will not prevent all pneumococcal disease.

PPSV23 is recommended for:

- All adults 65 years of age and older,
- Anyone 2 through 64 years of age with certain long-term health problems,
- Anyone 2 through 64 years of age with a weakened immune system,
- Adults 19 through 64 years of age who smoke cigarettes or have asthma.

Most people need only one dose of PPSV. A second dose is recommended for certain high-risk groups. People 65 and older should get a dose even if they have gotten one or more doses of the vaccine before they turned 65.

Your healthcare provider can give you more information about these recommendations.

Most healthy adults develop protection within 2 to 3 weeks of getting the shot.

3 Some people should not get this vaccine

- Anyone who has had a life-threatening allergic reaction to PPSV should not get another dose.
- Anyone who has a severe allergy to any component of PPSV should not receive it. Tell your provider if you have any severe allergies.
- Anyone who is moderately or severely ill when the shot is scheduled may be asked to wait until they recover before getting the vaccine. Someone with a mild illness can usually be vaccinated.
- Children less than 2 years of age should not receive this vaccine.
- There is no evidence that PPSV is harmful to either a pregnant woman or to her fetus. However, as a precaution, women who need the vaccine should be vaccinated before becoming pregnant, if possible.

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

VACCINE INFORMATION STATEMENT

Influenza (Flu) Vaccine (Inactivated or Recombinant): *What you need to know*

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

Hojas de información sobre vacunas están disponibles en español y en muchos otros idiomas. Visite www.immunize.org/vis

1 Why get vaccinated?

Influenza ("flu") is a contagious disease that spreads around the United States every year, usually between October and May.

Flu is caused by influenza viruses, and is spread mainly by coughing, sneezing, and close contact.

Anyone can get flu. Flu strikes suddenly and can last several days. Symptoms vary by age, but can include:

- fever/chills
- sore throat
- muscle aches
- fatigue
- cough
- headache
- runny or stuffy nose

Flu can also lead to pneumonia and blood infections, and cause diarrhea and seizures in children. If you have a medical condition, such as heart or lung disease, flu can make it worse.

Flu is more dangerous for some people. Infants and young children, people 65 years of age and older, pregnant women, and people with certain health conditions or a weakened immune system are at greatest risk.

Each year **thousands of people in the United States die from flu**, and many more are hospitalized.

Flu vaccine can:

- keep you from getting flu,
- make flu less severe if you do get it, and
- keep you from spreading flu to your family and other people.

2 Inactivated and recombinant flu vaccines

A dose of flu vaccine is recommended every flu season. Children 6 months through 8 years of age may need two doses during the same flu season. Everyone else needs only one dose each flu season.

Some inactivated flu vaccines contain a very small amount of a mercury-based preservative called thimerosal. Studies have not shown thimerosal in vaccines to be harmful, but flu vaccines that do not contain thimerosal are available.

There is no live flu virus in flu shots. **They cannot cause the flu.**

There are many flu viruses, and they are always changing. Each year a new flu vaccine is made to protect against three or four viruses that are likely to cause disease in the upcoming flu season. But even when the vaccine doesn't exactly match these viruses, it may still provide some protection.

Flu vaccine cannot prevent:

- flu that is caused by a virus not covered by the vaccine, or
- illnesses that look like flu but are not.

It takes about 2 weeks for protection to develop after vaccination, and protection lasts through the flu season.

3 Some people should not get this vaccine

Tell the person who is giving you the vaccine:

- **If you have any severe, life-threatening allergies.** If you ever had a life-threatening allergic reaction after a dose of flu vaccine, or have a severe allergy to any part of this vaccine, you may be advised not to get vaccinated. Most, but not all, types of flu vaccine contain a small amount of egg protein.
- **If you ever had Guillain-Barré Syndrome (also called GBS).** Some people with a history of GBS should not get this vaccine. This should be discussed with your doctor.
- **If you are not feeling well.** It is usually okay to get flu vaccine when you have a mild illness, but you might be asked to come back when you feel better.

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

4 Risks of a vaccine reaction

With any medicine, including vaccines, there is a chance of reactions. These are usually mild and go away on their own, but serious reactions are also possible.

Most people who get a flu shot do not have any problems with it.

Minor problems following a flu shot include:

- soreness, redness, or swelling where the shot was given
- hoarseness
- sore, red or itchy eyes
- cough
- fever
- aches
- headache
- itching
- fatigue

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

More serious problems following a flu shot can include the following:

- There may be a small increased risk of Guillain-Barré Syndrome (GBS) after inactivated flu vaccine. This risk has been estimated at 1 or 2 additional cases per million people vaccinated. This is much lower than the risk of severe complications from flu, which can be prevented by flu vaccine.
- Young children who get the flu shot along with pneumococcal vaccine (PCV13) and/or DTaP vaccine at the same time might be slightly more likely to have a seizure caused by fever. Ask your doctor for more information. Tell your doctor if a child who is getting flu vaccine has ever had a seizure.

Problems that could happen after any injected vaccine:

- People sometimes faint after a medical procedure, including vaccination. Sitting or lying down for about 15 minutes can help prevent fainting, and injuries caused by a fall. Tell your doctor if you feel dizzy, or have vision changes or ringing in the ears.
- Some people get severe pain in the shoulder and have difficulty moving the arm where a shot was given. This happens very rarely.
- Any medication can cause a severe allergic reaction. Such reactions from a vaccine are very rare, estimated at about 1 in a million doses, and would happen within a few minutes to a few hours after the vaccination.

As with any medicine, there is a very remote chance of a vaccine causing a serious injury or death.

The safety of vaccines is always being monitored. For more information, visit: **www.cdc.gov/vaccinesafety/**

5 What if there is a serious reaction?

What should I look for?

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

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

What should I do?

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

VAERS does not give medical advice.

6 The National Vaccine Injury Compensation Program

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

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

7 How can I learn more?

- Ask your healthcare provider. He or she 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/flu**

Vaccine Information Statement

Inactivated Influenza Vaccine

08/07/2015

Office Use Only

42 U.S.C. § 300aa-26

VACCINE INFORMATION STATEMENT

Influenza (Flu) Vaccine (Live, Intranasal): *What You Need to Know*

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

Hojas de información sobre vacunas están disponibles en español y en muchos otros idiomas. Visite www.immunize.org/vis

1 Why get vaccinated?

Influenza ("flu") is a contagious disease that spreads around the United States every year, usually between October and May.

Flu is caused by influenza viruses, and is spread mainly by coughing, sneezing, and close contact.

Anyone can get flu. Flu strikes suddenly and can last several days. Symptoms vary by age, but can include:

- fever/chills
- sore throat
- muscle aches
- fatigue
- cough
- headache
- runny or stuffy nose

Flu can also lead to pneumonia and blood infections, and cause diarrhea and seizures in children. If you have a medical condition, such as heart or lung disease, flu can make it worse.

Flu is more dangerous for some people. Infants and young children, people 65 years of age and older, pregnant women, and people with certain health conditions or a weakened immune system are at greatest risk.

Each year **thousands of people in the United States die from flu**, and many more are hospitalized.

Flu vaccine can:

- keep you from getting flu,
- make flu less severe if you do get it, and
- keep you from spreading flu to your family and other people.

2 Live, attenuated flu vaccine—LAIV, Nasal Spray

A dose of flu vaccine is recommended every flu season. Children younger than 9 years of age may need two doses during the same flu season. Everyone else needs only one dose each flu season.

The **live, attenuated influenza vaccine** (called LAIV) may be given to healthy, non-pregnant people **2 through 49 years of age**. It may safely be given at the same time as other vaccines.

LAIV is sprayed into the nose. LAIV does not contain thimerosal or other preservatives. It is made from weakened flu virus and **does not cause flu.**

There are many flu viruses, and they are always changing. Each year LAIV is made to protect against four viruses that are likely to cause disease in the upcoming flu season. But even when the vaccine doesn't exactly match these viruses, it may still provide some protection.

Flu vaccine cannot prevent:

- flu that is caused by a virus not covered by the vaccine, or
- illnesses that look like flu but are not.

It takes about 2 weeks for protection to develop after vaccination, and protection lasts through the flu season.

3 Some people should not get this vaccine

Some people should not get LAIV because of age, health conditions, or other reasons. Most of these people should get an injected flu vaccine instead. Your healthcare provider can help you decide.

Tell the provider if you or the person being vaccinated:

- have any allergies, including an allergy to eggs, or have ever had an allergic reaction to an influenza vaccine.
- have ever had Guillain-Barré Syndrome (also called GBS).
- have any long-term heart, breathing, kidney, liver, or nervous system problems.
- have asthma or breathing problems, or are a child who has had wheezing episodes.
- are pregnant.
- are a child or adolescent who is receiving aspirin or aspirin-containing products.
- have a weakened immune system.
- will be visiting or taking care of someone, within the next 7 days, who requires a protected environment (for example, following a bone marrow transplant)

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

VACCINE INFORMATION STATEMENT

Meningococcal Vaccines

What You Need to Know

Many Vaccine Information Statements are available in Spanish and other languages. See 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 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 covering of the brain and the spinal cord.

Meningococcal disease also causes blood infections.

About 1,000 – 1,200 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 live, another 11%-19% lose their arms or legs, have problems with their nervous systems, become deaf or 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 16-21 years. Children with certain medical conditions, such as lack of a spleen, have an increased risk of getting meningococcal disease. College freshmen living in dorms are also at increased risk.

Meningococcal infections can be treated with drugs such as penicillin. Still, many people who get the disease die 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**) is the preferred vaccine for people 55 years of age and younger.
- Meningococcal polysaccharide vaccine (**MPSV4**) has been available since the 1970s. It 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. There are other types of meningococcal disease; the vaccines do not protect against these.

3 Who should get meningococcal vaccine and when?

Routine Vaccination

Two doses of MCV4 are recommended for adolescents 11 through 18 years of age: the first dose at 11 or 12 years of age, with a booster dose at age 16.

Adolescents in this age group with HIV infection should get three doses: 2 doses 2 months apart at 11 or 12 years, plus a booster at age 16.

If the first dose (or series) is given between 13 and 15 years of age, the booster should be given between 16 and 18. If the first dose (or series) is given after the 16th birthday, a booster is not needed.

Other People at Increased Risk

- College freshmen living in dormitories.
- Laboratory personnel 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 persistent complement component deficiency (an immune system disorder).
- People who might have been exposed to meningitis during an outbreak.

Children between 9 and 23 months of age, and anyone else with certain medical conditions need 2 doses for adequate protection. Ask your doctor about the number and timing of doses, and the need for booster doses.

MCV4 is the preferred vaccine for people in these groups who are 9 months through 55 years of age. MPSV4 can be used for adults older than 55.

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

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 MCV4 or MPSV4 vaccine should not get another dose of either vaccine.
- 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.*
- Anyone who is moderately or severely ill at the time the shot is scheduled should probably wait until they recover. Ask your doctor. People with a mild illness can usually get the vaccine.
- Meningococcal vaccines may be given to pregnant women. MCV4 is a fairly new vaccine and has not been studied in pregnant women as much as MPSV4 has. It should be used only if clearly needed. The manufacturers of MCV4 maintain pregnancy registries for women who are vaccinated while pregnant.

Except for children with sickle cell disease or without a working spleen, 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.

Brief fainting spells and related symptoms (such as jerking or seizure-like movements) can follow a vaccination. They happen most often with adolescents, and they can result in falls and injuries.

Sitting or lying down for about 15 minutes after getting the shot – especially if you feel faint – can help prevent these injuries.

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 mild fever.

Severe problems

Serious allergic reactions, within a few minutes to a few hours of the shot, are very rare.

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 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 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 can learn about the program and about filing a claim by calling **1-800-338-2382** or visiting the VICP website at **www.hrsa.gov/vaccinecompensation**.

8 How can I learn more?

- Your doctor can give you the vaccine package insert or suggest other sources of information.
- Call your local or state health department.
- Contact the Centers for Disease Control and Prevention (CDC):
  - Call **1-800-232-4636 (1-800-CDC-INFO)** or
  - Visit CDC's website at **www.cdc.gov/vaccines**

Vaccine Information Statement (Interim)

Meningococcal Vaccines

10/14/2011

42 U.S.C. § 300aa-26

4 Risks of a vaccine reaction

With any medicine, including vaccines, there is a chance of side effects. These are usually mild and go away on their own, but serious reactions are also possible.

About half of people who get PPSV have mild side effects, such as redness or pain where the shot is given, which go away within about two days.

Less than 1 out of 100 people develop a fever, muscle aches, or more severe local reactions.

Problems that could happen after any vaccine:

- People sometimes faint after a medical procedure, including vaccination. Sitting or lying down for about 15 minutes can help prevent fainting, and injuries caused by a fall. Tell your doctor if you feel dizzy, or have vision changes or ringing in the ears.
- Some people get severe pain in the shoulder and have difficulty moving the arm where a shot was given. This happens very rarely.
- Any medication can cause a severe allergic reaction. Such reactions from a vaccine are very rare, estimated at about 1 in a million doses, and would happen within a few minutes to a few hours after the vaccination.

As with any medicine, there is a very remote chance of a vaccine causing a serious injury or death.

The safety of vaccines is always being monitored. For more information, visit: **www.cdc.gov/vaccinesafety/**

5 What if there is a serious reaction?

What should I look for?

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

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

What should I do?

If you think it is a severe allergic reaction or other emergency that can't wait, call 9-1-1 or get to the nearest hospital. Otherwise, call your doctor.

Afterward, the reaction should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your doctor might file this report, or you can do it yourself through the VAERS web site at **www.vaers.hhs.gov**, or by calling **1-800-822-7967**.

VAERS does not give medical advice.

6 How can I learn more?

- Ask your doctor. He or she 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**

Sometimes LAIV should be delayed. Tell the provider if you or the person being vaccinated:

- are not feeling well. The vaccine could be delayed until you feel better.
- have gotten any other vaccines in the past 4 weeks. *Live* vaccines given too close together might not work as well.
- have taken influenza antiviral medication in the past 48 hours.
- have a very stuffy nose.

4 Risks of a vaccine reaction

With any medicine, including vaccines, there is a chance of reactions. These are usually mild and go away on their own, but serious reactions are also possible.

Most people who get LAIV do not have any problems with it. Reactions to LAIV may resemble a very mild case of flu.

Problems that have been reported following LAIV:

Children and adolescents 2-17 years of age:

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

Adults 18-49 years of age:

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

Problems that could happen after any vaccine:

- Any medication can cause a severe allergic reaction. Such reactions from a vaccine are very rare, estimated at about 1 in a million doses, and would happen within a few minutes to a few hours after the vaccination.

As with any medicine, there is a very small chance of a vaccine causing a serious injury or death.

The safety of vaccines is always being monitored. For more information, visit: **www.cdc.gov/vaccinesafety/**

5 What if there is a serious reaction?

What should I look for?

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

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

What should I do?

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

VAERS does not give medical advice.

6 The National Vaccine Injury Compensation Program

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

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

7 How can I learn more?

- Ask your healthcare provider. He or she 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/flu**

Vaccine Information Statement

Live Attenuated Influenza Vaccine

08/07/2015

42 U.S.C. § 300aa-26

Office Use Only

How do I get a copy of the NJIIS immunization record?

There are two ways to get a copy of your/your child's immunization record:

- If you are a parent, legal guardian of a minor or a registrant 18 years of age or older you can request a copy from your health care provider who participates in NJIIS.
- A parent, legal guardian of a minor or a registrant 18 years of age or older can also complete a "Request for Copy of NJIIS Immunization Record" form available at http://njiis.nj.gov/njiis/html/forms.html and mail to the address listed on the form.

How do I make changes to my child's record on NJIIS?

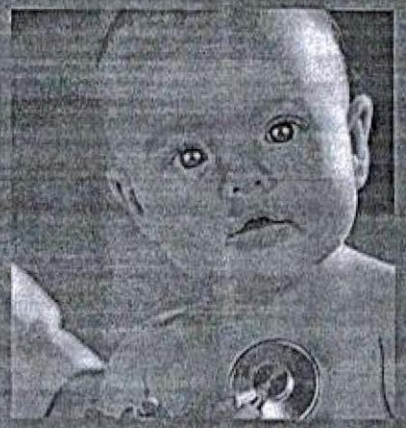
Requests for changes to a registrant's medical information can be made by completing a "Request for Change to NJIIS Immunization Record" form available on http://njiis.nj.gov/njiis/html/forms.html and mail to the address listed on the form.

Your participating NJIIS provider may be able to make changes to demographic information (changes in address, phone number, and contact information) on NJIIS. Talk to your provider's office for more information.

NJIIS
NEW JERSEY IMMUNIZATION INFORMATION SYSTEM

Where can I get more information about NJIIS?

- The NJIIS webpage, http://njiis.nj.gov/njiis
- The NJIIS forms are available online at http://njiis.nj.gov/njiis/html/forms.html
- N.J.S.A. 26:4-131 et. seq., particularly 26:4-134(i) and N.J.A.C. 8:57-3
- The New Jersey Vaccine Preventable Disease Program mailing address is PO Box 369, Trenton, New Jersey 08625-0369.
- The New Jersey Vaccine Preventable Disease Program telephone number for other questions regarding NJIIS is 609-826-4860.



Make sure your child gets all their vaccinations on time-every time to prevent diseases such as measles, mumps, rubella, hepatitis, polio, chickenpox, and whooping cough.

Enroll your child in NJIIS today!

NJIIS
NEW JERSEY IMMUNIZATION INFORMATION SYSTEM

C1821
11/12

Your Child's Best Shot:

Ask Your Doctor About the Immunization Registry

NJIIS
NEW JERSEY IMMUNIZATION INFORMATION SYSTEM

Chris Christie, Governor
Kim Guadagno, Lt. Governor

NJ Health
New Jersey Department of Health

Mary E. O'Dowd, MPH
Commissioner

What is NJIIS?

The New Jersey Immunization Information System (NJIIS) is a secure, computerized, statewide immunization registry that can help parents and health care providers keep track of immunizations given from birth through adulthood. NJIIS is managed by the New Jersey Department of Health, Vaccine Preventable Disease Program and has been operating since 1997.

What are the benefits of NJIIS?

NJIIS is an easy and convenient way to keep track of your child's immunization record in a secure, confidential, and centralized location.

- No more lost records, or trying to remember dates and vaccines. NJIIS can provide a complete and current record of your child's immunizations even if a family moves or switches health care providers or insurance companies.
- NJIIS helps health care providers know what vaccines your child needs for the next appointment. This helps avoid unnecessary vaccinations and catch up with missed doses.
- NJIIS provides an official immunization record of your child's immunization history for child care, school, camp and college enrollment.

Who has access to NJIIS?

Only authorized users who have signed a confidentiality agreement can access information on the registry such as:

- Health care providers
- Licensed child care centers, schools or college health nurses
- Local and state health departments
- Health insurance plans

How is information on NJIIS used?

Health care providers use NJIIS to record and review a patient's immunization status and consolidate immunization record histories from other health care providers. They can also record results for other important preventive screenings such as tuberculosis, lead and newborn hearing tests on NJIIS.

Licensed child care centers, schools or college health nurses use NJIIS to access students' immunization records to follow-up on State immunization requirements for enrollment.

Health insurance plans use NJIIS to determine how well their members are receiving preventive health services and immunizations from their participating health care providers.

Local and state health departments use NJIIS to identify populations at high risk for vaccine preventable diseases to prevent disease outbreaks in a community.

How do I enroll in NJIIS?

Since 2004, all children born on or after January 1, 1998 in New Jersey are automatically enrolled in NJIIS.

If you, or your child, were born before January 1, 1998 and would like to participate in NJIIS, complete a "NJIIS Consent to Participate" form at your provider's office or obtain a form at http://njiis.nj.gov/njiis/html/forms.html and mail to the address listed on the form.

How do I opt out of enrolling, or withdraw from NJIIS?

A parent or legal guardian of a newborn can decline from enrolling in NJIIS by completing a "Declination of Newborn Automatic Enrollment" form available at the birthing facility or obtaining a form at http://njiis.nj.gov/njiis/html/forms.html and mail to the address listed on the form.

If you want to withdraw participation at a later time, a parent, legal guardian of a minor or a person 18 years of age or older already in NJIIS may complete a "Registrant Withdrawal from NJIIS" form available from your participating provider or obtain the form at http://njiis.nj.gov/ njiis/html/forms.html and mail to the address listed on the form.

VINELAND PEDIATRICS, PA
NOTICE OF PRIVACY PRACTICES
As required by the Privacy Regulations Created as a Result of the Health Insurance Portability and Accountability Act of 1996 (HIPAA)
Effective Date of This Notice: April 28, 2003

THIS NOTICE DESCRIBES HOW MEDICAL INFORMATION ABOUT YOU (AS A PATIENT OF THIS PRACTICE) MAY BE USED AND DISCLOSED, AND HOW YOU CAN GET ACCESS TO THIS INFORMATION. PLEASE REVIEW IT CAREFULLY.

OUR COMMITMENT TO YOUR PRIVACY

The practice is dedicated to maintaining the privacy of your protected health information (PHI). In conducting our business, we will create records regarding you and the treatment and services we provide to you. We are required by law to maintain the confidentiality of health information that identifies you. We also are required by law to provide you with this notice of our legal duties and the privacy practices that we maintain in our practice concerning your PHI. By federal and state law, we must follow the terms of the notice of privacy practices that we have in effect at the time.

We realize these laws are complicated, but we must provide you with information regarding how we may use and disclose your PHI, your privacy rights in regard to your PHI and our obligations concerning the use and disclosure of your PHI

The terms of this notice apply to all records containing your PHI that are created or retained by our practice. We reserve the right to revise or amend this Notice of Privacy Practices at any time. Any revision or amendment to this notice will be effective for all of your records that our practice has created or maintained in the past, and for any of your records that we may create or maintain in the future. Our practice will post a copy of our current Notice in our office in a visible location at all times, and you may request a copy of our most current Notice at any time.

Your protected health information may be used and disclosed by the physicians, our office staff and others outside of our office who are involved in providing health care services to you. This information may also be used and disclosed to pay your health care bills and to support the operation of the practice. For disclosures not outlined below we will request your written authorization.

WE MAY USE AND DISCLOSE YOUR PROTECTED HEALTH INFORMATION (PHI) IN THE FOLLOWING WAYS:

TREATMENT: We will use and disclose your protected health information to provide, coordinate, or manage your health care and any related services. This includes the coordination or management of your health care with a third party who provides services to you, e.g. discussing your history and condition with other providers involved in your care, calling a prescription in to a pharmacy, arranging for durable medical equipment. We may send you information such as test results, recommendations immunization records and referrals. We may disclose PHI regarding a child including immunization records and medication dosages to parents and other patient-representatives such as but not limited to grandparents accompanying a child to the office, school nurses and teachers, and daycare providers.

PAYMENT: Our practice may use and disclose your PHI in order to bill and collect payment for the services you may receive from us. This may include contacting your health insurer to determine eligibility for benefits and preauthorization for care. We may also disclose PHI to a laboratory for ordered tests.

HEALTH CARE OPERATIONS: Our practice may use and disclose your PHI to operate our business. Examples of this include, but are not limited to, using a sign-in sheet, calling you by name in the reception area, appointment reminders or mailed recall notices. We may use your PHI to send you health-related or insurance information which may be of interest to you. Your PHI is accessible by your insurance carrier upon request, per your contract with them. They may make or request copies of records or specific PHI and inspect records during periodic audits.

The practice will also use and disclose your PHI when we are required to do so by federal, state or local law. Examples of this include but are not limited to such things as subpoenas, requests from DYFS, and reporting dog bites, communicable diseases, vital statistics and child abuse or neglect.

YOUR RIGHTS REGARDING YOUR PHI

You have the right to inspect and have a copy of your PHI that may be used to make decisions about you. There may be limitations on the information accessible to you. You may ask us to amend your health information if you believe it is incorrect or incomplete for as long as the information is kept by or for our practice. You have a right to request a restriction of the use of your PHI. We are not required to agree to your request; however, if we do agree, we will abide by the agreement unless emergency treatment is needed. Please note that in the case of children whose custody and health care issues have been addressed by the court system, we require that a copy of the court documents accompany a written request pertaining to one of the parties. Legal decrees may supercede an individual's request for PHI restriction. You have the right to request to receive confidential communications from us by alternative means or at an alternative location. General communication is to the address and phone numbers of the child's guarantor, who is usually the parent with whom the child resides. You have the right to receive an accounting of certain disclosures we have made, if any, of your PHI. This right applies to disclosures for purposes other than treatment, payment or healthcare operations as described in this Notice of Privacy Practices. It excludes disclosures we may have made to you, those made upon your request, to patient-representatives involved in their care, or for notification purposes. You have the right to obtain a paper copy of this notice from us, upon request. There may be a charge for copies of records that you request. Please contact a Privacy Officer below with any questions or requests about your PHI.

PRIVACY CONTACTS

Deborah McMaster, Office Manager or Olabode Ogidan, MD, Physician Manager
Vineland Pediatrics, PA, 1138 E. Chestnut Ave., Vineland, NJ 08360, phone 856-692-1108, fax 856-692-2077

If you feel your privacy rights have been violated, you may file a complaint with the practice in writing to the Privacy Contact above, or with the Secretary of the Department for Health and Human Services. You will not be penalized for filing a complaint.