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.

CDC
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

42 U.S.C. § 300aa-26

Office Use Only

VACCINE INFORMATION STATEMENT

DTaP Vaccine

(Diphtheria, Tetanus and Pertussis)

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?

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

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

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

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

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

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

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

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

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

2 Who should get DTaP vaccine and when?

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

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

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

3 Some children should not get DTaP vaccine or should wait

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

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

4 Older children and adults

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

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

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

5 What are the risks from DTaP vaccine?

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

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

Mild problems (common)

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

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

Other mild problems include:

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

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

Moderate problems (uncommon)

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

Severe problems (very rare)

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

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

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

6 What if there is a 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.

7 The National Vaccine Injury Compensation Program

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

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

8 How can I learn more?

- Ask your doctor.
- 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

DTaP Vaccine

5/17/2007

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

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

Pneumococcal Conjugate Vaccine (PCV13)

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 both children and 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).

Pneumococcal pneumonia is most common among adults. Pneumococcal meningitis can cause deafness and brain damage, and it kills about 1 child in 10 who get it.

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

Before there was a vaccine, the United States saw:

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

in children under 5 each year from pneumococcal disease. Since vaccine became available, severe pneumococcal disease in these children has fallen by 88%.

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

Treatment of pneumococcal infections with penicillin and other drugs is not as effective as it used to be, because some strains of the disease have become resistant to these drugs. This makes prevention of the disease, through vaccination, even more important.

2 PCV13 vaccine

Pneumococcal conjugate vaccine (called PCV13) protects against 13 types of pneumococcal bacteria.

PCV13 is routinely given to children at 2, 4, 6, and 12–15 months of age. It is also recommended for children and adults 2 to 64 years of age with certain health conditions, and for all adults 65 years of age and older. Your doctor can give you details.

3 Some people should not get this vaccine

Anyone who has ever had a life-threatening allergic reaction to a dose of this vaccine, to an earlier pneumococcal vaccine called PCV7, or to any vaccine containing diphtheria toxoid (for example, DTaP), should not get PCV13.

Anyone with a severe allergy to any component of PCV13 should not get the vaccine. *Tell your doctor if the person being vaccinated has any severe allergies.*

If the person scheduled for vaccination is not feeling well, your healthcare provider might decide to reschedule the shot on another day.

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.

Problems reported following PCV13 varied by age and dose in the series. The most common problems reported among children were:

- About half became drowsy after the shot, had a temporary loss of appetite, or had redness or tenderness where the shot was given.
- About 1 out of 3 had swelling where the shot was given.
- About 1 out of 3 had a mild fever, and about 1 in 20 had a fever over 102.2°F.
- Up to about 8 out of 10 became fussy or irritable.

Adults have reported pain, redness, and swelling where the shot was given; also mild fever, fatigue, headache, chills, or muscle pain.

Young children who get PCV13 along with inactivated flu vaccine at the same time may be at increased risk for seizures caused by fever. Ask your doctor for more information.

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

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 older children and adults 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 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—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 or 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/vaccines**

Vaccine Information Statement

PCV13 Vaccine

11/05/2015

42 U.S.C. § 300aa-26

Office Use Only

VACCINE INFORMATION STATEMENT

Hib Vaccine

(*Haemophilus Influenzae* Type b)

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?

Haemophilus influenzae type b (Hib) disease is a serious disease caused by bacteria. It usually affects children under 5 years old. It can also affect adults with certain medical conditions.

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

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

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

Before Hib vaccine, about 20,000 children in the United States under 5 years old got Hib disease each year, and about 3% - 6% of them died.

Hib vaccine can prevent Hib disease. Since use of Hib vaccine began, the number of cases of invasive Hib disease has decreased by more than 99%. Many more children would get Hib disease if we stopped vaccinating.

2 Hib vaccine

Several different brands of Hib vaccine are available. Your child will receive either 3 or 4 doses, depending on which vaccine is used.

Doses of Hib vaccine are usually recommended at these ages:

- First Dose: 2 months of age
- Second Dose: 4 months of age
- Third Dose: 6 months of age (if needed, depending on brand of vaccine)
- Final/Booster Dose: 12–15 months of age

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

Hib vaccine may be given as part of a combination vaccine. Combination vaccines are made when two or more types of vaccine are combined together into a single shot, so that one vaccination can protect against more than one disease.

Children over 5 years old and adults usually do not need Hib vaccine. But it may be recommended for older children or adults with asplenia or sickle cell disease, before surgery to remove the spleen, or following a bone marrow transplant. It may also be recommended for people 5 to 18 years old with HIV. Ask your doctor for details.

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

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

3 Some people should not get this vaccine

Hib vaccine should not be given to infants younger than 6 weeks of age.

A person who has ever had a life-threatening allergic reaction after a previous dose of Hib vaccine, OR has a severe allergy to any part of this vaccine, should not get Hib vaccine. *Tell the person giving the vaccine about any severe allergies.*

People who are mildly ill can get Hib vaccine. People who are moderately or severely ill should probably wait until they recover. Talk to your healthcare provider if the person getting the vaccine isn't feeling well on the day the shot is scheduled.

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. Serious reactions are also possible but are rare.

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

Mild Problems following Hib vaccine:

- redness, warmth, or swelling where the shot was given
- fever

These problems are uncommon. If they occur, they usually begin soon after the shot and last 2 or 3 days.

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 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.

Older children, adolescents, and adults might also experience these problems 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.

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 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

Hib Vaccine

4/02/2015

42 U.S.C. § 300aa-26

Office Use Only

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.

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

42 U.S.C. § 300aa-26

Office Use Only

VACCINE INFORMATION STATEMENT

Hepatitis B Vaccine

What You Need to Know

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

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

1 What is hepatitis B?

Hepatitis B is a serious infection that affects the liver. It is caused by the hepatitis B virus.

- In 2009, about 38,000 people became infected with hepatitis B.
- Each year about 2,000 to 4,000 people die in the United States from cirrhosis or liver cancer caused by hepatitis B.

Hepatitis B can cause:

Acute (short-term) illness. This can lead to:

- loss of appetite
- diarrhea and vomiting
- tiredness
- jaundice (yellow skin or eyes)
- pain in muscles, joints, and stomach

Acute illness, with symptoms, is more common among adults. Children who become infected usually do not have symptoms.

Chronic (long-term) infection. Some people go on to develop chronic hepatitis B infection. Most of them do not have symptoms, but the infection is still very serious, and can lead to:

- liver damage (cirrhosis)
- liver cancer
- death

Chronic infection is more common among infants and children than among adults. People who are chronically infected can spread hepatitis B virus to others, even if they don't look or feel sick. Up to 1.4 million people in the United States may have chronic hepatitis B infection.

Hepatitis B virus is easily spread through contact with the blood or other body fluids of an infected person. People can also be infected from contact with a contaminated object, where the virus can live for up to 7 days.

- A baby whose mother is infected can be infected at birth;
- Children, adolescents, and adults can become infected by:
  - contact with blood and body fluids through breaks in the skin such as bites, cuts, or sores;
  - contact with objects that have blood or body fluids on them such as toothbrushes, razors, or monitoring and treatment devices for diabetes;
  - having unprotected sex with an infected person;
  - sharing needles when injecting drugs;
  - being stuck with a used needle.

2 Hepatitis B vaccine: Why get vaccinated?

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

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

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

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

3 Who should get hepatitis B vaccine and when?

Children and adolescents

- Babies normally get 3 doses of hepatitis B vaccine:

  1st Dose: Birth
  2nd Dose: 1-2 months of age
  3rd Dose: 6-18 months of age

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

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

Adults

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

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

- household contacts of people infected with hepatitis B,
- residents and staff in institutions for the developmentally disabled,
- kidney dialysis patients,
- people who travel to countries where hepatitis B is common,
- people with HIV infection.

- Other people may be encouraged by their doctor to get hepatitis B vaccine; for example, adults 60 and older with diabetes. Anyone else who wants to be protected from hepatitis B infection may get the vaccine.
- Pregnant women who are at risk for one of the reasons stated above should be vaccinated. Other pregnant women who want protection may be vaccinated.

Adults getting hepatitis B vaccine should get 3 doses—with the second dose given 4 weeks after the first and the third dose 5 months after the second. Your doctor can tell you about other dosing schedules that might be used in certain circumstances.

4 Who should not get hepatitis B vaccine?

- Anyone with a life-threatening allergy to yeast, or to any other component of the vaccine, should not get hepatitis B vaccine. Tell your doctor if you have any severe allergies.
- Anyone who has had a life-threatening allergic reaction to a previous dose of hepatitis B vaccine should not get another dose.
- Anyone who is moderately or severely ill when a dose of vaccine is scheduled should probably wait until they recover before getting the vaccine.

Your doctor can give you more information about these precautions.

Note: You might be asked to wait 28 days before donating blood after getting hepatitis B vaccine. This is because the screening test could mistake vaccine in the bloodstream (which is not infectious) for hepatitis B infection.

5 What are the risks from hepatitis B vaccine?

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

The vaccine contains non-infectious material, and cannot cause hepatitis B infection.

Some mild problems have been reported:

- Soreness where the shot was given (up to about 1 person in 4).
- Temperature of 99.9°F or higher (up to about 1 person in 15).

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

A vaccine, like any medicine, could cause a serious reaction. But the risk of a vaccine causing serious harm, or death, is extremely small. More than 100 million people in the United States have been vaccinated with hepatitis B vaccine.

6 What if there is a serious reaction?

What should I look for?

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

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

What should I do?

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

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

7 The National Vaccine Injury Compensation Program

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

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

8 How can I learn more?

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

Vaccine Information Statement (Interim)

Hepatitis B Vaccine

2/2/2012

Office Use Only

42 U.S.C. § 300aa-26

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 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 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)

Hepatitis A Vaccine

10/25/2011

42 U.S.C. § 300aa-26

Office Use Only

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 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 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 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.

7 The National Vaccine Injury Compensation Program

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

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

8 How can I learn more?

- Ask your doctor.
- 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 Vaccine

10/14/2011

42 U.S.C. § 300aa-26

Office Use Only

VACCINE INFORMATION STATEMENT

HPV Vaccine Cervarix® (Human Papillomavirus)

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 What is HPV?

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

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

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

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

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

2 HPV vaccine: Why get vaccinated?

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

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

The vaccine you are getting is one of **two HPV vaccines that can be given to prevent cervical cancer**. It is given to females only.

The other vaccine may be given to both males and females. It can also prevent most genital warts. It has also been shown to prevent some vaginal, vulvar and anal cancers.

3 Who should get this HPV vaccine and when?

Routine vaccination

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

Why is HPV vaccine given to girls at this age?

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

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

Catch-up vaccination

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

HPV vaccine is given as a 3-dose series

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

Additional (booster) doses are not recommended.

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

4 Some people should not get HPV vaccine or should wait

- Anyone who has ever had a life-threatening allergic reaction to any component of HPV vaccine, or to a previous dose of HPV vaccine, should not get the vaccine. Tell your doctor if the person getting vaccinated has any severe allergies, including an allergy to latex.
- HPV vaccine is not recommended for **pregnant women**. However, receiving HPV vaccine when pregnant is not a reason to consider terminating the pregnancy. Women who are breast feeding may get the vaccine.

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

Any woman who learns she was pregnant when she got this HPV vaccine is encouraged to contact the manufacturer's **HPV in pregnancy registry** at 888-452-9622. This will help us learn how pregnant women respond to the vaccine.

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

5 What are the risks from this vaccine?

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

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

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

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

- Reactions where the shot was given:
  - Pain (about 9 people in 10)
  - Redness or swelling (about 1 person in 2)
- Other mild reactions:
  - Fever of 99.5°F or higher (about 1 person in 8)
  - Headache or fatigue (about 1 person in 2)
  - Nausea, vomiting, diarrhea, or abdominal pain (about 1 person in 4)
  - Muscle or joint pain (up to 1 person in 2)
- Fainting:

Brief fainting spells and related symptoms (such as jerking movements) can happen after any medical procedure, including vaccination. **Sitting or lying down for about 15 minutes after a vaccination can help prevent fainting and injuries caused by falls.** Tell your doctor if the patient feels dizzy or light-headed, or has vision changes or ringing in the ears.

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

6 What if there is a 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.

7 The National Vaccine Injury Compensation Program

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

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

8 How can I learn more?

- Ask your doctor.
- 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

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)

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

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

Office Use Only

42 U.S.C. § 300aa-26