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 included on this statement are likely to be given at the same time during infancy and early childhood. There are separate *Vaccine Information Statements* for other vaccines that are also routinely recommended for young children (measles, mumps, rubella, varicella, rotavirus, influenza, and hepatitis A)

Your child is getting these vaccines today:

☐ DTaP ☐ Hib ☐ Hepatitis B ☐ PCV ☐ Polio

(Provider: Check appropriate boxes.)

1. Why get vaccinated?

Vaccines can prevent disease. Childhood vaccination is essential because it helps provide immunity before children are exposed to potentially life-threatening diseases.

Diphtheria, tetanus, and pertussis (DTaP)

- **Diphtheria (D)** can lead to difficulty breathing, heart failure, paralysis, or death.
- **Tetanus (T)** causes painful stiffening of the muscles. Tetanus can lead to serious health problems, including being unable to open the mouth, having trouble swallowing and breathing, or death.
- **Pertussis (aP)**, also known as "whooping cough," can cause uncontrollable, violent coughing that makes it hard to breathe, eat, or drink. Pertussis can be extremely serious, especially in babies and young children, causing pneumonia, convulsions, brain damage, or death.

Hib (*Haemophilus influenzae* type b) disease

***Haemophilus influenzae* type b** can cause many different kinds of infections. Hib bacteria can cause mild illness, such as ear infections or bronchitis, or they can cause severe illness, such as infections of the blood. Hib infection can also cause pneumonia; severe swelling in the throat, making it hard to breathe; and infections of the blood, joints, bones, and covering of the heart. Severe Hib infection, also called "invasive Hib disease," requires treatment in a hospital and can sometimes result in death.

Hepatitis B

Hepatitis B is a liver disease that can cause mild illness lasting a few weeks, or it can lead to a serious, lifelong illness. Acute hepatitis B infection is a short-term illness that can lead to fever, fatigue, loss of appetite, nausea, vomiting, jaundice (yellow skin or eyes, dark urine, clay-colored bowel movements), and pain in the muscles, joints, and stomach. Chronic hepatitis B infection is a long-term illness that occurs when the hepatitis B virus remains in a person's body. Most people who go on to develop chronic hepatitis B do not have symptoms, but it is still very serious and can lead to liver damage (cirrhosis), liver cancer, and death.

Pneumococcal disease (PCV)

Pneumococcal disease refers to any illness caused by pneumococcal bacteria. These bacteria can cause many types of illnesses, including pneumonia, which is an infection of the lungs. Besides pneumonia, pneumococcal bacteria can also cause ear infections, sinus infections, meningitis (infection of the tissue covering the brain and spinal cord), and bacteremia (infection of the blood). Most pneumococcal infections are mild. However, some can result in long-term problems, such as brain damage or hearing loss. Meningitis, bacteremia, and pneumonia caused by pneumococcal disease can be fatal.

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Polio

Polio (or poliomyelitis) is a disabling and life-threatening disease caused by poliovirus, which can infect a person's spinal cord, leading to paralysis. Most people infected with poliovirus have no symptoms, and many recover without complications. Some people infected with poliovirus will experience sore throat, fever, tiredness, nausea, headache, or stomach pain, and most people with these symptoms will also recover without complications. A smaller group of people will develop more serious symptoms: paresthesia (feeling of pins and needles in the legs), meningitis (infection of the covering of the spinal cord and/or brain), or paralysis (can't move parts of the body) or weakness in the arms, legs, or both. Paralysis can lead to permanent disability and death.

2. DTaP, Hib, hepatitis B, pneumococcal conjugate, and polio vaccines

Infants and children usually need:

- 5 doses of **diphtheria, tetanus, and acellular pertussis vaccine (DTaP)**
- 3 or 4 doses of **Hib vaccine**
- 3 doses of **hepatitis B vaccine**
- 4 doses of **pneumococcal conjugate vaccine (PCV)**
- 4 doses of **polio vaccine**

Some children might need fewer or more than the usual number of doses of some vaccines to have the best protection because of their age at vaccination or other circumstances.

Older children, adolescents, and adults with certain health conditions or other risk factors or who did not get vaccinated earlier might also be recommended to receive 1 or more doses of some of these vaccines.

These vaccines are given as either stand-alone vaccines or as part of a combination vaccine (a type of vaccine that combines more than one vaccine together into one shot).

3. Talk with your health care provider

Tell your vaccination provider if the child getting the vaccine:

For all of these vaccines:

- Has had an **allergic reaction after a previous dose of the vaccine**, or has any **severe, life-threatening allergies**

For DTaP:

- Has had an **allergic reaction after a previous dose of any vaccine that protects against diphtheria, tetanus, or pertussis**
- Has had a **coma, decreased level of consciousness, or prolonged seizures within 7 days after a previous dose of any pertussis vaccine (DTP or DTaP)**
- Has **seizures or another nervous system problem**
- Has ever had **Guillain-Barré syndrome** (also called "GBS")
- Has had **severe pain or swelling after a previous dose of any vaccine that protects against diphtheria or tetanus**

For PCV:

- Has had an **allergic reaction after a previous dose of any type of pneumococcal conjugate vaccine (PCV13, PCV15, PCV20, or an earlier pneumococcal conjugate vaccine known as PCV7), or to any vaccine containing diphtheria toxoid** (for example, DTaP)

In some cases, your child's health care provider may decide to postpone vaccination until a future visit.

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

Your child's health care provider can give you more information.

4. Risks of a vaccine reaction

For all of these vaccines:

- Soreness, redness, swelling, warmth, pain, or tenderness where the shot is given can happen after vaccination.

For DTaP vaccine, Hib vaccine, hepatitis B vaccine, and PCV:

- Fever can happen after vaccination.

For DTaP vaccine:

- Fussiness, feeling tired, loss of appetite, and vomiting sometimes happen after DTaP vaccination.
- More serious reactions, such as seizures, non-stop crying for 3 hours or more, or high fever (over 105°F) after DTaP vaccination happen much less often. Rarely, vaccination is followed by swelling of the entire arm or leg, especially in older children when they receive their fourth or fifth dose.

For PCV:

- Loss of appetite, fussiness (irritability), feeling tired, headache, and chills can happen after PCV vaccination.
- Young children may be at increased risk for seizures caused by fever after a pneumococcal conjugate vaccine if it is administered at the same time as inactivated influenza vaccine. Ask your health care provider for more information.

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

5. What if there is a serious problem?

An allergic reaction could occur after the vaccinated person leaves the clinic. If you see signs of a severe allergic reaction (hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, or weakness), call **9-1-1** and get the person to the nearest hospital.

For other signs that concern you, call your health care provider.

Adverse reactions should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your health care provider will usually file this report, or you can do it yourself. Visit the VAERS website at **www.vaers.hhs.gov** or call **1-800-822-7967**. *VAERS is only for reporting reactions, and VAERS staff members 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. Claims regarding alleged injury or death due to vaccination have a time limit for filing, which may be as short as two years. Visit the VICP website at **www.hrsa.gov/vaccinecompensation** or call **1-800-338-2382** to learn about the program and about filing a claim.

7. How can I learn more?

- Ask your health care provider.
- Call your local or state health department.
- Visit the website of the Food and Drug Administration (FDA) for vaccine package inserts and additional information at **www.fda.gov/vaccines-blood-biologics/vaccines**.
- 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**.

Hepatitis B Vaccine:
What You Need to Know

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1. Why get vaccinated?

Hepatitis B vaccine can prevent **hepatitis B**. Hepatitis B is a liver disease that can cause mild illness lasting a few weeks, or it can lead to a serious, lifelong illness.

- **Acute hepatitis B** is a short-term illness that can lead to fever, fatigue, loss of appetite, nausea, vomiting, jaundice (yellow skin or eyes, dark urine, clay-colored bowel movements), and pain in the muscles, joints, and stomach.
- **Chronic hepatitis B** is a long-term illness that occurs when the hepatitis B virus remains in a person's body. Most people who go on to develop chronic hepatitis B do not have symptoms, but it is still very serious and can lead to liver damage (cirrhosis), liver cancer, and death. Chronically infected people can spread hepatitis B virus to others, even if they do not feel or look sick themselves.

Hepatitis B is spread when blood, semen, or other body fluid infected with the hepatitis B virus enters the body of a person who is not infected. People can become infected through:

- Birth (if a pregnant woman has hepatitis B, her baby can become infected)
- Sharing items such as razors or toothbrushes with an infected person
- Contact with the blood or open sores of an infected person
- Sex with an infected partner
- Sharing needles, syringes, or other drug-injection equipment
- Exposure to blood from needlesticks or other sharp instruments

Most people who are vaccinated with hepatitis B vaccine are immune for life.

2. Hepatitis B vaccine

Hepatitis B vaccine is usually given as 2, 3, or 4 shots.

Infants should get their first dose of hepatitis B vaccine at birth and will usually complete the series at 6–18 months of age. **The birth dose of hepatitis B vaccine is an important part of preventing long-term illness in infants and the spread of hepatitis B in the United States.**

Anyone **59 years of age or younger** who has not yet gotten the vaccine should be vaccinated.

Hepatitis B vaccination is recommended for **adults 60 years or older** at increased risk of exposure to hepatitis B who were not vaccinated previously. **Adults 60 years or older** who are not at increased risk and were not vaccinated in the past may also be vaccinated.

Hepatitis B vaccine may be given as a stand-alone vaccine, or as part of a combination vaccine (a type of vaccine that combines more than one vaccine together into one shot).

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

3. Talk with your health care provider

Tell your vaccination provider if the person getting the vaccine:

- Has had an **allergic reaction after a previous dose of hepatitis B vaccine**, or has any **severe, life-threatening allergies**

In some cases, your health care provider may decide to postpone hepatitis B vaccination until a future visit.

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Pregnant or breastfeeding women who were not vaccinated previously should be vaccinated. Pregnancy or breastfeeding are not reasons to avoid hepatitis B vaccination.

People with minor illnesses, such as a cold, may be vaccinated. People who are moderately or severely ill should usually wait until they recover before getting hepatitis B vaccine.

Your health care provider can give you more information.

4. Risks of a vaccine reaction

- Soreness where the shot is given, fever, headache, and fatigue (feeling tired) can happen after hepatitis B vaccination.

People sometimes faint after medical procedures, including vaccination. Tell your provider if you feel dizzy or have vision changes or ringing in the ears.

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

5. What if there is a serious problem?

An allergic reaction could occur after the vaccinated person leaves the clinic. If you see signs of a severe allergic reaction (hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, or weakness), call **9-1-1** and get the person to the nearest hospital.

For other signs that concern you, call your health care provider.

Adverse reactions should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your health care provider will usually file this report, or you can do it yourself. Visit the VAERS website at **www.vaers.hhs.gov** or call **1-800-822-7967**. *VAERS is only for reporting reactions, and VAERS staff members do not give medical advice.*

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7. How can I learn more?

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- 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

Polio Vaccine

What You Need to Know

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1 Why get vaccinated?

Vaccination can protect people from **polio**. Polio is a disease caused by a virus. It is spread mainly by person-to-person contact. It can also be spread by consuming food or drinks that are contaminated with the feces of an infected person.

Most people infected with polio have no symptoms, and many recover without complications. But sometimes people who get polio develop paralysis (cannot move their arms or legs). Polio can result in permanent disability. Polio can also cause death, usually by paralyzing the muscles used for breathing.

Polio used to be very common in the United States. It paralyzed and killed thousands of people every year before polio vaccine was introduced in 1955. There is no cure for polio infection, but it can be prevented by vaccination.

Polio has been eliminated from the United States. But it still occurs in other parts of the world. It would only take one person infected with polio coming from another country to bring the disease back here if we were not protected by vaccination. If the effort to eliminate the disease from the world is successful, some day we won't need polio vaccine. Until then, we need to keep getting our children vaccinated.

2 Polio vaccine

Inactivated Polio Vaccine (IPV) can prevent polio.

Children

Most people should get IPV when they are children. Doses of IPV are usually given at 2, 4, 6 to 18 months, and 4 to 6 years of age.

The schedule might be different for some children (including those traveling to certain countries and those who receive IPV as part of a combination vaccine). Your health care provider can give you more information.

Adults

Most adults do not need IPV because they were already vaccinated against polio as children. But some adults are at higher risk and should consider polio vaccination, including:

- people traveling to certain parts of the world,
- laboratory workers who might handle polio virus, and
- health care workers treating patients who could have polio.

These higher-risk adults may need 1 to 3 doses of IPV, depending on how many doses they have had in the past.

There are no known risks to getting IPV at the same time as other vaccines.

3 Some people should not get this vaccine

Tell the person who is giving the vaccine:

- **If the person getting the vaccine has any severe, life-threatening allergies.**
  If you ever had a life-threatening allergic reaction after a dose of IPV, or have a severe allergy to any part of this vaccine, you may be advised not to get vaccinated. Ask your health care provider if you want information about vaccine components.
- **If the person getting the vaccine is not feeling well.**
  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.

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.

Some people who get IPV get a sore spot where the shot was given. IPV has not been known to cause serious problems, and most people do not have any problems with it.

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Centers for Disease Control and Prevention

Other problems that could happen after this 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 provider if you feel dizzy, or have vision changes or ringing in the ears.
- Some people get shoulder pain that can be more severe and longer-lasting than the more routine soreness that can follow injections. 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 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 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 clinic.

  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.

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**

Pneumococcal Conjugate Vaccine: *What You Need to Know*

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1. Why get vaccinated?

Pneumococcal conjugate vaccine can prevent **pneumococcal disease**.

Pneumococcal disease refers to any illness caused by pneumococcal bacteria. These bacteria can cause many types of illnesses, including:

- Pneumonia (infection of the lungs)
- Ear infections
- Sinus infections
- Meningitis (infection of the tissue covering the brain and spinal cord)
- Bacteremia (bloodstream infection)

Anyone can get pneumococcal disease, but young children, older adults, and people with certain risk factors are at the highest risk.

Most pneumococcal infections are mild. However, some can result in long-term problems, such as brain damage or hearing loss. Meningitis, bacteremia, and pneumonia caused by pneumococcal disease can lead to death.

2. Pneumococcal conjugate vaccine

Pneumococcal conjugate vaccine helps protect against bacteria that cause pneumococcal disease. There are several pneumococcal conjugate vaccines (PCVs). The specific PCV and number of doses recommended are based on a person's age, vaccination history, and medical status. Your health care provider can help you determine which type of PCV, and how many doses, should be received.

- **Infants and young children** usually need 4 doses of PCV. These doses are recommended at 2, 4, 6, and 12–15 months of age.
- Certain **older children and adolescents** who did not receive the recommended doses as infants or young children need PCV. This depends on age and medical conditions, or other risk factors.
- **Adults 19 through 49 years old** who have not received PCV and have certain medical conditions or other risk factors should receive PCV. Some adults in this group who have already received PCV might be recommended to receive another dose.
- **Adults 50 years or older** who have not previously received PCV should receive a PCV vaccine. Some adults in this group who have already received PCV might be recommended to receive another dose.

3. Talk with your health care provider

Tell your vaccination provider if the person getting the vaccine:

- Has had an **allergic reaction after a previous dose of any type of PCV, or to any vaccine containing diphtheria toxoid** (for example, DTaP), or has any **severe, life-threatening allergies**

In some cases, your health care provider may decide to postpone PCV until a future visit.

People with minor illnesses, such as a cold, may be vaccinated. People who are moderately or severely ill should usually wait until they recover.

Your health care provider can give you more information.

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4. Risks of a vaccine reaction

- Redness, swelling, pain, or tenderness where the shot is given; fever; loss of appetite; fussiness (irritability); tiredness; headache; muscle aches; joint pain; or chills can happen after pneumococcal conjugate vaccination.

Young children may be at increased risk for seizures caused by fever after a PCV if it is administered at the same time as inactivated influenza vaccine. Ask your health care provider for more information.

People sometimes faint after medical procedures, including vaccination. Tell your provider if you feel dizzy or have vision changes or ringing in the ears.

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

5. What if there is a serious problem?

An allergic reaction could occur after the vaccinated person leaves the clinic. If you see signs of a severe allergic reaction (hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, or weakness), call **9-1-1** and get the person to the nearest hospital.

For other signs that concern you, call your health care provider.

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VACCINE INFORMATION STATEMENT

Rotavirus Vaccine:
What You Need to Know

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1 Why get vaccinated?

Rotavirus vaccine can prevent **rotavirus disease**.

Rotavirus 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.

2 Rotavirus vaccine

Rotavirus vaccine is administered by putting drops in the child's mouth. Babies should get 2 or 3 doses of rotavirus vaccine, depending on the brand of vaccine used.

- The first dose must be administered before 15 weeks of age.
- The last dose must be administered by 8 months of age.

Almost all babies who get rotavirus vaccine will be protected from severe rotavirus diarrhea.

Another virus called porcine circovirus (or parts of it) can be found in rotavirus vaccine. This virus does not infect people, and there is no known safety risk. For more information, see **http://wayback.archive-it.org/7993/20170406124518/https://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm212140.htm**.

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

3 Talk with your health care provider

Tell your vaccine provider if the person getting the vaccine:

- Has had an **allergic reaction after a previous dose of rotavirus vaccine**, or has any severe, life-threatening allergies.
- Has a **weakened immune system**.
- Has **severe combined immunodeficiency** (SCID).
- Has had a type of bowel blockage called **intussusception**.

In some cases, your child's health care provider may decide to postpone rotavirus vaccination to a future visit.

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

Your child's health care provider can give you more information.

4 Risks of a vaccine reaction

- Irritability or mild, temporary diarrhea or vomiting can happen after rotavirus vaccine.

Intussusception is a type of bowel blockage that is treated in a hospital and could require surgery. It happens naturally in some infants 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 first or second vaccine dose. This additional risk is estimated to range from about 1 in 20,000 US infants to 1 in 100,000 US infants who get rotavirus vaccine. Your health care provider can give you more information.

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

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5 What if there is a serious problem?

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 first or second dose of rotavirus vaccine, but look for them any time after vaccination. If you think your baby has intussusception, contact a health care provider right away. If you can't reach your health care provider, take your baby to a hospital. Tell them when your baby got rotavirus vaccine.

An allergic reaction could occur after the vaccinated person leaves the clinic. If you see signs of a severe allergic reaction (hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, or weakness), call **9-1-1** and get the person to the nearest hospital.

For other signs that concern you, call your health care provider.

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7 How can I learn more?

- Ask your health care provider.
- Call your local or state health department.
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VACCINE INFORMATION STATEMENT

Varicella (Chickenpox) Vaccine:

What You Need to Know

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1 Why get vaccinated?

Varicella (also called chickenpox) is a very contagious viral disease. It is caused by the varicella zoster virus. Chickenpox is usually mild, but it can be serious in infants under 12 months of age, adolescents, adults, pregnant women, and people with weakened immune systems.

Chickenpox causes an itchy rash that usually lasts about a week. It can also cause:

- fever
- tiredness
- loss of appetite
- headache

More serious complications can include:

- skin infections
- infection of the lungs (pneumonia)
- inflammation of blood vessels
- swelling of the brain and/or spinal cord coverings (encephalitis or meningitis)
- blood stream, bone, or joint infections

Some people get so sick that they need to be hospitalized. It doesn't happen often, but people can die from chickenpox. Before varicella vaccine, almost everyone in the United States got chickenpox, an average of 4 million people each year.

Children who get chickenpox usually miss at least 5 or 6 days of school or childcare.

Some people who get chickenpox get a painful rash called shingles (also known as herpes zoster) years later.

Chickenpox can spread easily from an infected person to anyone who has not had chickenpox and has not gotten chickenpox vaccine.

2 Chickenpox vaccine

Children 12 months through 12 years of age should get 2 doses of chickenpox vaccine, usually:

- First dose: 12 through 15 months of age
- Second dose: 4 through 6 years of age

People 13 years of age or older who didn't get the vaccine when they were younger, and have never had chickenpox, should get 2 doses at least 28 days apart.

A person who previously received only one dose of chickenpox vaccine should receive a second dose to complete the series. The second dose should be given at least 3 months after the first dose for those younger than 13 years, and at least 28 days after the first dose for those 13 years of age or older.

There are no known risks to getting chickenpox vaccine at the same time as other vaccines.

There is a combination vaccine called **MMRV** that contains both chickenpox and MMR vaccines. MMRV is an option for some children 12 months through 12 years of age. There is a separate Vaccine Information Statement for MMRV. Your health care provider can give you more information.

3 Some people should not get this vaccine

Tell your vaccine provider if the person getting the vaccine:

- **Has any severe, life-threatening allergies.** A person who has ever had a life-threatening allergic reaction after a dose of chickenpox vaccine, or has a severe allergy to any part of this vaccine, may be advised not to be vaccinated. Ask your health care provider if you want information about vaccine components.
- **Is pregnant, or thinks she might be pregnant.** Pregnant women should wait to get chickenpox vaccine until after they are no longer pregnant. Women should avoid getting pregnant for at least 1 month after getting chickenpox vaccine.
- **Has a weakened immune system** due to disease (such as cancer or HIV/AIDS) or medical treatments (such as radiation, immunotherapy, steroids, or chemotherapy).
- **Has a parent, brother, or sister with a history of immune system problems.**
- **Is taking salicylates (such as aspirin).** People should avoid using salicylates for 6 weeks after getting varicella vaccine.
- **Has recently had a blood transfusion or received other blood products.** You might be advised to postpone chickenpox vaccination for 3 months or more.
- **Has tuberculosis.**

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Centers for Disease Control and Prevention

- **Has gotten any other vaccines in the past 4 weeks**. Live vaccines given too close together might not work as well.
- **Is not feeling well**. A mild illness, such as a cold, is usually not a reason to postpone a vaccination. Someone who is moderately or severely ill should probably wait. Your doctor can advise you.

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.

Getting chickenpox vaccine is much safer than getting chickenpox disease. Most people who get chickenpox vaccine do not have any problems with it.

After chickenpox vaccination, a person might experience:

Minor events:

- Sore arm from the injection
- Fever
- Redness or rash at the injection site

If these events happen, they usually begin within 2 weeks after the shot. They occur less often after the second dose.

More serious events following chickenpox vaccination are rare. They can include:

- Seizure (jerking or staring) often associated with fever
- Infection of the lungs (pneumonia) or the brain and spinal cord coverings (meningitis)
- Rash all over the body

A person who develops a rash after chickenpox vaccination might be able to spread the varicella vaccine virus to an unprotected person. Even though this happens very rarely, anyone who gets a rash should stay away from people with weakened immune systems and unvaccinated infants until the rash goes away. Talk with your health care provider to learn more.

Other things that could happen after this vaccine:

- People sometimes faint after medical procedures, 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 shoulder pain that can be more severe and longer-lasting than routine soreness that can follow injections. This happens very rarely.
- Any medication can cause a severe allergic reaction. Such reactions to a vaccine are 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 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 and get to the nearest hospital. Otherwise, call your health care provider.

  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.

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/vaccines**

Vaccine Information Statement

Varicella Vaccine

Office use only

2/12/2018

42 U.S.C. § 300aa-26

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?

MMR vaccine can prevent **measles, mumps,** and **rubella**.

- **MEASLES (M)** can cause fever, cough, runny nose, and red, watery eyes, commonly followed by a rash that covers the whole body. It can lead to seizures (often associated with fever), ear infections, diarrhea, and pneumonia. Rarely, measles can cause brain damage or death.
- **MUMPS (M)** can cause fever, headache, muscle aches, tiredness, loss of appetite, and swollen and tender salivary glands under the ears. It can lead to deafness, swelling of the brain and/or spinal cord covering, painful swelling of the testicles or ovaries, and, very rarely, death.
- **RUBELLA (R)** can cause fever, sore throat, rash, headache, and eye irritation. It can cause arthritis in up to half of teenage and adult women. If a woman gets rubella while she is pregnant, she could have a miscarriage or her baby could be born with serious birth defects.

Most people who are vaccinated with MMR will be protected for life. Vaccines and high rates of vaccination have made these diseases much less common in the United States.

2 MMR vaccine

Children need 2 doses of MMR vaccine, usually:

- First dose at 12 through 15 months of age
- Second dose at 4 through 6 years of age

Infants who will be traveling outside the United States when they are between 6 and 11 months of age should get a dose of MMR vaccine before travel. The child should still get 2 doses at the recommended ages for long-lasting protection.

Older children, adolescents, and **adults** also need 1 or 2 doses of MMR vaccine if they are not already immune to measles, mumps, and rubella. Your health care provider can help you determine how many doses you need.

A third dose of MMR might be recommended in certain mumps outbreak situations.

MMR vaccine may be given at the same time as other vaccines. Children 12 months through 12 years of age might receive MMR vaccine together with varicella vaccine in a single shot, known as MMRV. Your health care provider can give you more information.

3 Talk with your health care provider

Tell your vaccine provider if the person getting the vaccine:

- Has had an **allergic reaction after a previous dose of MMR or MMRV vaccine**, or has any **severe, life-threatening allergies**.
- Is **pregnant**, or thinks she might be pregnant.
- Has a **weakened immune system**, or has a **parent, brother, or sister with a history of hereditary or congenital immune system problems**.
- Has ever had a **condition that makes him or her bruise or bleed easily**.
- Has recently **had a blood transfusion or received other blood products**.
- Has **tuberculosis**.
- Has **gotten any other vaccines in the past 4 weeks**.

In some cases, your health care provider may decide to postpone MMR vaccination to a future visit.

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

Your health care provider can give you more information.

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Centers for Disease Control and Prevention

4 Risks of a vaccine reaction

- Soreness, redness, or rash where the shot is given and rash all over the body can happen after MMR vaccine.
- Fever or swelling of the glands in the cheeks or neck sometimes occur after MMR vaccine.
- More serious reactions happen rarely. These can include seizures (often associated with fever), temporary pain and stiffness in the joints (mostly in teenage or adult women), pneumonia, swelling of the brain and/or spinal cord covering, or temporary low platelet count which can cause unusual bleeding or bruising.
- In people with serious immune system problems, this vaccine may cause an infection which may be life-threatening. People with serious immune system problems should not get MMR vaccine.

People sometimes faint after medical procedures, including vaccination. Tell your provider if you feel dizzy or have vision changes or ringing in the ears.

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

5 What if there is a serious problem?

An allergic reaction could occur after the vaccinated person leaves the clinic. If you see signs of a severe allergic reaction (hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, or weakness), call **9-1-1** and get the person to the nearest hospital.

For other signs that concern you, call your health care provider.

Adverse reactions should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your health care provider will usually file this report, or you can do it yourself. Visit the VAERS website at **www.vaers.hhs.gov** or call **1-800-822-7967**. *VAERS is only for reporting reactions, and VAERS staff 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. Visit the VICP website at **www.hrsa.gov/vaccinecompensation** or call **1-800-338-2382** to learn about the program and about filing a claim. There is a time limit to file a claim for compensation.

7 How can I learn more?

- Ask your healthcare provider.
- 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 **www.cdc.gov/vaccines**

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 Why get vaccinated?

Hepatitis A is a serious liver disease. It is caused by the hepatitis A virus (HAV). HAV is spread from person to person through contact with the feces (stool) of people who are infected, which can easily happen if someone does not wash his or her hands properly. You can also get hepatitis A from food, water, or objects contaminated with HAV.

Symptoms of hepatitis A can include:

- fever, fatigue, loss of appetite, nausea, vomiting, and/or joint pain
- severe stomach pains and diarrhea (mainly in children), or
- jaundice (yellow skin or eyes, dark urine, clay-colored bowel movements).

These symptoms usually appear 2 to 6 weeks after exposure and usually last less than 2 months, although some people can be ill for as long as 6 months. If you have hepatitis A you may be too ill to work.

Children often do not have symptoms, but most adults do. You can spread HAV without having symptoms.

Hepatitis A can cause liver failure and death, although this is rare and occurs more commonly in persons 50 years of age or older and persons with other liver diseases, such as hepatitis B or C.

Hepatitis A vaccine can prevent hepatitis A. Hepatitis A vaccines were recommended in the United States beginning in 1996. Since then, the number of cases reported each year in the U.S. has dropped from around 31,000 cases to fewer than 1,500 cases.

2 Hepatitis A vaccine

Hepatitis A vaccine is an inactivated (killed) vaccine. You will need **2 doses** for long-lasting protection. These doses should be given at least 6 months apart.

Children are routinely vaccinated between their first and second birthdays (12 through 23 months of age). Older children and adolescents can get the vaccine after 23 months. Adults who have not been vaccinated previously and want to be protected against hepatitis A can also get the vaccine.

You should get hepatitis A vaccine if you:

- are traveling to countries where hepatitis A is common,
- are a man who has sex with other men,
- use illegal drugs,
- have a chronic liver disease such as hepatitis B or hepatitis C,
- are being treated with clotting-factor concentrates,
- work with hepatitis A-infected animals or in a hepatitis A research laboratory, or
- expect to have close personal contact with an international adoptee from a country where hepatitis A is common

Ask your healthcare provider if you want more information about any of these groups.

There are no known risks to getting hepatitis A vaccine at the same time as other vaccines.

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 hepatitis A vaccine, or have a severe allergy to any part of this vaccine, you may be advised not to get vaccinated. Ask your health care provider if you want information about vaccine components.
- **If you are not feeling well.** 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 hepatitis A vaccine do not have any problems with it.

Minor problems following hepatitis A vaccine include:

- soreness or redness where the shot was given
- low-grade fever
- headache
- tiredness

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

Your doctor can tell you more about these reactions.

Other problems that could happen after this 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 provider if you feel dizzy, or have vision changes or ringing in the ears.
- Some people get shoulder pain that can be more severe and longer lasting than the more routine soreness that can follow injections. 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 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 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 clinic.

  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.

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

Hepatitis A Vaccine

7/20/2016

42 U.S.C. § 300aa-26

Office Use Only

VACCINE INFORMATION STATEMENT

MMRV (Measles, Mumps, Rubella, and Varicella) 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?

Measles, **mumps**, **rubella**, and **varicella** are viral diseases that can have serious consequences. Before vaccines, these diseases were very common in the United States, especially among children. They are still common in many parts of the world.

Measles

- Measles virus causes symptoms that can include fever, cough, runny nose, and red, watery eyes, commonly followed by a rash that covers the whole body.
- Measles can lead to ear infections, diarrhea, and infection of the lungs (pneumonia). Rarely, measles can cause brain damage or death.

Mumps

- Mumps virus causes fever, headache, muscle aches, tiredness, loss of appetite, and swollen and tender salivary glands under the ears on one or both sides.
- Mumps can lead to deafness, swelling of the brain and/or spinal cord covering (encephalitis or meningitis), painful swelling of the testicles or ovaries, and, very rarely, death.

Rubella (also known as German Measles)

- Rubella virus causes fever, sore throat, rash, headache, and eye irritation.
- Rubella can cause arthritis in up to half of teenage and adult women.
- If a woman gets rubella while she is pregnant, she could have a miscarriage or her baby could be born with serious birth defects.

Varicella (also known as Chickenpox)

- Chickenpox causes an itchy rash that usually lasts about a week, in addition to fever, tiredness, loss of appetite, and headache.
- Chickenpox can lead to skin infections, infection of the lungs (pneumonia), inflammation of blood vessels, swelling of the brain and/or spinal cord covering (encephalitis or meningitis) and infections of the blood, bones, or joints. Rarely, varicella can cause death.
- Some people who get chickenpox get a painful rash called shingles (also known as herpes zoster) years later.

These diseases can easily spread from person to person. Measles doesn't even require personal contact. You can get measles by entering a room that a person with measles left up to 2 hours before.

Vaccines and high rates of vaccination have made these diseases much less common in the United States.

2 MMRV Vaccine

MMRV vaccine may be given to children 12 months through 12 years of age. Two doses are usually recommended:

- First dose: 12 through 15 months of age
- Second dose: 4 through 6 years of age

A third dose of MMR might be recommended in certain mumps outbreak situations.

There are no known risks to getting MMRV vaccine at the same time as other vaccines.

Instead of **MMRV**, some children 12 months through 12 years of age might get 2 separate shots: MMR (measles, mumps and rubella) and **chickenpox** (varicella). MMRV is not licensed for people 13 years of age or older. There are separate Vaccine Information Statements for MMR and chickenpox vaccines. Your health care provider can give you more information.

3 Some people should not get this vaccine

Tell the person who is giving your child the vaccine if your child:

- **Has any severe, life-threatening allergies**. A person who has ever had a life-threatening allergic reaction after a dose of MMRV vaccine, or has a severe allergy to any part of this vaccine, may be advised not to be vaccinated. Ask your health care provider if you want information about vaccine components.
- **Has a weakened immune system** due to disease (such as cancer or HIV/AIDS) or medical treatments (such as radiation, immunotherapy, steroids, or chemotherapy).
- **Has a history of seizures**, or **has a parent, brother, or sister with a history of seizures**.
- **Has a parent, brother, or sister with a history of immune system problems**.
- **Has ever had a condition that makes them bruise or bleed easily**.
- **Is pregnant or might be pregnant**. MMRV vaccine should not be given during pregnancy.
- **Is taking salicylates (such as aspirin)**. People should avoid using salicylates for 6 weeks after getting a vaccine that contains varicella.

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

- **Has recently had a blood transfusion or received other blood products.** You might be advised to postpone MMRV vaccination of your child for at least 3 months.
- **Has tuberculosis.**
- **Has gotten any other vaccines in the past 4 weeks.** Live vaccines given too close together might not work as well.
- **Is not feeling well.** If your child has a mild illness, such as a cold, he or she can probably get the vaccine today. If your child is moderately or severely ill, you should probably wait until the child recovers. Your doctor can advise you.

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.

Getting MMRV vaccine is much safer than getting measles, mumps, rubella, or chickenpox disease. Most children who get MMRV vaccine do not have any problems with it.

After MMRV vaccination, a child might experience:

Minor events:

- Sore arm from the injection
- Fever
- Redness or rash at the injection site
- Swelling of glands in the cheeks or neck

If these events happen, they usually begin within 2 weeks after the shot. They occur less often after the second dose.

Moderate events:

- Seizure (jerking or staring) often associated with fever
  - *The risk of these seizures is higher after MMRV than after separate MMR and chickenpox vaccines when given as the first dose of the series. Your doctor can advise you about the appropriate vaccines for your child.*
- Temporary low platelet count, which can cause unusual bleeding or bruising
- Infection of the lungs (pneumonia) or the brain and spinal cord coverings (encephalitis, meningitis)
- Rash all over the body

If your child gets a rash after vaccination, it might be related to the varicella component of the vaccine. A child who has a rash after MMRV vaccination might be able to spread the varicella vaccine virus to an unprotected person. Even though this happens very rarely, children who develop a rash should stay away from people with weakened immune systems and unvaccinated infants until the rash goes away. Talk with your health care provider to learn more.

Severe events have very rarely been reported following MMR vaccination, and might also happen after MMRV. These include:

- Deafness
- Long-term seizures, coma, lowered consciousness
- Brain damage

Other things that could happen after this vaccine:

- People sometimes faint after medical procedures, including vaccination. Sitting or lying down for about 15 minutes can help prevent fainting and injuries caused by a fall. Tell your provider if you feel dizzy or have vision changes or ringing in the ears.
- Some people get shoulder pain that can be more severe and longer-lasting than routine soreness that can follow injections. This happens very rarely.
- Any medication can cause a severe allergic reaction. Such reactions to a vaccine are estimated at about 1 in a million doses, and would happen 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 and get to the nearest hospital. Otherwise, call your health care provider.

  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.

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

MMRV Vaccine

Office use only

2/12/2018

42 U.S.C. § 300aa-26

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.

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

Meningococcal ACWY 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?

Meningococcal ACWY vaccine can help protect against **meningococcal disease** caused by serogroups A, C, W, and Y. A different meningococcal vaccine is available that can help protect against serogroup B.

Meningococcal disease can cause meningitis (infection of the lining of the brain and spinal cord) and infections of the blood. 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, kidney damage, loss of limbs, nervous system problems, or severe scars from skin grafts.

Meningococcal disease is rare and has declined in the United States since the 1990s. However, it is a severe disease with a significant risk of death or lasting disabilities in people who get it.

Anyone can get meningococcal disease. Certain people are at increased risk, including:

- Infants younger 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*, the bacteria that cause meningococcal disease
- People at risk because of an outbreak in their community

2. Meningococcal ACWY vaccine

Adolescents need 2 doses of a meningococcal ACWY vaccine:

- First dose: 11 or 12 years of age
- Second (booster) dose: 16 years of age

In addition to routine vaccination for adolescents, meningococcal ACWY vaccine is also recommended for **certain groups of people**:

- People at risk because of a serogroup A, C, W, or Y meningococcal disease outbreak
- People with HIV
- Anyone whose spleen is damaged or has been removed, including people with sickle cell disease
- Anyone with a rare immune system condition called "complement component deficiency"
- Anyone taking a type of drug called a "complement inhibitor," such as eculizumab (also called "Soliris"®) or ravulizumab (also called "Ultomiris"®)
- Microbiologists who routinely work with isolates of *N. meningitidis*
- Anyone traveling to or living in a part of the world where meningococcal disease is common, such as parts of Africa
- College freshmen living in residence halls who have not been completely vaccinated with meningococcal ACWY vaccine
- U.S. military recruits

CDC U.S. CENTERS FOR DISEASE CONTROL AND PREVENTION

3. Talk with your health care provider

Tell your vaccination provider if the person getting the vaccine:

- Has had an **allergic reaction after a previous dose of meningococcal ACWY vaccine**, or has any **severe, life-threatening allergies**

In some cases, your health care provider may decide to postpone meningococcal ACWY vaccination until a future visit.

There is limited information on the risks of this vaccine for pregnant or breastfeeding women, but no safety concerns have been identified. A pregnant or breastfeeding woman should be vaccinated if indicated.

People with minor illnesses, such as a cold, may be vaccinated. People who are moderately or severely ill should usually wait until they recover before getting meningococcal ACWY vaccine.

Your health care provider can give you more information.

4. Risks of a vaccine reaction

- Redness or soreness where the shot is given can happen after meningococcal ACWY vaccination.
- A small percentage of people who receive meningococcal ACWY vaccine experience muscle pain, headache, or tiredness.

People sometimes faint after medical procedures, including vaccination. Tell your provider if you feel dizzy or have vision changes or ringing in the ears.

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

5. What if there is a serious problem?

An allergic reaction could occur after the vaccinated person leaves the clinic. If you see signs of a severe allergic reaction (hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, or weakness), call **9-1-1** and get the person to the nearest hospital.

For other signs that concern you, call your health care provider.

Adverse reactions should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your health care provider will usually file this report, or you can do it yourself. Visit the VAERS website at **www.vaers.hhs.gov** or call **1-800-822-7967**. *VAERS is only for reporting reactions, and VAERS staff members 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. Claims regarding alleged injury or death due to vaccination have a time limit for filing, which may be as short as two years. Visit the VICP website at **www.hrsa.gov/vaccinecompensation** or call **1-800-338-2382** to learn about the program and about filing a claim.

7. How can I learn more?

- Ask your health care provider.
- Call your local or state health department.
- Visit the website of the Food and Drug Administration (FDA) for vaccine package inserts and additional information at **www.fda.gov/vaccines-blood-biologics/vaccines**.
- 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**.

HPV (Human Papillomavirus) 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?

HPV (human papillomavirus) vaccine can prevent infection with some types of human papillomavirus.

HPV infections can cause certain types of cancers, including:

- cervical, vaginal, and vulvar cancers in women
- penile cancer in men
- anal cancers in both men and women
- cancers of tonsils, base of tongue, and back of throat (oropharyngeal cancer) in both men and women

HPV infections can also cause anogenital warts.

HPV vaccine can prevent over 90% of cancers caused by HPV.

HPV is spread through intimate skin-to-skin or sexual contact. HPV infections are so common that nearly all people will get at least one type of HPV at some time in their lives. Most HPV infections go away on their own within 2 years. But sometimes HPV infections will last longer and can cause cancers later in life.

2. HPV vaccine

HPV vaccine is routinely recommended for adolescents at 11 or 12 years of age to ensure they are protected before they are exposed to the virus. HPV vaccine may be given beginning at age 9 years and vaccination is recommended for everyone through 26 years of age.

HPV vaccine may be given to adults 27 through 45 years of age, based on discussions between the patient and health care provider.

Most children who get the first dose before 15 years of age need 2 doses of HPV vaccine. People who get the first dose at or after 15 years of age and younger people with certain immunocompromising conditions need 3 doses. Your health care provider can give you more information.

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

3. Talk with your health care provider

Tell your vaccination provider if the person getting the vaccine:

- Has had an **allergic reaction after a previous dose of HPV vaccine**, or has any **severe, life-threatening allergies**
- Is **pregnant**—HPV vaccine is not recommended until after pregnancy

In some cases, your health care provider may decide to postpone HPV vaccination until a future visit.

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

Your health care provider can give you more information.

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

4. Risks of a vaccine reaction

- Soreness, redness, or swelling where the shot is given can happen after HPV vaccination.
- Fever or headache can happen after HPV vaccination.

People sometimes faint after medical procedures, including vaccination. Tell your provider if you feel dizzy or have vision changes or ringing in the ears.

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

5. What if there is a serious problem?

An allergic reaction could occur after the vaccinated person leaves the clinic. If you see signs of a severe allergic reaction (hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, or weakness), call **9-1-1** and get the person to the nearest hospital.

For other signs that concern you, call your health care provider.

Adverse reactions should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your health care provider will usually file this report, or you can do it yourself. Visit the VAERS website at **www.vaers.hhs.gov** or call **1-800-822-7967**. *VAERS is only for reporting reactions, and VAERS staff members 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. Claims regarding alleged injury or death due to vaccination have a time limit for filing, which may be as short as two years. Visit the VICP website at **www.hrsa.gov/vaccinecompensation** or call **1-800-338-2382** to learn about the program and about filing a claim.

7. How can I learn more?

- Ask your health care provider.
- Call your local or state health department.
- Visit the website of the Food and Drug Administration (FDA) for vaccine package inserts and additional information at **www.fda.gov/vaccines-blood-biologics/vaccines**.
- 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

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 infections of the blood. Meningococcal disease often occurs without warning—even among 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 *N. 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 younger 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, kidney damage, amputations, nervous system problems, or severe scars from skin grafts.

Serogroup B meningococcal (MenB) vaccines 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—Bexsero® and Trumenba®—have been licensed by the Food and Drug Administration (FDA).

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 isolates of *N. meningitidis*

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.

For best protection, more than 1 dose of a serogroup B meningococcal vaccine is needed. The same vaccine must be used for all doses. Ask your health care provider about the number and timing of 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 health care 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 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 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

Other problems that could happen after these vaccines:

- 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 provider if you feel dizzy, or have vision changes or ringing in the ears.
- Some people get shoulder pain that can be more severe and longer-lasting than the more routine soreness that can follow injections. 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 and get to the nearest hospital. Otherwise, call your clinic.

  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.

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/vaccines**

Vaccine Information Statement
Serogroup B Meningococcal Vaccine

08/09/2016

Office Use Only

42 U.S.C. § 300aa-26

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 vaccine can prevent **influenza (flu)**.

Flu is a contagious disease that spreads around the United States every year, usually between October and May. Anyone can get the flu, but it is more dangerous for some people. Infants and young children, people 65 years and older, pregnant women, and people with certain health conditions or a weakened immune system are at greatest risk of flu complications.

Pneumonia, bronchitis, sinus infections, and ear infections are examples of flu-related complications. If you have a medical condition, such as heart disease, cancer, or diabetes, flu can make it worse.

Flu can cause fever and chills, sore throat, muscle aches, fatigue, cough, headache, and runny or stuffy nose. Some people may have vomiting and diarrhea, though this is more common in children than adults.

In an average year, **thousands of people in the United States die from flu**, and many more are hospitalized. Flu vaccine prevents millions of illnesses and flu-related visits to the doctor each year.

2. Influenza vaccines

CDC recommends everyone 6 months and older get vaccinated every flu season. **Children 6 months through 8 years of age** may need 2 doses during a single flu season. **Everyone else** needs only 1 dose each flu season.

It takes about 2 weeks for protection to develop after vaccination.

There are many flu viruses, and they are always changing. Each year a new flu vaccine is made to protect against the influenza viruses believed to be likely to cause disease in the upcoming flu season.

Even when the vaccine doesn't exactly match these viruses, it may still provide some protection.

Influenza vaccine **does not cause flu**.

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

3. Talk with your health care provider

Tell your vaccination provider if the person getting the vaccine:

- Has had an **allergic reaction after a previous dose of influenza vaccine**, or has any **severe, life-threatening allergies**
- Has ever had **Guillain-Barré Syndrome** (also called "GBS")

In some cases, your health care provider may decide to postpone influenza vaccination until a future visit.

Influenza vaccine can be administered at any time during pregnancy. Women who are or will be pregnant during influenza season should receive inactivated influenza vaccine.

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

Your health care provider can give you more information.

CDC U.S. CENTERS FOR DISEASE CONTROL AND PREVENTION

4. Risks of a vaccine reaction

- Soreness, redness, and swelling where the shot is given, fever, muscle aches, and headache can happen after influenza vaccination.
- There may be a very small increased risk of Guillain-Barré Syndrome (GBS) after inactivated influenza vaccine (the flu shot).

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. Tell your health care provider if a child who is getting flu vaccine has ever had a seizure.

People sometimes faint after medical procedures, including vaccination. Tell your provider if you feel dizzy or have vision changes or ringing in the ears.

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

5. What if there is a serious problem?

An allergic reaction could occur after the vaccinated person leaves the clinic. If you see signs of a severe allergic reaction (hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, or weakness), call **9-1-1** and get the person to the nearest hospital.

For other signs that concern you, call your health care provider.

Adverse reactions should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your health care provider will usually file this report, or you can do it yourself. Visit the VAERS website at **www.vaers.hhs.gov** or call **1-800-822-7967**. *VAERS is only for reporting reactions, and VAERS staff members 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. Claims regarding alleged injury or death due to vaccination have a time limit for filing, which may be as short as two years. Visit the VICP website at **www.hrsa.gov/vaccinecompensation** or call **1-800-338-2382** to learn about the program and about filing a claim.

7. How can I learn more?

- Ask your health care provider.
- Call your local or state health department.
- Visit the website of the Food and Drug Administration (FDA) for vaccine package inserts and additional information at **www.fda.gov/vaccines-blood-biologics/vaccines**.
- 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**.

IMMUNIZATION INFORMATION STATEMENT

Respiratory Syncytial Virus (RSV) Preventive Antibody: *What You Need to Know*

Why get immunized with a RSV preventive antibody?

A respiratory syncytial virus (RSV) preventive antibody can prevent severe lung disease caused by RSV.

RSV is a common respiratory virus that usually causes mild, cold-like symptoms but can also affect the lungs. Symptoms of RSV infection may include runny nose, decrease in appetite, coughing, sneezing, fever, or wheezing.

Anyone can become infected by RSV, and almost all children get an RSV infection by the time they are 2 years old. While most children recover from an RSV infection in a week or two, RSV infection can be dangerous for infants and some young children, causing difficulty breathing, low oxygen levels, and dehydration. In the United States, RSV is the most common cause of bronchiolitis (inflammation of the small airways in the lungs) and pneumonia (infection of the lungs) in children younger than 1 year of age. Children who get sick from RSV may need to be hospitalized, and some might even die.

RSV Preventive Antibodies

The RSV preventive antibody (generic name nirsevimab, trade name Beyfortus) is a shot that prevents severe RSV disease in infants and young children. Antibodies are proteins that the body's immune system uses to fight off harmful germs. Like traditional vaccines, preventive antibodies are immunizations that provide protection against a specific pathogen. While both are immunizations, the way they provide immunity is different. Nirsevimab is an immunization that provides antibodies directly to the recipient. Traditional vaccines are immunizations that stimulate the recipient's immune system to produce antibodies.

Infants born during the RSV season (typically fall through spring) should receive a single dose of the RSV Immunization within 1 week after birth. Most infants whose mothers got the RSV vaccine don't need to get nirsevimab, too. Both protect infants from severe RSV by providing antibodies, either from the mother to the infant or directly to the infant. Most infants will likely only need protection from either the maternal RSV vaccine or nirsevimab (not both). However, there may be some situations in which nirsevimab would be recommended for an infant after the mother received an RSV vaccine.

Infants born outside of the RSV season who are younger than 8 months should receive a single dose of the RSV Immunization shortly before their first RSV season (typically the fall), but infants who are younger than 8 months who have not yet received a dose may receive a dose at any time during the season.

Some infants and young children who are at increased risk for severe RSV disease may need a single dose of the RSV antibody before or during their second RSV season.

RSV preventive antibodies can be given at the same time as vaccines routinely recommended for infants and young children.

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

RSV (Respiratory Syncytial Virus) 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?

RSV vaccine can prevent lower respiratory tract disease caused by **respiratory syncytial virus (RSV)**. RSV is a common respiratory virus that usually causes mild, cold-like symptoms.

RSV can cause illness in people of all ages but may be especially serious for infants and older adults.

- RSV is the most common cause of hospitalization in U.S. infants. Infants up to 12 months of age (especially those 6 months and younger) and children who were born prematurely, or who have chronic lung or heart disease, or a weakened immune system, are at increased risk of severe RSV disease.
- RSV infections can be dangerous for certain adults. Adults at highest risk for severe RSV disease include older adults, especially those with chronic heart or lung disease, a weakened immune system, certain other chronic medical conditions, or who live in nursing homes.

RSV spreads through direct contact with the virus, such as when droplets from an infected person's cough or sneeze contact your eyes, nose, or mouth. It can also be spread by someone touching a surface, such as a doorknob, that has the virus on it, and then touching your face.

Symptoms of RSV infection may include runny nose, decreased appetite, coughing, sneezing, fever, or wheezing. In very young infants, symptoms of RSV may also include irritability (fussiness), decreased activity, or apnea (pauses in breathing for more than 10 seconds).

Most people recover in a week or two, but RSV can be more serious, resulting in shortness of breath and low oxygen levels. RSV can cause bronchiolitis (inflammation of the small airways in the lung) and pneumonia (infection of the lungs). RSV can also lead to worsening of other medical conditions such as asthma, chronic obstructive pulmonary disease (a chronic disease of the lungs that makes it hard to breathe), or heart failure (when the heart cannot pump enough blood and oxygen throughout the body).

Infants and older adults who get very sick from RSV may need to be hospitalized. Some may even die.

2. RSV vaccine

There are two immunization options available for protecting infants against RSV: maternal vaccine for the pregnant woman or preventive antibodies given to the baby. Only one of these options is needed for most babies to be protected.

CDC recommends a one-time dose of RSV vaccine for **pregnant women from week 32 through week 36 of pregnancy** for the prevention of RSV disease in their infants during the first 6 months of life. This vaccine is recommended to be given from September through January for most of the United States. However, in some locations (for example, the territories, Hawaii, Alaska, and parts of Florida), the timing of vaccination may differ based on the time of year when RSV circulates in the area.

CDC recommends a one-time-dose of RSV vaccine for **everyone 75 years and older** and for **adults 60 through 74 years of age who are at increased risk of severe RSV disease**. Adults 60 through 74 years old who are at increased risk include those with chronic heart or lung disease, a weakened immune system, or certain other chronic medical conditions, and those who are residents of nursing homes.

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

CDC U.S. CENTERS FOR DISEASE CONTROL AND PREVENTION

3. Talk with your health care provider

Tell your vaccination provider if the person getting the vaccine:

- Has had an **allergic reaction after a previous dose of RSV vaccine**, or has any **severe, life-threatening allergies**

In some cases, your health care provider may decide to postpone RSV vaccination until a future visit.

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

Your health care provider can give you more information.

4. Risks of a vaccine reaction

- Pain, redness, and swelling where the shot is given, fatigue (feeling tired), fever, headache, nausea, diarrhea, and muscle or joint pain can happen after RSV vaccination.

Serious neurologic conditions, including Guillain-Barré syndrome (GBS), have been reported after RSV vaccination in some older adults. At this time, an increased risk of GBS following RSV vaccine among persons aged 60 years and older cannot be confirmed or ruled out.

Preterm birth and high blood pressure during pregnancy, including pre-eclampsia, have been reported among pregnant women who received RSV vaccine. It is unclear whether these events were caused by the vaccine.

People sometimes faint after medical procedures, including vaccination. Tell your provider if you feel dizzy or have vision changes or ringing in the ears.

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

V-Safe is a safety monitoring system that lets you share with CDC how you, or your dependent, feel after getting RSV vaccine. You can find information and enroll in V-Safe at **vsafe.cdc.gov**.

5. What if there is a serious problem?

An allergic reaction could occur after the vaccinated person leaves the clinic. If you see signs of a severe allergic reaction (hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, or weakness), call **9-1-1** and get the person to the nearest hospital.

For other signs that concern you, call your health care provider.

Adverse reactions should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your health care provider will usually file this report, or you can do it yourself. Visit the VAERS website at **www.vaers.hhs.gov** or call **1-800-822-7967**. *VAERS is only for reporting reactions, and VAERS staff do not give medical advice.*

6. How can I learn more?

- Ask your health care provider.
- Call your local or state health department.
- Visit the website of the Food and Drug Administration (FDA) for vaccine package inserts and additional information at **www.fda.gov/vaccines-blood-biologics/vaccines**
- 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**.

Talk with your health care provider

Tell your health care provider if the person getting the preventive antibody has a:
- History of serious allergic reactions to an RSV preventive antibody (nirsevimab) or any of its components,
- Bleeding disorder, or
- Moderate or severe acute illness.

In some cases, your child's health care provider may decide to postpone giving RSV preventive antibodies until a future visit.

People who have a minor illness, such as a cold, can safely receive an RSV preventive antibody. People who are moderately or severely ill should usually wait until they recover.

Your health care provider can give you more information.

Risks of a reaction to RSV preventive antibodies

After getting an RSV preventive antibody, your child might have temporary pain, redness, swelling where the injection was given, or a rash.

As with any medicine, there is a very remote chance that RSV Immunization could cause a severe allergic reaction, other serious injury, or death.

An allergic reaction could occur after your child leaves the hospital or clinic. If you see signs of a severe allergic reaction (for example, hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, or weakness), call 9-1-1 and get your child to the nearest hospital.

Call your health care provider if you see any other symptoms that concern you.

What if there is a serious problem?

If your child got an RSV preventive antibody without getting a vaccine at the same time, and you suspect an adverse reaction, you or your health care provider can submit a report through https://www.fda.gov/medwatch or by phone at 1-800-FDA-1088.

If your child got an RSV preventive antibody and a vaccine at the same time and you suspect an adverse reaction, you or your health care provider should report it to the Vaccine Adverse Event Reporting System (VAERS) https://vaers.hhs.gov/ or call 1-800-822-7967. In your report, note that your child got an RSV Immunization along with a vaccine.

Note: MedWatch and VAERS are only for reporting reactions. MedWatch and VAERS staff members do not give medical advice.

How can I learn more?

- Ask your health care provider.
- Call your local or state health department.
- Visit U.S. Food and Drug Administration website at Drugs@FDA: FDA-Approved Drugs.
- Contact the Centers for Disease Control and Prevention (CDC):
  - Call 1-800-232-4636 (1-800-CDC-INFO) or
  - Visit the CDC website https://www.cdc.gov/rsv/about/prevention.html