VACCINE INFORMATION STATEMENT

Your Child's First Vaccines:

What You Need to Know

Many vaccine information statements are available in Spanish and other languages. See www.immunize.org/vis

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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.



Polio

Polio (or poliomyelitis) is a disabling and lifethreatening 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 <u>www.fda.gov/</u> <u>vaccines-blood-biologics/vaccines</u>.
- 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.



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Rotavirus Vaccine: What You Need to Know

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1. Why get vaccinated?

Rotavirus vaccine can prevent rotavirus disease.

Rotavirus commonly causes severe, watery diarrhea, mostly in babies and young children. Vomiting and fever are also common in babies with rotavirus. Children may become dehydrated and need to be hospitalized and can even die.

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" can be found in one brand of rotavirus vaccine (Rotarix). This virus does not infect people, and there is no known safety risk.

Rotavirus 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 rotavirus vaccine, or has any severe, lifethreatening 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 until 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 U.S. infants to 1 in 100,000 U.S. 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.



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.

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