VACCINE INFORMATION STATEMENT

Your Child’s First Vaccines

What You Need to Know

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

Your child will get these vaccines today:

- □ DTaP
- □ Hib
- □ Hepatitis B
- □ Polio
- □ PCV13

(Provider: Check appropriate boxes.)

1. Why get vaccinated?

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

7 childhood diseases that can be prevented by vaccines:

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

2. Tetanus (the ‘T’ in DTaP vaccine; also known as Lockjaw)
   - Signs and symptoms include painful tightening of the muscles, usually all over the body.
   - Tetanus can lead to stiffness of the jaw that can make it difficult to open the mouth or swallow.
     - Tetanus kills about 1 person out of every 10 who get it.

3. Pertussis (the ‘P’ in DTaP vaccine, also known as Whooping Cough)
   - Signs and symptoms include violent coughing spells that can make it hard for a baby to eat, drink, or breathe. These spells can last for several weeks.
   - Pertussis can lead to pneumonia, seizures, brain damage, or death. Pertussis can be very dangerous in infants.
     - Most pertussis deaths are in babies younger than 3 months of age.

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

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

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

- **Signs and symptoms** include fever, chills, cough, and chest pain. In infants, symptoms can also include meningitis, seizures, and sometimes rash.

- **Pneumococcal disease can lead to** meningitis (infection of the brain and spinal cord coverings); infections of the ears, sinuses and blood; pneumonia; deafness; and brain damage.

- About 1 out of 15 children who get pneumococcal meningitis will die from the infection.

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

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Vaccines that protect your baby from these seven diseases:

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

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

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2 Some children should not get certain vaccines

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

- A child who has a mild cold or other illness on the day vaccinations are scheduled may be vaccinated. A child who is moderately or severely ill on the day of vaccinations might be asked to come back for them at a later date.

- Any child who had a life-threatening allergic reaction after getting a vaccine should not get another dose of that vaccine. **Tell the person giving the vaccines if your child has ever had a severe reaction after any vaccination.**

- A child who has a severe (life-threatening) allergy to a substance should not get a vaccine that contains that substance. **Tell the person giving your child the vaccines if your child has any severe allergies that you are aware of.**

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Talk to your doctor before your child gets:

- **DTaP vaccine**, if your child ever had any of these reactions after a previous dose of DTaP:
  - A brain or nervous system disease within 7 days,
  - Non-stop crying for 3 hours or more,
  - A seizure or collapse,
  - A fever of over 105°F.

- **PCV13 vaccine**, if your child ever had a severe reaction after a dose of DTaP (or other vaccine containing diphtheria toxoid), or after a dose of PCV7, an earlier pneumococcal vaccine.

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3 Risks of a Vaccine Reaction

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

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

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

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

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

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

As with any medicine, there is a very remote chance of a vaccine causing a serious injury or death. The safety of vaccines is always being monitored. For more information, visit: [www.cdc.gov/vaccinesafety/](http://www.cdc.gov/vaccinesafety/)

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**What if there is a serious reaction?**

**What should I look for?**
- Look for anything that concerns you, such as signs of a severe allergic reaction, very high fever, or unusual behavior.

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

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

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

**VAERS does not give medical advice.**

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**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](http://www.hrsa.gov/vaccinecompensation). There is a time limit to file a claim for compensation.

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**How can I learn more?**

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

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**Vaccine Information Statement**

**Multi Pediatric Vaccines**

11/05/2015

42 U.S.C. § 300aa-26
Rotavirus Vaccine

What You Need to Know

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

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

Every year before the vaccine was available:
• more than 400,000 young children had to see a doctor for illness caused by rotavirus,
• more than 200,000 had to go to the emergency room,
• 55,000 to 70,000 had to be hospitalized, and
• 20 to 60 died.

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

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

Doses are recommended at these ages:
• First Dose: 2 months of age
• Second Dose: 4 months of age
• Third Dose: 6 months of age (if needed)

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

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

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

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

3 Some babies should not get this vaccine
A baby who has had a life-threatening allergic reaction to a dose of rotavirus vaccine should not get another dose. A baby who has a severe allergy to any part of rotavirus vaccine should not get the vaccine. Tell your doctor if your baby has any severe allergies that you know of, including a severe allergy to latex.

Babies with “severe combined immunodeficiency” (SCID) should not get rotavirus vaccine.

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

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

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

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

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

Mild problems following rotavirus vaccine:
• Babies might become irritable, or have mild, temporary diarrhea or vomiting after getting a dose of rotavirus vaccine.
Serious problems following rotavirus vaccine:

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

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

Problems that could happen after any vaccine:

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

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

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

5 What if there is a serious problem?

What should I look for?

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

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

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

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

What should I do?

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

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

Otherwise, call your doctor.

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

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