

VACCINE INFORMATION STATEMENT

Your Baby'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

Your baby will get these vaccines today:

- | | |
|--------------------------------------|------------------------------------|
| <input type="checkbox"/> DTaP | <input type="checkbox"/> Polio |
| <input type="checkbox"/> Hib | <input type="checkbox"/> Rotavirus |
| <input type="checkbox"/> Hepatitis B | <input type="checkbox"/> PCV13 |

(Provider: Check appropriate boxes.)

Ask your doctor about “combination vaccines,” which can reduce the number of shots your baby needs.

Combination vaccines are as safe and effective as these vaccines when given separately.



These vaccines protect your baby from 8 serious diseases:

- diphtheria
- tetanus
- pertussis (whooping cough)
- *Haemophilus influenzae* type b (Hib)
- hepatitis B
- polio
- rotavirus
- pneumococcal disease

About this vaccine information statement

Please read this Vaccine Information Statement (VIS) before your baby gets his or her immunizations, and take it home with you afterward. Ask your doctor if you have any questions.

This VIS tells you about the benefits and risks of six routine childhood vaccines. It also contains information about reporting an adverse reaction and about the National Vaccine Injury Compensation Program, and how to get more information about vaccines and vaccine-preventable diseases. (Individual VISs are also available for these vaccines.)

How vaccines work

Immunity from disease: When children get sick with an infectious disease, their immune system usually produces protective “antibodies,” which keep them from getting the same disease again. But getting sick is no fun, and it can be dangerous or even fatal.

Immunity from vaccines: Vaccines are made with the same bacteria or viruses that cause disease, but they have been weakened or killed—or only parts of them are used—to make them safe. A child’s immune system produces antibodies, just as it would after exposure to the actual disease. This means the child will develop immunity in the same way, but without having to get sick first.

Vaccine benefits: why get vaccinated?

Diseases have injured and killed many children over the years in the United States. **Polio** paralyzed about 37,000 and killed about 1,700 every year in the 1950s. **Hib disease** was once the leading cause of bacterial meningitis in children under 5 years of age. About 15,000 people died each year from **diphtheria** before there was a vaccine. Up to 70,000 children a year were hospitalized because of **rotavirus** disease. **Hepatitis B** can cause liver damage and cancer in 1 child out of 4 who are infected, and **tetanus** kills 1 out of every 5 who get it.

Thanks mostly to vaccines, these diseases are not nearly as common as they used to be. But they have not disappeared, either. Some are common in other countries, and if we stop vaccinating they will come back here. This has already happened in some parts of the world. When vaccination rates go down, disease rates go up.



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

Childhood vaccines can prevent these 8 Diseases

1. DIPHTHERIA

Signs and symptoms include a thick covering in the back of the throat that can make it hard to breathe.

Diphtheria can lead to breathing problems, and heart failure.

2. TETANUS (Lockjaw)

Signs and symptoms include painful tightening of the muscles, usually all over the body.

Tetanus can lead to stiffness of the jaw so victims can't open their mouth or swallow.

3. PERTUSSIS (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 weeks.

Pertussis can lead to pneumonia, seizures, and brain damage.

4. HIB (Haemophilus influenzae type b)

Signs and symptoms can include trouble breathing. There may 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 blood, joints, bones, and covering of the heart; brain damage; and deafness.

5. HEPATITIS B

Signs and symptoms can 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.

6. POLIO

Signs and symptoms can include flu-like illness, or there may be no signs or symptoms at all.

Polio can lead to paralysis (can't move an arm or leg).

7. PNEUMOCOCCAL DISEASE

Signs and symptoms include fever, chills, cough, and chest pain.

Pneumococcal disease can lead to meningitis (infection of the brain and spinal cord coverings), blood infections, ear infections, pneumonia, deafness, and brain damage.

8. ROTAVIRUS

Signs and symptoms include watery diarrhea (sometimes severe), vomiting, fever, and stomach pain.

Rotavirus can lead to dehydration and hospitalization.

Any of these diseases can lead to death.

How do babies catch these diseases?

Usually from contact with other children or adults who are already infected, sometimes without even knowing they are infected. A mother with **Hepatitis B** infection can also infect her baby at birth. **Tetanus** enters the body through a cut or wound; it is not spread from person to person.

Routine baby vaccines

Vaccine	Number of doses	Recommended ages	Other information
DTaP (diphtheria, tetanus, pertussis)	5	2 months, 4 months, 6 months, 15–18 months, 4–6 years	Some children should not get pertussis vaccine. These children can get a vaccine called DT.
Hepatitis B	3	Birth, 1–2 months, 6–18 months	Children may get an additional dose at 4 months with some “combination” vaccines.
Polio	4	2 months, 4 months, 6–18 months, 4–6 years	
Hib (<i>Haemophilus influenzae</i> type b)	3 or 4	2 months, 4 months, (6 months), 12–15 months	There are 2 types of Hib vaccine. With one type the 6-month dose is not needed.
PCV13 (pneumococcal)	4	2 months, 4 months, 6 months, 12–15 months	Older children with certain chronic diseases may also need this vaccine.
Rotavirus	2 or 3	2 months, 4 months, (6 months)	Not a shot, but drops that are swallowed. There are 2 types of rotavirus vaccine. With one type the 6-month dose is not needed.

Annual **flu vaccination** is also recommended for children 6 months of age and older.

Precautions

Most babies can safely get all of these vaccines. But some babies should not get certain vaccines. Your doctor will help you decide.

- A child who has ever had a serious reaction, such as a life-threatening allergic reaction, after a vaccine dose should not get another dose of that vaccine. *Tell your doctor if your child has any severe allergies, or has had a severe reaction after a prior vaccination.* (Serious reactions to vaccines and severe allergies are rare.)
- A child who is sick on the day vaccinations are scheduled might be asked to come back for them.

Talk to your doctor...

- before getting **DTaP** vaccine, if your child ever had any of these reactions after a 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.
- before getting **Polio vaccine**, if your child has a life-threatening allergy to the antibiotics neomycin, streptomycin or polymyxin B.
- before getting **Hepatitis B** vaccine, if your child has a life-threatening allergy to yeast.
- before getting **Rotavirus Vaccine**, if your child has:
 - SCID (Severe Combined Immunodeficiency),
 - A weakened immune system for any other reason,
 - Digestive problems,
 - Recently gotten a blood transfusion or other blood product,
 - Ever had intussusception (bowel obstruction that is treated in a hospital).
- before getting **PCV13** or **DTaP** vaccine, if your child ever had a severe reaction after any vaccine containing diphtheria toxoid (such as DTaP).

Risks

Vaccines can cause side effects, like any medicine.

Most vaccine reactions are **mild**: tenderness, redness, or swelling where the shot was given; or a mild fever. These happen to about 1 child in 4. They appear soon after the shot is given and go away within a day or two.

Other reactions: Individual childhood vaccines have been associated with other mild problems, or with moderate or serious problems:

DTaP vaccine

Mild problems: Fussiness (up to 1 child in 3); tiredness or poor 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. These problems happen so rarely that it is hard to tell whether they were actually caused by the vaccination or just happened afterward by chance.

Polio vaccine / Hepatitis B vaccine / Hib vaccine

These vaccines have not been associated with other mild problems, or with moderate or serious problems.

Pneumococcal vaccine

Mild problems: During studies of the vaccine, some children became fussy or drowsy or lost their appetite.

Rotavirus vaccine

Mild problems: Children who get rotavirus vaccine are slightly more likely than other children to be irritable or to have mild, temporary diarrhea or vomiting. This happens within the first week after getting a dose of the vaccine.

Serious problems: Studies in Australia and Mexico have shown a small increase in cases of intussusception within a week after the first dose of rotavirus vaccine. So far, this increase has not been seen in the United States, but it can't be ruled out. If the same risk were to exist here, we would expect to see 1 to 3 infants out of 100,000 develop intussusception within a week after the first dose of vaccine.

What if there is a serious reaction?

What should I look for?

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

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

What should I do?

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

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

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.

For more information

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

Vaccine Information Statement (Interim)

11/16/2012

42 U.S.C. § 300aa-26

Office Use Only

