

A Parent's Guide to Kids' Vaccines

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Vaccines have contributed to a significant reduction in many childhood diseases, such as diphtheria, measles, and whooping cough. Other diseases, such as polio and smallpox, have been eliminated in the United States due to effective vaccines.



It is now rare for children in the United States to experience the devastating and often deadly effects of these illnesses that were once common. Infant deaths due to vaccine preventable childhood diseases have nearly disappeared in the United States and other countries with high vaccination coverage.

Because immunization programs of the 20th century were so successful, many of today's parents have never seen many of the diseases and do not understand the potential for them to re-emerge. If too many individuals choose not to vaccinate themselves or their children, the diseases that are now rare or non-existent in this country may resurface.

The viruses and bacteria that cause vaccine-preventable diseases can be passed on to people who are not protected by vaccines, and cause severe disease and death. For example, from 1989-1991 a measles outbreak occurred in the United States resulting in more than 55,000 cases of measles and 123 measles-associated deaths. The Centers for Disease Control and Prevention (CDC) indicates that the "most important cause of the measles resurgence of 1989-1991 was low vaccination coverage." (<http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/meas-508.pdf>²)

Ensuring the safety and effectiveness of vaccines is one of the Food and Drug Administration's (FDA) top priorities. The Center for Biologics Evaluation and Research (CBER) is the center within FDA that regulates vaccines in the United States. Vaccines are developed in accordance with the highest safety standards. These high standards of safety are necessary as vaccines are administered to millions of individuals in the United States each year, including infants and children.

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Benefits and Risks

Like any medicine, vaccines have benefits and risks, and no vaccine is 100 percent effective in preventing disease or 100 percent safe in all individuals. Most adverse effects of vaccines are usually minor and short-lived. For example, an individual may feel soreness at the injection site or experience a fever. Serious vaccine reactions are extremely rare, but they can happen.

Examples of serious reactions include:

- anaphylaxis or severe allergic reaction in persons who are allergic to any vaccine components (ingredients)
- development of temporary arthritis following rubella vaccine

- development of a disease similar to the disease that the vaccine is intended to prevent if a “live-attenuated vaccine” (see below) is given to a person with a weakened immune system

For a more comprehensive list of risks, you should review the package insert or patient information for each vaccine. It is important to discuss with your health care provider any prior reactions to vaccines and any adverse reactions following vaccination.

"However, parents should know that the risk of being harmed by a vaccine is significantly smaller than the risk of serious illness that comes with infectious diseases," says Norman Baylor, Ph.D., director of the Office of Vaccine Research and Review in CBER. "Vaccination is a very important step to get children off to a healthy start."

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Types of Vaccines

Vaccines work by triggering a response by the body's immune system when administered. Vaccines stimulate the body to make antibodies—proteins that specifically recognize and target the disease-causing bacteria and viruses, and help eliminate them from the body before they cause disease. Vaccines are frequently given by injection (a shot), but some are given orally and one is given via nasal spray.

There are several types of vaccines: live-attenuated, inactivated (whole or subunit), and toxoids. Live-attenuated vaccines contain a living bacteria or virus that has been weakened in the laboratory so that it doesn't cause the actual disease in individuals with healthy immune systems. However, because they contain a small amount of the weakened live virus or bacteria, they should not be taken by people with incompetent or weakened immune systems. One example of a live attenuated vaccine is the Measles, Mumps and Rubella Virus Vaccine, Live.

Inactivated vaccines can be safely given to individuals with weakened immune systems. However, for such individuals, additional (booster) doses may be required to achieve immunity (protection). One example of a whole inactivated vaccine is the Poliovirus Vaccine Inactivated.

Scientists discovered that in some cases, the entire virus or bacteria is not required to elicit protective immunity and prevent disease; just a portion or a "subunit" of the disease-causing bacteria or virus is needed to provide protection. One example of a subunit inactivated vaccine is the Hepatitis B Vaccine, Recombinant.

Some bacteria cause illness by secreting a poison or toxin. Scientists discovered that inactivating the toxins, to create toxoids, and administering the toxoid can also protect individuals against the disease. One example of a toxoid vaccine is the Diphtheria toxoid vaccine.

Vaccines are available as single valent (one strain), multi-valent (several strains such as the seasonal influenza vaccine which has three strains of influenza) or combination vaccines (more than one virus or bacteria, such as MMR which contains measles, mumps and rubella viruses).

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Steps to Take When Your Child is Vaccinated

Review the vaccine information sheets. These sheets explain to vaccine recipients, their parents, or their legal representatives both the benefits and risks of a vaccine. Health care providers are required by law to provide them.

Talk to your health care provider about the benefits and risks of vaccines. Learn the facts about the benefits and risks, along with the potential consequences of not vaccinating against certain diseases. Some parents are surprised to learn that children can die of measles, diphtheria, pertussis, and other vaccine-preventable diseases.

Tell your health care provider about bad reactions. Before you or your child receives a vaccine, tell your health care provider if you, your child, or a sibling has ever had a bad reaction to a vaccine. If your child or a sibling has had an allergic reaction or other severe reaction to a dose of vaccine, talk with your health care provider about whether that vaccine should be taken again.

Ask about conditions under which your child should not be vaccinated. This might include being sick or having a history of certain allergic or other adverse reactions to previous vaccinations or their components. For example, eggs are used to grow influenza (flu) vaccines, so a child who is allergic to eggs should not get a flu vaccine. Children or others with weakened or incompetent immune systems should not receive live vaccines, but may be able to receive toxoids, inactivated (killed) or subunit vaccines. You should discuss these issues with your health care provider.

Report adverse reactions. Adverse reactions and other problems related to vaccines should be reported to the Vaccine Adverse Event Reporting System ([VAERS](#)³), which is maintained by FDA and the Centers for Disease Control and Prevention (CDC). For a copy of the vaccine reporting form, call 1-800-822-7967, or report online VAERS.

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Some Commonly Used Vaccines

Some of the vaccines commonly used are briefly discussed below. [A complete list of licensed vaccines in the United States](#)⁴ and supporting documents, such as package inserts, are available online.

Diphtheria and Tetanus Toxoids and Acellular Pertussis Adsorbed (DTaP)

- **What it's for:** Protects (immunizes) against the bacterial infections diphtheria, tetanus (Lockjaw), and pertussis (whooping cough). This combination vaccine is given as a five dose series in infants and children six weeks through six years of age. Diphtheria can infect the throat, causing a thick covering that can lead to problems with breathing, paralysis, or heart failure. Tetanus can cause painful tightening (spasms) of the muscles, seizures, paralysis, and death. Pertussis causes severe coughing spells and can lead to pneumonia, seizures, brain damage, and death.

- **Common side effects:** Fever, redness, soreness, or swelling at the injection site, fussiness/irritability, inconsolable crying, and decreased activity/lethargy.

- **Tell your health care provider beforehand if:** Your child is moderately or severely ill, has had a severe reaction to a previous shot, or has a known sensitivity to ingredients of the vaccine, including latex.

Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine Adsorbed

- **What it's for:** Protects (immunizes) against the bacterial infections diphtheria, tetanus (Lockjaw), and pertussis (whooping cough). Active booster immunization of individuals ages 10 or 11 years (dependent on product used) through 64 years of age.

- **Common side effects:** Pain, swelling, and redness at injection site, headache, body ache or muscle weakness, sore or swollen joints, tiredness or fatigue, nausea or gastrointestinal symptoms.

- **Tell your health care provider beforehand if:** The individual has had any allergic reaction to any vaccine that protects against diphtheria, tetanus, or pertussis diseases, any ingredient contained in the vaccine, including latex.

Haemophilus b Conjugate Vaccine (tetanus Toxoid Conjugate) (Hib)

- **What it's for:** Protects (immunizes) against Haemophilus influenzae type b disease, which can cause meningitis (an infection of the covering of the brain and spinal cord which can cause brain damage and deafness), pneumonia (lung infection), severe swelling of the throat, and infections of the blood, joints, bones, and covering of the heart. Approved for infants and children 2 through 18 months of age.
- **Common side effects:** Pain, redness, swelling at site of injection, fever, irritability and lethargy.
- **Tell your health care provider beforehand if:** Your child is moderately or severely ill, or has ever had a life-threatening allergic reaction to a previous dose of Hib vaccine.

Hepatitis A Vaccine, Inactivated

- **What it's for:** Protects (immunizes) against disease caused by Hepatitis A virus infection. Individuals infected with Hepatitis A may not have any symptoms; have a mild "flu-like" illness; or may have a severe illness including inflammation of the liver, resulting in jaundice (yellow skin or eyes), and even death. Hepatitis A can be transmitted by contaminated food or water, sharing contaminated utensils, and/or sexual contact with an infected person. Approved for persons 12 months of age and older.
- **Common side effects:** Soreness at the injection site, fever, headache, loss of appetite, tiredness.
- **Tell your health care provider beforehand if:** The individual has ever had a severe allergic reaction to a previous dose of the vaccine.

Hepatitis B Vaccine (Recombinant)

- **What it's for:** Protects (immunizes) against infection with the Hepatitis B virus. Hepatitis B can lead to chronic hepatitis (liver inflammation), liver cancer, and death. Approved for immunization of individuals of all ages, especially those at increased risk of exposure to Hepatitis B virus.
- **Common side effects:** Soreness, redness, swelling at injection site, irritability, fever, diarrhea, fatigue/weakness, loss of appetite and headache.
- **Tell your health care provider beforehand if:** The individual is moderately or severely ill or has ever had a life-threatening allergic reaction to baker's yeast used for making bread, or to a previous dose of the vaccine.

Human Papillomavirus Quadrivalent (Types 6, 11, 16 and 18) Vaccine, Recombinant

- **What it's for:** Prevents cervical, vaginal, and vulvar cancer caused by Human Papillomavirus (HPV) types 16 and 18, and genital warts caused by HPV types 6 and 11. Used to vaccinate girls and women ages 9 through 26 years of age.
- **Common side effects:** Headache, fever, nausea, dizziness, syncope (fainting), injection site pain, swelling, redness, itchiness or bruising.
- **Tell your health care provider beforehand if:** The individual has had an allergic reaction to baker's yeast or another component of HPV vaccine, or to a previous dose of the vaccine.

Influenza Virus Vaccine, Inactivated

- **What it's for:** Protects (immunizes) children as young as six months (depending on the specific age indications of the vaccine) and adults against the three influenza virus strains contained in the vaccine.

Influenza is a contagious respiratory virus that can cause mild to severe illness. More than 200,000 individuals are hospitalized each year from flu-related complications, and approximately 36,000 deaths each year in the United States are from flu-related causes. The elderly, young children, and people with certain health conditions (such as asthma, diabetes, or heart disease) are at high risk for serious flu complications. Complications from influenza include bacterial pneumonia, ear infections, sinus infections, dehydration, and worsening of chronic medical conditions such as congestive heart failure, asthma or diabetes. The strains of influenza virus that cause disease in people frequently change, so yearly vaccination is needed to provide protection against the influenza viruses likely to be in circulation each winter. This is a killed (inactivated) virus vaccine, so you can't get influenza from this vaccine.

- **Common side effects:** Pain, redness and swelling at the injection site, low grade fever, and muscle aches, headache, fatigue and general feeling of being unwell.

- **Tell your health care provider beforehand if:** The individual is moderately or severely ill, has a bleeding disorder or is on anticoagulant therapy, or has ever had an allergic reaction to eggs, latex, or to a previous dose or another component of the flu vaccine, or had Guillain-Barre Syndrome (GBS) within six weeks of receipt of a prior influenza vaccine.

Influenza Vaccine Live, Intranasal

- **What it's for:** Protects (immunizes) against influenza in children and adults ages 2 to 49 years of age. Should not be used in children less than 24 months of age.
- **Common side effects:** Runny nose, nasal congestion, fever greater than 100 degrees F in children ages 2 to 6 and sore throat in adults.
- **Tell your health care provider beforehand if:** The individual is moderately or severely ill, has a weakened immune system, has asthma or recurrent wheezing, has a history of Guillain-Barre Syndrome (GBS) within 6 weeks of any prior influenza vaccination, has ever had an allergic reaction to eggs, egg proteins, gentamicin, gelatin or arginine, or to a previous dose of the flu vaccine. Also inform them if your children or adolescents are currently receiving aspirin or aspirin-containing therapy because of the association of Reye's syndrome with aspirin and wild-type influenza infection.

Measles, Mumps and Rubella Vaccine, Live (MMRII)

- **What it's for:** Protects (immunizes) individuals 12 months of age and older against measles, mumps, and rubella. Measles is a respiratory infection that causes skin rash and flu-like symptoms. It can cause severe disease leading to ear infection, pneumonia, seizures, and brain damage. Mumps causes fever, headache and swollen glands, especially salivary glands. It can also lead to deafness, meningitis (infection of the brain and spinal cord covering), and painful swelling of the testicles or ovaries. Rubella, also called German Measles, is an infection of the skin and lymph nodes and can cause arthritis. Rubella infection during pregnancy can lead to birth defects.
- **Common side effects:** Fever, mild rash, fainting, headache, dizziness, irritability and in rare cases, swelling of the glands in the cheeks or neck, and a general feeling of being unwell. Burning/stinging, redness, swelling, and tenderness at the injection site.

- **Tell your health care provider beforehand if:** The individual is ill or has ever had an allergic reaction to eggs, gelatin, the antibiotic neomycin, or a previous dose of the MMR vaccine. This is a live vaccine so you should tell your health care provider if the individual has a fever, has a weakened immune system (is immunosuppressed), has cancer or AIDS.

Meningococcal Conjugate Vaccine or Meningococcal Polysaccharide Vaccine

- **What it's for:** Protects (immunizes) individuals' ages 2 through 55 years of age against meningococcal disease, a serious illness caused by a bacteria (*Neisseria meningitidis*). It is a leading cause of bacterial meningitis in children 2 to 18 years old in the United States. Bacterial meningitis is an infection of fluid surrounding the brain and the spinal cord that is fatal in approximately 10 percent of the cases and 10 to 20 percent of the survivors have serious adverse effects from the disease including neurologic disabilities, loss of digits or limbs, or hearing loss.

- **Common side effects:** Pain, redness and swelling at the injection site, irritability, joint pain, headache, fever, fatigue, loss of appetite and diarrhea.

- **Tell your health care provider beforehand if:** The individual is currently acutely ill, previously had a severe allergic reaction to a previous dose of meningococcal vaccine or diphtheria toxoid, has a known sensitivity to vaccine components or latex, or a history of Guillain-Barre Syndrome (GBS).

Pneumococcal 7-valent Conjugate Vaccine

- **What it's for:** Protects (immunizes) infants and toddlers against serious diseases, such as meningitis, pneumonia, blood stream infections

(bacteremia) and sinus and middle ear infections (otitis media) caused by infection with pneumococcal (*Streptococcus pneumoniae*) bacteria.

- **Common side effects:** Swelling at injection site, fever, fussiness or irritability, restless sleep, drowsiness, decreased appetite, vomiting or diarrhea.
- **Tell your health care provider beforehand if:** Your child is severely ill, has ever had an allergic reaction to a previous dose or component of the vaccine including diphtheria toxoid, has thrombocytopenia (low platelets), a bleeding (coagulation) disorder, or is on anticoagulant therapy.

Pneumococcal Vaccine, Polyvalent

- **What it's for:** A different pneumococcal vaccine that protects (immunizes) children who are at least 2 years old and have certain chronic health conditions (e.g., chronic heart, lung or kidney disease; sickle cell disease) and for routine vaccination of adults 50 years of age and older. The vaccine will help protect these children and adults from pneumococcal disease.
- **Common side effects:** Soreness, warmth, redness, swelling or hardening (induration) at the site of injection and fever.
- **Tell your health care provider beforehand if:** The individual is allergic to any component of the vaccine, has a respiratory illness or other active infection, or has severely compromised cardiovascular and/or pulmonary function.

Poliovirus Vaccine Inactivated

- **What it's for:** The inactivated (killed) poliovirus vaccine protects (immunizes) against the three types of viruses that cause polio, an illness that can cause paralysis or death. For immunization of infants 6 weeks of age and older, children, and adults.
- **Common side effects:** Redness, hardening (induration), and pain at injection site, fever, irritability, sleepiness, fussiness, and crying.
- **Tell your health care provider beforehand if:** The individual has ever had a severe allergic reaction to a previous dose of polio vaccine, any component of the vaccine, or an allergic reaction to 2-phenoxyethanol, formaldehyde, neomycin, streptomycin, or polymyxin B.

Rotavirus Vaccine, Live, Oral, Pentavalent

- **What it's for:** Prevents gastroenteritis caused by rotavirus infection in children. Rotavirus is the leading cause of severe diarrhea, vomiting, and fever in infants and young children in the United States and worldwide. Sometimes diarrhea and vomiting due to rotavirus infection can lead to the loss of body fluids (dehydration) and for approximately 55,000 U.S. children each year becomes severe enough to require hospitalization. Without the vaccine, rotavirus infects over 95% of children in the United States by their 5th birthday. Currently licensed vaccine is a liquid that is given by mouth to infants in a series of three doses between the ages of 6 and 32 weeks.
- **Common side effects:** Diarrhea, vomiting, irritability, runny nose and sore throat, wheezing or coughing, and ear infection.
- **Tell your health care provider beforehand if:** Your child has a weakened or compromised immune system, is allergic to any of the ingredients of the vaccine, or has ever had an allergic reaction to a previous dose of the vaccine.

Varicella Virus Vaccine Live

- **What it's for:** Protects (immunizes) against chickenpox, which is caused by the varicella-zoster virus. Chickenpox usually causes headache, fever, and an itchy rash that can turn into blisters, and can occasionally cause more serious complications such as skin infection, scarring, pneumonia, brain swelling, Reye's syndrome, and death. Severe disease and more serious complications are more likely to occur in adolescents and adults. Currently licensed for individuals 12 months of age and older.
- **Common side effects:** Soreness, pain, redness or swelling at the injection site, fever, mild rash, and irritability. Less common side effects include tingling of the skin and shingles.
- **Tell your health care provider beforehand if:** The individual is moderately or severely ill or has chronic medical problems that may weaken the immune system, has received a blood or plasma transfusion or immune globulin within the last 5 months, takes medicines, has allergies including any life-threatening allergic reaction to gelatin, the antibiotic neomycin, or a previous dose of chickenpox or any other vaccine, is pregnant or plans to become pregnant within the next three months, or is breast feeding. Important to note: This is a live vaccine, so people with a weakened immune system should not get this vaccine. Also, once vaccinated, the individual should avoid contact with individuals who have a weakened immune system, pregnant women who never had chickenpox, and newborn babies whose mothers never had chickenpox for at least 6 weeks. The individual should tell the health care provider if they expect to have contact with individuals who fall in one of these groups.

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This article appears on [FDA's Consumer Update page](#)⁵, which features the latest on all FDA-regulated products.

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