



# AAP Immunizations Frequently Asked Questions: Vaccine Safety

As a parent, you might have questions and concerns about vaccine safety. With so much incorrect information on the Internet and in the media, it is often hard to find trustworthy, clear, and up-to-date information. The truth is that today's vaccines are the most effective and safest in history and have protected and saved millions of lives from vaccine-preventable diseases. However, some children are too young or too sick to receive vaccines. And some children do have side effects. Listed below are common questions about vaccine safety and the AAP's response.

## How are vaccines licensed and monitored to ensure their safety?

The Food and Drug Administration (FDA) tests new vaccines for up to 10 years before issuing the vaccine a license. All vaccines must be safe and proven to work well in children. Once the vaccine is being used, the FDA and the Centers for Disease Control and Prevention (CDC) monitor it through the Vaccine Adverse Event Reporting System (VAERS). Researchers look for any problem with a vaccine, inspect the problem, and decide what to do. When VAERS found a problem in the past, changes included:

- Using different labels or packaging,
- Sending safety alerts,
- Inspecting manufacturers' records, and
- Taking away the vaccine's license.

For more information about VAERS, visit <http://vaers.hhs.gov/index> or call the toll-free VAERS information line at 1-800-822-7967. For more information about licensing vaccines, visit [http://www.aap.org/immunization/families/VaccineSafety\\_parenthandout.pdf](http://www.aap.org/immunization/families/VaccineSafety_parenthandout.pdf)

The Vaccine Safety Datalink (VSD) is a collaborative effort between the Centers for Disease Control and Prevention and 9 managed care organizations (MCOs) in the United States. The VSD began in 1990 to monitor immunization safety. Each participating VSD site gathers data on vaccination (vaccine type, date of vaccination, vaccines given with other vaccines), medical outcomes (outpatient visits, inpatient visits, urgent care visits), birth data, and census data.

For more information about VSD visit: <http://www.cdc.gov/vaccinesafety/activities/vsd.html>.

## What are the known side effects of vaccines?

Vaccines can sometimes cause certain side effects. The most common side effects include fever, redness or soreness where the shot was given, or fussiness of your child.

Sometimes more serious reactions occur, but they are very rare. It is important to talk to your pediatrician to identify possible side effects to watch for and how to contact him in case you observe something you are concerned about.

For more information about possible side effects from specific vaccines, visit <http://www.cdc.gov/vaccines/vac-gen/side-effects.htm>



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## Why do children get so many shots? Is it safe to give multiple shots in one visit?

Vaccines are the best way to prevent diseases. Children are given vaccines at a young age because this is when they are most likely to get the disease. If a child is not vaccinated and is exposed to a disease, the child's body may not be strong enough to fight the disease.

The CDC and the American Academy of Pediatrics (AAP) recommend vaccination against 16 diseases (including influenza). To be most effective, some of these vaccines need to be given more than once. As a result, children may receive up to 27 vaccines by the time they are 2 years old and may be given up to 6 vaccines during one visit to the doctor. Talk to your pediatrician about combination vaccines that are available to reduce the number of needle sticks your child will receive.

In a study published in the June 2010 issue of *Pediatrics*, M.J. Smith et al. examined a group of 1,047 children some of whom had gotten all of their shots on time, and others whom had gotten some shots late or missed some shots altogether. Then at 7-10 years old, children were studied for harmful effects, such as tics, poor memory, stuttering, and slowed response. Researchers found no evidence that getting all of the vaccines on time, during infancy, is associated with any unwanted effects.

Studies and years of experience show that vaccines used for routine childhood immunizations can be given together safely, at one visit. The vaccines work just as well, and this does not increase the risk of side effects. In addition, the scientific data show that receiving multiple vaccines has no harmful effect on a healthy child's immune system. Talk to your pediatrician if you are concerned about the number of vaccines your child is scheduled to receive.

**For more information on the childhood vaccine schedule and why it is recommended, visit <http://www.aap.org/immunization/families/toomany.html>**

## I had chickenpox as a kid and was fine, why does my child need this vaccine?

Many parents remember getting chickenpox (varicella) because it is a common childhood disease. Although this disease is common, parents should keep in mind how uncomfortable and potentially severe this disease can be for their child. Before the vaccine, there were 100 deaths and 12,000 hospitalizations per year in the United States. In addition to the uncomfortable rash, fever, itchiness, and tiredness that the disease causes, your child could also suffer severe side effects from the disease such as skin infection, pneumonia, and brain damage. The chickenpox vaccine can protect your child from the potential severity of this disease. Talk to your pediatrician about when your child should be vaccinated.

## Does the measles-mumps-rubella (MMR) vaccines cause autism?

No. Scientific data do not show a link between the MMR vaccine and autism. Children receive the MMR vaccine at 12-15 months. Signs of autism often appear when a child is 15-18 months. Because children get the MMR vaccine just before the signs of autism appear, some people were concerned about a link.

In 1998, Andrew Wakefield published a small study in *The Lancet* stating that MMR caused inflammatory bowel disease and autism. Later, his results were rejected because the study was seriously flawed. Ten out of the 13 co-authors agreed that the results were wrong and retracted their support. In February 2010, the editors of *The Lancet* retracted the paper and the United Kingdom's General Medical Council took away Wakefield's license. As a result of the study and its misleading results, many British parents refused to let their children get the vaccine and the number of measles and mumps outbreaks increased in areas where many children had not been vaccinated. Subsequent studies and a 2004 Institute of Medicine report have all concluded that there is no association between the MMR vaccine and autism.



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Some parents still question vaccine safety because the media gives false claims a lot of attention, and the Internet has wrong information that is easy to find. Measles, mumps, and rubella are serious - protect your children by immunizing them when they are 12-15 months old and again at 4-6 years old.

## A lot of people get the flu each season, it's not that serious, right?

It is true that a lot of people get the flu (influenza) each season. Every year in the United States, on average 5% to 20% of the population will get the flu. Despite how common it is, influenza is a serious disease and every year about 36,000 people die and 200,000 people end up in the hospital because of it. Young children are at high risk for serious flu complications such as bacterial pneumonia, ear and sinus infections, and dehydration. It is recommended that your child be vaccinated yearly starting at 6 months of age.

## What is the mercury containing ingredient thimerosal? Is it safe?

Thimerosal is a preservative used in some vaccines, medicines, and other products such as contact lens solutions, throat, and nose sprays. In vaccines, thimerosal stops bacteria and fungi from growing in open multi-dose vaccine containers. Thimerosal has a small amount of organic mercury in it. Some parents and others worry about a link between neurologic disorders and vaccines that use thimerosal. Reliable scientific studies have not shown that small amounts of thimerosal in vaccines cause harm. Minor side effects like swelling and redness where the vaccine was given are the same for thimerosal containing vaccines and non-thimerosal containing vaccines.

It is important to understand that mercury is a natural part of our environment and is found in the fish we eat, the water we drink, and in infant formula and breast milk, among other items. There is no evidence that thimerosal in vaccines is harmful. In 1999, the Public Health Service and the AAP recommended that thimerosal be taken out of vaccines administered in the United States as a precaution. We can't always remove the mercury from the environment, but we can control the mercury used in vaccines. By taking thimerosal out of vaccines, we lessen the amount of mercury a child will be exposed to early in life. Since 2001, all routinely recommended children's vaccines being made in the United States (except some influenza and Td vaccines) contain no thimerosal or only trace amounts.

**Note:** Many childhood vaccines never used thimerosal: measles/mumps/rubella (MMR), polio (IPV), varicella/chicken pox, some Haemophilus influenzae type b (Hib) vaccines, and some diphtheria/tetanus/pertussis (DTaP) vaccines. Some vaccines are only available with thimerosal, such as meningococcal vaccine, but this vaccine is NOT recommended for very young children.

## I'm not sure the hepatitis B vaccine is necessary for my baby. Why is it important?

The hepatitis B vaccine is important for all babies. This vaccine protects your baby from the serious hepatitis B virus. The virus can enter the bloodstream, attack the liver, and sometimes cause serious damage or even liver cancer. The younger a child is when exposed, the more likely that child will suffer from liver damage or liver cancer; 90% of infected infants will develop a serious, life-long infection. Vaccinating at birth (birth dose) ensures that your baby will be protected at the beginning of her life from any exposure to the hepatitis B virus.



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Even if the mother and the baby are both negative for hepatitis B at birth, it is important to get the vaccine. Since individuals that are infected with hepatitis B often do not feel sick or show symptoms of the disease, they can pass the virus on unknowingly. If your baby is not protected by the vaccine, he could be at risk for contracting the virus. In two-thirds of the cases of childhood transmission of the virus, the mother tested negative for hepatitis B but the unvaccinated infant was exposed from a family member or caregiver.

Talk to your pediatrician about the recommended schedule for the hepatitis B vaccine to guarantee all 3 doses are completed.

**For more information about hepatitis B disease, hepatitis B birth dose, or the Vaccine Information Statement on hepatitis B vaccine, visit: <http://www2.aap.org/immunization/illnesses/hepb/hepb.html> or <http://www.immunize.org/birthdose/>.**

**“Even if I choose not to vaccinate my child, my baby will be protected because other children are vaccinated.”**

The concept that your child will be protected from a vaccine-preventable disease because other children are vaccinated is known as ‘herd immunity.’ Herd immunity refers to the type of immunity that occurs when the vaccinated portion of the population provides protection against a disease to the unvaccinated individuals.

Those who are too young or too sick to be vaccinated depend on ‘the herd’ to keep disease away from them. However, relying on herd immunity to keep your child safe is risky. The more parents that follow this way of thinking, the fewer vaccinated children we will have, and the more likely a serious disease will return and infect all of those who are unvaccinated.

**Vaccines save lives and protect against the spread of disease. If you decide not to immunize your child, you put your child and other children around her at risk. Getting vaccinated is much safer than getting the disease. For more information, visit <http://www.cdc.gov/vaccinesafety/>.**



The information contained in this document should not be used as a substitute for the medical care and advice of your pediatrician. There may be variations in treatment that your pediatrician may recommend based on individual facts and circumstances.