
Frequently Asked Questions about Vaccine Safety

Many parents have heard concerning reports about vaccines being harmful. These reports are not true and in an effort to provide you with best information possible, we have gone to the experts for the latest, evidence-based information. And it is listed here for you to peruse. Happy Reading!

Vaccines are held to the highest standard of safety. The United States currently has the safest, most effective vaccine supply in history. Years of testing are required by law before a vaccine can be licensed. Once in use, vaccines are continually monitored for safety and effectiveness. However, like any medication, vaccines can cause side effects.

Are Vaccines Tested and Monitored for Safety?

Yes. Before vaccines are licensed, the FDA requires testing to ensure safety. This process can take 10 years or longer. Once a vaccine is in use, the CDC and FDA monitor its adverse events (health problems after vaccination) through the [Vaccine Adverse Event Reporting System \(VAERS\)](#). Any hint of a problem with a vaccine prompts further investigations by the CDC and FDA. If researchers find a vaccine may be causing a side effect, the CDC and FDA will initiate appropriate action that may include the changing of vaccine labels or packaging, distributing safety alerts, inspecting manufacturers' facilities and records, withdrawing recommendations for the use of the vaccine, or revoking the vaccine's license.

Who Should Not Be Vaccinated?

Some people should not get certain vaccines or should wait to get them. For instance, children with compromised immune systems, as occurs with cancer patients, often need to wait to be vaccinated. Similarly, if a person has had a severe allergic reaction to a vaccine, a following dose is not recommended. However, a person with a mild, common illness, such as a cold with a low-grade fever, does not have to wait to be vaccinated. For more information, visit [Who Should Not be Vaccinated with These Vaccines?](#)

What Should I Do if Someone Has a Reaction to a Vaccine?

- Call a doctor. If the reaction is severe, take the person to a doctor immediately.
- Tell your doctor what happened, when it happened, and when the vaccination was given.
- Ask your doctor, nurse, or health department to file a VAERS form, or call VAERS yourself at 1-800-822-7967.

What are Possible Side Effects of Vaccination?

Each person is unique and may react differently to vaccination.

- Occasionally, people who receive a vaccine do not respond to it and may still get the illness the vaccine was meant to protect them against.

- In most cases, vaccines are effective and cause no side effects, or only mild reactions such as fever or soreness at the injection site.
- Very rarely, people experience more serious side effects, like allergic reactions. Be sure to tell your health care provider if you have health problems or known allergies to medications or food.

What Every Parent Should Know about Vaccines?

All children need vaccines because vaccines protect your child from many diseases. These diseases can cause serious health problems including:

- Life-threatening illness
- Lasting disabilities
- Brain damage or even death

Children under age 2 are at special risk. They're more likely than older children to become very ill or disabled from a disease. That's why it's so important to vaccinate on time. So you see, the risks from disease are much greater than the risks from vaccines.

How Do Vaccines Work?

Vaccines help by:

- Strengthening the body's immune (defense) system. Vaccines cause the body to make antibodies that fight disease.
- Protecting your baby throughout childhood. Once vaccines are given, antibodies continue to fight diseases for months or years. Some vaccines can protect for life. Others have to be repeated.
- Keeping diseases from spreading. When you have your baby vaccinated, you'll also be helping to protect other babies, children and adults.

How Do I Prepare My Child for Shots?

- Be honest. Tell your child it may hurt, but only for a few seconds.
- Tell your child, "It's okay to cry".
- Allow him or her to bring a favorite stuffed toy or a blanket. Avoid telling your child to "be brave".
- Let you child know you will stay with him or her the whole time.



Sudden Infant Death Syndrome (SIDS) and Vaccines

From 2 to 4 months old, babies begin their primary course of vaccinations. This is also the peak age for sudden infant death syndrome (SIDS). The timing of these two events has led some people to believe they might be related. However, studies have concluded that vaccinations are not a risk factor for SIDS.

With babies receiving multiple doses of vaccines during their first year of life and SIDS being the leading cause of death in babies between one month and one year of age, CDC has led research studies to look for possible linkages. Results from studies below and continued monitoring reassure us about the safety of vaccines.

- The Institute of Medicine (IOM) released a report on Immunization Safety Review: Vaccination and Sudden Unexpected Death in Infancy in 2003. The committee reviewed epidemiologic evidence focusing on SIDS, all sudden unexpected death in infancy, and neonatal death (infant death, whether sudden or not, during the first 4 weeks of life). The committee also looked for possible relationships between SIDS and the individual vaccines diphtheria-tetanus-whole-cell pertussis (DTwP), DTaP, HepB, Hib, and polio; and specific combinations of vaccines. The committee did not find enough evidence to show vaccines cause SIDS.
- A study using Vaccine Safety Datalink (VSD) data, which included children who were covered by a managed care organization health plan, found no association between immunization and deaths in young children. The study investigated deaths in children one month to 7 years of age between 1991 and 1995. Data were analyzed by comparing vaccination histories for each vaccine during the week and month prior to the date of death for each child. Five hundred and seventeen deaths occurred between 1991 and 1995, most (59%) during the first year of life. Of these deaths, the results did not show an association between immunizations and childhood deaths.
- Studies that looked at the age distribution and seasonality of deaths reported to the Vaccine Adverse Event Reporting System (VAERS). SIDS and VAERS reports following DTP vaccination, and SIDS and VAERS reports following hepatitis B vaccination found no association between SIDS and vaccination.
- VAERS also monitors the safety of vaccines. Through VAERS the U.S. Food and Drug Administration carefully investigates all deaths following vaccination that are reported to VAERS.

As a result of the American Academy of Pediatrics' 1992 recommendation to place healthy babies on their backs to sleep, and the success of the National Institute of Child Health and Human Development's Back to Sleep campaign, fewer SIDS deaths are reported. According to "Targeting SIDS: A Strategic Plan:"

- Between 1992 and 1998, the proportion of infants placed to sleep on their stomachs declined from about 70 percent to about 17 percent.

- Between 1992 and 1998, the SIDS rate declined by about 40 percent, from 1.2 per 1,000 live births to 0.72 per 1,000 live births.

These results tell us that most SIDS deaths are due to factors like sleeping on their stomachs, cigarette smoke exposure, and mild respiratory infections.

Pregnancy and Influenza Vaccine Safety



Influenza (flu) vaccine safety studies are reporting good news for pregnant women. This research was presented at the 49th Annual Meeting of the Infectious Diseases Society of America (IDSA) in October 2011.

Research shows:

Influenza vaccination during pregnancy protects newborns from getting influenza.

Pregnant women who get influenza vaccine pass their immunity to their babies in the form of flu antibodies. This protection lasts for several months after birth. Influenza protection was seen in newborns up to four months old. Babies born to women who were not vaccinated during pregnancy showed no antibody protection.

Influenza vaccination does not cause miscarriage.

Research shows no association between flu vaccination during pregnancy and miscarriage. This largest study conducted during the first trimester showed pregnant women who got the flu vaccine were no more likely to miscarry than those who did not get the flu vaccine.

More pregnant women are getting vaccinated against influenza.

The number of pregnant women receiving influenza vaccine has increased dramatically in the last couple of years in large part due to a national effort to vaccinate against the 2009 H1N1 pandemic influenza during the 2009-10 influenza season. Prior to 2009, less than 15 percent of pregnant women got vaccinated. In the past two influenza seasons, over half of pregnant women were vaccinated.

Thimerosal

Information about Thimerosal

Since 2001, with the exception of some influenza (flu) vaccines, thimerosal is not used as a preservative in routinely recommended childhood vaccines.

Thimerosal is a mercury-containing preservative used in some vaccines and other products since the 1930's. There is no convincing evidence of harm caused by the low doses of thimerosal in vaccines, except for minor reactions like redness and swelling at the injection site. However, in July 1999, the Public Health Service agencies, the American Academy of Pediatrics, and vaccine manufacturers agreed that thimerosal should be reduced or eliminated in vaccines as a precautionary measure.

CDC Study on “Prenatal and Infant Exposure to Thimerosal from Vaccines and Immunoglobins and Risk of Autism”

How was this CDC study conducted?

CDC conducted a case-control study in three managed care organizations that participate in its [Vaccine Safety Datalink \(VSD\) Project](#). The [VSD](#) was established in 1990 as a collaborative effort between CDC's Immunization Safety Office and eight managed care organizations (MCOs) to monitor immunization safety and address the gaps in scientific knowledge about rare and serious adverse events following immunization.

A total of 1,008 children participated in the study; of these, 256 had ASD (case children) and 752 did not. The purpose of the study was to see if ethylmercury from thimerosal in vaccines or immunoglobulin products increased a child's risk of developing autism. Ethylmercury exposure of the children and their mothers was ascertained and evaluated for possible relationship to ASD or two subtypes of ASD – autistic disorder and ASD with regression.

Thimerosal is a mercury-containing preservative that is added to multi-dose vials (vials containing more than one dose) of vaccine to prevent contamination and growth of potentially harmful bacteria.

What are the main findings from this study?

This study found that children with any ASD conditions and those without ASD had similar ethylmercury exposures at the end of each exposure period from pregnancy to 20 months of age. Exposure to ethylmercury from thimerosal-containing immunizations during pregnancy (prenatally), or as a young child, was **not** associated with any of the ASD outcomes. The researchers found that the results were similar between boys and girls—thimerosal-containing immunizations **did not** increase the risk of any of the ASD outcomes.

Why is CDC releasing this study now?

Although thimerosal is currently used only in multi-dose vials of flu vaccine, CDC is aware of the concerns that arose when thimerosal was used as a preservative in other vaccines that children may have received, including misconceptions that these vaccines were related to autism (a neurodevelopment disorder). These concerns arose at a time when there was also an increase in autism prevalence in the United States. People began to question whether there may have been an association with thimerosal-containing immunizations and autism. In 2004, an [Institute of Medicine](#) review concluded that the scientific evidence did not support a causal association between thimerosal-containing vaccines and autism.

After IOM's report, the decision was made by the investigators on this study to proceed with the research because it provided new or stronger data in three areas: 1) impact of maternal exposure to ethylmercury while pregnant, 2) evaluation of ethylmercury exposure in association with the three autism spectrum disorder subtypes, and 3) a more rigorous approach to evaluating autism diagnosis and ethylmercury exposure.

Concerns around vaccine safety may have made the decision to elect to have children vaccinated difficult for some parents. This study adds more comprehensive data to the existing science on the safety of thimerosal in vaccines and immunoglobulin products, which should help to further lessen concerns about vaccinating children.

How is this study different than previous studies on thimerosal and autism?

To date, there have been several [published studies](#) on the safety of thimerosal in vaccines. The data shows that the low doses of thimerosal in vaccines do not cause harm, although it may be associated with minor reactions, such as redness and swelling at the injection site, and rare allergic reactions.

This new study adds more comprehensive data to the existing science on the safety of thimerosal. It is the most thorough to date because it is the first time CDC has gathered and examined maternal data and the first time CDC has examined ASD along with the various autism subtypes.

The study included consultation by external experts and representatives of autism advocacy groups, used state-of-the art in-person evaluations administered by research staff trained by leading autism experts, and was based on well-documented data on exposure to thimerosal-containing products. The study controlled for many factors that could influence the risk of autism or receipt of immunizations. Moreover, the study provides the strongest evidence to date that immunization during pregnancy with thimerosal-containing vaccines, including flu vaccine, does not increase risk of ASD.

How were children selected for this study?

Children were eligible to participate if they met the following criteria:

1. Were born between January 1, 1994 and December 31, 1999,

2. Had been continuously enrolled in the managed care organization from birth until their second birthday and were currently enrolled at the time of sample selection; and
3. Lived within 60 miles of a study assessment clinic.

Children were 6 to 13 years old at the time of data collection. All children in the study had to live with their biological mother since birth, and their family had to be fluent in English (for purposes of administering the surveys). Children were excluded if they had a medical condition with known links to ASD traits including: Fragile X syndrome, tuberous sclerosis, Rett's syndrome, congenital rubella syndrome, or Angelman's syndrome.

How was thimerosal exposure in children and during pregnancy monitored?

Children's immunization histories were obtained from computerized immunization records and abstracted from medical charts. The researchers used medical charts and personal interviews to determine immunization histories of mothers during their pregnancy with the study child. Maternal immunizations included were immune globins, tetanus toxoid, diphtheria-tetanus toxoids, and flu vaccine.

Mercury content of the thimerosal-containing immunizations was determined by linking the vaccine manufacturer, lot number, and year of receipt to published data and manufacturer records.

Exposure during pregnancy was calculated as the total amount (micrograms) of all thimerosal-containing immunizations received by the mother during her pregnancy with her child. Exposure during childhood was calculated as the micrograms of ethylmercury divided by the weight of the child (in kilograms) at the time of administration of each immunization.

What does CDC know about the safety of thimerosal in vaccines given during pregnancy?

Through this study, CDC has found that exposure to thimerosal during pregnancy and in young children was not associated with an increased risk of ASD.



Concerns about Autism

CDC Statement on Autism and Thimerosal



As the country's leading public health agency, the Centers for Disease Control and Prevention (CDC) is committed to protecting the health of all Americans—including infants, children, and adolescents. CDC shares with parents and many others great concern about the number of children with autism spectrum disorders (ASD). We are committed to understanding what causes autism, how it can be prevented, and how it can be recognized and treated as early as possible.

Recent estimates from [CDC's Autism Developmental Disabilities Monitoring network](#) found that about 1 in 150 children have ASD. This estimate is higher than estimates from the early 1990s. Some people believe increased exposure to thimerosal (from the addition of important new vaccines recommended for children) explains the higher prevalence in recent years. However, evidence from several studies examining trends in vaccine use and changes in autism frequency does not support such an association. Furthermore, a [scientific review](#) by the Institute of Medicine (IOM) concluded that "the evidence favors rejection of a causal relationship between thimerosal-containing vaccines and autism." CDC supports the IOM conclusion.

CDC recognizes that autism is an urgent health concern and supports comprehensive research as our best hope for understanding the causes of autism and other developmental disorders. Through collaborations with partners in government, research centers, and the public, CDC is focusing on three areas—

1. Understanding the frequency and trends of autism spectrum disorders.
2. Advancing research in the search for causes and effective treatments.
3. Improving early detection and diagnosis so affected children are treated as soon as possible