

What You Need to Know About Vaccine Safety



Vaccines are one of the greatest success stories in public health and have put an end to smallpox, nearly rid the world of polio, and greatly reduced cases and outbreaks of many infectious illnesses, such as measles, to all-time low levels.

The United States has access to the safest, most effective vaccines in history. By law before a vaccine can be licensed in the US it must undergo very extensive testing. Once in use, vaccines are continually monitored for safety and efficacy. Vaccines are our best defense against infectious diseases, but no vaccine is 100 percent safe or 100 percent effective.

Are Vaccines Tested and Monitored for Safety?

Yes. Vaccines are held to the highest standards for safety. Before a vaccine is licensed in the US, the FDA requires testing to ensure safety. After it is licensed, the FDA requires the vaccine's manufacturer to routinely submit samples from each vaccine lot for testing before its release. Manufacturers must also submit their own test results for each vaccine lot's safety, potency, and purity.

Once a vaccine is in use, CDC and FDA monitor its safety through the Vaccine Adverse Event Reporting System (VAERS). This system collects reports from healthcare providers, vaccine manufacturers, and the general public. An adverse event is any health problem or side effect that happens after a vaccination. VAERS cannot determine if an adverse event was caused by a vaccine, but can help determine if more investigations are needed. If researchers find a vaccine may be causing a serious

side effect, CDC and FDA will investigate further and take appropriate action. This may include distributing safety alerts, inspecting the vaccine manufacturer's facilities and records, changing the instructions to providers on the vaccine label and/or in the package insert, restricting who may receive the vaccine by withdrawing recommendations for its use, or discontinuing the vaccine's license.

Who Should Not Be Vaccinated?

Some people should not get certain vaccines or should wait to get them. Specific information for each vaccine is found in the vaccine's package insert. For instance, individuals with a weakened immune system, as occurs with cancer treatment, often need to wait to be vaccinated. Also, if a person has had a severe allergic reaction to a vaccine, a second 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.

What Vaccine Side Effects Occur and Why?

- Each person is unique and may react differently to an immunization.
- In most persons, vaccines are effective and often only cause mild reactions such as fever or soreness at the injection site.
- Some people may experience a more serious side effect, such as an allergic reaction, but these events are very rare and it may be very difficult to identify these individuals.
- Be sure to tell your healthcare provider if you have any health problems or known allergies to medications or food.

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

- If the reaction is severe call a doctor or 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.

For more information on vaccine safety and to receive updates on vaccine safety, visit www.cdc.gov/vaccinesafety or call 1-800-CDC-INFO.

For more information on VAERS, visit www.vaers.hhs.gov.