

How Do We Know Vaccines are Safe?

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Too often, we hear misinformation about vaccines and their safety. Some people claim that they are not tested for safety *before* being licensed and recommended for use in people in the United States. Others say that vaccines are not held to the same safety standards as drugs, when in fact they are held to a higher standard. And some others wrongly proclaim that vaccines are not monitored for safety *after* they are licensed by the U.S. Food and Drug Administration (FDA) and recommended for the public by the Centers for Disease Control and Prevention (CDC), as they are unaware of the strong vaccine surveillance systems we have in place in the U.S.

The United States has the safest, most effective vaccine supply in its history.

Below, we offer an overview of how vaccines are tested and monitored for safety and effectiveness:

Clinical trials

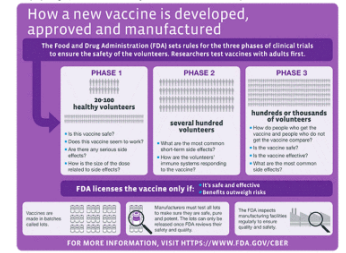
Vaccines are one of the most thoroughly tested medical products available in the U.S. Before a vaccine can be considered for approval by the FDA, a vaccine manufacturer must show it is safe and effective through clinical trials. Developing a new vaccine begins with exploratory stage and pre-clinical stage before advancing to three stages of clinical trials. Together, this scientific process can take over a decade and cost millions of dollars. The FDA then examines these studies and determines whether a vaccine is safe, effective, and ready to be licensed for use. The FDA only licenses vaccines that have data that shows that the vaccines' benefits outweigh the potential risks. If there is any question about the data, or any holes in the data, the FDA will request further studies before approving the vaccine.

Four monitoring systems

After a vaccine is licensed for use in the U.S., there are four systems in place that work together to help scientists monitor the safety of vaccines and identify any rare side effects that may not have been found in clinical trials. Even large clinical trials may not be big enough to find very rare side effects. For example, some side effects may only happen in 1 in 100,000 or 1 in 500,000 people. Second, vaccine trials may not include certain populations like pregnant women or people with specific medical conditions who might have different types of side effects or who might have a higher risk of side effects than the volunteers who got the vaccine during clinical trials.

The Journey of Your Child's Vaccine

Before a new vaccine is ever given to people, extensive lab testing is done that can take several years. Once testing in people begins, it can take several more years before clinical studies are complete and the vaccine is licensed.



If the FDA licenses a vaccine, experts may consider adding it to the recommended immunization schedule.

How a vaccine is added to the U.S. Recommended Immunization Schedule

The Advisory Committee on Immunization Practices (ACIP) is a group of medical and public health experts. Members of the American Academy of Pediatrics (AAP) and American Academy of Family Physicians (AAFP) are among some of the groups that also bring related immunization expertise to the committee. This group carefully reviews all available data about the vaccine from clinical trials and other studies to develop recommendations for vaccine use.

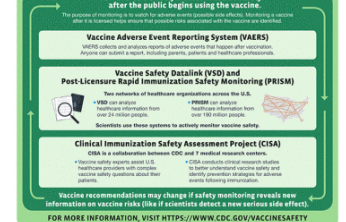
When making recommendations, ACIP considers:
- How safe is the vaccine when given at specific ages?
- How and when the vaccine needs to be given?
- How serious is the disease the vaccine prevents?
- How many people get sick, including young children and other people who don't have the vaccine?
ACIP recommendations are not official until the CDC Director reviews and approves them and they are published. These recommendations then become part of the United States official childhood immunization schedule.

New vaccine to protect your child against a disease is added to the schedule.

FOR MORE INFORMATION, VISIT [HTTPS://WWW.CDC.GOV/VACCINES](https://www.cdc.gov/vaccines)

After being added to the U.S. Recommended Immunization Schedule, health experts continue to monitor the vaccine's safety and effectiveness.

How a vaccine's safety continues to be monitored



FOR MORE INFORMATION, VISIT [HTTPS://WWW.CDC.GOV/VACCINESAFETY](https://www.cdc.gov/vaccinesafety)

The United States currently has the safest vaccine supply in its history. These vaccines help children, babies and communities protected from serious diseases.

CDC's *The Journey of Your Child's Vaccine* - www.cdc.gov/vaccines/parents/infographics/journey-of-child-vaccine-h.pdf

[Vaccine Adverse Events Reporting System \(VAERS\)](#)

VAERS is a passive reporting system. That means it relies on individuals to report vaccine reactions. Anyone can report a reaction or injury, including healthcare providers, patients and patients' representatives, such as caregivers or attorneys. The system is co-managed by the FDA and the CDC. However, it is important to note that VAERS data alone can't be used to answer the question, "Does a certain vaccine cause a certain side effect?" This is because adverse events reported to VAERS *may or may not* be caused by vaccines. There are reports in VAERS of common conditions that occur just by chance after vaccination. Further investigation may find no medical link between vaccination and these conditions. Instead, the purpose of VAERS is to see if unexpected or unusual patterns emerge, which may indicate a vaccine safety issue that needs to be researched further.

[The Vaccine Safety Datalink \(VSD\)](#)

Established in 1990, VSD is a collaboration between the CDC's Immunization Safety Office and eight health care organizations across the country. It conducts studies based on questions or concerns raised from the medical literature and reports to VAERS. In addition, when new vaccines are recommended or if changes are made in how a vaccine is recommended, VSD will monitor the safety of these vaccines.

[The Clinical Immunization Safety Assessment Project \(CISA\)](#)

CISA, which was created in 2001, is a national network of vaccine safety experts from the CDC's Immunization Safety Office, seven medical research centers and other partners. CISA addresses vaccine safety issues, conducts high quality clinical research and assesses complex clinical adverse events following vaccination. CISA also helps to connect clinicians with experts who can help consult on vaccine safety questions related to individual patients.

[The Post-Licensure Rapid Immunization Safety Monitoring System \(PRISM\)](#)

PRISM is a partnership between the FDA's Center for Biologics Evaluation and Research and leading health insurance companies. It actively monitors and analyzes data from a representative subset of the general population. PRISM links data from health plans with data from state and city immunization information systems (IIS). PRISM has access to information for over 190 million people allowing it to identify and analyze rare health outcomes that would otherwise be difficult to assess.

These four post-licensure monitoring systems have been able to address several important issues related to vaccines and their safety, including:

- Finding no connection between the [human papillomavirus \(HPV\) vaccine \(Gardasil\) and venous thromboembolism](#) in females 9 to 26 years of age.
- Identifying a link between a [rotavirus vaccine \(RotaTeq®\) and an increased risk of intussusception](#) in infants, which led to its withdrawal from the market.
- Establishing the [safety of thimerosal in vaccines](#).
- Establishing the [safety of the childhood immunization schedule](#) in the U.S.
- [Demonstrating the safety of vaccines during pregnancy](#) through fourteen separate studies.

The Department of Health and Human Services (HHS) and its agencies, health insurance companies, scientists, healthcare providers, and other public health and medical groups are all dedicated to ensuring people of all ages are protected against serious infectious diseases by a safe, effective supply of vaccines.