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.

How a new vaccine is developed, approved and manufactured

The Food and Drug Administration (FDA) sets rules for the three phases of clinical trials to ensure the safety of the volunteers. Researchers test vaccines with adults first.

PHASE 1

20-100 healthy volunteers

- Is this vaccine safe?
- Does this vaccine seem to work?
- Are there any serious side effects?
- How is the size of the dose related to side effects?

PHASE 2

several hundred volunteers

- What are the most common short-term side effects?
- How are the volunteers' immune systems responding to the vaccine?

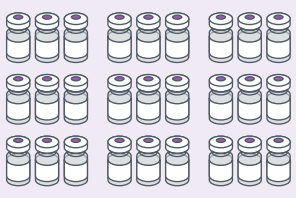
PHASE 3

hundreds or thousands of volunteers

- How do people who get the vaccine and people who do not get the vaccine compare?
- Is the vaccine safe?
- Is the vaccine effective?
- What are the most common side effects?

FDA licenses the vaccine only if:
- **It's safe and effective**
- **Benefits outweigh risks**

Vaccines are made in batches called lots.



Manufacturers must test all lots to make sure they are safe, pure and potent. The lots can only be released once FDA reviews their safety and quality.

The FDA inspects manufacturing facilities regularly to ensure quality and safety.

FOR MORE INFORMATION, VISIT HTTPS://WWW.FDA.GOV/CBER

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

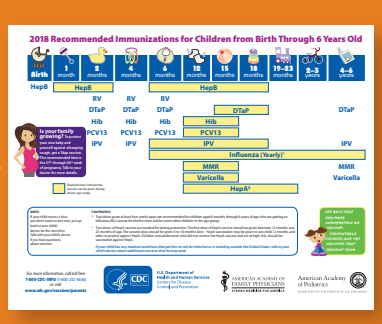
The Advisory Committee on Immunization Practices (ACIP) is a group of medical and public health experts. Members of the American Academy of Pediatrics (AAP) and American Academy of Family Physicians (AAFP) are among some of the groups that also bring related immunization expertise to the committee. This 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 well does the vaccine work at specific ages?
- How serious is the disease this vaccine prevents?
- How many children would get the disease the vaccine prevents if we didn'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.

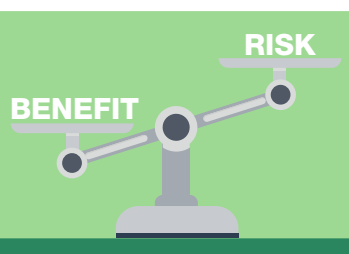
New vaccine to protect your child against a disease is added to the schedule.



FOR MORE INFORMATION, VISIT HTTPS://WWW.CDC.GOV/VACCINES

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



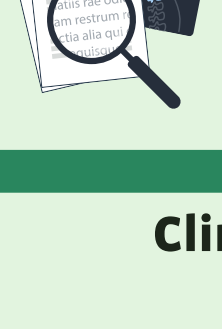
FDA and CDC closely monitor vaccine safety after the public begins using the vaccine.

The purpose of monitoring is to watch for adverse events (possible side effects). Monitoring a vaccine after it is licensed helps ensure that possible risks associated with the vaccine are identified.

Vaccine Adverse Event Reporting System (VAERS)

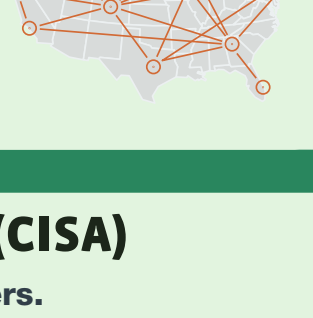
VAERS collects and analyzes reports of adverse events that happen after vaccination. Anyone can submit a report, including parents, patients and healthcare professionals.

Vaccine Safety Datalink (VSD) and Post-Licensure Rapid Immunization Safety Monitoring (PRISM)



Two networks of healthcare organizations across the U.S.

- **VSD** can analyze healthcare information from over 24 million people.
- **PRISM** can analyze healthcare information from over 190 million people.



Scientists use these systems to actively monitor vaccine safety.

Clinical Immunization Safety Assessment Project (CISA)

CISA is a collaboration between CDC and 7 medical research centers.

- Vaccine safety experts assist U.S. healthcare providers with complex vaccine safety questions about their patients.
- CISA conducts clinical research studies to better understand vaccine safety and identify prevention strategies for adverse events following immunization.

Vaccine recommendations may change if safety monitoring reveals new information on vaccine risks (like if scientists detect a new serious side effect).

FOR MORE INFORMATION, VISIT HTTPS://WWW.CDC.GOV/VACCINESAFETY

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

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

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