

How Vaccines are Produced

Concern: I have concerns about how the vaccines are tested and produced.

General Responses:

- Vaccines are placed through intense testing before arriving at your provider's office.
- There are several phases of trials that occur while developing and testing a vaccine. By the time the product is offered to the public, it has been studied for at least 10 to 15 years (usually longer), in tens of thousands of study participants, by thousands of scientists, statisticians, healthcare providers and other personnel.
- Monitoring of this process begins with the U.S. Food and Drug Administration (FDA). The FDA reviews all phases of clinical trials on vaccines and must approve the vaccine for use. Licensure of the vaccine only occurs after strict review of those studies on safety and effectiveness of the vaccine.
- Vaccines are made in several ways. However, all vaccines have the same general goal, which is to weaken the virus or bacteria in a way that allows the person to develop an immune response without developing any symptoms of infection.
- Vaccines are developed, tested, and regulated in a very similar manner to other drugs.
- In general, vaccines are even more thoroughly tested than non-vaccine drugs because the number of human subjects in vaccine clinical trials is usually greater.
- In addition, post-licensure monitoring of vaccines is closely examined by the Centers for Disease Control and the FDA, and the U.S. vaccine safety system continuously monitors for rare adverse events and effectiveness.
- The United States has the safest, most effective vaccine supply in its history.

Risk of Disease

- Vaccine-preventable diseases can be serious, or even deadly.
- Some vaccine-preventable diseases, like whooping cough (pertussis) and chickenpox, remain common in the United States. Without vaccines, your child is at risk for getting seriously ill and suffering pain, disability and even death from these diseases.
- Even with advances in healthcare, the diseases that vaccines prevent can still be very serious – and vaccination is the best way to prevent them.
- Other diseases prevented by vaccines, such as polio and diphtheria, are no longer common in the U.S. because of vaccines. However, if we stop vaccinating, even the few cases of disease we have in the U.S. could quickly become tens to hundreds of thousands of cases.
 - Each year we hear about disease outbreaks in under-vaccinated communities across the United States.
 - We have seen an increase in pertussis cases in Michigan for several years. Michigan has experienced infant deaths, including a 3-month-old little girl in 2012.
 - There were 1,301 cases of pertussis disease reported in Michigan in 2014.
 - We have also seen an increase in measles cases, with over 600 cases reported in the United States during 2014.
 - This is more cases than in any year since 1996; only 37 cases in 2004.

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Benefit of Vaccination:

- Vaccines can prevent diseases that once killed or harmed many infants, children and adults.
- Each and every vaccine will save lives and/or reduce the number of disabilities in children in the United States.
- With our advances in medical science, the United States has the safest vaccine supply in our history, and a child is far more likely to be seriously injured by a vaccine-preventable disease than by any vaccine.
 - Pneumococcal disease caused about 700 cases of meningitis, 13,000 cases of bacteremia, and 5 million middle ear infections each year among children younger than 5 years old before the vaccine was available in the U.S.
 - Rotavirus disease was responsible for 55,000-70,000 hospitalizations, more than 200,000 emergency room visits, more than 400,000 outpatient visits and 20-60 deaths among children younger than 5 years of age every year before the Rotavirus vaccine was introduced in the U.S.
 - Through research based on post-marketing evaluations in the U.S., the currently licensed rotavirus vaccines have been found to be highly protective against rotavirus disease requiring hospitalization (85%-90%) and in preventing emergency department care (greater than 80%)

Resources (*Available in Spanish)

The Children's Hospital of Philadelphia

*The Facts about Childhood Vaccines

<http://vec.chop.edu/export/download/pdfs/articles/vaccine-education-center/vaccines-fact.pdf>

Website page: How Vaccines Are Made

<http://vec.chop.edu/service/parents-possessing-accessing-communicating-knowledge-about-vaccines/vaccine-science/how-vaccines-are-made.html>

DVD: Vaccines and Your Baby and Vaccines: Separating Fact from Fear

<http://vec.chop.edu/video/vaccines-and-your-baby/home.html>

<http://vec.chop.edu/video/vaccine-separating-fact-from-fear/home.html>

Booklets: *Vaccines and Your Baby and *Vaccine Safety and Your Child

<http://vec.chop.edu/service/vaccine-education-center/order-educational-materials/order-educational-materials.html#booklets>

CDC

The Journey of Your Child's Vaccine

<http://www.cdc.gov/vaccines/parents/infographics/journey-of-child-vaccine.html>

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Ensuring the Safety of Vaccines in the United States

<http://www.cdc.gov/vaccines/hcp/patient-ed/conversations/downloads/vacsafe-ensuring-bw-office.pdf>

Vaccines work! CDC statistics demonstrate dramatic declines in vaccine-preventable diseases when compared with the pre-vaccine era

<http://www.immunize.org/catg.d/p4037.pdf>

Website page: Vaccine Testing and the Approval Process

<http://www.cdc.gov/vaccines/resdev/test-approve.htm>

Website page: Ensuring Vaccine Safety

<http://www.cdc.gov/vaccines/parents/vaccine-decision/safety.html>

American Academy of Pediatrics

*Facts for Parents about Vaccine Safety

<http://www2.aap.org/immunization/families/VaccineSafety1pagerEnglish.pdf>

Vaccine Safety: The Facts

http://www2.aap.org/immunization/families/VaccineSafety_parenthandout.pdf

History of Vaccines

*Website: The History of Vaccines - Vaccine Development, Testing and Regulation

<http://www.historyofvaccines.org/content/articles/vaccine-development-testing-and-regulation>

Vaccinate your Baby a program of Every Child By Two

Website: Are They Safe?

<http://www.vaccinateyourbaby.org/safe/index.cfm>

Statistics under Benefit of Vaccination

CDC

Vaccine Information Statement on Rotavirus Vaccine, Note to Providers

<http://www.cdc.gov/vaccines/hcp/vis/vis-statements/rotavirus-hcp-info.pdf>