

How Vaccines Are Developed

Bicycle helmets, sunscreen, car seats -- parents strive to provide everything their children need to protect them from harm. But what about vaccines? For many people, especially parents of young children, vaccines can be scary. Getting a shot doesn't feel good, and the long-term health benefit of the vaccine is not immediately clear. This leads some parents to question whether vaccines are safe and effective for children. To understand how we know that they are safe and effective, it helps to know a little about how vaccines are developed and approved.

Vaccine development begins in the laboratory. First, researchers use computers to predict how the vaccine will interact with the human immune system. If laboratory tests show that a vaccine has potential, it is usually tested in animals – usually first in rodents, such as rats, and finally in primates, such as rhesus monkeys, which have immune systems similar to ours. If a vaccine is safe in animals, and studies suggest that it will be safe in people, clinical trials with volunteers are next. Participation in these studies is completely voluntary. Volunteers agree to receive the vaccine and undergo any medical testing necessary to assess its safety and efficacy.

The Food and Drug Administration (FDA) requires that vaccines undergo three phases of clinical trials with humans before they can be licensed. Phase one trials are small, involving only 20 to 100 volunteers. The purpose of phase one trials is to evaluate basic safety and identify the most common reactions.

Phase two trials are larger and involve several hundred participants. These studies collect additional information on safety and efficacy. Data gained from phase two trials can be used to determine the composition of the vaccine, how many doses are necessary, and a list of common reactions.

If the vaccine is shown to be safe and effective in phase two trials, the trials are expanded to phase three, which involves several hundred to several thousand volunteers. Because the vaccinated groups are compared to those who have not received the vaccine, researchers are able to gather considerable data on safety and effectiveness, including rates of common adverse reactions, like pain where the vaccine was injected and fever.

Finally, if all of the clinical trials demonstrate that the vaccine is safe and effective, the vaccine maker applies to the FDA for two licenses: one for the vaccine (product license), and one for the production plant (establishment license). During the application process, the FDA reviews the clinical trial data and proposed product labeling. In addition, the FDA inspects the plant and goes over manufacturing protocols to ensure vaccines are produced in a safe and consistent manner. Only after the FDA is satisfied that the vaccine is safe and effective is it licensed for use.

After the FDA licenses a vaccine, public health experts may consider making a policy recommendation for its use and add it to the list of recommended immunizations (Recommended Immunization Schedule). The Advisory Committee on Immunization Practices (ACIP), a committee of medical and public health experts outside the federal government carefully reviews the data about the vaccine from clinical trials and other studies to develop recommendations for vaccine use.

When making recommendations, ACIP considers the safety and effectiveness of a vaccine; how serious, contagious, and common the disease is that the vaccine prevents; the public health impact of proposed recommendations; and how feasible it would be to implement a vaccination program. ACIP recommendations are not official until the director of the Centers for Disease Control and Prevention

(CDC) reviews and approves them, and they are published in the agency's Morbidity and Mortality Weekly Report (MMWR). These recommendations then become part of the United States official immunization schedule.