Vaccine Approval in the US

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How Vaccines Work

Vaccines work by mimicking the infectious bacteria or viruses that cause disease. Vaccines stimulate the body's immune system to build defenses against the infectious bacteria or virus without actually causing the disease.

Some vaccines contain part of a virus or bacteria, while others contain weakened versions of the virus or bacteria.

Other vaccines contain the genetic material for a specific protein that is found on the surface of the cells of the targeted virus.

Once a person receives the vaccine, the body's immune system detects the virus, bacteria, or protein and makes antibodies, which the body uses to identify a foreign substance like a virus or bacteria.

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If a vaccinated person is infected by the bacteria or virus in the future, the body quickly recognizes these cells and attacks it to prevent infection.

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By building these defenses and teaching the body to recognize a virus or bacteria ahead of time, your body is able to fight off the disease if you are exposed.

What are the ingredients in a vaccine?

1. Vaccines contain tiny fragments of the disease-causing organism or the blueprints for making the tiny fragments.
2. They also contain other ingredients to keep the vaccine safe and effective, such as preservatives to keep the vaccine usable while it is shipped from the production facility to your doctor's office.

The Vaccine Approval Process

Vaccine trials in the U.S. are conducted by pharmaceutical companies and monitored by the Food and Drug Administration (FDA), which is the federal organization that approves vaccines for public use. There are several steps required for a vaccine to receive FDA approval. There are three stages:

- Research and Discovery Stage
- Pre-clinical Stage
- Clinical Development Stage

COVID-19 Vaccine Approval

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The Vaccine Approval Process

Research and Discovery Stage

Scientists develop a plan for a vaccine based on how the virus or bacteria causes a disease. The scientists then conduct lab research to test their idea for a vaccine.

Pre-clinical Stage

Before a vaccine can be tested on people, a company or researcher performs additional lab research and testing in animals to collect information about how the vaccine works and whether it's likely to be safe and work well in humans.

Clinical Development Stage

When a company/researcher studies a vaccine in humans, test results are collected and the compiled results are submitted to the FDA in the form of an Investigational New Drug application (IND). The FDA then assesses the potential vaccine, its quality and safety, and its manufacturing to determine whether it is safe to test the vaccine on humans. Clinical testing takes place in three phases:

Phase One

Includes between 20-100 volunteers. This phase is closely monitored to determine the safety of the drug, possible side effects, and dosage levels.

Phase Two

Includes hundreds of people. Various dosages of the drug are tested. Includes people with different health backgrounds. Provides more information on safety, short-term side effects and risks, and the relationship between doses administered and immune response.

Phase Three

The vaccine is administered to thousands of people. More information is provided on effectiveness, important safety data, immune response, and compares the cases in the experimental group to the control groups.

Special Considerations

There is no predetermined timeline for vaccine development. The better scientists understand a disease, the more quickly a vaccine can be developed. However, in public health emergencies such as a pandemic, the process for making a vaccine may move more quickly. The U.S. government may work with researchers, government agencies, pharmaceutical or drug companies, and foreign governments to speed the process of developing vaccines while still ensuring they are safe. The FDA may also allow a vaccine to be given to the public under a special designation called Emergency Use Authorization (EUA) before it receives full FDA approval. Vaccines given under EUA are still safe, but the FDA continues to monitor results to make changes to their recommendations as needed.

Quality Control

After approving a vaccine, the FDA continues to oversee its production to ensure safety. Monitoring of the vaccine and how it is produced, including regularly inspecting the places where vaccines are made, must continue as long as the manufacturer holds a license for the vaccine.