

Five things you should know about vaccine safety

According to the Centers for Disease Control and Prevention (CDC), vaccines are one of the greatest success stories in public health.

As the first shipments of a safe and effective COVID-19 vaccine draw closer, it's important for you to have the most accurate and up-to-date information so you can make your personal health care decisions based on facts.

Here are five things you should know about vaccine safety:

1 SAFETY TESTING BEGINS EARLY

Prior to testing on humans, researchers use computers to simulate how the vaccine will act in the human body. Then, tests are done on animals in labs.

2 FDA APPROVAL IS NEEDED BEFORE TESTING ON HUMANS

When the vaccine is considered safe to test on humans, the manufacturer seeks approval from the FDA. If the FDA approves the vaccine for human testing, researchers recruit volunteers for three test phases:

- **Phase I** – Small groups of people are given the vaccine to test for safety, early effects and dosage.
- **Phase II** – Hundreds of people with different characteristics (such as age and health status) are given the vaccine to further test for safety, effects and dosage.
- **Phase III** – Thousands of people are given the vaccine to test if it's safe and effective against the virus. During this time an independent safety board reviews any reported concerns.

3 HOW A VACCINE IS APPROVED FOR USE

Once all three testing phases are complete, the FDA reviews the results and conducts other important safety inspections. Manufacturers must provide the FDA with their test results for vaccine safety, potency, and purity. Once approved, the FDA continues to oversee production and monitor activity to ensure safety.

4 SAFETY MONITORING CONTINUES AFTER APPROVAL

Monitoring continues even after vaccines hit the market. Their effectiveness and any rare side effects or safety issues become more apparent after millions of doses are given. If a link is found between a possible side effect and a vaccine, public health officials take action by determining if recommendations for vaccine use should change.

5 THE FEDERAL GOVERNMENT PROVIDES A VACCINE SAFETY NET

By taking the steps outlined above, the U.S. vaccine safety system ensures that all vaccines are as safe as possible. Learn how federal partners are working together to certify the safety of COVID-19 vaccines.