COVID-19 Vaccine FAQs

1. **What is a vaccine?**
   Think of a vaccine as a way for your immune system to practice for a virus. Vaccines give the body a preview of one or more key features of a virus before you get the actual virus. The immune system then develops a "memory" of how to react and stop the virus once you are exposed to it.

2. **How will the vaccine for the new coronavirus work?**
   The vaccine allows the immune system to produce antibodies that latch onto the spike protein that makes coronaviruses unique. (Coronaviruses got their name because the viruses have protein spikes that look like a crown.)

   This allows the immune system to quickly recognize the actual coronaviruses and interfere with its ability to multiply. The idea is to stop SARS-CoV-2, the virus that causes COVID-19, from getting into cells, replicating itself and making a person sick.

3. **How are COVID-19 vaccines tested for safety?**
   COVID-19 vaccines are being tested in large clinical trials to assess their safety. No vaccine will receive approval to be used outside of a clinical trial unless at least two months have gone by after the final shot in order to monitor for safety concerns. it may take more time, and more people getting vaccinated before we learn about extremely rare side effects. That is why safety monitoring will continue even after it is approved for use, like all other vaccines. The Centers for Disease Control and Prevention (CDC) and the U.S. Food and Drug Administration (FDA) each have an independent group of experts that review all the safety data as it comes in and provide regular safety updates. If a safety issue is detected, immediate action will take place to determine if the issue is related to the COVID-19 vaccine and determine the best course of action. To date there have been no serious safety concerns reported with either the Moderna or the Pfizer vaccines in people who have participated in the clinical trials.

4. **How do vaccine trials work in the United States?**
   There are several stages to vaccine development, such as the exploratory, pre-clinical, clinical, review and approval, manufacturing and quality control stages. In the clinical development stage, there are three Phases where humans participate in the trials:

   - **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 Data Safety Monitoring Board reviews any reported safety concerns.

   Once all three phases are complete, the FDA reviews the trial results and conducts other important safety inspections before approving a vaccine for use. Once approved, the FDA continues to oversee production and monitor activity to ensure safety.

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5. **What is the phase three trial for the COVID-19 vaccine?**
   A phase three trial is the last stage in before FDA approval. It tests the vaccine's safety and effectiveness with thousands of patients. The first vaccines being tested in the U.S. will include 30,000 or more participants each, and the trials will follow them for two years.

6. **In the trial, do all 30,000 COVID-19 vaccine trial participants receive the vaccine?**
   No. These trials are randomized, double-blind, placebo-controlled trials. In other words, some participants get the vaccine and others get a placebo injection of salt water. Which participants end up getting the drug or placebo is randomly assigned. Neither the participant nor the health care workers doing the injections know if the vaccine or placebo are in the vial. Even the researchers leading the trials do not know whether a given participant has gotten the vaccine or the saline injection. Which is why these trials are known as "double blind". The analysis of the data is done by an independent Data Safety Monitoring Board.

7. **Currently, what are they types of COVID-19 vaccines undergoing clinical trials?**
   According to the CDC, there are three main types of COVID-19 vaccines that are or soon will be undergoing large-scale (phase three) clinical trials in the United States. Below is a description of how each type of vaccine triggers our immune systems to recognize and protect us from the virus that causes COVID-19. **None of these vaccines can give you COVID-19 as they do not contain a live COVID-19 virus.**

   - **mRNA vaccines** contain material from the virus that causes COVID-19. This material gives our cells instructions for how to make a harmless protein that is unique to the virus. After our cells make copies of the protein, our bodies recognize that the protein should not be there and trigger an immune response that will remember how to fight the virus that causes COVID-19 if we are infected in the future.

   - **Protein subunit vaccines** include harmless pieces (proteins) of the virus that cause COVID-19 instead of the entire germ. Once vaccinated, our immune system recognizes that the proteins don't belong in the body and begins making antibodies. If we are ever infected in the future, memory cells will recognize and fight the virus.

   - **Vector vaccines** contain a weakened version of a live virus—a different virus than the one that causes COVID-19—that has genetic material from the virus that causes COVID-19 inserted in it (this is called a viral vector). Once the viral vector is inside our cells, the genetic material gives cells instructions to make a protein that prompts our bodies to build immunity that will remember how to fight that virus if we are infected in the future.

8. **What is the difference between a live vaccine and an inactivated vaccine?**

   - **Live vaccines** contain a version of the living virus or bacteria that is weakened so it does not cause a serious disease in people with healthy immune systems. These vaccines are a good teacher for the immune system because they are the closest thing to a natural infection. None of the vaccines currently being studied today for COVID-19 are live vaccines.
   - **Inactivated vaccines** are made by inactivating, or killing, the germ during the vaccine making process. This type of vaccine produces an immune response in a different way than a live vaccine. Multiple doses are often necessary to build or maintain an immunity.

9. **How can the COVID-19 vaccine be fast-tracked when other vaccines take years?**
   Under normal circumstances, from pre-clinical testing to distribution, a vaccine takes roughly 72 months, or six years, to develop. Under the federal government's Operation Warp Speed (OWS), the timeline to develop a COVID-19 vaccine has been reduced to only 14 months.

   According to the CDC, OWS provided the resources and funding needed from the federal government to create highly coordinated efforts, which accelerate development while maintaining standards for safety and efficacy.

   Specifically, clinical protocols that show the safety and efficacy of the vaccine are aligned, which allows the vaccine trials to proceed more quickly. Additionally, the protocols for the trials are overseen by the federal government, as opposed to traditional public-private partnerships, in which pharmaceutical companies decide on their own protocols.

   Rather than eliminating steps from traditional vaccine development timelines, the steps outlined under OWS advance simultaneously, such as starting manufacturing of the vaccine at an industrial scale well before the demonstration of vaccine efficacy and safety as happens under normal vaccine development. This increases costs associated with development but does not risk the safety or efficacy of the vaccine and compresses the overall timeline, but not the clinical study timeline.

   Additionally, according to the CDC, Severe acute respiratory syndrome (SARS) and Middle East respiratory syndrome (MERS) are two diseases caused by coronaviruses that are closely related to the virus that causes COVID-19.

   Researchers began working on developing vaccines for these diseases after they were discovered in 2003 and 2012, respectively. None of the SARS vaccines ever made it past the first stages of development and testing, in large part because the virus disappeared.

   One MERS vaccine (MVA-MERS-S) successfully completed a phase 1 clinical trial in 2019. Lessons learned from this earlier vaccine research have been used to inform strategies for developing a COVID-19 vaccine.

10. **How will we know the COVID-19 vaccine is safe?**
    Vaccines undergo at three phase testing process involving thousands of subjects. They receive approval from the FDA only after they demonstrate safety and meet at least the minimum standard of effectiveness. Monitoring continues after they hit the market; effectiveness and any rare side effects or safety issues become more apparent after millions of doses are given.

    The U.S. vaccine safety system ensures that all vaccines are as safe as possible. Learn how federal partners are working together to ensure the safety of COVID-19 vaccines.

11. **What is herd immunity?**
    Herd immunity is when enough of a population has immunity against a disease that it can no longer spread. The herd-immunity threshold for coronavirus is not known. However, it is thought to be between 60 and 80percent of the population. Herd immunity can be reached through vaccine immunization or through natural infection.

12. **How do you know a vaccine is effective?**
    Vaccines are tested for safety and effectiveness through clinical trials. Some people in the trail are given the vaccine, and some are given a placebo shot. The participants are then followed to see who gets COVID-19. By comparing how many people given the actual vaccine get sick to how many people who get the placebo get sick, we can tell how good the vaccine is in preventing COVID-19. In the case of the Moderna and Pfizer COVID-19 vaccines, both were near 95 percent effective in preventing COVID-19 illness in those vaccinated compared to those who got a placebo shot.

13. **Why do the COVID-19 vaccines need to be stored in such cold conditions?**
    Vaccines are stored in specific conditions to avoid losing effectiveness of the ingredients. In particular, mRNA vaccine technology requires cold temperatures to preserve the vaccine and its properties. Pfizer's vaccine needs to be kept extremely cold—minus 70 degrees Celsius—requiring special freezers, or the use of dry ice. Moderna's vaccine needs to be frozen too, but at only minus 20 Celsius—more like a regular freezer.

14. **When will the COVID-19 vaccine be available?**
    According to the CDC, the goal for Operation Warp Speed is to deliver safe vaccines that work, with the first supply becoming available before the end of 2020. When a vaccine is authorized or approved in the United States, there may not be enough doses available for all adults. Supplies will increase over time, and all adults should be able to get vaccinated later in 2021. However, a COVID-19 vaccine may not be available for young children or in those who are pregnant until more studies are completed.

15. **Who will get vaccinated first?**
    The National Institutes of Health has convened an expert group to help determine vaccination priorities. Right now, it looks like health care and essential workers as well as high-risk populations including older adults, residents of long-term-care facilities, and people with underlying medical conditions will be among the first to receive the vaccine.

16. **How many vaccine doses will be needed?**
    All but one of the COVID-19 vaccines currently in phase three clinical trials use two different injections with several weeks between each one. The same vaccine brand must be used for both shots. Two shots are generally needed to provide the best protection. The first one primes the immune system, helping it to recognize the virus, and the second one strengthens the immune response.

17. **Where can I get more information?**
    If you have additional questions, view the CDC's Frequently Asked Questions about COVID-19 Vaccination for regularly updated answers to common questions

Sources

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