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AMA AMERICAN MEDICAL ASSOCIATION

COVID-19 VACCINES: PATIENT FAQs

Vaccine safety and the speed of vaccine development

How do we know if COVID-19 vaccines are safe?

COVID-19 vaccines were tested in large clinical trials to make sure they meet safety standards. Many people were recruited to participate in these trials to see how the vaccines offers protection to people of different ages, races, and ethnicities, as well as those with different medical conditions.

The Food and Drug Administration (FDA) carefully reviews all safety data from clinical trials and an authorizes emergency vaccine use only when the expected benefits outweigh potential risks. The CDC's Advisory Committee on Immunization Practices (ACIP) reviews all safety data before recommending any COVID-19 vaccine for use in the U.S. population. The FDA and the CDC will continue to monitor the safety of COVID-19 vaccines, to make sure even very rare side effects are identified.

What is "Operation Warp Speed" and how were vaccines developed so quickly?

The federal government, through Operation Warp Speed (OWS), has been working since the start of the pandemic to make a COVID-19 vaccine available. This accelerated timeline has raised concerns for some that safety may be sacrificed in favor of speed. However, safety remains a top priority.

To accelerate vaccine development while maintaining standards for safety and efficacy, OWS has selected the most promising vaccine candidates and is providing coordinated government support. Rather than eliminating steps from traditional development timelines, steps have proceeded simultaneously, such as starting manufacturing of the vaccine at industrial scale well before the demonstration of vaccine efficacy and safety as happens normally. This increases the financial risk, but not the risk of the vaccines.

Natural immunity rather than immunity from vaccines

Does getting sick with COVID-19 provide better protection than the vaccine gives?

Both COVID-19 and the vaccines are new. We do not know how long protection lasts for those who get infected or for those who are vaccinated. What we do know is that COVID-19 has caused very serious illness and death for a lot of people. If you get COVID-19, you also risk giving it to loved ones who may get very sick. Getting a COVID-19 vaccine is a safer choice. Keep in mind that the vaccines are not a perfect fix. We will still need to practice other precautions like wearing a mask, social distancing, handwashing until public health officials say otherwise.

Do people who have tested positive for COVID-19 need to be vaccinated?

Data from clinical trials suggest that Pfizer-BioNTech COVID-19 vaccine is safe and likely effective in persons with evidence of a prior COVID-19 infection. Vaccination should be offered to persons regardless of history of prior symptomatic or asymptomatic COVID-19 infection. Testing to assess for prior infection solely for the purposes of vaccine decision-making is not recommended.

Vaccine side effects

Can COVID-19 vaccines cause you to get very sick?

Most people do not have serious problems after being vaccinated and the vaccines themselves will not give you COVID-19. We will understand more about mild side effects of the COVID-19 vaccine before it is used in the population. However, your arm may be sore, red, or warm to the touch. These symptoms usually go away on their own within a week. Some people report getting a headache or fever when getting a vaccine. These side effects are a sign that your immune system is doing exactly what it is supposed to do. It is working and building up protection to disease.

How do we know that these vaccines are safe, could they cause long-term problems?

COVID-19 vaccines are being tested in large clinical trials to assess their safety. However, it does take time, and more people getting vaccinated before we learn about very rare or long-term side effects. That is why safety monitoring will continue. CDC has an independent group of experts that reviews all the safety data as it comes in and provides 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.

How do I report a problem or possible side effect to a COVID-19 vaccine?

The CDC and FDA encourage the public to report possible side effects (called adverse events) to the Vaccine Adverse Event Reporting System (VAERS). This national system collects these data to look for adverse events that are unexpected, appear to happen more often than expected, or have unusual patterns of occurrence. Reports to VAERS help the CDC monitor the safety of vaccines. Health care professionals will be required to report certain adverse events following vaccination to VAERS.

The CDC is also implementing a new smartphone-based tool called v-safe to check-in on people's health after they receive a COVID-19 vaccine. When you receive your vaccine, you should also receive a v-safe information sheet telling you how to enroll in v-safe. If you enroll, you will receive regular text messages directing you to surveys where you can report any problems or adverse reactions you have after receiving a COVID-19 vaccine.

mRNA vaccines

mRNA vaccines are being held to the same safety and efficacy standards as all other types of vaccines in the United States. The only COVID-19 vaccines the FDA will make available for use in the United States are those that meet these standards. While there are currently no licensed mRNA vaccines in the United States, researchers have been studying and working with them for decades. mRNA vaccines have been studied before for flu, Zika, rabies, and cytomegalovirus (CMV). Beyond vaccines, cancer research has used mRNA to trigger the immune system to target specific cancer cells.

Can mRNA vaccines give someone COVID-19?

No, mRNA vaccines cannot give someone COVID-19. mRNA vaccines do not use the live virus that causes COVID-19.

Will mRNA vaccines interact with my DNA in any way?

mRNA vaccines do not affect or interact with our DNA in any way. mRNA never enters the nucleus of the cell where our DNA is kept. The cell breaks down and gets rid of the mRNA soon after it is finished using the instructions.

Vaccine administration

When will COVID-19 vaccines be available in the US?

It is anticipated that the first supply of COVID-19 vaccines will be available before the end of 2020. When a vaccine is authorized or approved in the United States, there will 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.

Will COVID-19 vaccines be available for young children?

At first, COVID-19 vaccines may not be recommended for children, as only non-pregnant adults participate in clinical trials. As more studies are completed, COVID-19 vaccine may be available for children.

How many doses of the vaccine are needed?

Nearly all COVID-19 vaccines being studied in the United States require two shots. The first shot starts building protection, but everyone has to come back a few weeks later for the second dose to get the most protection the vaccine can offer.

Are the vaccine candidates interchangeable?

The same vaccine brand must be used for both shots.

How much will the vaccine cost?

Vaccine doses purchased with U.S. taxpayer dollars will be provided at no cost. However, vaccination providers will be able to charge an administration fee for giving the shot to someone. Vaccine providers can get this fee reimbursed by the patient's public or private insurance company or, for uninsured patients, by the Health Resources and Services Administration's Provider Relief Fund.

Herd immunity

Once I have been vaccinated with two doses, can I stop wearing a mask and practicing social distancing?

As we learn more about the protection that COVID-19 vaccines provide under real-life conditions, it will be important for everyone to continue using all the tools available to us to help stop this pandemic, like covering your mouth and nose with a mask, washing hands often, and staying at least 6 feet away from others.

What percentage of the population needs to be vaccinated against COVID-19 for the population to have heard immunity?

Experts do not know what percentage of people would need to get vaccinated to achieve herd immunity to COVID-19. The percentage of people who need to have protection to achieve herd immunity varies by disease.