

COVID-19 Vaccine Frequently Asked Questions – January 19, 2021

Introduction

In response to a recent survey about the COVID-19 vaccine, many Empower staff members asked questions about the vaccines that are becoming available. We have compiled answers from various sources, to help you make an informed decision about receiving the vaccine.

This content is not meant to be a substitute for professional medical advice, diagnosis, or treatment, and does not constitute medical or other professional advice. This content is for general information purposes only. Empower makes no representation and assumes no responsibility for the accuracy of information provided here, which is compiled from third-party sources, and such information is subject to change as new information becomes available. You are encouraged to confirm any information contained in this document by consulting other sources, and to review all information regarding any medical condition or treatment with your physician.

How do the COVID-19 vaccines work? What do they do?

From the Centers for Disease Control and Prevention:

"Messenger RNA vaccines—also called mRNA vaccines—are some of the first COVID-19 vaccines authorized for use in the United States. mRNA vaccines are a new type of vaccine to protect against infectious diseases. To trigger an immune response, many vaccines put a weakened or inactivated germ into our bodies. Not mRNA vaccines. Instead, they teach our cells how to make a protein—or even just a piece of a protein—that triggers an immune response inside our bodies. That immune response, which produces antibodies, is what protects us from getting infected if the real virus enters our bodies."

"COVID-19 mRNA vaccines give instructions for our cells to make a harmless piece of what is called the 'spike protein.' The spike protein is found on the surface of the virus that causes COVID-19. COVID-19 mRNA vaccines are given in the upper arm muscle. Once the instructions (mRNA) are inside the immune cells, the cells use them to make the protein piece. After the protein piece is made, the cell breaks down the instructions and gets rid of them. Next, the cell displays the protein piece on its surface. Our immune systems recognize that the protein doesn't belong there and begin building an immune response and making antibodies, like what happens in natural infection against COVID-19."

"At the end of the process, our bodies have learned how to protect against future infection. The benefit of mRNA vaccines, like all vaccines, is those vaccinated gain this protection without ever having to risk the serious consequences of getting sick with COVID-19."

"They do not affect or interact with our DNA in any way. mRNA never enters the nucleus of the cell, which is where our DNA (genetic material) is kept. The cell breaks down and gets rid of the mRNA soon after it is finished using the instructions."

How effective are the vaccines?

From AARP:

"Both vaccines (Pfizer and Moderna) were shown to be about 95 percent effective in preventing COVID-19 during clinical trials."

Is a second shot needed?

From <u>AARP</u>:

"Both the Pfizer-BioNTech and Moderna vaccines require two doses, and following through with both doses is necessary to ensure effectiveness. (Other COVID-19 vaccines being tested in clinical trials require only one dose.) According to the CDC, the first shot starts building protection, while the second shot 'is needed to get the most protection the vaccine has to offer."

How were these vaccines developed and approved so quickly, when researchers knew nothing about the virus 10 months ago?

From the Centers for Disease Control and Prevention:

"Researchers have been studying and working with mRNA vaccines for decades. Interest has grown in these vaccines because they can be developed in a laboratory using readily available materials. This means the process can be standardized and scaled up, making vaccine development faster than traditional methods of making vaccines."

"mRNA vaccines have been studied before for flu, Zika, rabies, and cytomegalovirus (CMV). As soon as the necessary information about the virus that causes COVID-19 was available, scientists began designing the mRNA instructions for cells to build the unique spike protein into an mRNA vaccine."

From Henry Ford Health System:

"Production of the COVID-19 vaccines began sooner than is typical. Normally, production starts after a pharmaceutical company completes the development stage for a vaccine, which includes rigorous testing for safety and effectiveness. Every vaccine goes through a series of reviews and approvals by the FDA and the Advisory Committee on Immunization Practices (ACIP), among others. In the case of COVID-19 vaccines, the federal government invested taxpayer dollars to encourage pharmaceutical companies to start production before the development stage completed. The vaccines are still going through the same rigorous testing for safety and effectiveness, review and approval process."

Are the vaccines safe? Are there short-term side effects?

From the Centers for Disease Control and Prevention:

"None of the authorized and recommended COVID-19 vaccines or COVID-19 vaccines currently in development in the United States contain the live virus that causes COVID-19. This means that a COVID-19 vaccine cannot make you sick with COVID-19."

From <u>WebMD</u>:

"The FDA says common side effects, in the clinical trial involving some 44,000 people, included pain where they got the shot, fatigue, headache, chills, fever, and joint and muscle pain. But these are all described as temporary, or transient. The symptoms were generally mild or moderate, and happened more frequently after the second dose."

"People should also know that less serious adverse reactions -- side effects -- are pretty common with this vaccine, so it's not going to be like the flu shot, where you might just have a sore arm,' says Gigi Gronvall, MD, an immunologist and infectious disease specialist with the Johns Hopkins Center for Health Security. 'For a lot of people, they'll be pretty tired, they might have a small fever, and they can have headaches. And all of these reactions are normal, and that's the result of your body getting ready to be able to fight off COVID.'"

From <u>WebMD</u>:

"Paul Offit, MD, a member of the FDA advisory panel that recommended the vaccine's use, says rigorous clinical trials of the shot identified no safety concerns, despite its sped-up production.

'These vaccines were subjected to large phase III clinical trials,' says Offit, a vaccine expert at Children's Hospital of Philadelphia. 'Regarding safety, there was an insistence by the FDA that at least tens of thousands of people be observed for 2 months after the final dose to make sure that there were no … uncommon side effects.'"

"Offit says the fast-tracking of the vaccine was mostly a result of the upfront financing the federal government provided, so no shortcuts were taken in verifying its safety."

"Gigi Gronvall, MD, an <u>immunologist</u> and infectious disease specialist with the Johns Hopkins Center for Health Security, agrees and says the vaccine still underwent all of the safety checks involved in any clinical trial. 'It has been tested as other vaccines and drugs have been. There were no things done differently, but the financial part made things happen faster,' says Gronvall, an associate professor at the Johns Hopkins Bloomberg School of Public Health."

Are there long-term side effects?

From Children's Hospital of Philadelphia:

"The vaccine is not expected to have long-term negative effects for a few reasons:

- First, most negative effects occur within 6 weeks of receiving a vaccine, which is why the FDA asked the companies to provide 8 weeks of safety data after the last dose.
- Second, the mRNA in the vaccine breaks down pretty quickly because our cells need a way to stop mRNA from making too many proteins or too much protein.
- But, even if for some reason our cells did not breakdown the vaccine mRNA, the mRNA stops making the protein within about a week, regardless of the body's immune response to the protein."

How often are people experiencing Bell's Palsy?

The rate of Bell's palsy in the clinical trials of the Moderna and Pfizer vaccines is lower than the overall rate in the general population.

From <u>WebMD</u>:

"An FDA report said 4 of 30,000 participants in the Moderna clinical trial had Bell's palsy, including 3 participants who received the vaccine instead of the placebo. Similarly, 4 out of 43,000 participants in the Pfizer clinical trial had Bell's palsy, and all 4 received the vaccine."

"The paralysis occurred between 22 days and 32 days after the shot, the FDA staff said. Two of the Bell's palsy cases in the Moderna trial have resolved. The staff has endorsed both of the COVID-19 vaccines and said there's not enough data to show whether the cases were tied directly to the vaccines, according to CNBC."

"Importantly, the rate of Bell's palsy in the clinical trials is lower than the overall rate in the general population,' they wrote. About 35 per 100,000 people get Bell's palsy in the U.S. each year, according to the National Organization for Rare Disorders, and about 40,000 Americans are diagnosed annually."

"It's a relatively benign condition,' Anthony Geraci, MD, the director of neuromuscular medicine at Northwell Health in New York, told *USA Today*. Geraci sees at least two patients per month with Bell's palsy, and they tend to recover in several weeks, he said. Severe or permanent conditions are extremely rare, he added, and encouraged people to not let the report prevent them from getting a COVID-19 vaccine."

What is used in the manufacturing? Does it contain blood?

From Children's Hospital of Philadelphia:

"The mRNA vaccines include:

• mRNA – This mRNA is for the spike protein of SARS-CoV-2, the virus that causes COVID-19.

- Lipids These are molecules that are not able to dissolve in water. They protect the mRNA, so that it does
 not break down before it gets into our cells. These can be thought of as little 'bubbles of fat,' which
 surround the mRNA like a protective wall. There are four different lipids in the Pfizer vaccine and three in
 the Moderna vaccine. One of the lipids in both vaccines is cholesterol. The lipids are the most likely
 components of the vaccine to cause allergic reactions.
- Salts and amines The Pfizer vaccine contains four salts. One is table salt. The salts are used to keep the
 pH of the vaccine similar to that found in the body, so that the vaccine does not damage cells when it is
 administered. The Moderna vaccine also contains four chemicals to balance the pH, but two are in a class
 of organic compounds known as 'amines' and two are acetic acid and its salt form, sodium acetate. Acetic
 acid is the main component of vinegar (other than water).
- Sugar This ingredient is literally the same as that which you put in your coffee or on your cereal. It is used in both of the vaccines to help keep the 'bubbles of fat' from sticking to each other or to the sides of the vaccine vial."

"These are the only ingredients in the mRNA vaccines. The mRNA vaccines do not include any of the following:

- Fetal material
- DNA
- Antibiotics
- Blood products
- Preservatives, like thimerosal
- Gluten
- Egg proteins
- Pork products
- Microchips"

I have food allergies. Is it safe for me to be vaccinated?

From the Mayo Clinic:

"Neither the Pfizer/BioNTech COVID-19 vaccine nor the Moderna COVID-19 vaccines contain egg nor were eggs used the development or production of either vaccine. However, those with severe allergic reactions to eggs or any other substance (i.e., anaphylaxis) are encouraged to remain after vaccination for 30 minutes for observation."

From Children's Hospital of Philadelphia:

"The mRNA vaccines do not include gluten, egg proteins or pork products." (*Please see the question immediately before this one for a list of all ingredients.*)

From <u>WebMD</u>:

"The Centers for Disease Control and Prevention ... said people who have had severe reactions to vaccines or injectable drugs can still get the Pfizer vaccine for COVID-19. But they should discuss the risks with their doctors and be monitored for 30 minutes after getting the shot.

"That recommendation, issued Dec. 13, reverses an initial CDC proposal one day earlier that would have advised those with a history of reactions not to be vaccinated. During a follow-up webinar with doctors, CDC officials said patients who have had severe reactions should take precautions, but they did not recommend they avoid the COVID-19 shot."

Do the vaccines affect age groups differently?

From <u>WebMD</u>:

"Older people tend to have fewer side effects than people in the 18-to-55 range, possibly because ... younger people have more active immune systems."

What are the effects on individuals with autoimmune disorders? What about people with heart problems, or those in high-risk groups such as immunocompromised or with a history of cancer?

Empower urges you to speak to your doctor about your specific health profile and any risks in being vaccinated based on your past or present medical conditions.

From the New York State Department of Health:

"COVID-19 vaccination is especially important for people with underlying health problems like heart disease, lung disease, diabetes, and obesity. People with these conditions are more likely to get very sick from COVID-19. Please consult with your health care provider if you have specific questions about the COVID vaccine and your health."

From <u>WebMD</u>:

"Gigi Gronvall, MD, an immunologist and infectious disease specialist with the Johns Hopkins Center for Health Security, says there is no scientific evidence that mRNA can lead to immune system disorders or autoimmune diseases."

"There are a range of syndromes, even if they're very rare, that different sentinel [tracking] systems are looking for to see if there are any added risks for the vaccines, and those systems will be going on for years,' she says. 'But as of now, the data doesn't say that an autoimmune risk is something that we need to be concerned about."

"She adds that the vaccine is safe for people who have autoimmune disorders or those who are being treated with other immunotherapies – for allergies, cancer, arthritis, or other conditions. 'There are no contraindications at this point for people with those conditions,' she says.

Betty Diamond, MD, an immunologist and rheumatologist at the Feinstein Institutes for Medical Research of Northwell Health, agrees that there's no evidence that mRNA vaccines cause autoimmune disease or may cause problems for people with such conditions. "At the moment, there's every reason to suggest that people with autoimmune diseases ought to get either of these vaccines when they get rolled out," she says.

Will people be tested for antibodies before receiving the vaccine to make sure they need it?

No.

From <u>Children's Hospital of Philadelphia</u>: "We do not yet know how long immunity lasts after infection or vaccination."

From the Centers for Disease Control and Prevention:

"COVID-19 vaccination should be offered to you regardless of whether you already had COVID-19 infection. You should not be required to have an antibody test before you are vaccinated. However, anyone currently infected with COVID-19 should wait to get vaccinated until after their illness has resolved and after they have met the criteria to discontinue isolation."

"Additionally, current evidence suggests that reinfection with the virus that causes COVID-19 is uncommon in the 90 days after initial infection. Therefore, people with a recent infection may delay vaccination until the end of that 90-day period if desired."

Will a titer test be done afterward to ensure effectiveness?

No, but a person may choose to have an antibody test after the vaccination at his/her expense.

If someone becomes ill from the vaccine, does s/he need to be tested for COVID-19? Will Empower pay wages while the person is out of work, until symptoms subside? How long does a person need to be out of work: 10-14 days as if they actually had COVID-19? Will vaccine administration be staggered at different sites in case multiple staff are unable to work due to side effects?

It is not possible for the vaccine to cause COVID-19, as the vaccine does not include the live virus. Because it takes time for the two-stage vaccine to build immunity in a person's body, it is possible for a person to become infected by COVID-19 just before or just after being vaccinated – but such an infection would come from normal transmission, not from the vaccine.

Side effects are generally brief. If you are unable to work due to severe side effects – which will likely be very rare – please speak with your supervisor right away. These incidences will be handled on a case-by-case basis in compliance with federal and state requirements.

From the Centers for Disease Control and Prevention:

"None of the authorized and recommended COVID-19 vaccines or COVID-19 vaccines currently in development in the United States contain the live virus that causes COVID-19. This means that a COVID-19 vaccine cannot make you sick with COVID-19."

From the Mayo Clinic:

"Keep in mind that it will take a few weeks for your body to build immunity after getting a COVID-19 vaccination. As a result, it's possible that you could become infected with the virus that causes COVID-19 just before or after being vaccinated."

Will I need to be vaccinated every year, like the flu shot?

From Children's Hospital of Philadelphia:

"We do not yet know how long immunity lasts after infection or vaccination:

- Infection Scientists are working to learn more about immunity following infection. While some people have been re-infected after recovering from COVID-19, the number of people who have experienced this is small compared with the total number of people who have been infected. Likewise, although the virus has been changing since it was first recognized, antibodies from people who were sick early during the pandemic are still effective against the slightly modified version. For these reasons, scientists are hopeful that people will be protected for one or more years.
- Vaccination Clinical trial participants will be monitored to understand how long immunity lasts after vaccination."

"Since the first people in the trials were vaccinated at the end of July 2020 and the first vaccines were approved in December 2020, we only have information about protection against disease for a few months after vaccination. The degree to which these vaccines protect against COVID-19 one or two years after vaccination will be determined later. Trial participants will continue to be monitored, so we will learn more, but we do not yet know whether booster doses will be needed."

Will these vaccines cover new strains of COVID?

Dr. Anthony Fauci, director of the US National Institute of Allergy and Infectious Diseases, said (the new COVID strain that has emerged from the United Kingdom) doesn't appear to be resistant to the vaccines that've been developed. "It doesn't seem to evade the protection that's afforded by the antibodies that are induced by vaccines," Fauci said. "Even though you have one part of the virus that's changed, it's very likely that the other components of the vaccine-induced response will protect you." Fauci said that public health officials are keeping a close eye on the mutation, called B.1.1.7.

From Johns Hopkins Medicine:

Stuart Ray, M.D., Vice Chair of Medicine for Data Integrity and Analytics, says, "There is no evidence at this point that immune responses driven by current vaccines would not work against this new strain."

What are the differences between the Moderna and Pfizer vaccines? Does one seem to be more effective than the other? Does one vaccine seem to be safer with fewer side effects?

From the American Academy of Family Physicians:

"Both vaccines are mRNA vaccines that have a piece of mRNA specific for the SARS-CoV-2 spike protein. They have similar efficacy and safety profiles. The main differences between the two vaccines include the ages of individuals eligible to get the vaccines, the length of time between doses, the cold chain requirements for storage, and the preparation of the vaccine."

How does the vaccine affect or interact with medications you may be taking for conditions such as hypothyroid, high blood pressure, etc.?

Before receiving the vaccine, you should speak with your doctor about whether the vaccine might interact with any medications you currently take.

Can you have the vaccine if you have previously tested positive for COVID-19?

Yes.

From the Centers for Disease Control and Prevention:

"COVID-19 vaccination should be offered to you regardless of whether you already had COVID-19 infection. You should not be required to have an antibody test before you are vaccinated. However, anyone currently infected with COVID-19 should wait to get vaccinated until after their illness has resolved and after they have met the <u>criteria</u> to discontinue isolation. Additionally, current evidence suggests that reinfection with the virus that causes COVID-19 is uncommon in the 90 days after initial infection. Therefore, people with a recent infection may delay vaccination until the end of that 90-day period if desired."

Is there a cost to the vaccine or will the agency pay for it?

Federal and state law require that the COVID-19 vaccine be provided free of charge. We have not heard of anyone being charged. If you receive a bill for the vaccine, please notify your supervisor, and Empower will handle it.

From <u>AARP</u>:

"The federal government prepurchased hundreds of millions of vaccine doses with taxpayer money, and Americans will not have to pay to receive them. Vaccine providers are able to charge an administration fee for giving the shot, but this fee should be covered by public or private insurance, or by a government relief fund for the uninsured."

Online COVID-19 Informational Resources

<u>Centers for Disease Control and Prevention</u> <u>New York State Department of Health</u> Video from National Association of Direct Support Professionals