QeA COVID-19 MRNA VACCINES: WHAT YOU SHOULD KNOW

Volume 1 Winter 2020

In late 2019, a new coronavirus, SARS-CoV-2, was identified in China. The new virus had two important features. First, it could infect people. Second, infected people could easily spread the virus to others. These characteristics set the stage for a COVID-19 pandemic, or worldwide epidemic, which was declared by March 2020. Knowing the important role that vaccines would play, scientists, pharmaceutical companies and governments immediately started working to develop COVID-19 vaccines. With unprecedented speed, and fortuity, the first vaccines were ready by December 2020. Because vaccines typically take years — if not decades — to create, some wondered whether this shortened timeline affected COVID-19 vaccine safety.

Q. What is mRNA?

A. mRNA stands for messenger RNA, which is the blueprint for making proteins. DNA, which lives in the nucleus of cells, makes mRNA and ships it outside the nucleus to the surrounding cell cytoplasm. Once in the cytoplasm, mRNA is translated into a host of cell proteins and enzymes. Because our cells make proteins all the time, they also make mRNA all the time. Soon after making proteins, mRNA breaks down.

Q. How do mRNA vaccines work?

A. COVID-19 mRNA vaccines take advantage of the cellular process of making proteins by introducing mRNA that contains the blueprint for one of the coronavirus proteins, specifically the spike protein. This is the protein that attaches coronavirus to our cells. If we can prevent virus-cell attachment by making antibodies against the spike protein, then we can prevent coronavirus from infecting cells. The mRNA that codes for the SARS-CoV-2 spike protein is taken up by specialized cells of the immune system, called dendritic cells, which put small pieces of the spike protein on their surface, travel to a nearby lymph node, and stimulate other cells of the immune system (B cells) to make antibodies. This is why some



people who get the mRNA vaccine have swelling in the lymph nodes under the arm that was inoculated. The antibodies made during this process prevent virus-cell attachment in the future.

Q. Are mRNA vaccines effective?

A. Two companies, Pfizer and Moderna, have made mRNA vaccines. Both vaccines were found to be about 95% effective at preventing COVID-19. This high level of protection extended to people over 65, people with a variety of medical conditions that put them at risk of severe disease, and people with different racial and ethnic backgrounds. Both vaccines were released to the public in December 2020. During 2021 and 2022, studies will determine whether this high level of protection lasts.

Q. Can mRNA vaccines change a person's DNA?

A. No. In order for mRNA to alter someone's DNA, several events would need to occur. First, mRNA would need to enter the cell nucleus, where DNA resides. However, mRNA does not have the nuclear access signals that would allow it to enter. Put quite simply, mRNA vaccines can't get into the nucleus. Second, even if mRNA did enter the nucleus, it would have to be converted to DNA. This would require an enzyme called reverse transcriptase, which the mRNA vaccines don't contain. Third, the mRNA vaccines don't contain an enzyme called integrase, which would also be needed for mRNA to insert itself into the DNA. In short, the mRNA vaccines lack all of the basic requirements necessary to alter DNA. They remain in the cell cytoplasm for just a few days before they are destroyed. One other thing to remember is that there are more than 200,000 cellular mRNAs making a host of proteins and enzymes. The mRNA vaccines introduce only a few copies of mRNA into cells.

continued >



Learn more: vaccine.chop.edu

QgA COVID-19: WHAT YOU SHOULD KNOW



Q. Who should get the COVID-19 mRNA vaccine? A. Because SARS-CoV-2 virus can affect all people in all age groups, most people should get the COVID-19 vaccine, once supplies allow for their priority group to be vaccinated.

Q. Who should NOT get the COVID-19 mRNA vaccine?

A. A few groups should not get the vaccine, and some others should consult with their doctor or follow special procedures.

People who should NOT get the COVID-19 vaccine

- Anyone with a severe allergy to an mRNA vaccine component (i.e., one that causes anaphylaxis or requires medical intervention).
- Those younger than 16 years of age.
- People currently isolating or experiencing symptoms of COVID-19. These people can get vaccinated once they have finished isolation and their primary symptoms have resolved.

People who may get the vaccine after considering risks and benefits and consulting with their healthcare provider

- Individuals with a history of severe allergy to any vaccine or injectable medication
- Pregnant women
- People with certain immune-compromising or autoimmune conditions
- Breastfeeding women
- People on anticoagulants

People who should follow special procedures

- Someone with a history of severe allergy (requiring medical intervention) to anything other than a vaccine or injectable medication can get the vaccine, but they should remain at the vaccination location for medical observation for 30 minutes after receipt of the vaccine.
- Pregnant women who develop a fever after vaccination should take acetaminophen.
- People who recently had COVID -19 and were treated with antibody-based therapies (e.g., monoclonal antibodies or convalescent plasma) should wait until 90 days after treatment to be vaccinated.
- People with a known COVID-19 exposure should wait until their quarantine is over before getting vaccinated (unless they live in a group setting, such as a nursing home, correctional facility, or homeless shelter, in which case they can be vaccinated during the quarantine period).
- People who got another vaccine (non-COVID-19 vaccine) should wait at least 14 days before getting COVID-19 vaccine. Likewise, if a person got the COVID-19 vaccine, they should wait at least 14 days before getting any other vaccines (non-COVID-19 vaccines).

Q. How many doses of a COVID-19 mRNA vaccine are needed?

A. The mRNA vaccines require two doses. For the Pfizer vaccine, doses should be separated by 21 days. For Moderna's vaccine, doses should be separated by 28 days. The two mRNA vaccines are NOT interchangeable. A person should be sure they know which one they got as the first dose and be clear about when they should return for the second dose, particularly because both doses of the vaccine are required to have the best protection. However, even if more than the recommended time interval has elapsed between the first and second dose, the series doesn't need to be restarted. It can just pick up where it was left off.

Q. Can pregnant women get the COVID-19 mRNA vaccine?

A. Pregnant women were not included in the early COVID-19 vaccine studies, but some participants were either pregnant and did not know it or became pregnant during the course of the study. About two dozen women found out they were pregnant during the Pfizer vaccine trial and one dozen during the Moderna vaccine trial. As a result, we only have a small amount of data regarding the safety of these vaccines in pregnant women. The good news is that in this small group of women, no concerns were found and the vaccine worked, but it will be important to get data on larger numbers of women moving forward.

Despite the limited amount of data, both the Centers for Disease Control and Prevention (CDC) and the American College of Obstetricians and Gynecologists (ACOG) have recommended that pregnant women who are part of a group recommended to get the COVID-19 vaccine may be vaccinated if they choose to do so. These women should be supported in their decision-making efforts by their doctors and be provided with information related to the potential risks and benefits, but they do not have to wait to have a consultation with their healthcare provider before being vaccinated if they are comfortable doing so.

Two factors, in addition to the limited vaccine data, were important for informing these recommendations. First, some pregnant women will be at high risk for COVID-19, such as healthcare workers or those with certain health conditions. Second, pregnant women are at increased risk of developing complications, compared with their nonpregnant peers, when infected with COVID-19.

All pregnant women should know these two things:

- 1. Pregnant women who decide to get the COVID-19 vaccine should take acetaminophen if they develop a fever after vaccination, as fever during pregnancy can negatively affect a developing baby. Taking acetaminophen during pregnancy has been found to be safe.
- 2. Likewise, regardless of whether a pregnant woman decides to be vaccinated, she should practice recommended public health measures, particularly because of the increased risk to pregnant women infected with COVID-19.

Q. Can I get the COVID-19 mRNA vaccine if I am trying to get pregnant?

A. Yes. Women who are trying to get pregnant can get the vaccine. Likewise, if a woman gets the first dose and then finds out she is pregnant, she can still get the second dose on time.

Q. Can I get the COVID-19 mRNA vaccine if I am breastfeeding?

A. Yes. Although women who are breastfeeding were not included in the clinical trials, current data suggest that COVID-19 is not transmitted through breast milk, so it is not expected that vaccination would cause a concern either. On the other hand, some women who are breastfeeding, such as those in medical professions, will be at higher risk for exposure, so they could benefit from receiving the vaccine.

In addition, women do not need to delay breastfeeding for any period of time after they have been vaccinated.

Q. Are mRNA vaccines safe?

A. Yes. But, both mRNA vaccines do cause side effects as a consequence of the immune response to the SARS-CoV-2 spike protein produced by the mRNA. Side effects occur more often after the second dose and are more common in people younger than 55 years of age. In some ways, the more vigorous the immune response, the more common the side effects.

The most common side effects from the mRNA vaccines are:

- Fatigue
- Headache
- Muscle aches
- Low-grade fever
- Chills
- Joint pain

Typically, these side effects last for only one or two days. Although most people will not have significant side

effects, some people may wish to schedule their vaccination, so that they will not need to call out of work the next day if they don't feel well.





Q. What ingredients are in the mRNA vaccines? A. The mRNA vaccines contain:

mRNA – The 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 lipid particles can be thought of as little "bubbles of fat" that surround the mRNA like a protective wall and make it easier for the mRNA to enter cells.

Salts – Salts, similar to table salt, are used to keep the pH of the vaccine close to that found in the body, so the vaccine does not damage cells when it is administered.

Sugar – This ingredient is the same as the sugar you put in your coffee or on your cereal. In the vaccine, it helps keep the "bubbles of fat" from sticking to each other or to the sides of the vaccine vial.

mRNA vaccines do NOT contain:

- Blood products
- Antibiotics
- DNA
- Fetal cells
- Pork products
- Egg proteins
- Preservatives (e.g., thimerosal)

Q. If I had COVID-19, do I need the vaccine? A. Yes. People who had COVID-19 are recommended to get the vaccine after they have recovered. The Pfizer vaccine trial included people who were previously infected with SARS-CoV-2, and the vaccine was found to be safe and highly effective. Because we do not know how long antibodies last after infection and a small number of people have had more severe second bouts of infection, the vaccine can be beneficial in boosting a person's existing immunity from infection.

Q. Can a person spread the virus after they are vaccinated against COVID-19?

A. mRNA vaccines against COVID-19 have been shown to be highly effective at preventing disease, but they might not prevent infection without symptoms. What this means is that if a vaccinated person can still be infected, even without symptoms, they could spread the virus. Studies will soon be completed to determine whether this is possible. However, given this uncertainty, vaccinated people should still use masks and practice social distancing measures.

DON'T SEE YOUR QUESTION? CHECK COVIDVACCINEANSWERS.ORG

COVIDVaccineAnswers.org contains answers to dozens of questions related to COVID-19 and the vaccine. The page also includes a form that you can use to submit questions to experts from the Vaccine Education Center at Children's Hospital of Philadelphia.

This information is provided by the Vaccine Education Center at Children's Hospital of Philadelphia. The Center is an educational resource for parents and healthcare professionals and is composed of scientists, physicians, mothers and fathers who are devoted to the study and prevention of infectious diseases. The Vaccine Education Center is funded by endowed chairs from Children's Hospital of Philadelphia. The Center does not receive support from pharmaceutical companies. ©2020 Children's Hospital of Philadelphia, All Rights Reserved. 20137-12-20.



Learn more: vaccine.chop.edu