QeA COVID-19 VACCINES: WHAT YOU SHOULD KNOW

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In late 2019, a novel coronavirus, SARS-CoV-2, was identified in China. The 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 for prevention, work to develop COVID-19 vaccines started immediately. 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. Importantly, steps were not skipped. Two major reasons for the speed can be attributed to *resources* and *processes*. More resources than ever in history were dedicated to vaccine development. Likewise, processes typically completed one after the other were completed at the same time. So, instead of the steps occurring like the cars of a train going down the tracks, they were completed in concert, like vehicles traveling on a multilane highway.

COVID-19 MRNA VACCINES

(e.g., Pfizer and Moderna)

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 the coronavirus spike protein. This protein attaches coronavirus to our cells, so by preventing virus-cell attachment, we can prevent coronavirus from infecting our cells. The mRNA delivered in the vaccine is taken up by specialized cells of the immune system, called dendritic cells. These cells make the spike protein and put small pieces of it on their surface. The spike-protein-decorated cells then travel to a nearby lymph node and stimulate other cells of the immune system (B cells) to make antibodies. Antibodies made during this process prevent virus-cell attachment in the future.

Q. Do mRNA vaccines work?

A. mRNA vaccines prevent COVID-19 in more than 9 of 10 vaccinated people. To date, mRNA vaccines have also been effective against variants of COVID-19 that are circulating, but they will continue to be monitored as new variants arise.

COVID-19 ADENOVIRUS VACCINES

(e.g., J&J/Janssen and AstraZeneca)

Q. How do adenovirus-based vaccines work?

A. Adenoviruses are a family of viruses that can infect people and some animals. Some types cause the common cold, while others do not cause illness in people. COVID-19 adenovirusbased vaccines take advantage of these relatively harmless viruses to deliver the DNA for the spike protein of the coronavirus that causes COVID-19. The adenovirus used in these vaccines has been altered so that it cannot reproduce in people; as a result, people who get the vaccine do not develop an adenovirus infection. The DNA for the spike protein enters the nucleus of specialized cells of the immune system, where it is used to make mRNA. However, the adenovirus DNA cannot in any way alter cellular DNA. The mRNA is released into the cytoplasm where it serves as the blueprint for the cell's protein-making apparatus to produce the spike protein. As in the mRNA vaccine processing, protein pieces are put on the surface of the cell, which travels to a nearby lymph node and activates other immune system cells.

Q. Do adenovirus-based vaccines work?

A. The J&J/Janssen and AstraZeneca adenovirus vaccines prevent COVID-19 infection in 7 or 8 of every 10 vaccinated people, and in clinical trials, they prevented hospitalization

and death in all vaccine recipients. To date, the adenovirus vaccines have also been effective against variants of COVID-19 that are circulating, but they will continue to be monitored as new variants arise.



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COVID-19 VACCINE RECOMMENDATIONS

Q. Who should get the COVID-19 vaccine?

A. Because SARS-CoV-2 virus can affect all people in all age groups, most people should get the COVID-19 vaccine as the vaccine is approved for their age group.

Q. Who should NOT get the COVID-19 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 a vaccine component (i.e., one that causes anaphylaxis or requires medical intervention). These individuals may be able to get another type.
- Those younger than 12 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, with one exception. Specifically, people who were treated with antibody-based therapies (e.g., monoclonal antibodies or convalescent plasma) should wait until 90 days after treatment to be vaccinated.

People who may get the vaccine after considering risks and benefits and, if needed, consulting with their healthcare provider or who should follow special procedures:

- Individuals with a history of severe allergy to any vaccine or injectable medication. If vaccinated, these individuals should stay at the vaccination location for 30 minutes after receipt of the vaccine.
- People with certain immune-compromising or autoimmune conditions.
- · People on anticoagulants.
- 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).
- Pregnant women who develop a fever after vaccination should take acetaminophen.

Q. How many doses of a COVID-19 vaccine are needed? A. Most people require two doses of the mRNA vaccines. A small number of people with immune-compromising conditions may require three doses. Check with your healthcare provider or visit COVIDVaccineAnswers.org for a list. For those getting two doses, Pfizer vaccine doses should be separated by 21 days, and Moderna doses should be separated by 28 days. If a third dose is required, it should be given at least 28 days after the second dose. If more than the recommended time interval has elapsed between doses, the series doesn't need to be restarted; it can just pick up where it was left off. It is preferable to get the same version for all doses. The J&J/Janssen adenovirus-based vaccine requires only a single dose, regardless of immune status. The AstraZeneca adenovirus-based vaccine, currently not

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

A. Yes, data from thousands of pregnant women who received the COVID-19 vaccine have shown it to be safe for pregnant

approved for use in the U.S., requires two doses separated by

women and their unborn babies. Given that pregnant women diagnosed with COVID-19 are at increased risk of suffering severe illness, the safety of these vaccines is particularly important for this group. However, it is important to note that if a pregnant woman develops a fever as a side effect of COVID-19 vaccination, she should take acetaminophen as fever during pregnancy can negatively affect a developing baby.

four to 12 weeks.



Q. Can I get the COVID-19 vaccine while breastfeeding?

A. Yes. Studies of both COVID-19 disease and vaccination have shown that antibodies are transmitted through breast milk. On the other hand, the vaccine components would not be expected to be transmitted based on how the vaccines are processed, and the virus is not transmitted through breast milk as determined in studies of women who breastfed before realizing they were infected. For these reasons, women also do not need to delay breastfeeding after they have been vaccinated.

COVID-19 VACCINE SAFETY

Q. What side effects does the COVID-19 vaccine cause?

A. COVID-19 vaccines generally cause minor side effects, but in rare instances, more serious side effects have been identified for each type of vaccine:

mRNA vaccines

The mRNA vaccines tend to cause side effects more often after the second dose and more commonly in people younger than 55 years of age. The most common side effects from the mRNA vaccines include fatigue, headache and muscle aches, which typically last for a day or two. Less often, but still worth noting, these vaccines can also cause low-grade fever, chills and joint pain. Some people also experience swelling of the lymph nodes under the arm in which the vaccine was given.

In rare instances, young people, particularly boys and young men less than 30 years of age, may experience a short-lived inflammation of the heart, called myocarditis. Typically, this occurs within four days of vaccination and causes symptoms like chest pain and shortness of breath. Recently vaccinated individuals with these symptoms should seek medical care. Importantly, this condition appears to go away on its own and, to date, has not been shown to cause long-term heart damage.

Adenovirus-based vaccines

The J&J/Janssen vaccine is only given as a single dose, but the AstraZeneca vaccine is given as two doses. Studies of the AstraZeneca vaccine found that it causes fewer side effects after the second dose, but as with the mRNA vaccines, side effects were more common in younger people.

Typical side effects following receipt of adenovirus-based vaccines can include pain, redness or swelling at the injection site; headache; fatigue; muscle aches; and fever. These symptoms were most common in the first couple of days after vaccination.

Two rare, but potentially more concerning, side effects have also been identified:

Thrombosis with thrombocytopenia syndrome (TTS)

 TTS causes a unique situation characterized by both blood clots and a decrease in platelets, which help blood to clot. It can affect about 3 of every 1 million vaccinated people. While it can occur in people 18 to 64 years of age, it has occurred most commonly in women between the ages of 30 and 49 years old. TTS can occur in the three

- weeks after vaccination and can cause symptoms such as severe headache, shortness of breath, severe abdominal pain, unexplained leg pain, easy bruising or small red spots on the skin. Recently vaccinated individuals with these symptoms should seek immediate medical care.
- Guillain-Barré syndrome (GBS) GBS is a neurological disorder that causes muscle weakness and sometimes leads to paralysis; however, most people fully recover. About 3,000 to 6,000 people are diagnosed with GBS annually, often after having a viral infection. Receipt of the COVID-19 adenovirus-based vaccines has been associated with a small increase in cases, occurring in about 1 of every 120,000 vaccine recipients. Most cases occur in the first three weeks after vaccination, result in hospitalization, and more often occur in males younger than 65 years of age. It should be noted that GBS has also been reported following COVID-19, so natural infection with SARS-CoV-2 also appears to be a cause of GBS.

Q. Will COVID-19 vaccines cause long-term effects?

A. The mRNA and adenovirus-based vaccines are processed within the first few weeks after getting vaccinated. This processing includes a breakdown and removal of the vaccine components. As such, the only thing that remains after vaccination is the immunity generated to protect you against future encounters with the virus that causes COVID-19. For this reason, long-term effects would not be expected. Two hundred years of vaccine history provide additional evidence of this, as any negative effects following vaccination have occurred within six weeks of receipt of a vaccine. It is for this reason that the Food and Drug Administration (FDA) required at least eight weeks of clinical trial data before COVID-19 vaccines could be submitted for approval.

Q. Can COVID-19 vaccines change a person's DNA?

A. No. In order to alter someone's DNA, several events would need to occur. None of the COVID-19 vaccines can meet all of the criteria necessary for altering a person's DNA:

- Ability to enter the nucleus mRNA vaccines do not have the nuclear access signals that would allow mRNA to enter the nucleus. The adenovirus vaccine DNA does enter the nucleus but does not meet other necessary criteria for altering a person's DNA.
- Presence of an enzyme called integrase This enzyme is required for DNA to insert itself into a cell's DNA.

Q. What ingredients are in the COVID-19 vaccines? A. The types of ingredients in these vaccines are described below:

mRNA vaccines

- *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.

Adenovirus-based vaccines

- Adenovirus The J&J/Janssen vaccine contains a human adenovirus, known as Ad26, and the AstraZeneca vaccine contains a chimpanzee adenovirus.
- Stabilizers These include salts (including table salt), sugars, alcohols, polysorbate 80, and hydrochloric acid. These contribute to keeping the vaccine effective during transport and storage.
- *Manufacturing by-products* Amino acids

COVID-19 vaccines do NOT contain

- Animal products
- Antibiotics
- Blood products
- DNA (contained in adenovirus-based, but not mRNA versions)
- Egg proteins

- Fetal cells
- Gluten
- Microchips
- Pork products
- Preservatives (e.g., thimerosal)
- Soy

Q. Do COVID-19 vaccines cause fertility issues?

A. No. Several lines of evidence, as well as understanding of how these vaccines are processed, have indicated that the COVID-19 vaccines do not affect fertility in either males or females. In clinical trials of the mRNA vaccines, pregnancies occurred in the vaccinated groups as frequently as in the unvaccinated groups.

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

A. No. Neither mRNA nor adenovirus-based COVID-19 vaccines contain live virus. Additionally, since both types only include information for the spike protein, neither can lead to production of whole viral particles. As such, vaccinated people cannot shed the virus.

It is important to note, however, that if vaccinated people get infected, they may shed small quantities of the virus from their nose in the first few days before their immune response can stop the infection. Whether enough virus would be produced during this time to infect someone else depends on a variety of factors, including how much virus they produce, how transmissible the virus is, and how close they are to others during this time.

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. Evidence suggests that the vaccines more consistently provide greater levels and wider breadth of immunity than natural infection.

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 for submitting 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, the public and healthcare professionals and is composed of scientists, physicians, mothers and fathers 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. ©2021 Children's Hospital of Philadelphia. All Rights Reserved. 21150-07-21.

