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 reasons for the speed were *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 more 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 our muscle cells, which produce the spike protein. Specialized cells of our immune system, called dendritic cells, then process the protein by putting 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. Antibodies made as a result of this process prevent virus-cell attachment in the future.



Watch an animation on the Vaccine Makers Project YouTube channel, bit.ly/3T0vXYH.

Q. Do COVID-19 mRNA vaccines work?

A. mRNA vaccines prevent severe COVID-19 in most vaccinated people. While mRNA vaccines have been effective at preventing serious illness caused by newer variants, versions with a spike protein more similar to circulating types of the virus were approved beginning in September 2023.

COVID-19 PROTEIN-BASED VACCINES (e.g., Novavax)

Q. How do protein-based vaccines work?

A. Protein-based vaccines have been used for decades to prevent diseases like influenza, hepatitis B and shingles. These vaccines work by delivering the protein of interest (e.g., the spike protein from the virus that causes COVID-19) directly, so our cells do not need to produce it. Our immune system recognizes that the protein is "foreign" and becomes activated. Specialized immune system cells, called dendritic cells, take pieces of the protein to nearby lymph nodes to activate other cells of the immune system, creating a short-term "takedown" of the foreign protein and longer-lasting immunologic memory that can protect us during future encounters.

Watch an animation about the adaptive immune system on the Vaccine Makers Project YouTube channel to see this process in action, bit.ly/3Qv3Gb4.



Q. Do COVID-19 protein-based vaccines work?

A. Yes. In clinical trials, the COVID-19 protein-based vaccine, produced by Novavax, prevented severe disease and hospitalization in most vaccinated individuals. Beginning in the fall of 2023, the COVID-19 protein-based vaccine contains spike protein that is similar to a currently circulating strain of SARS-CoV-2 virus, the virus that causes COVID-19.

Adenovirus-based COVID-19 vaccines are no longer available in the U.S. For more information about that version, see the back page of this publication.



Learn more: COVIDVaccineAnswers.org

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COVID-19 VACCINE RECOMMENDATIONS

Q. If I had COVID-19, do I need the vaccine?

A. People who had COVID-19 are still recommended to be vaccinated for two reasons. First, vaccines more consistently provide greater levels and a wider breadth of immunity than natural infection. Second, people with so-called "hybrid immunity," meaning immunity that resulted from both infection and vaccination, appear to have the best immune protection.

Q. How many doses are needed and when?

A. Recommendations for additional doses of COVID-19 vaccine are based on an individual's immune status, age, and type of COVID-19 vaccine(s) received previously. Because of the variety of factors that are considered, recommendations vary between individuals. As such, it is recommended to check with your healthcare provider to get the latest information.

Q. Who should get the COVID-19 vaccine?

A. Because SARS-CoV-2 virus can affect all people, most people 6 months of age and older should get the COVID-19 vaccine.

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

A. Yes. The COVID-19 vaccine is safe for pregnant women and their unborn babies. Given that pregnant women diagnosed with COVID-19 are at increased risk of suffering severe illness, vaccination is particularly important for this group. Importantly, 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.

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 do not need to delay breastfeeding after they have been vaccinated.



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 6 months 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. But since they will have short-term protection, these individuals may opt to wait for at least three months before getting another dose. Some evidence suggests the delay allows for stronger immunity when they are vaccinated.

People who may get the vaccine after considering risks and benefits, and if needed consulting with their healthcare provider, and those 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 a known COVID-19 exposure can get vaccinated if they don't have symptoms.
- People who experience the rare, but severe, side effects of COVID-19 vaccines (myocarditis, TTS, or GBS) or who have a recent history of MIS-C or MIS-A should consult their healthcare provider regarding receipt of further doses as well as the timing and type of vaccine for future doses.

COVID-19 VACCINE SAFETY

Q. Can I spread the virus after getting COVID-19 vaccine? A. No. None of the COVID-19 vaccines used in the U.S. contain live virus. Both types (mRNA and protein-based) only include information for the spike protein, so vaccination does not involve whole viral particles; therefore, vaccinated people cannot shed the virus.

Importantly, however, 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. However, even in this scenario, an infected vaccinated person would be expected to shed much less virus over a shorter period than an infected unvaccinated person.

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

Protein-based vaccines

- Protein The spike protein of the virus that causes COVID-19 is delivered in this vaccine.
- Adjuvant Known as Matrix-M™, this material is made from the soap bark tree (Quillaja saponaria). It is also used in the shingles vaccine.
- Stabilizers These include polysorbate 80, salts (like table salt), and hydrochloric acid.

COVID-19 vaccines used in the U.S. do NOT contain:

Animal products, antibiotics, blood products, egg proteins, fetal cells, gluten, microchips, pork products, preservatives (e.g., thimerosal) or soy.

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 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. Protein-based vaccines do not deliver genetic material, so they can't enter the nucleus.
- Presence of an enzyme called integrase This enzyme is required for DNA to insert itself into a cell's DNA.
 Adenovirus vaccines do not include this enzyme.

Q. What side effects do COVID-19 vaccines cause? A. COVID-19 vaccines generally cause minor side effects, but one serious side effect, myocarditis (an inflammation of the heart),

has been identified in rare instances.

The mRNA vaccines tend to cause side effects more often after the second dose and more commonly in people 12 to 55 years of age. The most common side effects include fatigue, headache and muscle aches that last for about a day or two. Less often, these vaccines can also cause low-grade fever, chills and joint pain, and swelling of the lymph nodes under the arm in which the vaccine was given. Children less than 5 years of age tend to experience injection site tenderness, fever, irritability, decreased appetite and fatigue. Some also have headache, chills, achiness, joint pain, and nausea or vomiting.

In rare instances, young people, particularly teen 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 be less severe after vaccination than when it occurs during COVID-19 infection, and it goes away on its own without causing long-term damage.

Recipients of the protein-based vaccine are most likely to experience injection site pain, headache, fatigue and muscle aches. A small number of cases of myocarditis have been reported, so recently vaccinated individuals who experience heart-related symptoms should seek medical care.

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

A. COVID-19 vaccines are processed within the first few weeks after getting vaccinated. This processing includes breakdown and removal of the vaccine components. As such, the only thing that remains after vaccination is the immunity generated to protect 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. 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.



COVID-19 ADENOVIRUS-BASED VACCINES (e.g., J&J/Janssen and AstraZeneca)

Adenovirus-based COVID-19 vaccines are no longer available in the U.S.

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 adenovirus-based 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 muscle cells, which produce mRNA that is released to the cytoplasm. Pieces of the newly produced spike protein are put on the surface of specialized cells of the immune system, called dendritic cells, which then travel to a nearby lymph node and activate other immune system cells. Importantly, this process cannot change the DNA in our cells.

Watch an animation on the Vaccine Makers Project YouTube channel, bit.ly/3Adn3ia.



Q. Do COVID-19 adenovirus-based vaccines work?

A. In clinical trials, the adenovirus-based vaccines prevented COVID-19 infection in most vaccinated people, and they prevented hospitalization and death in all vaccine recipients. However, use of this type of COVID-19 vaccine was limited by some rare but serious side effects, including thrombosis with thrombocytopenia syndrome (TTS) and Guillain-Barré syndrome (GBS). As a result of alternative options (mRNA and protein-based versions) that did not cause these side effects, use of this vaccine has ceased in the U.S.

 $This information is provided by the Vaccine \ Education \ Center\ at\ Children's\ Hospital\ of\ Philadelphia.\ The\ Center\ is\ an\ educational\ resource\ for\ parents,\ the\ public\ and\ healthcare\ professionals\ and\ is\ composed\ of\ scientists,\ physicians,\ mothers\ and\ fathers\ devoted\ to\ the\ study\ and\ prevention\ of\ infectious\ diseases.\ The\ Vaccine\ Education\ Center\ is\ funded\ by\ endowed\ chairs\ from\ Children's\ Hospital\ of\ Philadelphia.\ The\ Center\ does\ not\ receive\ support\ from\ pharmaceutical\ companies.\ @2023\ The\ Children's\ Hospital\ of\ Philadelphia.\ 23238-10-23.$



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