

UNIVERSITY OF MINNESOTA	<b>Appendix E</b>
Community-University Health Care Center (CUHCC)	
<u>Related Procedure Name &amp; #:</u>	COVID Vaccine Manual
<b>Appendix (Full Text)</b>	

# Frequently Asked Questions (FAQs)

## Vaccine Development

What is an Emergency Use Authorization?

The FDA can issue an [Emergency Use Authorization \(EUA\)](#) to allow the use of unapproved medical products (or unapproved uses of approved medical products) in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions when specific criteria have been met, including that there are no adequate, approved, and available alternatives.

Manufacturers submit a request for an EUA to the FDA which is reviewed, and a determination is made by the FDA about authorizing the EUA.

How do the Pfizer and Moderna vaccines work?

There is no COVID-19 in vaccines. The Pfizer and Moderna vaccines help your body make antibodies to a protein on the virus surface. This allows your immune system to attack the virus and fight off infection if you are exposed.

How does the Johnson & Johnson vaccine work?

There is no COVID-19 in vaccine. The vaccine uses adenovirus-type 26 to deliver a piece of the DNA, or genetic material, that is used to make the distinctive “spike” protein of the SARS-CoV-2 virus. While adenoviruses are a group of viruses that are relatively common, Ad26, which can cause cold symptoms and pink eye, has been modified for the vaccine so that it cannot replicate in the human body to cause illness. After a person receives this vaccine, the body can temporarily make the spike protein, which does not cause disease, but triggers the immune system to learn to react defensively, producing an immune response against SARS-CoV-2.

Is the COVID-19 vaccine a live vaccine?

The mRNA vaccines don’t contain live, attenuated, or inactivated viruses. The mRNA vaccines contain the gene for a virus protein only.

The Johnson & Johnson vaccine contains an inactivated virus.

This means you can’t get COVID-19 from either type of vaccine.

What is in the mRNA COVID-19 vaccines?

You can't get COVID-19 from the vaccine. Vaccine components include:

- Active Ingredient nucleoside-modified messenger RNA (modRNA) encoding the viral spike protein of SARS-CoV-2

Four lipids (including polyethylene glycol or PEG)

- PEG is used in laxatives and in bowel preparation used before colonoscopy and is the most likely component to cause symptoms or allergic reaction
- Four salts (including NaCl) which act as a pH buffer
- Sugar (sucrose)

Current COVID-19 vaccine does not contain thimerosal, mercury, antibiotics, gelatin or preservatives. No fetal or animal products were used in the production process.

What is in the Johnson & Johnson COVID-19 vaccine?

The adenovirus vector is grown in media containing amino acids and no animal-derived proteins. The vaccine is then processed through several purification steps, formulated with inactive ingredients and filled into vials. Each 0.5 mL dose of Janssen COVID-19 Vaccine is formulated to contain:

- Active ingredient:  $5 \times 10^{10}$  virus particles (VP)
- inactive ingredients:
  - citric acid monohydrate (antioxidant)
  - trisodium citrate dihydrate (buffer)
  - ethanol (solvent)
  - 2-hydroxypropyl- $\beta$ -cyclodextrin (HBCD) (improves solubility and stability)
  - polysorbate-80 (emulsifier)
  - sodium chloride (salt).

Each dose may also contain residual amounts of host cell proteins ( $\leq 0.15$  mcg) and/or host cell DNA ( $\leq 3$  ng). Johnson & Johnson COVID-19 Vaccine does not contain a preservative. The vial stoppers are not made with natural rubber latex.

Are the vaccines made with fetal cells?

The Johnson and Johnson vaccine did use fetal cell cultures, specifically PER.C6 (a retinal cell line that was isolated from a terminated fetus in 1985), in order to produce and manufacture the vaccine.

For the Pfizer-BioNTech and Moderna vaccines, no fetal cell lines were used to produce or manufacture the vaccine, and they are not inside the injection you receive from your doctor/nurse. Fetal cells may have been used to test efficacy and/or proof of concept

Are COVID-19 vaccines safe?

The FDA is committed to science and the critical evaluation of all new vaccines for their safety and efficacy in an unbiased way before their authorization for use. No vaccine will be released until it has undergone rigorous scientific and clinical testing that all vaccines in development are held to. [Learn more about vaccine development in this presentation from the CDC.](#)

How can a safe vaccine be made so quickly?

Vaccine development typically takes many years, however, scientists had already begun research for coronavirus vaccines during previous outbreaks caused by related coronaviruses, such as SARS (Severe Acute Respiratory Syndrome) and MERS (Middle East Respiratory Syndrome). That earlier research provided a head start for rapid development of vaccines to protect against infection with the novel coronavirus SARS-CoV2, the virus that causes COVID-19.

There are currently no licensed mRNA vaccines in the United States. However, researchers have been studying them for decades. Early stage clinical trials using mRNA vaccines have been carried out for influenza, Zika, rabies, and cytomegalovirus (CMV). Challenges encountered in these early trials included the instability of free RNA in the body, unintended inflammatory outcomes, and modest immune responses. Recent technological advancements in RNA biology and chemistry, as well as delivery systems, have mitigated these challenges and improved their stability, safety, and effectiveness. Beyond vaccines, numerous preclinical and clinical studies have used mRNA to encode cancer antigens to stimulate immune responses targeted at clearing or reducing malignant tumors.

What are the side effects of the vaccine?

Any vaccine or medication can cause side effects. These are typically minor, such as a sore arm or low-grade fever, and go away within a few days. As with all vaccines, COVID-19 vaccines are not approved until clinical trials have taken place that show they are both safe and effective. Safety is the top priority of any vaccine. Side effects can include pain, swelling, and redness at the injection site and chills, tiredness, fever or headache throughout the rest of your body.

How many shots of COVID-19 vaccine will be needed?

The Pfizer and Moderna mRNA vaccines to prevent COVID-19 in the United States both need two shots to be effective. The Johnson & Johnson vaccine requires only one dose.

## Vaccine Availability

Who is paying for COVID-19 vaccine?

Vaccine doses purchased with U.S. taxpayer dollars will be given to the American people 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.

Are there special considerations on who should get the COVID-19 vaccine first?

CDC is making recommendations for [who should be offered COVID-19 vaccine first](#) when supplies are limited. To help guide decisions about how to distribute limited initial supplies of COVID-19 vaccine, CDC and the Advisory Committee on Immunization Practices have [published recommendations](#) for which groups should be vaccinated first. The goal is for everyone to be able to easily get a COVID-19 vaccination as soon as large quantities of vaccine are available.

While CDC makes recommendations for who should be offered COVID-19 vaccine first, each state has its own plan for vaccine prioritization, distribution and allocation. Please contact your state health department for more information on their planning for COVID-19 vaccines.

Learn how [CDC is making COVID-19 vaccine recommendations](#), including recommendations if there is a limited supply, based on input from the Advisory Committee on Immunization Practices (ACIP).

Are there other vaccines that can help prevent me from getting COVID-19?

There are currently no available vaccines that will prevent COVID-19. However, [multiple agencies and groups in the United States](#) are working together to make sure that a safe and effective COVID-19 vaccine is available as quickly as possible.

A flu vaccine will not protect you from getting COVID-19, but it can prevent you from getting influenza (flu) at the same time as COVID-19. This can keep you from having a more severe illness. While it's not

possible to say with certainty what will happen in the winter, CDC believes it's likely that flu viruses and the virus that causes COVID-19 will both be spreading during that time. That means that getting a flu vaccine is more important than ever.

Will the COVID-19 vaccine be mandatory for health care providers?

Similar to flu vaccine requirements, decisions regarding COVID-19 vaccine in health care settings will be determined by individual facilities. CUHCC highly recommends vaccination for all health care workers caring for persons with COVID-19 or those at high risk for severe disease (e.g., those working in long-term care facilities).

## Vaccine Effectiveness

If I have already had COVID-19 and recovered, do I still need to get vaccinated with a COVID-19 vaccine when it's available?

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.

Does immunity after getting COVID-19 last longer than protection from COVID-19 vaccines?

The protection someone gains from having an infection (called natural immunity) varies depending on the disease, and it varies from person to person. Since this virus is new, we don't know how long natural immunity might last. Current evidence suggests that reinfection with the virus that causes COVID-19 is uncommon in the 90 days after initial infection.

Regarding vaccination, we won't know how long immunity lasts until we have a vaccine and more data on how well it works.

Both natural immunity and vaccine-induced immunity are important aspects of COVID-19 that experts are trying to learn more about, and CDC will keep the public informed as new evidence becomes available.

What percentage of the population needs to get vaccinated to have herd immunity to COVID-19?

Experts do not know what percentage of people would need to get vaccinated to achieve herd immunity to COVID-19. Herd immunity is a term used to describe when enough people have protection—either from previous infection or vaccination—that it is unlikely a virus or bacteria can spread and cause disease. As a result, everyone within the community is protected even if some people don't have any protection themselves. The percentage of people who need to have protection in order to achieve herd immunity varies by disease.

Can I get more than one COVID-19 vaccine?

It's recommended that you receive only one type of COVID-19 vaccine. Some vaccines, like the Pfizer and Moderna vaccines, require two doses and you must receive both doses of the same brand of vaccine. The administration of more than one type of COVID-19 vaccine hasn't been tested so there isn't safety data available.

However, per the CDC's updated recommendations, in exceptional situations in which the first-dose vaccine product cannot be determined or is no longer available, any available mRNA COVID-19 vaccine may be administered at a minimum interval of 28 days between doses to complete the mRNA COVID-19 vaccination series. If two doses of different mRNA COVID-19 vaccine products are administered in these situations (or inadvertently), no additional doses of either product are recommended at this time.

Can other vaccines, including flu vaccines, be administered at the same time as the COVID-19 vaccines?

The COVID-19 vaccines should be administered alone, with a minimum interval of 14 days before or after administration with any other vaccines. If COVID-19 vaccines are inadvertently administered within 14 days of another vaccine, doses do not need to be repeated for either vaccine. However, COVID-19 and other vaccines may be administered within a shorter period in situations where the benefits of vaccination are deemed to outweigh the potential unknown risks of vaccine coadministration (e.g., tetanus toxoid-containing vaccination as part of wound management, measles or hepatitis A vaccination during an outbreak) or to avoid barriers or delays to COVID-19 vaccination (e.g., in long-term care facility residents or healthcare personnel who received influenza or other vaccinations prior to/upon admission or onboarding).

Can the second dose be given sooner than 21 or 28 days if that will help to ensure it is received?

Vaccine sites should not routinely offer the second dose of the vaccine earlier than the recommended time interval between shots. However, if a person arrives early for the second dose of vaccine, the day of arrival is within the 4-day grace period, and the person cannot return on the designated day (day 21 for Pfizer/BioNTech, day 28 for Moderna), then the vaccine should be given to ensure that the two doses are received. In other words, better to give the second vaccine dose a little early than not to give it at all.

Can the second dose be given later than 21 or 28 days and still be effective?

The goal of the first vaccine is to "prime" the immune response; the second "boosts" it. Although most participants in the trials received their second dose on or close to the scheduled time, there is no biological reason why receiving the second dose late would diminish the effectiveness of the vaccine, provided it's received before too long an interval. In practice, the second dose should be given as soon as possible after the missed scheduled dose.

Per the CDC's updated guidance, the second dose should be administered as close to the recommended interval as possible. However, if it is not feasible to adhere to the recommended interval, the second dose of Pfizer-BioNTech and Moderna COVID-19 vaccines may be scheduled for administration up to 6 weeks (42 days) after the first dose. There are currently limited data on efficacy of mRNA COVID-19 vaccines administered beyond this window. If the second dose is administered beyond these intervals, there is no need to restart the series.

Should a patient who is diagnosed with Covid-19 shortly after the first dose still receive the second scheduled dose?

The vaccine begins to generate protective immunity 10 to 14 days after the first shot. As a result, it is not surprising that some people have experienced Covid-19 shortly after their first immunization, and they naturally wonder whether they should proceed with the second shot as originally scheduled. The current recommendation is that people with current infection should wait until they have recovered from the acute illness and are [eligible to discontinue isolation](#). These recommendations apply both to those who developed Covid-19 before their first injection and to those who developed it after starting the vaccine series. On the basis of this guidance, some people in the latter group may be able to proceed with their scheduled second shot and others will need to wait. Treatment of Covid-19 with either monoclonal antibodies or convalescent plasma should delay receipt of the vaccine by 90 days, since these treatments could theoretically make the vaccine less effective.

Will the vaccines protect against the mutated strains of the coronavirus?

Early data shows the vaccines may be less effective at preventing the mutated strains, but still provide enough protection to make getting the vaccine worthwhile. The presence of these strains is another reason to encourage as many people as possible to get the vaccine as possible to combat resistance and spread of mutated strains.

## Public Health Safety

Do I need to wear a mask when I receive a COVID-19 vaccine?

Yes. CDC recommends that during the pandemic people [wear a mask](#) that covers their nose and mouth when in contact with others outside your household, when in healthcare facilities, and when receiving any vaccine, including a COVID-19 vaccine. Anyone who has trouble breathing or is unable to remove a mask without assistance should not wear a mask. For more information, visit [considerations for wearing masks](#).

Why would a vaccine be needed if we can do other things, like social distancing and wearing masks, to prevent the virus that causes COVID-19 from spreading?

Stopping a pandemic requires using all the tools available. Vaccines work with your immune system so your body will be ready to fight the virus if you are exposed. Other steps, like covering your mouth and nose with a mask and staying at least 6 feet away from others, help reduce your chance of being exposed to the virus or spreading it to others. Together, COVID-19 vaccination and following CDC's recommendations [to protect yourself and others](#) will offer the best protection from COVID-19.

Do I need to wear a mask and avoid close contact with others if I have received 2 doses of the vaccine?

Yes. While experts 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. Together, COVID-19 vaccination and following CDC's recommendations for [how to protect yourself and others](#) will offer the best protection from getting and spreading COVID-19. Experts need to understand more about the protection that COVID-19 vaccines provide before deciding to change recommendations on steps everyone should take to slow the spread of the virus that causes COVID-19. Other factors, including how many people get vaccinated and how the virus is spreading in communities, will also affect this decision.

When can I stop wearing a mask and avoiding close contact with others after I have been vaccinated?

There is not enough information currently available to say if or when CDC will stop recommending that people [wear masks](#) and [avoid close contact with others](#) to help prevent the spread of the virus that causes COVID-19. Experts need to understand more about the protection that COVID-19 vaccines provide before making that decision. Other factors, including how many people get vaccinated and how the virus is spreading in communities, will also affect this decision.

Does getting the vaccine change the need to quarantine after potential COVID-19 exposure?

Vaccinated persons with an exposure to someone with suspected or confirmed COVID-19 are not required to [quarantine](#) if they meet all of the following criteria†:

- Are fully vaccinated (i.e.,  $\geq 2$  weeks following receipt of the second dose in a 2-dose series, or  $\geq 2$  weeks following receipt of one dose of a single-dose vaccine)
- Are within 3 months following receipt of the last dose in the series

- Have remained asymptomatic since the current COVID-19 exposure

Persons who do not meet all 3 of the above criteria should continue to follow current [quarantine guidance](#) after exposure to someone with suspected or confirmed COVID-19.

What is the recommendation for receiving the flu vaccine this fall/winter with the current COVID-19 pandemic? CDC recommends that everyone six months and older receive a yearly flu vaccine. During this COVID-19 pandemic, reducing the overall burden of respiratory illnesses is especially important in order to protect vulnerable populations at risk for severe illness and reduce hospitalizations. Healthcare providers should offer the flu vaccine at every opportunity to all eligible patients.

Are there specific infection control procedures to follow when administering vaccines during a pandemic? It's important to apply infection prevention strategies to all patient encounters including physical distancing, respiratory and hand hygiene, surface decontamination, and source control. The CDC has developed [General Practices for Safe Delivery of Vaccination Services](#) and the Immunization Action Coalition has developed [Protective Measures for Vaccinating During Pandemic](#).

## Vaccine Safety

Is the vaccine safe for pregnant women?

Pregnant women are excluded from vaccine trials, so it hasn't been tested in pregnant women.

Pfizer and Moderna are mRNA vaccines, meaning they do not contain a live virus. The vaccines work by stimulating the body's immune system to produce antibodies to a protein on the virus surface. The theoretical risk of fetal harm from mRNA vaccines is very low. Counseling for pregnant women about the vaccine will be updated as more data is available. The Society for Fetal and Maternal Medicine recommends that healthcare workers who are prioritized for initial vaccination be offered the vaccine if pregnant.

Johnson & Johnson vaccine is an inactivated adenovirus vaccine, and there is not currently data to inform risk in pregnant women. There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to Janssen COVID-19 Vaccine during pregnancy. Women who are vaccinated with Janssen COVID- Revised: Feb/27/2021 16 19 Vaccine during pregnancy are encouraged to enroll in the registry by visiting <https://cviper.pregistry.com>.

In a reproductive developmental toxicity study female rabbits were administered 1 mL of the Johnson and Johnson COVID-19 Vaccine (a single human dose is 0.5 mL) by intramuscular injection 7 days prior to mating and on Gestation Days 6 and 20 (i.e., one vaccination during early and late gestation, respectively). No vaccine related adverse effects on female fertility, embryo-fetal or postnatal development up to Postnatal Day 28 were observed.

Data are not available to assess the effects of Janssen COVID-19 Vaccine on the breastfed infant or on milk production/excretion.

How do I report it if I have a problem or bad reaction after getting a COVID-19 vaccine?

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. Learn about the [difference between a vaccine side effect and an adverse event](#). Reports to VAERS help CDC monitor the safety of vaccines. Safety is a top priority.

Healthcare providers will be required to report certain adverse events following vaccination to VAERS. Healthcare providers also have to adhere to any revised safety reporting requirements according to FDA's conditions of authorized use throughout the duration of any Emergency Use Authorization; these requirements would be posted on [FDA's website](#).

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.

#### How long do v-safe check-ins last?

During the first week after you get your vaccine, v-safe will send you a text message each day to ask how you are doing. Then you will get check-in messages once a week for up to 5 weeks. The questions v-safe asks take less than 5 minutes to answer.

If you need a second dose of vaccine, v-safe will provide a new 6-week check-in process so you can share your second-dose vaccine experience as well. Finally, you'll receive check-ins 3, 6, and 12 months after your final dose of vaccine.

#### Who should not get the vaccine?

CDC considers a history of the following to be a contraindication to vaccination with both the Pfizer-BioNTech and Moderna COVID-19 vaccines:

- Severe allergic reaction (e.g., anaphylaxis) after a previous dose of an mRNA COVID-19 vaccine or any of its components
- Immediate allergic reaction of any severity to a previous dose of an mRNA COVID-19 vaccine or any of its components (including polyethylene glycol [PEG])\*
- Immediate allergic reaction of any severity to polysorbate (due to potential cross-reactive hypersensitivity with the vaccine ingredient PEG)\*

\* These persons should not receive mRNA COVID-19 vaccination at this time unless they have been evaluated by an allergist-immunologist and it is determined that the person can safely receive the vaccine (e.g., under observation, in a setting with advanced medical care available). See Appendix B for more information on ingredients included in mRNA COVID-19 vaccines.

Persons with an immediate allergic reaction to the first dose of an mRNA COVID-19 vaccine should not receive additional doses of either of the mRNA COVID-19 vaccines. Providers should attempt to determine whether reactions reported following vaccination are consistent with immediate allergic reactions versus other types of reactions commonly observed following vaccination, such as a vasovagal reaction or post-vaccination side effects (which are not contraindications to receiving the second vaccine dose).

Johnson & Johnson should not be administered to individuals with a known history of severe allergic reaction (e.g., anaphylaxis) to any component of the Janssen COVID-19 Vaccine.

Can a patient with a contraindication to one type of COVID vaccine receive a different type (Pfizer/Moderna versus Janssen)?



People with a contraindication to mRNA COVID-19 vaccines may be able to receive Janssen COVID-19 vaccine, and vice versa, provided certain measures are taken. People with a contraindication to one type of the currently authorized COVID-19 vaccines (e.g., mRNA) have a precaution to the other (e.g., Janssen viral vector). However, because of potential cross-reactive hypersensitivity between ingredients in mRNA and Janssen COVID-19 vaccines, consultation with an allergist-immunologist should be considered to help determine if the patient can safely receive vaccination. Healthcare providers and health departments may also request a consultation from the [Clinical Immunization Safety Assessment COVIDvax](#) project. Vaccination of these individuals should only be undertaken in an appropriate setting under the supervision of a health care provider experienced in the management of severe allergic reactions.

- People with a contraindication to mRNA COVID-19 vaccines (including due to a known PEG allergy): Consideration may be given to vaccination with Janssen COVID-19 vaccine. People who have received one mRNA COVID-19 vaccine dose but for whom the second dose is contraindicated should wait at least 28 days after the mRNA vaccine dose to receive Janssen COVID-19 vaccine.
- People with a contraindication to Janssen COVID-19 vaccine (including due to a known polysorbate allergy): Consideration may be given to mRNA COVID-19 vaccination. Of note, polysorbate allergy is no longer a contraindication to mRNA COVID-19 vaccination, it is a precaution.

Can people with certain medical conditions receive the mRNA vaccines?

- Weakened immune systems: People with HIV or other illnesses or receiving medications that weaken the immune system might be at increased risk for severe COVID-19 and CAN receive the mRNA COVID-19 vaccine. However, there is limited safety data at this time, and there is the potential for reduced immune responses to the vaccine so these patients should still follow social distancing, mask and hand hygiene recommendations to protect themselves.
- Autoimmune conditions: People with autoimmune conditions CAN receive the mRNA COVID-19 vaccines, but no data on safety is available. However, these patients were eligible for enrollment in the clinical trials.
- Guillan-Barre syndrome: People with a history of Guillan-Barre Syndrome CAN receive the mRNA COVID-19 vaccine. There have been no reported cases following vaccination with mRNA COVID-19 vaccine in the clinical trials.
- Bell's palsy: Cases of Bell's palsy were reported in the clinical trials, but the FDA does not consider these to be at the rate greater than expected in the general population. Therefore, they do not believe these cases were caused by vaccination and patients with a history of Bell's palsy CAN receive an mRNA COVID-19 vaccine.

What about patients who are receiving treatment for or have survived cancer?

Patients receiving chemotherapy were not included in the initial vaccine clinical trials. However, there is no evidence that they would not be safe for most cancer patients. Patients with cancer CAN receive the COVID-19 vaccine as long as components of the vaccine are not contraindicated. However, patients should be educated to continue the current guidance to protect themselves due to the potential for reduced immune responses to the vaccine. It is also reasonable to consult with the patient's oncologist for recommendations on when they should receive the vaccine. For example, they may recommend providing the vaccine in between cycles of chemotherapy or certain waiting periods after treatment.

Can I use Tylenol or Advil to help alleviate side effects from the vaccine?

Antipyretic or analgesic medications (e.g., acetaminophen, non-steroidal anti-inflammatory drugs) may be taken for the treatment of post-vaccination local or systemic symptoms, if medically appropriate. However, routine prophylactic administration of these medications for the purpose of preventing post-vaccination symptoms is not currently recommended, as information on the impact of such use on mRNA COVID-19 vaccine-induced antibody responses is not available at this time.

Can children and teenagers receive the vaccine?

Adolescents aged 16–17 years are included among persons eligible to receive the Pfizer-BioNTech COVID-19 vaccine under the EUA. While vaccine safety and efficacy data in this age group are limited, there are no biologically plausible reasons for safety and efficacy profiles to be different than those observed in persons 18 years of age and older. Adolescents aged 16–17 years who are part of a group recommended to receive a COVID-19 vaccine may be vaccinated with the Pfizer-BioNTech COVID-19 vaccine with appropriate assent. Children and adolescents younger than 16 years of age are not authorized to receive the Pfizer-BioNTech COVID-19 vaccine at this time.

Children and adolescents younger than 18 years of age are not authorized to receive the Moderna COVID-19 vaccine at this time.

Johnson & Johnson is approved for individuals 18 years of age and older.

How does the vaccine affect the evaluation of a patient and diagnostic testing for possible Covid-19?

The Covid-19 vaccines will not influence the results of PCR or antigen testing for the disease. The vaccines do generate antibodies to SARS-CoV-2, which are directed at the spike protein. Some available serologic assays test for this antibody; others do not. The manufacturers of the individual antibody tests should be able to provide this information, and it is often listed in the package insert.

How common is anaphylaxis after COVID vaccination?

As of January 10, 2021, over 4 million first doses of Moderna's COVID-19 vaccine had been administered, and 10 cases of anaphylaxis were identified. This is a rate of 2.5 cases/million. In 9 of the cases, the patients had a history of allergies or allergic reactions.

Is it safe to get the vaccine while taking other medications?

Taking antipyretic or analgesic medications prior to vaccination is not recommended due to potential for hindering the immune response. Additionally, patients on immunosuppressive medications may not develop as strong of an immune response and should be especially careful to continue social distancing, frequent handwashing, and wearing a mask in addition to getting the vaccine to protect themselves. However, in general, it is not expected that medications will interact with the COVID-19 vaccine, based on how the vaccine works and that patients with chronic conditions and on multiple medications were enrolled in clinical trials. Therefore, patients should be assured that the vaccine is safe to receive with their medications and they do not need to hold or alter their medication regimens.

Monoclonal antibody treatments for Covid-19 and convalescent plasma might interfere with the vaccine-induced immune response, making them less effective. Deferral of immunization for 90 days is recommended. However, for persons receiving antibody therapies not specific to COVID-19 treatment, no minimum interval is recommended prior to COVID-19 vaccine administration as these are unlikely to substantially impair development of immune response.

## Vaccine Myths

Myth: COVID-19 vaccines will alter my DNA.

Fact: The first COVID-19 vaccines to reach the market are likely to be messenger RNA (mRNA) vaccines. According to the CDC, mRNA vaccines work by instructing cells in the body how to make a protein that triggers an immune response. Injecting mRNA into your body will not interact or do anything to the DNA of your cells. Human cells break down and get rid of the mRNA soon after they have finished using the instructions.

Myth: COVID-19 vaccines cause infertility or miscarriage.

Fact: No, COVID-19 vaccines have not been linked to infertility or miscarriage. A sophisticated disinformation campaign has been circulating online, claiming that antibodies to the spike protein of COVID-19 produced from these vaccines will bind to placental proteins and prevent pregnancy. This disinformation is thought to originate from internet postings by a former scientist known to hold anti-vaccine views. These postings are not scientifically plausible, as COVID-19 infection has not been linked to infertility. Also, no other viral infection or vaccination-inducing immunity by similar mechanisms has been shown to cause infertility. Antibodies to the spike protein have not been linked to infertility after COVID-19 infection. There is no scientific reason to believe this will change after vaccination for COVID-19.

While there are no formal studies, the best evidence comes from women who got sick with COVID-19 while pregnant. While data clearly indicate pregnant women are at higher risk of hospitalization due to COVID-19 infection, there is no evidence of increased miscarriage rates. During natural infection, the immune system generates the same antibodies to the spike protein that COVID-19 vaccines would. Thus, if COVID-19 affected fertility, there already would be an increase in miscarriage rates in women infected with COVID-19. This has not happened.

Myth: The COVID-19 vaccine was developed to control the general population either through microchip tracking or "nanotransducers" in our brains.

Fact: There is no vaccine microchip, and the vaccine will not track people or gather personal information into a database. This myth started after comments made by Bill Gates from The Gates Foundation about a digital certificate of vaccine records. The technology he was referencing is not a microchip, has not been implemented in any manner and is not tied to the development, testing or distribution of COVID-19 vaccines.