

December 17, 2020

Dear Residents, Family Members, and Staff,

As you know the COVID-19 vaccine from Pfizer has been approved and the Moderna vaccine is likely to be approved as soon as this Friday. Distribution of the Pfizer vaccine has already begun. Assisted Living residents and staff have been designated as recipients of this vaccine in its first distribution Phase, 1A. We are glad the vaccine is coming so soon to our residents and staff.

We understand that some of you may be concerned about the safety of these new vaccines, as they have been developed and tested far more quickly than those in the past. We want to assure you that the speed with which these vaccines were developed is not due to skipping important safety steps, but rather the result of focused, collaborative work performed by experts across the globe. Vaccines approved for use by the U.S. Food and Drug Administration have undergone the same level of rigorous testing for safety and efficacy as other vaccines and have been tested in tens of thousands of people, including older adults.

Most of the COVID-19 vaccines require two separate doses given about three or four weeks apart, depending on the vaccine. Participants of clinical trials have reported experiencing short-term side effects after being vaccinated, with more possible discomfort after the second dose. These possible side effects include headache, muscle pains, fatigue, chills, fever and discomfort at the injection site. Sometimes there is misunderstanding about the cause of these reactions, should they happen, as you may have heard someone say a vaccine has “made them sick” or given them the disease that the vaccine was intended to prevent. This is not the case. The COVID-19 vaccine cannot give you a COVID-19 infection. The vaccine works by helping the body create antibodies to fight off the virus. Feeling discomfort after getting the vaccine means that the vaccine is doing its job and your body is making antibodies.

Thousands of skilled care and Assisted Living facilities across the country are participating in the Federal Pharmacy Partnership Program to bring COVID-19 vaccines to our communities for residents and staff. The safety and wellbeing of our residents and staff have been and remain our top priority. The COVID-19 vaccinations approved by FDA for EUA have proven to be safe and effective in fighting COVID-19 infection. This is a first step in working back to life before COVID-19.

We have included some information from the Ohio Department of Health regarding questions related to the vaccine. While the vaccine is not mandatory we want you to have the information available to make an informed decision before giving consent to get the vaccine. We have partnered with CVS who will be on site to administer the vaccine. While the date is still pending for this we are hopeful that it will be before year end. We look forward to doing our part in this effort by getting the COVID-19 vaccine and hope you will too.

Sincerely,



President/CEO

## Myths vs. Facts

# COVID-19 Vaccine

*Myth: COVID-19 vaccines aren't safe.*

**FACT: COVID-19 vaccines are safe and effective.**

Safety is a top priority of the U.S. vaccine safety development and approval process. The development process for COVID-19 vaccines involved several steps comparable with those used to develop other vaccines such as the flu or measles vaccine, which have successfully protected millions of Ohioans for decades. The U.S. Food and Drug Administration (FDA), as well as independent medical experts, have ensured that every detail of COVID-19 vaccines is thoroughly and rigorously evaluated. Evidence shows that COVID-19 vaccines are safe and work to prevent COVID-19. Of the first two vaccines to apply to the FDA for emergency use authorization, the Pfizer BioNTech vaccine was 95% effective, and the Moderna vaccine was 94% effective in phase 3 clinical trials with more than 70,000 participants between the two studies. Although the COVID-19 vaccines themselves have been developed recently, the technology used in mRNA vaccines, like those developed by Pfizer BioNTech and Moderna, has been studied for decades.

*Myth: COVID-19 vaccines were rushed and developed too quickly.*

**FACT: COVID-19 vaccine development and clinical trials were thorough and thanks to a strategic scientific effort to streamline processes, could be developed more efficiently.**

There have been no shortcuts in the vaccine development process. The process has been quicker as a result of strategic efforts to run concurrent trial phases, as well as a commitment to help condense timelines and reduce or eliminate months-long waiting periods during which documents would be prepared or be waiting for review. In addition, during the process of vaccine development, the CEOs of AstraZeneca, BioNTech, GlaxoSmithKline, Johnson & Johnson, Merck, Moderna, Novavax, Pfizer, and Sanofi made a historic pledge to the world, outlining a united commitment to uphold the integrity of the scientific process as they work toward potential regulatory filings and approvals of the first COVID-19 vaccines. Messenger RNA (mRNA), used by the first two vaccines to apply for FDA emergency use authorization (Pfizer BioNTech and Moderna), while new, is not unknown. Researchers have been studying mRNA for decades, and early-stage clinical trials using mRNA vaccines have been carried out for influenza, Zika, rabies, and cytomegalovirus (CMV). Recent technological advancements in RNA biology and chemistry, as well as delivery systems, have allowed these COVID-19 vaccines using mRNA to be developed as safe and effective vaccines.

*Myth: COVID-19 vaccines will be mandatory for every Ohioan.*

**FACT: Ohio will not make COVID-19 vaccination mandatory.**

The state of Ohio will not require anyone to get the COVID-19 vaccine. The vaccine will be available to all Ohioans who choose to receive it, as available supply of the vaccine increases.

*Myth: You can get COVID-19 from COVID-19 vaccines.*

**Fact: COVID-19 vaccines will not give you COVID-19.**

None of the COVID-19 vaccines currently in development in the United States use the live virus that causes COVID-19. The Pfizer/BioNTech and Moderna vaccines are messenger ribonucleic acid, or mRNA, vaccines. (See below for further explanation.) The goal for COVID-19 vaccines is to teach our immune systems how to recognize and fight the virus that causes COVID-19. Sometimes this process can cause side effects, such as fatigue, headache, soreness or redness at the injection site, and muscle or joint pain. These symptoms are normal and are a sign that the body is building immunity. It typically takes a few weeks for the body to build immunity after vaccination, and some vaccines require two doses. That means it is possible that a person could be infected with the virus that causes COVID-19 just before, or just after, getting the vaccination and become sick, since it takes the vaccine time to provide protection. Learn more about how COVID-19 vaccines work.

*Myth: Vaccines that use mRNA will alter my DNA or genetic makeup.*

**FACT: Receiving an mRNA vaccine will not alter your DNA.**

Messenger ribonucleic acid, or mRNA, is not able to alter or modify a person's genetic makeup (DNA). The mRNA from a COVID-19 vaccine never enters the nucleus of the cell, which is where your DNA is kept, and therefore does not affect or interact with your DNA in any way. The mRNA from COVID-19 vaccines can most easily be described as a set of instructions for your body on how to make a harmless piece of "spike protein" to allow our immune systems to recognize that this protein doesn't belong there and begin building an immune response and making antibodies. Essentially, COVID-19 vaccines that use mRNA work with the body's natural defenses to safely develop immunity to the virus, giving your cells a blueprint of how to make antibodies. Learn more about [how COVID-19 mRNA vaccines work](#).

*Myth: If I have recovered from COVID-19, I don't need to get the COVID-19 vaccine.*

**FACT: People who have recovered from COVID-19 may still benefit from getting vaccinated.**

At this time, experts do not know how long someone is protected from getting sick again after recovering from COVID-19. Due to the severe health risks associated with COVID-19, and because re-infection with COVID-19 is possible, people may be advised to get a COVID-19 vaccine even if they have been sick with COVID-19 before. The immunity someone gains from having an infection, called natural immunity, varies from person to person. Both natural immunity and vaccine-induced immunity are important aspects of COVID-19 that experts are trying to learn more about, and the federal Centers for Disease Control and Prevention (CDC) will keep the public informed as new evidence becomes available.

*Myth: COVID-19 isn't very serious, so I don't need to get the vaccine.*

**FACT: The severity of COVID-19 symptoms varies widely, and getting vaccinated can help prevent infection with COVID-19.**

While many people with COVID-19 have only a mild illness, others may get a severe illness or die. There is no way to know how COVID-19 will affect you, even if you are not at [increased risk of severe complications](#). Also, if you get COVID-19, you may spread the disease to friends, family, and others around you while you are sick. COVID-19 vaccination helps protect you by allowing your body to create an antibody response without having to experience sickness. Learn more about [how COVID-19 vaccines work](#).

*Myth: You will get a positive COVID-19 viral test if you receive the COVID-19 vaccine.*

**FACT: COVID-19 vaccines will not cause you to test positive on COVID-19 viral tests.**

Vaccines currently in clinical trials in the United States won't cause you to test positive on [viral tests](#), which are used to see if you have a current infection. If your body develops an immune response, which is the goal of vaccination, there is a possibility you may test positive on some [antibody tests](#). Antibody tests indicate you had a previous infection and that you may have some level of protection against the virus. Experts are currently looking at how COVID-19 vaccination may affect antibody testing results.

*Myth: Other vaccines, like the flu shot, will prevent COVID-19.*

**FACT: Only vaccines designed specifically to prevent COVID-19 will protect you from COVID-19.**

Other vaccines, such as those for flu, measles, or other diseases, will not protect you from COVID-19. Only the vaccines designed specifically to protect you from COVID-19, once approved for use by the FDA, can prevent it. While a flu vaccine will not prevent you from getting COVID-19, it can prevent you from getting influenza (flu) at the same time as COVID-19.

*Myth: There will not be enough vaccines for everyone.*

**FACT: As production of vaccine continues to grow, every Ohioan who chooses to do so will be able to receive a vaccine to prevent COVID-19.**

Initially, when the FDA first authorizes the use of specific COVID-19 vaccines in the United States, there will be a limited number of doses available. Ohio is committed to making the vaccine widely available, for those who want to receive it, as quickly as possible when shipments arrive in Ohio. In time, as vaccine production ramps up and large quantities are available, every Ohioan who chooses to do so will be able to get vaccinated.

*Myth: COVID-19 vaccines will implant tracking microchips in people.*

**FACT: Vaccine injections do not contain tracking microchips.**

No vaccine injections or nasal sprays – including the shots for COVID-19 – contain microchips, nanochips, RFID trackers, or devices that would track or control your body in any way. Much like the way any shipment or delivery is tracked, shipments of vaccine doses will be monitored as they are shipped and administered across the country. However, the notion that these shots will contain tracking devices implanted into Ohioans is false.

*Myth: COVID-19 vaccines cause infertility or other serious medical problems.*

**FACT: No serious safety concerns have been observed for the COVID-19 vaccines that have applied for emergency use authorization.**

In the [Pfizer BioNTech phase 3 clinical trial](#) of more than 43,000 individuals, and the [Moderna Phase 3 clinical trial](#) with 30,000 participants, no serious safety concerns were observed. The most common side effects were fatigue, headache, soreness or redness at the injection site, and muscle or joint pain. Side effects like these, while unpleasant, are a sign that your body is responding properly to create immunity from the virus that causes COVID-19.

*Myth: Vaccines cause autism.*

**FACT: Vaccines do not cause autism.**

Time after time, studies conducted across the globe continue to show that there is no connection between autism and vaccines.

**How do I know which sources of COVID-19 vaccine information are accurate?**

It can be difficult to know which sources of information you can trust. The internet, unfortunately, can be filled with dangerous misinformation about COVID-19 vaccines. The best thing you can do is educate yourself about the vaccines with trustworthy information. Learn more about [finding credible vaccine information](#) in this article from the CDC at <https://www.cdc.gov/vaccines/vac-gen/evalwebs.htm>.

Source: [Centers for Disease Control and Prevention \(CDC\)](#), [University of Maryland Medical System](#).

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For additional information, visit [coronavirus.ohio.gov](https://coronavirus.ohio.gov).

For answers to your COVID-19 questions, call 1-833-4-ASK-ODH (1-833-427-5634).

**Your mental health is just as important as your physical health. If you or a loved one are experiencing anxiety related to the coronavirus pandemic, help is available 24 hours a day, seven days a week. Call the COVID-19 CareLine at 1-800-720-9616.**



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## COVID-19 Vaccine FAQs



### **How will we know if a vaccine is safe and effective?**

The safety and efficacy of a vaccine is determined through clinical trials. Phase 1 clinical trials assess the safety and dosage of a vaccine in a small number of people, typically a dozen to several dozen healthy volunteers. Vaccine safety is also assessed in Phase 2 studies, in which adverse events not detected in Phase 1 trials may be identified because a larger and more diverse group of people receive the vaccine. However, only in the much larger Phase 3 clinical trials can it be demonstrated whether a vaccine is actually protective against disease and safety more fully assessed. Assessing safety is also a major goal of Phase 3 trials, both short-term safety (e.g., fever, tenderness, muscle aches) and long-term safety (e.g., autoimmune conditions or enhanced disease following infection). After a vaccine is approved and in more widespread use, it is critically important to continue to monitor for both safety and effectiveness. Some very rare side effects may only be detectable when large numbers of people have been vaccinated. (Source: [Johns Hopkins University Coronavirus Resource Center](#))

### **How long will protection last following vaccination?**

We do not know how long protection will last following vaccination. It will be critically important to measure long-term protection in Phase 3 trials and in other groups prioritized for early vaccination (at least two years). We are still learning about the duration of protection following infection with SARS-CoV-2, and it is too early to tell how long protection will last.

There are ways to potentially make protection after vaccination more durable than the protection that follows a natural infection, such as with an adjuvant, which is an ingredient used in some vaccines that helps create a stronger immune response, or with booster doses of vaccine. These strategies to enhance vaccines may be particularly important for vulnerable populations, such as the elderly and those with underlying diseases, who are at particular risk of severe COVID-19 but are also less likely to develop a protective immune response to a vaccine. (Source: [Johns Hopkins University Coronavirus Resource Center](#))

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

All but one of the COVID-19 vaccines currently in Phase 3 clinical trials in the United States need two shots to be effective. The other COVID-19 vaccine uses one shot. (Source: [CDC.gov](#))

### **If I already had COVID-19, do I still need to get the vaccine?**

There is not enough information currently available to say if or for how long after infection someone is protected from getting COVID-19 again — this is called natural immunity. Early evidence suggests natural immunity from COVID-19 may not last very long, and more studies are needed to better understand this. Until we have a vaccine available and the Advisory Committee on Immunization Practices makes recommendations on how to best use COVID-19 vaccines, we cannot comment on whether people who had COVID-19 should get a COVID-19 vaccine. (Source: [CDC.gov](#))



## COVID-19 Vaccine FAQs

### **Do I still need to wear a mask and avoid close contact with others if I have had two 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 **every available tool** to help stop this pandemic: cover your mouth and nose with a mask, wash your hands often, and stay at least 6 feet away from others. Together, the COVID-19 vaccination and following the 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 changing their recommendations on the 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. (Source: [CDC.gov](https://www.cdc.gov))

### **We have already heard concerns from clients and patients about the safety of a new vaccine. How do we address this?**

The CDC and FDA will address vaccine confidence throughout the COVID-19 vaccination campaign. The CDC is in the process of developing communication resources to address concerns about COVID-19 vaccines. Additional information will be shared when the resources are available.

It is vital that your staff understand the importance of vaccination as well as the benefits and risks:

- Communicate transparently about the COVID-19 vaccine risks and recommendations, immunization recommendations, public health recommendations, and prevention measures.
- Communicate early about the safety of vaccines in general and have government information to address myths, questions, and concerns easily accessible.
- Regularly visit [CDC.gov](https://www.cdc.gov) and your state and local health department websites for updated information.

Communicating what is currently known about COVID-19 and its vaccine, regularly updating this information, and continuing dialogue with residents, staff, and families throughout the vaccine distribution and administration process is essential to establish and maintain trust and credibility.

### **Can we require employees to take the vaccine?**

No\*. Vaccines authorized under the FDA's emergency use authority, as the COVID-19 vaccinations will be at the start, should **not** be mandated. Any COVID-19 vaccine brought to market under an EUA instead of the normal non-emergency approval process will, by necessity, lack long-term safety data. Therefore, mandating the use of a vaccine authorized only by EUA could raise potential OSHA issues, among others.

*\*Please take note of state and local mandates which may occur when the vaccine is released, as there could be special exemptions created for the healthcare industry.*





## COVID-19 Vaccine FAQs

### **What is the difference between a EUA and FDA Approval?**

During a public health emergency, the FDA can use its Emergency Use Authorization (EUA) authority to allow the use of unapproved medical products, or unapproved uses of approved medical products, to diagnose, treat, or prevent serious or life-threatening diseases when certain criteria are met, including that there are no adequate, approved, and available alternatives.

The issuance of an EUA allows manufacturers to temporarily circumvent the typical approval process in one of two ways: a manufacturer may distribute an approved product for an unapproved use or temporarily distribute an unapproved product.

To issue an EUA, the FDA along with representatives from a task force of other HHS agency members must find that the following conditions are met:

- The public health emergency identifies a serious or life-threatening disease or condition.
- Based on available quality evidence, it is reasonable to believe that an unapproved product may be effective in responding to the disease or condition.
- Known potential benefits of the product outweigh known potential risks.
- No adequate FDA-approved substitute exists.

These requirements closely mirror other statutory and regulatory exceptions to the FDA approvals process. Under such conditions, the FDA generally disclaims that unapproved products have not undergone sufficient safety or efficacy testing. The type of review that FDA conducts for an EUA is considerably less rigorous than how the agency would normally review a product for approval. However, under the emergent conditions, they may offer some benefit given the absence of any alternative. (Source: [FDA.gov](https://www.fda.gov))