

# Frequently Asked Questions COVID-19 Vaccines

### About COVID-19 Vaccines

### Q: Is there a COVID-19 vaccine?

**A:** In the United States, two COVID-19 vaccines have been granted emergency use authorization (EUA) from the Food and Drug Administration (FDA). These vaccines, manufactured by Pfizer-BioNTech and Moderna, began arriving in Ohio in December 2020.

### Q: Why is a COVID-19 vaccine needed if social distancing and wearing masks prevent the COVID-19 virus from spreading?

A: Getting us through the pandemic requires using all the tools available. Vaccines boost your immune system, so it will be ready to fight the virus if you are exposed. Other steps, like masks and social distancing, help reduce your chance of being exposed to or spreading the virus. Together, the coming COVID-19 vaccines and proper prevention measures will offer the best protection from COVID-19.

### **Q: Are COVID-19 vaccines effective?**

A: Yes. Evidence shows that COVID-19 vaccines are safe and work to prevent COVID-19. Of the first two vaccines to be granted FDA emergency use authorization, the <u>Pfizer-BioNTech vaccine was 95% effective</u> and the <u>Moderna vaccine was 94% effective</u> in phase 3 clinical trials with more than 70,000 participants between the two studies. Although the COVID-19 vaccines have been developed recently, the technology used in mRNA vaccines, like those developed by Pfizer-BioNTech and Moderna, has been studied for decades.

### Q: I've seen a lot of rumors on social media about vaccines. How can I tell what is true?

A: The internet is rife with dangerous misinformation about COVID-19 vaccines, and it can be difficult to know what to trust. The best thing you can do is educate yourself about the vaccines with information from trustworthy sources. Learn more about <u>finding credible</u> vaccine information in this article from the CDC, and separate myths from facts on this page from the Ohio Department of Health.

### Q: How many doses of COVID-19 vaccine will be needed? When is the second dose due?

**A:** Both the Pfizer-BioNTech vaccine and the Moderna vaccine, which have been granted emergency use authorization, require two doses. Ohioans who receive a dose of a particular vaccine must receive a second dose of the vaccine from the same manufacturer, as they are not interchangeable. For example, if you receive a first dose of the Pfizer-BioNTech vaccine, your second dose must be the Pfizer-BioNTech vaccine administered 21 days after the first dose. If you receive a first dose of the Moderna vaccine, your second dose must be the Moderna vaccine, administered 28 days after the first dose. These recommended intervals, with a standard four-day grace period, should be followed as closely as possible to receive full protection. If the intervals are exceeded, the second dose should be administered at the earliest opportunity. Doses would not need to be repeated due to a longer interval, meaning you do not have to start over, according to <u>Centers for Disease Control and Prevention (CDC) guidance</u>. There is a vaccine in development and Phase 3 clinical trials that uses one dose.

### Q: If I already had COVID-19 and recovered, do I still need to get vaccinated with the COVID-19 vaccine when it is available?

A: Yes, COVID-19 vaccination should be offered to you regardless of whether or not you already had COVID-19. 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. The timing for each vaccination phase is limited, so if you have been released from the isolation period, and are in an eligible audience, you should consider getting a COVID-19 vaccine as vaccination clinics become available to you.

### Q: Will the vaccine protect against the new COVID-19 variant now confirmed in the United States?

A: Viruses frequently change through mutation, and new variants of a virus are expected to occur over time. Multiple variants of the virus that causes COVID-19 have been documented in the United States and globally during this pandemic. Most variants do not change how the virus behaves, and many disappear. There is no evidence that these variants cause more severe illness or increased risk of death.Rapid spread of a new COVID-19 variant was first recognized in the United Kingdom in mid-December, and cases have been confirmed in the United States. According to the <u>CDC</u>, scientists are working to learn more about how easily this variant and other variants might spread, whether they could cause more severe illness, and whether currently authorized vaccines will protect people against them. Experts anticipate little to no impact on vaccine efficacy. Studies are pending to assess whether the immune response to infection with other variants or current vaccines will work effectively with this strain. Public health officials are also studying if variants are detected by currently available viral tests, and if they respond to medicines being used to treat COVID-19 patients.

The CDC's recommendations for slowing the spread — wearing masks, staying at least 6 feet apart from others, avoiding crowds, ventilating indoor spaces, and washing hands often — will also help prevent the spread of this variant.

Q: Should I alter the FDA recommended dosing of COVID-19 vaccines in any way (such as taking only a single dose, having half doses administered, extending the length of time between doses, or mixing and matching COVID-19 vaccines)?
A: No. According to the FDA, at this time, suggesting changes to the authorized dosing or schedules of these vaccines is premature and not rooted solidly in the available evidence. Without appropriate data supporting such changes in vaccine administration, we run a significant risk of placing public health at risk, undermining the historic vaccination efforts to protect the population from COVID-19. Full doses should be administered as directed, the second dose should be from the same manufacturer as the first dose, and should follow the FDA-recommended intervals (21 days between doses for the Pfizer-BioNTech vaccine, and 28 days between doses for the Moderna vaccine). Read more here.

### Q: Can other vaccines help prevent me from getting COVID-19?

A: 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 COVID-19. 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. Because the flu viruses and the virus that causes COVID-19 will both be spreading during this time, getting a flu vaccine will be more crucial than ever.

### **Q: What is Operation Warp Speed?**

A: Operation Warp Speed is a partnership between the U.S. Department of Health and Human Services and the Department of Defense focused on helping to develop, produce, and distribute millions of vaccine doses for COVID-19 while ensuring that vaccines are safe and effective. The Centers for Disease Control and Prevention (CDC) is focused on vaccine planning, working closely with the Ohio Department of Health and other state partners to prepare for vaccination availability.

### Q: Who is paying for the COVID-19 vaccine?

A: If you choose to get a COVID-19 vaccine, you will not have to pay. Vaccine doses purchased with taxpayer dollars will be given to Ohioans who choose to receive them at no out-of-pocket cost. Vaccine providers will be able to charge an administration fee for giving the shot to someone. Providers can get this fee reimbursed by the patient's public or private insurance company or, for uninsured patients, by the federal <u>Health Resources & Services Administration's Provider Relief Fund</u>.

### **Safety and Side Effects**

### Q: How will I know that the COVID-19 vaccine is safe?

A: The U.S. vaccine safety system ensures that all vaccines are as safe as possible. Safety is a top priority while federal partners work to make a coronavirus disease 2019 (COVID-19) vaccine(s) available. Clinical trials study the effectiveness of the vaccine in thousands of study participants. Data from these trials will be provided to the Food and Drug Administration (FDA) to determine vaccine safety and effectiveness. The FDA uses rigorous standards during the evaluation, and if it determines that a vaccine meets its safety and effectiveness requirements, it can make these available by approval or emergency use authorization. After the FDA decides, the Advisory Committee on Immunization Practices (ACIP) will review available data before making final vaccine recommendations to the CDC. There have been no shortcuts in the vaccine development process. The COVID-19 vaccine development process involved several steps comparable with those used to develop other vaccines, such as the flu or measles vaccine.

### Q: What are normal side effects from the COVID-19 vaccine?

A: When you get a COVID-19 vaccine, you can expect mild side effects, including soreness or redness at the injection site. Other common side effects are fever, chills, headache, tiredness, and muscle or joint pain. These side effects are normal as your body creates an immune response to protect you from COVID-19, and may increase with the second dose. Learn more about what to expect in this video from the CDC.

### Q: Will CDC continue to watch for problems with these new vaccines?

A: Yes. While no safety issues arose during the clinical trials, CDC and other federal partners continue to monitor the new vaccines for serious side effects (known as adverse events), using many vaccine safety monitoring systems. This continued monitoring can reveal side effects that may not have been seen in clinical trials. If there is an unexpected side effect with the new COVID-19 vaccines, experts can quickly study it further to determine if it is a true safety concern. Monitoring vaccine safety is critical to ensure that the benefits of COVID-19 vaccines continue to outweigh the risks for people who are vaccinated. The current vaccine safety system is strong and robust, with the capacity to effectively monitor COVID-19 vaccine safety. Existing data systems can rapidly detect if a vaccine has any possible safety problems, and additional systems and data sources are being developed. The Ohio Department of Health (ODH) will also monitor safety information to ensure that the people of Ohio have the best available information to make personal health and vaccination decisions. Systems being used include:

- CDC and FDA: Vaccine Adverse Event Reporting System (VAERS) The national system that collects reports of postvaccination adverse effects from healthcare professionals, vaccine manufacturers, and the public. Follow-up with specific studies is conducted for reports of adverse events that are unexpected, appear to happen more often than expected, or have unusual patterns.
- CDC: V-safe A new smartphone-based, post-vaccination health checker for people who receive COVID-19 vaccines. V-safe will use text messaging and web surveys to check in with vaccine recipients for health problems following vaccination. The system also will provide telephone follow-up to anyone who reports medically significant (important) adverse events.
- CDC: National Healthcare Safety Network (NHSN) An acute care and long-term care facility monitoring system reporting to VAERS.
- CDC: Vaccine Safety Datalink (VSD) A network of nine integrated healthcare organizations across the United States that
  conducts active surveillance and research; the system is also used to determine whether possible side effects identified using
  VAERS are related to vaccination.
- CDC: Clinical Immunization Safety Assessment (CISA) Project A collaboration between CDC and seven medical
  research centers to provide expert consultation on individual cases and conduct clinical research studies about vaccine safety.
- FDA: Other large insurer/payer databases A system of administrative and claims-based data for surveillance and research.
- FDA and the Centers for Medicare and Medicaid Services (CMS): Medicare data A claims-based system for active surveillance and research.
- FDA: Biologics Effectiveness and Safety System (BEST) A system of electronic health record, administrative, and claims-based data for active surveillance and research.
- FDA: Sentinel Initiative A additional system of electronic health record, administrative, and claims-based data for active surveillance and research.

### **Ohio's Vaccine Distribution Plan and Eligibility**

### Q: Will Ohio make COVID-19 vaccination mandatory?

A: No. The vaccine will be available, as supplies allow, to all Ohioans who choose to receive the vaccine.

### Q: How many vaccines are available?

A: Vaccine manufacturers are working hard to manufacture and distribute vaccines safely, quickly, and effectively. Each state will be informed, on a weekly basis, of how many vaccine doses they will receive that week.

### Q: Will there be enough vaccine for everyone in Ohio?

A: During the early phases of administration of COVID-19 vaccines in the United States, supply will be limited. This would mean that not everyone will be able to be vaccinated right away, but, in time, as vaccination production ramps up, every Ohioan who chooses may receive a vaccine as soon as large quantities are available.

### Q: Are there special considerations on who will receive the COVID-19 first in Ohio?

**A:** At first, there will be a limited supply of COVID-19 vaccine, with a phased approach to offering the vaccines. However, it is important that the initial vaccines are given to people in a fair, ethical, and transparent way. Those who are at highest risk of contracting and transmitting the virus will be among the first to be vaccinated.

### Q: Who can get the vaccine in Ohio?

A: Initially, there will be a limited number of vaccines available, and Ohio is committed to making it widely available for those that want to receive it, as quickly as possible, as shipments of vaccine arrive. In conjunction with the recommendations of medical experts at the Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP) and the National Academies of Sciences, Engineering, and Medicine (NASEM), Ohio has identified who will be among the first to receive those very early shipments in Phase 1A, should they choose to be vaccinated, listed below.

- Healthcare workers and personnel who are routinely involved in the care of COVID-19 patients.
- Residents and staff in nursing homes.
- Residents and staff in assisted living facilities.
- Patients and staff at state psychiatric hospitals.
- People with developmental disabilities and those with mental health disorders, including substance use disorders, who live in group homes, residential facilities, or centers, and staff at those locations.
- Residents and staff at our two state-run homes for Ohio veterans.
- EMS responders.

The goals of Phase 1B are to save lives and to have students back in school full-time by March 1. This phase will specifically include:

- Ohioans, age 65 and up.
- Ohioans with severe congenital, developmental, or early onset medical disorders that make them particularly vulnerable. This
  includes cerebral palsy; spina bifida; congenital heart disease; type 1 diabetes; inherited metabolic disorders; severe
  neurological disorders. including epilepsy; severe genetic disorders, including Down syndrome, fragile X syndrome, PraderWilli syndrome, and Turner syndrome; severe lung disease, including cystic fibrosis and severe asthma; sickle cell anemia;
  and alpha and beta thalassemia.
- Adults/employees in all schools that want to go back, or to remain, educating in person.

The vaccine distribution plan for future priority populations are still under development and will be shared publicly as soon as they are finalized. As more information becomes available on who can receive the vaccine, and when they can receive the vaccine, we will communicate this information publicly through the news media and share information at coronavirus.ohio.gov/vaccine.

## Q: If I am in an eligible audience, how will I know when I can get the vaccine during Phase 1A or 1B? Who do I call? How do I sign up?

A: During Phase 1A, the following providers will be responsible for distributing vaccines to the following audiences:

- Essential workers in healthcare settings hospitals, local health departments, and health systems.
- Long-term care/nursing home residents and staff the federal pharmacy distribution program, administered by CVS, Walgreens, PharmScript, and Absolute Pharmacy.
- Congregate care staff and residents, EMS first responders, any remaining long-term care facility staff local health departments.

Vaccinations in Phase 1B are expected to begin the week of January 19. Governor DeWine announced a tiered system for offering vaccinations to the estimated 2.2 million people who are eligible for the vaccine under this phase, beginning with those who are 80 or older. When a new age group begins, vaccinations may not be complete for the previous age group. It will take a number of weeks to distribute all of the vaccine given the limited doses available.

- The week of Jan. 19: Ohioans 80 years of age and older.
- The week of Jan. 25: Ohioans 75 years of age and older; those with severe congenital or developmental disorders.
- The week of Feb. 1: Ohioans 70 years of age and older; employees of K-12 schools that wish to remain or return to in-person or hybrid models.
- The week of Feb. 8: Ohioans 65 years of age and older.

Ohioans should check the websites of their local health departments and EMAs to learn more about vaccinations in their community or to sign up to receive updates from the local health department. Groups defined by age will receive the vaccine from local health departments, hospitals, federally-qualified health centers, as well as some retail pharmacies. Providers for other audiences are yet to be announced. A provider search will be available at coronavirus.ohio.gov on Thursday, January 14, allowing Ohioans to search by

county, ZIP code, and category to find a provider in their area to administer the vaccine.

### Q: I am not in one of the audiences that have been announced. When can I get the COVID-19 vaccine?

A: Initially, there will be a limited number of vaccines available, so we are committed to making it widely available for those that want to receive it as quickly as possible as shipments of the COVID-19 vaccines arrive in Ohio. Ohio continues to make plans for a way to distribute vaccines in a way that is fair, ethical, and transparent, in conjunction with the recommendations of medical experts at the Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP) and the National Academies of Sciences, Engineering, and Medicine (NASEM). As more information becomes available on who can receive the vaccine when we will communicate this information publicly, including through the news media, and share information at coronavirus.ohio.gov/vaccine.

### Q: When will the other distribution phases begin?

**A:** As vaccine supply increases, Ohio will continue to vaccinate Ohioans who choose to receive the vaccine. The speed at which Ohio will move through the phases depends on the number of vaccines available.

### Q: Will my children be able to receive the COVID-19 vaccine?

A: The Pfizer-BioNTech vaccine is currently recommended for patients age 16 and up, and the Moderna vaccine is currently recommended for patients age 18 and up. As more information becomes available on children and COVID-19 vaccines from the FDA, CDC, and vaccine manufacturers, it will be made available at coronavirus.ohio.gov/vaccine.

### Vaccine development

### Q: How were COVID-19 vaccines developed so quickly?

A: The process has been quicker as a result of <u>efforts</u> 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. Messenger RNA (mRNA), used by the first two vaccines to receive FDA emergency use authorization (Pfizer-BioNTech and Moderna) 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. Additionally, because COVID-19 comes from a family of viruses, including the SARS coronavirus of 2002 and the MERS coronavirus of 2012, scientists had already researched how coronaviruses behaved and had begun development on a vaccine for MERS using a modified "spike protein." Those years of research laid the groundwork for development of COVID-19 vaccines, which teach our bodies how to recognize COVID-19's spike protein and create antibodies against it.

### Q: What is the difference between an emergency use authorization (EUA) and an approval from the FDA?

**A:** An Emergency Use Authorization (EUA) authorizes the use of an unapproved medical product, or unapproved use of an approved medical product, for use during a public health emergency if the benefits of its use outweigh any known or potential risks. Both Pfizer-BioNTech and Moderna's COVID-19 vaccines have been granted EUA following rigorous review. In the past, EUAs have been issued for products, devices, and drugs related to Ebola, H1N1, Zika, and others. The EUAs are valid until the pandemic is over, the FDA revokes the EUAs, or the products are approved for traditional licensure by the FDA. The FDA closely monitors each vaccine for safety after the EUA is issued. Drug manufacturers are encouraged to obtain traditional FDA licensed vaccine approval as soon as possible.

### Q: Were minorities or people with high-risk health conditions included in the clinical studies?

A: Yes. The Phase 3 clinical trials for the Pfizer-BioNTech vaccine (more than 43,000 participants) and Moderna vaccine (more than 30,000 participants) included communities that have historically been under-represented in clinical research and have been disproportionately impacted by COVID-19. Approximately 42% of participants in Pfizer-BioNTech's worldwide clinical trials, and <u>37% of the Moderna study population were from communities of color</u>, which is similar to the diversity of the U.S. at large. In addition, the clinical studies included participants over age 65 (21% of Pfizer-BioNTech participants; 23% of Moderna participants); and those with high-risk chronic diseases that put them at increased risk of severe COVID-19, such as diabetes, severe obesity, and cardiac disease (46% of Pfizer-BioNTech participants).

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For additional information, visit <u>coronavirus.ohio.gov</u>. 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.