COVID-19 Fact Sheet
Safety and effectiveness of COVID-19 vaccines

COVID-19 can have serious, life-threatening complications, and there is no way to know how COVID-19 will affect each person. All three COVID-19 vaccines available in the United States have been proven safe and effective at preventing serious illness, hospitalization, and death from COVID-19 disease.

The first step to making an informed decision about whether to be vaccinated is accessing accurate and trusted information. The information below comes from leading experts from the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), the National Academies of Sciences, Engineering and Medicine (NASEM), the World Health Organization (WHO), and the U.S. Department of Health & Human Services (HHS).

How effective are COVID-19 vaccines?
COVID-19 vaccines from Pfizer-BioNTech, Moderna and Johnson & Johnson (Janssen) have been approved for emergency use by the FDA, and recommended for use by the CDC. During studies, the vaccines were proven to prevent serious illness from COVID-19 at high effectiveness rates. Leading national experts say there are challenges comparing efficacy rates from the clinical studies between the three products because the vaccines were not tested against one another, or under the same conditions or timelines. The CDC recommends getting the first vaccine available to you for protection from COVID-19.

Can I get COVID-19 from the vaccine?
None of the COVID-19 vaccines can cause COVID-19. Vaccines work to prepare the body’s natural defenses to fight specific viruses. The COVID-19 vaccines use different methods to achieve the same end result, which is using a harmless piece of the virus that causes COVID-19 – the surface or “spike” protein that latches onto cells – to teach the body how to recognize that protein, and protect against it if exposed to it in the future.

Messenger RNA (mRNA) vaccines, including the Pfizer and Moderna vaccines, don’t use a live virus. They teach cells how to make a protein that triggers an immune response inside the body. Viral vector vaccines, including the Janssen vaccine, use a modified version of a harmless adenovirus (such as the common cold) to deliver instructions to cells. The vaccine cannot cause infection with COVID-19 or with the inactive virus used as the transportation device.

How safe are the COVID-19 vaccines?
Safety has been a top priority throughout the vaccine development and approval process. It continues to be a top priority, as vaccine administration is under way, through continuous safety monitoring measures.

- **Rigorous testing:** The COVID-19 vaccine development process involved several steps comparable with those used to develop other vaccines, such as the flu or measles vaccine. Clinical trials study the safety and effectiveness of a vaccine in thousands of study participants. No serious safety concerns emerged during the clinical trials.

- **Thorough evaluation:** The FDA uses rigorous standards and insights from independent medical professionals to evaluate trial data to ensure that a vaccine is safe and effective and the benefits outweigh the risks. After an FDA decision, the CDC also reviews available data before making final recommendations for vaccine use.

- **Ongoing safety monitoring:** The CDC and other federal partners continue to monitor the new vaccines for any serious side effects, using many vaccine safety monitoring systems. This continued monitoring could reveal side effects that may not have been observed in clinical trials.

There were more than 116,000 participants between the three clinical studies. Dr. Jerome Adams, when he was serving as U.S. surgeon general, said typical studies only have about 5,000 participants before a vaccine is approved, explaining, “These vaccines, at the point of being administered to the American public, will have more data than any other vaccine developed in history.”

For more information, visit: coronavirus.ohio.gov
How was the COVID-19 vaccine developed so quickly?
In the past, vaccines have taken many years to develop. The process for COVID-19 vaccines has been quicker for many reasons. No steps were skipped, but researchers did conduct some stages of the process simultaneously. This included concurrent trial phases and condensed timelines that eliminated long waiting periods. 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 began developing similar vaccines. This paved the way for faster development of the COVID-19 vaccines.

Are the COVID-19 vaccines safe for all groups of people?
Clinical trials that studied the vaccine’s effectiveness and safety included a diverse cross-section of people, including communities that have historically been under-represented in clinical research. Those communities also have been disproportionately impacted by COVID-19. Approximately 42% of participants in Pfizer BioNTech’s worldwide clinical trials, 37% of the Moderna participants, and 35% of the Johnson & Johnson (Janssen) participants were from communities of color, which is similar to the diversity of the U.S. at large.

In addition, the clinical studies involved participants in the high-risk older population (21% of Pfizer-BioNTech participants, 23% of Moderna participants, 34% of Johnson & Johnson (Janssen) participants); and people with high-risk chronic diseases that put them at increased risk of severe COVID-19 (46% of Pfizer-BioNTech participants, 42% of Moderna participants, and 40% of Johnson & Johnson (Janssen) participants).

Children and pregnant or breastfeeding moms were not included in the clinical trials, so no data is available at this time on the safety of the vaccines for those populations. Trials with these groups are in progress or beginning soon.

What are the benefits of getting the COVID-19 vaccine?
COVID-19 vaccines create immunity without risk of illness. People who have had COVID-19 may develop short-term immunity from antibodies, but it is uncertain how long this protection will last. COVID-19 symptoms can vary widely from mild to serious, and may be long-lasting and life-threatening. Vaccination will protect you by creating an immune system response without sickness.

COVID-19 vaccines could help keep you from getting seriously ill if you contract the virus. Protection from COVID-19 is critically important because for some people, it can cause severe illness or death.

What are the side effects of the COVID-19 vaccines?
The most common side effects observed with COVID-19 vaccines are similar to side effects experienced with most vaccines. When you get a COVID-19 vaccine, you can expect mild side effects that could include: soreness, redness, or swelling at the injection site; fever and/or chills; headache; fatigue; and muscle or joint pain. These side effects are normal and a sign that your body is creating an immune response to protect you from COVID-19. Side effects typically last only a few days, and may increase with the second dose.

Have there been any safety concerns with the COVID-19 vaccines?
Severe allergic reactions, such as anaphylaxis, in which a person needs to be treated with epinephrine or is hospitalized, are rare. Chances of a bad reaction may be higher if you have certain health conditions, such as a weakened immune system, or if you have had an allergic reaction to a vaccine before. The CDC has learned about a small number of people who have experienced adverse events after getting a mRNA COVID-19 vaccine.

Is there anyone who should NOT get a COVID-19 vaccine?
Yes, the COVID-19 vaccines are not recommended in a few cases.

- People with severe vaccine allergies: People who have a known history of a severe allergic reaction to any component of the vaccines or anyone who had a severe allergic reaction to the first dose of the COVID-19 vaccine should NOT get the vaccine.
- People allergic to PEG or polysorbate: Polysorbate is not an ingredient in either mRNA COVID-19 vaccine but is closely related to PEG, which is in the two mRNA vaccines. People who are allergic to PEG or polysorbate should not get an mRNA vaccine.
- People who have an active case of COVID-19 or are under quarantine: If you’re currently infected with the coronavirus, wait until you’ve recovered and meet the CDC’s criteria for when you can stop isolating at home. If you’ve been exposed to COVID-19 and are under quarantine, wait until your quarantine period has ended to avoid potentially exposing others.

Updated March 4, 2021.

For additional information, visit coronavirus.ohio.gov or call 1-833-4-ASK-ODH (1-833-427-5634).