Answers to Frequently Asked Questions about the COVID-19 Vaccine

January 5, 2021

The FDA, CDC and vaccine oversight and review advisory committees have reviewed all the available information and determined the **Pfizer and Moderna SARS CoV-2 Vaccines** are safe and effective at preventing COVID-19.

The COVID-19 Vaccine and Safety

Is the COVID-19 vaccine safe?

Clinical development is a three-phase process. During Phase I, small groups of people receive the trial vaccine. In Phase II, the clinical study is expanded and vaccine is given to people who have characteristics (such as age and physical health) similar to those for whom the new vaccine is intended. In Phase III, the vaccine is given to thousands of people and tested for efficacy and safety. Many vaccines undergo Phase IV formal, ongoing studies after the vaccine is approved and licensed.

While phase 3 clinical data has not yet been published, neither Pfizer nor Moderna have reported any serious adverse events during phase 1 or phase 2 clinical trials. So far, no serious adverse events have been reported from the 38,955 patients who received the complete two-dose series. The FDA reviews two to three months of safety and efficacy data before issuing an Emergency Use Authorization (EUA) for the SARS CoV-2 vaccine.

How does the COVID-19 vaccine work?

The Pfizer and Moderna Corona Virus (SARS CoV-2) vaccines are what are called “messenger RNA” (mRNA) vaccines. Neither of the vaccines contains the virus itself. Once injected, your body’s cells receive mRNA and use it as a template to make viral proteins that mimic the same proteins found on the surface of the Corona virus that causes COVID-19. These proteins then activate the immune system to produce antibodies. If a vaccinated person is then subsequently exposed to SARS CoV-2, these antibodies will recognize the same viral protein and activate immune cells to detect and destroy the virus before it can cause illness. The COVID-19 vaccine does not change your DNA or enter the nucleus (center) of your cells. It is degraded in your body very quickly – within about 5 hours.

Does the vaccine work in preventing me from getting COVID-19?

The Pfizer vaccine is 95% effective and Moderna is 94.5% in their research across age, race, and ethnic demographics. Completing the 2-dose series is very important to optimize protection and achieve high efficacy.

Vaccine effectiveness is a mathematical calculation that compares the risk for developing disease (COVID-19) among a group of people who received the vaccine compared to the risk for developing the disease among a control group who did not receive the vaccine. So, a vaccine efficacy of 95% indicates a 95%

reduction in disease among those who were vaccinated, or a 95% reduction from the number of cases expected among those who were

Can the COVID-19 vaccine infect someone with COVID?

No. The COVID-19 vaccine does not contain any live virus.

Is there a microchip in the vaccine?

There is no microchip or tracking device in the COVID-19 vaccine doses.

Are the COVID-19 doses in shared vials?

Yes. Both the Pfizer and Moderna COVID-19 vaccines are in multi-dose vials. Manufacturers' recommendations and universal precautions will be taken to ensure each individual dose given is safe and effective.

What are the ingredients of the COVID-19 vaccine?

The ingredients outside of the mRNA are salt and lipid ingredients commonly used in vaccine stability.

The Pfizer BioNTech COVID-19 Vaccine includes the following ingredients: mRNA, lipids ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate), 2 [(polyethylene glycol)-2000]-N,N-ditetradecylacetamide, 1,2-Distearoyl-sn-glycero-3- phosphocholine, and cholesterol), potassium chloride, monobasic potassium phosphate, sodium chloride, dibasic sodium phosphate dihydrate, and sucrose.

The Moderna COVID-19 vaccine includes the following ingredients: mRNA, Lipids (SM-102, 1,2-dimyristoyl-rac-glycero3-methoxypolyethylene glycol-2000 [PEG2000-DMG], cholesterol, and 1,2-distearoyl-snglycero-3-phosphocholine [DSPC]), tromethamine, tromethamine hydrochloride, acetic acid, sodium acetate, sucrose.

The Vaccine Distribution Plan

Which COVID-19 vaccine will I get and when?

Affinia Healthcare will apply for the Pfizer and/or Moderna vaccine as available via the state distribution plan outlined below. Most likely Affinia Healthcare will begin offering the vaccine to patient-facing employees in January, 2021.

How many doses is the COVID-19 vaccine and how is it administered?

The Pfizer vaccine is an IM (intramuscular) injection given in two doses spaced 21 days apart. The Moderna vaccine is an IM (intramuscular) injection given in two doses spaced 28 days apart. People will need to receive 2 doses of the SAME vaccine. Persons who do not receive their second dose on time should try to do so as soon as possible. Full effectiveness as reported is based on two doses at the appropriate time frame.

Once I'm vaccinated, can I still spread COVID-19 to others?

We know the vaccine protects against symptomatic COVID-19 and against severe disease with COVID-19. It is unknown whether it is possible for someone who has been vaccinated to still acquire and spread COVID-

19 to others. This is one reason it will be essential to continue wearing a mask, avoiding crowds, physical distancing and washing your hands even after vaccination until this becomes clearer.

How long does immunity last, following a vaccination?

This is not yet entirely clear. The best immunity will be present approximately 2 weeks post the 2nd dose of vaccine. Studies have measured antibodies that persist for at least several months after vaccination. Antibodies are an important part of the immune system but not the only way disease is prevented. An important part of the FDA's decision about whether to authorize a COVID-19 vaccine will be whether it is safe and effective. How long a vaccine is likely to provide protection requires more study which is underway.

Will this protect me against other coronaviruses or influenza?

No. The Pfizer and Moderna SARS CoV-2 vaccines are specific to SARS CoV-2 and will not provide protection to other coronaviruses or influenza.

Special Situations

Should I get the vaccine if I've already had COVID? If so, when?

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, but more studies are needed to better understand this. Currently the COVID 19 vaccine is recommended for people who have had COVID infection. The best timing is about 90 days after infection.

Should I get the vaccine if I do not have symptoms, but was just exposed to someone with COVID?

Defer vaccination until quarantine period has ended to avoid exposing healthcare personnel (HCP) or other persons during a vaccination visit.

Should I get the COVID-19 vaccine with my influenza vaccine?

The COVID-19 vaccine should be given alone. It is recommended to wait 14 days before and after any other vaccination(s).

What is the approved age range of the COVID-19 vaccine?

The current Emergency Use Authorization is for ages 16 and up for Pfizer and 18 and up for Moderna.

Should someone with underlying medical conditions get the vaccine?

Vaccines may be administered to persons with underlying medical conditions who have no contraindications to vaccination. Phase 2/3 clinical trials demonstrate similar safety and efficacy profiles in persons with underlying medical conditions, including those that place them at increased risk for severe COVID-19 illness, compared to persons without co-morbidities.

Should I receive the vaccine if I'm immunocompromised?

Persons with HIV infection, other immunocompromised conditions, or who take immunosuppressive medications or therapies might be at increased risk for severe COVID-19. Data currently is not available to

establish safety and efficacy of vaccine in these groups. These individuals may still receive COVID-19 vaccine unless otherwise contraindicated. Individuals should be counseled about unknown vaccine safety and efficacy profiles in immunocompromised persons and the potential for a reduced immune responses. Immunocompromised persons should consider discussing with their physician and need to continue to follow all current guidance to protect themselves against COVID-19.

Should I get the COVID vaccine if I'm pregnant?

Experts agree that pregnant women should be offered the COVID-19 vaccine.

There are no data on the safety of COVID-19 vaccines in pregnant women and animal developmental and reproductive toxicity (DART) studies are ongoing. This is being studied and planned.

What we do know is that an mRNA vaccine is NOT live, degrades quickly in the body, and does not enter the nucleus of the cells. These are all characteristics of a vaccine that are safe in pregnancy. We also know that pregnant women are at increased risk of severe illness due to COVID-19 (ICU admission, mechanical ventilation and death and potentially an increase in preterm birth. A discussion with her healthcare provider can help her make an informed decision. Pregnant women who experience fever following vaccination should be counseled to take acetaminophen as fever has been associated with adverse pregnancy outcomes. Routine testing for pregnancy prior to receipt of a COVID-19 vaccine is not recommended. Please see attached for additional information (fertility also addressed).

Should I get the vaccine if I'm breastfeeding or lactating?

There are no data on the safety of COVID-19 vaccines in lactating women or the effects of mRNA vaccines on the breastfed infant or milk production/excretion. mRNA vaccines are not considered live virus vaccines and are not thought to be a risk to the breastfeeding infant. If a lactating woman is part of a group (e.g., healthcare personnel) who is recommended to receive a COVID-19 vaccine, she may choose to be vaccinated. Please see attached for additional information.

Post-Vaccination Concerns

What are the known side effects from the COVID vaccine?

At this time, the most common reported side effects of the Pfizer and Moderna vaccines are fever, headache, fatigue, and body or muscle aches in the days immediately following vaccination. From early reports, these effects are more common after the second dose.

If you develop side effects hydrate, rest, and call your primary care provider if needed. You may also consider acetaminophen or ibuprofen for symptomatic relief.

Unless a person develops a contraindication to vaccination, they should be encouraged to complete the series even if they develop post-vaccination symptoms in order to optimize protection against COVID-19. Antipyretic or analgesic medications may be taken for treatment of post-vaccination symptoms.

If side effects cause me to miss work, how will that be handled for employees?

If you experience side effects after the vaccine such that you would request time off work to rest and recover, contact your supervisor. Treatment required for post-vaccination side effects will not be covered

by, or claimed under, workers' compensation. Employees would use available PTO benefits for non-worked time.

Have there been reports of severe allergy to the COVID-19 vaccine?

Persons with severe allergic reaction (e.g., anaphylaxis) to any component of the Pfizer-BioNTech or Moderna COVID19 vaccine should not receive the vaccine. Because of reports of anaphylactic reactions outside of clinical trials, the additional guidance is proposed: Persons who have had a severe allergic reaction to any vaccine or injectable therapy (intramuscular, intravenous, or subcutaneous) should not receive the Pfizer-BioNTech or Moderna vaccine at this time.

Appropriate medical treatment used to manage immediate allergic reactions will be immediately available in the event an acute anaphylactic reaction occurs following administration of the vaccine. Vaccine providers should observe patients after vaccination to monitor for the occurrence of immediate adverse reactions for 15 minutes.

How to I report a side effect or an adverse (bad) event from the COVID-19 vaccine?

The CDC and FDA encourage the public, clinicians, and vaccinators 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.

Healthcare providers will be required to report certain adverse events following vaccination to VAERS. The VAERS toll-free number is 1-800-822-7967 or report online to https:vaers.hhs.gov/reportevent.html

CDC is 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.

Do I need to continue wearing a mask, socially distancing, and hand hygiene after I have received the COVID vaccine?

Yes. The CDC recommends that ALL current COVID-19 safety protocols continue, regardless of vaccination status. Please continue to wear masks, personal protective equipment as appropriate, socially distance, and perform hand hygiene. Patients and visitors also will continue to be required to wear masks and undergo symptom screening on arrival at our sites. Current guest/visitor policies and other facility policies related to COVID-19 will remain in place.

Supply and Availability

Is the COVID-19 vaccine free?

There is no charge to Affinia Healthcare employees or contractors for the COVID-19 vaccine.

Vaccine doses from the federal government will be given to people at no cost. Affinia Healthcare will collect no out-of-pocket fee from patients or individuals vaccinated in the community. An administration

fee for giving the shot may be 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.

If I refuse the vaccine now, can I change my mind later?

Yes. You can change your mind and receive it at any time given adequate supplies.

Does Affinia Healthcare require or mandate the COVID-19 vaccine?

No. The Affinia Healthcare Board of Directors has determined that receiving the vaccine is not a condition of employment, or otherwise to work at an Affinia Healthcare facility or service, at the present time. However, given its safety and efficacy, receiving the vaccine is encouraged. Affinia Healthcare supports the clinical evidence and recognizes the vaccine offers a valuable opportunity to protect yourself and loved ones from contracting COVID-19. We encourage review of accurate and evidence based data (i.e. CDC) and/or a discussion with your primary care provider to make an informed decision that is best for you.

With the limited supply of COVID-19 vaccines, the virus may still be circulating in our communities. What happens after the three to six months of protection goes away? Can I be revaccinated if the virus is still prevalent?

It is possible that the Pfizer and Moderna COVID-19 vaccines will be annual vaccinations, much like the influenza vaccine. Pfizer, Moderna and the FDA have not yet released guidance about appropriate vaccination intervals beyond the first two-dose series.

What is the planned national and Missouri roll-out of the COVID-19 vaccine?

Nationwide, the first round of vaccines will go to patient-facing health care personnel and the staff and patients of long-term care facilities.

After this priority group has had an opportunity to receive the vaccine, the next group is essential workers (non-patient facing health care workers), which includes teachers, food service workers in the community and first responders.

After that, it will be offered to individuals with conditions that make them high-risk for complications from COVID-19, including those ages 65 and older. This may include some Affinia employees working completely from home.

Then it will be offered to the general public. It is expected to be several months after the vaccines are released before they are available to the general public. This may include some Affinia employees working completely from home.

Decisions about who to prioritize for access to a COVID-19 vaccine are made by federal and state public health agencies. Affinia Healthcare is required to follow these prioritization decisions.

Research Process

How can the vaccine be safe and effective when it was produced so quickly?

It's quite unusual to have so many scientists from around the world working on the same problem at the same time. Instead of trying one solution at a time, hundreds are being tested at the same time. Vaccines that use mRNA are usually faster and easier to produce. Prior knowledge from other coronavirus vaccines (i.e. SARS/MERS) has also helped accelerate the process. No corners have been cut. Federal funding allowed vaccines to be manufactured while still in clinical trials. That allowed the vaccines to be available as soon as trials were completed, data reviewed, and the FDA/CDC deemed the vaccines safe and effective.

Why was at least one COVID vaccine clinical trial paused, and what does that mean?

Safety is a top priority during the vaccine approval process. It is not unusual for a clinical trial to be temporarily paused when a possible side effect (called an adverse event) is detected. Clinical trials are designed to pause when an unexpected health event (called a safety signal) is detected so scientists and physicians can investigate potential safety concerns. The approval process for COVID-19 vaccines is no different — safety is always the focus.

What is an Emergency Use Authorization (EUA)?

An Emergency Use Authorization (EUA) is an authority available to the Food and Drug Administration (FDA) to approve a medication/therapeutic agent/vaccine in response to a public health emergency. A EUA may be granted for therapies that "may be effective," or with a lower level of evidence than would otherwise be required for full FDA approval.

Resources

State of Missouri – https://covidvaccine.mo.gov/

Centers for Disease Control and Prevention (CDC) – https://www.cdc.gov/coronavirus/2019-ncov/vaccines/index.html

Affinia Healthcare will regularly communicate COVID-19 vaccine updates.