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**COVID19 Vaccine Update 12/19/2020**

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**Types of Vaccines:**

**Inactivated or weakened virus vaccines**, which use a form of the virus that has been inactivated or weakened so it does not cause disease, but still generates an immune response.

**Protein-based vaccines**, which use harmless fragments of proteins or protein shells that mimic the COVID-19 virus to safely generate an immune response.

**Viral vector vaccines**, which use a virus that has been genetically engineered so that it can't cause disease but produces coronavirus proteins to safely generate an immune response.

**RNA and DNA vaccines**, a cutting-edge approach that uses genetically engineered RNA or DNA to generate a protein that itself safely prompts an immune response.

**How effective will the vaccines be for disease prevention?**

In Phase 3 trials, the **Pfizer vaccine** showed a 95% efficacy rate 7 days after the second dose. The vaccine was 94% effective in adults >65 years old.

The **Moderna vaccine** showed a 94% efficacy rate 14 days after the second dose. These results were consistent across gender, age, race, and ethnicity.

**How do the Pfizer and Moderna mRNA vaccines work:**

The vaccines contain synthetic mRNA, which is genetic information used to make the SARS-CoV-2 spike protein. The spike protein is the part of the virus that attaches to human cells. The spike protein alone cannot cause COVID-19. Once the spike protein is created, it causes the immune system to make antibodies against the virus. These antibodies can then provide protection if a person comes into contact with the virus. **The mRNA vaccines are non-infectious and do not enter the human cell nucleus, so they cannot be inserted into human DNA. Additionally, mRNA is rapidly broken down, and this theoretically reduces chances for long-term side effects. The mRNA vaccines do not have the ability to cause cancer.**

## **FDA and FAA Approvals:**

— Following the Emergency Use Authorization from the U.S. Food and Drug Administration (FDA) for **Moderna's** COVID-19 vaccine, the FAA has determined that pilots may receive the vaccine under the conditions of their FAA-issued airman medical certification. FAA Air Traffic Controllers, who are subject to FAA medical clearance, may also receive the vaccine.

To maintain the highest level of safety in the National Airspace System, the agency will require pilots with medical certifications or air traffic controllers with medical clearances to observe a period of 48 hours following the administration of each dose of this vaccine before conducting safety-sensitive aviation duties, such as flying or controlling air traffic.

Because the vaccine requires two doses, 28 days apart for maximum effectiveness, the waiting period applies after each dose. **The Pfizer vaccine**, which was approved last week, requires two doses 21 days apart, but the waiting period after each dose applied to both brands.

**The FAA anticipates taking no additional measures to ensure safety after the initial window for side effects closes.** However, the agency's medical professionals will continuously monitor the initial distribution of the novel vaccine and documented clinical results and will adjust these recommendations as needed.

**The FAA encourages Americans to receive COVID-19 vaccinations as authorized by FDA. This policy announcement pertains to a specialized group of FAA-certificated persons who perform safety-sensitive aviation duties.**

## **Side effects: (NOT defined as Adverse Events):**

The most common side effects of the vaccine are similar to some routine vaccines, including a sore arm, tiredness, headache, and muscle pain. **Data from clinical trials showed the following in people younger than 55:**

About 80 percent reported pain at the injection site

About half reported tiredness and headache

Less than one-third (30 percent) reported muscle pain

**Most side effects occur within two days of getting the vaccine and last about a day**

**Side effects are more common among people 55 years or older than among those younger than 55**

**Side effects are more common after the second dose than the first dose.**

## **Serious Adverse Events:**

While uncommon (<1.0%), were observed at slightly higher numerical rates in the vaccine study group compared to the saline placebo study group, both overall and for certain specific adverse events occurring in **very small** numbers. These represented common medical events that occur in the general population at similar frequency. Upon further review by FDA, these imbalances do not raise a safety concern, nor do they suggest a causal relationship to vaccination for the vast majority of reported serious adverse events.

Serious adverse events considered by FDA to be plausibly related to the vaccine or vaccination procedure were one case of shoulder injury at the vaccination site and one case of swollen lymph node in the armpit opposite the vaccination arm.

No safety concerns were identified in subgroup analyses by age, race, ethnicity, medical comorbidities, or prior SARS-CoV-2 infection.

Severe allergic reactions have been reported following administration of Pfizer-BioNTech COVID-19 Vaccine during mass vaccination in another country outside of the clinical trial setting. Additional adverse reactions, some of which may be serious, may become apparent with more widespread use of the Pfizer-BioNTech COVID-19 Vaccine. (Tier 1)

#### **Use as a Single dose:**

The Pfizer-BioNTech COVID-19 Vaccine is administered intramuscularly as a series of two doses (0.3 mL each) 3 weeks apart. The vaccine was not studied for use as a single dose.

FDA's conclusions regarding the safety and effectiveness of the Pfizer-BioNTech COVID-19 Vaccine, and the Agency's determination that the criteria for an Emergency Use Authorization (EUA) were met, were based on the evidence generated by the clinical trials that studied two doses and are reflected in conditions described in the emergency use authorization (EUA).

Individuals who have received one dose of the Pfizer-BioNTech COVID-19 Vaccine should receive a **second dose** of Pfizer-BioNTech COVID-19 Vaccine on schedule to complete the vaccination series.

Protection is assumed to be less. In data that Moderna submitted to the FDA before its Dec. 17 review for its request for emergency use authorization, for instance, its analysis suggested that **the first dose provides protection from getting COVID-19, but the data did not allow for a "firm conclusion," the FDA says. Both the Pfizer and Moderna vaccines are believed to be around 50% effective after just one dose.**

#### **Will there be ongoing effectiveness data:**

Additional data on vaccine effectiveness will be generated from further follow-up of participants in clinical studies already underway before the EUA was issued, plus studies conducted by the manufacturer or by the U.S. government evaluating effectiveness of the vaccine as used under the EUA.

#### **How well do the vaccines work?**

Overall, the Pfizer and Moderna vaccines are about 95% effective. AstraZeneca's is about 70% overall, but that protection was found to be higher in some groups.

#### **How long does the protection last?**

Because the vaccines are new, this is not yet known for sure. Based on other viruses that are similar to the coronavirus that causes COVID-19, the COVID-19 vaccines that are shown to be highly effective might protect people for a few years

#### **After the FDA's emergency authorization (EUA) is granted, are the vaccines still tracked?**

Yes. The FDA expects the manufacturers to continue their clinical trials to find out more about how safe and effective they are, and pursue full FDA approval or licensure. The EUA, which is different from FDA approval, is based on the FDA's evaluation of available evidence, assessing risks and benefits. It issues the EUA if the benefit-risk balance is favorable.

**Do the COVID vaccines not only keep the person from getting sick, but also from spreading the virus if exposed?**

That is not yet known. As more data and monitoring are done, experts will be able to find out if a vaccinated person, if exposed to the virus, can still spread it even if they don't get the disease themselves.

**Are the vaccines free?**

Yes, for patients, but the health care providers will bill insurance companies, Medicaid and Medicare, or tap federal funds for the uninsured. In one estimate, the cost per dose was \$37 for Moderna's vaccine, \$20 for Pfizer's, and \$4 for AstraZeneca's.

**Will it be possible to choose which vaccine you prefer?**

In general, it does not matter, since once a vaccine gets the FDA's emergency use authorization (EUA), they all work. And even as more vaccines become authorized and available, you may have only one choice.

**After I get vaccinated, do I still have to wear a mask?**

Yes. Even after vaccination increases preventive behaviors will still be needed. "The ability to reduce transmission will require not just high vaccine uptake, but ongoing social distancing and masks," And herd protection may require high rates of vaccination in groups that are themselves at low risk.

**When can we expect herd immunity for COVID-19?**

COVID-19 is a very contagious disease. A large percentage of the population will need to be immune against the disease (through infection or vaccination) before herd immunity will be achieved. It is not known when that will happen, but it will depend on how many people develop immunity after COVID-19 infection, how soon a COVID-19 vaccine is widely available, how many vaccine doses will be available for distribution, and how many people get vaccinated. Throughout this time period until herd immunity is achieved, it is very important to continue to wear masks in public and social distance to slow the spread of COVID-19.

**Why are there still outbreaks of vaccine-preventable diseases?**

Measles was declared eliminated in 2000. Yet in 2019, there were 1,282 cases reported in the U.S. Outbreaks of vaccine-preventable diseases still occur when too few individuals in a population are vaccinated. Outbreaks often begin with an imported case (someone who was travelling outside the U.S.) or person coming into contact with an unvaccinated individual or people. These infected people then expose unprotected people to the disease. There are a number of reasons why people are unprotected: some protection from vaccines "waned" or "faded" after a period of time. Some people don't receive all

of the shots that they should to be completely protected. For example you need two measles, mumps, and rubella (MMR) injections to be adequately protected. Some people may only receive one and mistakenly believe they are protected. Some people may object because of religious reasons, and others are fearful of potential side effects or are skeptical about the benefits of vaccines.

#### **Co-administration of other routine vaccines:**

There is limited data on safety and efficacy of the COVID-19 vaccine when given with other vaccines. The Pfizer-BioNTech COVID-19 vaccine should be given alone, **at least 14 days (2 weeks) before or after you get any other type of vaccine.**

#### **Vaccine for pregnant hosts, children and immunocompromised:**

There is limited data on the use of the vaccine for pregnant people. If you are pregnant or lactating and part of a group who is recommended to receive a COVID-19 vaccine (for example, health care personnel), you may choose to be vaccinated. You should discuss this with your health care provider to make an informed decision. There's currently no data on the safety and efficacy of COVID-19 vaccines in pregnant women, children or individuals who are immunocompromised.

#### **Prior vaccine history of anaphylaxis:**

The vaccine should not be given to people with a known history of a severe allergic reaction such as anaphylaxis to any component of the Pfizer-BioNTech COVID-19 Vaccine. **People who have had a severe allergic reaction to any vaccine or injectable therapy (intramuscular, intravenous, or subcutaneous) should not receive the Pfizer-BioNTech vaccine at this time.**

#### **What role does COVID-19 vaccination play in helping to curb the pandemic:**

COVID-19 vaccination will help protect ourselves and others from the disease and save lives. Vaccines both prevent and reduce severity of disease. The COVID-19 vaccine is designed to work with immune systems so it will be ready to fight the virus if a person is exposed. If a large portion of a community becomes immune to COVID-19 through vaccination, it MAY reduce the spread of the disease to others.

#### **How does the FDA assess safety and effectiveness of a COVID-19 vaccine submitted for EUA?**

COVID-19 vaccines are undergoing a rigorous development process that includes tens of thousands of study participants to gather required safety and efficacy data. FDA evaluates the information submitted by a vaccine manufacturer and uses all available tools and information, including records reviews, site visits, and previous manufacturing compliance history. For an EUA to be issued, FDA must determine that the known and potential benefits outweigh the known and potential risks of the vaccine

#### **Should I take the COVID vaccine if I have a significant history of allergic reactions?**

The CDC states severe allergic reaction to any vaccine or injectable therapy (intramuscular, intravenous, or subcutaneous) is a precaution to receiving vaccination. Vaccine providers should observe these

patients for 30 minutes after vaccination to monitor for the development of immediate adverse reactions. This recommendation is due to two healthcare workers in the United Kingdom developing severe allergic reactions after receiving the vaccine. They both had a history of severe allergic reactions, carried epinephrine auto injectors, and fully recovered. Those with allergies to food, pets, insects, latex, or oral medications do not fall under this precaution and only have to be monitored for 15 minutes. Those with a history of severe allergic reactions should discuss this with their healthcare provider.

### **Are the mRNA vaccines safe for a woman who wants to become pregnant?**

There is no evidence the COVID-19 vaccine affects fertility. Women who are trying to become pregnant or who are pregnant and for whom the vaccine is recommended may choose to be vaccinated. A discussion with her health care provider can help to make an informed decision.

### **Should I take the vaccine if I have had convalescent plasma or monoclonal antibody?**

Currently, there is no data on the safety and efficacy of COVID-19 vaccines in people who received convalescent plasma or monoclonal antibody therapy. The Advisory Committee on Immunization Practices recommends that vaccination should be deferred until 90 days after receiving convalescent plasma or monoclonal antibodies. This is to avoid interference of these treatments with vaccine-induced immune responses. The risks and benefits of vaccination based upon the underlying risk factors, including living in a nursing home, could be considered. A discussion with the person's health care provider can help make an informed decision.

### **Should I take the vaccine if I already had COVID-19 and recovered? How long after should I take it?**

Those who have had COVID-19 and recovered should still receive the vaccine. **The length of immunity after recovering from COVID-19 is unknown; early studies show that it is not long lasting and rare cases of reinfection have been reported.** The Pfizer trial did include a small percentage of individuals who previously had COVID-19 and recovered. The CDC states current evidence suggests reinfection is uncommon within 90 days after initial infection, so vaccination can be deferred until the end of this period; however, it is not known when another vaccination will be available to you. **It is recommend to taking the vaccine once in the COVID-19 isolation period ends** and it is available.

### **Should I get the vaccine if I am in quarantine?**

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

### **How long after the flu shot do I have to wait to take the COVID-19 vaccine?**

Wait a minimum of 14 days after receiving the flu shot or any other vaccine to receive a COVID-19 vaccine. The safety or efficacy of taking the COVID-19 vaccine at the same time as other vaccines is currently unknown.

### **Should premedication be given prior to vaccination?**

Taking medications such as acetaminophen or ibuprofen before receiving the vaccine to try to prevent side effects like fever or pain is not recommended at this time. This is because there is not enough

information on how pain-relieving medications will impact antibody responses. These medications can be taken after receiving the vaccine if side effects present.

### **What is the V-safe After Vaccination Health Checker?**

V-safe is a smartphone-based tool that uses text messaging and web surveys to provide personalized health check-ins after a person receives a COVID-19 vaccination. Through V-safe, a person can quickly tell the CDC if they experience side effects after getting the COVID-19 vaccine. Depending on the person's responses, a CDC staff member may call for additional information. V-safe also sends reminders to get the second COVID-19 vaccine dose. Participation in the CDC's V-safe initiative makes a difference — it helps keep COVID-19 vaccines safe. For more information on V-safe: <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafe.html>

### **False positive HIV tests after Covid19 vaccination:**

British and French pharmaceutical giants GlaxoSmithKline and Sanofi Pasteur said the release of their vaccine would be pushed to late next year, while one of Australia's four vaccine candidates was axed after trial participants returned false positive test results for HIV. The announcements could present a potential setback in the global effort to gain control of the pandemic, given that experts believe that multiple vaccine options will be required to do so. This DID NOT occur in the Moderna nor the Pfizer trials.