COVID 19 Vaccine FAQs

December 6, 2020

The Immune System—The Body's Defense Against Infection

To understand how COVID-19 vaccines work, it helps to first look at how our bodies fight illness. When germs, such as the virus that causes COVID-19, invade our bodies, they attack and multiply. This invasion, called an infection, is what causes illness. Our immune system uses several tools to fight infection. Blood contains red cells, which carry oxygen to tissues and organs, and white or immune cells, which fight infection. Different types of white blood cells fight infection in different ways:

- **Macrophages** are white blood cells that swallow up and digest germs and dead or dying cells. The macrophages leave behind parts of the invading germs called antigens. The body identifies antigens as dangerous and stimulates antibodies to attack them.
- **B-lymphocytes** are defensive white blood cells. They produce antibodies that attack the pieces of the virus left behind by the macrophages.
- **T-lymphocytes** are another type of defensive white blood cell. They attack cells in the body that have already been infected.

The first time a person is infected with the virus that causes COVID-19, it can take several days or weeks for their body to make and use all the germ-fighting tools needed to get over the infection. After the infection, the person's immune system remembers what it learned about how to protect the body against that disease.

The body keeps a few T-lymphocytes, called memory cells, that go into action quickly if the body encounters the same virus again. When the familiar antigens are detected, B-lymphocytes produce antibodies to attack them. Experts are still learning how long these memory cells protect a person against the virus that causes COVID-19.

How COVID-19 Vaccines Work

COVID-19 vaccines help our bodies develop immunity to the virus that causes COVID-19 without us having to get the illness. Different types of vaccines work in different ways to offer protection, but with all types of vaccines, the body is left with a supply of "memory" T-lymphocytes as well as B-lymphocytes that will remember how to fight that virus in the future.

It typically takes a few weeks for the body to produce T-lymphocytes and B-lymphocytes after vaccination. Therefore, it is possible that a person could be infected with the virus that causes COVID-19 just before or just after vaccination and then get sick because the vaccine did not have enough time to provide protection.

Sometimes after vaccination, the process of building immunity can cause symptoms, such as fever. These symptoms are normal and are a sign that the body is building immunity.

Types of Vaccines

Currently, there are three main types of COVID-19 vaccines that are undergoing large-scale (Phase 3) clinical trials in the United States. Below is a description of how each type of vaccine prompts our bodies to recognize and protect us from the virus that causes COVID-19. **None of these vaccines can give you COVID-19.**

- **mRNA vaccines** contain material from the virus that causes COVID-19 that gives our cells instructions for how to make a harmless protein that is unique to the virus. After our cells make copies of the protein, they destroy the genetic material from the vaccine. Our bodies recognize that the protein should not be there and build T-lymphocytes and B-lymphocytes that will remember how to fight the virus that causes COVID-19 if we are infected in the future.
- **Protein subunit vaccines** include harmless pieces (proteins) of the virus that cause COVID-19 instead of the entire germ. Once vaccinated, our immune system recognizes that the proteins don't belong in the body and begins making T-lymphocytes and antibodies. If we are ever infected in the future, memory cells will recognize and fight the virus.
- **Vector vaccines** contain a weakened version of a live virus—a different virus than the one that causes COVID-19—that has genetic material from the virus that causes COVID-19 inserted in it (this is called a viral vector). Once the viral vector is inside our cells, the genetic material gives cells instructions to make a protein that is unique to the virus that causes COVID-19. Using these instructions, our cells make copies of the protein. This prompts our bodies to build T-lymphocytes and B-lymphocytes that will remember how to fight that virus if we are infected in the future.

Anticipated COVID 19 Vaccines in the next 3 months

Vaccine	Type	Efficacy	Storage/Cost	Shots
Pfizer	mRNA	95%	UltraCold (< 70 C) Dry Ice (every 5 days) 30 days of storage Fridge 5 days Once thawed, cannot be refrozen Approximately $25.00 US	2 (3 weeks apart)
Moderna	mRNA	95%	Cold (-20 C) 6 months, Fridge 2-8 C up to 30 days Room Temperature 12 hours post thaw Approximately $25.00 US	2 (4 weeks apart)
AstraZeneca	Modified chimpanzee adenovirus vector (ChAdOx1)	90% ½ dose followed by full dose 62% full dose x 2	Normal refrigerated temperature 2-8 C for 6 months Inexpensive ($5.00 US)	2 (4 weeks apart)

Johnson Johnson	Non-replicating viral vector Adenovirus Ad26	NA	?? Room Temperature	1
Novavax	SARS-CoV-2 recombinant spike protein nanoparticle with adjuvant	??	??	??

Notes:

Pfizer

https://www.pfizer.com/news/hot-topics/covid_19_vaccine_u_s_distribution_fact_sheet

Efficacy and Safety

- Primary efficacy analysis demonstrates it to be 95% effective against COVID-19 beginning 28 days after the first dose;170 confirmed cases of COVID-19 were evaluated, with 162 observed in the placebo group versus 8 in the vaccine group
- Efficacy was consistent across age, gender, race and ethnicity demographics; observed efficacy in adults over 65 years of age was over 94%
- Safety data milestone required by U.S. Food and Drug Administration (FDA) for Emergency Use Authorization (EUA) has been achieved
- Data demonstrate vaccine was well tolerated across all populations with over 43,000 participants enrolled; no serious safety concerns observed; the only Grade 3 adverse event greater than 2% in frequency was fatigue at 3.8% and headache at 2.0%

Operational Distribution: Pfizer

- In the U.S., our distribution approach will be to largely ship from the **Kalamazoo, Michigan**, site direct to the point of use (POU). We also will use the existing distribution center in **Pleasant Prairie, Wisconsin**.
- Utilizing **road and air modes** of transportation in the United States, expect product to any POU within a day or two.
- There are packaging and storage innovations to be fit for purpose for the range of locations where vaccinations will take place. There are specially designed, temperature-controlled thermal shippers utilizing dry ice to maintain recommended storage temperature conditions of **-70°C±10°C for up to 10 days unopened.** The intent is to utilize Pfizer-strategic transportation partners to ship by air to major hubs within a country/region and by ground transport to dosing locations.
- Utilizing **GPS-enabled thermal sensors** with a control tower that will track the location and temperature of each vaccine shipment across their pre-set routes, 24 hours a day, seven days a week, these GPS-enabled devices will allow Pfizer to proactively prevent unwanted deviations and act before they happen.
- Once a POU receives a thermal shipper with our vaccine, they have three options for storage:
    - - Ultra-low-temperature freezers, which are commercially available and can extend shelf life for **up to six months**.

    - The Pfizer thermal shippers, in which doses will arrive, that can be used as temporary storage units by refilling with dry ice every five days for **up to 30 days of storage**.
    - Refrigeration units that are commonly available in hospitals. The vaccine can be stored for **five days** at refrigerated **2-8°C conditions**.

- After storage for up to 30 days in the Pfizer thermal shipper, vaccination centers can transfer the vials to 2-8°C storage conditions for an additional five days, for a total of up to 35 days. Once thawed and stored under 2-8°C conditions, the vials cannot be re-frozen or stored under frozen conditions.
- The various storage options at the POU allow for equitable access to the Pfizer vaccine to areas with differing infrastructure.

Moderna

Efficacy

Phase 3 study met statistical criteria with a vaccine efficacy of 94.5% • Primary endpoint of the Phase 3 COVE study is based on the analysis of COVID-19 cases confirmed and adjudicated starting two weeks following the second dose of vaccine–Based on 95 cases, of which 90 cases of COVID-19 were observed in the placebo group versus 5 cases observed in the mRNA-1273 group, resulting in a point estimate of vaccine efficacy of 94.5% ($p < 0.0001$)

• Secondary endpoint analyzed severe cases of COVID-19 and included 11 severe cases (as defined in the study protocol)

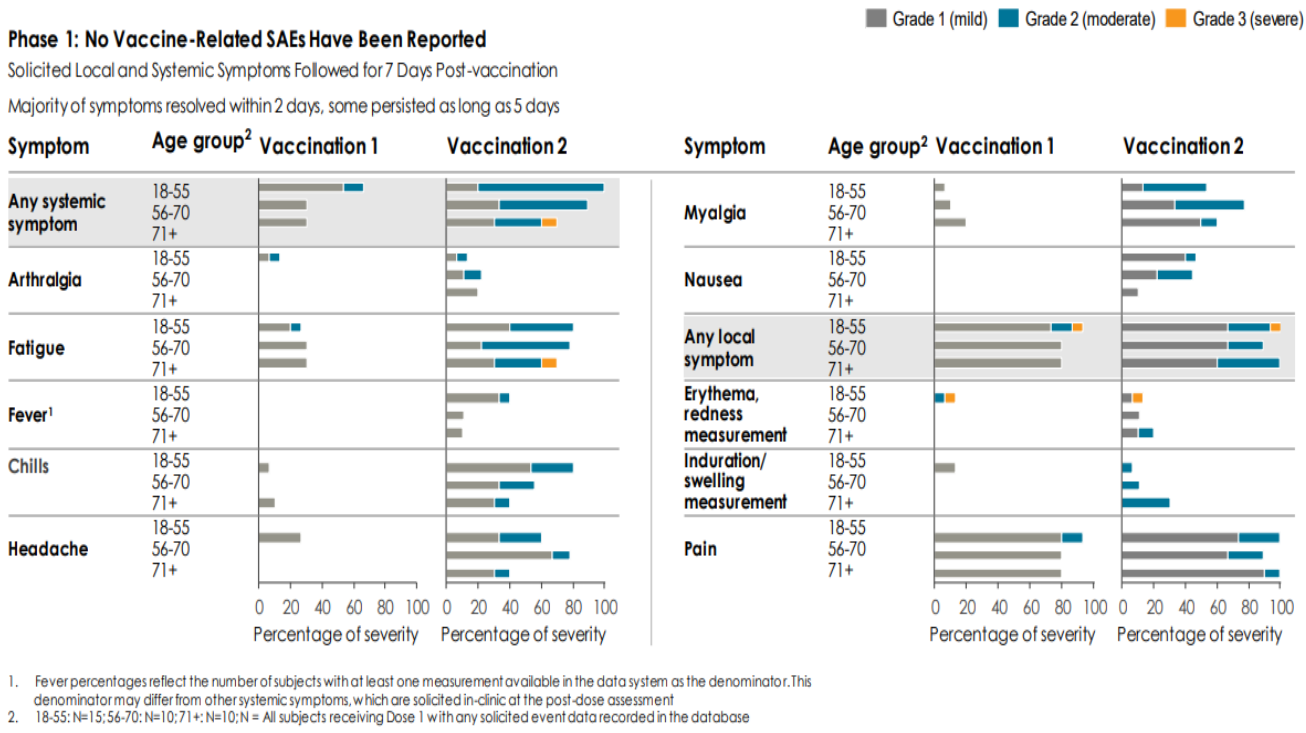
–All 11 cases occurred in the placebo group and none in the mRNA-1273 vaccinated group

• The 95 COVID-19 cases included 15 older adults (ages 65+) and 20 participants identifying as being from diverse communities (including 12 Hispanic or LatinX, 4 Black or African Americans, 3 Asian Americans and 1 multiracial)

Safety

No report of significant safety concerns during a concurrent review of the available safety data. A review of solicited adverse events demonstrated that vaccine was generally well tolerated; majority of adverse events were mild or moderate in severity and the solicited adverse events were generally short lived. Grade 3 (severe) events greater than or equal to 2% in frequency after the first dose included injection site pain (2.7%), and after the second dose included fatigue (9.7%), myalgia (8.9%), arthralgia (5.2%), headache (4.5%), pain (4.1%) and erythema/redness at the injection site (2.0%)

Safety data from Phase 1 trial



1. Fever percentages reflect the number of subjects with at least one measurement available in the data system as the denominator. This denominator may differ from other systemic symptoms, which are solicited in-clinic at the post-dose assessment
2. 18-55: N=15; 56-70: N=10; 71+: N=10; N = All subjects receiving Dose 1 with any solicited event data recorded in the database

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Jackson L, Anderson EJ, Rouphael NG, et al. An mRNA vaccine against SARS-CoV-2- preliminary report. N Engl J Med. 14 Jul 2020; DOI: 10.1056/NEJMoa2022483

moderna

AstraZeneca

Two different dosing regimens demonstrated efficacy with one showing a better profile
No hospitalizations or severe cases of COVID-19 in participants treated with AZD1222

Positive high-level results from an interim analysis of clinical trials of AZD1222 in the UK and Brazil showed the vaccine was highly effective in preventing COVID-19, the primary endpoint, and no hospitalizations or severe cases of the disease were reported in participants receiving the vaccine. There were a total of 131 COVID-19 cases in the interim analysis.

One dosing regimen (n=2,741) showed vaccine efficacy of 90% when AZD1222 was given as a half dose, followed by a full dose at least one month apart, and another dosing regimen (n=8,895) showed 62% efficacy when given as two full doses at least one month apart. The combined analysis from both dosing regimens (n=11,636) resulted in an average efficacy of 70%. All results were statistically significant (p<=0.0001). More data will continue to accumulate and additional analysis will be conducted, refining the efficacy reading and establishing the duration of protection.

Summary

In short, all of these vaccines appear to be very effective, and very safe. Consideration should be given for the mild symptoms the day following the vaccination in order to ensure employees are not scheduled for duty the following day. The mild side effects resolve within 24-36 hours.

I personally plan to get the vaccine myself, and my family as soon as it is available. I'm happy to answer additional questions. Please contact me at joe.holley@memphistn.gov.

Stay safe,

Joe Holley, MD FACEP FAEMS

Medical Director