SELF REGIONAL HEALTHCARE

COVID-19 Vaccination
Common Concerns and Questions

Safety Concerns

Deaths: There have been deaths associated with the vaccine. HOWEVER, it is important to understand that association does NOT mean the vaccine caused the death of a vaccine recipient. VAERS (the vaccine adverse event reporting system) keeps track of these deaths in the United States. This vaccine is the most closely monitored roll out of any medication or vaccine in the history of the world. Anyone, including physicians, nurses, patients or their family members can report a vaccine adverse event. Some of the events reported include patients who received the vaccine while actively infected with this virus and had an adverse event, including some people who died. But it is unclear if the vaccine contributed in these cases. Many other reports of death are made by family members and it is unclear if the vaccine was to blame. However, the FDA investigates each and every adverse event that is reported. When over 300 million doses of vaccine have been given out, there will be individuals in that 300 million patient encounters who were already battling cancer, heart disease, COPD, or other illnesses. These individuals may have been ill enough to pass in the next month following their vaccine anyway (for example, some nursing home patients). As of yet, there is not a statistically significant signal to associate the vaccine with any increased risk of death. Also, any potential deaths need to be put into context. Over 615,000 Americans are now dead from COVID-19.

Adverse Drug Reactions: In clinical studies, adverse reactions in participants 16 years of age and older for the Pfizer vaccine included pain at the injection site (84.1%), fatigue (62.9%), headache (55.1%), muscle pain (38.3%), chills (31.9%), joint pain (23.6%), fever (14.2%), injection site swelling (10.5%), injection site redness (9.5%), nausea (1.1%), malaise (0.5%), and lymphadenopathy (swollen lymph nodes) (0.3%). These were all short lived side effects with almost all recipients of the vaccine having no side effects beyond 48 hours. It is possible, however very rare, for serious allergic reactions to happen **at the time** of the injection.

Late Side Effects: With vaccines, unlike medications that we take for long periods of time, we only have short exposure to the vaccine (approximately 1-2 days) in most cases. So the concept of "late side effects" is not really likely to be an issue. For example, if you take an aspirin every single day for 1 year, it would make sense that side effects may slowly build over time and "pop up" later in life. With a vaccine, since it only stays in your body for a short period of time, you would not expect side effects to "pop up later" in life without first manifesting immediately during the vaccine administration and for a few days after that. Rumors online about infertility are just that. They are rumors. There has been no evidence in decreased birth rates or infertility visits amongst OBGYNs or infertility experts. With the vaccine being out of your system within 48 hours, this concept of side effects that crop up later is just not biologically possible.

Myocarditis: Myocarditis is inflammation of the heart and pericarditis is inflammation of the sac that surrounds the heart. These conditions occur naturally as a result of certain types of viral infections that people can get. On June 25, 2021 the FDA added a warning to the Pfizer and Moderna vaccine information sheets that showed from December 29, 2020 through June 11, 2021 there were 1226 cases of myocarditis following administration of a COVID-19 vaccine. These cases typically occurred in men (76%), people who are under age 30 (58%) and after the second dose of the vaccine (76%). Usually this happened within days of the administration of the vaccine. But to put this into context there were 1226 cases out of 296 million doses of vaccine that were administered at the time including 52 million doses in people under age 30. The chance of getting myocarditis is very rare at 0.0000414% of vaccinated people. Put another way, for every 1 million male patients aged 12 to 29 who get a 2 dose vaccination, 560 hospitalizations would be prevented and only 39-47 cases of myocarditis would occur. Most of these myocarditis cases were mild and typically resolve completely. As such, the benefits of the vaccine clearly outweigh the risks of this rare complication. Also, myocarditis has been seen in patients who contract COVID-19 naturally from another person. If a person develops chest pain, shortness of breath, or skipped heart beats after vaccination, they should be evaluated by their physician, but this again is a very rare condition.

GBS: Guillain-Barré syndrome (GBS) is a rare condition that often follows infections from a virus or from bacteria that causes an individual to become weak and have numbness or tingling. It sometimes can happen to people who have had vaccines, most commonly the flu shot. There have been 100 cases of GBS reported after having received a COVID-19 vaccination, and these were reported with the Johnson & Johnson vaccine. Pfizer and Moderna vaccines are not associated with GBS. There were 100 cases reported out of 12.5 million doses of J&J vaccine when the warning was reported on July 12, 2021.

Serious Allergic Reactions: There can be people who have serious allergic reactions to the vaccine, as can happen with any medication or vaccination. These cases are very rare.

Efficacy

Natural immunity: It would appear that approximately 90% of patients who catch COVID-19 naturally develop antibodies against SARS-CoV-2 and still have them detectable at 5 months. The antibody levels do tend to decrease with time though. Some patients who contract COVID-19 never make any antibodies to the actual virus (regardless of when they are measured), and the reason for this is unknown. But that is a small proportion of patients.

Original strain: Pfizer and Moderna are almost equally effective at protecting against the original strain of COVID-19.

Real-World data collected on ALL vaccine recipients in the US (Pfizer, Moderna, and J&J) showed that vaccination reduces the risk of hospitalization 94% in those 65 and older. A study out of Houston Methodist in Houston, TX showed that all ages receive benefits. Full immunizations were 96% effective at preventing Covid-19 related hospitalization and 98.7% effective at preventing Covid19 related death when participants were fully vaccinated through April 2021.

How effective is our vaccine against the Delta variant?: This is a great question to ask. How effective are our present Pfizer, Moderna, and J&J vaccines at stopping symptomatic disease from COVID-19 in the real world against Delta Variant SARS-CoV-2? The Delta variant is now the overwhelming majority of the virus that is circulating (over 93% of all infections in the US are Delta Variant.) In the United Kingdom, for those who were fully immunized with the Pfizer vaccine, the effectiveness of two doses was 93.7% among persons with the alpha variant and 88.0% among those with the delta variant. This is a published study in NEJM. In Canada it is reported that from December 2020 to May 2021 full vaccination with Pfizer's vaccine showed 87% protection against symptomatic disease with Delta Variant.

Will a booster be necessary? *This question has two parts.*

Will new vaccines for new variants be required? Possibly. For now, the original vaccine seems to be working fairly well against Delta and other strains in preventing any type of serious illness due to COVID-19. But it is very possible at some point that we will need a new version of the vaccine to combat a new variant that is significantly different from the original strain. If that were the case, and the virus mutates significantly to produce a variant that is very different, a new vaccine against that may become necessary.

How long will immunity last from the vaccine? It looks like at this time most people remain immune for a year. It is not yet known how long we remain immune after vaccination since this is a new disease and we have not been able to follow people for long periods of time to draw antibody levels. With all of this being said, Pfizer and Moderna are both working on a Delta Variant vaccination that is new and distinct from the original vaccines. Also, Pfizer has applied to the FDA to ask to allow a third booster shot (the original vaccine), which it says are well tolerated and significantly boosts immunity. Pfizer says it particularly helps boost immunity in the elderly and those with kidney disease.

Individuals with poor immune systems are now as of 8/13/21 encouraged by the FDA to get a third dose of the Moderna or Pfizer vaccines. There is insufficient evidence regarding the Johnson and Johnson vaccine to recommend another vaccine booster. Conditions that cause poor immune system function could be things such as active cancer, diabetes, chronic kidney disease (CKD), taking immune-suppressing medications, etc. Talk to your doctor about whether or not this might be the case for you if you are uncertain if your medical conditions cause you to have a poor immune system.

Special populations

Cancer: Most patients with cancer have poorly functioning immune systems. It is recommended that most cancer patients receive the vaccine. Please discuss this further with your oncologist, who will most likely encourage you to get the vaccine.

Autoimmune disorders (such as Crohn's, Ulcerative Colitis, Rheumatoid Arthritis, Psoriasis, etc): It is important to discuss your care with your rheumatologist, dermatologist, GI doctor, or other physician who is managing your condition to see if it is okay for you to get the vaccine. But for most people with autoimmune conditions, even those on medications that suppress the immune system, it is highly recommended that they receive immunization.

Immunocompromised status (patients with HIV, on steroids or other immune-suppressing medications): Talk with your infectious disease physician or doctor who is managing your immune-suppressing medications, but most likely they will advise you to be vaccinated. If you have stable HIV you should be vaccinated. There is a higher chance of patients with these conditions of having a negative outcome with COVID-19, so the vaccine is considered more beneficial to people in this category.

Diabetes, hypertension, heart disease, heart failure, being overweight, chronic kidney disease, COPD/Asthma, lung disease: Each one of these is a high-risk factor. Having one of these conditions puts you at greater risk of getting severely ill and requiring a hospital stay or possibly even dying. It is highly recommended people in these groups get vaccinated against COVID-19.

History of serious allergic reaction to prior vaccine: Any patient with a severe allergic reaction (e.g., anaphylaxis/throat closing up) to any component of the COVID-19 Vaccine or a severe allergic reaction to another vaccine should not receive the COVID-19 immunization. Talk to your doctor if you have previously had a severe allergic reaction to any vaccine to see if it is safe for you to receive the COVID-19 vaccine first.

Pregnancy: COVID-19 infection in pregnancy is associated with increased risk of maternal severe illness, ICU admission, mechanical ventilation and death. There is a growing body of data that demonstrate the safety of COVID-19 vaccines in pregnancy. There is no evidence of adverse maternal or fetal effects from vaccinating pregnant individuals with the COVID-19 vaccine.

Any of the currently authorized COVID-19 vaccines can be administered to pregnant or lactating people; ACIP does not state a product preference. However, pregnant, lactating, and post-partum people aged <50 years should be aware of the rare risk of thrombosis with thrombocytopenia syndrome (TTS) after receipt of the Janssen COVID-19 vaccine and that other FDA- authorized COVID-19 vaccines (i.e., mRNA vaccines) are available (see ACOG's Practice Advisory for more information regarding TTS related to the Janssen COVID-19 vaccine).

As of July 26, 2021, more than 139,000 v-safe participants have indicated they were pregnant at the time they received COVID-19 vaccination. No safety concerns have been identified from data from CDC's v-safe pregnancy registry.

There is accumulating data demonstrating that antibodies are passed to the fetus when a pregnant person is vaccinated.

Acetaminophen is recommended for pregnant women who experience fever after vaccination.

Breastfeeding: ACOG recommends that breastfeeding women get a COVID-19 vaccine.
There is no need to stop breastfeeding if the patient wants to be vaccinated. After vaccination, antibodies are passed through breastmilk and may help protect the child from the virus.

Study published in JAMA found robust secretion of SARS-CoV-2 specific IgA and IgG antibodies in breast milk. Antibodies found in the breast milk showed strong neutralizing effects, suggesting a potential protective effect against infection in the infant.

Patients trying to conceive: None of the COVID-19 vaccines available for use under EUA cause infertility. Claims linking COVID-19 vaccines to infertility are unfounded and have no scientific evidence supporting them. The American Society for Reproductive Medicine states that patients undergoing fertility treatments and pregnant patients should be encouraged to receive the COVID-19 vaccine.

Seniors: All patients over 65 are at an increased risk of hospitalization and death compared to younger populations. It is highly recommended that you get vaccinated if you are over age 65 and have no severe life threatening allergy to vaccines or vaccine ingredients.

Children: The FDA expanded its emergency use authorization (EUA) for the Pfizer vaccine to include adolescence age 12 to 15 years old on May 10, 2021. The vaccine has been approved for teenagers age 16 and older since December 2020.

Conspiracies

Microchips: There have been concerns raised by patients that there are microchips for tracking purposes contained within the vaccine. This is not accurate. The ingredients contained within the Pfizer vaccine are as follows: mRNA, Lipids, Salts, Sugar. There are not any preservatives contained within the vaccine. There is no mercury within the vaccine. It does not require this because the vaccine is kept at ultra-low temperatures (-80 [-112F] to -60 C [-76F]) to preserve it. Our vaccines are kept in multidose vials where the nurse or pharmacist draws up approximately 5 syringes from each vial. It would be literally impossible to place microchips within the vial and ensure that one microchip happens to fall into each one of the syringes used to draw the vaccine up with. This simply is not accurate. As an aside, if you have a cell phone of any kind, the government may obtain access to your GPS location data with proper warrants through your cell phone provider. Placing microchips into people for tracking individuals would not be necessary as there are alternative means of monitoring a person's whereabouts if they are under investigation.

DNA integration: We have heard concerns raised by many people that the mRNA in the vaccine can somehow "meld" or "integrate" or "permanently change" your DNA. This is not accurate. While there are many viruses such as HIV that are made out of RNA, very rarely do these viruses insert their genetic material into HUMAN DNA via enzymes called integrases. And when they do so, they require certain sequences in the RNA to do this. The bottom line is researchers thought about this ahead of time. There is no sequence in the COVID vaccine that would allow a patient infected with HIV to have an HIV integrase insert the mRNA from the vaccine into our human DNA. This is a very good question to ask and one that the author of this document thought to ask (and reached out to Moderna lead researchers to get an answer on). But the short answer here is, the mRNA in the vaccine cannot insert itself or change our DNA. DNA produces mRNA in our cells in a one way process, not the other way around.

Covid Shots Make Recipients Magnetic: No, there are no ferromagnetic metals in the vaccine. This is not possible. Unfortunately, people online enjoy their 15 minutes of fame and try to start online rumors to make money. Injecting liquid metals into the body would cause significant reactions within the tissues. There is no metal in the COVID vaccine. Moreover, if these injections magnetized people we would never be able to use the MRI scanners to scan their bodies, and this simply is not accurate information. We continue to use MRI scanners to assess patients who have had COVID-19 vaccination on a routine basis without any interference or magnetism detected.

Approval status

Emergency Use Authorization (EUA): In order to be approved by the FDA, a drug must be shown to be safe and effective. It must undergo 3 phases of testing (Phase I, Phase II, and Phase III). Each phase is larger than the prior phase. Pfizer and Moderna have undergone all of the normal testing with very large numbers of patients in these trials (over 65,000 participants together). There were not any significant safety concerns noted in these original submissions and the vaccines both showed significant effectiveness at preventing the original strain of the virus from infecting humans. As such, the FDA issued an EUA to allow the use of the vaccine. As of August 5, 2021, 348 million doses of vaccine have been given in the

US alone. Over 2.2 Billion people have received at least one dose of COVID-19 vaccine in the world. The FDA has had an unprecedented surveillance system called VAERS (Vaccine Adverse Event Reporting System) looking for side effects or deaths after taking the vaccine. At this point in time with these large numbers of people being vaccinated if there were significant, common, and lasting side effects we would be able to pick up on these issues by now. Millions of doctors and nurses across the country in the US agreed to be surveyed over the course of a year after being vaccinated regarding side effects of the vaccine. This system would also be picking up on serious side effects if there were any. To date this has not happened.

Final FDA approval status: This often is dependent on things such as shelf stability and review of side effects over time. It is anticipated that there will be final approval for vaccines in early September 2021. Why? Well the FDA is looking at things such as how long can the vaccine be stored long-term, which cannot be answered quickly. But that does not really impact the evaluation of safety or effectiveness.

Miscellaneous questions

What is in the vaccine?
Pfizer: mRNA, Lipids, Salts, Sugar. No preservatives
Moderna: mRNA, Lipids, Salts, Sugar. No preservatives.
Janssen: recombinant, replication-incompetent adenovirus Type 26 expressing the SARS-CoV-2 spike protein, citric acid monohydrate, trisodium citrate dihydrate, ethanol, 2 hydroxypropyl-B-cyclodextrin (HBCD), polysorbate-80, and sodium chloride

How many doses do you have to take?
Pfizer: 2 doses, 21 days apart.
Moderna: 2 doses, 28 days apart
Janssen (Johnson and Johnson): 1 dose only

How old do you have to be to get a vaccine?
Pfizer: 12 and older
Moderna: 18 and older
Janssen (Johnson and Johnson): 18 and older

I have had COVID-19 in the past, should I get the vaccine?
Yes, you should get immunized with a vaccine to increase the level of immunity that you have and to increase the amount of time you remain immune. Remember, studies have shown that many people lose or have reduced immunity over time. Some people who naturally contract COVID-19 do not produce antibodies to the virus at all. A study based off of citizens in Kentucky shows that if a person was infected with COVID-19 naturally and does not get a vaccinated, he or she is at a 234% increased risk of contracting COVID-19 a second time compared to those people previously infected naturally who get vaccinated. This shows significant benefit for getting the COVID-19 vaccine after you have had natural COVID-19 infection.

I received convalescent plasma (a blood transfusion of antibodies) when I was admitted to the hospital for COVID-19. **When can I get the vaccine?** 90 days after your discharge from the hospital, you can receive the vaccine.

I received Bamlanivimab/etesevimab or Casirivimab/imdevimab (Regen-Co-V) or Sotrovimab (Antibody Infusions) in the ER or in the infusion center as an outpatient to treat COVID-19. **When can I get the vaccine?** 90 Days after you received your antibody infusion as an outpatient, you can receive the vaccine.

When will I be immune?
Two weeks after your final vaccination in the series of two vaccines (Pfizer and Moderna) or two weeks after your one and only shot of Johnson and Johnson (AKA Janssen) vaccine.

When can I get the vaccine?
Self Regional Healthcare has a convenient drive-through vaccination clinic at 303 West Alexander Avenue that is open Monday through Friday, 8:00 AM - 5:00 PM. No appointment is necessary.

Where can I get the vaccine?

Self Regional Healthcare has a convenient drive-through vaccination clinic at 303 West Alexander Avenue that is open Monday through Friday, 8:00 AM - 5:00 PM. No appointment is necessary. Pfizer vaccine is used at our location.

CVS carries the Moderna Vaccines at its local affiliates in Greenwood. Vaccine appointments are made online.

Walgreens carries the Pfizer vaccine at its local affiliates in Greenwood. Vaccine appointments are made online.

How will I feel after the vaccination is given to me?
Great question, while there is variability, typically the older a person is the less immune response they mount. We often see older adults feel nothing at all after each immunization, though it can vary person to person. Some potential side effects can include: pain at the site of injection (generally mild to moderate), fatigue, headache, muscle pain, joint pain, and fever. These generally are quite quick to pass, typically less than 24 hours. They are more common after the second vaccination rather than the first. Again, they are more common in patients under age 40. Sometimes working-age adults or school-age students choose to get their second vaccination on a Friday in case they feel poorly for several hours the next day.

In clinical studies on the Pfizer vaccine, adverse reactions in participants 16 years of age and older included pain at the injection site (84.1%), fatigue (62.9%), headache (55.1%), muscle pain (38.3%), chills (31.9%), joint pain (23.6%), fever (14.2%), injection site swelling (10.5%), injection site redness (9.5%), nausea (1.1%), malaise (0.5%), and lymphadenopathy (swollen lymph nodes) (0.3%).

What is mRNA?

Messenger RNA (mRNA) is a very short-lived natural product that we use in all of our cells to send messages from the DNA in our nucleus (like the brain of our cells) to the cytoplasm to construct all of the proteins (structures) within our cells.

Doctors have been using mRNA technology to treat macular degeneration (an eye condition) since 2006 with injections into the eye. This mRNA technology has been successfully used for 15 years to treat humans.

The COVID-19 vaccines in the US all use mRNA technology to help your body learn to respond and produce antibodies against the SARS-CoV-2 virus that causes COVID-19.

How long does the vaccine stay in my body?
mRNA (either our own or the vaccine) is completely degraded in our cells over 8-40 hours by our own “cleaning” enzymes within our cells called exonucleases. These enzymes break down our own natural mRNA as well as the mRNA in the vaccine quite efficiently.

Can I transmit COVID-19 to other people after I receive the vaccination?
Yes. It is possible to become infected by the SARS-CoV-2 virus and transmit this to another person after immunization, BUT immunization greatly reduces the risk of catching and transmitting the virus to others. You CANNOT get COVID-19 from the COVID-19 immunizations, that is impossible. These vaccines do not use any actual live SARS-CoV-2 viruses to immunize you.

Is there anyone who should not receive the vaccination?
Yes. Anyone with an allergy to components of the vaccine or who has had a serious or life-threatening reaction to another vaccine probably should not take the vaccine.