



Making the best informed decision about COVID vaccination

How does the vaccine work?

The COVID vaccine is an mRNA vaccine.

- mRNA technology is new, but not unknown. They have been studied for more than a decade.
- mRNA vaccines do not contain a live virus and do not carry a risk of causing disease in the vaccinated person.
- mRNA from the vaccine never enters the nucleus of the cell and does not affect or interact with a person's DNA.

Is the vaccine approved?

Vaccines from both Pfizer and Moderna are being released by the Food and Drug Administration (FDA) under emergency use authorization (EUA).

An EUA is issued by the FDA to allow access to critical medical products that may help during a public health emergency. An EUA is different from approval/licensure.

The following criteria must be met for an EUA to be issued:

- The product will be used for a serious or life-threatening disease or condition.
- Based on the totality of scientific evidence available, it is reasonable to believe the product may be effective.
- The known and potential benefits of the product outweigh the known and potential risks of the product.
- There is no adequate FDA-approved alternative available.

Is the vaccine recommended?

The Advisory Committee on Immunization Practices (ACIP) issued an interim recommendation for use of the vaccines for the prevention of COVID-19 as follows:

- Pfizer-BioNTech COVID-19 vaccine in persons aged ≥ 16 years
- Moderna COVID-19 vaccine in persons aged ≥ 18 years

Is the vaccine effective?

Both vaccines were found to be $>95\%$ effective in preventing COVID infection.

Is the vaccine safe?

The vaccine was **well-tolerated** and the rate of adverse effects was low. There were no safety concerns after an average of 2 months of patient monitoring.

- The most common reactions were injection site pain, fatigue, headache, muscle pain, and joint pains.
- There were no serious neurological adverse effects.
- There are **no** concerns with any negative effect of the vaccine on male or female fertility.

COVID-19 VACCINE FAQs

Since mRNA vaccines are a new technology without long-term human data how can we know they are safe?

- Most adverse effects from vaccines happen within the first 6-8 weeks after vaccination.
- The Pfizer and Moderna trials have followed >70,000 people for more than 2 months and have observed no serious or unexpected side effects attributed to the vaccine.
- Researchers have a solid grasp on how mRNA interacts with the immune system and have no theoretical safety concerns.
- There have been many long-term animal studies done with mRNA that show no safety concerns.

We do not anticipate there will be any long-term safety concerns with mRNA vaccines.

Is there a difference between the Pfizer and Moderna vaccines and should I choose one preferentially?

- Both the Moderna and Pfizer vaccines are nearly identical, so there are no appreciable benefits of getting one over the other.

We recommend scheduling an appointment at a location that is convenient for your schedule both now and for the required booster in 3-4 weeks.

Can everyone get the vaccine?

When considering if the vaccine is right for you, it is important to consider the actual population in which the vaccine was studied.

Pfizer vaccine:

This trial included only individuals that were 16 and older. No children were enrolled.

There were also no pregnant/lactating women or immunosuppressed patients who were enrolled. Of the study participants:

- 40% were >55 and 25% were > 65
- 83% were White, 28% Hispanic/Latinx, and 9% Black/African American
- 46% had at least one comorbidity
- 35% were obese

Moderna vaccine:

This trial included only individuals that were 18 and older. No children were enrolled.

There were also no pregnant/lactating women or immunosuppressed patients who were enrolled. Of the study participants:

- 25% were > 65
- 79% were White, 20% Hispanic/Latinx, and 9.8% Black/African American
- 22% had at least one risk factor for severe COVID-19 infection

While there are limited data on the following special populations, we have attempted to summarize the considerations for each group and our general recommendation for considering vaccination.

Can persons with a current or prior history of COVID-19 infection get the vaccine?

- Data from clinical trials suggest the vaccine is safe and likely efficacious in persons with evidence of a prior COVID infection.
- Based on the estimated duration of antibodies from COVID infection as well as evidence suggesting that reinfection is uncommon in the 90 days after initial infection, vaccine deferral could prolong your overall period of immunity.

While there is no harm in receiving the vaccine at any time after your recovery from COVID, we favor deferring vaccination for 90 days from the time of infection (initial symptom onset).

COVID-19 VACCINE FAQs

If I got COVID infection, do I still need to get the vaccine? Shouldn't I be protected already?

- Antibodies from natural COVID infection last at least 90 days
- After these 90 days, there is a risk of reinfection (we have seen several cases - usually about 6 months later)
- Symptoms of a second infection tend to be milder but still worse than side effects expected with the vaccine
- There is early evidence that antibodies from the vaccine last for 3 months, and likely longer.
- Some research shows that the vaccine may induce a better immune response than natural infection

We favor those individuals who have had COVID infection also get the vaccine, waiting 90 days as above.

Can persons who previously received passive antibody therapy for COVID-19 get the vaccine?

- There are currently no available data on the safety and efficacy of vaccine in persons who received monoclonal antibodies or convalescent plasma as part of COVID-19 treatment.
- Based on the estimated half-life of such therapies as well as evidence suggesting that reinfection is uncommon in the 90 days after initial infection, vaccination deferral could avoid interference of the antibody treatment with vaccine-induced immune responses.

We favor deferring vaccination for 90 days from the time of receipt of antibody treatment.

Can persons with underlying medical conditions get the vaccine?

- The vaccine may be administered to persons with underlying medical conditions who have no contraindications to vaccination.
- Clinical trials demonstrated similar safety and efficacy profiles in persons with some underlying medical conditions, including those that place them at increased risk for severe COVID-19, compared to persons without comorbidities.

We strongly favor vaccine administration in individuals with comorbidities that might put them at increased risk for severe COVID infection.

Can immunocompromised persons get the vaccine?

- There are currently no available data on the safety and efficacy of the vaccine in people with HIV infection, other immunocompromising conditions, or who take immunosuppressive medications or therapies.
- Based on current knowledge, experts believe that mRNA vaccines are unlikely to pose a risk for people who are immunosuppressed.
- In the setting of underlying immunosuppression, there is a potential for reduced immune responses and the need to continue to follow other preventive measures (i.e. masking, distancing, avoiding crowds, etc.) to protect against COVID infection.
- Persons with HIV infection, other immunocompromising conditions, or who take immunosuppressive medications or therapies might be at increased risk for severe COVID-19.
- Because of the complexities with different forms of immunosuppression, the appropriateness and timing of vaccine needs to be carefully considered between the patient and provider.

We favor vaccine administration in immunocompromised persons in most situations after careful discussion with the patient's physician.

Can pregnant women get the vaccine?

- There are currently no available data on the safety and efficacy of the vaccine in pregnant people.
- Based on current knowledge, experts believe that mRNA vaccines are unlikely to pose a risk for people who are pregnant.

COVID-19 VACCINE FAQs

- Observational data demonstrate that while the absolute risk is low, pregnant people with COVID-19 have an increased risk of severe illness, including illness resulting in ICU admission, mechanical ventilation, or death. Additionally, they might be at an increased risk of adverse pregnancy outcomes, such as preterm birth.
- When making a decision, pregnant people and their health care providers should consider the level of COVID-19 community transmission, the patient's personal risk of contracting COVID-19, the risks of COVID-19 to the patient and potential risks to the fetus, the efficacy of the vaccine, the side effects of the vaccine and the lack of data about the vaccine during pregnancy.

We favor vaccine administration in pregnant women if they are interested after careful discussion with the patient's obstetrician.

Can lactating women get the vaccine?

- There are currently no available data on the safety and efficacy of the vaccine in lactating people or the effects of mRNA vaccines on the breastfed infant or milk production/excretion.
- Based on current knowledge, experts believe that mRNA vaccines are unlikely to pose a risk to the breastfeeding infant.

We favor vaccine administration in lactating women if they are interested after discussion with the child's pediatrician.

Can adolescents get the vaccine?

- While the vaccine is approved for individuals age 16 and above, only 153 participants out of >40,000 were aged 16–17 years.
- While vaccine safety and efficacy data in this age group are limited, there are no biologically plausible reasons for safety and efficacy profiles to be different than those observed in persons 18 years of age and older, and no safety concerns were observed in these individuals.

We favor Pfizer vaccine administration in adolescents aged 16-17.

Can you get the COVID vaccine along with other routine vaccinations?

- There are no data as far as the interaction between COVID-19 vaccination and other vaccines.

We recommend that other vaccines should not be given for two weeks before or after COVID-19 vaccination. If vaccines are given <2 weeks apart, there is no harm and the COVID booster does not need to be delayed.

Are there any contraindications to receiving the vaccine?

Please see our "COVID Vaccine Guidance for Allergies & Side Effects" document on the intranet.

Will receiving the vaccine cause me to test positive for COVID-19?

No. Receiving the vaccine should not affect future PCR test results for COVID, however, it is possible to coincidentally contract actual COVID around time of vaccination.

Can persons on quarantine for a COVID exposure or out-of-state travel still get the vaccine?

We recommend deferring vaccination until the quarantine period is over in order to ensure affected individuals don't actually have COVID infection that could be spread to others or affect their own immune response to the vaccine.

COVID-19 VACCINE FAQs

If I get the vaccine, do I still need to quarantine after travel or exposure to COVID?

Yes, the CDC recommendation for quarantine after travel and close exposure to individuals with COVID remains unchanged, regardless of your vaccination status.

What happens if I test positive after the first vaccination? Can I still get my 2nd booster shot?

Yes, you should continue to receive your 2nd booster shot. If you are still feeling ill or remain on isolation for COVID at the time your 2nd dose is scheduled, you should delay receiving this booster until you are well and off isolation.

If I have received the vaccine but end up getting COVID, can I still receive monoclonal antibody therapy?

Yes. If a patient is diagnosed with COVID and they meet the current criteria for monoclonal antibody therapy, treatment can still be administered regardless of their vaccination status.

Can I still donate blood if I receive the COVID vaccine?

Yes. Receiving the COVID vaccine will not affect your future ability to donate blood.

Per Miller-Keystone, individuals must wait 2 weeks after each dose of the vaccine before donating whole blood, platelets, or plasma. Vaccine recipients are NOT eligible for donating convalescent plasma.

What happens if I develop an adverse reaction after receiving the COVID vaccine?

Please see our "COVID Vaccine Guidance for Allergies & Side Effects" document on the intranet. Any severe or worrisome reaction should be reported and discussed with your PCP.

Mild reactions may be reported through the CDC V-safe app.

<https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafe.html>

How long does it take to be fully immune to COVID after receiving the vaccine?

While there is some protection after the first dose, it will generally take two weeks following the second dose of the vaccine for people to gain full immunity.

I had a bad reaction to the first shot and don't want to get my second dose. Will I still be protected?

- Yes, but not as much as you would with the full 2-dose series.
- It is estimated that the vaccine has a 50% efficacy after one dose, and >94% efficacy after the second dose.

We encourage individuals to complete the FULL vaccine series so to get maximum protection against COVID, with the use of acetaminophen and NSAIDs as needed to treat severe side effects.

Will the vaccine cover this "new" variant of the virus first seen in the U.K?

Yes, none of the observed mutations in the SARS CoV-2 virus should affect the efficacy of the vaccine.

Will St. Luke's require its employees to get the COVID vaccine?

While we are encouraging vaccination in all eligible individuals, the vaccine is not mandatory at this time.

Can my family members get vaccinated too?

Vaccination is currently being offered by the federal government to healthcare providers and residents of nursing facilities. If your family member is not in one of these groups, they will need to wait until vaccine is released to other phased risk groups. St. Luke's is planning to continue to offer vaccine to patients as vaccine supplies are expanded. We anticipate wider access to the vaccine by early spring.



COVID-19 VACCINE FAQs

Can I donate my vaccine to someone else (i.e family member, neighbor, etc.)?

Due to regulations on vaccine distribution phases by the state, unfortunately you cannot donate your allotted vaccine to another individual.

How can I learn more about the vaccine?

www.cdc.gov/vaccines/covid-19/index.html