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 may be 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.

- The most common reactions were injection site pain, fatigue, headache, muscle pain, and joint pains.

There were no safety concerns after an average of 2 months of patient monitoring.

- There were no serious neurological adverse effects.
- There are no concerns with any negative effect of the vaccine on male or female fertility.

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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 avoid interference of the natural antibody response with vaccine-induced immune responses.

We favor deferring vaccination for 90 days from the time of infection.

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.

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.
- 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.

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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 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.

Are there any contraindications to receiving the vaccine?

- Do not administer the vaccine to individuals with a known history of severe allergic reaction (e.g. anaphylaxis) to any component of the vaccine which include polyethylene glycol (PEG), lipids, and sucrose.
- Allergies to food, latex, or insects are not considered a contraindication, but for anaphylaxis to injectables, 30 minutes of observation is recommended, rather than the typical 15 minutes.

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.

How can I learn more?

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

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