Vaccine Safety

- **How do we know if the COVID-19 vaccine is safe?**
  The care and safety of our employees and the patients we serve is always our top priority. As with any vaccine, CommonSpirit Health will not administer a COVID-19 vaccine unless the FDA has determined it is safe and effective. CommonSpirit clinical leaders have reviewed clinical trial data and evidence for the Pfizer and Moderna vaccines, and concur with the FDA authorization.

- **How long after the 2nd dose are you theoretically immune?**
  Early findings suggest that some antibodies are produced within a few weeks after the first dose, but it will take longer for full immunity to be achieved. The duration of protection is unknown.

- **What are the long-term effects of COVID-19?**
  Experts have found that some patients experience long-term effects of COVID-19 that impact quality of life. Long-term symptoms can include ongoing respiratory, cardiac, and cognitive issues, in patients who had both mild and severe cases of COVID-19.

- **Did the vaccine clinical trials include participants from diverse racial/ethnic backgrounds?**
  Yes. Among the total participants in the Pfizer-BioNTech COVID-19 Vaccine trial, 9.1 percent were Black or African American, 28.0 percent were Hispanic/Latino, 4.3 percent were Asian, and 0.5 percent were American Indian/Alaska native. For the Moderna clinical trials, 20.5% of participants identified themselves as Hispanic or Latino, 10.2% as African American or Black, 4.6% as Asian, 0.8% as American Indian or Alaska Native, 0.2% as Native Hawaiian or other Pacific Islander, 2.1% identified their race as other, and 2.1% as multiracial. *Data provided by the FDA.*

Should I get the vaccine if I have an autoimmune disease?
According to the CDC, people with autoimmune conditions may receive a COVID-19 vaccine. However, they should be aware that no data are currently available on the safety of mRNA COVID-19 vaccines for them. Individuals from this group were eligible for enrollment in clinical trials.

Dignity Health Medical Group.
Nevada

Pfizer and Moderna Vaccine FAQ

Adopted from: [Advisory Committee on Immunization Practices (ACIP) Clinical Considerations for Use of mRNA COVID-19 Vaccines Currently Authorized in the United States](#)

- **What are the possible side effects of the Pfizer-BioNTech COVID-19 Vaccine?***
    - injection site pain
    - tiredness
    - headache
    - muscle pain
    - chills
    - joint pain
    - fever
    - injection site swelling
    - injection site redness
    - nausea
    - feeling unwell
    - swollen lymph nodes (lymphadenopathy)

    It is recommended that people with allergies to components of the vaccine not vaccinate. There is a remote chance that the Pfizer-BioNTech COVID-19 Vaccine could cause a severe allergic reaction. A severe allergic reaction would usually occur within a few minutes to one hour after getting a dose of the Pfizer-BioNTech COVID-19 Vaccine. Signs of a severe allergic reaction can include:

    - Difficulty breathing
    - Swelling of your face and throat
    - A fast heartbeat
    - A bad rash all over your body
    - Dizziness and weakness

    Pfizer-BioNTech COVID-19 Vaccine is still being studied in clinical trials. For more information about side effects please see the FDA fact sheet for vaccine recipients.
    *Adopted from [FDA fact sheet for vaccine recipients](#)

- **What are the possible side effects of the Moderna COVID-19 vaccine?***
    Side effects that have been reported with the Moderna COVID-19 Vaccine include:

    - Injection site reactions: pain, tenderness and swelling of the lymph nodes in the same arm of the injection, swelling (hardness), and redness
    - General side effects: fatigue, headache, muscle pain, joint pain, chills, nausea and vomiting, and fever

    There is a remote chance that the Moderna COVID-19 Vaccine could cause a severe allergic reaction. A severe allergic reaction would usually occur within a few minutes to one hour after getting a dose of the Moderna COVID-19 Vaccine. For this reason, your

vaccination provider may ask you to stay at the place where you received your vaccine for monitoring after vaccination. Signs of a severe allergic reaction can include:

- o Difficulty breathing
- o Swelling of your face and throat
- o A fast heartbeat
- o A bad rash all over your body
- o Dizziness and weakness

The Moderna COVID-19 Vaccine is still being studied in clinical trials. For more information about side effects please see the fact sheet for vaccine recipients
Adopted from FDA fact sheet for vaccine recipients

- **Can children get the vaccine?**
Under the Emergency Use Authorizations, the following age groups are authorized to receive vaccination:
    - o Pfizer-BioNTech: ages ≥16 years
    - o Moderna: ages ≥18 years

Children and adolescents outside of these authorized age groups should not receive COVID-19 vaccination at this time.

- **How is the vaccine administered?**
The COVID-19 vaccine series consist of two doses administered intramuscularly:

    - o Pfizer-BioNTech: three weeks (21 days) apart
    - o Moderna: one month (28 days) apart

Second doses administered within a grace period of ≤4 days from the recommended date for the second dose are considered valid; however, doses administered earlier do not need to be repeated. The second dose should be administered as close to the recommended interval as possible. However, there is no maximum interval between the first and second dose for either vaccine.

- **Will I need a "booster" shot after I get the first two-dose series?**
The need for and timing of booster doses for COVID-19 vaccines has not been established. No additional doses beyond the two-dose primary series are recommended at this time.

- **Does the vaccine offer any benefit if I have a history of COVID-19 infection and have a high antibody count?**
Yes, the vaccine does offer additional benefit as it is currently unknown how long natural immunity from infection lasts. As antibodies from natural infection decrease over time the Centers for Disease Control and Prevention (CDC) recommends vaccination as it has shown to be highly effective with a good safety profile. Therefore, it is recommended to have the vaccine, even if you have had COVID-19 infection. However, if you have had allergic reactions to vaccines in the past or allergic reactions to any of the ingredients, then it is NOT recommended for you to have the vaccine. If you have concerning health issues, please discuss with your primary physician.

- **Should individuals with a history of COVID-19 infection be offered the vaccine?**
  Yes, COVID-19 vaccine should be offered to individuals with prior history of COVID-19 infection that have fully recovered (no longer in quarantine, no longer contagious, but may have lingering symptoms). If you have other health issues and concerns about the vaccine, contact your primary physician.

- **I do not have any symptoms. Should I get tested for COVID-19 infection before I take the vaccine?**
  No, testing to assess for acute or prior infection solely for the purposes of vaccine decision-making is not recommended.

- **If I have an active COVID-19 infection, can I take the vaccine before I fully recover?**
  No, vaccination of persons with known current infection will be deferred until the person has recovered from the acute illness (if the person had symptoms) and criteria have been met for them to discontinue quarantine.

- **Can I get the COVID-19 vaccine and my flu shot at the same time?**
  The COVID-19 vaccine should be administered alone with a minimum interval of 14 days before or after administration with any other vaccines.

- **Should I get the vaccine if I have COVID-19 now, or if I was exposed to someone with COVID-19?**
  Vaccination should be deferred until the patient has recovered from symptoms of COVID-19 and after the isolation period is complete. There is no minimal interval between infection and vaccination. If you were exposed to someone with COVID-19, wait to get vaccinated until your quarantine period has ended to avoid potentially exposing those around you.

- **If I received monoclonal antibodies or convalescent plasma to treat COVID-19, should I get the vaccine?**
  Currently there are no data on safety or efficacy of COVID-19 vaccination in persons who received monoclonal antibodies or convalescent plasma as part of COVID-19 treatment. Patients should wait 90 days before getting the vaccine to avoid interference of the treatment with the vaccine-induced immune response.

- **Should pregnant or breastfeeding women get the vaccine?**
  If pregnant women are part of a group that is recommended to receive a COVID-19 vaccine (e.g., healthcare personnel), they may choose to be vaccinated. A conversation between the patient and their clinical team may assist with decisions regarding the use of a COVID-19 vaccine. There is no recommendation for routine pregnancy testing before receipt of a COVID-19 vaccine. Those who are trying to become pregnant do not need to avoid pregnancy after COVID-19 vaccination. There are no data on the safety of COVID-19 vaccines in lactating people or the effects of COVID-19 vaccines on the breastfed infant or milk production/excretion. A lactating person who is part of a group recommended to receive a COVID-19 vaccine (e.g., healthcare personnel) may choose to be vaccinated.

- **Why is it important to get both doses of the vaccine?**
  It is important to complete the 2-dose series in order to optimize protection. Protection from the vaccine is not immediate. It will take one to two weeks following the second dose to be considered fully vaccinated.

- **How effective is the vaccine?**
   No vaccine is 100% effective. Clinical trial data suggest the Pfizer-BioNTech COVID-19 vaccine has an average 95% efficacy after the second dose, and the Moderna COVID-19 has an average 94% efficacy after the second dose.

For more details on the ACIP recommendations related to the Pfizer-BioNTech and Moderna COVID-19 vaccines, visit https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html#authorized

Additional Information

Additional information on COVID-19 vaccine development, safety and distribution is available here:

- **FDA:** https://www.fda.gov/vaccines-blood-biologics/vaccines/emergency-use-authorization-vaccines-explained
- **CDC:** https://www.cdc.gov/coronavirus/2019-ncov/vaccines/index.html
- **ACOG:** https://www.acog.org/clinical/clinical-guidance/practice-advisory/articles/2020/12/vaccinating-pregnant-and-lactating-patients-against-covid-19

Additional information about the Emergency Use Authorization (EUA) is available here:

- **EUA:** Pfizer | Moderna
- **Fact sheet for Providers:** Pfizer | Moderna
- **Fact sheet for Recipients:** Pfizer | Moderna