

COVID-19 VACCINE UPDATE

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His wife is also a geriatrician and they run a private practice together, Complete HealthCare Services, in the Kansas City Metro and surrounding areas. Dr. Tadakamalla and his wife have a daughter and a son.

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VACCINE DETAILS

- The vaccine is recommended for people 16 years and older
- The initial phase of distribution is intended to vaccinate healthcare workers and residents of long-term care facilities
- The vaccine is to be given intramuscularly (IM) in two doses, three weeks apart
- The second dose should be given within a four-day grace period, both before and after the exact due date for the second vaccine; i.e. day 17-21 after the first vaccination
- If the second dose is late, there is no recommendation to give another dose, nor to re-start the series
- The vaccine is not interchangeable with other vaccines manufactured by other vendors
- The vaccine should be given alone; i.e. not in conjunction with any other vaccines, and it should include a minimal interval of 14 days (both prior to and following the dose) between the COVID-19 vaccine and any other vaccines

For persons with prior infection or exposure to COVID, the vaccine is safe and likely efficacious and should be given; viral or serologic testing in this population is not recommended

- For persons with active infection, vaccination should be deferred until after recovery
- There is no minimum interval between active infection and vaccination, though studies suggest most people have some immunity for the first 90 days following infection; therefore they may delay vaccination for 90 days but are not required to do so
- There is no data regarding patients who have received monoclonal antibody and/or convalescent plasma; the ACIP recommends delaying vaccination for 90 days following treatment with either monoclonal antibody or convalescent plasma

WHO SHOULD RECEIVE THE VACCINE?

VACCINE CLINIC RECOMMENDATIONS

- FOR PERSONS WITH KNOWN EXPOSURE TO COVID-19 IN A COMMUNITY SETTING, VACCINATION SHOULD BE DELAYED UNTIL THE QUARANTINE PERIOD IS COMPLETE
- RESIDENTS IN LONG-TERM CARE FACILITIES WITH EXPOSURE SHOULD RECEIVE VACCINATION WITHOUT DELAY
- RESIDENTS IN OTHER CONGREGATE SETTINGS, SUCH AS PRISONS OR HOMELESS SHELTERS, WITH EXPOSURE SHOULD RECEIVE VACCINATION WITHOUT DELAY
- SPECIAL POPULATIONS, OR THOSE WITH UNDERLYING MEDICAL CONDITIONS SUCH AS HIV OR OTHER IMMUNOCOMPROMISING CONDITIONS, SHOULD RECEIVE THE VACCINE AND BE COUNSELED THAT THERE IS NO DATA REGARDING VACCINATING THAT POPULATION
- THE VACCINE HAS NOT BEEN STUDIED IN PREGNANCY, BUT IF A PERSON IS CONSIDERED IN A HIGH-RISK CATEGORY FOR COVID, SUCH AS HEALTHCARE WORKERS, OR IN AN AREA WITH HIGH LEVELS OF COMMUNITY TRANSMISSION, THEY MAY RECEIVE THE VACCINE
- THERE IS NO DATA IN BREASTFEEDING WOMEN, BUT THEY MAY CHOOSE TO RECEIVE THE VACCINE

VACCINE CLINIC RECOMMENDATIONS

- Patients should be educated regarding the reactogenicity of the vaccine; i.e., expected to see some post-vaccination fever, aches, etc.
- Antipyretics and/or analgesics may be used to treat the above symptoms, but they are not recommended to be used prophylactically
- For optimal efficacy, both doses must be given
- Protection is not immediate; full protection is achieved one-to-two weeks following the second dose
- Protection does not occur in 100% of patients
- All transmission prevention guidance should continue to be followed, including social distancing, masking, frequent handwashing, etc.

VACCINE CLINIC RECOMMENDATIONS

- Contraindications include only a previous anaphylactic reaction to an ingredient of the vaccine
- Precautions exist for patients with a history of severe allergic reaction or anaphylactic reaction to an injectable vaccine (this does NOT include reactions to foods, animals, environmental allergens, or oral medications)
- Following vaccination, recipients should be observed for 15 minutes, UNLESS they have a prior history of anaphylactic reaction to an injectable medication
- Emergency treatment should be immediately available
- COVID-19 PCR and antigen test results are NOT affected by the vaccine
- COVID-19 antibody tests could be positive following a vaccine
- The primary endpoint of this vaccine trial is whether the recipients developed COVID-19 disease, not whether they tested positive
- Whether the vaccine impacts transmissibility is under study
- Clinical resources will be posted on the CDC website

FAQS

- Clinical FAQs –

These clinical FAQs will be incorporated into the next FAQ Update

- oCan the vaccine be given with other vaccines?

- 1.No data. Should be given alone at least 14 days before or after any other vaccines.

- oShould someone who was previously infected receive the vaccine?

- 1.CDC recommending to those regardless of whether they were previously infected (symptomatic or asymptomatic)

- oShould someone who is currently infected receive the vaccine?

FAQS

- Defer until patient is recovered from the illness and has met the CDC criteria to leave isolation (10 days from sx onset – 20 days if severe illness)
- Are vaccine products interchangeable?
 - No. No data on any other vaccines, nor data of doses
- Should patients with immune disorders get the vaccine?
 - Immunocompromised patients (either due to disease or due to medications they are taking) can receive the vaccine so long as they don't have any other contraindications
- What is the efficacy of the Pfizer vaccine (for completed series and just one dose)?
 - Efficacy was 95% - 7 days following the second dose
 - Efficacy after the first dose was around 52% - but this was just a datapoint reported – study wasn't designed to look at efficacy after the first dose
 - There is a booster effect with this vaccine

FAQS

oAre there any age restrictions to getting the vaccine?

1.Pfizer vaccine EUA is approved for 16 years and older (no upper age limit)

•No completed studies yet for younger populations

oWhat is the clinical guidance for someone who missed the second dose window (17-21 days)?

1.Pfizer recommended window is 17-21 days – guidance from the CDC is if they get after the 17-21 day window to just get the second dose as soon as possible, but the series does not need to be repeated

oWhat is the recommended observation time following administration?

1.15 minutes

2.Those with a history of severe allergic reactions (anaphylaxis) should be monitored for 30 minutes

3.It will be responsibility of the facility to monitor patients after receiving the vaccine

FAQS

oOther Clinical Pearls

- 1.For patients who have received monoclonal antibodies or convalescent plasma, reinfection is not common for 90 days after receiving therapy based on the half life of these treatments, so the vaccine should be deferred until 90 days after therapy to avoid the treatment countering the effect of the vaccine
- 2.Pregnant women – unlikely to pose a risk for women who are pregnant or lactating
- 3.Alternative vaccine sites – not aware of any data for the vaccine being given at any site other than the deltoid muscle
- 4.Will a person test positive after receiving the vaccine?
 - No. The vaccine will not impact test results.

•Clinic Schedule Roll-Up

- oAbout 1,100 clinics have been scheduled to date – 550 facilities
- oThey anticipate receiving the data from CVS by end of day today – then they will scrub against the SFDC data so we can filter by account
- oThey will go ahead and send out a rough file with what has been scheduled so far for visibility – but it will not be paired up with SFDC data

•Areas that have “opted out”

- oNo updates yet
- oIf the county/state doesn't activate with the federal program, the facilities will have to work with their respective departments of health on what their plan is for now.