



COVID-19 Vaccine 2020-2021 Clinical Information

Always consult state specific charts and the Immunization Selection Tool to determine vaccine administration and dispensing policies.

ACIP Vaccination Recommendations

- The following vaccine(s) are available and recommended for prevention of COVID-19 caused by SARS-CoV-2 infection in individuals 16 years of age and older in the U. S. Population under the FDA's Emergency Use Authorization:
 - Pfizer-BioNTech (BNT162b2, Pfizer) COVID-19 Vaccine**

COVID-19 Vaccine Basics

Approved Age	Dose Schedule	Route	Additional Information
Pfizer COVID-19 vaccine			
≥ 16 years	0.3 mL (0, 21 days)	IM Deltoid	<ul style="list-style-type: none">Pfizer COVID-19 vaccine is an inactivated mRNA vaccine administered as a 2-dose series (0,21 days).Pfizer is a frozen liquid, preservative-free vaccine (5-dose MDV)Vaccine is stored ultra-cold for up to 6 months, in thermal shipper on dry ice up to 30 days, or refrigerated for up to 5 days.Vaccine must be thawed and reconstituted with NaCl prior to administration.Reconstituted vaccine should be an off-white suspension with no particulates or discoloration.Discard reconstituted vaccine if not used within 6 hours.Detailed storage and handling information can be found on Storenet.

Contraindications

Severe allergic reaction to any component of the vaccine or after a previous dose of COVID-19 vaccine.

Precautions/Special Populations

- Pregnancy:** A pregnant woman in a COVID-19 priority group may be vaccinated if she chooses. Studies are on-going but limited safety data of COVID-19 vaccines in pregnant women is available. Can provide vaccine education and refer to her healthcare provider to make an informed decision.
 - Considerations for vaccination in pregnancy include level of COVID-19 community transmission, personal risk of contracting COVID-19, risks of COVID-19 to her and potential risks to the fetus, vaccine efficacy, side effects and limited data during pregnancy is available. Routine testing for pregnancy prior to vaccination is not recommended.
 - Pregnant women who experience fever following vaccination should be counseled to take acetaminophen as fever has been associated with adverse pregnancy outcomes.
- Breastfeeding/lactating women:** A lactating woman in a COVID-19 priority group may be vaccinated if she chooses. Limited safety data of COVID-19 vaccines during lactation is available at this time.
- Underlying Medical Conditions:** Vaccine may be administered to persons with underlying medical conditions who have no contraindications to vaccination
- Immunocompromised:** Vaccine may be administered to persons with underlying medical conditions who have no contraindications to vaccination.
 - Counsel patients that vaccine safety and efficacy in immunocompromised persons is still unknown, there is potential for reduce immune response, and to continue to follow current advice to protect from COVID-19.
- Children:** More studies need to be conducted before COVID-19 vaccines are recommended for children. Pfizer COVID-19 vaccine is authorized for use in persons age 16 and up.
- History of COVID-19 infection:** Vaccination should be offered to persons regardless of history of prior symptomatic or asymptomatic COVID-19 infection.

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- Vaccination should be **deferred for at least 90 days** in persons who received monoclonal antibodies or convalescent plasma as part of COVID-19 treatment to avoid interference of the treatment with vaccine-induced immune responses.
- **Current COVID-19 infection:** Vaccination for symptomatic COVID-19 patients should be **deferred until recovered** from acute illness *and* criteria have been met to discontinue isolation. No minimal interval is necessary between infection and vaccination. (Note: Persons with history of documented COVID-19 in the preceding 90 days may defer vaccination until the end of this period, if desired, as current evidence suggests reinfection is uncommon in the 90 days after initial infection).

Adverse Reactions

- Patients should be counseled about expected local and systemic adverse reactions.
 - Local injection site reactions: Common and reported to be mild-moderate.
 - Systemic adverse reactions: More commonly reported after the second dose than after the first dose and were generally more frequent and severe in persons younger than older (aged 18–55 years than in those aged >55 years). In trials, they typically occurred within 1-2 days and resolved in a median of 1 day.
 - Severe adverse reactions: Not common but were more commonly reported after the second dose than after the first dose and were less prevalent in older than in younger vaccine recipients.
 - Serious and unexpected side effects should be reported, even if unclear if related to vaccine.
- Patients should be encouraged to complete the vaccine series even if they develop post-vaccination symptoms unless they develop a contraindication to vaccination.
- Self-care management of post-vaccination reactions should be recommended including antipyretic or analgesic medications. Routine prophylaxis to prevent symptoms is not recommended.

Pfizer COVID-19 Vaccine:

- Local injection site reactions: pain, redness, swelling
- Systemic adverse reactions: headache, muscle pain, joint pain, fever, chills, nausea, fatigue, malaise, swollen lymph nodes (lymphadenopathy)
- Severe adverse reactions: <10% reported any grade ≥3 reaction. The most common symptoms were fatigue (4.2%), headache (2.4%), muscle pain (1.8%), chills (1.7%), and injection site pain (1.4%).
- **Anaphylaxis:** There is a remote chance that vaccine could cause a severe allergic reaction. A severe allergic reaction would usually occur within a few minutes to one hour after administration. Signs can include: difficulty breathing, swelling of face and throat, palpitations, body rash, dizziness and weakness.

Persons with a history of anaphylaxis to vaccine or other injectable products should not be vaccinated with COVID-19 vaccines.

Persons who develop anaphylaxis following vaccine administration should not be vaccinated with additional doses of COVID-19 vaccines.

Persons with a history of anaphylaxis to anything other than vaccines should be observed for 30 minutes following COVID-19 vaccine administration

Clinical Considerations

Spacing of Vaccine Doses:

Pfizer COVID-19 Vaccine

- Doses should be spaced a minimum of 21 days apart. If >21 days since 1st dose, 2nd dose should be administered at earliest opportunity (but dose does need to be repeated).
- If dose is inadvertently administered before 21 days, the dose is still valid if within a 4-day grace period (17-21 days) and revaccination is not required.
- Both doses are necessary for protection; efficacy of a single dose has not been evaluated.

Interchangeability:

- COVID-19 vaccines are not interchangeable. Persons initiating series with one COVID-19 vaccine should complete series with same product (safety and efficacy of a mixed series has not been evaluated).
- Note: If two doses of different mRNA COVID-19 vaccine products inadvertently administered, no additional doses of either vaccine recommended at this time.

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Coadministration with other vaccines:

- COVID-19 vaccines should be administered alone with a **minimum interval of 14 days** before or after administration with any other vaccines (due to lack of data on safety and efficacy of the vaccine administered simultaneously with other vaccines).
- If a COVID-19 vaccine is inadvertently administered within 14 days of another vaccine, doses do not need to be repeated for either vaccine.

Infection/Testing:

- Infection: COVID-19 vaccines do not cause COVID-19. However, it typically takes a few weeks for the body to build post-vaccination immunity in which time a person could be infected with SARS-CoV-2 immediately before or after vaccination and get COVID-19.
- Diagnostic test: COVID-19 vaccines will NOT affect the results of viral COVID-19 nucleic acid amplification or antigen tests.
- Antibody test: Vaccinated persons may test positive for certain antibody tests. To evaluate for evidence of prior infection in an individual with a history of Pfizer-BioNTech COVID-19 vaccination, a test specifically evaluating IgM/IgG to the nucleocapsid protein should be used.

COVID-19 Vaccine Patient Counseling/Talking Points

Vaccine Efficacy

- ✓ Patients should be counseled on importance of completing the 2-dose series in order to optimize protection.
- ✓ High vaccine efficacy (95%) is achieved after the 2nd dose.

Vaccine Adverse Events

- ✓ Review anticipated vaccine adverse events and management strategies. Unexpected, worsening, or severe events should be reported to VAERS.
- ✓ Routine post-vaccination observation for 15 minutes is recommended to address any unexpected and immediate vaccine-related reactions. (30 minutes for patients with a history of anaphylaxis)

General talking points:

- ✓ Protection from vaccine is not immediate; vaccine is a 2-dose series and will take 1 to 2 weeks following the second dose to be considered fully vaccinated.
- ✓ Limited data is available on how well the vaccine works in the general population, how much it may reduce disease, severity, or transmission; and how long protection lasts.
- ✓ Vaccinated persons should continue to follow all current guidance to protect themselves and others, including: wearing a mask, maintaining social distance, frequent hand washing, avoiding crowds, and following CDC or applicable travel, quarantine, or work/school guidance.

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CDC Algorithm for triage of persons presenting for Pfizer COVID-19 Vaccine

	PROCEED WITH VACCINATION	PRECAUTION TO VACCINATION	CONTRAINDICATION TO VACCINATION
CONDITIONS	CONDITIONS <ul style="list-style-type: none"> Immunocompromising conditions Pregnancy Lactation ACTIONS <ul style="list-style-type: none"> Additional counseling* 15-minute observation period 	CONDITIONS <ul style="list-style-type: none"> Moderate/severe acute illness ACTIONS <ul style="list-style-type: none"> Risk assessment Potential deferral of vaccination 15-minute observation period if vaccinated 	CONDITIONS <ul style="list-style-type: none"> None ACTIONS <ul style="list-style-type: none"> N/A
ALLERGIES	ALLERGIES <ul style="list-style-type: none"> History of food, pet, insect, venom, environmental, latex, etc., allergies History of allergy to oral medications (including the oral equivalent of an injectable medication) Non-serious allergy to vaccines or other injectables (e.g., no anaphylaxis) Family history of anaphylaxis ACTIONS <ul style="list-style-type: none"> 15-minute observation period 	ALLERGIES <ul style="list-style-type: none"> History of severe allergic reaction (e.g., anaphylaxis) to another vaccine (not including Pfizer-BioNTech vaccine) History of severe allergic reaction (e.g., anaphylaxis) to an injectable medication ACTIONS: <ul style="list-style-type: none"> Risk assessment Potential deferral of vaccination 30-minute observation period if vaccinated 	ALLERGIES <ul style="list-style-type: none"> History of severe allergic reaction (e.g., anaphylaxis) to any component of the Pfizer-BioNTech vaccine ACTIONS <ul style="list-style-type: none"> Do not vaccinate

COVID-19 Vaccine Clinical FAQs

Does receiving the COVID-19 vaccine cause COVID-19?	No, COVID-19 vaccines do not use the live virus that causes COVID-19. However, it typically takes a few weeks for the body to build immunity after vaccination so a person could be infected with SARS-CoV-2 just before or just after vaccination and get COVID-19.
Should a patient with a history of anaphylaxis receive the COVID-19 vaccine?	If a patient has had a severe allergic reaction to any vaccine (including COVID-19 vaccines) or other injectable therapy they should NOT be vaccinated at this time. If a patient has a history of anaphylaxis (to anything OTHER than vaccines), patients may be vaccinated but should be observed for 30 minutes following administration.
Does someone with a history of COVID-19 need to get vaccinated for COVID-19?	Yes, as long-term immunity data is not known following infection, COVID-19 vaccines should be administered to those with a history of COVID-19. Vaccine should be deferred for 90 days in persons who were treated for COVID-19 with monoclonal antibodies or convalescent plasma. Those with a current infection should wait until recovered and after discontinuing isolation.
Can I vaccinate someone for COVID-19 if they are not eligible according to CDC priority groups?	No, only people that are eligible for COVID-19 vaccines per CDC or jurisdiction can be vaccinated.
Is there a maximum length of time that between doses of the COVID-19 vaccine that would require a patient to restart the vaccine series?	No, there is currently no maximum dosing interval for COVID-19 vaccines. For 2-dose vaccines, if the patient waits longer than the stated interval to get the second dose, they should receive that dose as soon as possible. The patient does not have to start the series over.
If a patient starts with one COVID-19 vaccine product, if two doses are required, can they finish the series with a different product?	No, the same vaccine product must be used for both doses of the two-dose COVID-19 vaccine as safety and efficacy of a mixed series is unknown. If another mRNA product is inadvertently used, it should be reported but revaccination is not required.
Are both doses of a 2-dose COVID-19 vaccine required?	Yes, stated vaccine efficacy is only achieved after a person receives the recommended number of doses. The amount or length of immunity is unknown

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	following an incomplete series. Full protection occurs one to two weeks following the second dose.
Can pregnant or lactating women receive the COVID-19 vaccine?	Yes, if she wishes to be vaccinated and is eligible as part of a COVID-19 vaccine priority group. Very limited safety data is available on COVID-19 in pregnant or lactating women. Pregnant women should be encouraged to discuss with her healthcare provider. Pregnant women who are vaccinated and experience fever are recommended to take acetaminophen to reduce adverse pregnancy outcomes associated with fever.
Can the flu vaccine and COVID-19 vaccine be administered at the same time?	No, due to lack of efficacy and safety data of simultaneous administration, the COVID-19 vaccine should be administered 14 days before or after any other vaccine.
Can a patient with an underlying medical or someone who is immunocompromised receive the COVID-19 vaccine?	Yes, persons with underlying medical conditions or immunocompromised persons who have no contraindications to vaccination may receive COVID-19 vaccine.
Do patients who are vaccinated for COVID-19 still need to wear masks or other infection control measures?	Yes, vaccination is one step in helping combat COVID-19. Vaccinated persons should continue to follow all current proven infection control measures including wearing a mask, frequent hand-washing and social distancing.
Should patients who had a reaction following one dose of a 2-dose COVID-19 vaccine receive a second dose?	That depends. Patients who experience anaphylaxis or develop a contraindication to vaccination following dose 1 should NOT receive a second dose. Patients who experienced mild-moderate post-vaccination adverse reactions should be counseled about expected symptoms and encouraged to complete the series.
Will COVID-19 vaccines cause someone to test positive for viral COVID-19?	No, receiving the COVID-19 vaccine does NOT cause someone to test positive on a viral COVID-19 test. Because it triggers an immune response, vaccination may result in a positive antibody test depending on the test type.

References

Mbaeyi, Sarah. ACIP COVID-19 Vaccines Work Group Presentation December 12, 2020. Use of Pfizer-BioNTech COVID-19 Vaccine: Clinical Considerations. <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2020-12/slides-12-12/COVID-03-Mbaeyi.pdf>. Accessed December 13, 2020.

Pfizer COVID-19 EUA Fact Sheet. <https://selfservehosteu.pfizer.com/pfrrdownload/file/fid/77051>. Accessed December 13, 2020.

Oliver, Sara, et al. The Advisory Committee on Immunization Practices' Interim Recommendation for Use of Pfizer-BioNTech COVID-19 Vaccine MMWR Morb Mortal Wkly Rep 2020. Early Release/Vol 69. <https://www.cdc.gov/mmwr/volumes/69/wr/pdfs/mm6950e2-H.pdf>. Accessed December 13, 2020.

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