Prevaccination Checklist for COVID-19 Vaccines



Patient Name The following questions will help us determine if there is any reason you should not get the COVID-19 vaccine today. If you answer "yes" to any question, it does not necessarily mean you should not be vaccinated. It just means additional questions may be asked. If a question is not clear, please ask your healthcare provider to explain it.	Yes	No	Don't know
1. Are you feeling sick today?			KIIOW
2. Have you ever received a dose of COVID-19 vaccine?			
If yes, which vaccine product did you receive? Pfizer Moderna Another product			
3. Have you ever had an allergic reaction to: (This would include a severe allergic reaction [e.g., anaphylaxis] that required treatment with epinephrine or EpiPen [®] or that cault would also include an allergic reaction that occurred within 4 hours that caused hives, swelling, or respiratory distress, including	used you to ng wheezin	go to the g.)	hospital.
• A component of the COVID-19 vaccine, including polyethylene glycol (PEG), which is found in some medications, such as laxatives and preparations for colonoscopy procedures			
Polysorbate			
A previous dose of COVID-19 vaccine			
4. Have you ever had an allergic reaction to another vaccine (other than COVID-19 vaccine) or an injectable medication? (This would include a severe allergic reaction [e.g., anaphylaxis] that required treatment with epinephrine or EpiPen [®] or that caused you to go to the hospital. It would also include an allergic reaction that occurred within 4 hours that caused hives, swelling, or respiratory distress, including wheezing.)			
 Have you ever had a severe allergic reaction (e.g., anaphylaxis) to something other than a component of COVID-19 vaccine, polysorbate, or any vaccine or injectable medication? This would include food, pet, environmental, or oral medication allergies. 			
6. Have you received any vaccine in the last 14 days?			
7. Have you ever had a positive test for COVID-19 or has a doctor ever told you that you had COVID-19?			
8. Have you received passive antibody therapy (monoclonal antibodies or convalescent serum) as treatment for COVID-19?			
9. Do you have a weakened immune system caused by something such as HIV infection or cancer or do you take immunosuppressive drugs or therapies?			
10. Do you have a bleeding disorder or are you taking a blood thinner?			
11. Are you pregnant or breastfeeding?			

Date

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For additional information on COVID-19 vaccine clinical guidance, see: <u>https://www.cdc.gov/vaccines/</u> covid-19/info-by-product/clinical-considerations.html.

For additional information on ACIP general recommendations, see: <u>https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html.</u>

Two COVID-19 vaccines are currently authorized for use in the United States. These vaccines are authorized for use among different age groups.

PRODUCT	AUTHORIZED AGE GROUPS
Pfizer-BioNTech COVID-19 Vaccine	16 years of age and older
Moderna COVID-19 Vaccine	18 years of age and older

Anyone outside of the authorized age groups for a product should not receive the vaccine.

Postvaccination Observation Times for Persons without Contraindications to COVID-19 Vaccination

- 30 minutes: Persons with a history of an immediate allergic reaction of any severity to a vaccine or injectable therapy
 or a history of anaphylaxis due to any cause
- 15 minutes: All other persons

Are you feeling sick today?

There is no evidence that acute illness reduces vaccine efficacy or increases vaccine adverse events. However, as a precaution with moderate or severe acute illness, all vaccines should be delayed until the illness has improved. **Mild illnesses (e.g., upper respiratory infections, diarrhea) are NOT contraindications to vaccination.** Do not withhold vaccination if a person is taking antibiotics.

Vaccination of persons with current SARS-CoV-2 infection should be deferred until the person has recovered from acute illness and they can discontinue isolation. This recommendation applies to persons who develop SARS-CoV-2 infection before receiving any vaccine doses as well as those who develop SARS-CoV-2 infection after the first dose but before receipt of the second dose.

Have you ever received a dose of COVID-19 vaccine?

COVID-19 vaccines are **NOT** interchangeable. Currently authorized COVID-19 vaccines require two doses. Both doses of the series should be completed with the same product. Product dosing schedules vary.

Check medical records, immunization information systems, and vaccination record cards to help determine the initial product received. Those who received a trial vaccine should consult with the trial sponsors to determine if it is feasible to receive additional doses.

PRODUCT	DOSING SCHEDULE between doses 1 and 2	
Pfizer-BioNTech COVID-19 Vaccine	21 days	
Moderna COVID-19 Vaccine	28 days	

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COVID-19 Vaccine Components

Description	Pfizer-BioNTech COVID-19 vaccine	Moderna COVID-19 vaccine	
mRNA	Nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2	Nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2	
Lipids	2[(polyethylene glycol)-2000]-N, N-ditetradecylacetamide	PEG2000-DMG: 1,2-dimyristoyl-rac-glycerol, methoxypolyethylene glycol	
	1,2-distearoyl-sn-glycero-3-phosphocholine	1,2-distearoyl-sn-glycero-3-phosphocholine	
	Cholesterol	Cholesterol	
	(4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl) bis(2-hexyldecanoate)	SM-102: heptadecane-9-yl 8-((2-hydroxyethyl) (6-oxo-6-(undecyloxy) hexyl) amino) octanoate	
Salts, sugars, buffers	Potassium chloride	Tromethamine	
	Monobasic potassium phosphate	Tromethamine hydrochloride	
	Sodium chloride	Acetic acid	
	Dibasic sodium phosphate dihydrate	Sodium acetate	
	Sucrose	Sucrose	

Have you ever had an allergic reaction to:

- Any component of a COVID-19 vaccine, including polyethylene glycol (PEG), which is found in some medications, such as laxatives and preparations for colonoscopy procedures?
- Polysorbate
- A previous COVID-19 vaccine

History of anaphylaxis or an immediate allergic reaction (of any severity) to any COVID-19 vaccine or any component of an mRNA COVID-19 vaccine is a contraindication to any current COVID-19 vaccine. Polyethylene glycol (PEG) is an ingredient in mRNA COVID-19 vaccines. Because of potential cross-reactive hypersensitivity with the COVID-19 vaccine ingredient PEG, a history of allergic reaction to polysorbate is also a contraindication to an mRNA COVID-19 vaccine. Healthcare professionals should be familiar with identifying immediate-type allergic reactions, including anaphylaxis, and be competent in treating these events at the time of vaccine administration. Appropriate medical treatment for severe allergic reactions must be immediately available in the event that an acute anaphylactic reaction occurs following administration of a COVID-19 vaccine. See <u>Management of Anaphylaxis at COVID-19</u> <u>Vaccination Sites</u> | CDC for additional guidance.

Have you ever had an allergic reaction to another vaccine (other than COVID-19 vaccine) or another injectable medication?

A history of any immediate allergic reaction to any other vaccine or injectable therapy (i.e., intramuscular, intravenous, or subcutaneous vaccines or therapies not related to a component of mRNA COVID-19 vaccines or polysorbate) is a precaution to currently authorized COVID-19 vaccines. Vaccine may be given, but counsel patients about unknown risks of developing a severe allergic reaction and balance these risks against the benefits of vaccination. Deferral of vaccination and/or consultation with an allergist-immunologist may be considered. Considerations for vaccination include risk of exposure to SARS-CoV-2, risk of severe disease or death due to COVID-19, previous infection with COVID-19, unknown risk of anaphylaxis following mRNA COVID-19 vaccination, and ability of recipient to receive care immediately for anaphylaxis if necessary. **These individuals should be observed for 30 minutes after vaccination.**

When vaccine recipients report an immediate allergic reaction, providers should attempt to determine whether reactions reported following vaccination are consistent with immediate allergic reactions versus other types of reactions commonly observed following vaccination, such as vasovagal reaction or postvaccination side effects (which are not contraindications to receiving the second vaccine dose). See page 6 for additional information.

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Have you ever had a severe allergic reaction (e.g., anaphylaxis) to something other than a component of COVID-19 vaccine, polysorbate, or any vaccine or injectable medication? This would include food, pet, venom, environmental, or oral medication allergies.

Allergic reactions, including severe allergic reactions, NOT related to vaccines or injectable therapies, components of mRNA COVID-19 vaccines (including PEG), or polysorbates are NOT contraindications or precautions to vaccination with currently authorized COVID-19 vaccines. HOWEVER, individuals who have had severe allergic reactions to anything, regardless of cause, **should be observed for 30 minutes after vaccination.** All others, including those with immediate allergic reactions that were not severe, should be observed for 15 minutes.

Clinical Consideration Questions

Responses to these questions are not (on their own) contraindications or precautions to vaccination. However, healthcare professionals should be prepared to discuss information and options with patients based on their responses to the following questions.

Have you received another vaccine in the last 14 days?

The COVID-19 vaccine series should be administered alone, with a minimum interval of 14 days before or after administration of other vaccines. This recommendation is based on the lack of data on the safety and efficacy of mRNA COVID-19 vaccines administered simultaneously with other vaccines.

Have you had a positive test for COVID-19 or has a doctor ever told you that you had COVID-19?

Vaccination should be offered to persons regardless of history of prior symptomatic or asymptomatic SARS-CoV-2 infection. Vaccination of persons with known current SARS-CoV-2 infection should 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 isolation. Persons with documented acute SARS-CoV-2 infection in the preceding 90 days may delay vaccination until near the end of this period, if desired, because current evidence suggests reinfection is uncommon during this time. Viral testing to assess for acute SARS-CoV-2 infection or serologic testing to assess for prior infection solely for the purpose of vaccine decision-making is not recommended.

Have you received passive antibody therapy as treatment for COVID-19?

Based on the estimated half-life of monoclonal antibodies or convalescent plasma as part of COVID-19 treatment, as well as evidence suggesting that reinfection is uncommon in the 90 days after initial infection, vaccination should be deferred for at least 90 days, as a precautionary measure until additional information becomes available, to avoid interference of the antibody treatment with vaccine-induced immune responses.

Do you have a weakened immune system caused by something such as HIV infection or cancer or do you take immunosuppressive drugs or therapies?

Persons with HIV infection or other immunocompromising conditions, or who take immunosuppressive medications or therapies, might be at increased risk for severe COVID-19. mRNA COVID-19 vaccines may be administered to persons with underlying medical conditions who have no contraindications to vaccination. However, they should be counseled about the unknown vaccine safety profile and effectiveness in immunocompromised populations, as well as the potential for reduced immune responses and the need to continue to follow all current guidance to protect themselves against COVID-19, including wearing a mask, social distancing, and washing hands frequently. Revaccination is not recommended after immune competence is regained in persons who received mRNA COVID-19 vaccines during chemotherapy or treatment with other immunosuppressive drugs.

Do you have a bleeding disorder or are you taking a blood thinner?

As with all vaccines, COVID-19 vaccine may be given to these patients, if a physician familiar with the patient's bleeding risk determines that the vaccine can be administered intramuscularly with reasonable safety. ACIP recommends the following technique for intramuscular vaccination in patients with bleeding disorders or taking blood thinners: A fine-gauge needle (23-gauge or smaller caliber) should be used for the vaccination, followed by firm pressure on the site, without rubbing, for at least 2 minutes.

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Are you pregnant or breastfeeding?

If pregnant people are part of a group that is recommended to receive a COVID-19 vaccine (e.g., healthcare personnel), they may choose to be vaccinated. For pregnant people seeking guidance in making a decision, pregnant people and their healthcare 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 use of the vaccine during pregnancy.

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. There are no data on the safety of COVID-19 vaccines in lactating people or the effects of mRNA COVID-19 vaccines on the breastfed infant or milk production/excretion.

Potential characteristics of allergic reactions, vasovagal reactions, and vaccine side effects following mRNA COVID-19 vaccination

In patients who develop postvaccination symptoms, determining the etiology is important to decide whether a person can receive additional doses of mRNA COVID-19 vaccines. The following table of signs and symptoms is meant to serve as a resource but may not be exhaustive, and patients may not have all signs or symptoms. Providers should use their clinical judgement when assessing patients to determine the diagnosis and management.

Characteristic	Immediate allergic reactions (including anaphylaxis)	Vasovagal reaction	Vaccine side effects (local and systemic)			
Timing after vaccination	Most occur within 15-30 minutes of vaccination	Most occur within 15 minutes	Median of 1 to 3 days after vaccination (with most occurring day after vaccination)			
Signs and symptoms						
Constitutional	Feeling of impending doom	Feeling warm or cold	Fever, chills, fatigue			
Cutaneous	Skin symptoms present in ~90% of people with anaphylaxis, including pruritus, urticaria, flushing, angioedema	Pallor, diaphoresis, clammy skin, sensation of facial warmth	Pain, erythema or swelling at injection site, lymphadenopathy in same arm as vaccination			
Neurologic	Confusion, disorientation, dizziness, lightheadedness, weakness, loss of consciousness	Dizziness, lightheadedness, syncope (often after prodromal symptoms for a few seconds or minutes), weakness, changes in vision (such as spots of flickering lights, tunnel vision), changes in hearing	Headache			
Respiratory	Shortness of breath, wheezing, bronchospasm, stridor, hypoxia	Variable; if accompanied by anxiety, may have an elevated respiratory rate	N/A			
Cardiovascular	Hypotension, tachycardia	Variable; may have hypotension or bradycardia during syncopal event	N/A			
Gastrointestinal	Nausea, vomiting, abdominal cramps, diarrhea	Nausea, vomiting	Vomiting or diarrhea may occur			
Musculoskeletal	N/A	N/A	Myalgia, arthralgia			
Vaccine recommendations						
Recommended to receive second dose of mRNA COVID-19 vaccine?	No	Yes	Yes			

Healthcare professionals or health departments in the United States can request a consultation from the <u>Clinical Immunization</u> <u>Safety Assessment COVIDvax project</u> for a complex COVID-19 vaccine safety question not readily addressed by CDC guidance about an individual patient residing in the United States not readily addressed by CDC guidance.