

Prevaccination Checklist for COVID-19 Vaccines



For vaccine recipients:

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.

Patient Name _____

Age _____

	Yes	No	Don't know
1. Are you feeling sick today?			
2. Have you ever received a dose of COVID-19 vaccine?			
<ul style="list-style-type: none"> If yes, which vaccine product did you receive? <input type="checkbox"/> Pfizer <input type="checkbox"/> Moderna <input type="checkbox"/> Janssen (Johnson & Johnson) <input type="checkbox"/> 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 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.)			
<ul style="list-style-type: none"> A component of a COVID-19 vaccine including either of the following: <ul style="list-style-type: none"> <input type="radio"/> Polyethylene glycol (PEG), which is found in some medications, such as laxatives and preparations for colonoscopy procedures <input type="radio"/> Polysorbate, which is found in some vaccines, film coated tablets, and intravenous steroids. A previous dose of COVID-19 vaccine. A vaccine or injectable therapy that contains multiple components, one of which is a COVID-19 vaccine component, but it is not known which component elicited the immediate reaction. 			
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.)			
5. Have you ever had a severe allergic reaction (e.g., anaphylaxis) to something other than a component of COVID-19 vaccine, or any vaccine or injectable medication? This would include food, pet, venom, 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?			
12. Do you have dermal fillers?			

Form reviewed by _____

Date _____

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»Clinical Materials Update

On April 13, 2021, **CDC and FDA recommended a pause in the use of Janssen COVID-19 Vaccine (Johnson & Johnson)** out of an abundance of caution while they review data involving a small number of reports of cerebral venous sinus thrombosis (CVST) with thrombocytopenia in individuals after receiving Janssen COVID-19 Vaccine (<https://www.fda.gov/news-events/press-announcements/joint-cdc-and-fda-statement-johnson-johnson-covid-19-vaccine>). The Advisory Committee on Immunization Practices (ACIP, <https://www.cdc.gov/vaccines/acip/index.html>) met on April 14. After hearing additional data on these reports, ACIP agreed that more information is needed before policy recommendations can be made regarding continued use of the Janssen COVID-19 vaccine. CDC will collect more information and convene another ACIP meeting on April 23 to review any additional scientific evidence.

At this time, the recommended pause supersedes any other recommendations for use of Janssen COVID-19 Vaccine.

Recommendations for clinicians related to the detection, evaluation, proper management, and reporting of cases of CVST with thrombocytopenia after receipt of Janssen COVID-19 Vaccine are outlined in Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States at <https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html>. These can also be found in CDC's Health Alert (<https://emergency.cdc.gov/han/2021/han00442.asp>), issued April 13.

If you are a COVID-19 vaccination provider with Janssen COVID-19 Vaccine:

1. Mark any Janssen COVID-19 Vaccine in your inventory "Do not use. Awaiting guidance."
2. Continue to store the vaccine in the refrigerator between 2°C and 8°C (36°F and 46°F).
3. Continue to monitor and document storage unit temperatures and follow recommended vaccine storage practices.

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

For additional information on Advisory Committee on Immunization Practices *General Best Practice Guidelines for Immunization*, see <https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html>.

Three 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
Janssen COVID-19 Vaccine (Johnson & Johnson)	18 years of age and older

Anyone outside 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:** History of an immediate allergic reaction of any severity to a vaccine or injectable therapy. People with a contraindication to a different type of COVID-19 vaccine (for example, people with a contraindication to mRNA COVID-19 vaccines who receive Janssen viral vector vaccine should be observed for 30 minutes following Janssen vaccination). 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 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. COVID-19 vaccines are administered intramuscularly as either a two-dose series or single dose.

For two-dose products, 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. If the vaccine product used for the first dose cannot be determined or is no longer available, any available mRNA COVID-19 vaccine may be administered. Separate doses by at least 28 days. If two doses of different mRNA COVID-19 vaccine products are administered in these situations (or inadvertently), no additional doses of either product are recommended at this time.

Vaccine	NUMBER OF DOSES/SERIES	INTERVAL BETWEEN DOSES
Pfizer-BioNTech COVID-19 Vaccine	2	21 days
Moderna COVID-19 Vaccine	2	28 days
Janssen COVID-19 Vaccine	1	N/A

*The second dose should be administered as close to the recommended interval as possible. If this is not possible, the second dose of mRNA COVID-19 vaccine may be scheduled for administration up to 6 weeks (42 days) after the first dose.

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COVID-19 Vaccine Components*

Description	Pfizer-BioNTech mRNA COVID-19 Vaccine	Moderna mRNA COVID-19 Vaccine	Janssen COVID-19 Vaccine
Active ingredients	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	Viral Vector; Recombinant, replication-incompetent Ad26 vector, encoding a stabilized variant of the SARS-CoV-2 Spike (S) protein
Inactive ingredients	2[(polyethylene glycol {PEG})-2000]-N, N-ditetradecylacetamide	PEG2000-DMG: 1,2-dimyristoyl-rac-glycerol, methoxypolyethylene glycol	Polysorbate-80
	1,2-distearoyl-sn-glycero-3-phosphocholine	1,2-distearoyl-sn-glycero-3-phosphocholine	2-hydroxypropyl-β-cyclodextrin (HBCD)
	Cholesterol	Cholesterol	Citric acid monohydrate
	(4-hydroxybutyl)azanediy]bis(hexane-6,1-diyl)bis(2-hexyldecanoate)	SM-102: heptadecan-9-yl 8-((2-hydroxyethyl)(6-oxo-6-(undecyloxy) hexyl) amino) octanoate	Trisodium citrate dihydrate
	Sodium chloride	Tromethamine	Sodium chloride
	Monobasic potassium phosphate	Tromethamine hydrochloride	Ethanol
	Potassium 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, which is found in some vaccines, film-coated tablets, and intravenous steroids**
- **A vaccine or injectable therapy that contains multiple components, one of which is a COVID-19 vaccine component, but it is unknown which component elicited the immediate allergic reaction.**

Polyethylene glycol (PEG) is an ingredient in both mRNA COVID-19 vaccines, and polysorbate 80 is an ingredient in Janssen COVID-19 vaccine. PEG and polysorbate are structurally related, and cross-reactive hypersensitivity between these compounds may occur.

- » Persons with a contraindication to one of the mRNA COVID-19 vaccines should not receive doses of either of the mRNA vaccines (Pfizer-BioNTech or Moderna). Persons with a contraindication to mRNA COVID-19 vaccines (including due to a known [diagnosed] allergy to PEG) have a precaution to Janssen COVID-19 vaccine.
- » Persons with a contraindication to Janssen COVID-19 Vaccine (including due to a known [diagnosed] allergy to polysorbate) have a precaution to mRNA COVID-19 vaccines.

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 of an mRNA COVID-19 vaccine dose). See page 6 for additional information.

*None of the vaccines contain eggs, gelatin, latex, or preservatives.

- » In addition, persons with a reaction to a vaccine or injectable therapy that contains multiple components, one of which is a vaccine component, but in whom it is unknown which component elicited the immediate allergic reaction, have a precaution to vaccination.

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 [Management of Anaphylaxis at COVID-19 Vaccination Sites](#) | 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 COVID-19 vaccines) is a precaution to currently authorized COVID-19 vaccines. Vaccine may be given, but counsel patients

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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 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.

Have you ever had a severe allergic reaction (e.g., anaphylaxis) to something other than a component of COVID-19 vaccine, 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 COVID-19 vaccines (including PEG), 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 COVID-19 vaccines administered simultaneously with other vaccines.

However, COVID-19 and other vaccines may be administered within a shorter period in situation where the benefits of vaccination are deemed to outweigh the potential unknown risks of vaccine coadministration (e.g., tetanus toxoid-containing vaccination as part of wound management, rabies vaccination for post-exposure prophylaxis, measles or hepatitis A vaccination during an outbreak) or to avoid barriers or delays to COVID-19 vaccination.

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. There is no recommended minimum interval between infection and vaccination, suggesting that the risk of SARS-CoV-2 reinfection is low in the months after initial infection but may increase with time due to waning immunity. Thus, **while vaccine supply remains limited**, persons with recent documented acute SARS-CoV-2 infection may choose to temporarily delay vaccination, if desired, recognizing that the risk of reinfection and, therefore, the need for vaccination, may increase with time following initial infection. 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. 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 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. When 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 COVID-19 vaccines on the breastfed infant or milk production/excretion.

Do you have dermal fillers?

Persons who have received dermal fillers may develop temporary swelling at or near the filler injection site, usually face or lips, after a

dose of an COVID-19 vaccine. Administer vaccines to persons with injectable dermal fillers who have no contraindications to vaccination. These persons should be advised to contact their healthcare provider if swelling develops at or near the site of dermal filler following vaccination.

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

In patients who experience post-vaccination symptoms, determining the etiology (including allergic reaction, vasovagal reaction, or vaccine side effects) is important to determine whether a person can receive additional doses of the vaccine (including the 2nd dose of an mRNA COVID-19 vaccine). 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 appropriate management.

Characteristic	Immediate allergic reactions (including anaphylaxis)	Vasovagal reactions	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			
If vaccinated with mRNA COVID-19 vaccine as first dose, recommended to receive second mRNA vaccine dose?	No	Yes	Yes

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