Centers for Disease Control and Prevention

Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States

Interim considerations: preparing for the potential management of anaphylaxis after COVID-19 vaccination

Summary of recent changes (last updated March 5, 2021):

- Public health recommendations for vaccinated people have been moved to: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/fully-vaccinated-guidance.html

Key points

The Advisory Committee on Immunization Practices (ACIP) has issued interim recommendations for the use of Pfizer-BioNTech, Moderna, and Janssen (Johnson & Johnson) COVID-19 vaccines for the prevention of coronavirus disease 2019 (COVID-19) in the United States. These clinical considerations provide additional information to healthcare providers and public health officials on use of COVID-19 vaccines.

Background

The Advisory Committee on Immunization Practices (ACIP) has issued interim recommendations for the use of Pfizer-BioNTech, Moderna, and Janssen (Johnson & Johnson) COVID-19 vaccines for the prevention of coronavirus disease 2019 (COVID-19) in the United States. The Pfizer-BioNTech and Moderna vaccines are lipid nanoparticle-formulated, nucleoside-modified mRNA vaccines encoding the prefusion spike glycoprotein of SARS-CoV-2, the virus that causes COVID-19. The Janssen vaccine is a recombinant replication-incompetent adenovirus type 26 (Ad26) vector encoding the stabilized prefusion spike glycoprotein of SARS-CoV-2. None of the currently authorized COVID-19 vaccines are live virus vaccines.

These interim CDC clinical considerations are informed by data submitted to the Food and Drug Administration (FDA) for Emergency Use Authorization (EUA) of the vaccines, other data sources, general best practice guidelines for immunization, and expert opinion. These considerations apply only to the vaccine products currently authorized in the United States (i.e., Pfizer-BioNTech, Moderna, and Janssen COVID-19 vaccines). Considerations will be updated when additional information becomes available or if additional vaccine products are authorized.

In addition to the following considerations, the EUA conditions of use and storage, handling, and administration procedures described in the prescribing information should be referenced when using the Pfizer-BioNTech, Moderna, and Janssen COVID-19 vaccines.

Authorized age groups

Under the EUAs, the following age groups are authorized to receive vaccination:

- Pfizer-BioNTech: ages ≥16 years
- Moderna: ages ≥18 years
- Janssen: ages ≥18 years

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

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Vaccine Administration

COVID-19 vaccines are administered intramuscularly as either a two-dose series or single dose.

Vaccine	Dose	Dose volume	Number doses/series	Interval between doses
Pfizer-BioNTech	30 µg	0.3 ml	2	3 weeks (21 days)
Moderna	100 µg	0.5 ml	2	1 month (28 days)
Janssen	5×10^{10} viral particles	0.5 ml	1	N/A

A single, valid vaccination series (i.e., either a two-dose mRNA COVID-19 vaccine series or a single dose of Janssen COVID-19 vaccine) should be administered. People are not recommended to receive more than one complete COVID-19 vaccination series.

Interval between mRNA doses

The second dose of Pfizer-BioNTech and Moderna vaccines should be administered as close to the recommended interval as possible, but not earlier than recommended (i.e., 3 weeks [Pfizer-BioNTech] or 1 month [Moderna]). However, second doses administered within a grace period of 4 days earlier than the recommended date for the second dose are still considered valid. If it is not feasible to adhere to the recommended interval and a delay in vaccination is unavoidable, the second dose of Pfizer-BioNTech and Moderna COVID-19 vaccines may be administered up to 6 weeks (42 days) after the first dose. Currently, only limited data are available on efficacy of mRNA COVID-19 vaccines administered beyond this window.

Information on preventing, reporting, and managing COVID-19 vaccine administration errors is found in Appendix A. Vaccine administration errors should be reported to the Vaccine Adverse Event Reporting System (VAERS).

Interchangeability of COVID-19 vaccine products

Any currently authorized COVID-19 vaccine can be used when indicated; ACIP does not state a product preference. However, COVID-19 vaccines are **not** interchangeable.

mRNA COVID-19 vaccines (Pfizer-BioNTech and Moderna)

The safety and efficacy of a mixed-product series have not been evaluated. Both doses of the series should be completed with the same product.

Strategies to ensure that patients receive the second dose with the appropriate product and interval between doses include:

- Providing COVID-19 vaccination record cards to vaccine recipients, asking recipients to bring their card to their appointment for the second dose, and encouraging recipients to make a backup copy (e.g., by taking a picture of the card with their phone)
- Encouraging vaccine recipients to enroll in **v-safe**, a free smartphone-based tool that uses text messaging and web surveys to provide personalized health check-ins as well as second-dose reminders
- Encouraging vaccine recipients to enroll in VaxText[SM], a free text-message-based platform that provides COVID-19 vaccination second-dose reminders
- Recording each recipient's vaccination in the immunization information system (IIS)
- Recording vaccine administration information in the patient's medical record
- Making an appointment for the second dose before the vaccine recipient leaves, to increase the likelihood that patients will present at the same vaccination site for the second dose

Using the above strategies, every effort should be made to determine which vaccine product was received as the first dose to ensure completion of the vaccine series with the same product. In exceptional situations in which the vaccine product given for the first dose cannot be determined or is no longer available, any available mRNA COVID-19 vaccine may be administered at a minimum interval of 28 days between doses to complete the mRNA COVID-19 vaccination series. In situations where the same mRNA vaccine product is temporarily unavailable, it is preferable to delay the 2nd dose (up to 6 weeks) to receive the same product than to receive a mixed series using a different product. 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.

The safety and efficacy of Janssen COVID-19 vaccine administered after an mRNA COVID-19 vaccine has not been established. However, in limited, exceptional situations where a patient received the first dose of an mRNA COVID-19 vaccine but is unable to complete the series with either the same or different mRNA COVID-19 vaccine (e.g., due to contraindication), a single dose of Janssen COVID-19 vaccine may be considered at a minimum interval of 28 days from the mRNA COVID-19 vaccine dose. See Contraindications and Precautions section for additional information on use of Janssen COVID-19 vaccine and additional precautions in people with a contraindication to mRNA COVID-19 vaccines. Patients who receive Janssen COVID-19 vaccine after a dose of an mRNA COVID-19 vaccine should be considered to have received a valid, single-dose Janssen vaccination—not a mixed vaccination series.

Coadministration with other vaccines

None of the currently authorized COVID-19 vaccines are live virus vaccines. Because data are lacking on the safety and efficacy of COVID-19 vaccines administered simultaneously with other vaccines, the vaccine series should routinely be administered alone, with a minimum interval of 14 days before or after administration of any other vaccine. However, COVID-19 and other vaccines may be administered within a shorter period in situations 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 to or delays in to COVID-19 vaccination (e.g., in long-term care facility residents or healthcare personnel who received influenza or other vaccinations before or upon admission or onboarding). If COVID-19 vaccines are administered within 14 days of another vaccine, doses do not need to be repeated for either vaccine.

Booster doses

The need for and timing for COVID-19 booster doses have not been established. No additional doses are recommended at this time.

COVID-19 vaccination and SARS-CoV-2 infection

People with prior or current SARS-CoV-2 infection

Data from clinical trials indicate that the currently authorized COVID-19 vaccines can be given safely to people with evidence of a prior SARS-CoV-2 infection. People should be offered vaccination regardless of history of prior symptomatic or asymptomatic SARS-CoV-2 infection. Viral testing to assess for acute SARS-CoV-2 infection or serologic testing to assess for prior infection is not recommended for the purposes of vaccine decision-making.

Vaccination of people 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 they have met criteria to discontinue isolation. This recommendation applies to people who experience SARS-CoV-2 infection before receiving any vaccine dose and those who experience SARS-CoV-2 infection after the first dose of an mRNA vaccine but before receipt of the second dose.

While there is no recommended minimum interval between infection and vaccination, current evidence suggests 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, people 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, might increase with time following initial infection.

People who previously received passive antibody therapy

Currently, there are no data on the safety and efficacy of COVID-19 vaccines in people who received monoclonal antibodies or convalescent plasma as part of COVID-19 treatment. Based on the estimated half-life of such therapies and evidence suggesting that reinfection is uncommon in the 90 days after initial infection, vaccination should be deferred for at least 90 days. This is a precautionary measure until additional information becomes available, to avoid potential interference of the antibody therapy with vaccine-induced immune responses. This recommendation applies to people who receive passive antibody therapy before receiving any vaccine dose and to those who receive passive antibody therapy after the first dose of an mRNA vaccine but before the second dose, in which case the second dose should be deferred for at least 90 days following receipt of the antibody therapy. Receipt of passive antibody therapy in the past 90 days is not a contraindication to receipt of COVID-19 vaccine. COVID-19 vaccine doses received within 90 days after receipt of passive antibody therapy do not need to be repeated.

For people receiving antibody therapies not specific to COVID-19 treatment (e.g., intravenous immunoglobulin, RhoGAM), administration of COVID-19 vaccines either simultaneously with or at any interval before or after receipt of an antibody-containing product is unlikely to substantially impair development of a protective antibody response. Thus, there is no recommended minimum interval between antibody therapies not specific to COVID-19 treatment and COVID-19 vaccination.

Vaccinated people who subsequently develop COVID-19

For vaccinated people who subsequently experience COVID-19, prior receipt of a COVID-19 vaccine should not affect treatment decisions (including use of monoclonal antibodies, convalescent plasma, antiviral treatment, or corticosteroid administration) or timing of such treatments.

If a person is fully vaccinated (i.e., ≥2 weeks after completion of a two-dose mRNA series or single dose of Janssen vaccine) and tests positive for SARS-CoV-2, healthcare providers and local health departments are encouraged to request the specimen be held and to report the case to their state health department. CDC will work with the state health department to collect information about the case. In addition, information about these cases should be reported to VAERS.

Vaccinating people with a known COVID-19 exposure or during COVID-19 outbreaks

COVID-19 vaccines are not currently recommended for outbreak management or for post-exposure prophylaxis to prevent SARS-CoV-2 infection in a person with a known exposure. Because the median incubation period of COVID-19 is 4–5 days, it is unlikely that a dose of COVID-19 vaccine would provide an adequate immune response within the incubation period for effective post-exposure prophylaxis.

People in the community or in outpatient settings who have had a known COVID-19 exposure should not seek vaccination until their quarantine period has ended to avoid potentially exposing healthcare personnel and others during the vaccination visit. This recommendation also applies to people with a known COVID-19 exposure before receipt of the second mRNA vaccine dose.

Residents or patients with a known COVID-19 exposure in congregate healthcare settings (e.g., long-term care facilities) or congregate non-healthcare settings (e.g., correctional and detention facilities, homeless shelters) may be vaccinated. In these settings, exposure to and transmission of SARS-CoV-2 can occur repeatedly for long periods of time, and healthcare personnel and other staff are already in close contact with residents. People residing in congregate settings (healthcare and non-healthcare) who have had an exposure and are awaiting SARS-CoV-2 testing results may be vaccinated if they do not have symptoms consistent with COVID-19. Vaccinators should employ appropriate infection prevention and control procedures.

Considerations for vaccination of people with certain underlying medical conditions

Any currently authorized COVID-19 vaccine can be administered to people with underlying medical conditions who have no contraindications to vaccination; ACIP does not state a product preference. Clinical trials demonstrated similar safety and efficacy profiles in people with some underlying medical conditions, including those that place them at increased risk for severe COVID-19, compared to people without comorbidities. Additional information for people with specific underlying medical conditions is included below.

Immunocompromised people

Immunocompromised people

People with HIV infection or other immunocompromising conditions or people who take immunosuppressive medications or therapies might be at increased risk for severe COVID-19. No data are available to establish COVID-19 vaccine safety and efficacy in these groups. However, the currently authorized COVID-19 vaccines are not live vaccines and therefore can be safely administered to immunocompromised people. People with stable HIV infection were included in the COVID-19 vaccine clinical trials, though data remain limited.

Immunocompromised people can receive COVID-19 vaccination. Data are currently insufficient to inform optimal timing of COVID-19 vaccination among people who are planning to receive immunosuppressive therapies. However, based on general best practices for vaccination of immunocompromised people, ideally COVID-19 vaccination should be completed at least two weeks before initiation of immunosuppressive therapies. When it is not possible to administer a complete COVID-19 vaccine series (i.e., two doses of an mRNA vaccine or a single dose of Janssen COVID-19 vaccine) in advance, people on immunosuppressive therapy can still receive COVID-19 vaccination. Decisions to delay immunosuppressive therapy to complete COVID-19 vaccination should consider the person's risks related to their underlying condition.

Antibody testing is not recommended to assess for immunity to SARS-CoV-2 following COVID-19 vaccination. At this time, revaccination is not recommended after people who received COVID-19 vaccines during chemotherapy or treatment with other immunosuppressive drugs regain immune competence. Recommendations on re-vaccination or additional doses of COVID-19 vaccines may be updated when additional information is available.

People should be counseled about the unknown vaccine safety profile and effectiveness in immunocompromised populations, the potential for reduced immune responses, and the need to continue to follow current guidance to protect themselves against COVID-19.

People with autoimmune conditions

No data are available on the safety and efficacy of COVID-19 vaccines in people with autoimmune conditions, though these people were eligible for enrollment in mRNA COVID-19 vaccine clinical trials. No imbalances were observed in the occurrence of symptoms consistent with autoimmune conditions or inflammatory disorders in clinical trial participants who received COVID-19 vaccine compared to placebo. People with autoimmune conditions may receive any authorized COVID-19 vaccine.

People with a history of Guillain-Barré syndrome

No cases of Guillain-Barré syndrome (GBS) were reported following vaccination among participants in the mRNA COVID-19 vaccine clinical trials. One case of GBS was reported in a participant in the vaccine group in the Janssen COVID-19 vaccine clinical trial, compared to one GBS case among those who received placebo. With few exceptions, ACIP's general best practice guidelines for immunization do not include history of GBS as a contraindication or precaution to vaccination. People with a history of GBS may receive COVID-19 vaccination. Any occurrence of GBS following COVID-19 vaccination should be reported to VAERS.

People with a history of Bell's palsy

Cases of Bell's palsy were reported following vaccination of participants in the COVID-19 vaccine clinical trials. However, the FDA does not consider these to be above the frequency expected in the general population and has not concluded that these cases were causally related to vaccination. Post-authorization safety surveillance will be important to further assess any possible causal association. In the absence of such evidence, people with a history of Bell's palsy can receive a COVID-19 vaccine. Any occurrence of Bell's palsy following COVID-19 vaccination should be reported to VAERS.

People with a history of dermal filler use

Infrequently, people who have received dermal fillers might experience swelling at or near the site of filler injection (usually face or lips) following administration of a dose of an mRNA COVID-19 vaccine (no similar occurrences were observed in the Janssen COVID-19 vaccine clinical trials). The swelling appears to be temporary and resolves with medical treatment, including corticosteroid therapy. COVID-19 vaccines can be administered to people who have received injectable dermal fillers who have no contraindications or precautions for vaccination. However, these people should be advised to contact their healthcare provider for evaluation if they experience swelling at or near a dermal filler site following vaccination.

Vaccination of pregnant or lactating people

Any of the currently authorized COVID-19 vaccines can be administered to pregnant or lactating people; ACIP does not state a product preference.

Pregnant people

Observational data demonstrate that pregnant people with COVID-19 have an increased risk of severe illness, including illness resulting in intensive care admission, mechanical ventilation, extracorporeal membrane oxygenation, or death, though the absolute risk for these outcomes is low. Additionally, they might be at an increased risk of adverse pregnancy outcomes, such as preeclampsia, coagulopathy, and preterm birth.

Data on the safety of COVID-19 vaccines in pregnant people are limited. No female reproduction or fetal, embryonal, or postnatal development safety concerns were demonstrated in animals that received Pfizer-BioNTech, Moderna, or Janssen COVID-19 vaccines before or during gestation. In addition, the adenovirus vector platform used in the Janssen COVID-19 vaccine has also been used for other Janssen vaccine development programs that have included pregnant people vaccinated during any trimester, including in a large-scale Ebola vaccination trial. No adverse pregnancy-related outcomes—including infant outcomes—were determined to be related to the vaccine in these trials.

Based on current knowledge, experts believe that COVID-19 vaccines are unlikely to pose a risk to the pregnant person or fetus because the currently authorized COVID-19 vaccines are non-replicating vaccines and cannot cause infection in either the mother or the fetus. No evidence exists of risk to the fetus from vaccinating pregnant women with non-replicating vaccines in general. However, the potential risks of COVID-19 vaccines to the pregnant person and the fetus are unknown because these vaccines have not been studied in pregnant people. Clinical trials to evaluate the safety and efficacy of COVID-19 vaccines in pregnant people are underway or planned. Vaccine manufacturers are also following outcomes in people in the clinical trials who became pregnant.

Pregnant people may choose to receive a COVID-19 vaccine. A conversation between the patient and their clinical team may assist with decisions about the use of a COVID-19 vaccine, though a conversation with a healthcare provider is not required before vaccination. 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 limited data about the vaccine during pregnancy. Pregnant people who choose to receive COVID-19 vaccine are encouraged to enroll in v-safe. A **v-safe** pregnancy registry has been established to follow outcomes among pregnant people who are vaccinated. Based on self-reported information, no specific safety signals have been observed among pregnant vaccine recipients included in the **v-safe** registry. However longitudinal follow-up is needed to fully evaluate pregnancy and birth outcomes.

Side effects can occur with COVID-19 vaccine use in pregnant people, similar to those expected among non-pregnant people. Acetaminophen can be offered as an option for pregnant people experiencing fever (which has been associated with adverse pregnancy outcomes) or other post-vaccination symptoms.

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 is no evidence that any of the COVID-19 vaccines affect future fertility.

Lactating people

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 or excretion. Because non-live vaccines pose no risk for lactating people or their infants, COVID-19 vaccines are also not thought to be a risk. Therefore, lactating people may choose to be vaccinated.

Vaccination of children and adolescents

Adolescents aged 16–17 years are included among people eligible to receive the Pfizer-BioNTech COVID-19 vaccine under the EUA. While vaccine safety and efficacy data in this age group are limited, there are no biologically plausible reasons for safety and efficacy profiles to differ from those observed in people 18 years of age and older. Adolescents aged 16–17 years who are part of a group recommended to receive a COVID-19 vaccine may be vaccinated with the Pfizer-BioNTech COVID-19 vaccine with appropriate assent. Children and adolescents younger than 16 years of age are not authorized to receive the Pfizer-BioNTech COVID-19 vaccine at this time.

Children and adolescents younger than 18 years of age are not authorized to receive the Moderna or Janssen COVID-19 vaccines at this time.

Patient counseling

mRNA COVID-19 vaccines (Pfizer-BioNTech and Moderna)

Preliminary data suggest high vaccine efficacy in preventing COVID-19 following receipt of two doses of mRNA COVID-19 vaccine (Pfizer-BioNTech: 95.0% [95% CI: 90.3%, 97.6%]; Moderna: 94.1% [95% CI: 89.3%, 96.8%]). Patients should be counseled on the importance of completing the two-dose series with the same vaccine product to optimize protection.

Before vaccination, providers should counsel mRNA COVID-19 vaccine recipients about expected local (e.g., pain, swelling, erythema at the injection site, localized axillary lymphadenopathy on the same side as the vaccinated arm) and systemic (e.g., fever, fatigue, headache, chills, myalgia, arthralgia) post-vaccination symptoms. Depending on vaccine product (Pfizer-BioNTech vs. Moderna), age group, and vaccine dose, approximately 80–89% of vaccinated people experience at least one local symptom and 55–83% experience at least one systemic symptom following vaccination.

Most systemic post-vaccination symptoms are mild to moderate in severity, occur within the first three days of vaccination, and resolve within 1–3 days of onset. Overall, symptoms are more frequent and severe following the second dose and among younger people compared with older people (i.e., aged >55 or ≥65 years [for Pfizer-BioNTech or Moderna vaccines, respectively]). People with prior SARS-CoV-2 infection may be more likely to experience symptoms such as fever, chills, and myalgia after the first mRNA COVID-19 vaccine dose. Unless people have a contraindication to vaccination, they should be encouraged to complete the series to optimize protection against COVID-19 even if they experience local or systemic symptoms following the first dose.

Viral vector COVID-19 vaccine (Janssen)

Preliminary data suggest an overall efficacy of 66.3% (95% CI: 59.9%, 71.8%) against symptomatic, laboratory-confirmed COVID-19 from ≥14 days after vaccination with Janssen COVID-19 vaccine. Vaccine efficacy for the prevention of COVID-19-associated hospitalization was high; vaccine efficacy against hospitalization ≥14 days after vaccination was 93.1% (95% CI: 71.1%, 98.4%). No COVID-19–associated hospitalizations occurred ≥28 days after vaccination in the vaccine group, and 16 occurred in the placebo group (vaccine efficacy = 100%; 95% CI = 74.3%–100.0%). Vaccine efficacy against all-cause death was 75.0% (95% CI: 33.4%, 90.6%).

Before vaccination, providers should counsel Janssen COVID-19 vaccine recipients about expected local (e.g., pain, swelling, erythema at the injection site) and systemic (e.g., fever, fatigue, headache, chills, myalgia, arthralgia) post-vaccination symptoms. Fifty percent of vaccinated people experience at least one local symptom, with pain at the injection site most common, and approximately 55% experience at least one systemic symptom following vaccination. Most systemic post-vaccination symptoms are mild in severity and resolve within 1–2 days after vaccination. Overall, symptoms were more frequent in younger people than older people (aged ≥60 years).

Management of post-COVID-19-vaccination symptoms

For all currently authorized COVID-19 vaccines, antipyretic or analgesic medications (e.g., acetaminophen, non-steroidal anti-inflammatory drugs) can be taken for the treatment of post-vaccination local or systemic symptoms, if medically appropriate. However, routine prophylactic administration of these medications for the purpose of preventing post-vaccination symptoms is not currently recommended, because information on the impact of such use on COVID-19 vaccine-induced antibody responses is not yet available.

Anaphylactic reactions have been rarely reported following receipt of COVID-19 vaccines. Administration of antihistamines to COVID-19 vaccine recipients before vaccination to prevent allergic reactions is not recommended. Antihistamines do not prevent anaphylaxis, and their use might mask cutaneous symptoms, which could lead to a delay in the diagnosis and management of anaphylaxis. See section on contraindications and precautions to vaccination and interim considerations for anaphylaxis management for more information on management of anaphylaxis.

Infection prevention and control considerations are available for healthcare personnel and long-term care facility residents with systemic signs and symptoms following COVID-19 vaccination.

Contraindications and precautions

Contraindications and precautions to COVID-19 vaccines are described below and summarized in Appendix B. For the purposes of this guidance, an immediate allergic reaction to a vaccine or medication is defined as any hypersensitivity-related signs or symptoms such as urticaria, angioedema, respiratory distress (e.g., wheezing, stridor), or anaphylaxis that occur within four hours following administration.

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

Contraindications

CDC considers a history of the following to be a contraindication to vaccination with COVID-19 vaccines:

- Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of the COVID-19 vaccine
- Immediate allergic reaction of any severity to a previous dose or known (diagnosed) allergy to a component of the vaccine

See Appendix C for a list of ingredients in COVID-19 vaccines. 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. People 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). However, people with a contraindication to mRNA COVID-19 vaccines may be able to receive Janssen COVID-19 vaccine, and vice versa, provided certain measures are taken (see “precautions” below). As a change from previous versions of the guidance, known polysorbate allergy is no longer a contraindication to mRNA vaccination; however, known polysorbate allergy is a contraindication to Janssen COVID-19 vaccine and thus, a precaution to mRNA COVID-19 vaccination.

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 a vasovagal reaction or post-vaccination side effects (Appendix D). This will help determine which patients have a contraindication to vaccination, including to the second dose of an mRNA COVID-19 vaccine.

Precautions

CDC considers a history of an immediate allergic reaction to any other vaccine or injectable therapy (i.e., intramuscular, intravenous, or subcutaneous vaccines or therapies [excluding subcutaneous immunotherapy for allergies, i.e., “allergy shots”]) as a precaution but not a contraindication to vaccination. People 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.

People with a contraindication to one type of the currently authorized COVID-19 vaccines (e.g., mRNA) have a precaution to the other (e.g., Janssen viral vector). However, because of potential cross-reactive hypersensitivity between ingredients in mRNA and Janssen COVID-19 vaccines, consultation with an allergist-immunologist should be considered to help determine if the patient can safely receive vaccination. Healthcare providers and health departments may also request a consultation from the Clinical Immunization Safety Assessment COVIDvax project. Vaccination of these individuals should only be undertaken in an appropriate setting under the supervision of a health care provider experienced in the management of severe allergic reactions.

- People with a contraindication to mRNA COVID-19 vaccines (including due to a known PEG allergy): Consideration may be given to vaccination with Janssen COVID-19 vaccine. People who have received one mRNA COVID-19 vaccine dose but for whom the second dose is contraindicated should wait at least 28 days after the mRNA vaccine dose to receive Janssen COVID-19 vaccine.
- People with a contraindication to Janssen COVID-19 vaccine (including due to a known polysorbate allergy): Consideration may be given to mRNA COVID-19 vaccination. Of note, polysorbate allergy is no longer a contraindication to mRNA COVID-19 vaccination, it is a precaution.

The following considerations can be used to help the provider conduct a risk assessment for vaccination in individuals with a precaution to vaccination:

- Risk of exposure to SARS-CoV-2 (e.g., because of residence in a congregate setting such as a long-term care facility, occupation)
- Risk of severe disease or death due to COVID-19 (e.g., because of age, underlying medical conditions)
- The unknown risk of anaphylaxis (including fatal anaphylaxis) following COVID-19 vaccination in a person with a history of an immediate allergic reaction to other vaccines or injectable therapies
- Ability of the patient to be vaccinated in a setting where appropriate medical care is immediately available for anaphylaxis. Note, for people with a contraindication to another type of COVID-19 vaccines (e.g., mRNA vaccines), vaccination with another type (e.g., Janssen viral vector vaccine) should only be undertaken in an appropriate setting under the supervision of a health care provider experienced in the management of severe allergic reactions.

Neither contraindications nor precautions to COVID-19 vaccination

Allergic reactions (including severe allergic reactions) not related to vaccines (COVID-19 or other vaccines) or injectable therapies, such as allergic reactions related to food, pet, venom, or environmental allergies, or allergies to oral medications (including the oral equivalents of injectable medications), are **not** a contraindication or precaution to COVID-19 vaccination.

The vial stoppers of COVID-19 vaccines are not made with natural rubber latex, and there is no contraindication or precaution to vaccination for people with a latex allergy. In addition, because the COVID-19 vaccines do not contain eggs or gelatin, people with allergies to these substances do not have a contraindication or precaution to vaccination.

Delayed-onset local reactions have been reported after mRNA vaccination in some individuals beginning a few days through the second week after the first dose and are sometimes quite large. People with only a delayed-onset local reaction (e.g., erythema, induration, pruritus) around the injection site area after the first vaccine dose do not have a contraindication or precaution to the second dose. These individuals should receive the second dose using the same vaccine product as the first dose at the recommended interval, preferably in the opposite arm.

Observation periods following vaccination

CDC recommends the following observation periods after 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 people

Management of anaphylaxis after COVID-19 vaccination

Appropriate medical treatment used to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of COVID-19 vaccine. Further information on anaphylaxis management can be found in the interim considerations for the management of anaphylaxis following COVID-19 vaccination and laboratory evaluation of people who experience anaphylaxis after vaccination.

Reporting of vaccine adverse events

Adverse events that occur in a recipient following COVID-19 vaccination should be reported to VAERS. Vaccination providers are required by the FDA to report the following that occur after COVID-19 vaccination under EUA:

- Vaccine administration errors
- Serious adverse events
- Cases of Multisystem Inflammatory Syndrome
- Cases of COVID-19 that result in hospitalization or death

Reporting is encouraged for any other clinically significant adverse event, even if it is uncertain whether the vaccine caused the event. Information on how to submit a report to VAERS is available at https://vaers.hhs.gov or by calling 1-800-822-7967.

In addition, CDC has developed a new voluntary, smartphone-based tool, **v-safe**. This tool uses text messaging and web surveys to provide near real-time health check-ins after patients receive COVID-19 vaccination. Reports to **v-safe** indicating a medically significant health impact, including pregnancy, are followed up by the CDC/**v-safe** call center to collect additional information to complete a VAERS report, if appropriate.

Laboratory testing

Interpretation of SARS-CoV-2 test results in vaccinated people

Prior receipt of a COVID-19 vaccine will not affect the results of SARS-CoV-2 viral tests (nucleic acid amplification or antigen tests). Currently available antibody tests for SARS-CoV-2 assess IgM and/or IgG to one of two viral proteins: spike or nucleocapsid. Because COVID-19 vaccines are constructed to encode the spike protein, a positive test for spike protein IgM/IgG could indicate prior infection and/or vaccination. To evaluate for evidence of prior infection in an individual with a history of COVID-19 vaccination, a test that specifically evaluates IgM/IgG to the nucleocapsid protein should be used.

Antibody testing is not currently recommended to assess for immunity to SARS-CoV-2 following COVID-19 vaccination because the clinical utility of post-vaccination testing has not been established. Antibody tests currently authorized under an EUA have variable sensitivity, specificity, as well as positive and negative predictive values, and are not authorized for the assessment of immune response in vaccinated people. Furthermore, the serologic correlates of protection have not been established, and antibody testing does not evaluate the cellular immune response, which may also play a role in vaccine-mediated protection. Finally, antibody testing against nucleocapsid will not detect immune responses resulting from vaccination, but patients may not always know what type of antibody test was used. If antibody testing was performed following vaccination, additional doses of the same or different COVID-19 vaccines are not recommended based on antibody test results at this time. If antibody testing was done after the first dose of an mRNA vaccine, the vaccination series should be completed regardless of the antibody test result.

Use of immune-based tests for tuberculosis infection, such as the tuberculin skin test and interferon-gamma release assay

COVID-19 vaccines should not be delayed because of testing for TB infection. Testing for TB infection with one of the immune-based methods, either the tuberculin skin test (TST) or an interferon release assay (IGRA), can be done before or during the same encounter as COVID-19 vaccination. When testing with TST or IGRA cannot be done at the same time as COVID-19 vaccination, these tests should be delayed ≥4 weeks after the completion of COVID-19 vaccination but generally should not be cancelled.

Patients who have active TB disease or an illness that is being evaluated as active TB disease can receive a COVID-19 vaccine (note: the presence of a moderate or severe acute illness is a precaution to administration of all vaccines). Whereas a TST or IGRA test is part of a comprehensive evaluation for TB disease, positive TST or IGRA results are not required to diagnose active TB disease.
When considering a tuberculin skin test or interferon-gamma release assay:

- The TST is not expected to have an effect on the safety or the effectiveness of COVID-19 vaccine. IGRAs are blood tests and, thus, do not affect vaccine safety or effectiveness.
- The reliability of a positive TST or IGRA result after COVID-19 vaccination is expected to be the same as without the vaccination. COVID-19 vaccination is not expected to cause false positive results from a TB test that is done at the same encounter as or after COVID-19 vaccination.
- The reliability of a negative TST or IGRA result after COVID-19 vaccination has not been studied.
- The TST is not a vaccine. The guidance for separating other vaccines from COVID-19 vaccination by at least 2 weeks in time does not apply to the TST because the TST is not a vaccine.

When a tuberculin skin test or interferon gamma release assay is required by policy:

- A TST or IGRA to meet administrative requirements (for example, for healthcare employment or for admission to long-term care) can be done prior to COVID-19 vaccination or at the same encounter. COVID-19 vaccination should not be delayed because of testing for TB infection

delayed because of testing for TB infection.

- A TST or IGRA should be deferred until ≥4 weeks after the completion of COVID-19 vaccination. If testing requirements or policies cannot be modified for the COVID-19 pandemic to accept this delay in TST or IGRA testing, it should be understood that a false negative TST or IGRA cannot be excluded, and consideration should be given to repeating negative TST or IGRA tests at least 4 weeks after the completion of COVID-19 vaccination. If TST was the initial test, boosting could be a factor if the result of the repeat test is positive.

When a tuberculin skin test or interferon gamma release assay is indicated for medical care:

- The decision whether a TST or IGRA that is being done for medical diagnosis of latent TB infection (for example, during a contact investigation after exposure to contagious TB disease) should be delayed for 4 weeks after completion of COVID-19 vaccination is at the discretion of the responsible medical provider and local tuberculosis program overseeing the contact investigation. Medical providers and local tuberculosis programs may not wish to delay testing for people at high risk for progression to TB disease. However, patients who have a negative result in this context should be considered for retesting ≥4 weeks after the completion of COVID-19 vaccination.
- Patients who have symptoms or diagnostic findings consistent with active TB disease should receive further medical evaluation—for example with chest radiography and sputum bacteriology for *Mycobacterium tuberculosis*—regardless of TST or IGRA results.

Appendix A. Vaccine administration errors and deviations

A vaccine administration error is any preventable event that may cause or lead to inappropriate use of vaccine or patient harm. This appendix provides resources for preventing and reporting COVID-19 vaccine administration errors, as well as actions to take after an error has occurred. For completeness, this includes additional scenarios that deviate from CDC recommendations for vaccine intervals but are not considered administration errors. This document is intended to assist providers with handling exceptional situations in which a vaccination error or deviation has already occurred and may be updated when additional information becomes available.

The FDA-issued Emergency Use Authorization and Fact Sheet for Healthcare Providers Administering Vaccines should be referenced for detailed information on storage and handling, dosing and schedule, dose preparation, and administration of COVID-19 vaccines. The information provided below on managing vaccine administration errors should not be interpreted as a recommendation or promotion of unauthorized use of the vaccines.

For all vaccine administration errors:

- Inform the recipient of the vaccine administration error.
- Consult with the state immunization program and/or immunization information system (IIS) to determine how the dose should be entered into the IIS, both as an administered dose and to account for inventory.
- Report the error to the Vaccine Adverse Event Reporting System (VAERS), unless otherwise indicated in the table. Providers are required to report all COVID-19 vaccine administration errors—even those not associated with an adverse event—to VAERS. To file an electronic report, please see the VAERS website .
- Determine how the error occurred and implement strategies to prevent it from happening again. A discussion on strategies to prevent errors can be found in the "Vaccine Administration" chapter of *Epidemiology and Prevention of Vaccine-Preventable Diseases* (Pink Book). Additional resources can be found on CDC's vaccine administration web page, including a job aid for preventing errors.

Table. Interim recommendations for COVID-19 vaccine administration errors and deviations

Vaccines	Type	Administration error/deviation	Interim recommendation
All currently authorized vaccines	Site/route	• Incorrect site (i.e., site other than the deltoid muscle [preferred site] or anterolateral thigh [alternate site])	• Do **not** repeat dose.* Inform the recipient of the potential for local and systemic adverse events.

Vaccines	Type	Administration error/deviation	Interim recommendation
(Pfizer-BioNTech Moderna, and Janssen COVID-19 vaccines)			
		• Incorrect route (e.g., subcutaneous)	• Do **not** repeat dose.[*] Inform the recipient of the potential for local and systemic adverse events.
	Age	• Unauthorized age group	• If received dose at age less than 16 years, do not give any additional dose at this time.[∞] • If age 16 to 17 years and a vaccine other than Pfizer-BioNTech was inadvertently administered: ◦ If Moderna vaccine administered as the first dose, may administer Moderna vaccine as the second dose (as off-label use, because Moderna vaccine is not authorized in this age group). ◦ If Janssen vaccine administered, do **not** repeat dose with Pfizer-BioNTech vaccine.
	Dosage	• Higher-than-authorized dose volume administered	• Do **not** repeat dose.[*†]
		• Lower-than-authorized dose volume administered (e.g., leaked out, equipment failure, recipient pulled away)	• If more than half of the dose was administered, do **not** repeat dose.[*] • If less than half of the dose was administered or the proportion of the dose cannot be estimated, administer the authorized dose immediately (no minimum interval) in the opposite arm.[#]
	Storage and handling	• Dose administered after improper storage and handling (e.g., temperature excursion, more than allowed time after first vial puncture)	• Contact the manufacturer for guidance. If the manufacturer provides information supporting that the dose should be repeated, the repeated dose may be given immediately (no minimum interval) in the opposite arm.
		• Dose administered past the expiration/beyond-use date	• Contact the manufacturer for guidance. If the manufacturer provides information supporting that the dose should be repeated, the repeated dose may be given immediately (no minimum interval) in the opposite arm.
	Coadministration	• Dose administered within 14 days before or after another (i.e., non-COVID-19) vaccine	• Do **not** repeat COVID-19 vaccine[*] or other vaccine(s) doses. This deviation from CDC guidance does **not** require VAERS reporting.
		• Dose administered within 90 days of monoclonal antibodies or convalescent plasma for COVID-19 treatment	• Do **not** repeat COVID-19 vaccine dose. If person has already received one mRNA COVID-19 vaccine dose, defer administration of second dose for 90 days following receipt of antibody therapy. This deviation from CDC guidance does **not** require VAERS reporting.

Vaccines	Type	Administration error/deviation	Interim recommendation
mRNA vaccines only (Pfizer-BioNTech and Moderna)	Intervals	• Second dose administered fewer than 17 days (Pfizer-BioNTech) or fewer than 24 days (Moderna) after the first dose (i.e., administered earlier than the 4-day grace period)	• Do **not** repeat dose.
		• Second dose administered more than 42 days after the first dose	• Do **not** repeat dose. This deviation from CDC guidance does **not** require VAERS reporting.
	Mixed series	• Incorrect mRNA COVID-19 vaccine product administered for second dose in 2-dose series	• Do **not** repeat dose. [§]
Pfizer-BioNTech only	Diluent	• ONLY diluent administered (i.e., sterile 0.9% sodium chloride)	• Inform the recipient that no vaccine was administered. Administer the authorized dose immediately (no minimum interval) in the opposite arm.[#]
		• No diluent, resulting in higher than authorized dose (i.e., 0.3 ml of undiluted vaccine administered)	• Do **not** repeat dose[*†] Inform the recipient of the potential for local and systemic adverse events.
		• Incorrect diluent type (e.g., sterile water, bacteriostatic 0.9% NS)	• Contact the manufacturer for guidance. If the manufacturer provides information supporting that the dose should be repeated, the repeated dose may be given immediately (no minimum interval) in the opposite arm.
		• Incorrect diluent volume (i.e., the vial contents were diluted with a diluent volume other than 1.8 ml, but a 0.3 ml dose was still administered)	• For doses administered with diluent volume less than 1.8 ml, inform the recipient of the potential for local and systemic adverse events.[*†] • For doses administered with diluent volume greater than 1.8 ml, do **not** repeat dose.[*] (Note: Dilution with a volume up to 4.0 ml [which exceeds vial capacity] results in more-than-half of the authorized dose administered.)

Pfizer-BioNTech and Moderna vaccines only:
*If the dose given in error is the first dose, a second dose should be administered at the recommended interval (21 days [Pfizer-BioNTech] or 28 days [Moderna]). If this dose is the second dose, the series is complete, and no additional doses are needed.
∞Do not administer the second dose until the person becomes eligible to receive vaccination (either by reaching the authorized age or if the authorization is extended to include additional age groups), even if this results in the second dose being administered after the recommended interval between doses.
#If the dose given in error is the first dose, the second dose should be administered at the recommended interval (21 days [Pfizer-BioNTech] or 28 days [Moderna]) from the date of receipt of the valid dose (not the date of receipt of the erroneous

dose).
†If the administration error resulted in a higher-than-authorized vaccine dose, in general the second dose may still be administered at the recommended interval. However, if local or systemic side effects following vaccination are clinically concerning (outside of the expected side effect profile), lead to serious adverse reactions, or are ongoing at the time of the second dose, the decision to administer the second dose may be assessed on a case-by-case basis.
§Although CDC provides considerations for a mixed series in exceptional circumstances, this is still considered an administration error that requires VAERS reporting (as a mixed series is not authorized under the vaccine Emergency Use Authorizations).

Appendix B: Triage of people presenting for COVID-19 vaccination

CONTRAINDICATION TO VACCINATION	PRECAUTION TO VACCINATION	MAY PROCEED WITH VACCINATION
History of the following: • Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to component of the vaccine† • Immediate allergic reaction* of any severity after a previous dose or known (diagnosed) allergy to a component of the vaccine†	**Among people without a contraindication, a history of:** • Any immediate allergic reaction* to other vaccines or injectable therapies‡ Note: people with a contraindication to mRNA COVID-19 vaccines have a precaution to Janssen COVID-19 vaccine, and vice versa. See footnote for additional information on additional measures to take in these people.#	**Among people without a contraindication or precaution, a history of:** • Allergy to oral medications (including the oral equivalent of an injectable medication) • History of food, pet, insect, venom, environmental, latex, etc., allergies • Family history of allergies
Actions: • Do not vaccinate. • Consider referral to allergist-immunologist. • Consider other vaccine alternative.†	**Actions:** • Risk assessment • Consider referral to allergist-immunologist • 30-minute observation period if vaccinated	**Actions:** • 30-minute observation period: people with history of anaphylaxis (due to any cause) • 15-minute observation period: all other people

† See Appendix C for a list of ingredients. People 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).
* Immediate allergic reaction to a vaccine or medication is defined as any hypersensitivity-related signs or symptoms consistent with urticaria, angioedema, respiratory distress (e.g., wheezing, stridor), or anaphylaxis that occur within four hours following administration.
‡Includes people 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.
#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. People with a contraindication to mRNA COVID-19 vaccines (including due to a known allergy to PEG) have a precaution to Janssen COVID-19 vaccine. Among people who received one mRNA COVID-19 dose but for whom the second dose is contraindicated, consideration may be given to vaccination with Janssen COVID-19 vaccine (administered at least 28 days after the mRNA COVID-19 dose). People with a contraindication to Janssen COVID-19 vaccine (including due to a known allergy to polysorbate) have a precaution to mRNA COVID-19 vaccines. For people with these precautions, referral to an allergist-immunologist should be considered. Healthcare providers and health departments may also request a consultation from the Clinical Immunization Safety Assessment COVIDvax project. In patients with these precautions, vaccination should only be undertaken in an appropriate setting under the supervision of a health care provider experienced in the management of severe allergic reactions.

Appendix C: Ingredients included in COVID-19 vaccines

The following is a list of ingredients for the Pfizer-BioNTech , Moderna , and Janssen COVID-19 vaccines reported in the prescribing information for each vaccine.

Description	Pfizer-BioNTech (mRNA)	Moderna (mRNA)	Janssen (viral vector)
Active ingredient	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	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
	Cholesterol	Cholesterol	Citric acid monohydrate
	(4-hydroxybutyl)azanediyl)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	

* None of the vaccines contain eggs, gelatin, latex, or preservatives.
Note: Both the Pfizer-BioNTech and Moderna COVID-19 vaccines contain polyethylene glycol (PEG). PEG is a primary ingredient in osmotic laxatives and oral bowel preparations for colonoscopy procedures, an inactive ingredient or excipient in many medications, and is used in a process called “pegylation” to improve the therapeutic activity of some medications (including certain chemotherapeutics). Additionally, cross-reactive hypersensitivity between PEG and polysorbates (included as an excipient in some vaccines and other therapeutic agents) can occur. Information on active or inactive ingredients for vaccines and medications can be found in the package insert. CDC’s vaccine excipient summary and the National Institutes of Health DailyMed database can also be used as a resource.

Appendix D: 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 second dose of an mRNA COVID-19 vaccine). The following table of signs and symptoms is meant to serve as a resource but might not be exhaustive, and patients might not have all signs or symptoms. Providers should use their clinical judgement when assessing patients to determine the diagnosis and management.

Characteristic	Allergic reactions (including anaphylaxis)	Vasovagal reaction	Vaccine side effects (local and systemic)

Characteristic	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 the 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, might have an elevated respiratory rate	N/A
Cardiovascular	Hypotension, tachycardia	Variable; might have hypotension or bradycardia during syncopal event	N/A
Gastrointestinal	Nausea, vomiting, abdominal cramps, diarrhea	Nausea, vomiting	Vomiting or diarrhea might occur
Musculoskeletal	N/A	N/A	Myalgia, arthralgia
Vaccine and clinical management recommendations			
If vaccinated with mRNA COVID-19 vaccine as first dose, recommended to receive second mRNA vaccine dose?	No	Yes	Yes

References:

- The Advisory Committee on Immunization Practices' Interim Recommendation for Use of Pfizer-BioNTech COVID-19 Vaccine — United States, December 2020

- The Advisory Committee on Immunization Practices' Interim Recommendation for Use of Moderna COVID-19 Vaccine — United States, December 2020
- The Advisory Committee on Immunization Practices' Interim Recommendation for Use of Janssen COVID-19 Vaccine — United States, February 2021
- Pfizer-BioNTech COVID-19 Vaccine EUA Fact Sheet for Healthcare Providers (fda.gov)
- Moderna COVID-19 Vaccine EUA Fact Sheet for Healthcare Providers (fda.gov)
- Janssen COVID-19 Vaccine EUA Fact Sheet for Healthcare Providers (fda.gov)
- ACIP General Best Practice Guidelines for Immunization
- Interim considerations: preparing for the potential management of anaphylaxis after COVID-19 vaccination

Previous Updates:

March 3, 2021:

- Clinical considerations added for use of Janssen (Johnson & Johnson) COVID-19 vaccine.
- Updated recommendations for fully vaccinated people who subsequently develop COVID-19.
- Updated recommendations related to COVID-19 vaccination timing for immunocompromised people.
- Updated contraindications and precautions to mRNA COVID-19 vaccines.
- Updated information on interpretation of SARS-CoV-2 antibody test results after vaccination.

February 10, 2021:

- New recommendations for preventing, reporting, and managing mRNA COVID-19 vaccine administration errors (Appendix A).
- Clarification on contraindications and precautions. People with a known (diagnosed) allergy to PEG, another mRNA vaccine component, or polysorbate, have a contraindication to vaccination. People with a reaction to a vaccine or injectable therapy that contains multiple components, one of which is PEG, another mRNA vaccine component or polysorbate, but in whom it is unknown which component elicited the immediate allergic reaction have a precaution to vaccination.
- Updated information on delayed, local injection-site reactions after the first mRNA vaccine dose. These reactions are neither a contraindication or precaution to the second dose.
- Updated quarantine recommendations for vaccinated people. Fully vaccinated people who meet criteria will no longer be required to quarantine following an exposure to someone with COVID-19. Additional considerations for patients and residents in healthcare settings are provided.
- Additional information and updated recommendations for testing for TB infection. TB testing can be done before or at the same time as mRNA COVID-19 vaccination, or otherwise delayed for ≥4 weeks after the completion of mRNA COVID-19 vaccination.

Page last reviewed: March 5, 2021