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# FAQs for the Interim Clinical Considerations for COVID-19 Vaccination

This page has answers to commonly asked questions about the Interim Clinical Considerations for COVID-19 Vaccination.

For information about COVID-19 vaccine storage, preparation, and administration, visit the COVID-19 Vaccine FAQs for Healthcare Professionals.

#### Vaccination Schedule and Use

#### Is there a preferred COVID-19 vaccine?

Yes. For primary series vaccination, Moderna, Pfizer-BioNTech, and Novavax COVID-19 vaccines are recommended. For booster vaccination, Moderna and Pfizer-BioNTech are recommended.

Novavax COVID-19 vaccine for booster vaccination and Janssen COVID-19 Vaccine for primary series and booster vaccination should only be used in very limited situations.

For more information, see COVID-19 vaccines.

#### Is there a maximum interval between doses 1 and 2 of a COVID-19 primary vaccination series?

No. You should administer the second dose as close as possible to the recommended interval after the first dose. However, if the second dose is administered after this interval, there is no need to restart the series.

An 8-week interval may be optimal for some people, especially males ages 12–39 years because of the small risk of myocarditis and pericarditis associated with Moderna, Novavax, and Pfizer-BioNTech COVID-19 vaccines. Vaccine effectiveness may also be increased with an interval longer than 3 or 4 weeks.

For additional information on the vaccination schedule, see:

- People who are **not** moderately or severely immunocompromised
- People who are moderately or severely immunocompromised
- Considerations for extended intervals for COVID-19 vaccine primary series

#### Does the 4-day grace period apply to COVID-19 vaccine?

Yes. Doses administered up to 4 days before the minimum interval, known as the 4-day grace period, are considered valid. This applies to primary series and booster doses of vaccine. Do not use the grace period to schedule doses.

If a dose is administered earlier than the grace period, see Appendix D for guidance on corrective actions. It is considered a vaccine administration error; you are required to report COVID-19 vaccine administration errors to the Vaccine Adverse Event Reporting System (VAERS) .

Doses administered at any time after the recommended interval are valid.

For more information, see timing, spacing, interchangeability, and coadministration of COVID-19 vaccines.

#### Can COVID-19 vaccines and other vaccines be administered at the same time?

In accordance with general best practices for immunizations, routine administration of all age-appropriate doses of vaccines simultaneously is recommended for children, adolescents, and adults for whom no specific contraindications exist at the time of the healthcare visit. This includes simultaneous administration of COVID-19 vaccine and other vaccines. However, there are additional considerations for Moderna, Novavax, and Pfizer-BioNTech COVID-19 vaccines if administering an orthopoxvirus (monkeypox) vaccine.

For more information, see Coadministration of COVID-19 vaccines with other vaccines.

# Can COVID-19 vaccines be administered at the same time as an orthopoxvirus (monkeypox) vaccine?

People who previously received COVID-19 vaccination (i.e. Moderna, Novavax, or Pfizer-BioNTech) may be given orthopoxvirus vaccine (either JYNNEOS or ACAM2000) without a minimum interval between vaccinations.

People who previously received orthopoxvirus vaccination (either JYNNEOS or ACAM2000), particularly adolescent or young adult males, might consider waiting 4 weeks before receiving a COVID-19 vaccine (i.e. Moderna, Novavax, or Pfizer-BioNTech) because of the observed risk for myocarditis and pericarditis after receipt of ACAM2000 orthopoxvirus vaccine and COVID-19 vaccines (i.e. Moderna, Novavax, or Pfizer-BioNTech) and the unknown risk for myocarditis and pericarditis after JYNNEOS administration.

For more information, see Interim Clinical Considerations for Use of JYNNEOS and ACAM2000 Vaccines during the 2022 U.S. Monkeypox Outbreak and Coadministration of COVID-19 vaccines with other vaccines.

#### Can I vaccinate patients with underlying medical conditions?

Yes. COVID-19 vaccination is recommended for everyone ages 6 months and older, including people with underlying medical conditions. COVID-19 vaccines are especially important for people with underlying medical conditions associated with higher risk for severe COVID-19.

### My patient is sick. Can they receive a COVID-19 vaccine?

As with other vaccines, you can vaccinate patients with a mild illness. A moderate or severe illness is a precaution to receiving a COVID-19 vaccine; it is not considered a contraindication. Generally, vaccination should be delayed until the acute illness has improved. However, if you and your patient believe the potential benefits of vaccination outweigh the potential risks, they may receive COVID-19 vaccine.

For more information, see General Best Practice Guidelines for Immunizations and contraindications and precautions for COVID-19 vaccination.

# Vaccine Dosage and Formulation

# What should I do for a child who is moving from a younger age group with a lower dose formulation to an older age group with a higher dose formulation?

CDC recommends that people should receive the age-appropriate vaccine dosage based on their age on the day of vaccination. If a person moves from a younger age group to an older age group during the primary series or between the primary series and receipt of the booster dose, they should receive the vaccine dosage for the older age group for all subsequent doses.

However, Food and Drug Administration (FDA) authorization allows for different dosing for certain age transitions. For more information see:

- Moderna COVID-19 Vaccine for Children who Transition from a Younger to Older Age Group
- Pfizer-BioNTech for Children who Transition from a Younger to Older Age Group
- Interim COVID-19 Immunization Schedule for 6 Months of Age and Older 🔼

# What should be done if the incorrect vaccine formulation is administered based on a patient's age?

If the incorrect formulation is administered

- Resulting in a higher-than-authorized dose: Do not repeat dose.
- Resulting in a lower-than-authorized dose: Repeat the dose immediately (no minimum interval) with the ageappropriate dose and formulation. Some experts suggest delaying the repeat dose for 8 weeks after the invalid dose based on the potential for increased reactogenicity and the rare risk of myocarditis and pericarditis associated with Moderna, Novavax, and Pfizer-BioNTech vaccines, especially in males ages 12-39 years. See Considerations for extended intervals for COVID-19 vaccine primary series.

If a person moves from a younger age group to an older age group during the primary series or between the primary series and booster dose, they should receive the vaccine dosage for the older age group for all subsequent doses. However, FDA allows the formulation for either age group to be administered for certain age transitions. See Moderna COVID-19 Vaccine for Children who Transition from a Younger to Older Age Group Ag

#### Should the same COVID-19 vaccine product be used for all doses in the primary series?

In general, all doses of the primary series should be with the same product.

In the following exceptional situations, a different COVID-19 vaccine may be administered to complete a primary series at a minimum interval of 28 days from the last COVID-19 vaccine dose:

- The same vaccine is not available
- A previous dose is unknown
- The person would otherwise not complete the primary series
- A person starts but is unable to complete a primary series with the same COVID-19 vaccine due to a contraindication.

No VAERS report is required.

For more information, see:

• Timing, spacing, and interchangeability of COVID-19 vaccines.

- People who are **not** moderately or severely immunocompromised
- People who are moderately or severely immunocompromised

# Can the bivalent mRNA vaccines (i.e., Moderna and Pfizer-BioNTech) be used for the primary series?

No, the bivalent mRNA vaccines (i.e., Moderna and Pfizer-BioNTech) are **not** currently authorized to be used for the primary series; they may only be used for the booster dose.

If a bivalent **Pfizer-BioNTech** vaccine is administered for a primary series dose: Do not repeat the dose. The primary and booster dosages are the same; the bivalent dose can be counted as a primary series dose. Continue with the recommended vaccination schedule (i.e., complete the primary series with a monovalent Pfizer-BioNTech vaccine, then administer a bivalent booster dose at least 2 months after completion of the primary series).

If a bivalent **Moderna** vaccine is administered for a primary dose: Repeat the dose immediately (no minimum interval) with a monovalent Moderna vaccine because administration of the bivalent Moderna vaccine will result in a lower-than-authorized primary series dosage. Some experts suggest delaying the repeat dose for 8 weeks after the invalid dose. After the dose has been repeated, continue with the recommended vaccination schedule (i.e., complete the primary series with a monovalent Moderna vaccine, then administer a bivalent booster dose at least 2 months after completion of the primary series).

Both situations are considered vaccine administration errors and should be reported to Vaccine Adverse Event Reporting System (VAERS) .

For more information, see

- People who are **not** moderately or severely immunocompromised
- People who are moderately or severely immunocompromised
- Vaccine administration errors and deviations

#### Can a monovalent mRNA vaccine (i.e., Moderna or Pfizer-BioNTech) be used for the booster dose? $\vee$

No, the monovalent mRNA vaccines (i.e., Moderna or Pfizer-BioNTech) are no longer authorized for use as a booster dose; they can only be used for the primary series. A bivalent mRNA vaccine is recommended for the booster dose.

If a patient accidently received a monovalent mRNA vaccine for the booster dose, the dose generally does not need to be repeated. However, providers may administer 1 bivalent booster dose as a repeat dose based on clinical judgment and patient preference. The repeat dose should be administered at least 2 months after the monovalent booster dose.

For more information, see vaccine administration errors and deviations.

#### **Booster Doses**

#### Who should receive a booster dose?

Everyone ages 5 years and older is recommended to receive 1 bivalent mRNA booster dose if they have completed a primary series with any FDA-approved or FDA-authorized COVID-19 vaccine:

Children age 5 years are recommended to receive the Pfizer-BioNTech bivalent booster dose.

• People ages 6 years and older are recommended to receive either the Moderna or the Pfizer-BioNTech bivalent booster dose.

The booster dose is administered at least 2 months after the last primary dose. For people who previously received 1 or more monovalent booster doses, the bivalent booster dose should be administered at least 2 months after the last monovalent booster dose.

Novavax monovalent COVID-19 Vaccine may be used as a booster dose in limited situations for people ages 18 years and older.

For more information on booster doses see schedules for:

- People who are **not** moderately or severely immunocompromised
- People who are moderately or severely immunocompromised

For booster dose recommendations for people vaccinated outside the United States, see people who received COVID-19 vaccine outside the United States.

What is the interval between the primary series and the bivalent mRNA booster dose?

The bivalent booster dose is administered at least 2 months after completion of the primary series. The interval is the same regardless of which vaccine was administered for the primary series and which bivalent booster (Moderna or Pfizer-BioNTech) will be administered.

My patient already received a monovalent mRNA booster dose(s). What is the interval between a  $\sim$  previously received monovalent mRNA booster dose and the bivalent booster dose?

The bivalent booster dose is administered at least 2 months after the last monovalent mRNA booster dose.

My patient previously received a monovalent mRNA booster dose(s). Can they get a bivalent booster dose?

Yes. Everyone ages 5 years and older who completed a primary series is recommended to receive 1 bivalent booster dose regardless of previous booster dose history. For people who previously received 1 or more monovalent booster doses, the bivalent booster dose should be administered at least 2 months after the last monovalent booster dose.

My patient never received a monovalent mRNA booster dose(s) and now only 1 bivalent booster dose is recommended for everyone ages 5 years and older. Can my patient still get the previously recommended monovalent mRNA booster dose(s)?

The current recommendation is for everyone who is eligible to receive 1 bivalent booster dose: this includes people who received the primary series but did not receive the previously recommended monovalent mRNA booster dose(s) and people who received 1 or 2 monovalent mRNA booster doses. Because the guidance has changed, not everyone will receive the same number of booster doses. However, once a person receives 1 bivalent booster dose, no additional booster doses are currently recommended.

Can a child who completes a Pfizer-BioNTech primary series at ages 6 months–4 years get a booster dose when they turn age 5 years?

Yes. The child should receive 1 bivalent booster dose when they turn age 5 years, and it has been at least 2 months since completing their primary series.

#### What is the guidance for a use of the monovalent Novavax COVID-19 vaccine for a booster dose?

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The monovalent Novavax COVID-19 vaccine is authorized for a booster dose in **limited situations**. People ages 18 years and older who completed primary vaccination using any COVID-19 vaccine and have **not** received any previous booster dose(s) (including any previous mRNA monovalent or bivalent booster dose[s]) may receive a monovalent Novavax booster dose at least 6 months after completion of the primary series if they are unable to receive an mRNA vaccine (i.e., mRNA vaccine contraindicated or not available) or unwilling to receive an mRNA vaccine and would otherwise not receive a booster dose.

## People who are Moderately or Severely Immunocompromised

Are there special considerations for vaccinating people who are moderately or severely immunocompromised?



Yes. For COVID-19 vaccination guidance for people who are moderately or severely immunocompromised people, please refer to:

- Guidance for COVID-19 vaccination for people who are moderately or severely immunocompromised
- COVID-19 Vaccines for Moderately or Severely Immunocompromised People

#### How do I verify if a person is moderately or severely immunocompromised?



People can self-attest to their moderately or severely immunocompromised status and should be vaccinated according to the schedule for people who are moderately or severely immunocompromised. Vaccinators and clinic administrators should not deny COVID-19 vaccination to a person because of a lack of documentation.

My patient is moderately or severely immunocompromised and received the primary series and the previously recommended monovalent mRNA booster dose(s). Should they receive the bivalent mRNA booster dose?

Yes. Everyone ages 5 years and older who completed a primary series is recommended to receive 1 bivalent mRNA booster dose regardless of previous booster dose history; this includes people who are moderately or severely immunocompromised. The bivalent mRNA booster dose should be administered at least 2 months after the last monovalent booster dose.

My patient who is moderately or severely immunocompromised underwent HCT or CAR-T cell therapy after receiving the primary series and 2 monovalent mRNA booster doses. Should they be revaccinated?

Patients who undergo HCT or CAR-T-cell therapy should be revaccinated for the monovalent primary series and **bivalent** mRNA booster dose received before or during treatment. There is no revaccination for **monovalent** mRNA booster dose(s) received before or during treatment. After revaccination with the primary series, the patient should

receive 1 bivalent mRNA booster dose.

Below are three scenarios and the recommended action:

If your patient received the primary series before or during treatment: Revaccinate the patient with the primary series and administer 1 bivalent mRNA booster dose at least 2 months after repeating the primary series.

If your patient received the primary series and 1 or 2 (or more) monovalent booster doses before or during treatment: Revaccinate the patient with the primary series. Do not revaccinate for the monovalent mRNA booster dose(s). The patient is recommended to receive 1 bivalent mRNA booster dose at least 2 months after repeating the primary series.

If your patient received the primary series and a bivalent booster dose before or during treatment: Revaccinate the patient with the primary series and 1 bivalent mRNA booster dose.

Do I need to wait to administer tixagevimab/cilgavimab (EVUSHELD™) for pre-exposure prophylaxis against COVID-19 after my patient received a dose of COVID-19 vaccine?

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Yes. Administration of EVUSHELD<sup>™</sup> should be deferred for at least two weeks after COVID-19 vaccination per the EVUSHELD<sup>™</sup> EUA . You can administer COVID-19 vaccine any time after receipt of EVUSHELD<sup>™</sup>.

For all other passive antibody products for COVID-19, there is no deferral period between receipt of the product and COVID-19 vaccine administration.

For more information, see COVID-19 vaccination and EVUSHELD™ and CDC's EVUSHELD™ guidance.

My patient is moderately or severely immunocompromised and receiving EVUSHELD™. Should they also get COVID-19 vaccines?



Yes. Everyone ages 5 years and older should get the COVID-19 vaccine primary series and 1 bivalent mRNA booster dose including people who are moderately or severely immunocompromised and receiving EVUSHELD™ for pre-exposure prophylaxis.

For more information, see COVID-19 vaccination and EVUSHELD™ and CDC's EVUSHELD™ guidance.

My patient is moderately or severely immunocompromised and vaccinated according to current ACIP/CDC guidance; should they also get EVUSHELD™?



Yes. In addition to following the recommended COVID-19 vaccination schedule, EVUSHELD™ should be administered to people who are moderately or severely immunocompromised every 6 months to supplement vaccine protection.

Administration of EVUSHELD™ should be deferred for at least 2 weeks after COVID-19 vaccination per the EVUSHELD EUA

I M. COVID-19 vaccines can be administered any time after receipt of EVUSHELD™.

For more information, see COVID-19 vaccination and EVUSHELD™ and CDC's EVUSHELD™ guidance.

My patient is asking for an antibody test to decide whether to get vaccinated (or revaccinated). What do antibody tests tell us about immunity, and should these tests influence the decision to vaccinate or revaccinate?

Antibody testing is **not** currently recommended to assess the need for vaccination in an unvaccinated person or to assess immunity to SARS-CoV-2 following COVID-19 vaccination or after SARS-CoV-2 infection. Antibody tests for SARS-CoV-2 look for the presence of antibodies made in response to a previous infection or vaccination. Antibodies are an indicator of the body's efforts to fight off the SARS-CoV-2 virus. None of the currently authorized SARS-CoV-2 antibody tests  $\square$  have been validated to evaluate specific immunity or protection from SARS-CoV-2 infection.

For assistance with patient counseling and education related to COVID-19 testing and vaccination, please see:

- COVID-19 Testing: What you Need to Know [CDC]
- Using Antibody Tests for COVID-19: Information for Patients and Consumers [CDC]
- Antibody (Serology) Testing for COVID-19: Information for Patients and Consumers [FDA]

For more detailed information, please see: Interim Guidelines for COVID-19 Antibody Testing.

#### Vaccination and SARS-CoV-2 Infection

## Can people with prior or current SARS-CoV-2 infection receive a COVID-19 vaccine?

CDC recommends COVID-19 vaccination for all people ages 6 months and older, including people with a history of SARS-CoV-2 infection.

**Prior infection**: Offer vaccination regardless of history of prior symptomatic or asymptomatic SARS-CoV-2 infection, including to people with prolonged post-COVID-19 symptoms and people who experienced SARS-CoV-2 infection (symptomatic or asymptomatic) after vaccination. People who recently had SARS-CoV-2 infection may consider delaying their primary or booster COVID-19 vaccine dose by 3 months from symptom onset or positive test (if infection was asymptomatic).

**Current infection**: Defer vaccination of people with known current SARS-CoV-2 infection until the person has recovered from acute illness (if the person has symptoms) and until criteria have been met for them to discontinue isolation.

Laboratory testing is not recommended for the purpose of vaccine decision-making.

For more information, see COVID-19 vaccination and SARS-CoV-2 infection.

## Considerations Involving Pregnancy, Lactation, and Fertility

#### Can pregnant or breastfeeding people be vaccinated?

Yes. CDC recommends COVID-19 vaccination for all people who are pregnant, breastfeeding, recently pregnant, trying to get pregnant now, or who might become pregnant in the future. Monovalent mRNA (Moderna or Pfizer-BioNTech) and Novavax vaccines are recommended for the primary series and a bivalent mRNA vaccine (Moderna or Pfizer-BioNTech) is recommended for the booster dose for all vaccine-eligible populations including people who are pregnant or lactating. Those who are considering receipt of the Janssen COVID-19 Vaccine should see Appendix A: Guidance for use of Janssen COVID-19 Vaccine.

For more information, see COVID-19 Vaccines While Pregnant or Breastfeeding.

## **Special Populations and Situations**

#### What is the guidance for vaccinating preterm infants?

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In accordance with general best practices, preterm infants (infants born before 37 weeks' gestation), regardless of birth weight, should receive COVID-19 vaccination at their chronological age and according to the same schedule and guidance as for full-term infants and children.

What is the guidance for vaccinating infants of mothers who received COVID-19 vaccine and/or had COVID-19 or SARS-CoV-2 infection before or during pregnancy?

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Infants of mothers who were vaccinated and/or had COVID-19 or SARS-CoV-2 infection before or during pregnancy should be vaccinated according to the recommended schedule.

If my patient received a SARS-CoV-2 antibody product (anti-SARS-CoV-2 monoclonal antibodies or  $\sim$  convalescent plasma) can they be vaccinated?

People who previously received SARS-CoV-2 antibody products (anti-SARS-CoV-2 monoclonal antibodies or convalescent plasma) as part of COVID-19 treatment, post-exposure prophylaxis, or pre-exposure prophylaxis can be vaccinated at any time; COVID-19 vaccination does not need to be delayed following receipt of monoclonal antibodies or convalescent plasma.

However, people who are moderately or severely immunocompromised and received a COVID-19 vaccination should wait at least two weeks before receiving tixagevimab/cilgavimab (EVUSHELD $^{\text{\tiny M}}$ ) for pre-exposure prophylaxis per the product EUA  $\square$ .

For more information, see COVID-19 vaccination and EVUSHELD™ and CDC's EVUSHELD™ guidance.

#### Which COVID-19 vaccines are recommended for people with a history of Bell's palsy?

Rare cases of Bell's palsy (acute peripheral facial nerve palsy) were reported following vaccination of participants in mRNA COVID-19 vaccine clinical trials, but FDA was not able to determine whether these cases were causally related to vaccination. People with a history of Bell's palsy may receive any currently FDA-approved or FDA-authorized COVID-19 vaccine: mRNA (i.e., Moderna or Pfizer-BioNTech) and Novavax COVID-19 vaccines are recommended for the primary series and an age-appropriate mRNA vaccine is recommend for the booster dose.

For more information on the recommended vaccination, see COVID-19 vaccination schedule for people who are not moderately or severely immunocompromised.

Which COVID-19 vaccines are recommended for people with a history of Guillain-Barre syndrome  $\vee$  (GBS)?

GBS is a neurological disorder in which the body's immune system damages nerve cells, causing muscle weakness and sometimes paralysis. For people with a history of GBS, as for the general population, mRNA (i.e., Moderna or Pfizer-BioNTech) and Novavax COVID-19 vaccines are recommended for the primary series, and an age-appropriate mRNA

vaccine is recommended for the booster dose. No increased risk of GBS \(\sigma\) has been identified with receipt of mRNA COVID-19 vaccines.

See Guidance for use of Janssen COVID-19 Vaccine and Use of the Janssen (Johnson & Johnson) COVID-19 Vaccine Information on GBS and Janssen COVID-19 Vaccine.

For more information on the recommended vaccination, see COVID-19 vaccination schedule for people who are not moderately or severely immunocompromised.

Last Reviewed: October 26, 2022