COVID-19 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 table provides resources for preventing and reporting COVID-19 vaccine administration errors, as well as actions to take after an error has occurred. For completeness, it includes additional scenarios that deviate from CDC recommendations for vaccine intervals but are not considered administration errors.

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.
- Follow the revaccination guidance below, using an age-appropriate COVID-19 vaccine and formulation. Continue with the recommended schedule of subsequent dose(s) unless otherwise noted.
  - For doses recommended to be repeated, consider delaying the repeat dose for 8 weeks after the invalid dose based on the potential for increased reactogenicity and the rare risk of myocarditis from mRNA COVID-19 vaccines, particularly among males 12-39 years of age.
- The recommendations apply to all FDA-approved or FDA-authorized COVID-19 vaccines and all doses unless otherwise stated.
- Providers are required to report all COVID-19 vaccine administration errors—even those not associated with an adverse event—to VAERS.
- Determine how the error occurred and implement strategies to prevent it from happening again.

Interim recommendations for COVID-19 vaccine administration errors and deviations

Type	Administration error/deviation	Interim recommendation
Site/route	• Incorrect site (i.e., site other than the deltoid muscle [preferred site] or anterolateral thigh [alternate site])	• Do **not** repeat dose.
	• 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 (recipients ages less than 5 years)	• Do **not** give another dose at this time.*

	• Unauthorized age group (recipients ages 5-17 years)	• If Moderna COVID-19 Vaccine administered:
		  ○ As the first dose: Administer the age-appropriate Pfizer-BioNtech COVID-19 Vaccine at least 28 days after the Moderna COVID-19 Vaccine dose. Administer a Pfizer-BioNTech booster dose at least 5 months later.
		  ○ As the second dose (or as both the first and second dose): The primary series is complete. Administer a PFizer-BioNTech booster dose at least 5 months later.
		• If Janssen COVID-19 Vaccine administered:
		  ○ Administer a single dose of the age-appropriate PFizer-BioNTech COVID-19 Vaccine at least 28 days after the Janssen COVID-19 Vaccine. Administer a Pfizer-BioNTech booster dose at least 5 months later.

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Formulation and dosage	• If ages 5–11 years and Pfizer-BioNTech COVID-19 Vaccine ≥12 years formulation (purple or gray cap) inadvertently administered.	• If 0.1 mL administered, in general, do **not** repeat dose. However, based on clinical judgment (e.g., child received 2 doses of incorrect formulation), a repeat dose of Pfizer-BioNTech COVID-19 Vaccine 5-11 years formulation (orange cap) may be administered at an interval of ≥21 days after the dose given in error.[†] • If >0.1mL administered, resulting in a higher than authorized dose, do **not** repeat dose.[‡]
	• If ages 12–17 years and administered the Pfizer-BioNTech Vaccine 5–11 years formulation (orange cap), resulting in a lower-than-authorized dose.[§]	• In general, do **not** repeat dose. However, based on clinical judgment (e.g., the adolescent received two doses of incorrect formulation), a repeat dose of Pfizer-BioNTech COVID-19 Vaccine ≥12 years formulation (30 µg, purple cap) may be administered at an interval of 21 days after the dose given in error.[†]
	• If ages ≥18 years and administered the Pfizer-BioNTech Vaccine 5–11 years formulation (orange cap), resulting in a lower-than-authorized dose.	• **Repeat dose immediately** (no minimum interval) with the age-appropriate dose and formulation.[†]
	• Higher-than-authorized dose volume administered of the correct formulation.	• Do **not** repeat dose.[‡]
	• Lower-than-authorized dose volume administered of the correct formulation (e.g., leaked out, equipment failure, recipient pulled away)	• **Repeat dose immediately** (no minimum interval).[†] • However, if a half-volume formulation of vaccine is administered on the same clinic day to a patient recommended for the full-volume formulation, another half-volume dose can be administered, and the two doses can count as one full dose.
Storage and handling	• Dose administered after improper storage and handling (i.e., temperature excursion)	• Contact the manufacturer[¶] for information on the stability of the vaccine. If the manufacturer does not have data to support the stability of the vaccine, **repeat the dose immediately** (no minimum interval).[†]
	• Dose administered past the expiration/ beyond-use date	• Contact the manufacturer[¶] for information on the stability of the vaccine. If the manufacturer does not have data to support the stability of the vaccine, **repeat the dose immediately** (no minimum interval).[†]
Intervals[**]	• An mRNA primary series dose administered prior to the recommended interval[††]	• Repeat dose after the dose given in error by at least the minimum interval (i.e., no sooner than 21 days if Pfizer-BioNTech or 28 days of Moderna).[†]
	• Booster dose administered prior to the minimum interval (i.e., prior to 2 months after Janssen primary series or 3 months after mRNA vaccine primary series).	• Repeat dose if this is the first booster dose. Space repeat dose after the dose given in error by at least the minimum interval.[†] o 2-month minimum booster interval after Janssen vaccine primary series o 3-month minimum booster interval after mRNA vaccine primary series • Do not repeat dose if this is the second booster dose.
	• Any COVID-19 vaccine dose administered at any interval after the recommended interval	• Do **not** repeat dose. There is no maximum interval. This deviation from CDC guidance does **not** require VAERS reporting.
	• Tixagevimab/cilgavimab (EVUSHELD)™ administered less than 14 days after COVID-19 vaccination	• In general, do **not** repeat vaccine dose. However, based on clinical judgment, a repeat dose of vaccine may be administered at an interval of at least 28 days after the dose of vaccine.[†]

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Mixed series	• Incorrect mRNA COVID-19 vaccine product inadvertently administered as a part of a 2- or 3- dose primary series	• Do **not** repeat dose.
Diluent (Pfizer-BioNTech COVID-19 Vaccine purple and orange cap formulations only)	• ONLY diluent administered (i.e., sterile 0.9% sodium chloride)	• Administer the authorized dose immediately (no minimum interval).
	• 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 information on the stability of the vaccine. If the manufacturer does not have information to support the stability of the vaccine, **repeat the dose immediately** (no minimum interval).†
	• Vaccine is mixed with too little diluent	• Do **not** repeat dose. Inform the recipient of the potential for local and systemic adverse events.‡
	• Vaccine is mixed with too much diluent	• **Repeat dose immediately** (no minimal interval).†
	• Single-use vial of diluent is used to mix multiple vials of vaccine	• Do **not** repeat dose. Inform patients of the potential for bacterial infection.
Diluent (Pfizer-BioNTech COVID-19 Vaccine gray cap formulation that should *not* be mixed with diluent)	• Vaccine is mixed with any diluent (i.e., any type of volume of diluent)	• Contact the manufacturer for information on the stability of the vaccine. If the manufacturer dose not have information to support the stability of the vaccine, **repeat the dose immediately** (no minimum interval).†

* 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.

† 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 from mRNA COVID-19 vaccine, particularly in groups at increased risk for myocarditis (e.g., males ages 12–39 years). Individual risk for COVID-19 and the likelihood for an adverse event following vaccination should be taken into consideration when recommending a longer interval. It is acceptable to administer the repeat dose at an interval earlier than 8 weeks as long as the interval is not sooner than the minimal interval noted in the above table.

‡ If the administration error resulted in a higher-than-authorized vaccine dose, in general the subsequent 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 subsequent dose, this dose might be delayed, but this decision should be assessed on a case-by-case basis.

§ Persons who will turn from age 11 years to 12 years of age between their first and second dose in the primary regimen may receive either: (1) the Pfizer-BioNTech COVID-19 Vaccine formulation authorized for use in persons ages 5 through 11 years (each 0.2 mL dose containing 10 µg) (orange cap); or (2) the Pfizer-BioNTech COVID-19 Vaccine formulation authorized for use in persons ages 12 years and older (each 0.3 mL dose containing 30 µg) (purple or gray cap). This dosing is in accordance with the FDA EUA (https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/comirnaty-and-pfizer-biontech-covid-19-vaccine) and if such dosing occurred, this is not considered an error and VAERS reporting is not indicated.

¶ As of the date of this update, current manufacturer contact information is: Pfizer: 1-877-VAX-CO19 (1-877-829-2619) Moderna: 1-866-MODERNA (1-866-663-3762); medinfo@modernatx.com Janssen: US Toll Free: 1-800-565-4008; US Toll: 1-908-455-9922 Please see the package inserts and EUA provider factsheets for the most up-to-date manufacturer information.

** For the purpose of the public health definition of fully vaccinated, primary series doses administered with an interval error prior to October 25, 2021 do not need to be repeated. For the purpose of the public health definition of up to date, first booster doses administered with an interval error prior to March 30, 2022 do not need to be repeated..

†† Vaccine administered up to 4 days before the minimum interval may be counted and does not need to be repeated.