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.
- 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	• If received dose at age less than 5 years, do **not** give another dose at this time.∞ • If aged <18 years and the inappropriate Pfizer-BioNTech COVID-19 Vaccine formulation was administered, refer to the "Formulation and dosage" section below. • If aged 5–11 years and a vaccine other than a Pfizer-BioNTech COVID-19 Vaccine was inadvertently administered:§ o If Moderna COVID-19 Vaccine administered as the first dose, it is suggested to give a single dose of the Pfizer-BioNTech COVID-19 Vaccine 5–11 years formulation (orange cap) as the second dose (at least 28 days after the Moderna COVID-19 Vaccine dose) because it is authorized in this age group. o If Janssen COVID-19 Vaccine administered, because the efficacy of this vaccine in people aged <18 years has not been established, a single dose of the Pfizer-BioNTech COVID-19 Vaccine 5–11 years formulation (orange cap) could be considered at least 2 months after the Janssen COVID-19 Vaccine. • If aged 12–17 years and a vaccine other than a Pfizer-BioNTech COVID-19 Vaccine was inadvertently administered: o If Moderna COVID-19 Vaccine administered as the first dose, it is suggested to give Pfizer-BioNTech COVID-19 Vaccine ≥12 years formulation (purple cap)/COMIRNATY as the second dose (at least 28 days after the Moderna vaccine dose) because it is authorized in this age group. o If Janssen Vaccine administered, because the efficacy of this vaccine in people aged <18 years has not been established, a single dose of the Pfizer-BioNTech COVID-19 Vaccine ≥12 years formulation (purple cap)/COMIRNATY could be considered at least 2 months after the Janssen COVID-19 Vaccine.

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Formulation and dosage	• If aged 5–11 years and Pfizer-BioNTech COVID-19 Vaccine ≥12 years formulation (purple cap) /COMIRNATY inadvertently administered, resulting in a higher-than-authorized dose.	• Do **not** repeat dose.[†] • If the dose given in error is the first dose, administer the second Pfizer-BioNTech COVID-19 Vaccine 5–11 years formulation (orange cap) dose 21 days later.[§]
	• If aged 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 judgement (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 the dose given in error is the first dose, administer the Pfizer-BioNTech COVID-19 Vaccine ≥12 years formulation (30 µg, purple cap) dose 21 days after the last dose in order to complete the primary series.[§]
	• If aged ≥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. If the dose given in error is the first dose, administer the second dose at the recommended interval after the repeat dose (i.e., 21 days after repeat dose) with the age-appropriate formulation.
	• Higher-than-authorized dose volume administered of the correct formulation.	• Do not repeat dose.[*†] • Common errors may include: ○ 0.5 mL administered for a Moderna COVID-19 Vaccine booster 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.
		• Common errors may include:
		  ○ 0.25 mL administered for Moderna COVID-19 Vaccine primary series
		  ○ 0.2 mL of Pfizer-BioNTech COVID-19 Vaccine ≥12 years formulation (purple cap)/ COMIRNATY administered to an individual ≥12 years.

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).[*]
Administration	• Dose administered within 90 days of anti-SARS-CoV-2 monoclonal antibodies or convalescent plasma for COVID-19 treatment	• Do **not** repeat COVID-19 vaccine dose. If person is scheduled for a subsequent COVID-19 vaccine dose (e.g., second primary dose, additional primary dose, or booster dose), defer administration of subsequent dose for 90 days following receipt of antibody therapy. This deviation from CDC guidance does **not** require VAERS reporting.
	• Dose administered within 30 days of anti-SARS-CoV-2 monoclonal antibodies for post-exposure prophylaxis	• Do **not** repeat COVID-19 vaccine dose. If person is scheduled for a subsequent COVID-19 vaccine dose (e.g., second primary dose, additional primary dose, or booster dose), defer administration of subsequent dose for 30 days following receipt of antibody therapy. This deviation from CDC guidance does **not** require VAERS reporting.

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Intervals	• Second mRNA COVID-19 vaccine dose administered fewer than 17 days (Pfizer-BioNTech COVID-19 Vaccine /COMIRNATY) or fewer than 24 days (Moderna COVID-19 vaccine) after the first mRNA COVID-19 vaccine dose (i.e., administered earlier than the 4-day grace period)	• Repeat dose.* The repeat dose should be spaced after the improperly spaced dose by the minimum interval (i.e., 21 days after the improperly spaced dose for the Pfizer-BioNTech COVID-19 Vaccine formulation/ COMIRNATY and 28 days after the improperly spaced dose for Moderna COVID-19 Vaccine).
	• The interval between the incorrect administration of an initial single dose of an mRNA COVID-19 vaccine (Pfizer-BioNTech COVID-19 Vaccine/COMIRNATY or Moderna COVID-19 Vaccine) and Janssen COVID-19 Vaccine is fewer than 24 days from the mRNA COVID-19 vaccine dose.	• Do **not** administer a second primary dose of the mRNA COVID-19 vaccine.
	• Second dose of an mRNA COVID-19 vaccine (Pfizer-BioNTech COVID-19 Vaccine/COMIRNATY or Moderna COVID-19 Vaccine) 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.
	• For people with moderate and severe immune compromise aged ≥12 years (Pfizer-BioNTech recipients) or ≥18 years (Moderna recipients), the additional primary dose (i.e., third dose) of an mRNA COVID-19 vaccine is administered fewer than 24 days after the second dose (i.e., administered earlier than the 4-day grace period)	• Repeat dose.* The repeat dose should be spaced after the improperly spaced dose by the minimum interval (i.e., 28 days after the improperly spaced dose).
	• Any COVID-19 vaccine product is administered as a booster dose fewer than 6 months after a 2-dose primary mRNA COVID-19 vaccine series in a person who is not moderately or severely immunocompromised.	• Do **not** repeat dose.
	• Any product is administered as a booster dose fewer than 2 months after 1 dose of Janssen COVID-19 primary vaccine	• Do **not** repeat dose.
Mixed series	• Incorrect mRNA COVID-19 vaccine product inadvertently administered as a second dose in 2-dose primary series or as an additional primary dose	• Do **not** repeat dose.*

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Diluent (Pfizer-BioNTech COVID-19 Vaccine formulations/ COMIRNATY 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).
	• Incorrect diluent volume	• If dilution results in a higher-than-authorized dose, do not repeat dose and inform the recipient of the potential for local and systemic adverse events.*† o Pfizer-BioNTech COVID-19 Vaccine ≥12 years formulation (purple cap)/ COMIRNATY: Applies to doses administered with diluent volume less than 1.8 mL o Pfizer-BioNTech COVID-19 Vaccine 5–11 years formulation (orange cap): Applies to doses administered with diluent volume less than 1.3 mL • If dilution results in a lower-than-authorized dose, repeat dose immediately (no minimum interval).* o Pfizer-BioNTech COVID-19 Vaccine ≥12 years formulation (purple cap)/ COMIRNATY: Applies to doses administered with diluent volume greater than 1.8 mL o Pfizer-BioNTech COVID-19 Vaccine 5–11 years formulation (orange cap): Applies to doses administered with diluent volume greater than 1.3 mL

*In the case of an error, providers should follow the Interim Recommendations in this table then continue with any subsequent doses according to the recommended schedule and intervals.

∞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 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.

§ Individuals who will turn from 11 years to 12 years of age between their first and second dose in the primary regimen may receive, for either dose, either: (1) the Pfizer-BioNTech COVID-19 Vaccine formulation authorized for use in individuals 5 through 11 years of age (each 0.2 mL dose containing 10 µg) (orange cap); or (2) COMIRNATY or the Pfizer-BioNTech COVID-19 Vaccine formulation authorized for use in individuals 12 years of age and older (each 0.3 mL dose containing 30 µg (purple cap). This dosing is in accordance with the FDA EUAexternal icon and if such dosing occurred, this is not considered an error and VAERS reporting is not indicated.