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

Vaccines	Type	Administration error/deviation	Interim recommendation
All currently authorized vaccines (Pfizer-BioNTech Moderna, and Janssen COVID-19 vaccines) Inactive ingredients	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.
		• 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: o 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). o 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.

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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 type (e.g., sterile water, bacteriostatic 0.9% NS)	• 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 Authorizationsexternal icon).