APPENDIX 22 mRNA VACCINE ADMINISTRATION ERRORS AND DEVIATIONS

The information below is excerpted and adapted from Appendix A of the 2/10/21 Center for Disease Control and Prevention's (CDC's) Interim Clinical Considerations for Use of mRNA COVID-19 Vaccines Currently Authorized in the Unites States.

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 mRNA 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 mRNA 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 CA Immunization Registry (CAIR) 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 the 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 the *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.

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.*
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.
	• 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.

Type	Administration error/deviation	Interim recommendation
Mixed series	• Incorrect mRNA COVID-19 vaccine product administered for second dose in 2-dose series	• Do **not** repeat dose.[‖]
Dosage	• Higher-than-authorized dose volume administered	• Do **not** repeat dose*[§,] Inform the recipient of the potential for local and systemic adverse events.
	• 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 6 hours 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.
Diluent (Pfizer-BioNTech only)	• 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% sodium chloride)	• 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).
Age	• Unauthorized age group	• If received first dose at age less than 16 years, do not give second dose at this time.[‡] • If age 16 to 17 years and Moderna vaccine inadvertently administered instead of Pfizer-BioNTech 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 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.

† 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).

‡ 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.

‖ 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).