COVID-19 Vaccine Provider Responsibilities: VAERS

The Vaccine Adverse Event Reporting System (VAERS) is a national early warning system to help monitor the safety of U.S. licensed vaccines. VAERS is comanaged by the Centers for Disease Control and Prevention (CDC) and the U.S. Food and Drug Administration (FDA). VAERS accepts and analyzes reports of adverse events (possible side effects) following vaccination submitted by healthcare professionals, vaccine manufacturers, and the general public.

Healthcare providers are **required** to report to VAERS the following adverse events after COVID-19 vaccinations administered while under an emergency use authorization (EUA).

Vaccine administration errors

1. **Wrong dosage given.**
    - Amount larger than recommended in manufacturer-specific EUA.
        - Pfizer COVID-19 vaccine.
            - Dose greater than 0.3 milliliters.
            - Dose not properly diluted (1.7milliliters or less normal saline (NS) or no dilution).
        - Moderna COVID-19 vaccine.
            - Dose greater than 0.5 milliliters.
        - Johnson & Johnson (Janssen) COVID-19 vaccine.
            - Dose greater than 0.5 milliliters.
        - Do **not** repeat dose. Inform the vaccine recipient of the potential for local and systemic adverse events.
            - The second dose may still be administered at the recommended interval. (Pfizer or Moderna).
            - However, if local or systemic side effects following vaccination are clinically concerning (outside of the expected side effects), 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**.
    - Amount smaller than recommended in manufacturer-specific EUA
        - Loss of vaccine through loosened or disconnection of needle/syringe during administration.
        - Loss of vaccine from unexpected movement of recipient during administration (recipient pulls arm away from vaccinator).
        - Dosage less than specified in manufacturer-specific EUA.
            - Pfizer COVID-19 vaccine.
                - Dose less than 0.3 milliliters.
                - Over dilution (greater than 1.8 milliliters NS).
            - Moderna COVID-19 vaccine.
                - Dose less than 0.5 milliliters.
            - Johnson & Johnson (Janssen) COVID-19 vaccine.
                - Dose less than 0.5 milliliters.

- Doses inadvertently administered smaller than the dosage stated in the manufacturer EUA.
    - Pfizer and Moderna: Dose does not need to be repeated at this time, **if estimated <u>more than half</u> of the dose** was administered. If ***<u>less than half</u> 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**.
    - Janssen: Immediately give full dose in opposite arm.
- Incorrect diluent type (e.g., sterile water, bacteriostatic 0.9% NS) (Pfizer only).
    - 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**.

2. **Wrong route:** COVID-19 vaccines are intramuscular (deltoid is preferred site or anterolateral thigh).
    - Dose given subcutaneously.
        - Needle length too short for client size.
        - Improper technique used for intramuscular delivery (wrong angle).
    - Dose does not need repeating.
3. **Wrong age of recipient receiving COVID-19 vaccine.**
    - Manufacturer-specific ages in EUA.
        - Pfizer COVID-19 vaccine recipients must be at least 16 years old per EUA.
        - Moderna COVID-19 vaccine recipients must be at least18 years old per EUA.
        - Janssen COVID-19 vaccine recipients must be at least 18 years old per EUA.
            - If vaccine is incorrectly given to someone younger than 18 years old, the recipient is considered vaccinated.
    - Second doses for Pfizer and Moderna.
        - Pfizer recipients younger than 16 years of age.
            - Return for second dose in 21 days.
            - Dose will be “off label.”
        - Moderna recipients younger than 18 years of age.
            - Return in 28 days.
            - Dose will be “off label.”
4. **Wrong spacing between Moderna or Pfizer COVID-19 vaccine doses (second dose given too soon).**
    - Manufacturer-specific spacing in EUA (four-day grace period allowed).
        - Pfizer COVID-19 vaccine: at least 21 days between first and second dose.
        - Moderna COVID-19 vaccine: at least 28 days between first and r second dose.
        - Doses inadvertently administered earlier than the grace period are still **considered valid** and ***<u>should not be repeated.</u>***
    - The second COVID-19 dose should be administered as close to the recommended interval as possible. However, if it is not feasible to adhere to the recommended interval, the second dose of Pfizer and Moderna COVID-19 vaccines may be scheduled for administration up to six weeks (42 days) after the first dose.
        - A second dose administered more than 42 days after the first dose does not require reporting to VAERS.
        - Currently, there are limited data on efficacy of mRNA COVID-19 vaccines administered beyond this window. If the second dose is administered beyond these intervals, restarting the series is not necessary.
    - Administration of a COVID-19 vaccine within 14 days before or after a non-COVID-19 vaccine.
        - Dose does not need to be repeated or reported to VAERS.
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5. **Wrong vaccine product used for COVID-19 vaccine series completion.**
    - Both doses in a two-dose series should come from the same manufacturer.
    - In extremely rare situations in which the first-dose vaccine product cannot be determined or is no longer available, any available mRNA COVID-19 vaccine may be administered at a minimum interval of 28 days between doses to complete the mRNA COVID-19 vaccination series.
    - If two doses of different mRNA COVID-19 vaccine products are administered in these situations (or inadvertently), no additional doses of either product are recommended at this time.
    - If first dose was mRNA COVID-19 vaccine and second dose was Johnson & Johnson (Janssen) COVID-19 vaccine (viral vector vaccine), recipient is considered fully vaccinated.
    - Recommendations may be updated as more information becomes available or other types of vaccine are authorized.

Vaccine storage and handling errors

6. **Storage and handling.**
    - Dose administered after improper storage and handling
        - Deviations from recommended temperatures..
            - Stored at temperatures not compliant with manufacturer guidelines listed in EUA for storage.
            - Deviations from recommended temperatures during transport.
                - Refreezing.
                - Exposure to sunlight.
                - Warmer than room temperature guidelines.
    - Dose administered past the expiration/beyond-use date.
        - Seek manufacturer guidance. If the manufacturer provides information supporting that the dose should be repeated, the repeated dose may be given immedately (no minimum interval) in the opposite arm.

Serious Events

7. Serious adverse events **regardless of causality**. Serious adverse events per FDA are defined as:
    - Death.
    - A life-threatening adverse event.
    - Inpatient hospitalization or prolonged existing hospitalization.
    - A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions.
    - A congenital anomaly/birth defect.
    - An important medical event that, based on appropriate medical judgment, may jeopardize the individual and may require medical or surgical intervention to prevent one of the outcomes listed above.
8. **Cases of Multisystem Inflammatory Syndrome (MIS-A for adults and MIS-C for children).**
9. **Cases of COVID-19 that result in hospitalization or death.**

Other Events

Healthcare providers are encouraged to report to VAERS ***any additional clinically significant*** adverse events following vaccination, *even if they are not sure if vaccination caused the event*. Also report any additional select adverse events and/or any revised safety reporting requirements per the FDA's conditions of authorized use of vaccines throughout the duration of any COVID-19 vaccine being authorized under an emergency use authorization (EUA).

How to report adverse reactions to VAERS

There are two ways to submit a report to VAERS:

- **Option 1 (preferred):** Submit a VAERS report online at https://vaers.hhs.gov/esub/index.jsp.
    - The online VAERS report must be completed and submitted in the same session; it cannot be saved and edited later.
    - Sessions time out after 20 minutes of inactivity; no information is saved.
- **Option 2:** Download a writable PDF form and upload, when ready, to https://vaers.hhs.gov/uploadFile/index.jsp.
    - The writable PDF form can be downloaded and completed electronically on your own time. Return to the VAERS writable PDF web page (use link above) and follow Step 2 instructions to upload the form.
- **Understanding VAERS:** https://www.cdc.gov/vaccines/hcp/patient-ed/conversations/downloads/vacsafevaers-color-office.pdf.

More information on reporting an adverse event: https://vaers.hhs.gov/reportevent.html. If you need further assistance, please email info@VAERS.org or call 1-800-822-7967.

For additional clinical considerations, please visit **Interim Clinical Considerations for Use of mRNA COVID-19 Vaccines Currently Authorized in the United States.**

https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html

Updated April 19, 2021.

For more information on COVID-19, please visit coronavirus.ohio.gov. For answers to your COVID-19 questions, call 1-833-4-ASK-ODH (1-833-427-5634).