

COVID-19

VACCINATION ADVERSE EVENT REPORTING SYSTEM – JANUARY 7, 2021

Vaccine Adverse Event Reporting System (VAERS) is a national system for individuals to report adverse events after receiving a vaccination. VAERS is co-managed by the Centers for Disease Control and Prevention (CDC) and the U.S. Food and Drug Administration (FDA). Health care professionals are required to report certain adverse events.

The health care professional administering vaccines (the vaccinator) is required by the Emergency Use Authorization (EUA) to complete the VAERS reporting form for:

- Vaccine administration errors whether or not associated with an adverse event
- Serious adverse events* (irrespective of attribution to vaccination), including:
 - Death;
 - A life-threatening side effect;
 - Inpatient hospitalization;
 - Prolongation of existing hospitalization;
 - A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions;
 - A congenital anomaly/birth defect;
 - o Cases of Multisystem Inflammatory Syndrome (MIS) in adults and children;
 - Cases of COVID-19 that result in hospitalization or death; or
 - Based on appropriate medical judgement, an important medical event that may jeopardize the individual and may require medical or surgical intervention to prevent one of the outcomes listed above.

Best Practices for Health Care Professionals:

- 1. After vaccinations are completed and prior to leaving the site, the vaccinator should provide contact information to the site lead (individual overseeing the location where the vaccinations were held).
- 2. The site lead should be reminded to report all serious adverse events to the vaccinator as soon as they are identified and that sharing this information is both allowed and a requirement of the vaccine program.

VAERS Reporting Form Steps:

- 1. Go to https://vaers.hhs.gov and review the information needed.
- 2. Collect additional information needed to complete the VAERS form from the individual(s) in the best position to have witnessed the event, such as the health care provider or site lead. The VAERS form can be saved as a PDF while entering data by clicking on "preview report" on the left side of the screen.
- 3. Submit the online VAERS form online once complete (within 24 hours of the event). Although not all sections are required, it is recommended to have the form be as complete as possible prior to submission.
- 4. Send a copy of the saved PDF file to the West Virginia Poison Center via fax to (304) 347-3908 or by secure email to Dr. Elizabeth Scharman, escharman@hsc.wvu.edu. If saving the PDF is not possible, contact Dr. Scharman directly to provide the key information by calling the WV Coronavirus Hotline, 1-800-887-4304.
- 5. Problems or questions may be directed to Dr. Elizabeth Scharman, <u>escharman@hsc.wvu.edu</u> or 1-800-887-4304.