SMALLPOX FACT SHEET – *Information for Clinicians*

Smallpox (Vaccinia) Vaccine Adverse Event Reporting

Most people experience normal, typically mild reactions to smallpox (vaccinia) vaccine. However, some people may experience reactions that may require medical attention and should be reported.

- **Normal, typically mild reactions** include a sore arm, fever, swollen glands, and body aches.
- **Moderate to severe reactions** include contact spread of the smallpox vaccine virus (vaccinia) to other parts of the body or to other persons (inadvertent inoculation), spread of vaccinia to other parts of the body through the blood (generalized vaccinia), and a toxic or allergic reaction (erythema multiforme).
- **Potentially life threatening** include widespread infection of the skin (eczema vaccinatum), ongoing tissue destruction (progressive vaccinia or vaccinia necrosum) and inflammation of the brain (postvaccinal encephalitis). These reactions require immediate medical attention.
- **Other severe events** include events that result in hospitalization, permanent disability, life-threatening illness, or death. These events are temporally-associated with smallpox vaccination but have not been documented to be causally associated.

What to do if vaccinees or close contacts experience serious or life-threatening smallpox vaccine reactions

Healthcare providers may call the Clinician Information Line (CIL) at 1-877-554-4625 or their Health Department. If needed, the Centers for Disease Control and Prevention (CDC) will be available to provide guidance and consultation on clinical management issues, including use of Vaccine Immune Globulin (VIG) and cidofovir.

When to use the Vaccine Adverse Event Reporting System (VAERS) to report adverse events or reactions to smallpox vaccine

VAERS, the primary U.S. vaccine safety monitoring system, encourages reporting of **any** unexpected or serious event occurring after smallpox vaccination as well as adverse events occurring in persons following close contact with a vaccine recipient. An **adverse event** is any clinically significant medical event that occurs following administration of a vaccine. A VAERS report should be submitted even if it is not certain that the event was caused by the vaccine.

Adverse events that are serious or unexpected and require expert consultation or IND (investigational new drug) therapeutics (VIG or cidofovir) should be immediately reported by phone to the Health Department or CDC, and should also be reported to VAERS as soon as possible. All other smallpox vaccine adverse events judged to be serious should be reported directly to VAERS within 48 hours of recognition. Other clinically significant adverse events should be reported to VAERS within one week.

Anyone can report smallpox vaccine adverse events

Healthcare providers who clinically evaluate individuals having adverse events are strongly encouraged to report to facilitate follow-up and medical treatment. Health department personnel also can report or assist providers reporting.

It is important to report smallpox vaccine adverse events

Reporting to VAERS helps assure that smallpox vaccination will be conducted as safely as possible. Data from VAERS reports are analyzed by the CDC and the Food and Drug Administration (FDA) to identify

- new and/or rare vaccine side effects
- increases in rates of known side effects
- patient risk factors for particular types of adverse events

Submitting a VAERS report

Electronic reporting of all smallpox vaccine adverse events is strongly encouraged because it is the most timely and efficient method of providing information. Secure web-based reporting is available at https://secure.vaers.org/VaersDataEntryintro.htm. Detailed instructions for web-based reporting are provided on-line at www.vaers.org. .

Printable VAERS forms are available online at http://www.vaers.org/pdf/vaers_form.pdf. Completed forms can be faxed toll-free to 1-877-721-0366 or mailed to P.O. Box 1100; Rockville, MD 20894-1100. If further assistance is needed to complete a form, please call 1-800-822-7967 or send an email to info@vaers.org.

Filling out a VAERS form

The VAERS form has not been changed for smallpox vaccination. Because of limited knowledge about smallpox vaccine adverse events, it is particularly important that the VAERS form be filled out as completely and accurately as possible.

As with all VAERS reporting

- when completing the form, boxes 3, 4, 7, 8, 10, 11, and 13 are considered essential;
- when reporting electronically, information from other electronic records can be copied and pasted into boxes 7, 17, 18, and 19;
- when submitting follow-up information (such as medical records) to VAERS by fax or mail, use the VAERS E-report number, VAERS ID, PVN, or other unique vaccination number. This number should be written in the upper right hand corner of each page.

Sources for more information about VAERS reporting

Vaccine Adverse Event Reporting System:	www.vaers.org
Centers for Disease Control and Prevention:	www.cdc.gov/nip/vacsafe/#VAERS
Food and Drug Administration:	www.fda.gov/cber/vaers/vaers.htm

For more information, visit www.cdc.gov/smallpox, or call the CDC public response hotline at (888) 246-2675 (English), (888) 246-2857 (Español), or (866) 874-2646 (TTY)
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