

Smallpox

Clinical Description &
Recommendations for a Vaccination Program

Completing the VAERS form

Instructions for completing the VAERS form are on the back of the form. (Please see Figure 2.) To complete the VAERS form, as much of the requested information as possible should be obtained. Each report should be reviewed for completeness, accuracy, and legibility with specific attention to the following:

Dates: All dates should make chronological sense. For example: the vaccine date cannot precede the birth date; the report date cannot precede the vaccine date, etc. All date fields require entry of the full month, day, and year.

Patient name: Verify that the patient's first and last names are correct. This assists in the identification of duplicate reports and facilitates the follow-up process.

Reporter information: (In the upper right corner of form.) The reporter's name and complete mailing address are required. Verification letters and requests for missing or follow-up information are sent to this address. If you do not receive a verification letter within a reasonable amount of time (e.g., month) check with the VAERS program at www.vaers.org

Critical boxes: Certain items are crucial to the analysis of VAERS data and have been designated by critical boxes. If all critical boxes are complete, no missing data will be requested and the report is considered complete. Critical boxes are differentiated by a square around their respective item numbers on the form as follows:

Date Box 3 of birth

Age Box 4 of patient at the time of vaccination

Box 7 Narrative description of adverse events, symptoms,
etc.

Box 8

Determines whether a report is regarded as serious or nonserious, and identifies the most serious reports for 60-day and annual follow-up

Serious Reports

- Patient died/date patient died
- Life-threatening illness
- Resulted in permanent disability
- Required hospitalization and number of days of hospitalization
- Resulted in prolonged of hospitalization

Non-Serious Reports

- Required emergency room or doctor’s visit
- None of the above

Box 10

Date of vaccination (and time, if known)

Box 11

Date of onset of adverse event (and time, if known)

Box 13

All vaccines given on the date listed in Box 10, including name of vaccine, vaccine manufacturer, vaccine lot number, route and site of administration and number of previous doses given

Box 15 and 16

Identify potential public health reports; VAERS immunization report number if not supplied

Box 24

NCVIA requires tracking of vaccine(s) administered; the immunization project report number is assigned by the state health coordinator (SHC) and is an identifier between the SHC and the VAERS ID

Timely Reporting: All reports are to be sent to VAERS as they arise, especially any serious reports. Do not send batches of reports. Do not wait for complete documentation before sending to VAERS, especially if the report appears serious. VAERS data is downloaded on a daily basis so that review and follow-up of serious reports can be conducted. Timely reporting is essential to timely follow-up investigation, especially if clinical specimens must be obtained.

VAERS ID: VAERS will send a confirmation notice to the reporter for all reports received, whether mailed, faxed, or sent electronically. A

unique VAERS ID number will be provided with the confirmation notice. Any follow-up correspondence about a report must include the VAERS ID number. Reports are entered into the VAERS database under the unique ID number. It is also helpful to have the patient's name and date of birth, if available, to help identify the specific report.

Missing, corrected, or supplemental information: Information such as medical records, autopsy reports may be submitted to VAERS by phone, mail or fax as follows:

Phone: 800-822-7967

Fax: Using a blank VAERS form, record the following information in the appropriate boxes: VAERS ID, the SHC immunization project number (if appropriate), the patient's name and date of birth, the corrected or missing information you are providing, your name and phone number.

Mail: See instructions for FAX above. Mail to:

**VAERS
P.O. Box 1100
Rockville, MD 20849-1100**

Summary of Contact Information for Vaccine Safety Concerns

Contact the CDC Drug Services for information regarding the IND protocol smallpox vaccine or access to Vaccinia Immune Globulin (VIG):

CDC Drug Services
National Center for Infectious Diseases
Mail stop D-09
1600 Clifton Road NE
Atlanta, GA 30333
Phone: 404-639-3670
Fax: 404-639-3717

Contact VAERS for information on the reporting of vaccine adverse events:

VAERS
PO Box 1100
Rockville, MD 20849-1100
Phone: 1-800-822-7967
Fax: 1-877-721-0366
Email: www.vaers.org

Contact the National Immunization Program when VIG or cidofovir use is needed for treatment of vaccine adverse events:

Centers for Disease Control and Prevention
National Immunization Program

Vaccine Safety and Development Activity
Phone: 404-639-8256
Fax: 404-639-8834