Annex 3

Vaccine Adverse Events Reporting
Vaccine Safety  
Monitoring and Reporting of Adverse Events following Smallpox Vaccination

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Monitoring and Reporting of Adverse Events following Smallpox Vaccination

It is well documented that smallpox vaccination was associated with significant morbidity and mortality. When non-selective vaccination of the U.S. population was conducted, each year 5 to 10 deaths, several hundred hospitalizations, and several thousand non-hospitalized complications resulted from the vaccine. However, smallpox vaccine has not been routinely used in the United States since 1971 and familiarity with its adverse reactions has diminished. Therefore, careful monitoring of adverse events needs to be conducted to re-familiarize health professionals with the safety profile of the vaccine. Additionally, re-institution of the smallpox vaccine may reveal known safety concerns with increased frequency or ones not previously known. Known side effects and adverse reactions of the vaccinia (smallpox) vaccine are included in the recommendations of the Centers for Disease Control and Prevention’s (CDC) Advisory Committee on Immunization Practices (ACIP) for vaccinia vaccine [CDC. MMWR 2001;50(No.RR-10)] and in other sections of this response plan (Guide B).

Timely recognition of and response to, vaccine adverse events (VAEs) is important to protect the public from unnecessary risk and to maintain confidence in the immunization effort. Individuals who are most susceptible to adverse effects of smallpox vaccine are those with active skin disorders (e.g., eczema, burns, atopic dermatitis, impetigo, varicella zoster) and immunodeficiency states (e.g., HIV, AIDS, leukemia, lymphoma, generalized malignancy, agammaglobulinemia, or therapy with alkylating agents, antimetabolites, radiation, or large doses of corticosteroids). The following complications may follow either primary vaccination or revaccination:

- encephalitis
- encephalomyelitis
- encephalopathy
- transverse myelitis
- acute infectious polyneuritis
- vaccinia necrosum
- eczema vaccinatum
- generalized vaccinia
- accidental infection (autoinoculation)
- generalized rashes (erythematous, urticarial, nonspecific)
- secondary pyogenic infections at the site of vaccination
Such complications may result in severe disability (e.g., blindness from autoinoculation of the eye), permanent neurological sequelae, and/or death.

This document is intended to act as a guide for monitoring the safety of smallpox vaccine in preparation for a smallpox outbreak. It addresses the need for vaccine safety monitoring, identifies the range of potential safety activities, describes the safety actions that should take place before and at the time of vaccination, the process for reporting adverse events following smallpox vaccine under different vaccination scenarios, provides relevant safety contact information, and includes copies of the adverse event reporting forms. This document provides useful information for smallpox response teams and for state and local health department involved in any aspect of vaccine safety.

**Investigational New Drug Protocol**

The vaccinia vaccine is no longer a licensed product and is classified under an Investigational New Drug protocol (IND). The vaccine is only available from CDC Drug Service. Because of the IND status there is increased emphasis on and requirements for the monitoring of vaccine adverse events. The vaccine safety members of the CDC Smallpox Response Teams will be designated as IND sub-investigators and will be trained by CDC Drug Services in the regulations and requirements applicable to the IND protocol. Appropriate state health department physicians will also be identified, designated, and trained to be sub-investigators.

In the event of an outbreak, questions regarding the IND protocol should first be addressed to the CDC Response Team vaccine safety member(s). If necessary, questions can then be referred by the vaccine safety member to

**CDC Drug Services**  
National Center for Infectious Diseases  
Mail stop D-09  
Atlanta, GA 30333  
*Phone:* 404-639-3670  
*FAX:* 404-639-3717

**Reporting Vaccine Adverse Events**

**Report all adverse events to VAERS**

The Vaccine Adverse Event Reporting System (VAERS) will receive all vaccine adverse event reports. The VAERS staff will give priority to smallpox reports and will be in daily contact with the CDC/NIP vaccine safety personnel. The VAE reports will be shared with the CDC Drug Services Center who holds the IND protocol for CDC and the reports will be reviewed by both CDC and the Food and Drug Administration. VAERS can be contacted at

**VAERS**  
P.O. Box 1100  
Rockville, Maryland 20849-1100  
*Phone:* 1-800-822-7967  
*FAX:* 1-877-721-0366
Follow-up Surveillance Actions

Depending on the extent of vaccine administration, a number of surveillance activities will be conducted.

- **Active surveillance** for adverse events will be conducted when the number of vaccine doses administered is limited (see description below). Every vaccine recipient will be provided with a diary report card to document their response to the vaccine. To make certain that serious VAEs are identified, active surveillance will be conducted for persons receiving vaccinia immune globulin (VIG) or cidofovir – pharmaceutical agents indicated for the treatment of certain severe vaccine complications. Active surveillance for VIG and cidofovir use will not be limited based on the number of vaccine doses administered.

- **Stimulated passive surveillance** and follow-up of serious adverse events will be conducted whether limited or large numbers of vaccine doses are administered. VAERS is considered a passive surveillance system because reports are not actively solicited. However, because of enhancements to VAERS, such as indicating to very vaccine recipient how VAERS can be contacted, implementation of electronic reporting, and follow-up of all smallpox reports, the passive system is “stimulated”.

- If **universal vaccination** is instituted, CDC’s Vaccine Safety Datalink can be utilized. The datalink is an economical and rapid mechanism for detection as well as evaluation of new hypothesized vaccine adverse events. It holds computerized vaccination and medical records for more than 2.5 percent of the U.S. population served by health maintenance organizations across the country.

Surveillance and reporting for Small Outbreaks

When there are a limited number of cases in one geographic location (potential number of vaccinees in the 100s) or when there are a limited number of cases in more than one geographic location (potential number of vaccinees in the 1,000s), the following actions should be conducted.

**Prior to administering vaccine**

Vaccine providers, immunization programs, and hospitals in the vicinity of the outbreak should be given the following:

- Hard copies of VAERS form (Figures 1 and 2)
- Instructions on how to access the VAERS report form and submit electronically to [www.vaers.org](http://www.vaers.org). Electronic reporting is the preferred method as of 01/01/02.
- Vaccine Information Statements (VIS) that contain instructions on how to contact VAERS and should include the state health department contact information also.
Clinical description of known vaccine complications: inadvertent inoculation, generalized vaccinia, eczema vaccinatum, progressive vaccinia, post-vaccinal encephalitis

Notification form to FAX to 404-639-8834 if VIG or cidofovir used (Figure 3)

VIG information: indications for use (See Guide B, Section G of this plan), where and how to obtain this information. The contact point for VIG is:

CDC Drug Services
National Center for Infectious Diseases
Mail stop D-09
Atlanta, GA 30333
Phone: 404-639-3670
FAX: 404-639-3717

State health departments should be given the material listed above, and should take the following actions:

- Designate and train physician(s) (sub-investigators) to be responsible for monitoring and complying with the IND protocol regulations.
- Designate a person who is trained and available for coordinating vaccine safety activities of surveillance and reporting.
- Designate staff who are trained and available for active surveillance tracking, follow up of serious reports submitted to VAERS (Figure 4), for providing assistance in completing VAERS forms, and for telephone follow up of adverse event reports identified by contact tracing personnel during their follow up of smallpox contact vaccine recipients.

At time of vaccination
Vaccine recipients or their parent/guardians should be given the following:

- Vaccine Information Statements (VIS) with instructions on how to contact VAERS and the respective State Health Department
- VAE diary card and instructions for active surveillance (Figure 5)

Surveillance and reporting for Large Outbreaks

When there are large numbers of cases in one or more geographic locations (number of potential vaccinees in the 100,000s or more), all of the previously described vaccine safety actions should occur, with one exception. Active surveillance for vaccine adverse events using a diary card will not be feasible. Thus, at the time of vaccination, vaccine recipients or their parent/guardians should only be given the only the VIS with instructions on how to contact VAERS and their respective state health department.

Additional Vaccine Safety Activities

In a large immunization effort reports of adverse events both coincidentally and causally associated with the smallpox vaccine are to be expected. Standardized follow-up of
VAEs reported to VAERS (Figure 4) and assessment of the causal association between the vaccine and reported adverse events will be performed. This will be done to increase understanding of the safety profile of the vaccine and identify potential risk factors and to maintain confidence in the vaccine.

**Smallpox Vaccine Expert Committee**

The Smallpox Vaccine Expert Committee (SVEC) will be established as a standing committee to evaluate all smallpox vaccine VAERS reports and make recommendations for the need of additional collection of clinically relevant history or further clinical investigation. The SVEC will consist of clinical experts derived from CDC’s Clinical Immunization Safety Assessment (CISA) Centers and/or from the Vaccine Healthcare Center (VHC) Network along with other expertise as required. CISA consists of four geographically diverse centers recently funded by CDC to evaluate individual clinical adverse events reported to VAERS. The VHC Network was established by a partnership between CDC and DoD to create centers for excellence in the military immunization healthcare system to study issues of safety and acceptability of vaccines in military populations.

**Adverse event reports forwarded from CISA to Smallpox Vaccine Expert Committee**

The VAERS contractor shall forward all smallpox vaccine VAERS reports to the attention of both the VAERS project officer and the CISA project officer *in the same packet*, while simultaneously generating a standardized follow-up form already mentioned (Figure 4). The responsible project officer will then submit all VAERS smallpox vaccine adverse event case reports, in a timely manner, to the SVEC for their expert consideration. The committee shall meet via conference call at least weekly and more often or on an emergency basis as needed to review emerging concerns from smallpox vaccine VAERS reports and existing follow-up records.

**Protocols for assessment of adverse reactions**

The CISA centers are developing protocols for the evaluation and clinical management of adverse events following immunization. Such protocols will allow for the intensive clinical study of individuals with true vaccine reactions and for standard assessment of persons reporting previously unrecognized adverse events. The evaluation component will consider the potential differential diagnosis and include questions to address patients’ current and past medical history, risk factors, medications, vaccinations, allergies, family history, social and developmental factors, symptom assessment, physical examination, laboratory tests, radiological and other studies. The management component will discuss supportive care and the indications for and instruction pertaining to the use of Vaccinia Immune Globulin and cidofovir. The CISA clinicians will provide consultation to other health care providers for clinical safety questions, follow-up, and outcome of vaccine complications.
**Reports from clinics**

Ideally, to accurately and rapidly monitor the occurrence of vaccine adverse events, rates of VAEs would be calculated on a daily basis by CDC. This would require daily submission of information on the number of vaccine doses administered from the vaccination/clinic site(s) to the CDC. In the event of a large outbreak, or outbreaks in multiple locations, it might not be feasible to accomplish daily submission from the field. However, at a minimum, data should be available weekly or the timeliness of vaccine safety monitoring would be greatly diminished. If rates of VAEs are observed to be unusually high for serious VAEs (i.e., higher than expected based on historical published information), increased efforts would be made to obtain data more frequently than on a weekly basis. The data available from each clinic should include, for each vaccine recipient, information on age, gender, vaccine lot, and clinic location. Thus, the calculated rates of VAEs will be age and gender specific. And, it will be possible to quickly detect unusual VAE rates for specific vaccine lots.

**Tracking serious adverse events using VIG or cidofovir**

To track the most serious adverse events, presumably those most likely to be treated with VIG and/or cidofovir (under an IND), it will be necessary to identify the requests for VIG and/or cidofovir using multiple mechanisms. Requests for VIG must go through the CDC Drug Services center; daily contact with the CDC Drug Services center will be performed to obtain this information. Additionally, vaccine safety personnel will contact hospitals and pharmacies in the area of an outbreak to identify VIG and/or cidofovir use. Prior to vaccine being administered, notification postcards (Figure 3) will be given to all vaccine providers, immunization programs, and hospitals in the outbreak area. For each person receiving VIG or cidofovir, a notification postcard should be returned to CDC. Case follow up will be performed for all vaccine recipients or contacts of vaccine recipients requiring such treatment.

**Instructions for Reporting to VAERS**

(Please refer to figures 1 and 2 for a sample VAERS form.)

**Getting a VAERS form**

Additional report forms, assistance in completing the form, or answers to other questions about VAERS are available via a 24-hour toll-free telephone number: **1-800-822-7967**. The reporting form can be downloaded from the VAERS web page at [www.vaers.org](http://www.vaers.org). A sample copy of the VAERS form, which can be copied for reporting purposes, is also available in the American Academy of Pediatrics’ *Red Book*. The Vaccine Information Statements developed by DHHS also contain instructions on how to report adverse events to VAERS.
Submitting the VAERS form

*Mailed:* The VAERS form is preaddressed and postage paid. It may be sent directly to VAERS at the following address:

VAERS  
P.O. Box 1100  
Rockville, Maryland 20849-1100

*FAXED:* The form can also be FAXED toll-free to **1-877-721-0366**.

*Electronic:* As of 01/01/02, the preferred method of reporting will be electronic. The instructions for reporting and the electronic report form are available at VAERS web page [www.vaers.org](http://www.vaers.org)

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, date, 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 ability to conduct follow up.

**Reporter information:** (This is in the upper right corner of form.) The reporter 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](http://www.vaers.org)

**Critical boxes:** Certain items are crucial to the analysis of VAERS data and have been designated as 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 of**  
  - **Box 4** patient at the time of vaccination

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

- **Determines whether a report is regarded as serious or non-serious, and identifies the most serious reports for**
  - **Box 8**
60-day and annual follow-up

**Serious Reports**
- Patient died/date patient died
- Life threatening illness
- Resulted in permanent disability
- Resulted in prolongation of hospitalization
- Required hospitalization and number of days 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 occur, 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 may need to 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**

**Serious reports**

For serious reports, the VAERS program will send a letter to the reporter requesting information on patient status at 60 days and 1 year. The reporter may also provide additional information on critical boxes if not originally available and pertinent supporting documentation may be attached if available (e.g., medical records, autopsy report). Include the following information:

- VAERS ID Number
- Patient name
- Your name and phone number
- Box 3—Patient date of birth
- Box 7 or 9—Patient status. Indicate the date that the follow-up information was obtained.
- Report patient status as follows.
  - Recovered—if patient health condition is the same as it was prior to the vaccine.
  - Not recovered—if patient health condition has not returned to pre-vaccination state of health.
  - Unknown—if patient condition or whereabouts are unknown.
  - Died—if patient has expired since initial report. Include date of death and supporting documentation (copies of hospital records, autopsy report, death certificate, etc.) as available.

**Secondary transmission**

Because vaccine virus can be transmitted from the vaccination site if not appropriately covered and cared for, adverse events have been known to occur in contacts of vaccinated persons (e.g., eczema vaccinatum). If an adverse event is suspected or identified in a contact of a vaccine recipient, a VAERS report should be submitted with information on the person experiencing the adverse event. Such reports will be coded as the result of secondary transmission.
Local health departments or immunization projects

Clinic staff at the local level are responsible for initiating the VAERS report when an adverse event is suspected or occurs. Because of the need to rapidly monitor the occurrence of adverse events and to follow up on serious reports, local clinic or health department staff are requested to send reports directly to VAERS. Note that this differs from the procedure usually employed for non-smallpox vaccine reports; for non-smallpox vaccine reports each VAERS report is sent first to the SHC or VAERS Coordinator before being sent to the VAERS program.
### VAERS Reporting Form

#### VACCINE ADVERSE EVENT REPORTING SYSTEM

- **VAERS Number:**
- **Date Received:**

#### For CDC/VA Use Only

- **VAERS Number:**
- **Date Received:**

#### Patient Information

- **Patient Name:**
- **Date of birth:**
- **Patient age:**

#### Vaccine Information

- **Vaccine administered by (Name):**
- **Lot number:**

#### Adverse Event Information

- **Adverse event onset:**
- **Date of vaccination:**

#### Other Information

- **Other medications:**
- **Illness at time of vaccination (specify):**
Figure 2. Instructions for Completion of VAERS Form

"Fold in thirds, tape & mail - DO NOT STAPLE FORM"

**BUSINESS REPLY MAIL**
FIRST-CLASS MAIL PERMIT NO. 1895 ROCKVILLE, MD
POSTAGE WILL BE PAID BY ADDRESSEE

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

**DIRECTIIONS FOR COMPLETING FORM**
(Additional pages may be attached if more space is needed)

**GENERAL**
Use a separate form for each patient. Complete the form to the best of your abilities. Items 3, 4, 7, 8, 10, 11, and 13 are considered essential and should be completed whenever possible. Parents/Guardians may need to consult the facility where the vaccine was administered for some of the information (such as manufacturer, lot number or laboratory data.) Refer to the Reportable Events Table (RET) for events mandated for reporting by law. Reporting for other serious events felt to be related but not on the RET is encouraged.

Health care providers other than the vaccine administrator (VA) treating a patient for a suspected adverse event should notify the VA and provide the information about the adverse event to allow the VA to complete the form to meet the VA’s legal responsibility. These data will be used to increase understanding of adverse events following vaccination and will become part of CDC Privacy Act System 09-20-0136, “Epidemiologic Studies and Surveillance of Disease Problems”. Information identifying the person who received the vaccine or that person’s legal representative will not be made available to the public, but may be available to the vaccinee or legal representative.

Postage will be paid by addressee. Forms may be photocopied (must be front & back on same sheet).

**SPECIFIC INSTRUCTIONS**
Form Completed By: To be used by parents/guardians, vaccine manufacturers/distributors, vaccine administrators, and/or the person completing the form on behalf of the patient or the health professional who administered the vaccine.

Item 7: Describe the suspected adverse event. Such things as temperature, local and general signs and symptoms, time course, duration of symptoms, diagnosis, treatment and recovery should be noted.

Item 9: Check "YES" if the patient’s health condition is the same as it was prior to the vaccine, "NO" if the patient has not returned to the pre-vaccination state of health, or "UNKNOWN" if the patient’s condition is not known.

Item 10: Give dates and times as specifically as you can remember. If you do not know the exact time, please place "AM" or "PM" when possible. If this information is known, if more than one adverse event, give the onset date and time for the most serious event.

Item 12: Include "negative" or "normal" results of any relevant tests performed as well as abnormal findings.

Item 13: List ONLY those vaccines given on the day listed in item 10.

Item 14: List any other vaccines that the patient received within 4 weeks prior to the date listed in item 10.

Item 16: This section refers to how the patient who gave the vaccine purchased it, not to the patient’s insurance.

Item 17: List any prescription or non-prescription medications the patient was taking when the vaccine was given.

Item 18: List any short term illnesses the patient had on the date the vaccine was given (i.e., cold, flu, ear infection).

Item 19: List any pre-existing physician-diagnosed allergies, birth defects, medical conditions (including developmental and/or neurologic disorders) for the patient.

Item 21: List any suspected adverse events the patient, or the patient's brothers or sisters, may have had to previous vaccinations. If more than one brother or sister, or if the patient has reacted to more than one prior vaccine, use additional pages to explain completely. For the onset age of a patient, provide the age in months if less than two years old.

Item 26: This space is for manufacturers' use only.
Notification of Vaccinia Immune Globulin (VIG) /Cidofovir (Vistide) Therapy

Dear Provider,

Rare serious adverse reactions are known to occur following smallpox vaccination. The CDC is attempting to follow those individuals who experience such vaccine complications, especially those who receive vaccinia immune globulin (VIG) or cidofovir (Vistide) for the treatment of their adverse events. Please use this form to report initiation of either VIG or cidofovir therapy in the treatment of serious adverse events associated with administration of smallpox vaccine.

This form should NOT be used to request VIG, VIG can be obtained from CDC Drug Services:

Centers for Disease Control and Prevention
Drug Services, National Center for Infectious Diseases
Mailstop D-09
1600 Clifton Road NE
Atlanta GA 30333
Telephone: 404-639-3670
Facsimile: 404-639-3717

Once VIG / cidofovir therapy is initiated, please fax this completed form to:

National Immunization Program
Vaccine Safety and Development Activity
Facsimile: 404-639-8834

<table>
<thead>
<tr>
<th>Patient Identification</th>
<th>Provider Identification</th>
<th>VIG / Cidofovir Therapy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient Name:</td>
<td>Provider Name:</td>
<td>Date therapy started:</td>
</tr>
<tr>
<td>Address:</td>
<td>Address:</td>
<td><strong><strong><strong>/</strong></strong><em>/</em></strong>_______</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Which therapy is being used?</td>
</tr>
<tr>
<td>Daytime Phone Number:</td>
<td>Daytime Phone Number:</td>
<td>(please circle)</td>
</tr>
<tr>
<td>(<em><strong>)</strong></em>_______________</td>
<td>(<em><strong>)</strong></em>_______________</td>
<td>VIG or Cidofovir</td>
</tr>
<tr>
<td>Evening Phone Number:</td>
<td>Evening Phone Number:</td>
<td>Why was therapy started?</td>
</tr>
<tr>
<td>(<em><strong>)</strong></em>_______________</td>
<td>(<em><strong>)</strong></em>_______________</td>
<td>____________________________</td>
</tr>
<tr>
<td></td>
<td></td>
<td>__________________________</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Vaccination Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vaccine:________________</td>
</tr>
<tr>
<td>Manufacturer:___________</td>
</tr>
<tr>
<td>Lot #:__________________</td>
</tr>
<tr>
<td>Expiration Date:________</td>
</tr>
<tr>
<td><strong><strong><strong>/</strong></strong><em>/</em></strong>_______</td>
</tr>
<tr>
<td>Date Vaccinated:________</td>
</tr>
<tr>
<td><strong><strong><strong>/</strong></strong><em>/</em></strong>_______</td>
</tr>
<tr>
<td>Vaccine diluted: Yes or No</td>
</tr>
<tr>
<td>(please circle)</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>Was a VAERS Report Submitted:</td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>
Figure 4. VAERS Smallpox Follow-up Form

SMALLPOX VACCINE ADVERSE EVENT FOLLOW-UP

1. VAERS #: ____________________  2. Form completed by: ____________________

MISSING INFORMATION: Check for missing information on original VAERS form, and obtain if needed.

THIS INFORMATION WAS COLLECTED FROM THE FOLLOWING PERSONS:

3. Name______________________  3a. Name______________________
4. Title______________________   4a. Title______________________
5. Telephone # _____–_____–_____  5a. Telephone # _____–_____–_____
6. Address___________________  6a. Address___________________

7. Fax # _____–_____–_______  7a. Fax # _____–_____–_______
8. E-mail____________________  8a. E-mail____________________

9. Date spoken with___/____/___  9a. Date spoken with___/____/___

CONFIRM VAERS FORM INFORMATION:

10. Patient Name: __________________________
11. Date of Birth: __________________________
12. Gender: _____ M _____ F

13. Update pt’s status/VAERS information since the original VAERS form:

MEDICAL HISTORY (has the patient ever had any of the following medical conditions):

14. Heart disease             Yes   No  21. Acquired Immune deficiency (HIV)   Yes

No

15. Stroke                   Yes   No  22. Congenital immune deficiency       Yes

No
16. Seizure                  Yes   No  23. Sickle Cell Disease               Yes

No
17. Asthma/emphysema        Yes   No  24. Spleen Removal                    Yes

No
18. Cancer /leukemia        Yes   No  25. Autoimmune disorder (ex: lupus)    Yes

No
19. Eczema                   Yes   No  26. Hepatitis                          Yes

No
19a. If yes: Active __ or History of ___ (check one)

20. Other chronic skin condition Yes   No  27. Frequent/recurrent/severe infections Yes

No

28. Other (specify): ______________

29. If you checked “YES” to Cancer/leukemia, other chronic skin conditions, autoimmune disorder, or frequent/recurrent/severe infections, please specify what type, when it was diagnosed, and how it was treated:

________________________________________________________________________
________________________________________________________________________
________________________________________________________________________

____________________________
30. Describe any hospitalizations in the last 1 year (dates, where, why, outcome):
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________

MEDICATION HISTORY:
31. Were you taking any medications at the time of vaccination or since vaccination?  Yes  No
If yes, specify drugs/dates:
32d. Drug________________ 32e. Start dt: ___/___/___  32f. Stop dt:___/___/___
32g. Drug________________ 32h. Start dt: ___/___/___  32i. Stop dt:___/___/___
32j. Allergic to any medications?  Yes  No  If yes, specify:

VACCINATION HISTORY:
34. Previous vacc with smallpox?  Yes  No  Not sure  If yes, when/where:
________________________________________________________________________
Other vaccines received within 30 days before or after smallpox vaccine:
35l. Loc: ______
36. Have you ever had a serious reaction after any vaccination?  Yes  No
36a. If yes, specify the immunization, the approximate date, the events that occurred, and what
 was done in response to the reaction:
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________

FEMALES ONLY:
38. Date of LMP___/____/____  39. Are you currently pregnant?  Yes  No

DETAILS OF ADVERSE EVENT AND MANAGEMENT
40. Which type of adverse event did the patient experience? (check all that apply)
   Generalized Vaccinia __
   If yes, was it: maculopapular __ vesicular __ unknown __ (check one)
   Eczema Vaccinatum __
   If yes, describe location(s) of skin involvement:
   Progressive Vaccinia (Vaccinia necrosum) __
   Post-Vaccinial Encephalitis __
   Inadvertant Innoculation __
   If yes, involved anatomic area: eye __ mouth __ lips __ genitals __
   Other location (describe) ________________________________
   Other __
   If other, was it: severe local reaction __
   bacterial superinfection of vaccination site __
   erythema multiforme __
   other (describe) ________________________________________
41. Which if any of the following were used to treat the patient: (check all that were used)
   Vaccinia Immune Globulin (VIG) __
   Cidofovir __
   Antibiotics __
   Other antiviral agents ___  If yes, list agent(s):

42. Was the patient hospitalized overnight or for more than one night?
   Yes __  No __  Unknown __

43. Was the patient seen or treated in a hospital emergency room or department?
   Yes __  No __  Unknown __

44. What is the patient’s current recovery status? (check one)
   Acutely ill or illness still evolving __
   Fully recovered __
   Recovered with sequelae __
   Died __
   If yes, please describe:

   _______________________________________________________
   Unknown __
Figure 5. Smallpox Vaccine Adverse Event Report Card

A copy of the Adverse Event Diary Report Card and the Instructions must be given to every vaccine recipient at the time of vaccination

1. Patient name: ______________________     2. Date of Birth: ___/___/____
3. Gender: Male  Female  If female: 3a. Date of last menstrual period: ___/___/___    3b. Are you currently pregnant? Yes No
4. Today's date:  ____/____/ ____  5. Date of most recent smallpox vaccination: ____/____/____
5a. Vacc manufacturer: _____________   5b. Vacc Lot Number: #___________
6. Have you received other vaccinations in the last month? Yes No
   If yes, list vaccine(s) and approximate date(s) and describe any reaction:
   6a. Vaccine1 ______________________   6b. Date ___/___/ ___  6c. Reaction:_______________________________________
   6d. Vaccine2 ______________________   6e. Date ___/___/___   6f. Reaction:_______________________________________
7. Have you ever previously received smallpox vaccine? Yes No  If yes: 7a Vaccination year: 19__ 7b. Adverse Event? Yes No 7c. If yes, describe:____________________________
8. Have you taken any medications since your most recent smallpox vaccination? Yes No
   If yes, please list:____________________________________________________________________________

Do you have any of the following medical conditions:
9. Seizure Yes No 16. Congenital Immune deficiency Yes
    No
10. Asthma Yes No 17. Sickle Cell disease Yes
    No
11. Cancer/leukemia Yes No 18. Spleen removal Yes
    No
12. Eczema Yes No 19. Autoimmune disorder (e.g., lupus) Yes
    No
12a. If yes: Active __ or History of __ (check one)
13. Other chronic skin condition Yes No 20. Frequent/recurrent/severe infections Yes
    No
14. Renal/kidney disease Yes No 21. Other (specify): ____________________ Yes
    No
15. Acquired Immune deficiency (e.g., HIV) Yes No

If you checked “YES” to Cancer/leukemia, other chronic skin conditions, autoimmune disorder, immune deficiency, or frequent/recurrent/severe infections, please specify what type, when it was diagnosed, and how it was treated:
**WEEK 1 THROUGH WEEK FOUR AFTER SMALLPOX VACCINATION**

<table>
<thead>
<tr>
<th>Symptom(s)</th>
<th>Day 1</th>
<th>Days 2 through 21</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Day of vaccine</td>
<td>2</td>
</tr>
<tr>
<td>No symptoms</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fever (write down temperature)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chills</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Joint paint</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Muscle pain</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fatigue</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Loss of Appetite</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cough</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vaccination site rash/lesion (describe):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rash elsewhere (describe):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Swelling/tender lymph nodes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Itching at vaccination site</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Itching on body</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain at vaccination site</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Headache</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Backache</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Abdominal pain</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Difficulty breathing</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vaccinia lesions other than at vaccination site (describe):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other (describe in additional comments)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Was medical care sought? (describe below)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

If medical care sought, where? Name of facility/MD:

Address: ____________________________ Phone: ______-____-______

Permission to acquire medical records? Yes No

Has a VAERS form been submitted? Yes __ No __ Unsure __ If yes, on what date? __/__/____

**Additional comments**

________________________________________________________________________________
Figure 5. Smallpox Vaccine Adverse Event Report Card
(reverse side)

Please return to:
VAERS-Active Surveillance
P.O. Box 1100
Rockville, MD 20849-1100

Or FAX to: 1-877-721-0366
Instructions for Completing the Smallpox Adverse Event Report Card

A copy of the Adverse Event Diary Report Card must be given to every vaccine recipient at the time of vaccination

- Please write clearly using dark ink if possible.

- **Questions 1-2:** This personal identifying information will be kept confidential.

- **Question 5:** The clinic or other place you are being vaccinated has this information and will complete it before you leave.

- **Question 7:** If you are not sure, please leave this question blank.

- **Questions 9-21:** This personal medical information will be kept confidential. If you answered “yes” to any of these questions, please provide details in the space provided.

- **Week 1 Through Week 4 After Smallpox Vaccination** chart
  - If on any day, you are not having any of the symptoms listed, please check only the “No symptoms” box.
  - If you notice more than one symptom, please check all that apply for a particular day.

- If you sought medical care for any of the symptoms you report, please tell where you received the care in the space provided. If you do not want your medical records to be reviewed, please check “No,” otherwise check “Yes.” Any information from your medical records will be kept confidential.

- If you experienced side effects you think may have been caused by the vaccine and would like to report them to the Vaccine Adverse Event Reporting System (VAERS), you may report them online at [www.vaers.org](http://www.vaers.org) or you may call 1-800-822-7967.

- After completing the form, please fold it, seal it and mail it to the address listed on the back of the form or fax it toll-free to 1-877-721-0366.
Summary of Contact Information for Vaccine Safety Concerns

Contact the CDC Drug Services for information pertaining to the smallpox vaccine Investigational New Drug (IND) protocol 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
  - P.O. Box 1100
  - Rockville, Maryland 20849-1100
  - Phone: 1-800-822-7967
  - FAX: 1-877-721-0366
  - E-Mail: www.vaers.org

Contact the National Immunization Program when VIG or cidofovir use initiated for treatment of vaccine adverse event:

- Centers for Disease Control and Prevention
  - National Immunization Program
  - Vaccine Safety and Development Activity
  - Phone: 404-639-8256
  - FAX: 404-639-8834