Annex 4

Vaccine Adverse Event Reporting

Monitoring and Reporting of Adverse Events Following Smallpox Vaccination

During the smallpox era, routine use of smallpox vaccine was associated with significant morbidity and mortality. When nonselective vaccination of the U.S. population was conducted, 5 to 10 deaths, several hundred hospitalizations, and several thousand nonhospitalized complications resulted from the vaccine each year.

Recommendations for routine smallpox vaccinations were rescinded in the United States in 1971, and familiarity with its adverse reactions has diminished. Therefore, careful monitoring of adverse events needs to be conducted to familiarize health professionals with the safety profile of the vaccine.

Additionally, reintroduction 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 and guidance for clinicians are included in the recommendations of the CDC's Advisory Committee on Immunization Practices (ACIP) for vaccinia vaccine [CDC. MMWR 2001;50(No.RR-10); CDC.MMWR 2003;52(RR-4)] and in other sections of this response plan, such as Guide B:

- www.bt.cdc.gov/agent/smallpox/response-plan/files/guide-b-part1of3.pdf
- www.bt.cdc.gov/agent/smallpox/response-plan/files/guide-b-part2of3.pdf
- www.bt.cdc.gov/agent/smallpox/response-plan/files/guide-b-part3of3.pdf

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., atopic dermatitis/eczema, burns, impetigo, and 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
- Progressive vaccinia (also known as vaccinia necrosum, vaccinia gangrenosa)
- Eczema vaccinatum
- Generalized vaccinia
- Inadvertent inoculation
- Autoinoculation
- Contact transmission
- Ocular vaccinia (when transmission occurs in or around the eye
- Generalized rashes (erythematous, urticarial, nonspecific)
- Secondary pyogenic infections at the site of vaccination
- Myo/pericarditis

Such complications may result in severe disability (e.g., blindness from inoculation 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 following a smallpox outbreak. (One single laboratory confirmed case is an 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 departments involved in any aspect of vaccine safety.

Availability of smallpox (vaccinia) vaccine

The vaccine currently being used for smallpox vaccination of response teams is a licensed product that is only available from the CDC. However, in the setting of an outbreak, it is possible that more vaccine might be needed than is currently licensed. If licensed vaccine supplies are not sufficient for the number of vaccination needed in an outbreak, some vaccine may be provided under Investigational New Drug (IND) protocols. For vaccine used under IND status there are increased emphases on and requirements for the monitoring of vaccine adverse events. Monitoring of vaccine adverse events is the joint responsibility of the designated state adverse event coordinators and the CDC, through the established reporting mechanisms.

In the event of an outbreak, questions regarding VAE monitoring and reporting should first be addressed to the state adverse event coordinators and CDC Response Team vaccine safety member(s). Questions may also be forwarded to a designated state or national response line.

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 VAE reports will be reviewed by the CDC and the Food and Drug Administration (FDA). The VAERS form and instructions on reporting to VAERS are provided in Annex 4 (Figures 1 and 2). Standardized followup of VAERS reports will be conducted (Figure 3).

Adverse events following smallpox vaccination that are judged to be serious, unexpected, or for which Vaccinia Immune Globulin (VIG) or cidofovir (CDV) are indicated, should be reported without delay to the state adverse event coordinator.

A VAERS report should be filed within 48 hours for serious or unexpected VAEs; all other VAEs should be reported within 7 days of VAE identification.

Follow-up Surveillance Actions

Depending on the extent of vaccine administration and whether vaccine is used under an IND protocol, a number of surveillance activities will be conducted.

- *Active surveillance* for adverse events will be conducted only if IND vaccine is used and the number of vaccine doses administered is limited (e.g., several thousand vaccine doses over a several week period). Vaccine recipients will be provided with a diary report card to document their response to the vaccine (Figure 4).
- 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 or IND status of the vaccine.
- *Stimulated passive surveillance* and followup of serious adverse events will be conducted regardless of the number of vaccine doses administered or license status of vaccine. VAERS is a passive surveillance system because reports are not actively solicited. However, because of the advice to vaccinees, healthcare providers, vaccination programs, and health departments to report adverse events to VAERS, the passive system is "stimulated."

When there is a recognized smallpox outbreak, the following actions should be undertaken.

Prior to administering vaccine

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

- 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. Electronic reporting is preferred to other submission methods of VAERS reports, and
- CDC vaccination packet for post-event vaccination which may include (but are not limited to):
    a. Vaccine Information Statements (VIS) that contain instructions on how to contact VAERS and state health department adverse event personnel.

b. Clinical description of known vaccine complications (i.e., inadvertent inoculation, generalized vaccinia, eczema vaccinatum, progressive vaccinia, post-vaccinial encephalitis, myo/pericarditis, and fetal vaccinia).
c. Instructions for care of the vaccination site.

VIG information and indications for use (See Guide B, Section 8 of this plan), where and how to obtain this information. The contact point for VIG is:

Clinician Information Line
Phone: 1.877.554.4625

State health departments should take the following actions:

- Identify physicians trained in the evaluation and management of patients with adverse events following smallpox vaccination. These physicians must be able to comply with the guidance contained herein and, if necessary, IND protocols,
- Designate a person (state adverse events coordinator) 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, followup of serious reports submitted to VAERS (Figure 4), for providing assistance in completing VAERS forms, and for telephone followup of adverse event reports identified by contact tracing personnel during their followup of smallpox contact vaccine recipients, and
- Implement a response line for vaccination and VAE inquiries.

At time of vaccination

Vaccine recipients or their parent/guardians should be given the following:

- Vaccination packet containing the VIS with instructions on how to contact VAERS and state health department personnel, and
- Instructions for active surveillance and VAE diary card if IND vaccine is used (Figure 5)

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 followup of VAEs reported to VAERS (Figure 4) will be performed to increase understanding of the safety profile of the vaccine and to identify potential risk factors.

Advisory Committee on Immunization Practices: Smallpox Vaccine Safety Working Group

The Advisory Committee on Immunization Practices (ACIP) Smallpox Vaccine Safety Working Group (SVS WG) will be established as a standing committee to review unusual or unexpected adverse events or changes in the expected rates of adverse events that could change vaccination policy. The SVS WG reports to the full ACIP and will consist of members from the ACIP, the Department of Defense Armed Forces Epidemiology Board, and other experts (e.g., smallpox eradication experts) as required. The committee shall meet (via conference call weekly and more often or on an emergency basis) as needed to review emerging concerns from smallpox vaccine VAERS reports.

Clinical tools for assessment of adverse reactions

Clinical tools to assist clinicians in the evaluation and management of dermatologic, neurologic, and ophthalmologic adverse events following smallpox vaccination have been developed and are available at:

www.bt.cdc.gov/agent/smallpox/vaccination/clinicians.asp

The tools provide information related to differential diagnosis and includes suggestions for clinical criteria or diagnostic tests to confirm a diagnosis. The management tool discusses supportive care and the indications for and instruction pertaining to the use of Vaccinia Immune Globulin and cidofovir.

Reports from vaccination clinics

In order to calculate the rate of reported adverse events, timely information on the number of doses of vaccine administered and the proportion of successful take responses are needed. Data should be available weekly or the timeliness of vaccine safety monitoring would be greatly diminished. Reported rates of VAEs will be compared to the expected rates based on historical published information, the experience from the pre-event vaccination program, and the cut points identified by the ACIP SVS WG. 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. It will also be possible to quickly detect unusual VAE rates for specific vaccine lots. The PreEvent Vaccination System (PVS) or the certified state equivalent system will likely be used to enter the demographic and vaccination information from the vaccination clinics.

Monitoring serious adverse events using VIG or cidofovir

To monitor the most serious adverse events, presumably those most likely to be treated with VIG and/or cidofovir (under an IND), the requests for VIG and/or cidofovir will be tracked. Requests to CDC for VIG and CDV will be received through the CIL. State adverse event coordinators will conduct case followup for all vaccine recipients or contacts of vaccine recipients requiring such treatment and forward the follow-up information to CDC, as is required under the IND protocol. VAERS reports will also be reviewed for indications of either VIG or CDV use.

Instructions for Reporting to VAERS

(Refer to Figures 1 and 2 for a sample VAERS form.)

Getting a VAERS form

Additional report forms and assistance in completing the form 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. 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.

VAERS can be contacted at:

VAERS
P.O. Box 1100
Rockville, Maryland 20849-1100
Phone: 1-800-822-7967
FAX: 1-877-721-0366
E-Mail: www.vaers.org

Submitting the VAERS form

Electronic: The preferred method of reporting is electronic. The instructions for reporting and the electronic report form are available at VAERS Web page www.vaers.org.

Mail: 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

FAX: The form can also be FAXED toll-free to **1.877.721.0366.**

Completing the VAERS form

Instructions for completing the VAERS form are on the back of the form (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 be internally consistent. 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 followup.

Reporter information: (This is in the upper right corner of form.) The reporter's name and complete mailing address are required. Requests for missing or follow-up information are sent to this address.

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:

Box 3	Date of birth
Box 4	Age of patient at the time of vaccination
Box 7	Narrative description of adverse events, symptoms, etc. (For electronic reports, "copy and paste" from other electronic documents can be used)
Box 8	Determines whether a report is regarded as serious or nonserious, and identifies the most serious reports for 60-day and annual followup **Serious Reports** • Patient died/date patient died • Life threatening illness • Resulted in permanent disability • Resulted in prolongation of hospitalization • Required hospitalization and number hospitalized days **Nonserious 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	Used to identify potential public health reports
Box 24	The National Childhood Vaccine Injury Act requires tracking of vaccine(s) administered; the immunization project report number is assigned by the state health adverse events 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 followup 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, or Electronic Report Number (ERN) if report submitted electronically, will be provided with the confirmation notice. Any follow-up correspondence about a report must include the VAERS ID number or ERN 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 or autopsy reports may be submitted to VAERS by mail or 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 to:

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

FAX: **Submit information to: 1.877.721.0366**

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

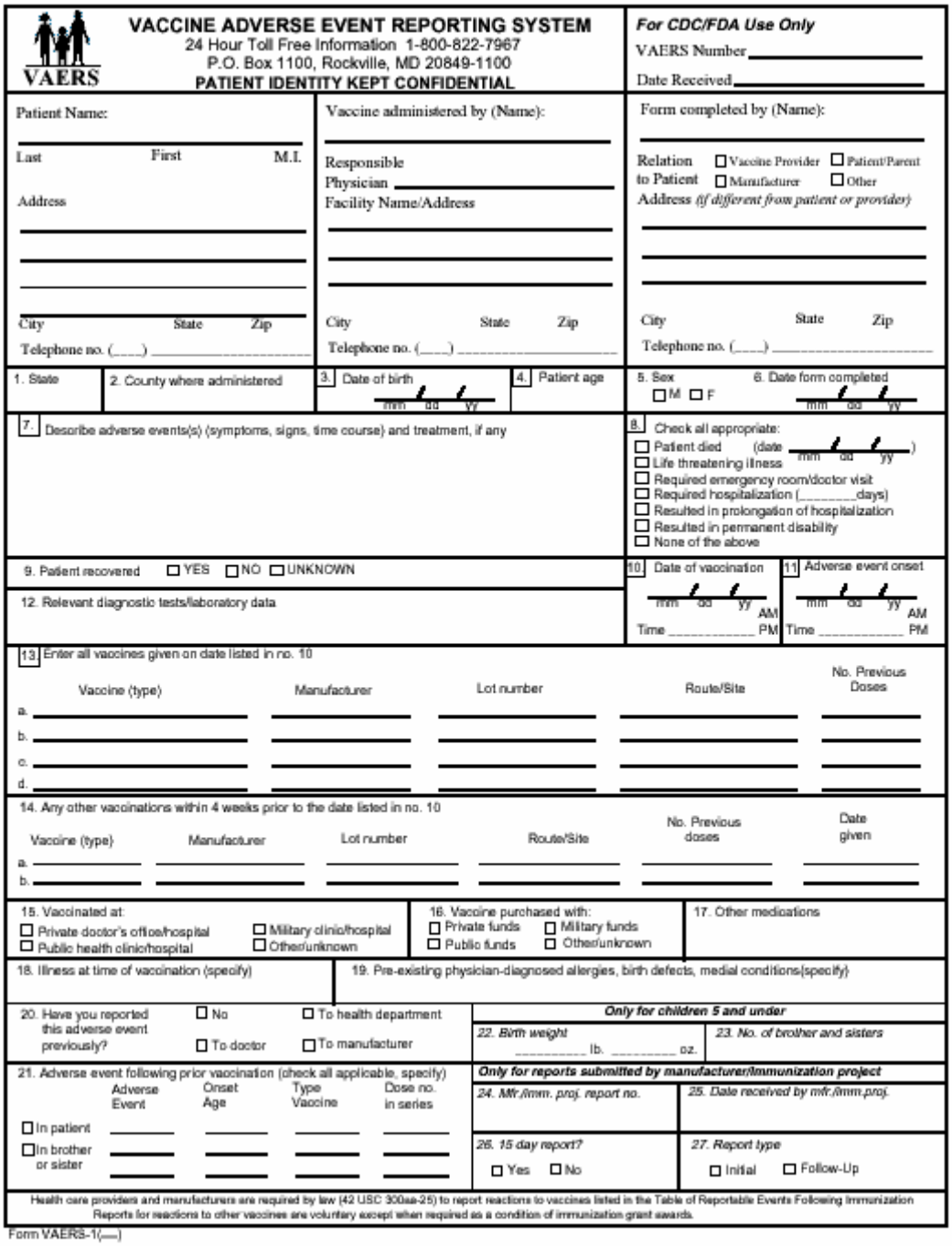
Because vaccine virus can be transmitted from the vaccination site if not appropriately covered and cared for, adverse events have been known to occur in contacts of vaccinated persons (e.g., eczema vaccinatum). If an adverse event is suspected or identified in a contact of a vaccine recipient, a VAERS 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 and treating health care providers in conjunction with the state adverse event coordinator 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, preferably via electronic reporting. Note 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.

Figure 1. VAERS Reporting Form



VACCINE ADVERSE EVENT REPORTING SYSTEM
24 Hour Toll Free Information 1-800-822-7967
P.O. Box 1100, Rockville, MD 20849-1100
PATIENT IDENTITY KEPT CONFIDENTIAL

VAERS

For CDC/FDA Use Only
VAERS Number _____
Date Received _____

Patient Name:
Last First M.I.
Address
City State Zip
Telephone no. (____) _____

Vaccine administered by (Name):
Responsible Physician _____
Facility Name/Address
City State Zip
Telephone no. (____) _____

Form completed by (Name):
Relation to Patient ☐ Vaccine Provider ☐ Patient/Parent ☐ Manufacturer ☐ Other
Address *(if different from patient or provider)*
City State Zip
Telephone no. (____) _____

1. State | 2. County where administered | 3. Date of birth mm dd yy | 4. Patient age | 5. Sex ☐ M ☐ F | 6. Date form completed mm dd yy

7. Describe adverse events(s) (symptoms, signs, time course) and treatment, if any

8. Check all appropriate:
☐ Patient died (date mm dd yy)
☐ Life threatening illness
☐ Required emergency room/doctor visit
☐ Required hospitalization (_____days)
☐ Resulted in prolongation of hospitalization
☐ Resulted in permanent disability
☐ None of the above

9. Patient recovered ☐ YES ☐ NO ☐ UNKNOWN

10. Date of vaccination mm dd yy AM PM Time _____

11. Adverse event onset mm dd yy AM PM Time _____

12. Relevant diagnostic tests/laboratory data

13. Enter all vaccines given on date listed in no. 10

	Vaccine (type)	Manufacturer	Lot number	Route/Site	No. Previous Doses
a.					
b.					
c.					
d.					

14. Any other vaccinations within 4 weeks prior to the date listed in no. 10

	Vaccine (type)	Manufacturer	Lot number	Route/Site	No. Previous doses	Date given
a.						
b.						

15. Vaccinated at:
☐ Private doctor's office/hospital ☐ Military clinic/hospital
☐ Public health clinic/hospital ☐ Other/unknown

16. Vaccine purchased with:
☐ Private funds ☐ Military funds
☐ Public funds ☐ Other/unknown

17. Other medications

18. Illness at time of vaccination (specify)

19. Pre-existing physician-diagnosed allergies, birth defects, medical conditions(specify)

20. Have you reported this adverse event previously?
☐ No ☐ To health department ☐ To doctor ☐ To manufacturer

Only for children 5 and under
22. *Birth weight* _____ lb. _____ oz.
23. *No. of brother and sisters*

21. Adverse event following prior vaccination (check all applicable, specify)

	Adverse Event	Onset Age	Type Vaccine	Dose no. in series
☐ In patient				
☐ In brother or sister				

Only for reports submitted by manufacturer/immunization project
24. *MfrJImm. proj. report no.*
25. *Date received by mfr./imm.proj.*
26. *15 day report?* ☐ Yes ☐ No
27. *Report type* ☐ Initial ☐ Follow-Up

Health care providers and manufacturers are required by law (42 USC 300aa-25) to report reactions to vaccines listed in the Table of Reportable Events Following Immunization. Reports for reactions to other vaccines are voluntary except when required as a condition of immunization grant awards.

Form VAERS-1(___)

Figure 2. Instructions for Completion of VAERS Form

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

NO POSTAGE NECESSARY IF MAILED IN THE UNITED STATES OR APO/FPO

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

DIRECTIONS 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 orthat person's legal representativewill not be made available tothe 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

Item 11: indicate "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 person 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(s) was given.

Item 18: List any short term illnesses the patient had on the date the vaccine(s) 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 priorvaccine, 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.

Figure 3. VAERS Smallpox Follow-up Form

Smallpox Vaccine VAERS Report Follow-up Worksheet

INSTRUCTIONS: To be used for followup of designated VAERS reports. Please request additional medical records, such as hospital discharge summary as appropriate.

Smallpox Vaccination History

Diagnosis and Therapy

1. Has the patient been vaccinated with smallpox vaccine before 2002? *(Please circle answer)*

Never vaccinated Don't Know Vaccinated
If yes, when? In childhood On entry into the military Laboratory worker

2. Has the patient been vaccinated with smallpox vaccine recently (2002-3)? If so, when?

Vaccination date:____/___/_____ Patient Vaccination Number (PVN):_____

3. Do you have a working diagnosis for this patient? YES NO
If yes, what is it?
_____

4. Was VIG used? YES NO

5. Was cidofovir used? YES NO

6. PATIENT VACCINATED DESPITE CONTRAINDICATION: N/A APPLICABLE (circle one)

Did patient have any of these conditions at the time of vaccination?

____Pregnancy ____Immunosuppression ____Skin Disease ____Inflammatory Eye Disease

Life-threatening allergic reactions to polymyxin, neomycin, streptomycin, tetracycline at previous smallpox vaccination?
YES NO
If patient vaccinated despite contraindications, please
elaborate:_____

CONTACTS: N/A APPLICABLE (circle one):

7. Location of Exposure: ___Home ___Hospital ___Other ___Workplace ___Not known

8. Means of Exposure: ___Known ___Not known
If known, please check:
___Direct to skin
___Needle stick
___Contact with dressing
___Handled objects
___Health care contact within 3 weeks
___Sexual
___Nursing mother
___Other

9. Is the timing and duration of exposure known? YES NO
If yes, complete: Start date:____/___/_____ Start Time:___:___AM/PM End Date:____/___/_____ End Time:___:___AM/PM

10. Contact information of vaccinee to whom patient exposed:

NAME:_____ADDRESS:_____
_____
TELEPHONE NUMBER:_____

Disposition/outcome: _____Recovered_____Recovered with sequelae (specify)_____Recovering (specify)_____
_____Deceased
VAERS ID:_____ E-report #:_____ Date of followup____/___/_____
Reviewer_____

Summary of Contact Information for Vaccine Safety Concerns

Contact the Clinician Information Line and the state smallpox vaccine adverse events coordinator for access to Vaccinia Immune Globulin (VIG) or cidofovir for the treatment of indicated vaccine adverse events:

Clinician Information Line
1.877.554.4625

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

VAERS
E-Mail: **www.vaers.org**
P.O. Box 1100
Rockville, MD 20849-1100
Phone: **1.800.822.7967**
FAX: **1.877.721.0366**

Figure 4. Smallpox Vaccine Adverse Event Diary Report Card

PATIENT IDENTIFIERS:	**CLINIC OR SITE WHERE VACCINATION WAS GIVEN** (Stamp here or fill out information below)	**Have you taken any prescription medications for symptoms related to this vaccination since the day of your smallpox vaccination?**
_____ Last name First name MI ____ _____ SSN Number Mo____/Day____/Yr____ (_____) Date of Birth Age Gender ☐ Male ☐ Female Number of Household Contacts:_____	_____ Clinic Name _____ Address _____ City State Zip Code (_____)_____ Phone Number Date of Vaccination: _____/_____/_____ Mo Day Year	Yes ☐ No ☐ If yes, please list:_____ _____ _____ **If medical care was sought, where?** _____ **Address State Zip Code** _____ **Phone Provider's name** **Permission to acquire medical records?** Yes ☐ No ☐ **Vaccinee's signature:_____**

Please use the following scale to grade symptoms you experience following vaccination. Enter the appropriate code into the corresponding box for symptoms with new onset following vaccination.

Figure 5.

Code	Grade	Description
1	Mild	Does not interfere with daily activities
2	Moderate	Interferes with routine activities
3	Severe	Unable to perform routine activities

Figure 6a. Smallpox Vaccine Adverse Event Diary Report Card

Symptom(s) New onset following vaccination	**DAY POST VACCINATION** Please note that the day of vaccination is denoted as Day 0 and others numbered sequentially																				Week 4 (Days 21-27)
	0	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**	**19**	**20**	
Day scab fell off:																						
No Symptoms																						
Fever (Record temperature)																						
Chills																						
Joint pain																						
Muscle pain																						
Fatigue																						
Loss of Appetite																						
Cough																						
Swelling/tender lymph nodes																						
Itching on body																						
Headache																						
Backache																						
Abdominal pain																						
Difficulty breathing																						

Figure 6b. Smallpox Vaccine Adverse Event Diary Report Card *(continued)*

SKIN FINDINGS:	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**	**19**	**20**	Wk 4
Vaccine site lesion																						
Pimple																						
Vesicle (blister)																						
Ulcer																						
Scab																						
Redness																						
Swelling																						
Warmth																						
Itching																						
Pain																						
Streaks on arm																						
Site reaction >3 inches																						
Vaccinia-type lesion NOT at site of vaccination. Describe and indicate location	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**	**19**	**20**	
Non-Vaccinia type rashes (e.g., hives) Describe and indicate location.	**0**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**	**19**	**20**	

Other comments:
(Extra pages as needed)

DATA PRIVACY NOTICE: Data requested are collected under the authority of Section 301 of the PHS Act. The SSN is being collected because it is a unique identifier that will enable CDC staff to contact with participants over time. Every effort will be made to safeguard the confidentiality of the information provided.

INSTRUCTIONS TO THE PATIENT:

When you have completed this form, immediately return it to the responsible party at the clinic or site where you were vaccinated. It is imperative that this diary card is returned in a timely manner.

Do *NOT* delay in returning the diary card to the clinic when completed at the end of week 4 following your vaccination.

If you experience an adverse event prior to completion of this form, contact the IND investigator at the clinic where you were vaccinated.

IND Investigator Contact Number: _____

In the event that you require emergency care and are unable to notify your clinic provider, please seek medical care for a prompt clinical consult. Have the emergency care physician contact the IND investigator at the clinic where you received the vaccine to report your adverse event. See above.

It is important that your adverse event be reported. We encourage you, in consultation with your doctor to report adverse events to the Vaccine Adverse Event Reporting System (VAERS). The VAERS reporting form can be obtained at www.vaers.org or by calling **1.800.822.7967**.