

Smallpox

Clinical Description &
Recommendations for a Vaccination Program

Adverse Event Reporting

Compared to our current vaccines, smallpox vaccination was associated with a much higher rate of serious adverse effects. It is imperative that we carefully monitor smallpox vaccinees and educate healthcare professionals about normal vaccination reactions and adverse effects. Known side effects and adverse reactions are described in the Vaccination Reactions section of this program.

As with any other vaccination, prompt identification and reporting of adverse effects related to smallpox vaccine is necessary to protect the public's health. However, not all adverse effects need to be reported, as many minor symptoms, such as redness, tenderness, fever and itchiness at the site, are normal reactions to the smallpox vaccine. Descriptions of normal versus serious adverse effects related to vaccinia vaccine are listed in the Vaccination Reactions section of this program.

All patients receiving smallpox vaccine must receive follow-up site and dressing evaluations. Any adverse effects, especially serious symptoms, must be evaluated and reported immediately, which may include a referral to an Infectious Disease physician or other specialist.

In anticipation of questions regarding the normal process for site care, referral and acquisition of treatment for serious adverse effects related to the smallpox vaccine, the CDC developed a 5-step referral pyramid.

The following information is based on the CDC's November 5th, 2002 draft of the Smallpox Immunization Safety System, or SISS, Referral Pyramid.

The Smallpox Immunization Safety System, or SISS, Referral Pyramid is a draft of a minimally funded data management strategy. This 5-step process has been altered to reflect an adverse event reporting strategy without implying a specific implementation (i.e., national or state-based) or funding level. The assumption is that the follow-up and referral process for adverse events related to smallpox vaccination is required, regardless of funding or implementation decisions. The intent of this document is to spark discussion, not to suggest a final system solution.

Step 1: Pre-event smallpox vaccination occurs, which includes administration of the vaccinia vaccine to approximately 500,000 vaccinees nation-wide.

Vaccinees should receive appropriate follow-up care, including daily inoculation site evaluations and dressing changes, as described in the Smallpox Vaccine Administration section of this program.

Step 2: Following vaccine administration, vaccinees will receive initial evaluation of side effects during daily site evaluation visits. It is estimated that approximately 35%, or 175,000, vaccinees, will have questionable reactions at the inoculation site that cannot be properly addressed or evaluated by the staff performing the daily inoculation site visit. These vaccinees will require a safety call to an on-call physician or specialist that will attempt to evaluate the situation over the phone. Many questions and conditions can be handled in this manner and will require no further action, except the continuation of daily site visits.

Step (level) 3: Approximately 10%, or 17,500 vaccinees will have reactions/conditions that cannot be appropriately evaluated from a phone call and will require referral to an Infectious Disease physician, or other specialist, for an office evaluation or visit.

Some percentage of vaccinees that receive a level 3 physician referral will require a VAERS report, but only those that meet the VAERS criteria. See the Instructions for Reporting to VAERS section of this program for more information.

Step (level) 4: Approximately 30%, or 5,250 vaccinees will require further consultation through CISA, the Clinical Immunization Safety Assessment. CISA is a program consisting of a consultation hotline provided through the CDC and is the only mechanism for release of VIG, Vaccinia Immune Globulin, or Cidofovir treatment protocols to be used in the treatment of serious or unexpected adverse effects related to the smallpox vaccine. You may contact CISA through the CDC National Immunization Program by telephone: 404-639-8256.

All patients that need a CISA phone consultation will require a VAERS report.

Step (level) 5: Approximately 2%, or 100 vaccinees will have serious adverse effects related to the smallpox vaccination that will require VIG or cidofovir for treatment.

Instructions for Reporting to VAERS

The Vaccine Adverse Event Reporting System, or VAERS, is a cooperative program for vaccine safety of the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA). It monitors adverse effects related to the administration of US-licensed vaccines. Although the vaccinia vaccine is no longer licensed in the US, it is being released as an Investigational

New Drug, or IND. Because the smallpox vaccine is an IND, it will be closely monitored for adverse effects.

Certain members of the CDC Smallpox Response Teams as well as some state health department physicians will be designated as IND sub-investigators and will receive specialized training on the regulations and requirements applicable to the smallpox vaccine IND protocol. CDC Response Team members may be reached through CDC Drug Services at phone (404) 639-3670. Other important contact numbers will be provided at the end of this section.

VAERS reports are evaluated daily and staff have been educated to give priority to smallpox reports. The Vaccine Adverse Effect, or VAE, reports will be forwarded to the CDC Drug Services Center and the FDA for immediate review.

VAERS may be contacted at:

VAERS

PO Box 1100

Rockville, Maryland 20849-1100

Phone: 1- 800-822-7967

Fax: 1-877-721-0366

Website: www.vaers.org

For immediate assistance in obtaining or completing forms, or answers to other questions about VAERS, you should call the 24-hour toll-free telephone number: **1-800-822-7967** or visit the website: 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 the Department of Health and Human Services also contain instructions on how to report adverse events to VAERS.

Submitting the VAERS form

Normal processes for submitting a VAERS form include mailing, faxing, phoning or electronically submitting the form. **However, for smallpox vaccination, it is highly recommended that the report be sent either electronically or by phone so that it may be acted upon immediately.**

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