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Notice to Readers: Smallpox Vaccine Adverse Events Monitoring and Response System for the First Stage of the Smallpox Vaccination Program

Smallpox vaccination of civilian volunteer health-care workers began on January 24, 2003. As of February 4, a total of 37 states and counties have received shipments of smallpox vaccine, and 18 states and counties have begun smallpox vaccination; no serious adverse events have been reported. To monitor the occurrence of adverse events associated with vaccination, both those expected on the basis of previous experience and possible new unexpected adverse events, CDC and state health departments have established the Smallpox Vaccine Adverse Events Monitoring and Response System. The system also will be used to monitor the effectiveness of contraindication screening, identify new contraindications, and coordinate the distribution of vaccinia immune globulin (VIG) and cidofovir to the civilian population. This notice describes the components of the system, delineates roles and responsibilities, and explains how data from the system will be compiled and communicated.

The first stage of the vaccination program targets 1) smallpox response teams designated by terrorism and public health authorities to conduct investigation and follow-up of initial smallpox cases and 2) health-care teams whose members are trained to provide medical care for initial smallpox patients (*1*). During this stage, the Institute of Medicine (IOM) has recommended active surveillance for adverse events following smallpox vaccination (*2*). To implement this recommendation among all vaccinees and their contacts, the system will track adverse events that require hospitalization or outpatient care, contraindications to vaccination among vaccinees or household contacts not identified at the time of vaccination, and vaccinia transmission to contacts of vaccinees. CDC also will collect data from persons experiencing more common, nonserious adverse events in a telephone survey of approximately 10,000 vaccinees from at least eight states and cities administered at days 10 and 21 following vaccination.

Successful monitoring of and response to adverse events following smallpox vaccination depends on the efforts of vaccination clinic staff, vaccination-site--care monitors at hospitals and other locations, health-care providers, state health departments, and CDC. At smallpox vaccination clinics, a unique identifying number will be assigned to each vaccinee, and each vaccinee's vaccination information will be entered into an electronic tracking system (either the Pre-event Vaccination System (PVS)

maintained by CDC or the state equivalent). In the days following vaccination, monitors at hospitals and other locations should assess vaccination-site care, symptoms reported by the vaccinees, and vaccine take (i.e., response to vaccination). For hospital staff, monitors also should determine fitness for duty. CDC's web-based Hospital Smallpox Vaccine Monitoring System can be used to facilitate monitoring and to enter tracking data. Vaccination-site--care monitors and health-care providers should report adverse events associated with vaccination as they occur (Table). When vaccination follow-up is completed (usually 21--28 days after vaccination), vaccination-site--care monitors should ensure that information about adverse events that require hospitalization or outpatient care, contraindications identified after vaccination, and contact transmission are documented for all vaccinees. CDC will provide a data entry mechanism linked to PVS for documenting this information.

Health-care providers who need assistance with evaluating a smallpox vaccinee with a potential adverse event should contact their state health department or CDC's Clinician Information Line, telephone 877-554-4625. Staffed by nurses 24 hours a day, 7 days a week, this information line is a source for general smallpox clinical adverse event information and for assistance with adverse event reporting. As needed for clinical consultation and release of VIG and cidofovir, callers to this line will be connected to CDC's Smallpox Vaccine Adverse Events Clinical Consultation Team, whose members are experts in infectious diseases, ophthalmology, and neurology, and have back-up from smallpox/vaccinia disease experts. For general information about diagnosis and management of smallpox vaccination--associated adverse events, health-care providers should consult CDC's guidance for clinicians (*3*). Clinical evaluation tools to assist health-care providers in the diagnosis and management of smallpox vaccine adverse events also are available at http://www.bt.cdc.gov/agent/smallpox/vaccination/clineval.

Adverse events following smallpox vaccination should be reported to state health departments and the Vaccine Adverse Event Reporting System (VAERS), the national surveillance system for adverse events following the administration of U.S.-licensed vaccines (*4,5*). Any adverse event that is of concern to the clinician or patient should be reported. In addition, certain events are recommended to be reported (Table). Those adverse events that require VIG or cidofovir should be reported immediately (*3*). Other serious adverse events (i.e., those resulting in hospitalization, permanent disability, life-threatening illness, or death) should be reported within 48 hours after recognition. Reports may be submitted to VAERS at http://secure.vaers.org/vaersdataentry.intro, by toll-free fax at 877-721-0366, or by mail to P.O. Box 1100, Rockville, Maryland 20849-1100. Report forms and assistance with reporting are available from VAERS, telephone 800-822-7967.

CDC's secure web-based communications network for public health investigation and response, the *Epidemic Information Exchange* (*Epi-X*) (http://www.cdc.gov/mmwr/epix/epix.html), will be used for rapid and regular exchange of smallpox vaccine adverse events data among state and local health departments and CDC. These data will be tabulated regularly and reported on CDC's smallpox website and in *MMWR*. The reported rates of known serious adverse events will be compared with historically reported rates. If higher-than-expected rates of known adverse events or unexpected adverse events are detected from either active or passive surveillance analysis, further investigation will be conducted. A workgroup of the Advisory Committee on Immunization Practices will assess the data regularly. In addition, to ensure that the smallpox vaccination program is conducted safely and effectively, IOM will provide ongoing programmatic evaluation.

References

1. Advisory Committee on Immunization Practices. Draft supplemental recommendations of the

ACIP: use of smallpox (vaccinia) vaccine, June 2002. Available at http://www.bt.cdc.gov/agent/smallpox/vaccination/acip-guidelines.asp.
2. Institute of Medicine Committee on Smallpox Vaccination Program Implementation. Review of the Centers for Disease Control and Prevention's Smallpox Vaccination Program implementation. Letter report #1. Washington, DC: Institute of Medicine, National Academy of Sciences, 2003. Available at http://www.nap.edu/books/NH000489/html.
3. CDC. Smallpox vaccination and adverse reactions: guidance for clinicians. MMWR 2003;52 (Dispatch):1--29. Available at http://www.cdc.gov/mmwr/preview/mmwrhtml/di52cha1.htm.
4. Chen RT, Rastogi SC, Mullen JR, et al. The Vaccine Adverse Event Reporting System (VAERS).Vaccine 1994;12:542--50.
5. Zhou W, Pool V, Iskander J, et al. Surveillance for safety after immunization: Vaccine Adverse Event Reporting System (VAERS)---United States, 1991--2001. In: CDC surveillance summaries (January 24). MMWR 2003;52(No. SS-1).

Table

TABLE. Adverse events after smallpox vaccination that are recommended to be reported to the Vaccine Adverse Event Reporting System and to state health departments*

Eczema vaccinatum
Erythema multiforme major or Stevens-Johnson syndrome
Fetal vaccinia
Generalized vaccinia
Inadvertent inoculation
Ocular vaccinia
Post-vaccinal encephalitis or encephalomyelitis
Progressive vaccinia
Pyogenic infection of vaccination site
Vaccinia transmission to contacts
Vaccination of persons with a contraindication to vaccination
Other serious adverse events (i.e., those resulting in hospitalization, permanent disability, life-threatening illness, or death)

* Any adverse event that is of concern to the clinician or patient should be reported.

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