Council of State and Territorial Epidemiologists
Position Statement

03-ID-04

Committee: **Infectious Disease**

Title: **Surveillance for Smallpox Vaccine Adverse Events**

Statement of the Problem:
Civilian smallpox vaccination in the United States ceased in 1972, and the World Health Organization declared smallpox eradicated in 1980. Because of concerns about re-emergence of smallpox as an agent of bioterrorism, a federally directed program of state and local health deparment based smallpox vaccination has begun to be implemented. Smallpox vaccine is known to cause rare but serious adverse reactions, including potentially life threatening ones such as eczema vaccinatum and progressive vaccinia. Concern exists that the vaccine's adverse event profile could be significantly different than when then the vaccine was last routinely used because of an aging population with an increased number of immune suppressed individuals.

Statement of the desired action(s) to be taken:
CSTE recommends that:

1. States and territories develop the means and assure legal authority to conduct surveillance for diseases, findings or adverse reactions that occur as a result of inoculation to prevent smallpox, including but not limited to the following list:

Accidental administration
Accidental implantation (inadvertent autoinoculation)
Bacterial infection of site of inoculation
Congenital vaccinia
Contact vaccinia (i.e., vaccinia virus infection in a contact of a smallpox vaccinee)
Eczema vaccinatum
Erythema multiforme
Generalized vaccinia
Post-vaccinial encephalitis
Progressive vaccinia (vaccinia necrosum, vaccinia gangrenosa, disseminated vaccinia)
Vaccinia keratitis
Myo/pericarditis

2. States and territories utilize one or more of the following surveillance methods: making the above events reportable, conducting active surveillace of all vaccinees, or using other methods that assure complete and timely ascertainment of cases. Smallpox vaccine adverse event surveillance should not replace or compete with reporting to the national Vaccine Adverse Event Reporting System (VAERS). States and territories should consider collecting copies of the VAERS reporting forms as the mechanism of state-level surveillance in order to reduce the reporting burden on providers.

3. CDC should provide technical assistance to states in conducting surveillance for smallpox vaccine adverse events.

Case definitions: The ACIP Work Group on Smallpox Vaccine Safety is developing case definitions that will be posted on the CDC web site.

Public Health Impact:

Improved surveillance for smallpox vaccine adverse events will provide key data needed to implement smallpox vaccination as safely as possible, and may identify vaccine contraindications and precautions not previously recognized. Enhanced reporting will also support quantification of risks of particular public health concern such as secondary transmission of vaccine virus to contacts of vaccinees. Information reported from states to VAERS will be used in conjunction with other surveillance data sources to establish rates for specific adverse reactions among the current U.S. population. An up to date understanding of the adverse reaction profile of the currently licensed smallpox vaccine will be of great assistance in weighing the risks and benefits of expanded pre-event smallpox vaccination or mass vaccination in the setting of a smallpox disease emergency.

Agencies for Information:

(1) George Hardy, MD, MPH
Executive Director
Association of State and Territorial Health Officers
1275 K. Street NW, Suite 800
Washington, D.C. 20005-4006
Telephone: (202) 371-9090
Fax: (202) 371-9797
Email: ghardy@astho.org

(2) Susan S. Ellenberg PhD.
Center for Biologics Evaluation and Research (CBER)
Food and Drug Administration
1401 Rockville Pike
Rockville, MD 20852-1448

Agencies for Response:

(1) Julie L. Gerberding, MD, MPH
Director,
Centers for Disease Control and Prevention
1600 Clifton Road, Mailstop D14
Atlanta, Georgia 30333
Telephone: (404) 639-7000
Fax: (404) 639-7111
E-Mail:jyg2@cdc.gov

Authors:

(1) Guthrie Birkhead, MD, MPH
New York State Health Department
Room 1483, Corning Tower ESP
Empire State Plaza
Albany, New York 12237
Telephone: (518) 402-5382
Fax: (518) 486-1455
E-mail: gsb02@health.state.ny.us