

# Notice to Readers: Supplemental Recommendations on Adverse Events Following Smallpox Vaccine in the Pre-Event Vaccination Program: Recommendations of the Advisory Committee on Immunization Practices



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The Advisory Committee on Immunization Practices (ACIP) has issued recommendations previously for use of smallpox vaccine (1) and supplemental recommendations for use of smallpox vaccine in the pre-event civilian vaccination program (2). On March 28, 2003, CDC reported cases of cardiac adverse events among persons vaccinated recently with smallpox vaccine (3). In response to these reports, ACIP held an emergency meeting on March 28 to make recommendations to CDC about medical screening of potential vaccinees and follow-up of persons with cardiovascular risk factors after vaccination. These recommendations supplement those previously issued by ACIP (1,2).

As of March 28\*, a total of 10 cases of myopericarditis had been reported among approximately 240,000 primary vaccinees in the military vaccination program, and two such cases (one of myocarditis and one of pericarditis) had been reported among civilian vaccinees (3). No cases of myopericarditis had been reported among approximately 110,000 military revaccinees. Patients whose cases were reported to the U.S. Department of Defense had onset 7--12 days after vaccination and had illness diagnosed based on clinical features, laboratory studies, and electrocardiographic or echocardiographic features. Compared with the rate reported in an unvaccinated military population during 1998--2000, the rate of myopericarditis is substantially elevated (U.S. Department of Defense, unpublished data, 2001).

As of March 28, CDC had received reports of five civilian patients with cardiac ischemic events after smallpox vaccination, including three patients with myocardial infarctions and two patients with angina. The five patients with ischemic events ranged in age from 43 to 60 years, and four of the five were aged  $\geq 54$  years; four were women. Four of the five had underlying cardiovascular risk factors. One had known cardiovascular disease, and two others had histories of chest pain (not clearly identified as cardiac in origin on the basis of available information). Two patients died, both from myocardial infarctions with out-of-hospital cardiac arrests. Onset of cardiac symptoms occurred 4, 4, 5, 9, and 17 days after vaccination in the five patients; the patient who experienced a cardiac arrest 17 days after vaccination had symptoms of nausea, dizziness, shortness of breath, fever, and productive cough 5 days after vaccination. Two patients were revaccinees, but the previous vaccination status of the other patients is unknown; all were children at a time when the majority of children in the United States received smallpox vaccine. The two deaths due to cardiac disease among civilian vaccinees are similar to the numbers expected among persons in these age groups in the general population in the absence of vaccination (3). The military reported an additional case of a myocardial infarction and out-of-hospital cardiac arrest in a man aged 55 years with multiple cardiac risk factors; the cardiac arrest occurred 5

days after vaccination (U.S. Department of Defense, personal communication, 2003).

These data are consistent with a causal relation between myocarditis/pericarditis and smallpox vaccination, but no causal association between the ischemic cardiac events and smallpox vaccination has been identified. In response to these reports, CDC issued a health advisory on March 26, recommending as a precautionary measure that persons with known cardiac disease not be vaccinated as response team members in the pre-event smallpox vaccination program at this time (4). Persons receiving smallpox vaccine should be informed that myopericarditis is a potential complication of smallpox vaccination and that they should seek medical attention if they develop chest pain, shortness of breath, or other symptoms of cardiac disease within 2 weeks after vaccination.

ACIP recommends that persons be excluded from the pre-event smallpox vaccination program who have known underlying heart disease, with or without symptoms, or who have three or more known major cardiac risk factors (i.e., hypertension, diabetes, hypercholesterolemia, heart disease at age 50 years in a first-degree relative, and smoking). ACIP supported including these risk factors in prevaccination education materials so that potential vaccinees can evaluate their risk status, if they have concerns, with their personal physician before reporting for vaccination; at the vaccination clinic, verbal screening for known risk factors is recommended. In response to these recommendations, prevaccination screening forms and other materials have been revised; these materials have been provided to state health departments and are available at <http://www.bt.cdc.gov/agent/smallpox>.

ACIP did not recommend special medical follow-up for persons with cardiovascular risk factors who have been vaccinated. Persons with risk factors or known atherosclerotic coronary artery disease should be cared for by their physicians in accordance with standard guidelines for treatment and control of these conditions, such as those issued by the National Cholesterol Education Program Expert Panel and other expert groups (5).

## References

\* Data were current at the time of the ACIP meeting. Cases reported after March 28 will be included in subsequent reports of adverse events.

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