



HEALTH AFFAIRS

THE ASSISTANT SECRETARY OF DEFENSE

WASHINGTON, D. C. 20301-1200

APR 10 2003

MEMORANDUM FOR ASSISTANT SECRETARY OF THE ARMY (M&RA)
ASSISTANT SECRETARY OF THE NAVY (M&RA)
ASSISTANT SECRETARY OF THE AIR FORCE (M&RA)
DIRECTOR, JOINT STAFF

SUBJECT: Policy for Smallpox Vaccine and Persons with Cardiac Conditions

On March 28, 2003, the Centers for Disease Control and Prevention (CDC) Advisory Committee on Immunization Practices (ACIP) met to review data (summary attached) and consider recommendations for the use of smallpox vaccine in persons with known cardiac condition and/or known cardiac risk factors. After careful deliberation, the committee recommends: 1) add myopericarditis as an expected adverse event of smallpox vaccination, and 2) exempt from vaccination persons with known cardiac condition(s) and persons with three or more known major cardiac risk factors (summary of ACIP recommendations attached). The Services should exempt personnel with the following cardiac conditions: myocardial infarction, angina pectoris, cardiomyopathy, congestive heart failure, stroke, transient ischemic attacks, chest pain or shortness of breath with activity and associated with a heart condition, other coronary artery disease, and other heart conditions under the care of a physician. Persons with any of the listed conditions should be exempted from smallpox vaccination.

The following cardiac risk factors should be identified during pre-immunization processing: current cigarette smoking, hypertension, hypercholesterolemia, diabetes mellitus, and family history of heart disease in 1st degree relative with onset before age 50. Persons with three or more of the above referenced risk factors should be exempted from receiving smallpox vaccine. Along with the ACIP, Health Affairs recommends that recent smallpox vaccine recipients who have a cardiac condition or three or more major cardiac risk factors be evaluated by a health care professional if they develop any symptoms of chest pain, shortness of breath, or other symptoms of heart disease. All people with heart disease or risk factors should receive the routine care recommended for persons with these conditions.

I direct the Services to make appropriate adjustments to their smallpox vaccination programs to incorporate these recommendations. DoD smallpox vaccine education and screening materials will be modified accordingly and posted at www.smallpox.army.mil.

HA POLICY: 03-002

My points of contact are COL Benedict Diniega ((703) 575-2669), and COL John Grabenstein (Military Vaccine Agency, (703) 681-5059).



William Winkenwerder, Jr., MD

Attachments:

As stated

cc:

Joint Staff (J-4 (HSSD))

Surgeon General, Army

Surgeon General, Navy

Surgeon General, Air Force

Medical Officer, HQ, U.S. Marine Corps

Director of Health and Safety, U.S. Coast Guard

Press Release

March 27, 2003
Contact: CDC Press Office
(404) 639-3286

ACIP Summary Statement

The ACIP held an emergency meeting by conference call on Friday, March 28, 2003, to make recommendations to CDC regarding cases of cardiac adverse events that have been reported following smallpox vaccination. A [list of participants](#) appears at the bottom of this page.

The specific questions that the Committee was asked to address were:

1. While more information is gathered, are there levels and types of cardiac-related conditions that should be added to the list of reasons for pre-event smallpox vaccine medical deferral?
2. If so, what are the specific pragmatic and feasible methods to screen for these conditions in the vaccine clinic setting?
3. What additional specific operational, policy, or research/investigation advice can the Committee provide to move us forward?
4. Is special follow-up required for persons with cardiovascular risk factors who have been recently vaccinated.

Ten cases of myopericarditis have been reported among several hundred thousand members of the military, and two such cases (one of myocarditis and one of pericarditis) have been reported among civilian vaccinees. Additionally, CDC has received reports of 5 patients with cardiac ischemic events following smallpox vaccination, including 3 patients with myocardial infarctions and two patients with angina. Two of the persons with heart attacks, have died. These cases were reported this week in the *MMWR*.

Options considered by the Committee included:

1. Exclusion of persons with known underlying heart disease, with or without symptoms.
2. In addition to exclusion of persons with known underlying heart disease, exclude those with 3 or more major cardiac risk factors.
3. In addition to exclusion of persons with known underlying heart disease and three or more risk factors, exclude persons 50 years of age and older.

The Committee recommended that CDC exclude persons with known underlying heart disease and persons with 3 or more major cardiac risk factors (option 2). Draft screening questions were presented to the Committee and will be further reviewed with cardiologists and finalized early next week. The Committee approved CDC's proposed research and did not recommend that special medical follow-up was needed for persons with cardiovascular risk factors who had been vaccinated.

However, persons who have received the smallpox vaccine should see a health care provider right away if they develop shortness of breath, chest pain or other symptoms of cardiac disease. Persons who have been diagnosed by a physician as having heart disease and have questions, should contact their heart disease specialist or regular health care provider. All people with heart disease or risk factors should receive the routine care recommended for persons with

these conditions.

The ACIP is an advisory committee of the Centers for Disease Control and Prevention.

Participants on March 28 ACIP Meeting

MODLIN, John F., M.D.

Professor of Pediatrics and Medicine

Dartmouth Medical School

SNIDER, Dixie E., Jr., M.D.

Associate Director for Science

Centers for Disease Control and Prevention

Atlanta, Georgia

BIRKHEAD, Guthrie S., M.D.

Director, Center for Community Health

New York State Department of Health

BONOW, Robert (Cardiologist)

American Heart Association

BROOKS, Dennis A., M.D., M.P.H.

Assistant Professor of Pediatrics

Johns Hopkins School of Medicine

Johnson Medical Center

BRAINWALD, Eugene (retired) (Cardiologist)

Harvard AHA

FOSTER, Valentine (Cardiologist)

Past President AHA

GARDENER, Pierce, M.D.

Fellow of the American College of Physicians Diplomate, ABIM Assoc. Dean of Academic Affairs

GUERRA, Fernando A., M.D.,

Dir. of Health San Antonio Metropolitan Health District

HANSON, I. Celine, M.D.

Bureau Chief

Bureau of Communicable Disease Control

Texas Department of Health

MENSAH, George (Cardiologist)
CDC

LEVIN, Myron J., M.D.
Professor of Pediatrics & Medicine
Chief, Pediatric Infectious Diseases
University of Colorado School of Medicine

NEFF, John M.D. (SP Vac. Safety Working Gp.)
Dir. Center for Children with Special Needs
Div. of General Pediatrics Children's Hospital and Regional Medical Center
Univ. of Washington School of Medicine

NEWCASTLE, Katherine
State Health Dept. AE coordinator

OFFIT, Paul A., M.D.
Chief, Section of Infectious Diseases
The Children's Hospital of Philadelphia

RENNELS, Margaret B., M.D.
Professor, Department of Pediatrics
University of Maryland School of Medicine

SALAMONE, John E.
National Italian American Foundation

SIEGEL, Jane D., M.D. (SP Vaccine Safety Working group (SVSWG))
Professor of Pediatrics
Department of Pediatrics
University of Texas

SMITH, Natalie J., M.D., M.P.H.
Chief, Immunization Branch
Division, Communicable Disease Control
California Department of Health Services

TOMPKINS, Lucy S., M.D., Ph.D.
Professor, Department of Medicine and Microbiology and Immunology
Stanford University Medical Center

Other Who Spoke

GRABENSTEIN, John (DOD)
Deputy Dir. Of Clinical Operations
Smallpox Vaccine Immunization Program

For more information on smallpox, visit <http://www.bt.cdc.gov/agent/smallpox/>.

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CDC protects people's health and safety by preventing and controlling diseases and injuries; enhances health decisions by providing credible information on critical health issues; and promotes healthy living through strong partnerships with local, national, and international organizations.

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION

A SUMMARY OF CARDIAC EVENTS FOLLOWING SMALLPOX VACCINATION

In recent weeks, CDC received several reports of heart-related problems among the 25,645 people who have been vaccinated in the civilian smallpox vaccination program. The seven cases prompting recent precautionary action include three cases of myocardial infarction (heart attack), two cases of angina (cardiac chest pain); and two cases of myopericarditis (inflammation of the heart muscle and/or sac surrounding the heart). In the DoD smallpox vaccination program, fourteen cases of myocarditis and/or pericarditis, and one case of myocardial infarction have occurred among vaccines since the program began on December 13, 2002. In each case, the individual's medical history, including risk factors for heart disease, is being studied.

CDC asked the Smallpox Vaccine Safety Review Board, composed of members from the Armed Forces Epidemiological Board and the Advisory Committee on Immunization Practices to examine reports of heart-related adverse events occurring in connection with the smallpox vaccination programs. This board regularly reviews adverse event data from both the civilian and DoD smallpox vaccination programs. This board met on March 20-21, 2003, to review these cardiac-related adverse events.