

SMALLPOX VACCINATION PROGRAM SUMMARY

DoD Smallpox Vaccination Program as of May 16, 2003

Background:

On December 13, 2002, the President directed smallpox vaccinations for about 500,000 selected military personnel. DoD vaccinations began immediately for emergency response personnel and hospital staff members. Comprehensive training programs in vaccination technique, infection-control safeguards, screening and education methods, adverse event monitoring, and product storage and handling, aggressively launched in October 2002, made immediate vaccinations possible. In early January 2003, DoD began smallpox vaccinations of selected US military forces, and emergency-essential civilians and contractors deployed or deploying in support of U.S. Central Command missions.

Program Status: DoD operational forces and healthcare workers vaccinated against smallpox: over 430,000

NOTE: All appropriate program information is provided regularly to federal health authorities, including all safety-surveillance data.

Safety Assessment:

DoD smallpox vaccine recipients have experienced the temporary symptoms expected after smallpox vaccination (e.g., itching, swollen lymph nodes, fever, malaise). About 1% of vaccine recipients developed “flat” rashes that are not dangerous and not contagious. These people have been treated according to their symptoms (such as itching) and have remained on the job with their units. These rashes are consistent with known responses after smallpox vaccination.

Sick leave, overall	3% of vaccinated people
Average length of sick leave	1.5 days
Auto-inoculation (inadvertent infection) of skin or eye	48 cases, none severe, mostly primary vaccinations, mostly outpatients
Transfer of vaccinia virus to contacts	19 cases, none severe, 18 treated as outpatients and 1 as an inpatient
Generalized vaccinia	36 cases, all mild, mostly outpatients

Treatments with vaccinia immune globulin (VIG)	2 cases
Severe reactions (e.g., eczema vaccinatum, progressive vaccinia)	0 cases
Deaths due to smallpox vaccination	0 cases * (see note below)

Noteworthy Adverse Events:

For privacy issues, no personal identification is provided on any patient. Safety surveillance information is shared regularly with civilian health authorities.

No new cases of encephalitis (as defined by the AFEB-ACIP Vaccine Safety Working Group) have occurred since the last report.

AFEB – Armed Forces Epidemiological Board
ACIP – Advisory Committee on Immunization Practices

Twenty-seven cases of myocarditis and/or pericarditis (probable—26, confirmed—1) have been identified among over 430,000 smallpox vaccinees. The cases have ranged from relatively mild (no changes on ECG or echocardiogram) to severe (transient heart failure, one case). All recovered. Myocarditis has been reported previously following smallpox vaccinees in Europe, notably in military recruits in Finland. Myocarditis had not been a well-recognized complication following vaccination with the U.S.-licensed New York City Board of Health vaccine.

All previously reported patients have recovered and returned to duty or are expected to do so soon.

* A 55-year-old male National Guard soldier called to active duty had a heart attack on March 25, 2003. He died late on March 26, 2003. The heart attack occurred 5 days after smallpox vaccination. Autopsy findings indicate that this man had substantial narrowing of the blood vessels in his heart that existed before vaccination, as well as prior heart disease. This evidence of pre-existing illness, coupled with other findings and risk factors in his medical history, indicate that smallpox vaccination was unlikely to be the cause of his death. This conclusion was corroborated by analyses performed at the Armed Forces Institute of Pathology (AFIP).

Perspective:

“Our smallpox vaccination program expanded rapidly and effectively to include more than 430,000 people. The program continues to go well, and has been administered in a thorough, careful and professional manner. We continue to experience the types of reactions that we expected overall. Close monitoring has afforded these individuals prompt, effective care. Rates of reactions are lower than those reported historically from

an earlier era. We have adjusted our screening guidelines to defer those with a history of cardiac disease, based on guidance from the CDC and other medical experts. DoD's Smallpox Vaccination Program provides service members and the Nation an enhanced level of preparedness against the threat of smallpox."

- William Winkenwerder, Jr., MD, Assistant Secretary of Defense for Health Affairs