



HEALTH AFFAIRS

THE ASSISTANT SECRETARY OF DEFENSE

WASHINGTON, D. C. 20301-1200

SMALLPOX VACCINATION PROGRAM SUMMARY

DoD Smallpox Vaccination Program
as of March 31, 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 350,000

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	29 cases, none severe, mostly primary vaccinations, mostly outpatients

Transfer of vaccinia virus to contacts	10 cases, none severe, 9 treated as outpatients and 1 as inpatient
Generalized vaccinia	25 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

Fourteen 14 cases of myocarditis and/or pericarditis among 350,000 smallpox vaccinees. All occurred among those receiving smallpox vaccination for the first time, and none occurred among those receiving re-vaccination. The incidence rate of myo-pericarditis is roughly 1 in 20,000 primary vaccinations. These 14 people had clinical conditions that varied from mild to severe. They all recovered. The others have been discharged from hospital, and have either returned to duty or been given short-term convalescent leave to regain their strength. Myocarditis has been reported previously following smallpox vaccination 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 strain of smallpox vaccine. All previously reported patients have recovered and returned to duty.

* A 55-year-old male National Guard soldier called to active duty had a heart attack on March 25, 2003, at a U.S. installation. 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. At this stage of the investigation, 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. Additional tests will be conducted, including tests at the Armed Forces Institute of Pathology (AFIP).

Perspective:

“Our smallpox vaccination program expanded rapidly and effectively to include more than 350,000 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. 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