



THE ASSISTANT SECRETARY OF DEFENSE
WASHINGTON, D. C. 20301-1200

SMALLPOX VACCINATION PROGRAM SUMMARY

DoD Smallpox Vaccination Program
as of February 12, 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 healthcare workers vaccinated against smallpox:	More than 8,000
DoD operational forces vaccinated against smallpox:	Well over 100,000

NOTE: All appropriate program information is provided 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). Several dozen 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
- Sick leave after primary (first) vaccination	4% to 5%
- Sick leave after revaccination	1% to 2%
- Average length of sick leave	1.5 days
Auto-inoculation (inadvertent infection)	1 case, see note below
Transfer of vaccinia virus to contacts	0 cases
Treatments with vaccinia immune globulin (VIG) *	0 cases
Deaths due to smallpox vaccination	0 cases
Noteworthy cases	Described below

* NOTE: VIG - an antibody product used to treat certain severe skin reactions after vaccination.

Noteworthy Adverse Events:

Due to privacy issues, no personal identification is provided on any patient. Information about each case is shared with civilian health authorities.

On February 9, a 38-year-old U.S. Army soldier at a U.S. base was admitted to a civilian hospital with fever and confusion, later diagnosed as encephalitis. He became ill 9 days after smallpox vaccination. He recovered completely and was discharged on February 11. We know no reason for the soldier not to deploy with his unit as scheduled. Diagnostic studies did not establish vaccinia virus as a cause, but the timing of the encephalitis acts as circumstantial evidence.

As previously described, on January 26, a U.S. Army soldier was admitted for encephalitis in an overseas military hospital. The 23-year-old male had been vaccinated against smallpox prior to deployment. He became ill eight days after

the vaccination and was medically evacuated to the facility where he is being treated. He recovered completely, has been discharged from hospital, and has returned to duty. Diagnostic studies did not establish vaccinia virus as a cause, but the timing of the encephalitis acts as circumstantial evidence.

On February 5, a 26-year-old U.S. Air Force airman developed chest pain and went to a U.S. emergency room for treatment. This visit occurred 11 days after smallpox vaccination. After a series of tests, he was diagnosed with a heart condition called acute myocarditis (inflammation of the heart). He recovered after a 2-night stay in hospital and has been discharged. He plans to return to work within a week. Myocarditis can be caused by many bacteria and viruses, including influenza virus. No viral tests conclusively link this man's illness to vaccinia virus (the ingredient in smallpox vaccine), but the timing of the event acts as circumstantial evidence that smallpox vaccination may have been the cause.

Mild conditions that may qualify as generalized vaccinia developed in two members of the U.S. Air Force and four members of the U.S. Marine Corps. Like the first case (Jan 25, described below), these servicemembers were treated as outpatients and have remained on the job. Civilian health advisors have suggested to the CDC that these rashes are so mild that they may not meet a draft definition of "true" cases of generalized vaccinia.

As previously described, on January 26, a U.S. Army soldier was admitted for encephalitis in an overseas military hospital. The 23-year-old male had been vaccinated against smallpox prior to deployment. He became ill eight days after the vaccination and was medically evacuated to the facility where he is being treated. He recovered completely, has been discharged from hospital, and has returned to duty. Diagnostic studies did not establish vaccinia virus as a cause, but the timing of the encephalitis acts as circumstantial evidence.

On January 25, a U.S. Army soldier at a U.S. base developed a rash about 10 days after smallpox vaccination that included several pustules (pus-filled blisters). The 30-year-old man's rash appears to qualify as "generalized vaccinia," one of the expected and somewhat rare skin reactions after smallpox vaccination. Generalized vaccinia can sometimes develop into a serious skin condition. But in this case, the soldier is well and continues to work at his usual location. Contrary to some media reports, this soldier is not and never was in serious condition.

(NEWLY REPORTED CASE) On January 24, a U.S. Army soldier at a U.S. base developed redness in the eyes and was diagnosed as a possible case of ocular vaccinia, vaccinia infection of the eye. This condition can develop if vaccinia virus (the virus in smallpox vaccine) is moved from the vaccination site to the eye. Laboratory tests did not find vaccinia virus in his eye. This soldier has

been treated as an outpatient with antiviral eye drops, has almost completely healed, has no scarring of the eyes, and has remained on the job with his unit.

Perspective:

“Our smallpox vaccination program has expanded rapidly to include more than 100,000 individuals. 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. Our expert medical advisors have indicated that the small number of skin-related reactions seen are quite mild and may not qualify as generalized vaccinia. Close monitoring has afforded these individuals prompt, effective care. All individuals with noteworthy conditions are now doing well.”

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