

## **SMALLPOX VACCINE – Cardiac Related Reactions (updated 25 AUG 04)**

### **Heart-Related Problems After Smallpox Vaccination**

#### **What has the Department of Defense (DoD) seen in terms of heart inflammation after smallpox vaccination?**

The Department of Defense reported its first case of inflammation in or around the heart (myo-pericarditis) after smallpox vaccination in early February 2003. To date, DoD has identified 78 cases of acute myocarditis and/or pericarditis among 625,000 smallpox vaccinees, with symptoms appearing 7 to 19 days after vaccination. These people had clinical conditions that varied from mild to moderate; the condition was severe in two cases.

Most cases occurred among those receiving smallpox vaccination for the first time. Most cases occurred among men.

The health of our people is foremost in our priorities. These cases were followed carefully to evaluate their recovery, at 27 hospitals in 21 states and several countries overseas. Detailed follow-up cardiac testing is available in 46 cases: all had normal electrocardiograms (EKGs), echocardiograms ("echos") and normal treadmill test results. Based on our data and European experience, we have reason to believe these people should recover and remain well. Indeed, in a ll 46 people tested, heart function returned to normal, based on ECGs, echocardiograms, and treadmill stress tests.

### **Difference between Myo-Pericarditis, Myocarditis and Pericarditis**

#### **How was the myocarditis or pericarditis diagnosed in service members?**

The patients with myocarditis and/or pericarditis sought medical care after developing chest pain. Blood tests showed that they had elevated levels of enzymes (such as CKMB or troponin), suggesting myocarditis or pericarditis. They had temporary changes in ECG (electro-cardiogram) and/or echocardiogram readings.

#### **Was the finding of myo-pericarditis a surprise to DoD officials? Is this a new or previously unknown reaction?**

Because rare cases of myo-pericarditis have been reported previously following smallpox vaccination, notably in a study of Finnish military recruits in the 1980s, DoD was watching for the occurrence of myocarditis and was not surprised. In Finland, 1 per 10,000 vaccinees developed myo-pericarditis.

#### **What is the difference between myo-pericarditis, myocarditis, and pericarditis?**

Myocarditis is an inflammation of heart muscle tissue (the myocardium). Pericarditis is an inflammation of the sac surrounding the heart (the pericardium). When both conditions occur at the same time or to group categories together, it is called myo-pericarditis.

#### **Is there a relationship between the recently reported heart attacks and DoD's findings of myocarditis and/or pericarditis in smallpox vaccinees?**

Myocarditis and heart attacks are different diseases. Myocarditis involves inflammation of the heart muscle. Heart attacks are different, in that they involve problems with heart rhythm or blood vessels in the heart. At present, we see no evidence of a link between myocarditis and heart attacks. But our minds are open and we continue to look into it.

#### **How does smallpox vaccine cause myocarditis or pericarditis?**

The precise cause is unknown. However, a reasonable theory is that the vaccinia virus in smallpox vaccine gets into the blood stream and then causes inflammation in some heart tissue.

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**How was the myocarditis or pericarditis diagnosed in servicemembers?**

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**Has the military seen any heart attacks in people vaccinated against smallpox?**

Yes. We identified 16 cases of heart attacks or other kinds of ischemic heart disease (e.g., angina) within six weeks after smallpox vaccination among 630,000 military personnel vaccinated since December 2002. The cases are similar to the number of cases of heart attacks and other ischemic disease we would expect to see in a population of 630,000 unvaccinated people of similar age. This leads us to conclude that there is no apparent association between smallpox vaccination and heart attacks.

A 55-year-old servicemember died 5 days after smallpox vaccination. A 47-year-old servicemember died of atherosclerosis ("hardening of arteries") 2 days after smallpox vaccination. We regret the death of any servicemember, whatever the reason. Based on our investigation of medical records and autopsy findings, the Department of Defense considers it unlikely that smallpox vaccination caused or triggered deaths, based on pre-existing heart disease in both cases.

Between 1998 and 2000, before the DoD Smallpox Vaccination Program began, an average of 150 active-duty servicemembers were admitted each year to DoD hospitals for heart attacks. Each year in DoD, several dozen active-duty personnel die of heart disease. In the Total Army (Active, Guard, and Reserve), roughly 50 deaths due to heart conditions occur each year.

Heart pain (angina) and heart attack also have been reported in the civilian smallpox vaccination program, largely among people 50 years and older. It is not known if smallpox vaccination caused these problems or if they occurred by chance alone (heart problems are very common). For more information on the civilian program, go to [www.bt.cdc.gov](http://www.bt.cdc.gov).

**Heart Conditions That Exempt From Smallpox Vaccination**

**Will DoD defer from smallpox vaccination people who have had heart conditions?**

Yes. We will defer people with serious heart- or vessel-related conditions. Importantly from the standpoint of military readiness, people with major heart conditions are unlikely to be in military service. Some examples include a history of angina, an earlier heart attack, artery disease, congestive heart failure, cardiomyopathy, stroke, "mini stroke," or chest pain or shortness of breath with activity (such as walking up stairs). If you have concerns about your health history, speak with your health care provider before vaccination.

Similar to the CDC, and based on input from the American College of Cardiology, we will also defer people with three or more cardiac risk factors. The risk factors include:

- (1) current smoker or tobacco user,
- (2) high blood pressure,
- (3) high cholesterol or triglycerides,
- (4) high blood sugar, and
- (5) a heart condition before age 50 in a parent, brother, or sister.

Vaccination of other people should continue as planned.

If you smoke, we encourage you to stop.

**What about people who had a smallpox vaccination when they were younger, and then later had a heart attack or heart condition? Should these people be deferred?**

Yes, if someone has a history of a serious heart condition, he or she should be deferred from receiving smallpox vaccine in a non-emergency situation. In event of a smallpox outbreak, vaccination would be recommended.

**If somebody with a serious heart condition is exposed to the disease smallpox, should they get the smallpox vaccine?**

In most cases, experts agree people directly exposed to the disease smallpox (i.e., variola virus) should get the smallpox vaccine. In an emergency situation, this would apply to people with serious heart conditions.