

July 27, 2003

To the Editor:

The current stalled smallpox vaccine program and debate around it need to be resolved. This will only be accomplished through dissemination of accurate information regarding the risks and benefits of vaccination, so a reasoned assessment of when and whom to vaccinate can be made.

Unfortunately, your two articles on the military smallpox vaccine program (1,2) brought no clarity to this debate. The articles failed to make clear that the reported rates of myopericarditis (1 in 12,819) and other vaccine complications were derived using passive, rather than active surveillance. Therefore, the very favorable comparison of military side effect rates to historical rates (1) is both meaningless and misleading.

Furthermore, claims that no deaths were associated with the military vaccine program and that no females developed myopericarditis are incorrect, and cast doubt over the accuracy of other data presented.

Two military deaths were reported to be associated with smallpox vaccination (3,4). One, in a previously healthy 22 year old female reservist who died one month after receiving both anthrax and smallpox vaccines, was definitely associated with pericarditis, according to her autopsy at the Mayo Clinic. (I would be glad to provide JAMA a copy of her death certificate.)

The rate of myopericarditis found by CDC in civilians under active surveillance was over seven times higher than the military rate: 1 in 1725 vaccinees. Seventy-one per cent of the cases were female (5).

Of even greater concern, CDC reports that two women are now known to have developed dilated cardiomyopathy following smallpox vaccination (6). The total number of serious civilian adverse events from January 24 through June 20, 2003 is 71 (6), or a rate of one in 500 smallpox vaccinations. These included 5 myocardial infarctions and one stroke.

It is this type of data physicians need in order to make prudent clinical decisions. Reference to them should have been required in the articles you published, particularly since the military and civilian smallpox vaccine programs routinely share data.

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