

# **U.S. Smallpox Vaccination Program**

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# Vaccination Summary

## 1/24/03 – 10/31/03

- 38,759 vaccinated since 1/24/03
  - 25,098 health care workers
  - 11,715 public health workers
  - 1,946 others
- 2,230 hospitals with at least one worker vaccinated (45% of US hospitals)
- 188,900 doses of vaccine available in states (estimated)

# U.S. Smallpox Vaccination Program Adverse Event Monitoring & Response

- Clinical Consultation
  - Civilian: Clinician Information Line and CDC physician consultation
  - Military: Vaccine Healthcare Centers
- Surveillance
  - Active surveillance (rare, serious events in vaccinees and contacts)
  - Passive surveillance: Vaccine Adverse Event Reporting System
  - Pregnancy registry
  - Bandage evaluation for healthcare workers
  - Common adverse events
- Oversight
  - Smallpox Vaccine Safety Working Group of the Advisory Committee on Immunization Practices and the Armed Forces Epidemiology Board

# Adverse Event Overview

## Jan 24, 2003 – Oct 1, 2003

	Military	Civilian
VAERS reports	1061	816
Only smallpox vaccine	77%	>99%
Female	22%	76%
Revaccinees	~10%	~67%
Serious reports	15%	12%

# Anticipated Adverse Event Reports – October 1, 2003

	Military	Civilian
<b>Preventable</b>		
<b>Eczema vaccinatum</b>	0	0
<b>Progressive vaccinia</b>	0	0
<b>Fetal vaccinia</b>	0	0
<b>Contact Transmission – Nosocomial</b>	0	0
<b>Contact Transmission - Not Nosocomial</b>	24 secondary 2 tertiary	0
<b>Auto-inoculation – Non-ocular</b>	51	6 suspected 1 confirmed
<b>Auto-inoculation- Ocular</b>	11	1
<b>Not Preventable</b>		
<b>Generalized vaccinia</b> (All mild, no sequela)	33 suspected	2 suspected 1 confirmed
<b>Post-vaccination encephalitis</b>	1	1

# Vaccinia Transmission to Contacts

- **Characteristics of vaccinees who transmitted**
  - Predominantly primary vaccinees
  - No health care workers
- **Characteristics of vaccinia-infected contacts**
  - Predominantly unvaccinated
  - Half are family members
  - Usually result from intimate body contact
- **Characteristics of transmission settings**
  - Not in performance of work
  - No nosocomial transmissions
  - Bed partners at highest risk

# Unanticipated Adverse Event Reports as of October 1, 2003

	Military	Civilian
<b>Unanticipated Adverse Events – Presumed vaccine-associated</b>		
<b>Myo/pericarditis</b>	<b>58</b> 0 suspected 56 probable 2 confirmed	<b>22</b> 16 suspected 6 probable 0 confirmed
<b>Unanticipated Adverse Events – Currently under investigation</b>		
<b>Dilated Cardiomyopathy</b>	<b>2</b> <b>Both male</b> <b>37 and 43 years</b> <b>Both revaccinees</b> <b>Onset recognized ~4.5 and 5 months after vaccination</b>	<b>2</b> <b>Both female</b> <b>53 and 55 years</b> <b>Both revaccinees</b> <b>Onset recognized ~ 3 months after vaccination</b>

# Pregnancy Registry Status Report

- 160 women enrolled in registry because of exposure to smallpox vaccine during or immediately before pregnancy
  - About 70% vaccinated pre-conception or post conception but before pregnancy identifiable by testing
  - At least 3 previously vaccinated
- Outcomes of most pregnancies will be known by February 2004
  - To date, rates of spontaneous abortions & ectopic pregnancies do not appear to be higher than anticipated for age, risk factor history
  - No vaccinia identifiable in products of conception available for testing; N=3

# Other Serious Adverse Events

- **Acute MI**
- **Angina**
- Anoxic encephalopathy
- Appendicitis
- Arrhythmias
- Asthma
- Cancer: CNS, pancreatic
- Cerebral vascular accident
- Chest pain, non-cardiac
- Chest pain, non-specific
- Cholecystitis
- Facial paralysis
- GERD
- Headache
- Herpes Zoster
- Hypertension
- Neuropathy
- Pneumonia
- Prostatitis
- Sinusitis
- Transient global amnesia
- Urinary tract infection
- Vertigo
- Vomiting and diarrhea

# Adverse Events Summary

- Few adverse events historically associated with smallpox vaccine have been reported
  - **No eczema vaccinatum, progressive vaccinia, or fetal vaccinia**
- Rates of non-cardiac adverse events within or below ranges reported in historical studies
- No civilian to civilian contact transmission
- No nosocomial contact transmission
- A causal association between smallpox vaccination and myo/pericarditis is likely

# Future Considerations

## Current Vaccine

- What more is planned?
  - Cardiac adverse events
    - Prospective investigation
    - Guidance on evaluation of myo/pericarditis
    - 6-month follow-up of vaccinees with cardiac symptoms (n=200)
    - Case-control study of risk factors for myo/pericarditis among vaccinees (DoD)
  - Other
    - Surveillance case definitions

# Challenges for Smallpox Preparedness

- **Public complacency:**
  - Smallpox threat perceived to be near zero since end of the Iraq war
  - Smallpox preparation perceived to be low priority or not worth the risk
- **Public health and hospital workforce that is:**
  - Not fully engaged
  - Skeptical about the credibility of the smallpox threat
  - Confused about vaccination risks and available protections
- **Vaccination of citizens who insist on being vaccinated:**
  - Licensed vaccine perhaps in late 2004
  - Current access limited to clinical trials
  - No other program initiated
  - So far demand is very small