



Department of Defense
Individual's
Briefing

SMALLPOX

9 Oct 08



Key Messages

- Preserving the health and safety of our people is our top concern
- Smallpox vaccine prevents smallpox, but requires very careful use
- Smallpox would disrupt military missions, because it is contagious and deadly
- Smallpox protection helps our War on Terrorism; new threats require new measures of force protection



Smallpox Vaccination:

- Mandatory for personnel assigned to CENTCOM AOR, the Korean Peninsula and USPACOM Forward Deployed Naval Forces 15+ days
- Required for Smallpox Response Teams
- Can be given up to 120 days before deployment
- Policy requires ACAM2000 Medication Guide and DoD smallpox trifold distribution

Recipients must be screened

- Screening form located at www.smallpox.mil/screeningform





● Disease Progression:

- From exposure to onset of symptoms usually takes 7 to 17 days (12 to 14 days is typical)
- People become contagious a day or two before rash appears
- Characteristic rash—deep, tense blisters by day 2 of rash
- Rash forms round, deep pustules that dry out and become scabs around day 9
- Scabs fall off later, leaving scars

● Risk of Death:

- Overall, about 30% of unvaccinated people die
- Risk of death higher among infants, elderly, immunocompromised (> 40%)



Smallpox would disrupt military missions because it is contagious and deadly

- Before smallpox was eradicated, it killed many millions of people over hundreds of years
- Terrorists or governments hostile to US may have or could obtain variola virus
- A smallpox outbreak would significantly affect military readiness
- An outbreak could restrict movement of troops, aircraft, ships
- Smallpox would stress medical operations to maximum capacity





Smallpox vaccine prevents smallpox but requires very careful use

- World Health Organization (WHO) used Dryvax vaccine to eradicate natural smallpox
 - 95% of people are protected within 10 days (some may take longer)
 - Solid protection lasts for 3 years; partial protection lasts longer
 - ACIP recommends people at high risk for exposure be revaccinated every 10 years (pre-event); during an actual event, consider revaccinating if more than 3 years has elapsed since last vaccination
 - Can protect up to 3 days after exposure
- Contains live vaccinia virus, cannot cause smallpox



Smallpox Vaccine

- The current vaccine in use in the United States is a new cell culture vaccine that is a derivative of the Dryvax vaccine that was used during the global smallpox eradication program
- Dryvax was made from a virus called *vaccinia*, which is another “pox”-type virus related to smallpox
- ACAM2000, is manufactured by Acambis
- Live Vaccinia virus (NYCBOH strain) not smallpox (variola) virus
- Percutaneous inoculation with bifurcated needle (scarification)
 - Pustular lesion/induration surrounding central scab/ulcer 6-8 days post-vaccination
 - Vaccine protects within a few days of vaccination
 - A cutaneous response demonstrates successful vaccination
 - Immunity not life-long



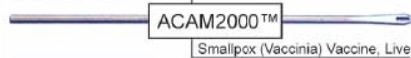


Comparison Chart

ACAM2000™

Manufacturer	Acambis Inc.
Indication	For the induction of immunity against Smallpox
Description	Live vaccinia virus manufactured using cell culture technology
Pharmaceutical Properties	~ 2% human serum albumin USP, 0.5-0.7% sodium chloride USP, 5% mannitol USP, and trace amounts of neomycin and polymyxin B ~ Diluent for ACAM2000 contains 50% (v/v) Glycerin USP, 0.25% (v/v) Phenol USP in Water for Injection USP supplied in 3mL clear glass vials containing 0.6mL of diluent ~ 100 dose vial
Medium	Vero (African Green Monkey kidney cells)
Route	Percutaneous using a bifurcated needle traditionally at an upper deltoid site (Also called scarification)
Dosing	Primary: 15 Jabs Revaccination: 15 Jabs
Revaccination	DoD policy requires individuals at high risk for exposure, such as laboratory personnel handling variola virus, be re-vaccinated every 3 years. Individuals deemed to be at an increased risk, such as segments of the military must be re-vaccinated every 10 years.
Storage & Handling	~ Un-reconstituted ACAM2000 vaccine is shipped and stored at 2-8°C (36-46°F) ~ Un-reconstituted ACAM2000 vaccine should not be exposed to room temperature (23-27°C, 73-81°F) for more than 48 hours ~ After reconstitution, ACAM 2000 vaccine may be administered within 6 to 8 hours at room temperature (20-25°C, 68-77°F) ~ Vaccine must be discarded as a bio-hazardous material 30 days after reconstitution ~ Gloves should be worn when reconstituting or administering ACAM2000 vaccine ~ Expiration dates will not be extended
Required Educational Material	DoD Smallpox individual information trifold brochure AND Medication Guide

Medication Guide



Please read this Medication Guide before you receive a vaccination with ACAM2000. This Guide does not take the place of talking to your healthcare provider about ACAM2000 and the smallpox disease.

What is the most important information I should know about the ACAM2000 smallpox vaccine?

If you are at a high risk for being exposed to smallpox, you should be vaccinated even if you have health problems, unless you have certain problems with your immune system. People who have health problems may have a higher chance of getting serious side effects from vaccination but are also those who have a higher chance of dying from the smallpox disease.

ACAM2000 may cause serious heart problems called myocarditis and pericarditis, or swelling of the heart tissues. In studies, about 1 in every 175 persons who got the vaccine for the first time may have experienced myocarditis and/or pericarditis. On rare occasions these conditions can result in an irregular heart beat and death. Your chances of getting heart problems from the vaccine are lower if you have already had this vaccine before. You can have myocarditis and/or pericarditis even if you have no symptoms.

Call your healthcare provider or get emergency help right away if you have:

- o chest pain or pressure
- o fast or irregular heartbeat
- o breathing problems

See "What are the possible side effects of ACAM2000?"

Because the vaccine has a live virus, it can spread to other parts of your body or to other people if you touch the vaccination site and then touch other parts of your body or other people. The vaccine virus can spread until the vaccination scab falls off (2 to 4 weeks after vaccination). If the virus is spread to a person who should not get the vaccine, the side effects can be very serious and life-threatening.

See "How do I care for the smallpox vaccination site?"

What is the ACAM2000 smallpox vaccine?

ACAM2000 is a prescription vaccine used to protect people against smallpox disease. It is for use in people who have a high chance of getting the disease.

ACAM2000 contains live vaccinia virus (a "pox"-type virus) to protect against smallpox disease.

WHAT YOU NEED TO KNOW ABOUT SMALLPOX VACCINE



For more information visit
www.smallpox.mil
or
Contact us at:
vaccines@amedd.army.mil
877-GET-VACC
DSN 761-4245

1 August 2007

Local point of contact

www.smallpox.mil/ACAM2000



Screening

- Carefully read & complete screening form; medical professionals available to explain in layman's terms
- Ask for clarification if unsure how to answer screening questions
- Contact family members who may know about childhood history of recurrent rashes like eczema
- Talk to close contacts and family members about the vaccination program and safety precautions
- Ask for assistance at any point, if you or your Family members have safety concerns
- Screening form can be located at: www.smallpox.mil/screeningform

All potential vaccinees must be screened

CHRONOLOGICAL RECORD OF MEDICAL CARE
Smallpox Vaccination Initial Note Page 1 of 2
This page may be completed by potential vaccinee recipient

1. Today's Date (MMDD/YYYY) / /
2a. GENDER Male Female 2b. First day of last normal menstrual period: / /
2c. FEMALES: Was your last menstrual period normal and on time? Yes No Unsure
2d. Are you currently breastfeeding? Yes No

3. Could someone you LIVE WITH or YOU be pregnant? Yes No Unsure
4. Did you ever receive smallpox vaccine? Yes No Unsure
4a. IF YES: Were you vaccinated within the last 10 years? Yes No Unsure
4b. IF UNSURE: Birth Year / / First Year in Military (if applicable): / /

5. Have you ever had a serious problem after smallpox or other vaccination? (Describe below) Yes No Unsure
6. Do you currently have an illness with fever? Yes No Unsure
7. Are you allergic to any of these products: polymyxin B, neomycin, latex? Yes No Unsure

Before vaccinating against smallpox, we want to know if you or your household close contacts have any of several medical conditions. Please answer the following questions to the best of your knowledge.

	Myself	Close Contact
8. Do you OR someone you currently live with NOW HAVE any of the following skin problems: Psoriasis (scaly skin rash), Burns (other than mild sunburn), Impetigo (skin infection), Uncontrolled Acne, Shingles (herpes zoster), Chickenpox, Darnier's disease or Other skin conditions (describe below)?	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unsure	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unsure
9. Do you OR someone you currently live with NOW HAVE or RECENTLY HAD a problem or take(s) medication that affects the immune system? For example: have or take medication for HIV, AIDS, leukemia, lymphoma, or chronic liver problem; have or take medication for Crohn's disease, lupus, arthritis, or other immune disease; have had radiation or X-ray treatment (not routine X-rays) within the last 3 months; have EVER had a bone-marrow or organ transplant (or take medication for that); or have another problem that requires steroids, prednisone or a cancer drug for treatment.	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unsure	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unsure
10. Have you OR someone you currently live with EVER HAD Eczema or Atopic Dermatitis? (Usually this skin condition involves an itchy, red, scaly rash that lasts more than 2 weeks. It often comes and goes.) IF YES or UNSURE: for either you or your close contact, Answer 10a-10e	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unsure	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unsure
10a. A doctor has made the diagnosis of eczema or atopic dermatitis.	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unsure	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unsure
10b. There have been itchy rashes that have lasted more than 2 weeks.	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unsure	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unsure
10c. At least once, there is a history of an itchy rash in the folds of the arms or legs.	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unsure	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unsure
10d. There is a history of eczema and food allergy during childhood.	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unsure	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unsure
10e. A doctor has made the diagnosis of asthma or hayfever (including first-degree relatives).	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unsure	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unsure
11. Are you being treated with steroid eye drops or ointment or have you had recent eye surgery?	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unsure	
12. Do you have a heart or vessel condition, such as angina, earlier heart attack, coronary artery disease, congestive heart failure, cardiomyopathy, stroke, "mini stroke", chest pain or trouble breathing on exertion?	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Unsure	
13. Check EACH of the following conditions that apply to you: <input type="radio"/> Heart Condition before age 50 in mother, father, brother, sister <input type="radio"/> Smoke cigarettes now <input type="radio"/> High blood pressure <input type="radio"/> High cholesterol <input type="radio"/> Diabetes or high blood sugar		
14. Do you have a child in home less one year of age?	<input type="radio"/> Yes <input type="radio"/> No	
15. Do you have other questions or have other concerns you would like to discuss? Explain "other," "unsure," or additional concerns (may use additional page). NOTE: If you might have a risk factor for HIV infection, we can arrange for HIV testing. FOR FEMALES: If you might be pregnant, or likely to become pregnant, please tell us. You may need additional pregnancy testing.	<input type="radio"/> Yes <input type="radio"/> No	

Last Name
First Name MI
Social Security Number --

Patient's identification (May use mechanical imprint)
RECORDS MAINTAINED AT:
RANK/GRADE:
SEX:
DATE OF BIRTH:
SPONSOR NAME (or Sponsor SSN):
RELATIONSHIP TO SPONSOR (or FMP):
ORGANIZATION:
STATUS:
DEPT/SVC:

Standard Form 600 (Rev. 6-97) Electronic Copy SVP Overprint (2-08)



HIV infection is a contraindication to smallpox vaccination

- Service Members must be up-to-date with Service HIV screening policies before smallpox vaccination
- DoD civilian will be offered HIV testing before vaccination
- HIV testing recommended for anyone with a history of risk factor for HIV infection, especially since last HIV test, and not sure of HIV infection status
- Because known risk factors cannot be identified for some people infected with HIV, people concerned they could be infected should be tested



Contact Contraindications

People who have close contact with a person who has a contraindication to smallpox vaccination shall:

- Have alternative housing arrangements or be exempted from smallpox vaccination until household contact situation no longer applies (i.e., 30 days after vaccination)

Unacceptable:

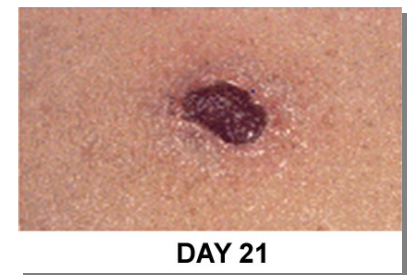
- Permitting vaccinated SM to reside in house, trailer, apartment, or similar close arrangements (e.g., “hot-bunking”) with medically-barred contact

Acceptable:

- Vaccinated SM uses alternate lodging (e.g., barracks, dorm room, tents) on military installation, vessel, or aircraft, or in contracted space
- Berthing barges, familiar to naval forces in shipyards
- Vaccinated SM voluntarily arranges for alternate lodging in privately-owned or managed space is acceptable, if the commander has reasonable expectation that SM will comply with requirement
- Schedule vaccinations shortly before or during 2- to 4-week deployments or family separation



Successful Response to Vaccination



If someone does not get the expected vaccination site reaction, the original vaccination clinic should be informed



Documentation

- Screening: Record contraindications in medical record and ITS
- Vaccination: Individual medical records and ITS
- Confirmation of Take
 - Instruct all: Come back to clinic, if no characteristic lesion
 - Healthcare workers and response team members (traveling into smallpox outbreak area) will have take recorded in their health records and ITS
 - Other personnel should have vaccination take recorded in health records and ITS by medic or provider trained in vaccination evaluation
- Adverse events
 - Medical records, VAERS, VHC access



Medical Readiness Reporting System



Care of Vaccination Site



Vaccine virus remains at the site for at least 30 days and until the skin has healed, and can potentially infect others

- **Don't touch any vaccination site**
 - **If you touch it by accident, wash your hands right away**
 - **Don't let others touch your vaccination site or materials that covered it**
 - **Don't let others use a towel used after vaccination until laundered**
-
- **Wear sleeves to cover the site**
 - **Wear sleeves at night, if you sleep in bed with someone**
 - **Use bandages; change them every few days**
 - **Discard bandages in sealed or double plastic bags; carefully add bleach if desired**
Keep site dry; bathe normally, but dry the site last, with something disposable (avoid rubbing)
 - **Avoid swimming or public bathing facilities**
 - **Launder clothing, towels, and sheets in hot water with detergent or bleach**
 - **When the scab falls off, place it in a sealed plastic bag with a little bleach and throw it away.**



Hand Washing & Hand Hygiene

Wash hands with soap and warm water

- Rub hands together vigorously for at least 10 seconds
- Cover all surfaces of the hands and fingers
- Rinse hands with warm water
- Dry hands thoroughly with a paper towel
- Use paper towel to turn off the faucet

Alcohol-based waterless hand rinse, e.g., CalStat®

- Excellent alternative if hands are not visibly soiled
- Apply product to palm and rub hands together, covering all surfaces of hands and fingers, until hands are dry
- May have sticky feel after repeated use – wash hands with soap and water as needed

Be extremely careful with contact lens use!

- Wearing glasses until the site heals is preferred
- If contact lenses are used, wash hands thoroughly before touching eyes or contact lenses





Pregnancy & Infant Care

- Smallpox vaccination should be deferred until after pregnancy
- Avoid pregnancy for 4 weeks after vaccination
- If a female is pregnant at the time of vaccination, or if a vaccinee becomes pregnant within 4 weeks after vaccination,
 - Contact Smallpox Vaccine in Pregnancy Registry:
 - 619.553.9255
 - NHRC-birthregistry@med.navy.mil
 - www.smallpox.mil/pregnancy
 - Submit VAERS with Smallpox Pregnancy Supplement
- In an outbreak, personal benefit from vaccination may outweigh risks
- Take care to prevent spread of vaccine virus to children. ALWAYS wash hands before handling (e.g., feeding, changing diapers) and keep site covered with a bandage and sleeves
- Smallpox vaccine not recommended for nursing mothers, as it may put infants in close contact with mother's vaccination site





Serious reactions that may require medical attention

- Accidental spread of virus elsewhere on body or to another person
- Widespread vaccine rash where sores break out away from vaccination site (generalized vaccinia)
- Allergic rash after vaccination (erythema multiforme)
- Inflammation of or around heart (myo-pericarditis)

Life-threatening reactions that need immediate attention

- Serious skin rashes in people such as those with eczema or atopic dermatitis (eczema vaccinatum)
- Ongoing infection of skin with tissue destruction (progressive vaccinia or vaccinia necrosum)
- Postvaccinal encephalitis, inflammation of the brain
- Chest pain or shortness of breath



Adverse Event Reporting

- Vaccine Adverse Event Reporting System (VAERS)
 - FDA and CDC review 100% of reports submitted
 - Anyone can submit a VAERS form, online preferred
<https://secure.vaers.org>
 - Reporting with medical help results in more detail
- DoD requires a VAERS form for:
 - Loss of duty 24 hours or longer (\geq 1 duty day)
 - Hospitalization
 - Suspected vaccine vial contamination
 - Auto-inoculation or contact vaccinia
- Other submissions encouraged
- Report to VAERS at www.vaers.hhs.gov or call 800-822-7967
- For assistance with VAERS submission contact your local clinic or the VHC Network

AskVHC@amedd.army.mil or www.VHCInfo.org



- Adverse events after DoD or USCG directed vaccinations are line-of-duty conditions
- Someone with an adverse event in a non-duty status possibly associated to any vaccination
 - Seek medical evaluation at a DoD, USCG, or civilian medical treatment facility, if necessary
 - Must report the event to the unit commander or designated representative as soon as possible
 - See local medical department or squadron for guidance
- Commander will determine Line of Duty and/or Notice of Eligibility status, if required



- Carefully read & complete screening form
- Contact family members who may know about your childhood history of recurrent rashes like eczema
- Talk to your close contacts and family members about smallpox vaccination and safety precautions
- Ask for assistance at any point, if needed by you or your close contacts or if you have safety concerns
- Refer to www.smallpox.mil for more information
- Take care of your vaccination site to minimize adverse events in you and others



MILVAX Agency

- www.smallpox.mil; www.vaccines.mil/smallpox
- vaccines@amedd.army.mil
- **877.GET.VACC** (877.438.8222)

DoD Vaccine Clinical Call Center

- **866.210.6469**

DoD Vaccine Healthcare Centers

for help with complicated adverse-event management

- www.vhcinfo.org
- Askvhc@amedd.army.mil
- **202.782.0411**

Information for Civilian Healthcare Providers

*Call the Military Treatment Facility (MTF) where the member is enrolled
–OR– contact the Military Medical Support Office (MMSO)*

- **888.647.6676** (if the member is not enrolled to an MTF)

Smallpox Vaccine in Pregnancy Registry

- NHRC-birthregistry@med.navy.mil
- **619.553.9255**



MILVAX





www.vaccines.mil



www.vaccines.mil