



**Smallpox Vaccination Program
Question and Answers**

Prepared by

Military Vaccine (MILVAX) Agency,
Office of The Army Surgeon General, U.S. Army

Last Updated: 20 Feb 08

www.smallpox.mil

877-GET-VACC

vaccines@amedd.army.mil

Smallpox Vaccination Program Questions and Answers

Smallpox Policy

- Policy and Management Questions
- Military Discipline

Smallpox Threat

- Smallpox Weapons – The Threat

Smallpox – The Disease

- Smallpox Disease – What is it?
- Side Effects – Smallpox Vaccine vs. Smallpox Disease

Smallpox in the Environment

- Testing the Environment
- Decontamination of a Contaminated Environment
- How to Detect Smallpox Around You

Smallpox – Vaccine Description

- Overview
- ACAM2000
- Dryvax and ACAM2000 Comparison Chart
- Smallpox Vaccine – Ingredients
- Smallpox Vaccinations Over Time

Smallpox – Vaccine Effectiveness

- Efficacy

Smallpox Vaccine – Safety

- Safety
- Rare but Serious Side Effects After Vaccination
- Long Term Safety
- Smallpox Vaccine – Risks vs. Benefit
- Reproductive Health
- Smallpox Vaccine – Vaccination Site Care
- Smallpox Vaccine – Eligibility Criteria

Smallpox Vaccine – Cardiac Related Reactions

- Heart-Related Problems After Smallpox Vaccination
- Heart Conditions That Exempt Someone From Smallpox Vaccination

Questions and Answers for Household Members and Community Members

- Laundering Information
- Possible Family Member Reactions to the Smallpox Vaccine
- After Receiving the Smallpox Vaccination – Bathing

Healthcare Workers

- Vaccination for Healthcare Workers
- Additional Concerns for Healthcare Workers

Adapted from the Immunization Action Coalition (with permission) and the Centers for Disease Control and Prevention (CDC).

Smallpox Vaccination Given Simultaneously With Other Drugs and Vaccines
Questions That Must Be Asked Before Administering Smallpox Vaccine
People Who Should Not Be Vaccinated During a Smallpox Outbreak
Civilian Healthcare Responsibilities

Treating Complications of the Smallpox Vaccination

Treatment for Patients Who Develop a Reaction to the Smallpox Vaccine
Additional Treatment Options

How To Administer Smallpox Vaccine

Protective Measures To Follow While Administering Smallpox Vaccine

Evidence of Immunity and Vaccination – Response Interpretation

Evidence of Immunity Against Smallpox
Smallpox Vaccine – Major Reaction
Smallpox Vaccine – Equivocal Reaction

Vaccination Site Care

Precautions to Avoid Spreading Smallpox Vaccine Virus

Linen Precautions For Hospital Workers and Institutional Settings After Smallpox Vaccination

Precautions for Your Uniform While at Work – Laundry
Working Out at the Gym (Towels) – Laundry
How to Care For Your Uniform at Home – Laundry
Personal Protective Equipment for Laundry Workers

Smallpox Policy

Policy and Management Questions

1) Why get vaccinated?

Authorities are concerned that terrorists or governments hostile to the United States may have some of the variola virus that causes smallpox disease. If so, they could use it as a biological weapon in bombs or sprays or by other methods. People exposed to variola virus, or those at risk of being exposed, can be protected by vaccinia (smallpox) vaccine.

Smallpox can be prevented through the use of the smallpox vaccine. The World Health Organization (WHO) used smallpox vaccine to eradicate natural smallpox from the planet. About 95% of people are protected within 10 days of getting a single smallpox vaccination.

Until recently, most service members had not been vaccinated against smallpox. The rest don't have much immunity left from vaccine given years ago. Until the late 1970s, many billions of people around the globe received smallpox vaccine. Smallpox vaccine is still used routinely to protect a small number of people who work with smallpox vaccine virus (vaccinia) or similar viruses. Between December 2002 and January 2008, more than 1.4 million service members received smallpox vaccination.

There is no proven treatment for the smallpox disease, but research to evaluate new antiviral medications is ongoing. Patients infected with smallpox can benefit from supportive therapy (e.g., intravenous fluids, medicine to control fever or pain) and antibiotics for any secondary bacterial infections that occur from all the skin problems smallpox causes.

2) What if somebody has already been vaccinated years ago?

Research indicates that the first dose of smallpox vaccine offers an increased level of protection from smallpox for 3 years. Immunity decreases thereafter. Substantial, but waning immunity persists for 7-10 years. Subsequent vaccinations increase and extend protection. After 3 doses substantial protection persists for >30 years.

In that European study, about 30% of unvaccinated people infected with smallpox died. About 1.4% of people vaccinated up to 10 years earlier died. Among people vaccinated 11 to 20 years earlier, 7% died. Among people vaccinated 21 or more years earlier, 11% died. These data show that immunity falls off over time and that revaccination is needed to maintain immunity. [Mack TM. Smallpox in Europe, 1950-1971. J Infect Dis 1972; 125:161-169]

3) Who in DoD is going to get the smallpox vaccine?

In December 2002, the Secretary of Defense decided to vaccinate certain emergency response and medical personnel and other designated personnel that constitute critical mission capabilities to include those essential to the accomplishment of U.S. Central Command's (CENTCOM) missions. In June 2004, DoD expanded the program to include more forces and people in Korea, the US Pacific Command Forward Deployed Naval Forces and CENTCOM Area of Operations (AOR). In September 2007, the ASD (P & R) changed the pre-deployment timeframe for smallpox vaccine administration to 120 days.

For complete information regarding policy, please review the "Policy" section of our website under "Resource Center."

4) Will Service members still be deployable if they have not received the smallpox vaccine?

Yes, if they are in one of the groups that should not receive the smallpox vaccine they will still be deployable. In the event of an actual smallpox attack, their vaccination status will be reevaluated and they would likely be vaccinated.

5) How much vaccine does the DoD have?

The DoD has sufficient FDA-licensed vaccine to continue implementation of this program.

6) If the threat is low, why is the Department of Defense administering the smallpox vaccine?

We cannot quantify the threat that smallpox would be used as a bio-weapon, but we do know that the consequences of its use could be great. Military missions must go on even if a smallpox outbreak occurs. If an outbreak occurs, America will expect military units to be on the job, not on the sideline. It may not be feasible to vaccinate military forces soon after exposure if they are deployed to remote locations and/or engaged in military operations. Some military personnel will not be able to postpone vital missions if smallpox is used as a weapon. Vaccination is a prudent course for preparedness and may serve as a deterrent.

Military Discipline

1) What will happen to a Service member who refuses the vaccine?

We begin with the assumption that any service member covered by this policy who refuses vaccination may be uninformed about the facts related to the deadly effects of the smallpox virus and the protection afforded by the vaccine. Our first action with those who might refuse the vaccine will be to determine their concern and provide information.

This is a force protection issue. If a service member continues to refuse the vaccine, then a commander will manage the situation as he or she would for any failure to obey a lawful order, including educating the member about the smallpox vaccine as appropriate.

Smallpox Threat

Smallpox Weapons – The Threat

1) How does the threat of a smallpox attack on US forces compare with that of an anthrax attack?

They are both known threats. Many factors go into such determinations, including intelligence information, known capabilities and other variables. We cannot quantify the threat of either one being used as a bioweapon, but we do know the consequences of their use could be great. Vaccination is a prudent, logical step to ensure preparedness for the U.S.

2) Will the people receiving anthrax vaccinations be the same ones receiving the smallpox vaccinations?

Yes. The June 2004 expansion of the smallpox immunization program, identified military forces, emergency-essential civilians and mission-essential contractors assigned to the CENTCOM area of responsibility (AOR), the Korean Peninsula, and US Pacific Command Forward Deployed Naval Forces as those required to receive both vaccinations.

3) How serious is the threat that a terrorist would attack us by releasing the smallpox virus?

Terrorists or governments hostile to the United States may have, or could obtain, some of the variola virus that causes smallpox disease. If so, these adversaries could use it as a biological weapon. People

exposed to variola virus, or those at risk of being exposed, can be protected by vaccinia (smallpox) vaccine. The United States is taking precautions to deal with this possibility.

4) How dangerous is the smallpox threat?

Smallpox is one of the bio-agents determined by the Centers for Disease Control and Prevention to pose the greatest potential threat of adverse impact on public health and medical systems. Other bio-agents in this category are anthrax, plague, botulism, tularemia, and viral hemorrhagic fevers.

5) Did the former regime in Iraq have smallpox?

It is possible, but not confirmed, that elements of the former regime in Iraq possessed the virus that causes smallpox.

6) What other countries have smallpox?

A number of other countries may possess the virus that causes smallpox, but only a few are authorized. After eradication, the only places authorized to possess the variola virus are high-containment civilian government laboratories in the Russian Federation and the U.S. The virus was allowed to be retained for scientific purposes. Anyone else possessing the virus is breaching an international agreement with the World Health Organization, an official instrument of the United Nations.

7) Does Al-Qaida have smallpox?

It is unknown, but unlikely, that Al-Qaida at this time possesses the virus that causes smallpox.

8) Do you believe that North Korea may use a smallpox weapon?

If North Korea possesses the variola virus, it may be used under any number of circumstances. By preparing ourselves to respond to any smallpox attack, through pre-outbreak and post-outbreak vaccination plans, we help in deterring such attacks.

Smallpox – The Disease

Smallpox Disease – What is it?

1) What is smallpox?

Smallpox is a very serious disease; it is contagious and sometimes fatal. Smallpox is caused by a germ called variola virus.

The symptoms of smallpox begin with high fever, head and body aches, and sometimes vomiting. These symptoms are followed by a rash that spreads from the head and extremities toward the center of the body, then progresses to raised bumps that eventually scab over and fall off after about three weeks, leaving a pitted scar.

Smallpox can cause:

- A severe rash covering the whole body that can leave permanent scars.
- High fever.
- Severe headache or body ache.
- Death (in about 30% of infected people).
- Blindness in some survivors.

Natural cases of smallpox have been eradicated. The last natural case of smallpox was in Somalia in 1977.

The incubation period for smallpox is about 12 to 14 days (range: 7 to 17 days) after exposure.

2) Is smallpox fatal?

Most patients infected with smallpox recover. Smallpox kills about 3 out of 10 people infected. Many smallpox survivors have permanent scars over large areas of their body, especially their face. People who survive smallpox have lifelong immunity against smallpox.

3) Is smallpox contagious? How does smallpox spread?

The disease usually requires face-to-face contact with a contagious person for several hours. Contact with infected skin could also transmit the virus. Spread by contact with inanimate objects (e.g., clothing, towels, linens) would be less common.

People with smallpox are contagious from when their temperature goes over 101°F (38.3°C). They stay contagious until all their scabs fall off.

Not everybody who talks with a smallpox patient will get the disease. People with smallpox can infect about half of the people who live in their household. On average, each infected person can infect about 5 other people. Those other people show symptoms about 15 days after exposure.

The most common way to transmit smallpox would be from prolonged face-to-face contact. People infected with smallpox exhale little droplets that carry the virus to the nose or mouth of bystanders. The greatest risk comes from prolonged face-to-face contact (6 feet or less, most often after 1 or more hours), with an infected person, especially one who is coughing. Indirect contact through fine-particle aerosolization or contaminated inanimate objects can spread the virus as well, though less efficiently.

Special precautions need to be taken to thoroughly clean all bedding and clothing of smallpox patients with bleach and hot water. Disinfectants such as household bleach or hospital-approved quaternary ammonia disinfectants can be used for cleaning contaminated surfaces.

Animals and insects do not carry or transmit smallpox disease. Smallpox is not spread by food or water.

4) Is there any treatment for smallpox?

Smallpox can be prevented through the use of the smallpox vaccine. There is no proven treatment for smallpox, but research to evaluate new antiviral agents is ongoing. Preliminary results with the drug cidofovir suggest it may be useful. The use of cidofovir to treat smallpox or smallpox vaccine reactions requires the use of an Investigational New Drug (IND) protocol and should be evaluated and monitored by medical experts. Patients with smallpox can benefit from supportive therapy such as intravenous fluids, medicine to control fever or pain and antibiotics for any secondary bacterial infections that may occur.

5) How many people would have to get smallpox before it is considered an outbreak?

One confirmed case of smallpox is considered a public health emergency.

Side Effects – Smallpox Vaccine vs. Smallpox Disease

1) Are the potential side effects of smallpox vaccine the same as if I got infected with smallpox?

No. The *symptoms* of the *disease start* with body ache and sometimes vomiting with a high fever over 101°. Over the next few days, pus-filled blisters develop over large portions of the body.

The vaccine side effects are usually limited to itching, fever, body ache, swollen lymph nodes, sore

arm, mild rash as well as a rash at the injection site. People given a smallpox vaccination need to know the expected response at the vaccination site.

Smallpox in the Environment

Testing the Environment

1) Do tests exist to show if smallpox is in the environment, like tests for anthrax spores?

There are various methods that can be utilized for detecting bioterrorist agents, including smallpox. These include surface and air sample gathering techniques, followed by identification methods such as culture growth or polymerase chain reaction (PCR). However, smallpox virus is relatively fragile, would not persist for long in the environment, and therefore sampling and analysis would not be considered necessary. In the event of a bioterrorist attack involving smallpox, local, state, and federal responders would determine the need for sampling based on the specific circumstances associated with the release.

Decontamination of a Contaminated Environment

1) If smallpox is discovered or released in a building, or if a person develops symptoms in a building, how can that area be decontaminated?

The smallpox virus is fragile. In laboratory experiments, 90% of aerosolized (vaccinia virus [a model for smallpox virus]) dies within 24 hours; in the presence of ultraviolet (UV) light, this percentage would be even greater. If an aerosol release of smallpox occurs, 90% of virus matter will be inactivated or dissipated in about 24 hours.

Standard hospital-grade disinfectants such as quaternary-ammonia compounds are effective in killing the virus. They should be used on surfaces to disinfect hospitalized patients' rooms or other contaminated surfaces. Although less desirable because it can damage equipment and furniture, hypochlorite (bleach) is an acceptable alternative. In the hospital setting, patients' linens should be autoclaved or washed in hot water with bleach added. Infectious waste should be placed in biohazard bags and autoclaved before incineration.

2) What should people do if they suspect a person has smallpox or suspect that smallpox has been released in their area?

On military installations, report suspected cases of smallpox or suspected intentional release of smallpox to your local hospital or clinic. In civilian communities, report suspected cases of smallpox or suspected intentional release of smallpox to your local health department. The hospital, clinic, or local health department will evaluate the situation and make needed reports to higher headquarters, the CDC, and the state health department. Report suspicious activities to law-enforcement personnel.

How to Detect Smallpox Around You

1) How can we stop the spread of smallpox after someone comes down with it?

The most important steps to stop a smallpox epidemic are isolation of smallpox cases, tracing of the contacts of these cases, and vaccination.

Patients showing signs of smallpox infection are capable of spreading the virus. Patients should be placed in medical isolation, so that they will not continue to spread the virus. In addition, people who

have come into close contact with smallpox patients should be vaccinated immediately and closely watched for symptoms of smallpox. Vaccination and isolation are the key strategies for stopping a smallpox outbreak from spreading.

Smallpox – Vaccine Description

Overview

1) What is smallpox vaccine?

Smallpox vaccine contains live vaccinia virus (not smallpox virus) to protect against smallpox. This same vaccine has been given to millions of Americans, including Service members during World War I, World War II, and until the 1980s. Between December 2002 and January 2008, more than 1.4 Million Service members received smallpox vaccination.

The vaccine is made from a virus called vaccinia, which is another “pox”-type virus related to smallpox. The vaccine helps the body develop immunity to smallpox. The vaccine does not contain the smallpox virus and cannot spread smallpox. The vaccine was successfully used to eradicate smallpox from the human population.

The vaccine virus (vaccinia) is similar to the smallpox virus (variola). Edward Jenner reported in 1796 that people given vaccinia (smallpox) vaccine become protected from smallpox. Smallpox vaccine was the very first vaccine and has been used successfully for over 200 years.

Getting smallpox vaccine before exposure will protect about 95 percent of people from getting smallpox. Vaccination within 3 days after exposure will prevent or significantly lessen the severity of smallpox symptoms in the vast majority of people. Vaccination 4 to 7 days after exposure likely offers some protection from disease or may modify the severity of disease. Vaccination after this time may not offer any benefit.

2) How long has smallpox vaccine been around?

Smallpox vaccination was the very first vaccination. Edward Jenner first developed it in 1796. Smallpox vaccines were first licensed in the United States in 1903. The original license for Dryvax® has been continuously in effect since 1931. FDA recently licensed a supply of smallpox vaccine made by Acambis Laboratories called ACAM2000. Smallpox vaccine used for Service members passes all tests required by the FDA.

3) Is ACAM2000 the same smallpox vaccine that was used in the past?

Both Dryvax and ACAM2000 are derived from the New York City Board of Health strain using a pox virus called vaccinia, but Dryvax was grown on the skin of calves and essentially freeze-dried for storage. Dryvax was licensed and approved by the FDA, in 1931 and is now in limited supply because it is no longer manufactured.

ACAM2000, Smallpox (Vaccinia) Vaccine, Live, approved by FDA in 2007, is a live vaccinia virus derived from plaque purification cloning from Dryvax®, grown in African Green Monkey kidney (Vero) cells, and tested to be free of adventitious agents.

ACAM2000

1) Is ACAM2000 an effective vaccine?

Based on historical evidence, vaccinated individuals are considered protected against smallpox after a major cutaneous reaction is observed following primary vaccination. From a clinical perspective, ACAM2000 elicited a strong immune response in all study populations. ACAM2000 induced positive cutaneous responses in >96% of vaccinia-naïve subjects and in >84% of previously vaccinated subjects in pre-licensure studies.

2) Who is the manufacturer of ACAM2000?

Acambis
Peterhouse Technology Park
100 Fulbourn Road
Cambridge CB1 9PT, UK
acambis@acambis.com

3) What are Acambis's responsibilities to CDC and DoD?

Acambis developed ACAM2000 under contracts with the US Centers for Disease Control and Prevention (CDC) as part of its preparations for a public health emergency. ACAM2000 is the primary smallpox vaccine for use in an emergency and forms the majority of the US Government's smallpox vaccine Strategic National Stockpile (SNS). Acambis is currently in negotiations with the CDC to provide the US Government with a long-term ACAM2000 production capability that is located entirely in the US.

4) How will it be supplied?

ACAM2000, Smallpox (Vaccinia) Vaccine, Live is supplied in multiple-dose 3 mL clear glass vials containing lyophilized powder (freeze-dried vaccine). After reconstitution with 0.3 mL of diluent, the vial contains approximately 100 nominal doses of 0.0025 mL of vaccinia virus (live,) $1.0 - 5.0 \times 10^8$ PFU/mL or $2.5 - 12.5 \times 10^5$ PFU/dose.

Diluent for ACAM2000 is supplied in 3 mL clear glass vials containing 0.6 mL of diluent.

Bifurcated needles are supplied in boxes (5 x 5 x 1 in) containing 100 needles.

1 mL tuberculin syringes with 25 gauge x 5/8" needles are supplied for vaccine reconstitution.

5) How is ACAM2000 stored and handled?

Prior to reconstitution, ACAM2000 vaccine retains a potency of 1.0×10^8 PFU or higher per dose for at least 18 months when stored at refrigerated temperatures of 2-8°C (36-46°F).

After reconstitution, ACAM2000 vaccine may be administered during a 6 to 8 hour workday at room temperature (20-25°C, 68-77°F). Do not expose ACAM2000 to room temperature conditions for more than 48 hours. Reconstituted ACAM2000 vaccine may be stored in a refrigerator (2-8°C, 36-46°F) no longer than 30 days, after which it should be discarded.

Diluent for Smallpox Vaccine, (Vero Cells) Lyophilized, ACAM2000 should be stored in a refrigerator (2-8°C, 36-46°F). ACAM2000 contains live vaccinia virus that is transmissible, and should be handled as an infectious agent once vials are opened.

6) When will DoD stop using Dryvax and start using ACAM2000?

ACAM2000 will begin arriving for use at DoD locations in late January, 2008. Dryvax can be used until 29 February, 2008. All Dryvax vaccine and diluent will be destroyed by 31 March, 2008. On 1 April, 2008 DoD will fully transition to ACAM2000.

7) How will the implementation of ACAM2000 affect the Smallpox Vaccination Program (SVP)

policy?

The current DoD Smallpox Vaccination Program policy remains the same. It is mandatory for uniform personnel and all emergency essential and equivalent personnel assigned to CENTCOM AOR or to the Korean Peninsula for 15 or more consecutive days. It is voluntary for U.S. Citizen adult family members accompanying DoD military and civilian personnel for 15 or more consecutive days to the CENTCOM AOR or Korea. The overall success of immunizing the force establishes a stronger footprint of military readiness.

8) Do vaccinees need signed consent to receive this vaccine?

No, since it is FDA approved, there is no requirement for signed consent.

9) Is there a change in the process to administer ACAM2000?

Yes, all personnel (primary vaccinees and re-vaccinees) who receive ACAM2000 will receive 15 jabs with a bifurcated needle.

10) If a vaccinee has a question about ACAM2000, what DoD resources are available to them?

Military Vaccine Agency:

- www.vaccines.mil
- vaccines@amedd.army.mil
- Toll Free 1-877-GET.VACC

DoD Vaccine Clinical Call Center:

- Toll Free: 1-866-210-6469

DoD Vaccine Healthcare Centers:

- www.vhcinfo.org

11) Do those vaccinated with Dryvax need to be revaccinated with ACAM2000 sooner than 10 years?

No. Personnel previously vaccinated with Dryvax have an increased level of protection against smallpox and should only be re-vaccinated IAW DoD policy. Most people will require re-vaccination after 10 years.

12) What education information will a vaccinee receive?

Anyone vaccinated with the smallpox vaccine will receive a DoD Smallpox Information Brochure, a Medication Guide, and additional information as requested.

13) Is this smallpox vaccine diluted?

The smallpox vaccine is stored as a powder and then a diluent (liquid) is added to reconstitute the powder shortly before use. The reconstituted vaccine is the same as the original full-strength concentration.

14) Is smallpox vaccine live or synthetic?

Smallpox vaccine is "live". It contains natural, live vaccinia viruses.

15) How is smallpox vaccine given?


The smallpox vaccine is not given with a typical needle. It is not a "shot," like many vaccinations. The vaccine is given using a bifurcated (two-pronged) needle that is dipped into the vaccine solution. A bifurcated needle looks like a little pitchfork or tuning fork. When dipped into the vaccine vial, the needle retains a droplet of the vaccine between the two prongs. The needle is then used to prick the skin 15 times in a few seconds. The pricking is not deep, but it will cause a sore spot and a very small drop of blood to form. The vaccine usually is given on the upper arm.

16) Who will administer smallpox vaccine?

Trained healthcare workers will administer the vaccine. Typically this would be a nurse or a medic.

Dryvax and ACAM2000 Comparison Chart

1) How do Dryvax and ACAM2000 compare?

 DRYVAX/ACAM2000 Comparison Chart		
	DRYVAX® (est. thru 29 Feb 08)	ACAM2000™ (est. after 01 Mar 08)
Manufacturer	Wyeth Lab	Acambis Inc.
Indication	For the induction of immunity against Smallpox	For the induction of immunity against Smallpox
Description	Live vaccinia virus cultured from Calf Lymph	Live vaccinia virus manufactured using cell culture technology
Pharmaceutical Properties	~ The calf lymph is purified, concentrated and dried by lyophilization. During processing, polymyxin B sulfate, dihydrostreptomycin sulfate, chlortetracycline hydrochloride and neomycin sulfate are added. ~ Diluent contains: 50% glycerin and 0.25% phenol ~ 100 dose vial	~ 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	Calf Lymph	Vero (African Green Monkey kidney cells)
Route	Percutaneous using a bifurcated needle traditionally at an upper deltoid site (Also called scarification)	Percutaneous using a bifurcated needle traditionally at an upper deltoid site (Also called scarification)
Dosing	Primary: 3 Jabs Revaccination: 15 Jabs	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.	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	~ Dryvax is shipped and stored at 2-8°C or 36-46°F ~ Discard vaccine 90 days after reconstitution ~ Expiration date subject to extensions	~ 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	DoD Smallpox individual information trifold brochure AND Medication Guide

Military Vaccine Agency www.vaccines.mil (877) GET-VACC 11 Jan 08

Smallpox Vaccine – Ingredients

1) What are the ingredients of smallpox vaccine?

The vaccine contains live vaccinia virus derived from plaque purification cloning from Dryvax (Wyeth Laboratories, Marietta, PA, calf lymph vaccine, New York City Board of Health Strain) and grown in African Green Monkey kidney (Vero) cells.

Inactive ingredients: 6-8 mM HEPES (pH 6.5-7.5), 2% human serum albumin USP, 0.5 – 0.7% sodium chloride USP, 5% mannitol USP, and trace amounts of the antibiotics neomycin and polymyxin B.

Diluent for ACAM2000: 50% (v/v) Glycerin USP, 0.25% (v/v) Phenol USP in Water for Injection USP, 0.3 mLs.

Smallpox Vaccinations Over Time

1) Who received smallpox vaccination in the past?

Smallpox vaccination of US military forces dates back to 1812. Smallpox vaccine has been given to millions of Americans, including Service members during World War I, World War II, and into the 1980s.

In the United States, routine vaccination against smallpox ended around 1972 in most places. Military smallpox vaccination programs continued longer. In 1984, routine military vaccinations were limited to recruits entering basic training. Between 1984 and 1989, some service members were immunized but not others. In 1990, the Department of Defense discontinued routine vaccination of recruits.

Between December 2002 and January 2008 more than 1.4 M Service members received smallpox vaccination.

Smallpox – Vaccine Effectiveness

Efficacy

1) How long does a smallpox vaccination last?

Past experience indicates that the first dose of the vaccine offers protection from smallpox for three to five years, with decreasing immunity thereafter. If a person is vaccinated again later, immunity lasts longer. A report from Europe in the 1970s suggests that people vaccinated 10 or 20 or more years ago have enough immunity to lessen their chance of death if infected. However, these people need another dose of smallpox vaccine to restore their full immunity.

2) Is there a test to determine if someone is still immune from a past smallpox vaccination?

There are no reliable blood tests to determine if someone is still immune to smallpox.

3) If someone already had a smallpox vaccination in the past (when they were younger, or in the 1980's in the military), will they have to get it again?

If more than 10 years have passed since your last vaccination, you will be revaccinated in accordance with DoD's Policy on Administrative Issues Related to Smallpox Vaccination Program.

<http://www.vaccines.mil/documents/240SPadminissuespolicy.pdf>

4) Will I have to get another dose of smallpox vaccine 5 or 10 years from now?

The need for additional smallpox vaccination will be based on the threat assessment at the time. If there is still a perceived threat, then, yes, you may be given another vaccination, depending on your job and location.

5) Will I be protected against all types of smallpox?

Smallpox vaccine contains live vaccinia viruses. Once administered, it evokes an immune response that protects against variola virus, the virus that causes smallpox.

Smallpox Vaccine – Safety

Safety

1) Is smallpox vaccine safe?

The smallpox vaccine is the best protection you can get if you are exposed to the smallpox virus. Most people experience mild, reactions, such as sore arm, fever, headache, body ache, and fatigue. These symptoms may peak 8 to 12 days after vaccination.

2) Why should I take this vaccine?

People in many countries are concerned about the potential use of smallpox as a bioterrorism agent. The U.S. government has been preparing for some time for the remote possibility of an outbreak of smallpox as an act of terror. Those preparations quickened after September 11, 2001.

The likelihood that smallpox would be used as a bioweapon is unknown. About 30 percent of people who contract smallpox die; about 70% survive.

Vaccination prevents almost all cases of smallpox. If symptoms of smallpox do appear, they are generally milder than in unvaccinated people.

3) What are the temporary side effects after smallpox vaccination?

Mild reactions include swelling and tender lymph nodes that can last two to four weeks after the blister heals. Most people develop itching, headache, fatigue, muscle aches, pain, or chills after smallpox vaccination, usually about eight to 12 days later. Some individuals may have rashes that last two to four days. These side effects are usually temporary and self-limiting, meaning they go away on their own or with minimal medical treatment, for example aspirin and rest.

If the vaccination is successful, a red and itchy bump develops at the vaccine site in three or four days. Then, in the first week, the bump becomes a large blister and fills with pus. During the second week, the blister begins to dry up and a scab forms. The scab falls off in the third or fourth week, leaving a small scar. People who are being vaccinated for the first time have a stronger reaction than those who are being revaccinated.

If someone does not get the expected vaccination site response, they need to be revaccinated. If someone has a question or concern about the smallpox vaccination site they should contact their primary-care manager, medical department representative or their healthcare provider.

4) Is it okay to take multiple vaccines at the same time?

Multiple inoculations do not weaken or overwhelm the immune system. The immune system has an enormous capacity to respond to immune stimuli from vaccines. Far from weakening an immune system, vaccines actually strengthen the body's natural defenses against serious and potentially fatal infections. Even infants are capable of generating protective immune responses to multiple vaccines given at the same time.

5) Can someone vaccinated against smallpox infect someone else?

Yes. However, infection of this kind can be prevented with covering the site and frequent hand washing. Adverse reactions, sometimes severe, can also occur in people who come in contact with a

vaccinated person. These problems result from touching the vaccination site and transferring the vaccine virus to another person.

Rare but Serious Side Effects After Vaccination

1) What are the rare but serious side effects after smallpox vaccination?

Smallpox vaccination is generally a safe and effective means of preventing smallpox. However, in a number of individuals, smallpox vaccination can result in untoward effects and adverse reactions. Most are totally benign, but may be alarming in appearance. Some are serious, but treatable. A few, which rarely occur, are serious, life threatening and can be fatal. Severe adverse reactions are more common in persons receiving primary vaccination compared to those being revaccinated.<</p>

Local Reactions

- Progressive vaccinia. Progressive vaccinia is one of the most severe complications of smallpox vaccination. It is almost always life threatening (primary vaccination site fails to heal dies and turns black. This necrosis then spreads to surrounding tissue, often affecting major portions of the body).

Systemic Reactions

- Generalized Vaccinia (systemic spread of the vaccinia virus from the vaccination site)
- Erythema Multiforme (a hypersensitivity/allergic reaction to vaccination resulting in lesions erupting in multiple areas of the body)
- Progressive Vaccinia (primary vaccination site fails to heal dies and turns black. This necrosis then spreads to surrounding tissue, often affecting major portions of the body).
- Eczema Vaccinatum (extensive vaccinia lesions developing either through direct inoculation of the virus onto diseased skin or possibly viremic spread if they were recently vaccinated)
- Ocular Vaccinia (eye infection resulting from transfer of the vaccinia virus to the eye)
- Fetal Vaccinia (vaccinia virus infects the unborn baby, usually resulting in stillbirth)
- Post Vaccinia Encephalitis (inflammation of the brain occurring shortly after vaccination), Ecephalopathy (infection of the brain), Encephalomyelitis (inflammation of the brain and spinal cord)
- Myocarditis (inflammation of the heart muscle)
- Pericarditis (inflammation of the sac surrounding the heart)

In the past, about 1,000 people for every 1,000,000 vaccinated people experienced reactions that were serious, but not life-threatening. Most involved the spread of virus elsewhere on the body.

In the past, between 14 and 52 people out of 1,000,000 vaccinated for the first time experienced potentially life-threatening reactions. These reactions included serious skin reactions and inflammation of the brain (encephalitis).

From past experience, one or two people per 1 million who received smallpox vaccine died as a result of vaccination side effects. Serious side effects generally are rarer after revaccination, compared to first time vaccinations. Careful screening of potential vaccine recipients is essential to ensure that those at increased risk for serious side effects do not receive the vaccine.

These side effect rates are based on data collected in the United States during the 1960s, when about 300,000 adults got their first smallpox vaccination and over 4,000,000 adults got repeat smallpox vaccinations (revaccinations).

A few heart attacks, some fatal, have been reported after smallpox vaccination. After reviewing these cases, the rate of heart attacks in smallpox vaccinated and unvaccinated people is the same and there is no evidence of a cause-and-effect link between smallpox vaccine and heart attacks. Even so, DoD medically exempts people with heart conditions.

We try to reduce the risk of side effects by exempting people who should not receive this vaccine.

For more information about side effects of the smallpox vaccine please visit <http://emergency.cdc.gov/agent/smallpox/vaccination/reactions-vacc-clinic.asp>

Long Term Safety

1) What are the long-term effects of the smallpox vaccine?

Smallpox vaccine was given to millions of Americans over many decades and used in the eradication of smallpox around the world. No long-term side effects were ever found to be due to smallpox vaccination.

Smallpox Vaccine – Risks vs. Benefit

1) What are the risks of being vaccinated versus not being vaccinated with smallpox vaccine?

The risk of smallpox vaccination is associated with potential side effects listed in the package insert, which are usually mild and temporary. The benefit of being vaccinated is the avoidance of contracting actual smallpox disease from a known or unknown exposure to the smallpox virus. The odds that smallpox would be used as a bio-weapon cannot be known with certainty.

Reproductive Health

1) Should pregnant women receive the smallpox vaccine?

No. Pregnant women should not receive the smallpox vaccine, unless they have been exposed to smallpox. Most of the time, when pregnant women get smallpox vaccine, the pregnancy goes well. In an outbreak, personal benefit from vaccination may outweigh the risks of vaccination. Women who are pregnant or planning to become pregnant within 4 weeks after vaccination should **NOT** get the smallpox vaccine. In addition, anyone who has a close contact who is pregnant should not get the vaccine. Close contacts include anyone living in your household and anyone you have close, physical contact with such as a sex partner or someone you share a bed with.

Smallpox vaccine can cause a very rare but serious complication in the fetus called fetal vaccinia. Less than 50 cases of fetal vaccinia have ever occurred. Most babies born to women who got smallpox vaccine will be fine. If a woman is vaccinated, she should avoid pregnancy for a month. She should wait until the vaccination site has completely healed and the scab has fallen off before trying to become pregnant after vaccination. Until that time, effective measures should be taken to prevent pregnancy, such as abstinence, birth control pills, injections, implants, or IUDs. Other methods of birth control, such as condoms, diaphragms, spermicide, and natural family planning are less effective than abstinence.

Women uncertain about whether or not they are pregnant should get a medical evaluation. Clinics should display warning signs about asking women if they are pregnant. Urine or blood tests can help women find out if they are pregnant before immunization.

2) Is smallpox vaccine safe for women who are breastfeeding?

Women who are breastfeeding should not get the smallpox vaccine. Breastfeeding places the baby close to the vaccination site on a woman's arm. This advice is true even if women are pumping and then bottle-feeding breast milk. It is unknown whether the vaccine virus or antibodies pass on to the baby through breast milk. A woman who desires to maintain her milk supply may continue to pump breast milk, but the milk should be discarded until the vaccination site has completely healed and not be given to the baby.P>

3) Is it safe for a woman to breastfeed her baby if a close contact received the smallpox vaccine?

Yes, if clothing is not contaminated and proper hand washing is used. Anyone who receives the smallpox vaccine should remember to wash their hands with soap and warm water after direct contact with the vaccination site, or anything that has touched the vaccination site (bandages, clothing, towels, bedding, etc.). This will help prevent the spread of vaccinia virus to contacts, including young babies.

4) If a breastfeeding mother who has close contact with a recently vaccinated person develops a rash, should she stop nursing?

First, she should check with her healthcare provider to determine if the rash is related to the smallpox vaccine. If she has a vaccine-related rash, breastfeeding should not take place until all scabs from the rash have fallen off and the skin is completely healed. A woman who desires to maintain her milk supply may continue to pump breast milk, but the milk should be discarded until her scabs fully separate and the skin is completely healed.P>

5) Should women or men defer conceiving a child after receiving the smallpox vaccine?

Women receiving a smallpox vaccination should wait until the scab has fallen off and the vaccination site has completely healed before trying to become pregnant after vaccination. Generally, this means vaccinated women should wait four weeks after their smallpox vaccination. Until that time, effective measures should be taken to prevent pregnancy, such as abstinence, birth control pills, injections, implants, or IUDs. Other methods of birth control, such as condoms, diaphragms, spermicide, and natural family planning are less effective than abstinence.

Vaccinated men may wish to wait a similar amount of time before fathering a child. Until the vaccination site has completely healed, they can be the source of spreading vaccinia to a close contact (such as a sex partner). Covering the vaccination site is very important for both men and women.

6) Is smallpox vaccination or close contact with a recently vaccinated person during pregnancy a reason to consider pregnancy termination?

There have been less than 50 cases of fetal vaccinia ever reported in the world. Because fetal vaccinia is so rare, smallpox vaccination during pregnancy should not be a reason to consider termination of pregnancy.

7) Are pregnant women who receive the smallpox vaccine more likely than other pregnant women to have a miscarriage?

Smallpox vaccine has not been associated with an increased risk of miscarriage. There is no evidence that smallpox vaccine causes spontaneous abortion (miscarriage).

8) Are there any other special risks after birth for children who are born to mothers who received smallpox vaccine during pregnancy?

Except for the rare case of fetal vaccinia, smallpox vaccination of pregnant women has not been linked with premature birth, low birth weight, or other serious birth problems.

9) Are there special considerations at the time of delivery for women exposed to smallpox vaccine during pregnancy?

Most women who receive smallpox vaccine during pregnancy will deliver normal babies, and standard delivery procedures should be followed. All pregnant women who have received the smallpox vaccine during pregnancy should let their healthcare provider and their baby's healthcare provider know about their vaccination. Their providers should contact the registry by calling 619.553.9255 or e-mailing NHRC-birthregistry@med.navy.mil.

10) Does the vaccine cause sterility?

No formal studies have ever been performed on sterility rates after smallpox vaccination. Smallpox vaccine has been given to billions of people around the globe over many decades and no effects on sterility have ever been found.

11) What is being done to learn more about the effects of smallpox vaccine on pregnant women and their babies?

DoD works with the CDC in operating the National Smallpox Vaccine in Pregnancy Registry. This registry is used to monitor the outcomes of pregnant women who received the smallpox vaccine. This will help us better understand the risks of smallpox vaccine in pregnancy. The registry has already provided important information, which is generally reassuring to women in these circumstances.

Pregnant women who received the smallpox vaccine, or pregnant women whose close contacts received the smallpox vaccine, may contact their healthcare provider or their state health department for help in enrolling in the registry. Health-care providers and staff from state health departments (see www.cdc.gov/other.htm#states) are encouraged to report all exposed pregnant women to the registry by calling 619.553.9255 or e-mailing NHRC-birthregistry@med.navy.mil. To learn more, click here: www.smallpox.mil/pregnancy

Smallpox Vaccine – Vaccination Site Care

1) How should I care for the vaccination site?

Three Key Points:

1. Don't touch your vaccination site.
2. If you touch it by accident, wash your hands right away.
3. Don't let others touch your vaccination site or materials that touched it.

Vaccinia virus is present at the vaccination site for 30 days and until the vaccination site is completely healed. This means other people can get infected if they come in contact with virus from your arm.

Most vaccination sites can be left unbandaged, when not in close contact with other persons. Airing the site will speed healing. Wear sleeves covering the site and/or use an absorbent bandage to make a touch-resistant barrier when around others. Dispose of bandages in sealed or double plastic bags. You may carefully add a little bleach, if desired.

Keep the site dry. Do not use creams or ointments; they will delay healing. Long-sleeve clothing worn during the day and at night can protect the site from dirt. Launder clothing and linens that touch the site in hot water with soap or bleach.

Normal bathing can continue. Dry off carefully, so the towel does not rub or spread virus elsewhere. Don't allow others to use that towel until laundered. Don't use public towels, unless laundry workers are aware of special handling precautions. Use a waterproof adhesive bandage if you exercise enough

to cause a sweat. Avoid swimming pools and spas until the site is completely healed.

Take good care of your vaccination site.

2) Does everybody need one of those big bandages I saw on the clinic workers?

No. Health care workers will get large bandages so they can stay on the job in a healthcare center without taking time off. Regular Band-Aids are sufficient for covering the vaccination site for most people.

3) How long should the dressing or bandage or Band-Aid stay in place, before being replaced by a new one?

The dressing or bandage should be kept in place until a change is needed. A change would be necessary when there is enough drainage from the vaccination site to soak the pad. It can be changed more often, if the person wants. Always wash your hands, before and after changing a bandage.

4) Who should change the dressing or bandage?

You can change the dressing or bandage yourself if you carefully dispose of it and wash your hands in soapy water before and afterwards. Some healthcare facilities have bandage-changing stations set up for Healthcare workers.

Smallpox Vaccine – Eligibility Criteria

1) Are there any medical conditions that would exempt me from taking the smallpox vaccine?

Some people should not get the smallpox vaccine unless under emergency situations:

- People whose immune system is not working fully (due to disease, medication, or radiation), such as HIV/AIDS, cancer, transplant, immune deficiency
- People diagnosed with eczema or atopic dermatitis, now or earlier in life
- People with current skin conditions, such as burns, impetigo, contact dermatitis, chickenpox, shingles, psoriasis, or uncontrolled acne, until the condition clears up
- Pregnant women
- People with a household contact who meets any of the conditions above
- People with serious heart or vessel conditions (such as angina, heart attack, artery disease, congestive heart failure, stroke, other cardiac problem)
- People with 3 cardiac risk factors (smoking, high blood pressure, high cholesterol, diabetes, family history of heart disease before age 50)
- People taking steroid eye drops or ointment
- Breastfeeding mothers
- Anyone who had problems after previous doses or is allergic to the vaccine or any component

In a smallpox outbreak, even people with exemptions to vaccination should be vaccinated if exposed to smallpox, unless extremely immunosuppressed.

2) Should people with lupus get vaccinated?

People who have been diagnosed with lupus should talk with their physician about whether or not they should be vaccinated, considering the state of their disease, the medications they take, and their personal risk for specific infections. Several medical studies have shown that people with lupus can be safely and effectively vaccinated against influenza, hepatitis B, pneumococcal disease, and other diseases that would pose a significant risk if they were infected. For military personnel with lupus, providers are authorized to grant medical exemptions according to the patient's specific situation. Medical specialists can advise how to get the best benefit from vaccination in such circumstances.

3) Can I get smallpox vaccine if I don't have a spleen?

You should discuss your concerns and your individual situation with your medical provider to be sure.

Certain medical conditions, such as the absence of a working spleen (asplenia) may increase a person's risk for certain infections. Some vaccines, particularly pneumococcal, meningococcal, and Haemophilus vaccines, are specifically recommended for people without a spleen. People with asplenia are generally not considered immunosuppressed for the purposes of vaccination and should receive routine vaccinations with both live and inactivated vaccines according to the usual schedules.

4) What other medical conditions should I inform the medical staff about?

You should inform your Health Care Provider if you have heart disease, with or without symptoms, or if you have three or more known major cardiac risk factors (i.e., hypertension, diabetes, hypercholesterolemia, heart disease at age 50 years in a first-degree relative, and smoking).

Other contraindications include:

- Current or a history of skin conditions,
- Positive for HIV or otherwise immunocompromised or immunosuppressed
- Pregnant or planning to become pregnant
- Allergies to vaccine components,
- Recent or scheduled eye surgery
- Breastfeeding
- Contact with children 12 months of age or younger
- Close contact with any of the above

Also if you have had a serious reaction to polymyxin B, neomycin, latex or a previous dose of smallpox vaccine it may be a contraindication for you to receive smallpox vaccine at this time. If you have concerns, please consult with your health care provider before vaccination.

Careful prevaccination screening will help determine any risk issues you may have.

The standardized DoD smallpox screening form can be viewed at the MILVAX website at

www.smallpox.mil/screeningform

5) Will family members be allowed to get the smallpox vaccine?

Family members and non-essential civilian personnel in designated high-threat areas overseas (e.g., Korea) are authorized to receive smallpox vaccine on a voluntary basis. Our procedures will be consistent with FDA guidelines for use of the vaccine and our need to protect mission critical capabilities of the Department of Defense. It remains the Department's policy to evacuate non-emergency essential civilians and family members from threat areas in crisis situations.

6) Is it okay to go to my dentist after I receive the smallpox vaccine?

Yes, if you are careful. Inform your dentist that you have been recently vaccinated. Be sure to cover your vaccination site with a bandage and/or long-sleeve clothing to provide a barrier to protect your dentist.

7) How long does the vaccination site remain contagious?

The vaccinia is present at the vaccination site for up to 30 days after vaccination and until the site is completely healed. Other people can get infected through contact with the vaccinia from your vaccination site

8) If vaccinia gets on a dressing or bandage, how long will it stay alive and capable of being spread to someone else who touches it?

Vaccinia virus can survive in the environment for about 24 hours. It might survive longer if it stays moist and in the dark. If the bandage dries out, the virus is still present, but less able to spread.

No matter the time, it is always best to carefully dispose of used dressings or bandages in sealed or double plastic bags. Always wash your hands after handling dressings or bandages.

9) What should I do if I'm going to be around at-risk people (e.g. small children, eczema sufferers)?

In a household, people have much more intimate or close contact than in work sites or other social settings (e.g., church, malls). As usual, the key here is to not move the virus from your vaccination site to another person. So be careful when around others and follow the standard precautions (band-aids, long-sleeves, hand-washing).

Regarding household members with contraindications:

You shouldn't be vaccinated if you have household members with contraindications to the smallpox vaccine, unless you can be separated from them until your scab falls off (about 14 to 28 days).

Regarding children under 1 year of age:

"Minimizing close physical contact with infants less than one year of age is prudent until the scab falls off. If unable to avoid infant contact, wash hands before handling an infant (e.g., feeding, changing diapers) and ensure that the vaccination site is covered with a porous bandage [e.g., Band-Aid, or gauze] and clothing. It is preferable to have someone else handle the infant." This quote comes from the October 2002 recommendations of the Advisory Committee on Immunization Practices.

10) Can I give blood after a smallpox vaccination?

People who receive the smallpox vaccine and have no complications will be deferred from donating blood for 4 weeks. Individuals with vaccine complications will be deferred until 14 days after all vaccine complications have completely resolved. Consult your blood-donor center for details.

11) Does the vaccine get into my blood stream?

Usually not. Experts believe it is very uncommon for vaccinia virus to move from your vaccination site into your blood stream.

12) Could people be exposed to the vaccine virus (vaccinia) if I cut myself?

Spreading the vaccinia virus by cutting yourself is highly unlikely. But you would want to clean up any blood spills to protect people against other blood borne pathogens.

13) Can I travel after receiving the smallpox vaccine?

Traveling is permitted after smallpox vaccination. Remember to use Band-Aids or long-sleeved clothing to prevent your vaccination site from touching other people. Wash your hands at appropriate intervals.

Smallpox Vaccine – Cardiac Related Reactions

Heart-Related Problems After Smallpox Vaccination

1) 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 (myopericarditis) after smallpox vaccination in early February 2003. As of January 2008, DoD has identified 161 cases of acute myocarditis and/or pericarditis among 1.4M 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 vaccinations 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.

2) What is the difference between myopericarditis, 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 both categories together, it is called myopericarditis.

3) Is there a relationship between the 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, there is no evidence of a link between myocarditis and heart attacks. But DoD continues to investigate any possibilities of a relationship between vaccination and an adverse event.

4) 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 the heart tissue.

5) Was the finding of myopericarditis a surprise to DoD officials? Is this a new or previously unknown reaction?

Because rare cases of myopericarditis 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 in 10,000 vaccinees developed myopericarditis.

6) 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 (electrocardiogram) and/or echocardiogram readings.

Heart Conditions That Exempt Someone From Smallpox Vaccination

1) Will DoD defer smallpox vaccination in people who have heart conditions?

Yes. We will defer people with serious heart or blood vessel-related conditions. 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,
- (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.

2) I recently received the smallpox vaccination, and I have a history of heart conditions. What should I do?

Unless you are experiencing symptoms, such as chest pain, difficulty breathing, shortness of breath, or pain radiating down your arm or to your neck, you shouldn't do anything special. If you start having these symptoms, you should seek medical care right away.

3) 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 the event of a smallpox outbreak, vaccination would be recommended.

4) 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.

Questions and Answers for Household Members and Community Members

Laundering Information

1) I go home every night to my family. What do I need to do with my personal laundry?

Wear clothing that is washable and launder your clothing separately with hot soapy water (with bleach, if desired). Keep your personal linens separate (e.g., towels) as well, from the rest of the family's.

2) How much personal protective equipment do laundry workers need?

If laundry workers wear gloves, this is sufficient protection.

3) My spouse and I sleep in the same bed. How do I care for the bed linens (e.g., sheets, pillow cases)?

Be sure to cover your vaccination site while you are in bed with your spouse. Sleeves (preferably long sleeves) and a Band-Aid will suffice. Wash your linen, along with personal towels and washcloths, separately in hot soapy water (with bleach, if possible).

4) You've told us to wash our clothes and linens in hot water and bleach. The bleach will ruin my clothes and linens. Will using just detergent or color-safe bleach be effective?

Color-safe bleach is not as powerful a disinfectant as regular bleach. Washing your clothes and linens with detergent in the hottest water possible is a good alternative to using bleach

5) Hot water will ruin some of my clothes. Can I just use detergent and cold water?

Cold water alone will not kill the virus if it is on the clothes. But the detergent will. You should try to wear clothing that is washable in hot water, if possible.

6) Can I wear dry cleanable clothes?

It is not known if the dry cleaning process will kill the vaccinia virus. Until such data is available, dry cleaning should not be assumed to properly disinfect material contaminated with vaccinia virus. Any cloth material contaminated with vaccinia virus should be laundered in hot water with detergent. Follow with a hot-air drying cycle. If you must wear "dry clean only" clothes, we recommend that you wear a washable shirt and/or a bandage under your "dry clean only" clothing to avoid contact between the clothing and the vaccination site.

7) Are there any environmental effects from the wash water after washing clothes and linen that come into contact with the vaccination site?

There are no additional environmental effects from the used water after washing your clothes. The vaccinia virus will be killed and harmless. Used water discharged by your washing machine from your house will be treated at a wastewater treatment plant.

Possible Family Member Reactions to the Smallpox Vaccine

1) What if a family member accidentally develops a small blister or set of blisters or other reaction that might be the result of having contact with vaccine virus from the vaccinated person? What should they do?

They should go to their usual source of care (e.g., military clinic) and explain the situation. Mention that the Service member was recently vaccinated against smallpox. For Service members in the Reserve Component, contact the Military Medical Support Office (MMSO) 888-647-6676 if the member is not enrolled in an MTF.

2) What can I do to prevent spreading vaccinia virus to my household pets?

There are no restrictions for recently vaccinated people in regards to contact or handling of animals, other than keeping animals away from the vaccination site and bandages that covered it.

There is no evidence that vaccinia virus infects cats, dogs, or other household pets. The same steps you take to prevent spreading the virus elsewhere on your body or to somebody else (e.g., sleeves, bandages, hand washing) will keep the virus from reaching your pet.

After Receiving the Smallpox Vaccination – Bathing

1) After I take a bath or shower, do I need to sanitize the bathtub before other people in my household use it?

It's not necessary to sanitize the bathtub or the sink after use. You may want to clean any surface that you place a dirty bandage upon with a disinfectant. Pay attention to any surface or object that rubs against your vaccination site.

2) What's the risk of children spreading the vaccinia virus to one another at day care centers if their parents have been vaccinated?

We are investing a great deal of effort into training personnel to prevent them from spreading vaccine virus anywhere. If you have received a smallpox vaccination, the risk of passing vaccine virus (vaccinia) to your child is extremely low if you follow the standard precautions (band-aids, long-sleeves, hand washing). Spreading vaccinia from a child of a vaccinee to another child would be even rarer.

Healthcare Workers

Vaccination for Healthcare Workers

1) Should vaccinators be vaccinated themselves?

Yes, Department of Defense personnel who are vaccinating others should be vaccinated themselves. This is outlined in the “Clinical Policy for the DoD Smallpox Vaccination Program (SVP).”

<http://www.vaccines.mil/documents/219SPclinicalpolicy.pdf>

2) Why aren't ALL healthcare workers getting vaccinated?

The Department of Defense Smallpox Vaccination Program is designed so that a team at each hospital and clinic is prepared to provide care to the 1st set of smallpox (variola) patients in case of an outbreak. If an outbreak occurred, additional health care workers would then be vaccinated.

Additional Concerns for Healthcare Workers

1) In addition to the normal side effects already covered in earlier questions, is there more I need to know as a health-care provider?

Yes. You should know a few of the more serious complications related to vaccination that can occur. Inadvertent inoculation is the most frequent complication of vaccinia vaccination. It accounts for about half of all complications of primary (first) vaccination and revaccination. Inadvertent inoculation usually results from auto-inoculation of vaccinia virus, transferred from the site of vaccination. The most common sites involved are places that itch: the face, eyelids, nose, mouth, genitalia, and rectum.

Most auto-inoculation lesions heal without specific therapy, but vaccinia immunoglobulin (VIG) can help treat severe cases. If vaccinia keratitis develops, VIG is not recommended because of the risk of corneal scarring.

Erythematous or urticarial rashes can occur about 10 days after primary (first) vaccination and can be confused with generalized vaccinia. In these circumstances, the vaccinee is usually afebrile and the rash resolves spontaneously within 2 to 4 days. Rarely, an allergic reaction to the vaccination called erythema multiforme (i.e., Stevens-Johnson syndrome), may occur.

2) What about moderate to severe adverse reactions?

Moderate and severe complications of vaccinia vaccination include eczema vaccinatum, generalized vaccinia, progressive vaccinia, and postvaccinial encephalitis. These complications are rare, but occur more often among primary vaccinees than among revaccinees. These serious skin complications also are more frequent among infants than among older children and adults. A study of 10,000 Israeli military recruits aged 18 years or older, who were vaccinated during 1991 and 1996, reported no cases of progressive vaccinia or postvaccinial encephalitis. These results were similar to those reported in previous studies.

3) What is eczema vaccinatum?

Eczema vaccinatum is a localized or systemic dissemination of vaccinia virus among people who have atopic dermatitis or a history of atopic dermatitis or other exfoliative skin conditions (e.g., atopic dermatitis). Usually, this illness is mild and self-limited, but can be severe or fatal. The most serious cases among vaccine recipients occur among primary vaccinees, even among people who do not have active skin disease. Severe cases have been observed after recently vaccinated people had contact

with people with atopic dermatitis or a history of atopic dermatitis.

4) What is generalized vaccinia?

Generalized vaccinia involves a vesicular rash of varying extent that can occur among people without underlying illnesses. The rash is generally self-limited and requires minor or no therapy, except among patients whose conditions might be “toxic” (as it refers to children) or who have serious underlying immunosuppressive illnesses (e.g., acquired immunodeficiency syndrome [AIDS]).

5) What is progressive vaccinia?

Progressive vaccinia (also called vaccinia necrosum or vaccinium gangrenosa) is a severe, potentially fatal illness. It appears as progressive necrosis reaching out from the vaccination site, often with metastatic lesions. It occurred almost exclusively among people with cellular immunodeficiency.

6) What is postvaccinial encephalitis?

The most serious complication is postvaccinial encephalitis. Two main forms were noted. The first affected children younger than 1 year old receiving their first (primary) smallpox vaccination, involving convulsions. These children may have residual paralysis after recovery.

The second form affected children 2 years or older, adolescents, and adults receiving their first (primary) smallpox vaccination. These patients developed abrupt onset of fever, vomiting, headache, and malaise, followed by loss of consciousness, amnesia, confusion, convulsions, and coma. About 1 in 3 of these patients died.

Smallpox Vaccination Given Simultaneously With Other Drugs and Vaccines

1) How does smallpox vaccine interact with other drugs?

Smallpox vaccine is not known to interact with any medications; however, circulating antibodies from recent blood product administration or the use of immuno-suppressive medications could interfere with smallpox antibody production.

2) What about giving smallpox vaccinations at the same time as other vaccinations?

The smallpox vaccine may be administered concurrently with other inactivated vaccines or at any interval before or after inactivated vaccines, consistent with ACIP recommendations. To avoid confusion in determining which vaccine may have caused post-vaccination skin lesions or other adverse events, and to facilitate managing such events, varicella vaccine and smallpox vaccine should be administered at least 4 weeks. Smallpox vaccine should be administered simultaneously with other live virus vaccines or separated by 4 weeks. Do not administer other vaccines near an active smallpox vaccination site.

Questions That Must Be Asked Before Administering Smallpox Vaccine

1) What should we ask about before people get smallpox vaccine?

Before smallpox vaccination, ask people if they have any problems with their immune system (e.g., due to cancer treatment, transplantation, AIDS, other conditions), if they are infected with HIV, if they have atopic dermatitis or other chronic skin conditions, if they are pregnant or breastfeeding or if they had atopic dermatitis as a child, or if they have a heart condition. Also, ask about the health of people in the household.

People Who Should Not Be Vaccinated During a Smallpox Outbreak

1) Who is exempt (contraindicated) from smallpox vaccination in an outbreak?

No absolute exemptions (contraindications) exist for vaccination of a person with an actual high-risk exposure to smallpox. People at greatest risk for experiencing serious vaccination complications are also at greatest risk for death if exposed to smallpox.

If a relative contraindication to vaccination exists, the risk for experiencing serious vaccination complications must be weighed against the risk for experiencing a potentially fatal smallpox infection. When the level of exposure risk cannot be determined, the decision to vaccinate should be made after discussion between the clinician and the patient of the potential risks versus the benefits of smallpox vaccination.

Civilian Healthcare Responsibilities

1) I just got vaccinated against smallpox and I “moon-light” at a civilian hospital downtown. Should I tell the civilian hospital?

Yes. You should inform the other hospital of your recent vaccination and tell them about your bandaging procedures and infection-control practices. You should then abide by any further instructions from the civilian hospital.

How To Administer Smallpox Vaccine

Protective Measures To Follow While Administering Smallpox Vaccine

1) Introduction:

Vaccination has been successfully and safely administered to people of all ages, from birth onward. As with all vaccinations, the smallpox vaccination process should begin with careful individualized assessment of vaccine indications and contraindications.

The site of vaccination is the upper arm over the insertion of the deltoid muscle. No skin preparation should be performed unless the skin at the intended site of vaccination is obviously dirty, in which case an alcohol swab(s) may be used to clean the area. If alcohol is used, the skin must be allowed to dry thoroughly to prevent inactivation of the live vaccine virus by the alcohol.

The multiple-puncture technique uses a sterilized bifurcated needle inserted vertically into the vaccine vial, causing a droplet of vaccine to adhere between the needle prongs. The droplet contains the recommended dosage of vaccine. Confirm the presence of the droplet between the prongs visually. Holding the bifurcated needle perpendicular to the skin, make 15 punctures rapidly with strokes vigorous enough to allow a trace of blood to appear after 15 to 20 seconds. Wipe off any remaining vaccine with dry sterile gauze, then dispose of the gauze in a biohazard waste container.

Cover the site with a bandage to deter touching the site and perhaps transferring virus to other parts of the body.

2) Should vaccinators wear goggles?

Smallpox vaccine is a very thick fluid not prone to splashing. Goggles are not necessary during vaccine reconstitution or administration; however, workers may take this extra precaution if they wish.

Treating Complications of the Smallpox Vaccination

Treatment for Patients Who Develop a Reaction to the Smallpox Vaccine

1) What treatment can be given to patients who had a reaction to smallpox vaccine?

Recognition and prompt treatment of a serious adverse event after smallpox vaccination is essential. Consult as appropriate with allergy-immunology, infectious-disease, dermatology, neurology, or other appropriate specialist(s) to assist with diagnosis and treatment methods when necessary.

Some conditions respond to intravenous vaccinia immunoglobulin (IV-VIG), including eczema vaccinatum, progressive vaccinia, severe ocular vaccinia, severe generalized vaccinia. IV-VIG is not effective in treating post-vaccinial encephalitis.

IV-VIG consists of human IgG antibody from people vaccinated with smallpox vaccine. Current supplies of IV-VIG are limited.

Once a definite or probable diagnosis of a medication-indicating adverse event has been made by a qualified provider (e.g., infectious-disease, dermatology, allergy-immunology physician), that military provider may request use of IV-VIG for a named patient by telephoning the Military Vaccine Agency at 877-GET-VACC, DSN 761-4245, email patrick.garman@us.army.mil. Procedures for ordering IV-VIG appear at www.smallpox.mil/documents/1101MIP-VIG-ordering-infoNo07.pdf. Healthcare providers from civilian institutions should contact the CDC directly by calling the CDC Director's Emergency Operation Center (DEOC) at (770) 488-7100 and request to speak with the Division of Bioterrorism Preparedness and Response (DBPR) on-call person. The CDC is the release authority for IV-VIG.

Additional Treatment Options

1) Are there other treatment options for those that have smallpox vaccine complications?

The Food and Drug Administration has not approved the use of any antiviral compound for the treatment of the smallpox vaccine virus infections or other Orthopoxvirus infections, including smallpox (variola infection). Certain antiviral compounds are effective against smallpox vaccine virus (vaccinia) or other Orthopoxviruses in vitro and among test animals. However, the safety and effectiveness of these compounds for treating the vaccinia vaccination complications or other Orthopoxvirus infections among humans is unknown. Questions also remain regarding the dosing, timing and length of administration of these antiviral compounds.

Additional information could become available. Health-care providers should consult infectious disease experts for updated information regarding treatment options for the smallpox vaccination complications.

Evidence of Immunity and Vaccination – Response Interpretation

Evidence of Immunity Against Smallpox

1) After vaccination, what evidence suggests an individual developed immunity against smallpox?

Smallpox vaccination with live vaccinia virus causes the body to produce neutralizing IgG antibodies, as well as vaccinia-specific cell-mediated immunity. In a person with normal immune function, neutralizing antibodies appear about 10 days after primary vaccination and 7 days after revaccination. Clinically, people are considered fully protected after a successful response is demonstrated at the site of

vaccination, about 7 days after vaccination.

The vaccination site should be inspected 6 to 8 days after vaccination and the response interpreted at that time. The World Health Organization (WHO) Expert Committee on Smallpox defines two types of responses. The responses include:

(a) a major reaction, which indicates that virus replication has taken place and vaccination was successful; or

(b) an equivocal reaction, which either indicates (1) a possible consequence of immunity adequate to suppress viral multiplication or (2) allergic reactions to an inactive vaccine without production of immunity.

Smallpox Vaccine – Major Reaction

1) What is a “major reaction”?

A “major reaction” is the internationally accepted term for a successful smallpox vaccination.

Major (i.e., primary) reaction is defined as a vesicular (blister) or pustular lesion or an area of definite palpable induration (hardness) or congestion surrounding a central lesion that might be a crust or an ulcer. The usual progression of the vaccination site after primary vaccination is as follows:

a. The inoculation site becomes reddened and itchy 3 to 4 days after vaccination.

b. A vesicle (blister) surrounded by a red areola then forms, which becomes umbilicated (sunken center) and then pustular (pus-filled) by days 7 to 11 after vaccination.

c. The pustule begins to dry, the redness subsides, and the lesion becomes crusted between the second and third week.

d. By the end of about the third or fourth week, the scab falls off, leaving a permanent scar that at first is pink in color, but eventually becomes flesh-colored.

Skin reactions after revaccination might be less pronounced with more rapid progression and healing than those after primary vaccinations. Revaccination is considered successful if a pustular lesion is present or an area of definite induration or congestion surrounding a central lesion (i.e., scab or ulcer) is visible upon examination 6 to 8 days after revaccination.

Smallpox Vaccine – Equivocal Reaction

1) What is an “equivocal reaction”?

Equivocal reactions consolidate a variety of previous terms, including accelerated, modified, vaccinoid, immediate, early, or immune reactions. Equivocal reactions are defined as all responses other than “major reactions”.

If an equivocal reaction is observed, check vaccination procedures and repeat the vaccination by using vaccine from another vial, if available. It is often difficult to determine if the reaction was blunted by immunity, insufficiently potent vaccine, or vaccination technique failure. If the repeat vaccination using different vaccine fails to elicit a major reaction, health-care providers should consult an allergist or immunologist before attempting another vaccination.

Vaccination Site Care

Precautions to Avoid Spreading Smallpox Vaccine Virus

1) Are there precautions I can take as a healthcare provider to help my patients avoid spreading smallpox vaccine virus to others?

You should follow the same instructions on “**How should I care for the vaccination site?**” and read the following:

Even patients vaccinated in the past may be at increased risk due to current immunodeficiency. If contact with unvaccinated patients is essential and unavoidable, healthcare workers can continue to have contact with patients, including those with immune deficiencies, as long as the vaccination site is well-covered and thorough hand-hygiene is maintained. In this setting, a more occlusive dressing might be appropriate. Semi-permeable polyurethane dressings (e.g., Opsite®, Tegaderm®) are effective barriers to vaccinia and recombinant vaccinia viruses.

However, exudate may accumulate beneath the dressing, and care must be taken to prevent viral contamination when the dressing is removed. In addition, accumulation of fluid beneath the dressing may increase the maceration of the vaccination site. To prevent accumulation of exudates, cover the vaccination site with dry gauze, and then apply the dressing over the gauze. The dressing should also be changed daily or every few days (according to type of bandaging and amount of exudate), such as at the start or end of a duty shift.

Military treatment facilities will develop plans for site-care stations, to monitor workers' vaccination sites, promote effective bandaging, and encourage scrupulous hand hygiene. Wearing long-sleeve clothing can further reduce the risk for contact transfer. The most critical measure in preventing inadvertent contact spread is thorough hand-hygiene after changing the bandage or after any other contact with the vaccination site.

Linen Precautions For Hospital Workers and Institutional Settings After Smallpox Vaccination

Precautions for Your Uniform While at Work – Laundry

1) I wear scrubs. What do I do about my laundry at work?

Wear a warm-up jacket over your short-sleeve scrubs. Have your dressing evaluated every day and changed if exudates appear.

If applicable: When you go to the scrub-replacement machine with dirty scrubs, please have your scrubs rolled or folded so that the arm area is on the inside. Wash your hands and wear clean gloves to feed the scrub machine. Wash your hands after putting the dirty scrubs into the machine. Carry Cal-Stat or other alcohol-based rinse with you.

2) I bought my own scrubs. What do I do with my own laundry?

Launder them in hot water (160^o F), with soap. Use bleach, if desired.

3) I wear a lab coat that the hospital provided. What do I do when I need to get a fresh lab coat?

Please place your used lab coat into a plastic bag and take it down to linen turn in. You will be issued a

new lab coat when you turn in your dirty-bagged lab coat. Use a standard plastic bag (not a red bag).

4) I wear a long-sleeved shirt/blouse for work. How do I care for this?

The long sleeves help remind you not to scratch your vaccination site. Make it a point to wear a shirt/blouse or some type of apparel that can be washed in hot water.

Working Out at the Gym (Towels) – Laundry

1) I work out in the gym several days a week. What do I do with my dirty towel?

If this is a hospital towel, you should deposit it into a hospital laundry bag. If it's an institutional towel and the laundry workers know that some of the towels come from recently vaccinated people, you may deposit it in the institutional laundry bag. If this is your personal towel from home, place this towel into a plastic bag and bring it home for routine laundering (separate from other family members clothing and linens) in hot soapy water.

How to Care For Your Uniform at Home – Laundry

1) I am on call for the next several nights. I sleep in one of the sleep rooms and then I shower in the morning. What do I do with my laundry?

Pick up all of your personal laundry and place it into a plastic bag to take home for laundering in hot soapy water. Hospital-issued linens and towels should be placed into a hospital laundry hamper. If it's an institutional towel and the laundry workers know that some of the towels come from recently vaccinated people, you may deposit it in the institutional laundry bag.

2) I go home every night to my family. What do I need to do with my personal laundry?

If possible, wear clothing that is washable with hot water. You may segregate your personal shirts, linens, and towels from the rest of your family.

Personal Protective Equipment for Laundry Workers

1) How much personal protective equipment do laundry workers need?

If laundry workers wear gloves, this is sufficient protection.

Remember: Hand washing, Hand washing, Hand washing.