



**Smallpox Vaccine Program (SVP)  
Questions and Answers**

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## Smallpox Policy

### Policy and Management Questions

#### 1) Why are we vaccinating servicemembers?

Authorities are concerned that 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.

#### 2) 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.

Most Servicemembers have 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.

There is no proven treatment for the smallpox disease, but research to evaluate new antiviral medications is ongoing. Patients 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.

#### 3) What if somebody has already been vaccinated?

Immunity from smallpox vaccination decreases with the passage of time. 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 immunity.

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]

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

The Secretary of Defense has decided at this time 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 missions. The Department may expand the program at a later date.

The Secretary's decision will be implemented using a portion of the existing supplies of Wyeth Laboratories' Dryvax smallpox vaccine. DoD will use the FDA-licensed smallpox vaccine now available.

#### 5) Will servicemembers 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.

#### 6) How much vaccine does the DoD have?

The DoD has sufficient FDA-licensed vaccine to implement this program.

#### 7) 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 bioweapon, but we do know that the consequences of its use could be great. Military missions must go on even if a smallpox outbreak occurs. 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.

#### 8) What will happen to a servicemember who refuses the vaccine?

We begin with the assumption that any servicemember covered by this new mandatory 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 health protection issue. If a servicemember 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.

## **Military Discipline**

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## **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. While we cannot quantify the threat of either one being used as a bioweapon, we 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?**

Generally speaking, forces currently designated to receive anthrax vaccine also will receive smallpox vaccine. Additional forces will be vaccinated against smallpox given that smallpox, unlike anthrax, is contagious and can be prevented only with vaccine. The Secretary of Defense may decide in the future to expand the scope of both the anthrax and smallpox vaccination programs.

#### **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 for adverse impact on the health of the public. Other bio-agents in this category are anthrax, plague, botulism, tularemia, and viral hemorrhagic fevers.

#### **5) Does Iraq have smallpox?**

It is possible, but not confirmed, that Iraq possesses the virus that causes smallpox.

#### **6) What other countries have smallpox?**

It is possible, but not confirmed, that a number of other countries may possess the virus that causes smallpox, but we are not going to delineate them at this time. After eradication the only places authorized to possess the 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 unlikely that Al Qaida at this time possesses the virus that causes smallpox.

#### **8) Do you believe that Iraq may use a smallpox weapon if attacked by the United States?**

If Iraq possesses a smallpox weapon, it may use it under any number of circumstances. By preparing ourselves to respond to any smallpox attack, including through pre-exposure and post-exposure vaccination plans, we also help to deter such attacks.

### **Smallpox Vaccine – Effectiveness Against Mutated Strains**

#### **1) Will the smallpox vaccination protect me from any man-made variations or mutations of smallpox?**

The current smallpox vaccine will prevent all known types of smallpox.

## **Smallpox – The Disease**

### **Smallpox Disease – What It Is**

#### **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. A rash follows that spread and progresses to raised bumps that crust, scab, 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 from the planet. 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. Initial symptoms include high fever, fatigue, headache, and severe body aches.

### **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 getting smallpox a second time.

### **3) Is smallpox contagious? How does smallpox spread?**

The disease spreads slowly, usually by face-to-face contact with a contagious person. Contact with infected skin could also transmit the virus. Spread by contact with inanimate objects (e.g., clothing, towels, linens) would be uncommon.

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 infected. 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 is less efficient at spreading the virus, but it still occurred via fine-particle aerosols or inanimate objects carrying the virus.

Contaminated clothing or bed linen could spread the virus. 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 protocol and should be evaluated and monitored by medical experts, for example at the NIH and CDC. 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.

The next section of questions and answers go into great detail about the expected and potential side effects regarding the vaccine and site care recommendations.

## **Smallpox in the Environment**

## Testing the Environment

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

Various agencies are currently developing tests designed to test for the smallpox virus in the environment. Like all tests of their kind, these tests can generate both false-positive results (test says positive, but it's really negative) and false-negative tests (test says negative, but it's really positive). These tests must be interpreted carefully by experienced laboratory professionals.

## 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.

## 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 case isolation and contact tracing and vaccination.

Patients showing signs of smallpox 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 the spread of smallpox.

## 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 Servicemembers during World War I, World War II, and until the 1980s.

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. It was successfully used to eradicate smallpox from the human population.

The vaccine virus (vaccinia) is similar to the smallpox (variola) virus. 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 205 years.

Getting smallpox vaccine before exposure will protect about 95 percent of people from getting smallpox. Vaccination within 3 days of 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.

#### **2) Is this the same smallpox vaccine that was used in the past?**

Yes, the current vaccine being used is the same vaccine used in the past. It will be administered in the standard full-strength concentration (as per original labeled reconstitution instructions), unless the CDC, FDA, or other responsible health authority issues explicit instructions to the contrary.

#### **3) Is this smallpox vaccine diluted?**

This smallpox vaccine is stored as a powder and then a liquid is added to dissolve it shortly before use. But the concentrate we will use is the original full-strength concentration.

#### **4) Is smallpox vaccine live or synthetic?**

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

#### **5) How is smallpox vaccine given?**

The smallpox vaccine is not given with a typical hypodermic 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 a number of 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.

**6) Who will administer smallpox vaccine?**

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

## **Smallpox Vaccine – Ingredients**

**1) What are the ingredients of smallpox vaccine?**

The smallpox vaccine contains purified, concentrated freeze-dried calf lymph. Antibiotics called polymyxin B sulfate, dihydrostreptomycin sulfate, chlortetracycline hydrochloride, and neomycin sulfate are added during processing and trace amounts may be in the final product. The diluent for smallpox vaccine contains 50% glycerin, with 0.25% phenol in Sterile Water for injection, USP. Once reconstituted, the vaccine contains approximately 100 million infectious vaccinia viruses per mL, with 100 doses per vial.

## **Smallpox – Vaccine Effectiveness**

### **Smallpox Vaccine – 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 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.smallpox.army.mil/media/pdf/SPadminIssuespolicy.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 we still think there is a threat, then, yes, you might be given another vaccination depending on your job and location.

## **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 Servicemembers 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 servicemembers were immunized but not others. In 1990, the Department of Defense discontinued routine vaccination of recruits.

**2) What are the odds of being inoculated against the right strain of smallpox?**

Very high. The current smallpox vaccine will prevent all known types of 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 normal, usually 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 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, but this would be very rare, and can be prevented with covering the site and 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. More information on this appears below.

## **Long Term Safety**

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

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

## **Reproductive Health**

### **1) What if I am pregnant or breast-feeding?**

As with most vaccination guidance, woman should be deferred routine smallpox vaccinations until after pregnancy. 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. Refer women uncertain about pregnancy status for medical evaluation and ensure that you display a warning against unintentionally vaccinating pregnant women. Screen women of childbearing potential before immunization to avoid unintended vaccination during pregnancy. There have been rare cases of infection of the fetus (unborn baby) with the vaccine material. Most of these cases occurred in women who received the vaccine for the first time. When fetal vaccinia does occur, it usually results in stillbirth. Fewer than 50 such cases around the world were reported over the last 100 years. As far as we know, the US-licensed smallpox vaccine does not cause a fetus to be malformed. Minimize close contact with infants younger than 1 year of age. People with infants in their household should be vaccinated only if alternate care-giving arrangements are observed until scab falls off. Be sure to wash hands before handling infant (e.g., feeding, changing diapers). Smallpox vaccine is not recommended for nursing mothers, unless an outbreak occurs and personal benefit from vaccination outweighs the risk. Breast-feeding is not a medical contraindication to any immunization but could put the infant in close contact with the mother's vaccination site.

### **2) Should women or men defer conceiving a child after receiving the smallpox vaccine?**

Women receiving a smallpox vaccination should wait until the vaccination site has healed and the scab fallen off before trying to become pregnant after vaccination. Generally, this means vaccinated women should wait four weeks (28 days) after their smallpox vaccination. Vaccinated men may wish to wait a similar amount of time before fathering a child. Until the scab falls off, vaccination sites can be the source of spreading vaccinia to a close contact (such as a sex partner). Covering the vaccination site is very important.

### **3) 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.

### **4) 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 will be used to monitor the outcome of pregnant women who have received the smallpox vaccine. This will help us better understand the risks of smallpox vaccine in pregnancy. To learn more, click here: <http://www.smallpox.army.mil/event/pregnancy.asp>

## **Rare but Serious Side Effects After Vaccination**

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

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 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 in 1 million who receive smallpox vaccine may die as a result. Serious side effects generally are rarer after

revaccination, compared to first vaccinations. Careful screening of potential vaccine recipients is essential to ensure that those at increased risk 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). After the first 350,000 military smallpox vaccinations thru March 2003, few serious reactions occurred. Fourteen first-time vaccinees had chest pain due to myocarditis and/or pericarditis (inflammation in or around the heart). These cases ranged from mild to serious. A few heart attacks, some fatal, have been reported. At this time, they are not believed to be caused by vaccine. DoD medically exempts people with heart conditions. Further investigation is underway. We try to reduce the risk of side effects by exempting people who should not receive this vaccine.

## **Smallpox Vaccine – Risks vs. Benefit**

### **1) What are the risks of taking vs not taking the smallpox vaccine?**

The risk of taking the vaccine is equivalent to the side effects. Which are almost always mild and temporary. The risk of not taking the vaccine is the risk of contracting the infection if a smallpox weapon is released. The odds that smallpox would be used as a weapon cannot be known with certainty.

## **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. Vaccine virus is present at the vaccination site for about 14 to 21 days, until the scab falls off. This means other people can get infected if they come in contact with virus from your arm. You can infect others if you touch your blister and then touch another person. Most vaccination sites can be left unbandaged, especially when not in close contact with other persons. Wear sleeves covering the site and/or use an absorbent bandage to make a touch-resistant barrier. Dispose of bandages in sealed or double plastic bags. You may carefully add a little bleach, if desired. Keep the site dry. Airing will speed healing. Do not use creams or ointments, or 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 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 alerted that you were vaccinated. Use a waterproof adhesive bandage if you exercise enough to cause sweat to drip. Swimming can make the site soft and delay healing, so avoid swimming. 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 those large bandages so they can stay on the job in a health care center without taking time off. 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 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 afterwards. Health care workers can go to a health care facility. They will set-up changing stations.

## **Smallpox Vaccine – Eligibility Criteria**

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

Some people should not get smallpox vaccine, except under emergency situations. In a smallpox outbreak, even people with exemptions to vaccination should get it, if exposed to smallpox.

- 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 or cholesterol, diabetes, family history)
- 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.
- Women should avoid getting pregnant for 4 weeks after smallpox vaccination. People directly exposed to smallpox virus should get vaccinated regardless of health status (unless extremely immune suppressed).

### **2) Should people with lupus (SLE) 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 with 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 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?**

If you have had a serious reaction to polymyxin B, streptomycin, chlortetracycline, neomycin, latex, or a previous dose of smallpox vaccine, it may not be appropriate to get vaccinated. Talk with your physician.

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

We are continuing to develop procedures to offer vaccine, on a voluntary basis, to certain DoD family members and non-essential civilian personnel. 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. After Receiving a Smallpox Vaccination

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

Yes. Inform your dentist that you have been recently vaccinated. You should cover your vaccination site with a bandage or long-sleeve clothing to provide a barrier to protect your dentist.

**7) How long does vaccine virus (vaccinia) last on a surface of the skin with the potential to be transferred to another person?**

Until the scab falls off on its own

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

We don't precisely know. 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 (church, malls, etc). As usual, the key here is to not move the virus from your vaccination site to another person. So be mindful and 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 21 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 vaccination and have no complications will be deferred from donating blood until the scab spontaneously separates (14-21 days after vaccination). In cases where a scab is otherwise removed, the donor may be deferred for two months after vaccination. 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. 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 germs.

**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.

## Cardiac Related Reactions

### DoD Findings Regarding 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 (myo-pericarditis) after smallpox vaccination in early February 2003. DoD identified several cases of myocarditis and/or pericarditis among 350,000 smallpox vaccinees, with symptoms appearing 7 to 19 days after vaccination. These people had clinical conditions that varied from mild to severe. They all survived. They have been discharged from hospital, and have either returned to duty or been given short-term convalescent leave to regain their strength. Each case occurred among those receiving smallpox vaccination for the first time. None occurred among those receiving re-vaccination. The health of our people is foremost in our priorities. We will continue to monitor these people for the next year to ensure they receive the care they need and deserve. Based on European experience, we have reason to believe these people should recover and remain well.

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

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

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

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

Myocarditis and heart attacks are different diseases. Myocarditis involves inflammation of the heart muscle. Heart attacks are different, in that they involve problems with heart rhythm or blood vessels in the heart. At present, we don't see evidence of a link between myocarditis and heart attacks. But our minds are open and we continue to look into it.

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

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

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

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

### **5) How was the myocarditis or pericarditis diagnosed in servicemembers?**

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

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

Yes. A 55-year-old servicemember died 5 days after smallpox vaccination. We regret the death of any servicemember, whatever the reason. Based on our investigation of medical records and autopsy findings, the Department of Defense does not consider smallpox vaccination likely to be the cause of death, based on pre-existing heart disease. Additional testing at the Armed Forces Institute of Pathology confirmed this finding. Several other cases of cardiovascular disease have occurred among smallpox vaccinated people. These appear to be occurring at rates similar to what is expected among unvaccinated people. We will provide more information when available. Between 1998 and 2000, before the DoD Smallpox Vaccination Program began, an average of 150 active-duty servicemembers were admitted each year to DoD hospitals for heart attacks. Each year in DoD, several dozen active-duty personnel die of heart disease. In the Total Army (Active, Guard, and Reserve), roughly 50 deaths due to heart conditions occur each year. Heart pain (angina) and heart attack also have been reported in the civilian smallpox vaccination program, largely among people 50 years and older. It is not known if smallpox vaccination caused these problems or if they occurred by chance alone (heart problems are very common). For more information on the civilian program, go to [www.bt.cdc.gov](http://www.bt.cdc.gov).

## **Heart Conditions That Would Exempt Someone From Taking Smallpox Vaccine**

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

Yes. We will defer people with serious heart- or vessel-related conditions. Importantly from the standpoint of military readiness, people with major heart conditions are unlikely to be in military service. Some examples include a history of angina, an earlier heart attack, artery disease, congestive heart failure, cardiomyopathy, stroke, "mini stroke," or chest pain or shortness of breath with activity (such as walking up stairs). If you have concerns about your health history, speak with your health care provider before vaccination. Similar to the CDC, and based on input from the American College of Cardiology, we will also defer people with three or more cardiac risk factors. The risk factors include: (1) current smoker, (2) high blood pressure, (3) high cholesterol, (4) high blood sugar, and (5) a heart condition before age 50 in a parent, brother, or sister. Vaccination of other people should continue as planned. If you smoke, we encourage you to stop.

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

Unless you start displaying symptoms such as chest pains, difficulty breathing, shortness of breath, or pain radiating down arm or to 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.

**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 that 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

### Vaccination Site Care

**1) I just received my smallpox vaccination. How do I care for the injection 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. Vaccine virus is present at the vaccination site for about 14 to 21 days, until the scab falls off. This means other people can get infected if they come in contact with virus from your arm. You can infect others if you touch your blister and then touch another person. Most vaccination sites can be left unbandaged, especially when not in close contact with other people. Wear sleeves covering the site and/or use an absorbent bandage to make a touch-resistant barrier. Dispose of bandages in sealed or double plastic bags. You may carefully add a little bleach, if desired. Keep the site dry. Airing will speed healing. Do not use creams or ointments, or 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 carefully, so the towel does not rub or spread virus elsewhere. Don't allow others to use that towel until it is laundered. Don't use public towels, unless laundry workers are alerted that you were vaccinated. Use a waterproof adhesive bandage, if you exercise enough to cause sweat to drip. Swimming can make the site soft and delay healing, so avoid swimming. Take good care of your vaccination site.

### After Receiving a Smallpox Vaccination – Conduct Around At-Risk People

**1) 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 (church, malls, etc). As usual, the key here is to not move the virus from your vaccination site to another person. So be mindful and 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 21 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

### Laundering Information

**1) 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 soapy water (with bleach, if desired) Keep your personal linens separate (e.g., towels) 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) or a Band-Aid will suffice. Wash your linen, along with personal towels and washcloths, in hot soapy water, with bleach if desired.

**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?**

We're checking on this issue. Until we have an answer, we recommend that you wear a washable shirt under your dry cleanable clothing to avoid contact with 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.

## After Receiving a Smallpox Vaccination – Breastfeeding

### **1) I am breastfeeding my child. Are there any special precautions that I can take to ensure my child is protected from my vaccination site?**

Vaccination of breast-feeding mothers is not recommended, except under emergency conditions, because the infant might come in contact with the vaccination site. The Advisory Committee on Immunization Practices recommends that parents caring for infants and young children take extra care of their vaccination sites. The site should be covered with gauze or a similar absorbent material, and a shirt or other clothing should be worn. Pay careful attention to hand hygiene (hand washing). Alternate care-giving arrangements for infants and young children are preferred, until the scab at the injection site falls off.

## Possible Family Member Reactions to 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 moving 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, including that the family member was recently vaccinated against smallpox. For family members in the Reserve Component, contact the Military Medical Support Office (MMSO) 888-647-6676 if the member is not enrolled to 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 can infect cats, dogs, or other household pets, nor that pets can spread the virus to other people in the household. 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 a 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 any disinfectant. Do pay attention to any surface or object that rubs against your vaccination site.

### **2) What's the risk of children spreading the vaccine (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). Then, for one child to spread the vaccine virus to another child would be even more rare.

## Health-Care Providers (HCP)

### Vaccination for Healthcare Workers

#### **1) Should vaccinators be vaccinated themselves?**

Yes, Department of Defense personnel who are vaccinating others should be vaccinating themselves. This is outlined in the "Clinical Policy for the DoD Smallpox Vaccination Program (SVP)". <http://www.smallpox.army.mil/media/pdf/SPclinicalpolicy.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 Side Effects or Concerns for Healthcare Workers

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

Inadvertent inoculation at other sites 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 immune globulin (VIG) can help treat severe cases of ocular implantation. However, if vaccinia keratitis is present, VIG is barred (contraindicated) because it might increase corneal scarring. Erythematous or urticarial rashes can occur about 10 days after primary (first) vaccination and can be confused with generalized vaccinia. However, the vaccinee is usually afebrile with this reaction, and the rash resolves spontaneously within 2 to 4 days. Rarely, bullous erythema multiforme (i.e., Stevens-Johnson syndrome) occurs.

### **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 Israeli military recruits aged 18 years or older, who were vaccinated during 1991 and 1996, reported rates of progressive vaccinia (0 out of 10,000 vaccinees) and postvaccinial encephalitis (0 out of 10,000 vaccinees) 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 a 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 Vaccines**

### **1) How does the smallpox vaccination interact with other drugs?**

The smallpox vaccine should not be given to people taking medications that suppress their immune system.

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

Dryvax® may be administered concurrently with other inactivated vaccines, if necessary, or at any interval before or after inactivated vaccines, consistent with ACIP recommendations. See the following paragraph for operational examples. Except for varicella vaccine, smallpox vaccine may be administered simultaneously with other live virus vaccines. To avoid confusion in ascertaining 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 only be administered 4 weeks apart or greater. If not given simultaneously, live virus vaccines should be separated by 4 weeks or more. Do not administer other vaccines near an active smallpox vaccination site.

## **Questions That Must Be Asked Prior to Administering Smallpox Vaccination**

### **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. Also, ask about the health of people in the household.

## **People That Should Not Be Vaccinated During a Smallpox Outbreak**

### **1) Who is exempt (contraindicated) from smallpox vaccine 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 by 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 – HCP**

## 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. Use skin over the insertion of the deltoid muscle (preferred) or the posterior aspect of the arm over the triceps muscle for smallpox vaccination. Cleansing of the vaccination site may be performed with soap and water, followed by water only, and then drying. Acetone or alcohol may be used only if adequate time is allowed for it to evaporate or if the site is wiped dry with (non-sterile) gauze to prevent unintentional inactivation of the live virus vaccine. Acetone may be preferred over alcohol, because acetone evaporates more quickly. 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 the appropriate number of 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. Leave the site uncovered, if the individual is thoroughly counseled about the hazards of touching the vaccination site. Alternately, cover the site with a loose 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. There is no need for goggles. However, if workers feel more comfortable, workers may wear goggles if they wish.

## Treating Complications of Smallpox Vaccination – HCP

### 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 of a serious adverse event after smallpox vaccination will be infrequent, but of high consequence to the patient. Consult as appropriate with allergy-immunology, infectious-disease, dermatology, neurology, or specialist(s). Some conditions respond to vaccinia immune globulin (VIG). Eczema vaccinatum, progressive vaccinia, severe ocular vaccinia, severe generalized vaccinia. VIG not effective in treating post-vaccinial encephalitis. VIG consists of human IgG antibody from people vaccinated with smallpox vaccine. Current supplies of 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 VIG for a named patient by telephoning USAMRIID at 1-888-USA-RIID or 301-619-2257. Healthcare providers from civilian institutions should contact the CDC Drug Service for VIG or cidofovir: CDC Drug Service, National Center for Infectious Diseases, Mail stop D-09, Atlanta, GA 30333; 404-639-3670, fax 404-639-3717.

### 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 smallpox vaccine virus infections or other Orthopoxvirus infections, including smallpox (variola infection). Certain antiviral compounds are active 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 effective dose and the 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 smallpox vaccination complications.

## Evidence of Immunity and Vaccination – Response Interpretation

### Evidence to Suggest 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"?

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 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.

### **2) 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 – HCP**

### **HCP Precautions to Avoid Spreading Smallpox Vaccine Virus**

#### **1) Are there precautions I can take as a health-care 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:

Recently vaccinated healthcare workers should minimize contact with unvaccinated patients, particularly those with immunodeficiencies, until the scab falls off. 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 immunodeficiencies, 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**

#### **2) Are there precautions I can take as a health-care 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: Recently vaccinated healthcare workers should minimize contact with unvaccinated patients, particularly those with immunodeficiencies, until the scab falls off. 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 immunodeficiencies, 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.

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## **Linen Precautions For Hospital Workers and Institutional Settings After Smallpox Vaccination**

### **Precautions For Your Uniform While at Work– Laundry**

**1) 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.

**2) 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).

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

Be prepared to change from scrubs to street clothes at work, wear a long-sleeve shirt or warm-up jacket, and bring a plastic bag to carry the scrubs home with you. Launder them in hot water (1600 F), with soap. Use bleach, if desired.

**4) 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.

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**8) 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 in hot soapy water.

**2) 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 in hot soapy water.

### **How to Care For Your Uniform at Home – Laundry**

**1) 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 family's.

**2) 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.

**3) 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.

**4) 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 family's.

**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.

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

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