



Defense Health Agency
Public Health Division

Immunization Healthcare

Smallpox Vaccination Program (SVP)

Questions and Answers

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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, sprays or 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.

From 1983 through 2002, most Service members did not get vaccinated against smallpox. Those vaccinated before 1983 do not have much immunity left. 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 in labs with the smallpox vaccine virus (vaccinia) or similar viruses. Between December 2002 and December 2017, more than 2.6 million service members received smallpox vaccinations.

There is no proven treatment for the smallpox disease, but research to evaluate new antiviral medications is ongoing. Patients infected with smallpox likely will benefit from these antivirals and immune globulins, as well as supportive therapy (e.g., intravenous fluids, medicine to control fever or pain) and antibiotics, as indicated.

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 three doses, substantial protection persists for 30 years or longer.

In a European study from the 1970s, 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?

Smallpox vaccination is currently required for uniformed personnel deploying or assigned to the Korean Peninsula for 15 or more consecutive days. It is also mandatory for certain designated emergency-essential personnel and contractors, uniformed personnel assigned to special units, and comparable U.S. government civilian employees. However, requirements may change based on threat.

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 Food and Drug Administration (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 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. 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 carefully listen to and identify their concern and provide education which addresses the concern.

If an individual continues to refuse despite efforts to educate, the Commander will be notified and determine next steps.

Smallpox Weapons – The Threat

1. How does the threat of a smallpox attack on U.S. 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. military.

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

Not necessarily. A May 2014 exception to policy states smallpox vaccination is no longer mandatory for the U.S. Central Command (CENTCOM) Area of Responsibility (AOR) although anthrax vaccination is still a CENTCOM requirement.

http://www.usamma.amedd.army.mil/assets/apps/nala_qaweb/message.cfm?MSG=MMQC-14-1488. Both vaccinations are still mandatory for uniformed personnel deploying or assigned to the Korean Peninsula for 15 or more consecutive days, as well as other designated units and emergency-essential personnel. Threat risks are assessed continuously and requirements may change as necessary.

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 biological agents determined by the Centers for Disease Control and Prevention (CDC) to pose the greatest potential threat of adverse impact on public health and medical systems. Col. Kanatjan Alibekov, First Deputy Chief of the Soviet Union's offensive biological weapons program, stated that after smallpox was eradicated, and vaccination ended, the virus had the potential to be the most powerful and effective weapon ever created. Other biological 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.

The Disease

Smallpox Disease – What it is

1. What is smallpox?

Smallpox is a very serious disease; and it is contagious and sometimes fatal. Smallpox is caused by the 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 pustules 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. The most common form of smallpox kills about 3 out of 10 adults, and 4 out of 10 children. However, two less common forms of smallpox kill over 90% of those 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, as described below. Contact with infected skin could also transmit

the virus. Spread through contact with inanimate objects (e.g., clothing, towels, linens) is less common.

People with smallpox are contagious from when their temperature goes over 101°F (38.3°C), a day or so before the rash develops. They stay contagious until all their scabs fall off. Not everyone who is routinely in close contact 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.

People infected with smallpox exhale little droplets that carry the virus to the nose or mouth of bystanders. Therefore, 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 both before exposure and within about 3 (perhaps up to 7) days after exposure. There is no proven treatment for smallpox, but research to evaluate new antiviral agents is ongoing. Three antiviral drugs, Cidofovir, Brincidofovir, and Tecovirimat have all been shown to be effective against the smallpox virus in animals. Because there has been no natural smallpox disease since 1977, these antivirals have not been tested in humans with smallpox. However, Cidofovir and Tecovirimat are currently stockpiled in the Strategic National Stockpile for use in the event of a smallpox outbreak. The use of these antivirals 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 intensive care for pulmonary and renal complications, intravenous fluids, medication 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 – Vaccine vs. 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°F. Over the next few days, pus-filled blisters develop over large portions of the body. These symptoms affect 100% of individuals infected with the smallpox virus and up to 30% will die.

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 significant enough to seek medical care in about 10% of vaccinees. Other, more serious side effects occur in between about 1/1,500 (cardiac) to 1/10,000,000 (neurologic) vaccinees. 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.

For diagnostic support of suspected contact transmission of the vaccinia virus, please see page 17 below.

How to Detect Smallpox Around You

1. How is the spread of smallpox stopped 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.

Vaccine Description

Overview

1. What is smallpox vaccine?

Smallpox vaccine contains live vaccinia 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 December 31, 2017, more than 2.6 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.

Edward Jenner reported in 1796 that people given vaccinia vaccine became protected from smallpox. Before this, people purposely infected themselves with "small doses" of the smallpox virus in a process called variolation. The resulting case of smallpox was generally milder. But not always!

Smallpox vaccine was the very first vaccine and has been used successfully for more than 200 years.

Getting smallpox vaccine before exposure will protect about 95 % 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. The FDA licensed a smallpox vaccine made by Acambis Laboratories called ACAM2000® in 2007. Smallpox vaccine used for Service members passes all tests required by the FDA. Dryvax is no longer available for use.

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, but 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 any residual or undesired processing 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 vaccinees.

2. Who is the manufacturer of ACAM2000?

ACAM2000 was originally manufactured by Acambis of Cambridge, UK.

In 2008 Acambis was acquired by Sanofi Pasteur. Emergent BioSolutions then acquired ACAM2000 from Sanofi in 2017. This acquisition by Emergent BioSolutions includes transferring of ACAM2000 production from Austria to U.S.-based manufacturing.

3. What are Acambis's/Emergent BioSolutions' responsibilities to CDC and DoD?

Acambis developed ACAM2000 under contracts with the 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 U.S. Government's smallpox vaccine stored in the Strategic National Stockpile (SNS). Emergent BioSolutions will continue the existing 10-year contract with the CDC for deliveries of ACAM2000 to the SNS, and will develop a manufacturing facility and a lease to a fill/finish facility, both U.S.-based.

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 - 5.0x10⁸ PFU/mL or 2.5-12.5x10⁵ PFU/dose. Note: the 0.3 mL of diluent used to reconstitute the vaccine is not the entire volume of the diluent vial.

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?

ACAM2000 should be stored in a freezer with an average temperature of -15°C to -25°C (+5°F to -13°F).

Prior to reconstitution, ACAM2000 vaccine retains a potency of 1.0x10⁸ PFU or higher per dose for at least 18 months when stored at refrigerated temperatures of 2-8°C (36-46°F).

Diluent for smallpox vaccine should be stored at room temperature (15-30°C, 59-86°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.

6. Do vaccinees need signed consent to receive this vaccine?

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

7. 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.

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

The Immunization Healthcare Support Center is available 24/7 for clinical consultation at 877-GETVACC (438-8222) or DSN (312) 761-4245 (select Option 1). You can also email questions to DoDVaccines@mail.mil.

9. Do those previously 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 who, by occupation or deployment require re-vaccination, should do so after 10 years.

10. What education information will a vaccinee receive?

Anyone vaccinated with the smallpox vaccine will receive a DoD Smallpox Information Brochure, an ACAM2000 Medication Guide, and additional information as requested.

11. 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.

12. Is smallpox vaccine live or synthetic?

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

13. 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 minute 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 is given on the upper arm.

14. Who will administer smallpox vaccine?

Trained health care workers who have themselves received the smallpox vaccine will administer the vaccine. Typically this would be a nurse or a medic/corpsman.

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 (an organic chemical buffering agent -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.

Vaccinations Over Time

1. Who received smallpox vaccination in the past?

Smallpox vaccination of U.S. military forces dates 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 December 31, 2017 more than 2.6 M Service members received smallpox vaccination.

Vaccine Effectiveness

1. How long does a smallpox vaccination last?

Past experience indicates that the first dose of the vaccine offers protection from smallpox for 3 to 5 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 needed another dose of smallpox vaccine to restore their full immunity. Subsequent vaccinations increased and extended protection.

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 1980s in the military), will they have to get it again?

If more than 10 years have passed since your last vaccination and you're still at risk through occupation or deployment, you will be revaccinated in accordance with DoD's [Policy on Administrative Issues Related to Smallpox Vaccination](#). (click to download pdf document).

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.

Vaccine Safety

Safety

1. Is it safe to go swimming after my smallpox vaccination?

Do not swim in pools, hot tubs or whirlpools until your smallpox vaccination site has healed. There is a potential for spreading the virus to others through shared towels, etc. Also, the chemicals used in pool water could make your vaccination less effective.

2. Is smallpox vaccine safe?

People have been vaccinated against smallpox using the vaccinia virus for more than 200 years. Millions of children and adults in the U.S. have been vaccinated against smallpox with today's vaccine strain since 1931. The smallpox vaccine has proven to be generally a safe and effective means of preventing smallpox. However, like all medicines, in some 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 and can be life-threatening. Severe adverse reactions are more common in persons receiving primary vaccination compared to those being revaccinated.

3. 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 % 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.

4. What are the temporary side effects after smallpox vaccination?

Mild reactions include swelling and tender lymph nodes that can last two to four weeks. Most people develop vaccination site 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-limited, 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 health care provider.

5. Is it okay to take multiple vaccines at the same time?

Multiple vaccinations 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. The only recommendation is that an individual not receive the smallpox vaccine at the same time either the chickenpox, and/or the live shingles (Zostavax) vaccines, because if a rash were to develop, it would be difficult to determine the cause for the rash.

6. Can someone vaccinated against smallpox infect someone else?

Yes. However, infection of this kind can be prevented by covering the vaccination 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.

7. Is it safe to have surgery soon after I get the smallpox vaccine?

If you must have surgery, inform your surgeon that you have just received smallpox vaccine. Elective or non-urgent surgery is not recommended within 30 days after smallpox vaccination. This allows time for the vaccination site to heal completely, so that it cannot spread smallpox vaccine virus to your surgical wound. Eye surgery, for example, is a special contraindication to receiving smallpox vaccine. Eye surgery should be delayed until after the smallpox

vaccination site has healed completely. Please [contact the IHB](#) if you have questions or concerns.

8. Can I get smallpox disease from smallpox vaccine?

No. The smallpox vaccine is made from vaccinia virus, which is a live virus similar to smallpox virus. Vaccinia virus cannot cause smallpox disease.

Diagnosis of contact transmission of the vaccinia virus

1. What laboratory tests should I order if I suspect a contact transmission of the vaccinia virus?

If following receipt of, or exposure to, the smallpox vaccine you develop one or more pustular lesions, the IHB, in cooperation with the CDC and its state-wide laboratories, can use PCR of material taken from the lesion(s) to quickly determine its origin. Herpes simplex (cold sores) and varicella (chickenpox) lesions can look very much like vaccinia lesions. Patients, family members, or providers can contact the IHB 24/7 by calling 1-877-GETVACC (438-8222) or DSN (312) 761-4245 (select Option 1), for help with any suspected contact transmitted vaccinia virus.

2. How do I obtain a PCR (polymerase chain reaction) assay for Vaccinia?

PCR (polymerase chain reaction) assay for vaccinia is available through military or state regional laboratories participating in the Emergency Response Lab Network. If unable to obtain prompt local support for PCR and culture, contact IHB by email or telephone (www.health.mil/ContactIHB). After hours, Call the Immunization Healthcare Support Center at 877-GETVACC (438-8222) or DSN (312) 761-4245 (select Option 1).

Information on obtaining viral PCR and culture specimens is available on the IHB website at <https://health.mil/Reference-Center/Fact-Sheets/2017/01/09/Guideline-for-Obtaining-Vaccinia-PCR-Assay> (click to download pdf document) or the CDC website at <https://www.cdc.gov/smallpox/lab-personnel/specimen-collection/vaccinia-specimen.html>

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 and can be life-threatening. Severe adverse reactions are more common in persons receiving primary vaccination compared to those being revaccinated.

- Progressive vaccinia. Progressive vaccinia is one of the most severe complications of smallpox vaccination. It occurs in severely immunocompromised individuals whose immune system is not able to limit the spread of the vaccinia virus. This leads to sepsis, organ failure, and death without specialized intensive care.
- Generalized Vaccinia. Systemic spread to four or more skin sites of the vaccinia virus in immunocompetent individuals.
- Eczema Vaccinatum. Extensive vaccinia lesions developing in individuals whose skin lacks certain natural defenses, especially in those with atopic dermatitis (a form of eczema). While the spread of the skin lesions is the most obvious finding, Eczema Vaccinatum can become a life-threatening condition similar to progressive vaccinia if the immune system is overwhelmed.
- Ocular Vaccinia. Eye infection resulting from transfer of the vaccinia virus to the eye. This can lead to blindness. If recognized early, there is an effective treatment.
- Fetal Vaccinia. An extremely rare complication of smallpox vaccination. In the 20th century, three cases of fetal vaccinia were reported in the United States, and 47 cases were reported from other countries. While there is concern over serious consequences should the fetus become infected with vaccinia, recent reviews examining the overall risk of maternal smallpox vaccination found no association between the vaccine and stillbirths or miscarriages. In one study, there was a suggestion of a slightly increased risk of congenital defects associated with first trimester vaccination (Badell et al., *Obstet Gynecol* 2015 Jun;125(6):1439-51.) Studies from the National Smallpox Vaccine in Pregnancy Registry (NSVIPR), however, have not verified the increased risk.
- Post-Vaccinia Encephalitis, Encephalopathy, transverse myelitis, and Encephalomyelitis. Rare inflammation of the brain and/or spinal cord occurring shortly after vaccination.
- Myocarditis, Pericarditis, myopericarditis. Inflammation of the heart muscle, the sac surrounding the heart, or both.

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

Between 14 and 52 people out of 1 million vaccinated for the first time experienced potentially life-threatening reactions. These reactions included serious skin reactions and inflammation of the brain (encephalitis) and 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 vaccination. 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 million adults got revaccinated.

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

With its mandatory pre-vaccination screening, the DoD has been very successful in reducing the number of vaccine-associated adverse events. For example there have been only three cases of Eczema Vaccinatum reported – a 3- to 10-fold reduction over historical expectations.

For more information about side effects of the smallpox vaccine, please visit our [smallpox vaccine-associated adverse events webpage](#).

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.

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 bioweapon cannot be known with certainty.

Reproductive Health

1. Should pregnant women receive the smallpox vaccine?

No. But understand that smallpox vaccine recommendations have changed over time. In the mid-20th century, when smallpox disease was still naturally occurring, billions of women around the world, both pregnant and not pregnant, received the vaccine. During smallpox outbreaks, health officials intentionally gave pregnant women smallpox vaccine to protect them from potential lethal infections. However, after the eradication of smallpox, the recommendation is that 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. Should smallpox return (as in a terrorist event), personal benefit from vaccination would again 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.

There is no historic evidence that smallpox vaccine causes increased rates of miscarriage, but smallpox vaccine may cause a very rare but serious complication in the fetus called fetal vaccinia. In the 20th century, three cases of fetal vaccinia were reported in the United States, and 47 cases were reported from other countries. 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.

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.

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 so as to prevent spread of the vaccine virus to the breastfeeding woman. Anyone, especially close contacts of pregnant or breastfeeding women, 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.

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 health care provider and the IHB (1-877-GETVACC (438-8222), Option 1, or DSN (312) 761-4245) 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.

5. Should women or men avoid 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.

Vaccinated men may wish to wait a similar amount of time before attempting to father a child. Until the vaccination site has completely healed, they can spread vaccinia to a close contact (such as a sex partner). Covering the vaccination site and good hand washing 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?

No. Neither historic evidence nor recent scientific reviews show that smallpox vaccine caused increased rates of pre-term births, stillbirths or miscarriages. There are conflicting conclusions regarding the risk for birth defects. While a recent review suggested that first-trimester vaccination was associated with a small increase in congenital defects, it was noted that the effect size was small and based on limited data. The National Smallpox Vaccine in Pregnancy Registry (NSVIPR), established in 2003 and managed by the Department of Defense Birth and Infant Health Registry, follows women who inadvertently receive smallpox vaccine while pregnant. The NSVIPR collects confidential information to better understand if smallpox vaccine in pregnancy is associated with problems for mothers or infants in the modern era.

In the United States, approximately 17% of all recognized pregnancies end in miscarriage, and 3% to 5% of infants are born with birth defects. Unfortunately, the causes of most miscarriages and birth defects are unknown.

As of 2018, information from the NSVIPR indicates that miscarriages, pre-term births, and birth defects occur at rates similar to, or less than, rates seen in the general population. Women who inadvertently receive smallpox vaccine while pregnant may be reassured that current data support historic data, and do not suggest that they are at higher risk for pregnancy loss or giving birth to a child with a birth defect. There have been no cases of fetal vaccinia among pregnancies followed by the Registry. Therefore, 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?

No. Neither historic evidence nor recent scientific reviews show that smallpox vaccine caused increased rates of pre-term births, stillbirths or miscarriages. The National Smallpox Vaccine in Pregnancy Registry (NSVIPR), established in 2003 and managed by the Department of Defense Birth and Infant Health Registry, follows women who inadvertently receive smallpox vaccine while pregnant.

In the United States, approximately 17% of all recognized pregnancies end in miscarriage. Thus far (2018), the NSVIPR has also found that miscarriages, preterm births, and stillbirth occur at rates similar to, or less than, rates seen in the general (unvaccinated) population.

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

No. 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 health care provider and their baby's health care provider know about their vaccination. Their providers should contact the National Smallpox Vaccine in Pregnancy Registry by calling 619.553.9255 (DSN 553-9255) or e-mailing DOD.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 fertility 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 health care provider or their state health department for help in enrolling in the registry. Health care providers and staff from state health departments are encouraged to report all exposed pregnant women to the registry by calling 619.553.9255 (DSN 553-9255) or e-mailing DOD.NHRC-birthregistry@med.navy.mil. To learn more, please visit the IHB's [smallpox vaccine-associated adverse events webpage](#).

Vaccination Site Care

1. How should I care for the vaccination site?

Key points:

- Wear a non-stick bandage that covers the vaccination site
- Wear long sleeves to cover the bandage
- Don't touch your vaccination site.
- If you touch it by accident, wash your hands right away.
- Don't let others touch your vaccination site or materials that touched it.
- Wash your hands!!

As a superficially applied live virus vaccine, the virus can be transferred to other parts of your body or transmitted to persons who have close contact with you. 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.

To reduce complications and the spread of the disease elsewhere on your body or to someone else:

- Keep site completely covered with a dry non-stick bandage (i.e., Band-Aid®, telfa™ pad); DO NOT use gauze (as virus may leak through and the gauze may stick to the pustule or scab and pull it off when you change the dressing)
- Avoid directly touching the vaccination site
- Do NOT let others touch your vaccination site or materials that may have touched your blister; like clothing and bandages
- Keep site as dry as possible and when showering keep site covered
- Avoid swimming, wrestling, or other contact sports until site is healed
- Do not use creams or ointments; they may spread the virus and they will delay healing

- Wash your hands frequently with soap and water or an alcohol- based hand sanitizer

Make sure you cover the site with a bandage and wear long sleeves to prevent scratching, especially in bed. Change your bandages frequently so the surface remains dry. If you exercise enough to cause sweat to drip, temporarily use a waterproof or reinforced bandage. When not around others, you can leave the site uncovered; air drying will speed healing. Dispose of bandages in sealed or double plastic bags.

Normal bathing can continue, but don't touch or scrub the vaccination site. Dry off carefully, so the towel does not rub or spread virus elsewhere. Dry the site last by blotting with tissue, toilet paper, or paper towel. Don't allow others to use that towel until laundered. Don't use public towels, unless laundry workers are aware of special handling precautions. Avoid swimming pools and spas until the site is completely healed.

Discard used bandages and tissue paper in sealed or double plastic bags. You may add bleach, alcohol, or soap to the bag to kill the virus. Reapply a clean, dry bandage after showering and do not use creams or ointments; they will delay healing and can spread the virus.

Do not share clothes, towels, linen, or toiletries with others. To avoid the handling of these items by others, vaccine recipients should wash their own laundry in hot water with detergent.

Take good care of your vaccination site.

2. Is it true that the smallpox vaccine virus can be spread to others?

Yes, as a superficially applied live virus vaccine rather than an injected live virus vaccine like MMR, the smallpox vaccine virus can possibly be spread any time there is direct contact with the uncovered vaccination site or contact with fluid from the site. This spread is called "contact transmission." To prevent contact transmission, follow these three simple steps: wash your hands, keep the vaccination site covered, and properly dispose of vaccination dressings.

3. How long does it take for the smallpox vaccination site to heal?

It takes on average 30 days for the smallpox vaccination site to heal. Keep in mind that everyone heals at a different rate, some faster than average and others slower than average.

4. I want to get a tattoo placed on my smallpox vaccination site. How long should I wait?

Before getting a tattoo, wait until the smallpox vaccination site has fully healed, the scab has fallen off, and the skin is intact and dry. It may take longer than the average 30 days after your vaccination before the skin is ready for tattooing. Please [contact the IHB](#) if you have additional questions.

5. What should I do if I bump the smallpox scab and it falls off?

If the scab falls off, put it in a plastic bag with a small amount of bleach and throw the bag away. Wash your hands thoroughly. Replace the old bandage with a new clean bandage, and then wash your hands again. For more information on proper care of your vaccination site, click here to download the [“What You Need to Know About Smallpox Vaccine”](#) brochure.

6. What should I do if my smallpox vaccination site touched the shower wall?

Keep your smallpox vaccination site covered with a bandage while you shower. If the bandage gets wet, after your shower put it in a plastic bag with a small amount of bleach, discard it, and then wash your hands. Pat the vaccination site dry with tissue, toilet paper, or paper towel and dispose of it in a plastic bag. Then put on a new bandage. If your vaccination site does touch a surface, such as the shower wall, clean the surface with a household disinfectant. This will help to make sure that no smallpox vaccine virus remains on that surface.

7. My dog came in contact with my used smallpox dressing. What should I do?

Wash the part of the dog that came in contact with your used dressing. Then wash your hands well. Keep an eye on your pet, and if any rash or sore develops, contact your veterinarian. Remember to continue good hand washing, keep your vaccination site covered, and dispose of used dressings in a plastic bag with disinfectant.

8. I got a smallpox vaccination about a week ago. Now my armpit hurts and there is redness and swelling around the vaccination site. What should I do?

What you are describing sounds like a typical reaction that occurs after the smallpox vaccination, known as a "robust take." A "robust take" occurs when your body has a vigorous response to the vaccine. This response is a normal variation and usually goes away on its own; over-the-counter pain relievers may be useful. If you have questions or concerns you may contact an IHB health care

provider at 1-877-GETVACC (438-8222) or DSN (312) 761-4245 (select Option 1) and take a photo of the reaction.

9. Are there precautions I can take as a health care provider to avoid spreading smallpox vaccine virus to others?

You should follow the same instructions regarding vaccination site care and site and hand hygiene found in this section and in the brochure [“What You Need to Know About Smallpox Vaccine”](#) that you should have received upon vaccination.

Health care 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. An excellent article on the subject can be found in the journal; *Clinical Infectious Diseases* (CID 2003; 37:281–4). 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. Reviews of the efficacy and issues of various dressings can be found at:

- *Infect Control Hosp Epidemiol* 2007; 28:1339-1343
- *Am J Infect Control* 2004;32:126-30
- *Infect Control Hosp Epidemiol* 2006; 27:1184-1192CID 2004; 39:1004–7

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 3–5 days, or more frequently if exudates accumulate (according to type of bandaging and amount of exudate).

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.

10. What should I do if the bandage over my smallpox vaccination site gets wet?

If the bandage over your smallpox vaccination site gets wet, you need to change it. It is important to keep your vaccination site clean and dry. The first step when

changing the dressing is to wash your hands. Then replace the wet bandage with a new clean bandage. Put the old bandage, and any tissue used to blot dry the vaccination site, in a plastic bag with a small amount of bleach, and throw the bag away. Then wash your hands again. For more information about taking care of your vaccination site, click here to download the "[What You Need to Know About Smallpox Vaccine](#)" brochure.

11. 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 health care center without taking time off. Different types of dressings have been discussed in this section. Whichever dressing you use should fully cover the vaccination site to prevent accidental transfer of the vaccine virus to other parts of your body or to other individuals.

12. How long should the dressing or bandage stay in place, before being replaced by a new one?

The dressing or bandage should be kept in place until a change is needed. Most dressings are changed every 3-5 days, or sooner if when there is enough drainage from the vaccination site to soak the pad. Always wash your hands, before and after changing a bandage.

13. 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 health care facilities have bandage-changing stations set up for health care workers.

Eligibility Criteria

1. Is it safe to get a smallpox vaccination if I have herpes?

Having a history of herpes (either oral or genital) is not a contraindication to receiving the smallpox vaccine. However, if you are having an active herpes outbreak, do not get a smallpox vaccination until your skin lesions have healed. If you have questions or concerns, you may contact an IHB health care provider at 1-877-GETVACC (438-8222) or DSN (312) 761-4245 (select Option 1).

2. I have a condition that requires me to use steroid eye drops. Should I receive the smallpox vaccination?

You should not be vaccinated while you are using steroid eye drops. Steroid eye drops decrease your resistance to eye infections. It is a serious problem if your eye becomes infected with the smallpox vaccine virus. This exposure can happen when you touch your eye when the vaccine virus is on your finger. If you have had refractive eye surgery and are using steroid eye drops you should not be vaccinated until after the prescribed period. If you are planning to have refractive eye surgery, you must wait at least 30 days after your smallpox vaccination or until the scab has fallen off your vaccination site, whichever is longer. Please [contact the IHB](#) if you have any questions.

3. Are there any medical conditions that would exempt me from taking the smallpox vaccine?

The following groups of people should not get the smallpox vaccine unless under emergency (outbreak) situations:

- People whose immune system is not working fully due to disease, medication, or radiation, such as HIV/AIDS, cancer, transplant, immune deficiency, etc.
- People diagnosed with 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, a history of significant arrhythmia with or without corrective/ablative surgery, or other cardiac problems)
- 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.

4. 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.

5. 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 Hib 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, including the smallpox vaccine, according to the usual schedules.

6. 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 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, or a previous dose of smallpox vaccine it may be a contraindication for you to receive smallpox

vaccine at this time. The ACAM2000 vial stopper and syringe are latex-free. 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 vaccine screening form](#) can be viewed or downloaded at the IHB website.

7. 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.

8. 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 long-sleeve shirt to provide a barrier to protect your dentist.

9. 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.

10. 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.

11. 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 (a dressing fully covering the vaccination site, 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:

Because the most serious complication of exposure to the virus used in the smallpox vaccine is postvaccinial encephalitis, which occurs most in children <1 year of age, it is DoD policy that you shouldn't be vaccinated if you have a child less than 1 year of age living in the household, unless you can be separated from the child until your scab falls off (about 14 to 28 days).

12. What should I do if I was inadvertently vaccinated (despite the above temporary exemptions), and family contact is unavoidable?

For the vaccinee:

Be sure the vaccination site is well-covered and thorough hand hygiene is maintained. Wear a protective bandage and a long-sleeve shirt around others; and long sleeves/pajamas to bed so the bandage is not dislodged during sleep or during sexual relations. If the risk to household contacts is great (e.g., pregnant wife), a more occlusive dressing should be applied. Semi-permeable polyurethane dressings (e.g., Opsite®, Tegaderm®, Cosmopore®) are effective barriers. To prevent accumulation of exudate, cover the vaccination site with dry gauze, and then apply the dressing over the gauze. The dressing should be changed daily or every few days (depending on the type of bandage and amount of exudate). The bandage and all dressings should be disposed of in a sealed plastic (Ziploc®) bag with small amount bleach in the bag. Wash hands and work surfaces (sink, faucets, door knobs, etc.) after dressing change. Make sure pets or small children cannot get into the trash.

For family members:

If you are with someone who has received a smallpox vaccination, do NOT touch the vaccination site, bandages, clothing, sheets, towels, etc. If you do, then

WASH your hands including under your fingernails with warm soap and water. If none available, then use hand sanitizer.

If there is an infant at home under 1 year of age, monitor closely that there is no contact between that infant and the vaccination site or items that have been in contact with the vaccination site.

Breast-feeding is discouraged as breastfeeding could put the infant in close contact with the mother's vaccination site.

13. 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.

14. 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.

15. 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.

16. Can I travel after receiving the smallpox vaccine?

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

17. I have recently had surgery, is it safe to get the smallpox vaccine?

If you have recently had surgery, ask your health care provider whether it is safe for you to get the smallpox vaccine. You may need to wait until your surgical wound heals before you get the vaccine. This is to prevent the smallpox vaccine virus from infecting your surgical wound. Eye surgery, for example, is a special contraindication to receiving smallpox vaccine. Smallpox vaccination must be postponed until after your eye has healed. Please [contact the IHB](#) if you have questions or concerns.

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 2018, DoD has identified 356 cases of acute myocarditis and/or pericarditis among 2.6 million 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.

Over 96% of myopericarditis occurred among those receiving smallpox vaccinations for the first time. Ninety-five percent of cases were men. Seventy-two percent were Caucasian.

The health of our people is foremost in our priorities. These cases are being followed carefully to evaluate their recovery.

While the majority of individuals recover fully and quickly, about 15% of cases do not achieve full resolution of clinical symptoms and perceived return to pre-event health at 3 months following the acute illness. The predominant persistent symptom is intermittent chest pain. However, based on our data, and European experience, we have reason to believe these people will eventually 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. What is known is that the live vaccine (vaccinia) virus does not infect the heart.

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 myopericarditis 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. Some had temporary changes in ECG (electrocardiogram) and/or echo-cardiogram 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," a history of significant arrhythmia with or without corrective/ablative surgery, 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:

- current smoker or tobacco user
- high blood pressure

- high cholesterol or triglycerides
- high blood sugar
- 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 smallpox disease (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 just got a smallpox vaccination. How do I wash my clothes?

Always keep your clothes and towels separate from those of your family and other people. Wear clothing that you can wash in the washing machine. Do not share clothes, towels, or toiletries with anyone. If clothes or towels touch your smallpox vaccination site, wash them in hot water with detergent and/or bleach to kill the virus. You, the vaccinee, should handle all such textiles prior to

completion of the wash cycle (e.g., removing linens from the bed, picking up clothing, placing cloths and linens in the washing machine, etc.). You must wash your hands well after handling linens. For more information about taking care of your vaccination site, click here to download the "[What You Need to Know About Smallpox Vaccine](#)" brochure.

2. 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.

3. How much personal protective equipment do laundry workers need?

If laundry workers wear gloves, this is sufficient protection.

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

Be sure your vaccination site is well-covered and thorough hand hygiene is maintained. Wear a protective bandage and long sleeves/pajamas to bed so the bandage is not dislodged during sleep or during sexual relations. Wash your linen, along with personal towels and washcloths, separately in hot soapy water (with bleach, if possible).

5. 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.

6. 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.

7. 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 a bandage under your "dry clean only" clothing to avoid contact between the clothing and the vaccination site.

8. 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. May I visit with friends and family after my smallpox vaccination?

Yes, you may visit with other people after your smallpox vaccination, but keep your vaccination site covered with both a bandage and a shirt sleeve. Also, wash your hands if you touch your smallpox vaccination site. There are some individuals who you need to be especially careful around. These individuals include those for whom the vaccine is contraindicated: pregnant females, elderly, children (especially those less than 1 year of age), and those with chronic medical conditions, cancer, immune deficiency diseases, and those on immunosuppressive medications.

2. My wife is pregnant. Should I receive smallpox vaccine?

You should not receive smallpox vaccine if you will have close contact with a pregnant woman because of the small risk of spreading the vaccine virus to the woman. Fetuses of pregnant women who inadvertently receive the vaccine or receive a contact transmission of the vaccine are at risk for a rare complication called fetal vaccinia. The military offers options for military personnel in these circumstances such as temporary exemption or alternative housing. For further questions, see our [pregnancy page](#) or [contact the IHB](#).

3. I live with someone who has a chronic skin condition (i.e., eczema, acne, psoriasis, etc). Should I receive smallpox vaccine?

You should not receive smallpox vaccine if you have close contact with someone who has an atypical skin condition. This is because the virus can spread through direct contact with the vaccination site or fluids, and persons with a history of

chronic skin conditions or active skin lesions have higher risks for developing serious health problems related to the smallpox vaccine.

If you have specific questions or concerns, please [contact the IHB](#) for help.

4. Is it safe for me to be around a child younger than 1 year old if I get the smallpox vaccination?

The most serious complication of exposure to the virus used in the smallpox vaccine is postvaccinial encephalitis. Most frequently it affects primary vaccinees <1 year of age. About 15% to 25% with this complication die and 25% have permanent neurologic sequelae. Therefore, if you are in close contact or live with a child who is younger than 1 year old, a medical provider will usually recommend, IAW DoD policy, deferment of the smallpox vaccination until you report to your mobility/deployment assignment. However, if your commander decides that your vaccination is mission-essential prior to deployment, he or she can authorize and arrange separate quarters for you.

5. I just received the smallpox vaccine. Is it safe for me to sleep in the same bed with my significant other?

You can sleep in the same bed and continue intimate relationships as long as you make sure the vaccination site is covered and neither of you touch it. Wear a protective bandage and long sleeves/pajamas to bed so the bandage is not dislodged during sleep or during sexual relations. Some people have medical conditions that make them more likely to have serious complications if they are infected with the smallpox vaccine virus. In this case, special precautions might be necessary. If you have a question or concern about this, please [contact the IHB](#).

6. 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. Your provider should contact the IHB at 1-877 GETVACC (438-8222) or DSN 761-4245 (select Option 1). For Service members in the Reserve Component, contact Defense Health Agency-Great Lakes (formerly the Military Medical Support Office (MMSO)) at 888-647-6676 if the member is not enrolled in an MTF. If a close contact who is ineligible for DoD medical care develops a lesion, his/her civilian health care provider should contact the IHB or the CDC (770-488-7100) for guidance.

7. 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, either farm animals or household pets, 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), as well as taking care that pets do not have access to discarded dressings or other contaminated materials, 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 should 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 (bandages, long-sleeves, hand washing). Any child of a smallpox vaccinee who develops a suspicious lesion (especially if similar to the papule, vesicle, or pustule that the vaccinee developed after vaccination) should be evaluated by a provider familiar with the smallpox vaccine and contact transmission. The child should follow all the precautions to prevent spread of vaccinia virus to others until the cause of the suspicious lesion is determined. Parents or providers can contact the IHB at 1-877 GETVACC (438-8222) or DSN 761-4245 (select Option 1) for assistance with the evaluation.

Health Care Workers

Vaccination for Health Care 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 "[Update to Clinical Policy for the Department of Defense Smallpox Vaccination Program](#)" (click to download pdf document).

2. Why aren't ALL health care 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 first 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 Health Care 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?

Although the vaccinia virus can be found in the bloodstream and pharynx of patients with adverse events involving vigorous viral replication and/or abnormal host defenses, particularly eczema vaccinatum and progressive vaccinia, there is no epidemiologic evidence for airborne or droplet spread of vaccinia virus from the respiratory tract of healthy vaccinees. Standard and contact precautions will prevent transmission from patients with serious vaccinia complications in routine circumstances. Airborne infection isolation precautions, such as use of negative-pressure rooms and N-95 respirators, are not necessary for care of patients with vaccinia, unless procedures that cause aerosolization of the virus are performed.

Good hand hygiene is essential for health care workers who are in contact with vaccinia virus, including their own vaccination sites. The vaccination site should be covered with gauze, a semipermeable dressing, and a layer of clothing during patient care and that dressings should be changed every 3–5 days or more frequently if exudates accumulate. It is preferred that vaccinated health care workers provide direct care for patients with serious vaccinia complications. However, if an insufficient number of vaccinated health care workers are available, then only those without contraindications for smallpox vaccination should be allowed to provide direct care.

Inadvertent inoculation is the most frequent complication of smallpox 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 (VIGIV) can help treat severe cases. If vaccinia keratitis develops, VIGIV 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 immune reaction to the vaccination called erythema multiforme 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 postvaccinia encephalitis. These complications are rare, but occur more often among primary vaccinees than among revaccinees. These serious 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 postvaccinia encephalitis. These results were similar to those reported in previous studies.

a. 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. 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.

b. What is generalized vaccinia?

Generalized vaccinia involves a vesicular rash involving at least 4 separate locations 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]).

c. What is progressive vaccinia?

Progressive vaccinia (also called vaccinia necrosum or vaccinium gangrenosa) is a severe, potentially fatal illness. It appears as progressive necrosis extending beyond the vaccination site, often with metastatic lesions. It occurs in severely immunocompromised individuals whose immune system is not able to limit the spread of the vaccinia virus. This leads to sepsis, organ failure, and death without specialized intensive care. It occurred almost exclusively among people with cellular immunodeficiency.

d. 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 (or contact transmission), 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 (or contact transmission). 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 live 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, individuals should not receive the smallpox vaccine at the same time as either chickenpox, and/or the live shingles (Zostavax) vaccines. Smallpox vaccine may be administered simultaneously with other live vaccines

(other than chickenpox and live shingles 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?

Every smallpox vaccine eligible individual must complete the Smallpox Vaccination Screening Form Page 1 of 2 (Standard Form 600 (Rev. 11/2010) Electronic Copy SVP Overprint (02-18)) prior to receipt of the vaccine even if there is foreknowledge that he/she would be medically exempted (e.g., an individual with atopic dermatitis). A copy of the completed screening form must be placed in the individual's health record. This screening form will address a patient's and any close contacts' potential vaccine-contraindicating conditions such as 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. The standardized [DoD smallpox vaccine screening form](#) can be viewed or downloaded at the IHB website.

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 Health Care Responsibilities

1. I just got vaccinated against smallpox and I "moonlight" 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

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.

3. What should be done when reconstituted or unreconstituted smallpox vaccine is spilled?

Smallpox vaccine contains a poxvirus called "vaccinia." Unreconstituted or reconstituted, vaccinia is potentially infectious and should be treated using Biosafety Level 2 (BSL2) precautions. The techniques used for Universal Precautions suffice as protection for clean-up. Spilled smallpox vaccine should be cleaned with a solution containing 10% household bleach and 90% water. The solution should be prepared immediately prior to use, as it is less effective if it is more than one day old. For optimal disinfection, use household bleach which has been opened for less than 3 months. Absorb the spill with paper towels and then slowly pour the bleach from the edge of the spill towards the center. Allow absorbed spill to sit for 20 minutes; then clean it up. Wipe the area with towels soaked in the bleach solution, followed by clean water. The area is now disinfected. In clinical settings, the waste should be disposed of as biohazardous or regulated medical waste.

Treating Complications of the Smallpox Vaccination

Treatment for Patients Who Develop a Reaction to the Smallpox Vaccine

1. I got a smallpox vaccination and now I have a rash. What do I do?

Rashes can sometimes occur after smallpox vaccination. They can range from mild to severe. We recommend that you have your symptoms evaluated by a health care provider. You may contact an IHB health care provider at 1-877-GETVACC (438-8222) or DSN (312) 761-4245 (select Option 1) and take a picture of the rash.

2. 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. Patients, family members, or health care workers can also contact an IHB health care provider 24/7 at 1-877-GETVACC (438-8222) or DSN (312) 761-4245 (select Option 1) for assistance.

Some conditions respond to intravenous vaccinia immunoglobulin (VIGIV). These include but are not limited to: eczema vaccinatum; progressive vaccinia; severe generalized vaccinia; aberrant infections induced by vaccinia virus that include accidental implantation in eyes, mouth, or other areas where vaccinia infection would constitute a special hazard; vaccinia infections in people who have skin conditions such as burns, impetigo, varicella-zoster, or poison ivy; or in people who have eczematous skin lesions because of either the activity or extensiveness of such lesions. VIGIV is not indicated for isolated vaccinia keratitis or postvaccinial encephalitis.

VIGIV consists of human IgG antibody from people vaccinated with smallpox vaccine. It is manufactured by Cangene Corporation and is FDA-licensed. The DoD has VIGIV stockpiles strategically placed worldwide. VIGIV is also maintained in the CDC's Strategic National Stockpile.

Once a definite or probable diagnosis of a VIGIV-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 VIGIV for a named patient by calling the DHA's 24/7 Immunization Healthcare Support Center at 877 GETVACC (438-8222) or DSN (312) 761-4245 (select Option 1). Please click [here](#) to download procedures for ordering VIGIV. Health care providers from civilian institutions caring for non-DoD beneficiaries with possible VIGIV-requiring conditions (from contact transmitted vaccinia) 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.

Additional Treatment Options

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

The FDA 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). However, three antiviral drugs, Cidofovir, Brincidofovir, and Tecovirimat, have all been shown to be effective against smallpox vaccine virus (vaccinia) or other Orthopoxviruses in vitro and in test animals. The use of these antivirals to treat smallpox vaccine reactions requires the use of an Investigational New Drug (IND) protocol as questions remain regarding the dosing, timing and length of administration of these antiviral compounds. Topical trifluridine (Viroptic®), an antiviral approved by the FDA for

use in ocular CMV infections, has been found effective for the treatment of ocular vaccinia.

Additional information will become available. Health care providers should consult the IHB clinical staff as well as 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 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 major reaction, which indicates that virus replication has taken place and vaccination was successful; or
- An equivocal reaction, which can be caused by suboptimal vaccination technique, use of sub-potent vaccine, or residual vaccinia immunity among previously vaccinated persons. Persons with equivocal reactions cannot be presumed to be immune to smallpox, and revaccination is recommended.

Major Reaction

1. What should I do if a re-vaccinee does not have a major reaction/take?

An individual (a) born before 1972, or (b) employed as a health care worker before 1977, or (c) who travelled internationally before 1983, or (d) who was on

active duty before 1991 or after 2002, or (e) who has a Jennerian scar and who does not have a cutaneous response (“major reaction” or “take”) following smallpox vaccination is presumed to have been previously vaccinated and therefore, in accordance with the ACAM2000 package insert, does not require a second vaccination attempt to try to elicit a cutaneous response. The patient is considered adequately protected against smallpox (immune) and is fit for all military-related assignments, including deployment. No further diagnostic evaluation is required.

A smallpox vaccinee not meeting the presumptive prior-vaccination criteria (above) who fails to demonstrate a cutaneous response after receiving 15 jabs with ACAM2000 requires a second vaccination attempt in accordance with the ACAM2000 package insert. If after a second attempt there is still no evidence of a cutaneous reaction the individual is considered adequately protected against smallpox (immune) for all military- related assignments, including deployment. No further diagnostic evaluation is required.

2. 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:

- The inoculation site becomes reddened and itchy 3 to 4 days after vaccination.
- 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.
- The pustule begins to dry, the redness subsides, and the lesion becomes crusted between the second and third week.
- 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 or papular lesion is present or an area of

definite induration or congestion surrounding a central lesion is visible upon examination 6 to 8 days after revaccination.

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 in a primary vaccinee, 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, the patient is considered adequately protected against smallpox (immune) and is fit for all military-related assignments, including deployment. No further diagnostic evaluation is required.

No-Take Reaction

1. I had a no-take reaction to my smallpox vaccination. Do I need to get another smallpox vaccination?

An experienced health care provider should have determined whether you have had a successful smallpox vaccination by evaluating the vaccination site for a reaction. If this was your first smallpox vaccination in which there was no reaction, a second attempt to vaccinate will be made using a different vaccine vial (if available) and using a different vaccination site. This site may need to be checked more carefully and more often for a take reaction.

If after your second smallpox vaccination there is still no evidence of a take reaction, you are considered immune to smallpox for military-related requirements, including deployment. Please [contact the IHB](#) if you have additional questions or concerns.

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?

To lessen, but not necessarily prevent, spread of vaccinia virus outside your site dressing onto your 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 degrees 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.