

Questions and Answers

1. a. Smallpox - The Disease.

What is smallpox?

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

The symptoms of smallpox begin with high fever, head and body aches, and sometimes vomiting. A rash follows that spreads and progresses to raised bumps that crust, scab, and fall off after about three weeks, leaving a pitted scar.

Smallpox can cause:

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

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

The incubation period for smallpox is about 12 to 14 days (range: 7 to 17 days) after exposure. Initial symptoms include high fever, fatigue, headache, and severe body aches.

Is smallpox fatal?

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

Is smallpox contagious? How does smallpox spread?

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

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

Not everybody who talks with a smallpox patient will get the disease. People with smallpox can infect about half of the people who live in their household. On average,

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each infected person can infect about 5 other people. Those other people show symptoms about 15 days after infected.

The most common way to transmit smallpox would be from prolonged face-to-face contact. People infected with smallpox exhale little droplets that carry the virus to the nose or mouth of bystanders. The greatest risk comes from prolonged face-to-face contact (6 feet or less, most often after 1 or more hours), with an infected person, especially one who is coughing. Indirect contact is less efficient at spreading the virus, but it still occurred via fine-particle aerosols or inanimate objects carrying the virus.

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

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

Is there any treatment for smallpox?

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

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.

1. b. Smallpox - Vaccine Overview.

What is smallpox vaccine?

Smallpox vaccine contains live vaccinia virus (not smallpox virus) to protect against smallpox. This same vaccine has been given to millions of Americans, including Service Members during World War I, World War II, and until the 1980s.

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

The vaccine virus (*vaccinia*) is similar to the smallpox (*variola*) virus. Edward Jenner reported in 1796 that people given *vaccinia* (smallpox) vaccine become protected from smallpox. Smallpox vaccine was the very first vaccine and has been used successfully for over 205 years.

Getting smallpox vaccine *before* exposure will protect about 95 percent of people from getting smallpox. Vaccination within 3 days of exposure will prevent or significantly lessen the severity of smallpox symptoms in the vast majority of people”. Vaccination 4 to 7 days after exposure likely offers some protection from disease or may modify the severity of disease.

Why get vaccinated?

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

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

Most Service Members have not been vaccinated against smallpox. The rest don't have much immunity left from vaccine given years ago. Until the late 1970s, many billions of people around the globe received smallpox vaccine. Smallpox vaccine is still used routinely to protect a small number of people who work with smallpox vaccine virus (*vaccinia*) or similar viruses.

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

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

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license for Dryvax® has been continuously in effect since 1931. FDA recently licensed a limited supply of smallpox vaccine made by Wyeth Laboratories, called Dryvax®. Smallpox vaccine used for Service Members will pass all tests required by the FDA.

Can I give blood after a smallpox vaccination?

Individuals who receive the vaccination and have no complications will be deferred from donating blood until the scab spontaneously separates (14-21 days after vaccination). In cases where a scab is otherwise removed, the donor may be deferred for two months after vaccination. In cases where a scab is otherwise removed, the donor may be deferred for two months after vaccination. Individuals with vaccine complications will be deferred until 14 days after all vaccine complications have completely resolved.

1.c. Smallpox - Vaccine Effectiveness.

How long does a smallpox vaccination last?

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

Who received smallpox vaccination in the past?

Smallpox vaccination of US military forces began in 1812. Smallpox vaccine has been given to millions of Americans, including Service Members during World War I, World War II, and until 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.

1. d. Smallpox Vaccine - Safety.

Is smallpox vaccine safe?

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

Why should I take this vaccine?

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

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

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

What are the temporary side effects after smallpox vaccination?

Mild reactions include swelling and tender lymph nodes that can last two to four weeks after the blister heals. Up to 20 percent of people develop headache, fatigue, muscle aches, pain, or chills after smallpox vaccination, usually about eight to 12 days later. Some individuals may have rashes that last two to four days. These side effects are usually temporary and self-limiting, meaning they go away on their own or with minimal medical treatment, for example aspirin and rest.

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

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

How should I care for the vaccination site?

Three Key Points:

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

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Vaccine virus is present at the vaccination site for about 14 to 21 days, until the scab falls off. This means other people can get infected if they come in contact with virus from your arm. You can infect others if you touch your blister and then touch another person.

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

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

Normal bathing can continue. Dry carefully, so the towel does not rub or spread virus elsewhere. Don't allow others to use that towel until laundered. Don't use public towels unless laundry workers are alerted that you were vaccinated. Use a waterproof adhesive bandage if you exercise enough to cause sweat to drip. Swimming can make the site soft and delay healing, so avoid swimming.

Take good care of your vaccination site.

What are the serious side effects after smallpox vaccination?

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

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

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

Can someone vaccinated against smallpox infect someone else?

Adverse reactions, sometimes severe, can also occur in people who come in contact with a vaccinated person. These problems result from touching the vaccination site and transferring the vaccine virus to another person. More information on this appears below.

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

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

- People whose immune system is not working fully (due to disease, medication, or radiation). Examples: HIV/AIDS, cancer, transplant, immune deficiency.
- People diagnosed with eczema or atopic dermatitis, now or earlier in life.
- Some people with other skin conditions, such as burns, impetigo, contact dermatitis, chickenpox, shingles, psoriasis, or uncontrolled acne, until the condition clears up.
- Women who are pregnant.
- People with a household contact who meets any of the conditions above.
- Breastfeeding mothers.
- People who had problems, such as allergies, after previous doses of smallpox vaccine or its ingredients.
- People who have been directly exposed to the smallpox virus should get the vaccine, regardless of their health status.

What if I am pregnant or breast-feeding?

As with most vaccination guidance, woman should be deferred routine smallpox vaccinations until after pregnancy. Most of the time, when pregnant women get smallpox vaccine, the pregnancy goes well. But in an outbreak, personal benefit from vaccination may outweigh the risks.

Refer women uncertain about pregnancy status for medical evaluation and ensure that you display a warning against unintentionally vaccinating pregnant women. Screen women of childbearing potential before immunization to avoid unintended vaccination during pregnancy.

There have been rare cases of infection of the fetus (unborn baby) with the vaccine material. Most of these cases occurred in women who received the vaccine for the first time. When fetal vaccinia does occur, it usually results in stillbirth. Fewer than 50 such cases around the world were reported over the last 100 years. As far as we know, smallpox vaccine does not cause a fetus to be malformed.

Minimize close contact with infants < 1 year of age. People with infants < 1 year old in their household should be vaccinated only if alternate care-giving arrangements are observed until scab falls off. Be sure to wash hands before handling infant (e.g., feeding, changing diapers).

Smallpox vaccine is not recommended for nursing mothers, unless an outbreak occurs and personal benefit from vaccination outweighs the risk. Breast-feeding is not a

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medical contraindication to any immunization but could put the infant in close contact with the mother's vaccination site.

Should men defer fathering a child after receiving the smallpox vaccine?

There is no reason for men to defer starting a family.

Should women wait to get pregnant after getting vaccinated against smallpox?

Woman receiving a smallpox vaccination should avoid becoming pregnant for four weeks after their smallpox vaccination.

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

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

1. e. Smallpox In The Environment.

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

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

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 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.

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

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

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

The most important steps to stop a smallpox epidemic are case isolation and contact tracing and vaccination.

Patients showing signs of smallpox are capable of spreading the virus. Patients should be placed in medical isolation so that they will not continue to spread the virus. In addition, people who have come into close contact with smallpox patients should be vaccinated immediately and closely watched for symptoms of smallpox. Vaccination and isolation are the key strategies for stopping the spread of smallpox.

2. For Health-Care Providers.

2. a. Smallpox Vaccine Safety - Health-Care Providers (HCP).

Besides the normal side effects covered already, is there more information I need to know as a health-care provider?

Inadvertent inoculation at other sites is the most frequent complication of vaccinia vaccination. It accounts for about half of all complications of primary (first) vaccination and revaccination. Inadvertent inoculation usually results from auto-inoculation of vaccinia virus, transferred from the site of vaccination. The most common sites involved are places that itch: the face, eyelids, nose, mouth, genitalia, and rectum.

Most auto-inoculation lesions heal without specific therapy, but vaccinia immune globulin (VIG) can help treat cases of ocular implantation. However, if vaccinia keratitis is present, VIG is barred (contraindicated) because it might increase corneal scarring.

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

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How does the smallpox vaccination interact with other drugs?

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

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

The Advisory Committee of Immunization Practices (ACIP) accepts administration of live and inactivated vaccines simultaneously or at any interval.

The only major restriction to combining vaccinations is with multiple live-virus vaccines. In this case they should either be given simultaneously or separated by 28 days or more.

Health care providers should separate varicella (chickenpox) and smallpox (vaccinia) vaccinations by 28 days, to avoid confusing lesions.

Do not administer other vaccines near smallpox site.

What about moderate to severe adverse reactions?

Moderate and severe complications of vaccinia vaccination include eczema vaccinatum, generalized vaccinia, progressive vaccinia, and postvaccinial encephalitis. These complications are rare, but occur more often among primary vaccinees than among revaccinees. These serious skin complications also are more frequent among infants than among older children and adults. A study of Israeli military recruits aged 18 years or older, who were vaccinated during 1991 and 1996, reported rates of progressive vaccinia (0 out of 10,000 vaccinees) and postvaccinial encephalitis (0 out of 10,000 vaccinees) similar to those reported in previous studies.

What is eczema vaccinatum?

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

What is generalized vaccinia?

Generalized vaccinia involves a vesicular rash of varying extent that can occur among people without underlying illnesses. The rash is generally self-limited and requires minor or no therapy, except among patients whose conditions might be “toxic” (as it refers to

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children) or who have serious underlying immunosuppressive illnesses (e.g., acquired immunodeficiency syndrome [AIDS]).

What is progressive vaccinia?

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

What is postvaccinial encephalitis?

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

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

What should we ask about before people get smallpox vaccine?

Before smallpox vaccination, ask people if they have any problems with their immune system (e.g., due to cancer treatment, transplantation, AIDS, other conditions), if they are infected with HIV, if they have atopic dermatitis or other chronic skin conditions, or if they had atopic dermatitis as a child.

Who is exempt (contraindicated) from smallpox vaccine?

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

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

2. b. How To Administer Smallpox Vaccine - HCP.

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

Use skin over the insertion of the deltoid muscle (preferred) or the posterior aspect of the arm over the triceps muscle for smallpox vaccination. Cleansing of the vaccination site may be performed with soap and water, followed by water only, and then drying. Acetone or alcohol may be used only if adequate time is allowed for it to evaporate or if the site is wiped dry with (non-sterile) gauze to prevent unintentional inactivation of the live virus vaccine. Acetone may be preferred over alcohol, because acetone evaporates more quickly.

The multiple-puncture technique uses a sterilized bifurcated needle inserted vertically into the vaccine vial, causing a droplet of vaccine to adhere between the needle prongs. The droplet contains the recommended dosage of vaccine. Confirm the presence of the droplet between the prongs visually. Holding the bifurcated needle perpendicular to the skin, make 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.

Leave the site uncovered, if the individual is thoroughly counseled about the hazards of touching the vaccination site. Alternately, cover the site with a loose bandage to deter touching the site and perhaps transferring virus to other parts of the body.

2. c. Treating Complications of Smallpox Vaccination - HCP.

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

Recognition of a serious adverse event after smallpox vaccination will be infrequent, but of high consequence to the patient. Consult as appropriate with allergy-immunology, infectious-disease, dermatology, neurology, or specialist(s).

Some conditions respond to vaccinia immune globulin (VIG). Eczema vaccinatum, progressive vaccinia, severe ocular vaccinia, severe generalized vaccinia. VIG not effective in treating post-vaccinial encephalitis.

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

Once a definite or probable diagnosis of a medication-indicating adverse event has been made by a qualified provider (e.g., infectious-disease, dermatology, allergy-immunology physician), that military provider may request use of VIG for a named patient by telephoning USAMRIID at 1-888-USA-RIID or 301-619-2257. Healthcare

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providers from civilian institutions should contact the CDC Drug Service for VIG or cidofovir: CDC Drug Service, National Center for Infectious Diseases, Mail stop D-09, Atlanta, GA 30333; 404-639-3670, fax 404-639-3717.

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

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

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

2. d. Evidence of Immunity and Vaccination-Response Interpretation.

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

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

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

- (a) a major reaction, which indicates that virus replication has taken place and vaccination was successful; or
- (b) an equivocal reaction, which either indicates (1) a possible consequence of immunity adequate to suppress viral multiplication or (2) allergic reactions to an inactive vaccine without production of immunity.

What is a “major reaction”?

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

- a. The inoculation site becomes reddened and itchy 3 to 4 days after vaccination.
- b. A vesicle (blister) surrounded by a red areola then forms, which becomes umbilicated (sunken center) and then pustular (pus-filled) by days 7 to 11 after vaccination.
- c. The pustule begins to dry, the redness subsides, and the lesion becomes crusted between the second and third week.
- d. By the end of about the third week, the scab falls off, leaving a permanent scar that at first is pink in color, but eventually becomes flesh-colored.

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

What is an “equivocal reaction”?

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

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

2. e. Vaccination Site Care - Health-Care Providers

Are there precautions I can take as a health-care provider to help my patients avoid spreading smallpox vaccine virus to others?

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

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

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

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

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3. Smallpox – Policy/Threat

Why are we vaccinating servicemembers?

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

Who in DoD is going to get the smallpox vaccine?

The Secretary of Defense has decided at this time to vaccinate certain emergency response and medical personnel and other designated personnel that constitute critical mission capabilities, to include those essential to the accomplishment of U.S. Central Command's missions. The Department may expand the program at a later date.

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

Will servicemembers still be deployable if they have not received the smallpox vaccine?

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

What if somebody has already been vaccinated?

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

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

Will family members be allowed to get the smallpox vaccine?

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We are continuing to develop procedures to offer vaccine, on a voluntary basis, to certain DoD family members and non-essential civilian personnel. Our procedures will be consistent with FDA guidelines for use of the vaccine and our need to protect mission critical capabilities of the Department of Defense. It remains the Department's policy to evacuate non-emergency essential civilians and family members from threat areas in crisis situations.

How much vaccine does the DoD have?

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

The threat is low, why is the Department of Defense administering the smallpox vaccine?

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

What will happen to a servicemember who refuses the vaccine?

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

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

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

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

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

Questions and Answers

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

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.

How dangerous is the smallpox threat?

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

Does Iraq have smallpox?

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

What other countries have smallpox?

It is possible, but not confirmed, that a number of other countries may possess the virus that causes smallpox, but we are not going to delineate them at this time. After eradication the only places authorized to possess the virus are high containment civilian government laboratories in the Russian Federation and the U.S. The virus was allowed to be retained for scientific purposes. Anyone else possessing the virus is breaching an international agreement with the World Health Organization, an official instrument of the United Nations.

Does Al Qaida have smallpox?

It is unlikely that Al Qaida at this time possesses the virus that causes smallpox.

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

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

Questions and Answers

Questions and Answers for Household Members and Household Pets

I just received my smallpox vaccination. How do I care for the injection site?

Three key points:

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

Vaccine virus is present at the vaccination site for about 14 to 21 days, until the scab falls off. This means other people can get infected if they come in contact with virus from your arm. You can infect others if you touch your blister and then touch another person.

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

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

Normal bathing can continue. Dry carefully, so the towel does not rub or spread virus elsewhere. Don't allow others to use that towel until it is laundered. Don't use public towels, unless laundry workers are alerted that you were vaccinated. Use a waterproof adhesive bandage, if you exercise enough to cause sweat to drip. Swimming can make the site soft and delay healing, so avoid swimming.

Take good care of your vaccination site.

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

If possible, wear clothing that is washable with hot soapy water (with bleach, if desired) Keep your personal linens separate (e.g., towels) from the rest of the family's.

How much personal protective equipment is needed by laundry workers?

If laundry workers wear gloves, this is sufficient protection.

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

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

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

Vaccination of breast-feeding mothers is not recommended, except under emergency conditions, because the infant might come in contact with the vaccination site.

The Advisory Committee on Immunization Practices recommends that parents that caring for infants and young children take extra care of their vaccination sites. The site should be covered with gauze or a similar absorbent material, and a shirt or other clothing should be worn. Pay careful attention to hand hygiene (hand washing).

Alternate care-giving arrangements for infants and young children is preferred, until the scab at the injection site falls off.

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

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

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

In the history of smallpox and its eradication, there are no reported instances of direct or indirect transmission of the disease between animals and man. However, Vaccinia virus, the live-virus used to vaccinate humans to prevent smallpox, has been experimentally shown to infect a wide variety of animals. The risk of transmission of the Vaccinia virus from a recently immunized person to animals and the possible clinical signs in animals is currently unknown. There are no restrictions for recently vaccinated people in regards to contact or handling of animals. To minimize potential animal or human risk of transmission, immunized persons handling animals should practice the same precautions that they would use to prevent spread to another person (covering the vaccination site as prescribed, frequent hand washing, not letting animals have any direct contact with the vaccination site or the bandages/clothing/bed sheets that touch the scab, etc.).

Questions and Answers

LINEN PRECAUTIONS FOR HOSPITAL WORKERS & INSTITUTIONAL SETTINGS AFTER SMALLPOX VACCINATION

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

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

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

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

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

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).

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.

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

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

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

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some of the towels come from recently vaccinated people, you may deposit it in the institutional laundry bag.

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

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

How much personal protective equipment is needed by laundry workers?

If laundry workers wear gloves, this is sufficient protection.

Remember: Hand washing, Hand washing, Hand washing.