ANNEX E TO SMALLPOX RESPONSE PLAN 29 September 2002
COMMUNICATIONS PLANS AND ACTIVITIES.

REFERENCES.

a. CDC Smallpox Response Plan, Guide E, Communications Plans and Activities, 23 September 2002. http://www.bt.cdc.gov/DocumentsApp/Smallpox/RPG/GuideE/Guide-E.doc.

b. United States Army. Army Crisis Communications Preparation Guide. Washington, DC: January 1999. http://www.dtic.mil/armylink/apac/Documents/crisiscommguide.pdf.

1. General. This DoD Annex implements reference a. Appendix E-1 summarizes CDC Guide E and this DoD Annex on one page.

a. Mission: Public affairs officers (PAOs) throughout DoD will use risk-communication principles as they inform and educate relevant audiences about smallpox infection, its symptoms, and consequences. PAOs will also educate relevant audiences about important health strategies to prevent and control smallpox (e.g., vaccination, contact tracing, isolation). Further, PAOs will support and augment the Centers for Disease Control & Prevention's Joint Information Center (JIC), to respond to media queries relating to military support to civilian authorities.

b. Assumption: The first suspected or confirmed case of smallpox will generate intensive local, regional, state, national, and international media interest. Dealing with a smallpox outbreak will require extensive communications activities among numerous government agencies.

c. Background: Reference a outlines CDC plans and activities before and after a smallpox outbreak. This document reflects CDC goal of synchronizing messages from federal agencies ("speaking with one voice"). Reference b provides suggestions for developing installation communications plans and stakeholder-involvement plans for dealing with emergency situations.

d. Coordination. PAOs will coordinate with representatives of the Lead Federal Agency during a smallpox outbreak.

2. Communications Objectives.

a. To instill and maintain public confidence in the DoD leadership's credibility, its healthcare system, and its ability to work in coordination with civilian authorities to respond to, and manage, a smallpox outbreak. Public messages from DoD will provide accurate, rapid, and complete information to educate, calm fears, and maintain public order.

b. To minimize, as much a possible, public panic and fear related to smallpox.

c. To rapidly provide the public, healthcare providers, policymakers, and the media access to accurate, consistent, and comprehensive information about smallpox, smallpox vaccine, and the management of the situation.

d. To address, as quickly as possible, rumors, inaccuracies, and misperceptions.

e. To provide accurate, consistent, and highly accessible information and materials through the coordination of communication efforts with other federal, state, and local partners.

3. Strategies.

a. Support timely and aggressive education for military members, DoD civilians, retirees, and their families about smallpox.

b. Ensure the public and media perceive that the military and public health systems are prepared for such contingencies and are working to treat those affected and to contain the disease. This would be demonstrated by establishing stakeholder-involvement plans before an outbreak.

c. Ensure all services have credible and trained spokespersons to answer media, Congressional, and public queries related to the military's support of the CDC's efforts.

d. Encourage media and other interested parties with questions to use DoD and CDC websites (e.g., www.bt.cdc.org).

e. Leverage all DoD communications tools and products to support the CDC's efforts and to educate the various publics.

f. Decentralize information to the lowest level, empowering local commands to provide answers to media and other public inquiries about the military's support of CDC's efforts as well as the military's handling of any cases that occur on military installations.

4. Communication Challenges and Threats. To address these challenges, the Military Vaccine Office developed message maps to guide future communications (Appendix E-2). Appendix E-3 provides extensive questions and answers on smallpox and smallpox vaccine. Additional specific communication tools will be developed.

a. Identifying source of outbreak.

b. The subtle differences between quarantine, isolation, and restriction of movement.

c. The purpose of contact tracing and surveillance.

d. Prioritization for immunization priorities.

e. Counteracting misinformation, controlling rumors and minimizing alarm.

5. Primary Audiences and Stakeholders.

a. U.S. military personnel, including active duty, reserve components, civilians and contractors.

b. Family members and other healthcare beneficiaries.

c. DoD leadership.

d. Congress and the Executive Branch.

e. Government civilian agencies that respond to terrorist events.

f. American public via public media.

6. Responsibilities:

a. Office of the Assistant Secretary of Defense (Public Affairs).

(1) Provide Public Affairs Guidance (PAG), including expected questions and answers.

(2) Respond to incoming media inquiries on DoD-wide policy issues.

(3) Coordinate media interviews with DoD personnel and subject matter experts.

b. Office of the Assistant Secretary of Defense (Health Affairs).

(1) Engage internal and external (third-party) experts to explain the science underlying DoD smallpox policies.

(2) Take action necessary to maintain public confidence in the DoD healthcare system, and its ability to work in coordination with civilian authorities to respond to and manage a smallpox outbreak.

(3) Address as quickly as possible, rumors, inaccuracies, and misperceptions by providing accurate, consistent, and highly accessible information and materials.

(4) Conduct education programs with targeted information products for Active and Reserve Components, DoD civilians, retirees and their families about smallpox and the smallpox vaccine

(5) Inform key executive and legislative branch leaders of DoD's operations, plans, and policies.

c. Services' Chief of Public Affairs Office.

(1) Prepare and distribute press releases, in coordination with DoD, if an outbreak develops and as it progresses. Additional involvement needed for outbreaks directly affecting military installations.

(2) Create and maintain an on-going crisis communications plan.

(3) Create and distribute PAG and other informational products as needed to Services' major commands and other subordinate units.

(4) Prepare advisories and respond to media queries.

(5) Train senior leadership to respond to smallpox interview questions.

(6) Post appropriate messages/articles about smallpox on the Service websites.

(7) Support smallpox education efforts in Service command information products and ensure all products include the CDC's website: www.bt.cdc.org.

d. Public Affairs Offices Supporting the Service Surgeons General.

(1) Provide PAG and all other products to Service Medical Department family PAOs, to assist in answering media queries.

(2) Encourage each Military Treatment Facility (MTF) commander to act as a media spokesperson and/or to identify a subject matter expert for local media queries.

(3) Coordinate with DoD agencies and CDC subject matter experts to respond to requests for interviews.

(4) Design or modify websites with smallpox information, updates, fact sheets, frequently asked questions and answers, and healthcare provider resources, including patient and public education materials. DoD's Military Vaccine Office is coordinating this work now, in advance of any outbreak.

(5) Monitor public media for articles and inform leadership of stories that have high impact on the medical department(s).

(6) Provide public-affairs advice to all agencies that request assistance.

e. Installation Public Affairs Offices.

(1) Identify PAO representatives to augment the CDC's Joint Information Center once established.

(2) Respond quickly and accurately to requests for information about the military's support of CDC.

(3) Use all available command information tools to educate the public on smallpox.

(4) Establish contact with the CDC's Field Communications Media Liaison, who will serve as the principal CDC media advisor in the field, and assist the CDC smallpox response team leader in serving, as appropriate, as a media spokesperson.

(5) Design or modify websites with smallpox information, updates, fact sheets, frequently asked questions and answers, and healthcare provider resources, including patient and public education materials. Support for this effort will come from DoD's Military Vaccine Office.

(6) Monitor public media for articles and inform leadership of stories that have high impact on the medical command.

(7) Provide public affairs advice to all agencies that request assistance.

f. Healthcare Providers: Augment their own knowledge of smallpox disease and smallpox vaccination, to ensure their ability to answer soldiers' questions and relieve anxiety.

APPENDIX E-1
Communications Plans and Activities – Summary.

1. The Office of the Assistant Secretary of Defense (Public Affairs) will:

a. Provide Public Affairs Guidance (PAG), including questions and answers.
b. Respond to incoming media inquiries on DoD-wide policy issues.
c. Coordinate media interviews with DoD personnel and subject matter experts.
d. Coordinate with Lead Federal Agency.

2. The Office of the Assistant Secretary of Defense (Health Affairs) will:

a. Engage medical experts to explain the science underlying DoD smallpox policies.
b. Address inaccuracies and misperceptions with accurate, consistent information.
c. Conduct education programs with targeted information products.
d. Inform key executive and legislative branch leaders of DoD's plans and policies.

3. Service Public Affairs Offices will:

a. Prepare and distribute press releases.
b. Create and maintain an on-going crisis communications plan.
c. Create and distribute PAG and informational products commands and units.
d. Prepare advisories and respond to media queries.
e. Train senior leadership to respond to smallpox interview questions.
f. Post appropriate messages or articles about smallpox on Service websites.
g. Support smallpox education efforts in Service command information products.

4. Public Affairs Offices Supporting the Service Surgeons General will:

a. Provide PAG and other products to Service Medical Department family PAOs.
b. Encourage commanders to identify subject matter expert for media queries.
c. Coordinate with DoD agencies and CDC experts to respond to requests.
d. Design or modify websites to provide smallpox information.
e. Monitor public media for articles and inform leadership of relevant stories.
f. Provide public-affairs advice to all agencies that request assistance.

5. Installation Public Affairs Offices will:

a. Identify PAO representatives to augment the CDC's Joint Information Center.
b. Respond accurately to requests for information about the military's role.
c. Use command information tools to educate the public on smallpox.
d. Establish contact with the CDC's Field Communications Media Liaison.
e. Design or modify websites to provide smallpox information.
f. Monitor public media for articles and inform leadership of relevant stories.
g. Provide public affairs advice to all agencies that request assistance.

APPENDIX E-2
Smallpox Message Maps

Smallpox Message Maps

Key Messages:

I. Smallpox would disrupt military missions, because it is contagious and deadly.

II. Smallpox vaccine prevents smallpox, but requires very careful use.

III. Preserving the health and safety of our people are our top concerns.

IV. Smallpox protection helps our War on Terrorism: New threats require new measures of force protection.

I. THREAT. SMALLPOX WOULD DISRUPT MILITARY MISSIONS, BECAUSE IT IS CONTAGIOUS AND DEADLY.

1. Disruptive.
2. Contagious.
3. Dangerous.

1. Disruptive. A smallpox outbreak would significantly affect military readiness.

a. A smallpox outbreak could cause many casualties among unvaccinated troops, disrupting a unit's ability to perform its mission.
b. If a smallpox outbreak occurred, troops would not be able to cross international borders until they had been vaccinated.
c. A smallpox outbreak would stress military medical operations, because there is no way to cure the smallpox patients.
d. Most Service Members entering military service after 1984 have never been vaccinated against smallpox. The rest were vaccinated 15 to 20 years ago, and are susceptible to infection. `

2. Contagious. Smallpox is a contagious disease that spreads from one person to another.

a. A germ called variola virus causes smallpox infection.
b. Smallpox spreads slowly, usually by face-to-face contact for an hour or more with a contagious person.
c. People with smallpox become contagious just before a rash begins, just after their temperature goes over 101°F (38.3°C). They stay contagious until all their scabs fall off.
d. Contact with infected skin could also transmit the virus. Smallpox can be spread by contact with inanimate objects (such as clothing, towels, linens), but this would be uncommon.
e. Not everybody who is near 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 3 to 5 other people. Those other people begin to show symptoms 7 to 17 days after they are infected (usually 12 to 14 days).
f. Smallpox is not known to be transmitted by insects or animals.

3. Dangerous. Before smallpox was eradicated, it killed many millions of people over hundreds of years.

a. About 3 out of every 10 people infected with smallpox died.
b. Survivors were often permanently scarred or, rarely, blinded.
c. There is no accepted way to treat smallpox. Medications can help control the pain and fever.

II. VACCINE. SMALLPOX VACCINE PREVENTS SMALLPOX, AND WE WILL USE IT VERY CAREFULLY.

1. Efficacy. The World Health Organization (WHO) used smallpox vaccine to eradicate natural smallpox from the planet.
2. Expected Effects and Side Effects. All vaccines cause side effects, but smallpox vaccine causes a unique reaction at the vaccination site.
3. Care of the Vaccination Site. Smallpox vaccination leaves vaccine virus on the surface of the skin, so you have to be careful not to touch the smallpox vaccination site. You don't want to spread the virus somewhere else.
4. Side Effects--Serious. Very rarely, smallpox vaccine can cause serious side effects.
5. Exemptions to Vaccination. Some people should not get smallpox vaccine, except in an outbreak.
6. Smallpox Vaccine**.** The Defense Department will use smallpox vaccine licensed by the Food & Drug Administration (FDA).

1. Efficacy. The World Health Organization (WHO) used smallpox vaccine to eradicate natural smallpox from the planet.

a. Smallpox vaccine is so effective that it eradicated the natural disease from the planet.
b. After a single smallpox vaccination, about 95% of people develop protection within 10 days.
c. Smallpox vaccination up to 3 days after someone is exposed to smallpox virus will prevent or reduce the severity of smallpox in most people. Vaccination 4 to 7 days after exposure likely offers partial protection.
d. Solid protection lasts for 3 to 5 years after first vaccination. Solid protection after revaccination lasts about 10 years. Partial protection lasts longer, but people need to be revaccinated if too much time has passed.
e. Published studies show that diluted smallpox vaccine is as effective as full-strength vaccine.
f. Smallpox vaccine contains live vaccinia virus, which produces an immune response that protects against variola virus, the virus that causes smallpox. Smallpox vaccine cannot cause smallpox.

2. Expected Effects and Side Effects. All vaccines cause side effects, but smallpox vaccine causes a unique reaction at the vaccination site.

a. After smallpox vaccination, a red blister appears that should turn white 6 to 8 days after vaccination. Then it will turn into a scab. This shows successful vaccination.
b. 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.

1. Most people feel a stinging or burning sensation right after vaccination that lasts less than a minute.
2. The lymph nodes in the armpit of the vaccinated arm or in the neck may become large and painful for a week or so.
3. The vaccination site should become tender, red, and itchy. A blister will form there, and then fill with pus. When the scab dries and falls off on its own, after about 2 to 3 weeks, a permanent scar remains.

3. Care of the Vaccination Site. Smallpox vaccination leaves vaccine virus on the surface of the skin, so vaccine recipients must be careful not to spread the virus to other areas of the body.

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.

a. 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 spread the virus if you touch your blister and then touch the other person.

1. Vaccine virus can also spread to close contacts by touch. In the 1960s, the risk of spreading vaccine virus to a contact was about 30 per 1,000,000 vaccinations. This spread usually involved a household member, most often from child to child.
2. Wash your hands frequently and don't touch a smallpox vaccination site. These are the best ways to avoid spreading vaccine virus. An information sheet describes how to care for the site.
3. Until the scab falls off, avoid close or household contact with people who cannot receive the vaccine. Do not share sleeping space with these people. Do not share clothes, towels, linen, or toiletries.

b. Most vaccination sites can be left unbandaged, especially when not in close contact with other persons. Airing will help speed healing of the vaccination site. 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, to kill the virus.

c. Keep the site dry. Airing will speed healing. Do not use creams or ointments because they will delay healing. Long-sleeved 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.

d. Normal bathing can continue. Dry the vaccination site last, 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. Avoid getting the site wet in pools or spas.

e. Take good care of your vaccination site.

i. Avoid activities that complicate site care and cleanliness while the site heals. Arrange clothing and load-bearing equipment to avoid excessive pressure or rubbing at site. Avoid contact sports, such as wrestling. Avoid immersion in public pools or spas.

ii. Today, more people in the community have problems with their immune systems. Follow instructions to reduce the chance of spreading vaccine virus to these people.

iii. The risk of complications after smallpox vaccination for people infected with human immunodeficiency virus (HIV) is not known. At present, there is no evidence that smallpox vaccination speeds up HIV-related disease. Even so, people infected with HIV should not be vaccinated, except in an outbreak.

iv. Most cases of contact vaccinia do not lead to serious illness. However, some lead to a severe skin infection in people who have atopic dermatitis, eczema, or other chronic skin problems.

4. Side Effects-Serious. Very rarely, smallpox vaccine can cause serious side effects.

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

b. 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.

i. If 1,000,000 adults got smallpox vaccine for the first time, about 40 would develop a severe skin reaction. Among these 1,000,000 adults, about 4 would develop swelling of the brain (encephalitis). If 1,000,000 adults got smallpox vaccine, 1 or 2 could die. Serious side effects are generally more rare after revaccination, compared to first vaccinations.

ii. About 40 serious skin reactions happened for each 1,000,000 adults vaccinated in the 1960s. Some reactions were more common in people whose immune system was not working fully or in people who had atopic dermatitis, eczema, or other chronic skin conditions. The severe skin reactions can be treated with injections of human antibodies called “vaccinia immune globulin” or VIG.

iii. About 4 serious neurologic reactions (like encephalitis) happened for each 1,000,000 adults vaccinated in the 1960s. There are no known risk factors for encephalitis and there are no known treatments.

iv. These side-effect rates are based on data collected in the United States during the 1960s, when about 300,000 adults got their first smallpox vaccination and over 4,000,000 adults got repeat smallpox vaccinations (revaccinations).
v. DoD's experience in the 1970s and 1980s was about 54 complications (hospitalizations) per 1,000,000 vaccinations. We know of no confirmed deaths due to smallpox vaccination from that time, but three deaths were linked with smallpox vaccination of World War II soldiers.

c. Serious side effects are generally more rare after revaccination, compared to first vaccinations.
d. We will try to reduce the risk of side effects by actively looking for and exempting out people whose immune system is not working fully and people who have or had certain skin conditions.

5. Exemptions to Vaccination. Some people should not get smallpox vaccine, except under emergency situations.

In a smallpox outbreak, all people who are exposed to smallpox should get vaccine. When it is not an emergency outbreak situation, some people should not get smallpox vaccine, including:

a. People whose immune system is not working fully (due to disease, medication, or radiation). Examples: HIV/AIDS, cancer, transplant, immune deficiency.
b. People diagnosed with eczema or atopic dermatitis, now or earlier in life.
c. Some people with other skin conditions, such as burns, impetigo, contact dermatitis, chickenpox, shingles, psoriasis, or uncontrolled acne, until the condition clears up.
d. Pregnant women and breastfeeding mothers.
e. People with a household contact who meets any of the conditions above.
f. People who had problems, such as allergies, after previous doses of smallpox vaccine or its ingredients.

Usually, when pregnant women get smallpox vaccine, the pregnancy goes well. But there have been rare cases of infection of the fetus (unborn baby) with the vaccine virus. 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.

g. Smallpox vaccine is not recommended for nursing mothers, except in an outbreak. Breast-feeding is not a medical exemption to any immunization, but breast-feeding could put the infant in close contact with the mother's vaccination site.

h. In a smallpox outbreak, even people who otherwise would avoid vaccination should be vaccinated, if they were exposed to the virus or to someone contagious with smallpox.

6. Smallpox Vaccine. The Defense Department will use smallpox vaccine licensed by the Food & Drug Administration (FDA).

a. Smallpox vaccine contains live vaccinia virus, which produces protection against smallpox. The vaccine was prepared on calfskin. The calves' lymph was purified, concentrated, freeze-dried, and stored in a freezer until recently when it was thawed and prepared for use.
b. This same vaccine was administered to Service Members during World War I, World War II, and until the 1980s.
c. FDA recently licensed a limited supply of smallpox vaccine made by Wyeth Laboratories, called *Dryvax*®. The vaccine had been stored in a freezer since the late 1970s. Recent tests show that this vaccine still protects well against smallpox. Vaccine used for Service Members passes all tests required by the FDA.
d. If there is a smallpox outbreak, the Defense Department might run out of FDA-licensed smallpox vaccine. In that case, the Food and Drug Administration (FDA) will authorize DoD use previously licensed smallpox vaccine, but it must be called "investigational" and DoD must tell you how it differs from licensed vaccine.
e. Here are the ways the investigational vaccine differs from licensed vaccine:

    i. Today, five times more liquid than was used in the past is mixed with the vaccine. This helps to make the vaccine available to more people. This is the main difference. This diluted vaccine contains only one-fifth as much vaccinia virus as full-strength vaccine. Even so, studies show that this is enough virus for the vaccine to work.
    ii. The liquid used to dilute the vaccine no longer contains a colored dye. Both the vaccine and its diluent have passed all FDA tests.

III. CONCERN. PRESERVING THE HEALTH AND SAFETY OF OUR PEOPLE IS OUR TOP CONCERN.

1. Healthy troops complete their missions. Vaccines will keep you and your team healthy.
2. Vaccines have kept troops healthy since the days of George Washington.
3. Vaccination offers a layer of protection that adds to other measures used to protect certain members of the Armed Forces.

1. Healthy troops complete their missions. Vaccines will keep you and your team healthy.

a. Vaccines shield you from dangerous germs. These germs can kill you or cause lasting harm. Vaccines prevent infections, such as tetanus, typhoid fever, measles, yellow fever, smallpox, and anthrax, to name just a few.
b. Vaccines keep units fit to fight. We fight as a team. All team members must be healthy. That is why vaccinations are mandatory.
c. Vaccines benefit both individuals and units. Vaccines keep people healthy so they can live better lives. Vaccines keep people healthy so they can do their mission. Vaccines help you return home healthy.

2. Vaccines have kept troops healthy since the days of George Washington.

a. George Washington protected his troops from smallpox in 1777 using a forerunner of vaccination called “variolation.”
b. We lost the Battle of Quebec in 1776 because our troops weren't protected against smallpox. Americans suffered 5,500 smallpox casualties among 10,000 continental troops. The task force commander, Major General John Thomas, died of smallpox.
c. From 1777 to today, vaccines have prevented American troops from dangerous infections. Typhoid vaccine reduced typhoid casualties from 20,000 in the Spanish-American War of 1898 to just 1,500 in World War I. During all of World War II, only 12 cases of tetanus occurred among vaccinated US troops, but numerous tetanus deaths occurred among the unvaccinated German troops.
d. Vaccines are among the most important accomplishments in medicine. Vaccines have saved more lives throughout the world than any other medical invention. Vaccines have saved more lives than antibiotics or surgery. Only clean water has saved more lives than vaccines.

3. Vaccination offers a layer of protection that adds to the other measures used to protect certain members of the Armed Forces.

a. We protect troops by using detection devices, protective gear, and in other ways.

b. But these means of Force Health Protection have their limitations. People can't stay in protective gear for days on end and perform well. Our best bioweapon detectors don’t work fast enough to prevent exposure to the smallpox virus. There is no treatment for smallpox.
c. Vaccines are one of our best ways to keep you healthy. The President directed us to use safe and effective vaccines to protect against bioweapons and deployment infections.
d. Vaccines provide the only round-the-clock protection.
e. Vaccines, combined with other measures, offer the best chance for individual survival and mission accomplishment.

IV. Big Picture. Smallpox vaccination of military personnel is part of our national strategy to safeguard Americans against smallpox attack.

Smallpox protection helps our War on Terrorism: New threats require new measures of force protection.

1. The Defense Department is working with other federal departments to strengthen America's defenses against smallpox.

a. Intentional release of smallpox virus as a bioweapon could result in smallpox cases over a wide area. Disease could cross boundaries, from military to civilian communities, and vice versa. Major disruptions in civil, political, medical, and economic order could follow.
b. The World Health Organization used smallpox vaccine to eradicate natural smallpox. Current supplies of smallpox vaccine are limited because production ceased in the early 1980s. Additional supplies of smallpox vaccine are being produced now, using modern production methods.
c. The federal government ordered enough smallpox vaccine to protect every American in a potential bioterrorist attack.

2. The government has been preparing for years for the remote possibility of an outbreak of smallpox as an act of terror.

a. These preparations quickened after September 11, 2001. Although we are planning for this possibility to protect public health, we have no indication that there is an imminent threat.
b. If there is a smallpox outbreak, only people in the outbreak area might need vaccination. If this limited vaccination is not enough to contain the spread of smallpox, vaccination of a wider group of people might be needed.
c. One suspected case of smallpox is considered a public health emergency. Smallpox surveillance in the United States includes detecting the infection and preventing further spread. A suspected smallpox case should be reported immediately by telephone to health officials.

APPENDIX E-3
Common Questions & Answers.

Table of Contents.

1. a. Smallpox - The Disease.

What is smallpox?

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

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

Smallpox can cause:

- A severe rash covering the whole body that can leave permanent scars.
- High fever.
- Severe headache or 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,

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.

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

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 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?

This same 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?

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.

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 a 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.

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 and breastfeeding mothers.
- People with a household contact who meets any of the conditions above.
- 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

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 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 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.

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 vaccinial 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.

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

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.

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

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”?

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:

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.

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 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.

Will family members be allowed to get the smallpox vaccine?

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

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?

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?

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.