

PROTECTING AMERICANS: Smallpox Vaccination Program

Smallpox Q&A – Table of Contents

Smallpox response teams.....	page 3
General public	page 6
Military personnel	page 8
State Department and overseas issues.....	page 11
Smallpox disease	page 13
Smallpox vaccine.....	page 15
Smallpox vaccine safety.....	page 18

Smallpox Response Teams

Why vaccinate health care workers and first responders?

We're asking these groups to volunteer to serve on smallpox response teams to help our country respond in the event of an attack. By vaccinating groups of health care workers and emergency responders, we will make sure that smallpox response teams are available who can vaccinate others and provide critical services in the days following an attack. This approach will make us better able to protect the American people in an emergency, which is our highest priority.

What will the smallpox response teams do?

Members of the Smallpox Response Teams will include people who will administer the smallpox vaccine in the event of an emergency and will be the first to investigate and evaluate initial suspected case(s) of smallpox and initiate measures to control the outbreak.

HHS and CDC will continue to advise and assist states in development of these teams.

How will the government decide who should serve on a smallpox response team?

State officials – in consultation with CDC and local health departments – are working to identify health care workers and first responders who could serve on response teams following a smallpox release. Participation on these teams and in the vaccination program is purely voluntary.

How many first responders and health care workers will be vaccinated?

We have asked states to identify workers who might serve on smallpox response teams to vaccinate others and provide critical services in the days following an attack. We are working with states to determine the exact number of individuals who will fall in these categories. To protect the American people, the important thing is to ensure that we have health care workers and first responders ready to serve as smallpox response teams. However, we expect that some of the people identified by the states will not be eligible for vaccination because of a medical condition, and others may choose not to be vaccinated.

It has been reported that we will be vaccinating up to 10 million health care workers and first responders. However, we do not expect that the numbers of first responders and health care workers vaccinated in this part of the program to be that high.

Are we less prepared to protect the American people if we don't get participation from millions of public health and health care workers or first responders?

Whatever the number of people who choose to participate and get vaccinated, we will be much more prepared to protect the American people than we are today.

Also, the very fact that states, hospitals and communities will have vaccination plans – for emergency responders and for mass-vaccinating the general public – makes us better prepared to protect Americans in an emergency.

These efforts will increase deterrence.

Will you administer tests to ensure that health care workers and first responders receiving the vaccine are not pregnant or HIV positive?

Every person volunteering to receive the vaccine will be asked detailed questions regarding their medical history and physical health and will be educated to the risks and possible side effects of the vaccine. If there is any indication that a person has a contraindication for the vaccine, the individual will be referred to the local public health department or another health care provider for testing.

How can a person protect against the risk of inadvertent transmission of the vaccine to another person?

Anyone receiving the vaccine will be instructed on several readily available steps to prevent the accidental transmission of the vaccine to another person. For example, the vaccinated person should use breathable bandages, wear a long-sleeve shirt, and use good hand hygiene.

How will the government monitor and report side effects?

The CDC is enlisting an outside group that will constitute an external data monitoring and safety review board. This external review board will review, in real time, vaccine adverse event reports and data, interpret findings, and provide guidance and advice for strengthening the overall safety of the program if needed.

How does this decision differ from the vaccination program in Israel? The vaccination program in the U.K.?

Israel is vaccinating health care workers and military personnel who were previously vaccinated. In the U.K., a small group of roughly 1000 people are being vaccinated.

Is it true that those who were vaccinated previously have a lower risk of adverse reaction?

Those who were vaccinated previously may have a lower risk of adverse reactions. It is appropriate for individuals, in deciding whether to be vaccinated, to consider whether they were vaccinated previously.

How will vaccine adverse events be handled? What protocols will be followed for actual or claimed serious adverse events?

Prospective vaccinees will be educated about the contraindications to smallpox vaccination in order to minimize serious adverse reactions to the vaccine. A good system to monitor and treat

adverse events will be an integral part of this policy, and will be done in close collaboration between the CDC, states, and public health agencies and hospitals. The states will maintain records of people vaccinated and will work with hospitals to set up systems to diagnose, manage, and treat people who experience adverse reactions from the vaccine. This will include rapid access to the primary treatment for most serious adverse events, Vaccinia Immune Globulin (VIG).

It is expected that most of the side effects caused by smallpox vaccinations will not require special treatment or therapy. There are two treatments that may help people who have certain serious reactions to the smallpox vaccine. These are: Vaccinia Immune Globulin (VIG) and Cidofovir. Patients receiving these drugs would need to stay in the hospital for observation and possible additional treatment, as the VIG and Cidofovir may cause a number of side effects as well. CDC will review summary reports of adverse events and will investigate all individual reports of serious events.

General Public

What is the current threat assessment? Who are likely countries to obtain and use the 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. This potential along with an appreciation for the potentially devastating consequences of a smallpox attack, suggests that we should take prudent steps to prepare our critical responders to protect the American public should an attack occur. 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.

If a person wants to sign up to receive the vaccine as soon as possible, what should they do?

The federal government is not recommending that members of the general public be vaccinated at this point. Our government has no information that a biological attack is imminent, and there are significant side effects and risks associated with the vaccine. HHS is in the process of establishing an orderly process to make unlicensed vaccine available to those adult members of the general public without medical contraindications who insist on being vaccinated either in 2003, with an unlicensed vaccine, or in 2004, with a licensed vaccine. (A member of the general public may also be eligible to volunteer for an on-going clinical trial for next generation vaccines).

How long will it take before HHS begins administering vaccines to the general public under the new program?

Again, we do not recommend at this point that the general public be vaccinated. However, we expect to be able to make the unlicensed vaccine available to those who insist on being vaccinated sometime this spring. The immediate task for state and federal government will remain the implementation of our program to vaccinate our emergency responders. This is necessary to best protect Americans in the event of a release.

Of course, in the event of an actual attack, we will immediately make vaccine available to those at risk from disease.

Who will administer the vaccines?

State health departments, with guidance from CDC, will set up vaccination clinics and determine who will be staffing clinics and administering smallpox vaccine. The number of vaccination sites will be determined in the state plans, and depends in large part on the demand for the vaccines. CDC is assisting states with planning, technical assistance and education.

If you aren't recommending that the general public be vaccinated, why are you setting up this special program to allow them to get the vaccine?

We understand that some Americans will want to be vaccinated despite the risks. The President decided that the best course was to provide Americans with as much information as we can, help them weigh the risks, then let them decide for themselves.

Will you administer tests to ensure that members of the general public receiving the vaccine are not pregnant or HIV positive?

Every person volunteering to receive the vaccine will be asked detailed questions regarding their medical history and physical health. They will be educated to the risks and possible side effects of the vaccine. If there is any indication that a person has a contraindication for the vaccine, the individual will be referred to the local public health department or another health care provider for testing.

How will the government monitor and report side effects?

The CDC will enlist an outside group to constitute an external data monitoring and safety review board. This external review board will review vaccine adverse event reports and data, interpret findings, and provide guidance and advice for strengthening the overall safety of the program.

Military Personnel

Why are we vaccinating servicemembers?

We 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?

As part of this plan, the decision at this time is 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 decision will be implemented using a portion of the existing licensed supplies of smallpox vaccine.

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.

When are the smallpox vaccinations going to start?

Smallpox vaccinations of DOD personnel will begin as soon as the vaccine is in place and medical training and troop education have been accomplished.

Has the Department of Defense vaccinated people against smallpox before?

Yes, the Department conducted major vaccination programs during WWI and WWII and servicemembers were routinely vaccinated from the 1940s until 1984. In 1984, routine military vaccinations were limited to recruits entering basic training. Between 1984 and 1990, recruit vaccinations were intermittent. In 1990, the Department of Defense discontinued vaccination of recruits.

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 wise, 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 does the smallpox vaccination interact with other drugs and vaccinations?

The smallpox vaccine should not be given to people taking medications that suppress their immune system. Smallpox vaccines should be spaced by one month from chickenpox vaccination. Other combinations of vaccines (e.g. smallpox and influenza or smallpox and anthrax) can be given.

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 wise course for preparedness and may serve as a deterrent.

What should a person do if they don't get a blister?

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.

What should a person do if they have any adverse reactions?

If a person suspects an adverse reaction from the smallpox vaccine he or she should seek care from their primary-care manager, medical department representative, or go to their healthcare provider as soon as possible.

They should request that their healthcare provider file a Vaccine Adverse Event Reporting System (VAERS) form. If they don't believe their reaction is serious enough to visit a medical treatment facility, but they still wish to report it, they can contact VAERS themselves at 1.800.822.7967 or file a report at the following Web site: www.vaers.org.

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.

State Department and Overseas Issues

Has the Department decided to vaccinate its personnel against smallpox or anthrax?

The Department plans to offer, on a voluntary basis, vaccination against anthrax and smallpox to personnel at certain posts.

While it is impossible to quantify the threat that such bio-weapons could be used, we know that the consequences of such use could be very grave. In that context, the Department believes offering the vaccine is a wise step.

What if someone cannot take the vaccine? Is the Department planning to evacuate those persons?

Pre-exposure administration of the vaccines is considered the most effective means to protect against these two health risks. However, we understand that there will be a number of people who cannot, or opt not to, receive the vaccines. We will be prepared to offer the vaccines or other appropriate treatment in the event of actual exposure.

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

It is possible, but not confirmed, that Iraq possesses the virus that causes smallpox. By protecting ourselves to respond to any smallpox attack, including through pre-exposure and post-exposure vaccination plans, we also help deter such attacks.

What is the Department planning to do for private American citizens in that region?

We provide extensive information to the American public about travel, security, health, and other conditions abroad to assist private Americans in making individual decisions about their own security and risks. We are following the same approach in this instance.

Has the Department told American citizens to leave the Middle East because of these biological threats? Have any warden messages been prepared for a possible attack?

The Department of State has issued a Worldwide Caution Public Announcement and a Middle East and North Africa Update that alerts American citizens to the continuing threat of terrorist actions that may target private Americans. The Department of State works with posts to disseminate threat information through its warden network when specific information is available. At present, there is no specific information to indicate that there is a likelihood of use of anthrax or smallpox as a weapon in the immediate future. Also, a Chemical-Biological Agent Fact Sheet, which includes information on anthrax and smallpox, is available on the Consular Affairs website at: <http://travel.state.gov>.

Are we planning to assist any other country in obtaining supplies of vaccines?

The United States recognizes that a smallpox attack in any nation is a potential threat to all nations. The United States, therefore, will work with like-minded nations and the World Health Organization (WHO) to facilitate and coordinate nations' access to existing global smallpox vaccine supplies and to increase the global supply through new production.

Will smallpox vaccine be provided to other countries for their civilian populations?

The United States will work with like-minded nations and the WHO to facilitate and coordinate nations' access to existing global smallpox vaccine supplies and to increase the global supply through new production.

Will the United States assist nations in the event of an actual smallpox or anthrax attack?

Recognizing the global threat posed by a bio-weapon attack, the U.S. Government stands prepared to lend all feasible assistance in the event of an actual anthrax or smallpox attack against a country.

Smallpox Disease

What is smallpox and what should I know about it?

Smallpox is a very serious disease; it is contagious and sometimes fatal. Smallpox is caused by the variola virus, which spreads from contact with infected persons.

Smallpox can cause:

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

Natural cases of smallpox have been eradicated from the Earth. The last natural case of smallpox was recorded in 1977. In 1980, the disease was declared eradicated following worldwide vaccination programs.

However, in the aftermath of the events of September and October, 2001, the U.S. government is taking precautions to be ready to deal with a bioterrorist attack using smallpox as a weapon. As a result of these efforts:

- 1) There is a detailed nationwide smallpox response plan designed to quickly vaccinate people and contain a smallpox outbreak, and
- 2) There is enough smallpox vaccine to vaccinate everyone who would need it in the event of an emergency.

For more information, please visit the CDC Website at www.cdc.gov.

What are the symptoms of smallpox?

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 and pus-filled blisters that crust, scab, and fall off after about three weeks, leaving a pitted scar.

If someone comes in contact with smallpox, how long does it take to show symptoms?

After exposure, it takes between 7 and 17 days for symptoms of smallpox to appear (average incubation time is 12 to 14 days). During this time, the infected person feels fine and is not contagious.

Is smallpox fatal?

About 70 percent of patients infected with smallpox recover. Many smallpox survivors have permanent scars over large areas of their body, especially their face. Some are left blind.

Is smallpox contagious? How is smallpox spread?

Yes, smallpox is contagious. Smallpox normally spreads from contact with infected persons. Generally, direct and fairly prolonged face-to-face contact is required to spread smallpox from one person to another. People infected with smallpox exhale small droplets that carry the virus to the nose or mouth of close contacts. The greatest risk comes from prolonged close contact exposure (within seven feet) to an infected person. The longer somebody is in close contact with an infected person, the greater the chance of transmission. Indirect contact is less likely to transmit the virus, but infection still can occur via fine-particle aerosols or inanimate objects carrying the virus. For example, contaminated clothing or bed linen could spread the virus. Smallpox is not known to be transmitted by insects or animals.

People are most infectious during the first week of the rash, but a person with smallpox is sometimes contagious with the onset of fever (prodrome phase). The infected person is contagious until the last smallpox scab falls off.

Is smallpox contagious before the smallpox symptoms show?

A person with smallpox is sometimes contagious with onset of fever (prodrome phase), but the person becomes most contagious with the onset of rash. The infected person is contagious until the last smallpox scab falls off.

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. Early results from laboratory studies suggests that the drug cidofovir may fight against the smallpox virus. Currently, studies with animals are being done to better understand the drug's ability to treat smallpox disease. . 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.

Smallpox Vaccine

What is the smallpox vaccine, and is it still required?

The smallpox vaccine is the best way to prevent smallpox. 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.

Getting smallpox vaccine *before* exposure will protect about 95 percent of people from getting smallpox. Vaccination within three days of exposure will prevent or significantly lessen the severity of smallpox in the vast majority of people. Vaccination four to seven days *after* exposure likely offers some protection from disease or may modify the severity of disease. Solid protection lasts for three to five years after vaccination. Partial protection lasts longer, but people need to be revaccinated if too much time has passed.

Routine vaccination of the American public against smallpox stopped in 1972 after the disease was eradicated in the United States. Until recently, the U.S. government provided the smallpox vaccine only to a few hundred scientists and medical professionals who work with smallpox and similar viruses in a research setting. After the events of September and October 2001, however, the U.S. government took further actions to improve its level of preparedness against terrorism. For smallpox, this included updating a response plan and ordering enough smallpox vaccine to immunize the American public in the event of a smallpox outbreak. The plans are in place, and there is sufficient vaccine available to immunize everyone who might need it in the event of an emergency.

How is the vaccine given?

The smallpox vaccine is not given with a hypodermic needle. It is not a “shot,” like many vaccinations. The vaccine is given using a bifurcated (two-pronged) needle that is dipped into the vaccine solution. When removed, the needle retains a droplet of the vaccine. The needle is then used to quickly prick the skin several times for a few seconds. The pricking is not deep, but it will cause a sore spot and one or two drops of blood to form. The vaccine usually is given in the upper arm.

If the vaccination is successful, a red and itchy bump develops at the vaccination site in three or four days. In the first week after vaccination, the bump becomes a large blister, fills with pus, and begins to drain. During week two, 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 may have a stronger “take” (a successful reaction) than those who are being revaccinated.

Why aren't people still routinely vaccinated for smallpox?

The last case of smallpox in the United States was in 1949. The last naturally occurring case in the world was in Somalia in 1977. After the disease was eliminated from the world, routine vaccination against smallpox among the general public was stopped because it was no longer necessary for prevention, and because of the risk of adverse events from the vaccine.

If someone receives that vaccine now or before an attack, will they need to be revaccinated if there is an attack?

In a post-attack emergency, to ensure everyone is protected as rapidly as possible, all exposed persons will be vaccinated regardless of smallpox vaccine history.

If someone is exposed to smallpox, is it too late to get a vaccination?

Vaccination within 3 days of exposure will completely prevent or significantly modify smallpox in the vast majority of persons. Vaccination 4 to 7 days after exposure likely offers some protection from disease or may modify the severity of disease.

How long does a smallpox vaccination last?

Past experience indicates that the first dose of the vaccine offers protection from smallpox for 3 to 5 years, with decreasing immunity thereafter. If a person is vaccinated again later, immunity lasts longer. A report from Europe 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.

Are diluted doses of smallpox vaccine as effective?

Recent tests have indicated that diluted smallpox vaccine is just as effective in providing immunity as full-strength vaccine.

What is the smallpox vaccine made of?

The vaccine is made from a virus called *vaccinia*, a virus related to smallpox but that does not cause smallpox. The smallpox vaccine helps the body develop immunity to smallpox. It does not contain the smallpox virus and cannot spread smallpox.

Is it possible for people to get smallpox from the vaccination?

No. The smallpox vaccine does not contain smallpox virus and cannot spread or cause smallpox.

Is it possible for someone to get vaccinia, the virus in the vaccine, from someone who has been vaccinated?

The smallpox vaccine does contain another virus called vaccinia, which is “live” in the vaccine. Because the virus is live, it can spread to other parts of the body or to other people from the vaccine site. This can be prevented through proper care of the vaccination site (e.g. hand washing and careful disposal of used bandages).

What are the symptoms of the vaccine virus (vaccinia)?

In the unlikely event that the vaccinia virus is spread, symptoms may include rash, fever, and head and body aches.

How is the vaccine virus (vaccinia) spread?

The vaccine virus (Vaccinia) is spread by touching a vaccination site before it has healed or by touching bandages or clothing that have become contaminated with live virus from the vaccination site. Vaccinia is not spread through airborne contagion. Proper handling of the vaccine site includes these three key points:

1. Don't touch your vaccination site or materials that touched it.
2. If you touch either the site or materials in contact with the site by accident, clean your hands right away.
3. Don't let others touch your vaccination site or materials that touched it.

Vaccine Safety

How safe is the smallpox vaccine?

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 eight to 12 days after 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.

People most likely to have side effects are people who have, or even once had, skin conditions, (especially eczema or atopic dermatitis) and people with weakened immune systems, such as those who have received a transplant, are HIV positive, or are receiving treatment for cancer. Anyone who falls within these categories, or lives with someone, who falls into one of these categories, should NOT get the smallpox vaccine unless they are exposed, or at risk of exposure, to the disease. In addition, anyone who falls within the following categories should not get the smallpox vaccine unless they are exposed or at risk of exposure: pregnant women, breastfeeding mothers, anyone who is allergic to the vaccine or any of its components, and anyone under the age of 18.

So your estimate is that at least one person per million will die as a result of this vaccine?

This is a statistical estimate based on prior experience with the vaccine. However, we will work hard to prevent even these rare events from happening. Severe reactions can be minimized by screening people for bars to vaccination before vaccinating them and closely monitoring individuals for severe reactions with prompt treatment as necessary.

Is there any way to treat bad reactions to the vaccine?

Two treatments may help people who have certain serious reactions to the smallpox vaccine. These are Vaccinia Immune Globulin (VIG) and Cidofovir. We will have more than 2,700

treatment doses of VIG (enough for predicted reactions with more than 27 million people) at the end of December, and 3,500 doses of Cidofovir (enough for prediction reactions with 15 million people).

Has FDA approved the use of 15 pricks to vaccinate both primary vaccinees and revaccinees? If not, will this approval have come before DoD begins to vaccinate troops? If it does not, will DoD be giving 15 pricks to 1st time vaccinees under IND? (The current package insert states 3 pricks for primary vaccinees and 15 pricks for revaccinees).

CDC and others are currently in the process of submitting data to the FDA to support changing the recommendation of 3 needle sticks for primary vaccinations to 15 needle sticks for both primary and revaccination. It is important to note that during the smallpox eradication period, the World Health Organization (WHO) program utilized 15 needle sticks universally to avoid confusion and to help decrease the number of vaccine take failures from flaws in vaccine administration techniques. However, until the FDA approves a package insert change, vaccinators should follow the instructions found on the vaccine package insert on the number of needle sticks to administer for primary vaccines and revaccinees.

What should I expect at the vaccination site?

If the vaccination is successful, a red and itchy bump develops at the vaccination site in three or four days. In the first week after vaccination, the bump becomes a large blister, fills with pus, and begins to drain. During week two, 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 may have a stronger “take” (a successful reaction) than those who are being revaccinated.

Most people experience normal, usually mild, reactions, such as sore arm, fever, headache, body ache, and fatigue. These symptoms may peak eight to 12 days after vaccination.

The vaccine virus (vaccinia) is present on the skin at the vaccination site until the scab falls off. One must take care not to touch it so that the vaccine virus (vaccinia) is not spread elsewhere, especially to the eyes, nose, mouth, genitalia or rectum.

Are there any side effects of the vaccine?

Yes, side effects can result from 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.

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.

Medical experts believe that with careful screening, monitoring and early intervention the number of serious adverse reactions can be minimized.