

New York City Department of Health and Mental Hygiene's Information Sheet for Health Care Workers on the Smallpox Vaccination Program

The World Trade Center attacks and the intentional outbreak of anthrax in the fall of 2001 have demonstrated that the threat of terrorism in New York City is real. As health care and public health professionals, we need to ensure our preparedness against future terrorist threats, including the threat of smallpox.

The federal government has announced its plans for a voluntary smallpox vaccination program for hospital-based health care and public health and safety smallpox response teams. By volunteering for vaccination, these health care, public health and public safety workers are volunteering to take care of the first victims of a smallpox attack, and to help vaccinate other health and emergency responders who would be needed to control the outbreak. These smallpox response teams would be our first line of defense in the event of a smallpox outbreak and so these volunteers need to be protected ahead of time by offering smallpox vaccination now, before such an attack occurs.

The risk of a smallpox attack is unknown at this time. The federal government has no definite information that the smallpox virus might be used as a terrorist weapon. However, there are concerns that certain countries or groups may have this virus and might use it as a terrorist weapon against the United States.

In New York City, we are planning to form teams of volunteer health care and public health and safety workers who will be vaccinated against smallpox and form a strategic reserve of responders in the event of a smallpox attack. These vaccinated teams will provide care for the initial victims, establish emergency vaccine clinics, conduct public health investigations and implement the public health measures that would be needed to control a smallpox outbreak rapidly and effectively, if one were to occur.

The New York City Department of Health and Mental Hygiene will work closely with our partners in the hospital community to be sure that this smallpox vaccine program is done as safely as possible. A critical part of this program will be making certain that anyone who volunteers to be on a health care smallpox response team is fully educated about the smallpox vaccine, including the potential risks of vaccination. In the absence of a smallpox outbreak or a definite and credible threat that a smallpox attack is imminent (or likely), vaccine will not be offered to anyone who has a medical condition that puts them at higher risk for a severe reaction to the smallpox vaccine. Since the smallpox vaccine contains a live virus, vaccine will also not be offered to anyone who lives with or has close intimate contact with someone who has a medical condition that puts them at higher risk for a severe vaccine reaction.

The first phase of this program will target health care personnel who work in acute care hospitals and will start in March 2003. After this first phase is completed, smallpox vaccine may be offered to all other health care personnel, as well as public health and safety workers. There is no recommendation to vaccinate the general public at this time. The fact sheet that follows is to help answer any questions that potential volunteers may have about smallpox, the smallpox vaccine and the City's vaccination plans.

The decision about whether or not to volunteer for the healthcare smallpox response team is a difficult one. All potential volunteers should understand all the information concerning the risks of the vaccine and weigh this against the benefits of serving on a health care smallpox response team to help protect New York City against a potential attack.

New York City Department of Health and Mental Hygiene

Frequently Asked Questions about Smallpox Vaccine and the Voluntary Program for Vaccination of Health Care Smallpox Response Teams

1) What is smallpox?

Smallpox is a virus that causes an illness with high fevers and a severe rash. The rash spreads and progresses to raised bumps and pus-filled blisters that crust, scab, and fall off after about three weeks, leaving pitted scars, which can be permanent. The smallpox virus is contagious, though less contagious than viruses such as influenza and chickenpox. Up to one-third of persons who are infected may die.

The smallpox virus no longer occurs naturally, due to the success of the vaccination program led by the World Health Organization to rid the world of this disease. The last natural case of smallpox in the world was in 1977.

2) Is there any treatment for smallpox?

No. There is currently no proven treatment for smallpox. But scientists are evaluating new anti-virus medications. Early results from laboratory studies suggest that the anti-viral drug, cidofovir, may work against the smallpox virus. Currently, studies with animals are being done to better understand this drug's ability to treat smallpox disease. However, this medicine has never been used to treat patients with smallpox so we can not be sure that it will work in people.

Patients with smallpox can benefit from supportive therapy (for example, intravenous fluids, medicine to control fever or pain) and antibiotics for any secondary bacterial infections that may occur.

3) What is smallpox vaccine?

The smallpox vaccine is a live virus vaccine that helps the body develop immunity (antibodies) to smallpox virus. It contains *vaccinia* virus, which is closely related to, but is a different virus than smallpox virus. The vaccine does not contain the smallpox virus, and can not give you smallpox disease.

Smallpox vaccination was used for more than 200 years. The vaccine is the best way to prevent smallpox disease and death in someone who may be or has been exposed to the smallpox virus. The vaccine protects against smallpox even if given up to 3 days after exposure. In the United States, we stopped routine use of smallpox vaccine for all persons in 1972, except for certain laboratory workers and the military. The military stopped using the vaccine by 1990. In most parts of the world, smallpox vaccinations ended by 1980.

4) What is this new smallpox vaccination program being started by the United States government?

The United States government has decided to offer smallpox vaccine to a small group of hospital, public health and public safety workers, as well as to some military troops overseas. Approximately 500,000 civilian health care, public health and public safety workers in the United States will be offered smallpox vaccine during the next several months.

5) Since there is no longer any smallpox in the world, why is the United States government starting a new vaccine program?

The smallpox virus is still kept in government research laboratories in the United States and Russia. However, there are concerns that countries or terrorist groups hostile to the United States may have stockpiles of the smallpox virus. The risk of a deliberate release of smallpox as a biologic weapon is unknown, but if it did occur, there could be a large outbreak with many people becoming seriously ill, and up to one third dying. Therefore, the United States government has decided to prepare for a smallpox outbreak by vaccinating teams of volunteer hospital staff, public health and public safety workers before such an attack occurs. These persons would then be able to care for the first few patients until other hospital staff who are not yet vaccinated get the vaccine.

6) What might we expect if an outbreak of smallpox occurred today?

If an outbreak of smallpox were to occur, several factors could contribute to a more rapid spread of smallpox than was usually seen before this disease was eradicated in 1977.

These factors include:

- a) There are almost no persons who are immune (have protective antibodies) to smallpox due to the absence of naturally occurring disease worldwide and the end of routine vaccinations in the United States in 1972,
- b) It may take longer for doctors to recognize the first cases of smallpox, as many doctors today are not familiar with smallpox disease, and
- c) Smallpox virus may spread faster today due to the ease of travel and crowding of the population compared to 30 years ago, when routine vaccination stopped.

Though outbreaks in the past have been controlled by rapidly vaccinating close contacts of smallpox patients (ring vaccination strategy), the success of this control was based on rapidly recognizing and isolating the first smallpox patients. The concern is that many doctors today have not seen smallpox and might not be able to recognize it in a timely manner before the outbreak spreads.

For these reasons, just one case of smallpox would require an immediate and coordinated public health and medical response to control the outbreak and to prevent further infection of susceptible individuals (*people without immunity {antibodies} to smallpox*). We would need vaccinated health care workers to care for the first victims. We would also need public health staff to work at emergency smallpox vaccine clinics as well as to

find the close contacts of the initial smallpox cases who would be most at risk for smallpox infection.

We need to protect these health care, public health and public safety teams who will be essential to our response in the event of a smallpox outbreak. It is best if these first responder teams receive smallpox vaccine ahead of time, so they are ready to respond immediately as soon as the first smallpox cases are identified.

If there were an outbreak of smallpox, the federal government has enough smallpox vaccine for the entire country, if needed. By vaccinating health care and public health response teams ahead of time, we also would have emergency workers ready and able to give vaccine to all others who needed to be vaccinated after a smallpox outbreak had been confirmed.

7) Why is smallpox vaccine being offered to all acute care hospitals in the city?

If a smallpox outbreak occurs in New York City, it is likely that there would be more than a few cases. As we can not predict which hospitals might see the first cases, it is important to be sure that all hospitals that care for acutely ill patients have staff available who are protected against the smallpox virus, and who would be available to take care of these patients until other staff could be vaccinated.

8) Why are we asking your hospital to participate in this program?

Although the risk of a smallpox attack is unknown, it is important for every hospital to have plans in place in case a patient with smallpox is seen in the hospital's emergency department or clinics. If there was a smallpox outbreak in the City, it will help to have a team of vaccinated hospital staff ready and willing to take care of the first few patients while all other staff were being vaccinated.

9) How many staff are being vaccinated at each hospital?

We are offering smallpox vaccine to between 100 and 150 staff at each hospital. Some hospitals may decide to vaccinate fewer staff members. Larger hospitals (hospitals with more than 500 beds) may vaccinate up to 200 staff.

10) Why are only certain hospital staff being asked to volunteer?

This is the first step in the United States government's smallpox vaccination program. In this first step, hospitals like yours have been asked to reach out to those staff who would be needed to care for the first few smallpox patients that might come to your hospital if an outbreak occurs. This includes medical and nursing staff who work in the emergency department, the intensive care unit, the adult and pediatric wards, and certain specialty areas as well as respiratory therapists, radiology technicians, security, housekeeping, other clinical support staff, and some administrative staff.

Each hospital that decides to participate in this program will be responsible for deciding what types of staff are needed for their health care smallpox response teams.

11) Will other staff be vaccinated in the future?

In the future, during the second step of this vaccine program, the United States government may be offering smallpox vaccine to all other health care, public health and public safety workers.

12) I work in an outpatient clinic setting. Why am I not able to volunteer during this first step of the program, as it is possible that I might see the first smallpox cases?

The goal of this first step of the pre-event smallpox vaccination program is to protect those health care workers who would be asked to “care for” the initial smallpox victims in the hospital once an outbreak is recognized or suspected.

As the amount of licensed smallpox vaccine is limited, we are not able to pre-vaccinate any one who works in a medical office or clinic, in the first phase of the vaccination program. During the second phase of the program, possibly starting in the late spring/early summer of 2003 when more licensed vaccine is available, the federal government may offer smallpox vaccine to all other health care workers. At that time, you are likely to have the opportunity to get the vaccine.

Until then, if an outpatient provider sees a patient with a disease that is suspected to be caused by a bioterrorist agent, such as smallpox, s/he should report the case immediately to the New York City Department of Health and Mental Hygiene. In the event that smallpox is confirmed, the provider would be prioritized to get smallpox vaccine as soon as possible and by no more than 3 days after exposure.

13) If I my work makes me eligible to receive the smallpox vaccine, do I have to get it?

No. This is a *voluntary* vaccination program and you have the right to refuse this vaccine. The decision on whether or not to get the vaccine is a personal decision that should be made after you have attended your hospital’s education program and read the materials on the smallpox vaccine. If you do not want to get this vaccine, you do not have to explain why, and your job will not be affected.

14) Why should I consider getting the smallpox vaccine?

If smallpox virus is released in New York City, we will need staff at your hospital who are already vaccinated and protected against smallpox, so that they will be willing and able to care for patients and would feel safe in doing so. Although the vaccine may protect you from becoming infected or at least make the disease less severe even if given up to 3 days after contact with a smallpox patient, it is better to be vaccinated before being exposed to the virus. Staff who volunteer to be vaccinated ahead of time are also volunteering to be on the health care response teams that will care for the first smallpox victims who come to your hospital in the event of a smallpox outbreak. If you volunteer, you will be providing a critical service, as you would also be able to care for the initial victims of a smallpox attack and help vaccinate other health and emergency workers who would be on the front lines of our efforts to control the outbreak.

15) What smallpox vaccine is being used?

The vaccine that is being used is the “Dryvax” vaccine. It is the same vaccine that was used in the United States up until 1972. This vaccine was recently tested in clinical trials and was shown to be effective. The vaccine lots that will be used were recently licensed by the Food and Drug Administration.

16) If I received smallpox vaccine in the past, am I still protected?

Protection against smallpox lasts about 3 to 5 years, and then the immunity to the smallpox virus begins to decrease. If exposed to the smallpox virus, persons who were vaccinated over 10 years ago may no longer be fully protected and may become infected with smallpox, but they are less likely to develop severe disease and to die than someone who was never vaccinated. As most people in the United States were either never vaccinated or received smallpox vaccine over 30 years ago, there is probably little or no immunity to smallpox in the United States population.

17) How is the vaccine given?

The smallpox vaccine is given using a different method than all other vaccines. The vaccine is given using a bifurcated (two-prong) needle that is dipped into the vaccine solution. This needle is then used to quickly prick a small area on the skin in just a few seconds. The pricking is not deep, but it will cause a sore spot and a few drops of blood at the site. The vaccine is usually given on the outside of the upper arm.

18) How do you know if the vaccination was successful?

If the vaccination is successful, a red and itchy bump will form at the vaccine site in 3 to 4 days. About a week after vaccination, the bump becomes a large blister, fills with pus, and begins to drain. In about 2 weeks, the blister begins to dry up and a scab forms. The scab usually falls off in about 3 weeks, leaving a small scar. If someone is getting the vaccine for the first time, this reaction may be stronger (*with more redness and swelling*) compared to someone who got the vaccine in the past. It will be important to have the vaccine site checked at 7 days after vaccination, to know if the vaccine worked. If not, a second vaccination may be needed.

19) Why do I need to go to the educational program at my hospital to hear more about the vaccine, if I have already decided to volunteer to be on my hospital’s health care smallpox response team?

A critical part of this vaccine program is to be sure that anyone who considers volunteering for their hospital’s smallpox health care response team fully understands the benefits and risks of being vaccinated. There will be at least two required education sessions for all persons who decide to volunteer for the vaccine – one at least a week before the vaccine clinic starts and one during the vaccine clinic session. This is to be sure we provide enough information so that everyone can make an informed decision on whether or not to receive the smallpox vaccine.

We want to do everything we can to prevent any person from receiving the smallpox vaccine who has a medical problem or who has a household or close (*intimate*) contact who has a medical problem that puts them at higher risk for severe side effects from the vaccine.

After considering the information provided at these education sessions, you can decide if you want to participate in this voluntary smallpox vaccination program. If you decide at any time that you do not want to be vaccinated, no explanation will be needed and the hospital will not need to know the reason for your decision.

20) The smallpox vaccine contains a live virus, named vaccinia. Can this virus spread to other persons?

Yes. In the past, the vaccinia virus spread to somebody else between 8 and 27 times out of every million smallpox vaccinations. However, this most often happened when children were vaccinated, and spread the vaccine virus to other children.

The virus in the smallpox vaccine, the *vaccinia* virus, can be found at the site of the vaccination until the scab falls off (which usually takes about 3 weeks). The vaccinia virus can spread to other people and even to other parts of the body far from the vaccine site. It spreads by touching the vaccine site and then touching another part of the body or another person. This can be prevented by not touching the vaccine site and by proper care of the vaccine site, including covering the site with the recommended dressing and clothing that has sleeves long enough to cover the vaccine site, carefully washing your hands after touching the site or the dressing, and by disposing of used dressing materials in sealed plastic (zip-locked) bags when at home, and in the infectious waste containers (red bags) at work.

The vaccine virus is NOT spread by kissing, coughing, sneezing, or sexual contact.

21) Why will you be asking me about the health of my household and close, intimate contacts if I am the one being vaccinated?

Since this vaccine contains a live virus and it is possible for someone who has been vaccinated to spread this virus to their close contacts, especially to those who live in the same household or sexual contacts. Therefore, persons should only volunteer for the vaccine if their household or close, intimate contacts have none of the medical problems listed below.

22) What are the health problems and conditions that might cause more severe side effects from the smallpox vaccine? (READ THIS ANSWER CAREFULLY IF YOU ARE CONSIDERING VOLUNTEERING FOR SMALLPOX VACCINE)

There are certain health problems that may put you or your close contacts at higher risk for a severe side effect from the vaccine. Close contacts include the persons in your household and anyone you have close, intimate (physical) contact with, such as a sexual partner. Close contacts do NOT include friends or people you work with.

Anyone who has ANY of the following health conditions, or **lives with or has close intimate contact** with someone with ANY of these conditions, should NOT get vaccinated unless there is a smallpox outbreak:

- Weakened immune systems - including persons with HIV infection or AIDS, cancer, leukemia, lymphoma, multiple myeloma, organ transplants, severe autoimmune diseases (like lupus), or problems producing antibodies (for example, the disease agammaglobulinemia {*lack of normal antibodies*}). If someone is a cancer survivor and (a) their cancer is cured, (b) they are no longer on chemotherapy or radiation therapy and (c) their doctor feels their immune system is normal and no longer weakened, it is okay to get the smallpox vaccine.

Also, persons receiving treatment or medicines that weaken the immune system should not get vaccinated. Examples of these include cancer chemotherapy or radiation therapy in the past 3 months, or high dose oral or intravenous steroids (such as oral prednisone for 2 weeks or longer within the past month). (*For example, with prednisone, a medication dose of more than 2mg per kg body weight per day for 2 weeks or longer within the past month is considered immunosuppressive.*)

- A history of EVER having the skin diseases named “eczema or atopic dermatitis” - Persons who have ever had a skin problem that caused them to have red, patchy, scaly, itchy skin for more than 2 weeks that was not due to another cause, and especially if this skin problem tended to come and go, may have the diseases of eczema/atopic dermatitis. Please talk to your doctor if you are not sure if you have ever had eczema or atopic dermatitis. If there is any question about whether or not you have these diseases, even if the diseases are mild or you only had them as a child, we will recommend that you not get the vaccine at this time. (See Question 23 for more information on these two skin diseases.)
- Darier’s disease – an inherited (genetic) chronic skin disease that usually begins in childhood. Skin lesions commonly include firm, small, skin-colored papules (bumps) that can coalesce (melt together). The skin is usually itchy, and can crust. Most commonly involves the face, neck, arms, chest, back, tongue, nail bed, and the inside of the cheek.
- Active skin diseases - Any currently active skin diseases that causes breaks in the normal barrier of the skin, such as burns, psoriasis, shingles, an allergic rash, impetigo or severe acne. (If these skin diseases are not active and have fully healed, it is okay to get the vaccine.)
- Pregnancy - Women who are pregnant or who will be trying to get pregnant in the 4 weeks after vaccination.

- Close, physical contact with an infant less than one year of age - The US Centers for Disease Control and Prevention does not currently list having an infant less than one year of age in the home as a reason NOT to get the smallpox vaccine. Data from the past suggest that there is an extremely small risk of a severe reaction to the vaccine in an infant who lives in the same home as an adult who gets the smallpox vaccine. However, there is evidence from the past that shows that when infants younger than one year of age *were vaccinated themselves*, there was a higher risk of bad reactions to smallpox vaccine than when the vaccine was administered to older children.

Therefore, as a precautionary measure, the New York City Department of Health and Mental Hygiene recommends that *persons who live with a child less than one year of age or who have close, physical contact with a child less than one year of age **not** get vaccinated at this time*, as young infants may be at higher risk for side effects if they are exposed to the vaccinia virus in the smallpox vaccine and because it is difficult to avoid close contact when caring for an infant. However, if a person who lives with a child less than one year of age still wishes to be vaccinated, he/she will be allowed to receive the vaccine.

In addition to the health conditions listed above, **persons who themselves have any of the following health problems or conditions** should NOT get the smallpox vaccine:

- Women who are breastfeeding,
- Anyone who is ill at the time of the vaccination clinic,
- Anyone who has inflammation of the eyes and/or is using steroid eye drops, a
- Anyone with allergies to one of the ingredients in the vaccine (*polymyxin B, streptomycin, chlortetracycline, or neomycin*) or an allergy to the vaccine itself
- Anyone with a severe allergy to latex (*severe allergy reactions include life threatening symptoms such as difficulty breathing, wheezing, weakness, a fast heart beat, dizziness or low blood pressure within a few minutes to hours after being exposed to latex*).

You may need to speak to your doctor to review your medical history to be sure it is okay to get the smallpox vaccine. You should bring this fact sheet or other materials on the smallpox vaccine with you when you see your doctor or other health care provider. Also, before you decide to get the vaccine, you may need to have your close contacts (household or close intimate contacts) talk to their doctor to be sure that they do not have any of these health problems or conditions.

23) What are eczema and atopic dermatitis?

Eczema is a disease of the skin. Early eczema can be red, blistering, or have oozing areas of skin. Later on, eczema can be scaly, brownish, or thickened. Almost always, eczema itches. There are several different types of eczema. A special type of eczema called “atopic dermatitis” has the greatest risk for severe skin reactions after smallpox vaccination.

**New York City Department of Health and Mental Hygiene’s
Question and Answer Fact Sheet for Health Care Workers Considering
Volunteering for the Smallpox Vaccine**

Last revised on February 20 2003

Atopic dermatitis is a chronic disease that affects the skin. “Dermatitis” means inflammation of the skin. “Atopic” refers to a group of allergic diseases (*for example, asthma and hay fever*) that run in families. In atopic dermatitis, the skin becomes extremely itchy and inflamed, causing redness, swelling, cracking, weeping, crusting and scaling. Atopic dermatitis most often affects infants and young children, but it can continue into adulthood or occur for the first time later in life. In most cases, there are periods of time when the disease is worse, called “exacerbations or flares”, followed by periods when the skin improves or clears up entirely, called “remissions”. Many children with atopic dermatitis will completely recover from this skin disease when they get older, although their skin often remains dry and easily irritated. Environmental factors can bring on symptoms of atopic dermatitis at any time in people who have inherited the atopic disease trait.

Although it is difficult to know exactly how many people are affected by atopic dermatitis, an estimated 10 percent of infants and young children experience symptoms of the disease. Roughly 60 percent of these children continue to have one or more symptoms of atopic dermatitis into adulthood. This means that more than 15 million people in the United States have symptoms of the disease. None of these people should volunteer to be vaccinated or be in close contact with someone who is volunteering to get vaccinated because of the potential risk posed by exposure to the live virus in the smallpox vaccine. However, if there is a smallpox outbreak, and persons with eczema or atopic dermatitis have exposure to a smallpox patient, they should get the smallpox vaccine as the risk of serious illness or death from the smallpox virus is likely to be much greater than the risk from the vaccine.

24) If one of my close contacts or I have one of these medical problems, can I still get the smallpox vaccine?

No. The reason that people with the diseases or conditions listed above in Question 22 should not receive the smallpox vaccine is because severe reactions to the vaccine are much more common in persons with these health problems or conditions. Since there is no smallpox outbreak now or a definite threat that smallpox will be used as a biologic weapon against the United States, it is not worth taking the risk that the vaccine might harm you, a household member or a close, intimate contact. So, we only want persons to volunteer for the vaccine who have none of the medical problems listed, and are sure that none of their household or close, intimate contacts have any of the problems listed above.

However, if a person who lives with or has close, physical contact with an infant less than one year of age still wants to be vaccinated despite the New York City Department of Health and Mental Hygiene’s recommendation, s/he will be allowed to receive the vaccine.

25) What if I have one of the medical conditions listed in Question 22, and there is a smallpox outbreak in New York City and I am exposed to a patient with smallpox? Can I get the smallpox vaccine then?

Yes. If there is an outbreak of smallpox, the recommendations on who should get smallpox vaccine will change. If you had direct contact with a patient with smallpox, you would be offered smallpox vaccine as soon as possible, even if you have one of the medical problems listed above in Question 22. If you were directly exposed to a person with smallpox, the risk of serious illness or death from the smallpox virus is likely to be much greater than the risk from the vaccine.

26) If I decide not to get the vaccine, will this have any effect on my job?

No. If you decide not to get the vaccine, this will not affect your job at the hospital. This is a completely voluntary program and you do not need to tell the hospital your reasons for deciding not to get the smallpox vaccine.

27) I do not think that I have HIV infection or that I am pregnant, but should I still get tested to be sure?

Yes. The New York City Department of Health and Mental Hygiene strongly urges anyone who is considering smallpox vaccination to be absolutely certain that they do not have any health problems that might cause more severe side effects. So, we strongly recommend that you get tested to be sure that you do not have HIV and are not pregnant before volunteering for the vaccine.

It is especially important for persons to get tested if they have any history of a risk factor for HIV infection and are not sure of their HIV status. If any of the risk factors below apply to you, you may be at higher risk for HIV infection and you should be tested for HIV before getting the smallpox vaccine:

- Use of needles to take drugs, or steroids, or anything not prescribed by a doctor
- Had an accidental needle-stick and have not yet been tested for HIV exposure
- Had sexual contact with someone who has HIV/AIDS or has had a positive test for HIV/AIDS virus
- Had sexual contact with a prostitute or someone else who takes money or drugs or payment for sex
- Had sexual contact with someone who has ever used needles to take drugs, or steroids, or anything not prescribed by a doctor
- For women: Had sexual contact with a man who has ever had sexual contact with another male
- For men: Had sexual contact with another man

If any of these situations apply to you, now or in the past, you should talk to your doctor about getting tested for HIV before going to the vaccine clinic or go to one of the confidential or anonymous HIV testing sites provided by the New York City Department of Health and Mental Hygiene. Also, if there is any question that a household member

or close, intimate contact has HIV infection or is pregnant, they should get tested too, before you decide to get the smallpox vaccine.

Somewhere between 15-20% of persons who have HIV infection are not aware of having a risk factor for HIV. Therefore, the New York City Department of Health and Mental Hygiene strongly recommends that anyone who is interested in volunteering for smallpox vaccine get tested for HIV to be sure that it is okay to get vaccinated.

28) I would like to get tested for HIV and/or get a pregnancy test, but do not want to do this at my hospital. Is there a place that I can get free and confidential testing done?

Yes. The New York City Department of Health and Mental Hygiene will provide information on clinics that offer free, confidential or anonymous HIV testing, as well as clinics that offer free pregnancy testing to all persons who are considering volunteering to get the smallpox vaccine.

You can call the following numbers to get information on clinics that offer free HIV and pregnancy testing:

For HIV testing sites, call the AIDS Hotline at 1-800-TALK HIV (1-800-825-5448).

TTY/TDD 212-676-2388

For pregnancy testing sites, call the Women's Healthline at (212) or (718) 230-1111.

TTY/TDD 212-442-1802

Information on these clinics (*the locations and hours that the clinics are open*) will also be given out at the educational sessions that will be held at your hospital in early 2003.

29) I never got the smallpox vaccine when I was a child? Is it okay for me to get the smallpox vaccine now for the first time?

The risk of severe side effects is thought to be lower for people who have received the smallpox vaccine at least once in the past, even if it has been more than 30 years since the last vaccine. It is hoped that most persons who volunteer to be on the hospital's health care smallpox response team will have been vaccinated at least once in the past. If there are more than enough volunteers, hospitals will be asked to select volunteers from among those who have had the smallpox vaccine before. However, if needed, persons who have never had the smallpox vaccine can be vaccinated as long as neither you nor your close contacts have any of the health problems that put you or them at higher risk for severe reactions from the vaccine.

30) When I get the vaccine, will I need to sign any paperwork?

Yes. During the vaccine clinic, you will be asked to take part in an education session to be sure you understand the risks of the vaccine, as well as what medical problems or conditions may put you or your close contacts at higher risk of getting a severe reaction to the vaccine. After that education session and before you get the vaccine, you will be interviewed confidentially by one of the clinic staff. The purpose of the interview is so

that we can be as careful as possible that you do not receive the vaccine if you have any of these medical problems or conditions. You will then be asked to sign a piece of paper that says you have been given educational materials explaining the risks and the benefits of the smallpox vaccine, have had the opportunity to ask questions, and that you give your permission (consent) to be vaccinated.

31) If I decide to get the smallpox vaccine, when will I be vaccinated?

The New York City Department of Health and Mental Hygiene will be starting this vaccine program in March 2003. As it will likely take 2 to 4 months to complete, the vaccine clinics at each hospital may occur anytime between March and May 2003.

32) How do you know if my smallpox vaccination is successful?

If the vaccination is successful, a red and itchy bump will form on the vaccine site in three to four days. About a week after vaccination, the bump will become a large blister, fill with pus, and then begin to drain. In about two weeks, the blister will begin to dry up and a scab will form. The scab usually falls off about three weeks after the vaccination, leaving a small scar. When people receive the vaccine for the first time, it is likely they will have *more redness and swelling* than those who have received the vaccine at some other time in their lives. You will need to be seen at 7 days after vaccination to be sure that your vaccine worked. If not, a second vaccination will be given.

33) If I get vaccinated, will I need to take special care of the vaccination site on my arm?

Yes. If you decide to get the smallpox vaccine, you will receive detailed instructions on how to care for the vaccine site until the vaccine scab falls off (which can take about 3 weeks). Because the smallpox vaccine contains the live virus, *vaccinia*, if you touch the vaccine site you can spread the virus in the vaccine to other parts of your body (*for example, your eyes*) or to another person. For this reason, it is very important that you follow the instructions you will be given after your vaccination on the proper care of the vaccine site on your arm.

The best way to prevent problems is by (1) using the recommended bandages over the vaccine site, (2) wearing clothes with sleeves that cover the bandages (including pajamas at night), and (3) always washing hands after touching the vaccine site or used bandages.

You should not touch, scratch or rub the vaccine site even though it may be very itchy. After you are vaccinated, it is important to keep the site covered. A dry, sterile gauze dressing will be placed loosely over the vaccination site to absorb any drainage. In addition, while in the hospital, staff who take care of patients will need to have a plastic covering (*e.g., semi-permeable dressing*) placed over the dry gauze dressing while they are at work to provide an additional barrier. Finally, long sleeved clothing should be worn over the dressing.

After changing the dressing, the used dressing should be placed in the infectious waste containers at the hospital. When at home, the used dressing should be placed in a plastic bag that can be sealed (zipped) and then placed in the trash receptacle. Do the same with the scab when it falls off.

Every day before starting work, vaccinated hospital workers will have their vaccination sites checked at Employee Health or by the clinic or staff person designated by the hospital to do this. If the dressing needs to be changed, it will be done at that time. If the dressing comes off at home, you should replace it with another dry gauze dressing.

After you touch the vaccination site or the dressing, you should always wash your hands thoroughly with soap and running warm water (*or hand hygiene alcohol-based disinfecting products*). Do not touch any part of your body, including your eyes, after changing the bandage or touching the vaccine site until your hands have been washed.

Try and keep the vaccine site dry. When bathing, you should wrap the vaccine site with plastic wrap. You should be sure that no one else besides you handles any clothing, towels, washcloths, or sheets that touched your vaccine site or dressing. Keep a separate laundry hamper or bag for your clothes and linens until the vaccine site has healed. These items should be washed in your regular laundry with hot water and detergent and/or bleach.

34) Are there any risks to my pets if I get the smallpox vaccine?

Smallpox is a disease of humans only, but there are closely related viruses (including the *vaccinia* virus in the smallpox vaccine) that can infect some animals. While dogs have a low risk of any reaction if they accidentally contact the *vaccinia* virus, some animals such as hamsters and cattle may be more likely to have a reaction to the vaccine. The best way to avoid a problem is to protect your pets from any possible contact with the *vaccinia* virus found in the vaccine site or in the used dressings during the 3 weeks after you have been vaccinated (*until the scab falls off*).

If you have pets, we recommend that you take the following steps to lessen any risk of exposing them to the *vaccinia* virus:

- Do not let animals sniff or have any direct contact with the vaccination site or the bandage dressings, clothing or sheets that touch the vaccine site or scab.
- Do not play roughly with your pets to avoid any accidental contact with your vaccine site.
- Keep pets out of the room when you are changing bandages or changing clothes.
- After touching the vaccine site or changing the dressing, carefully dispose of the dressing, put any clothing, linens or towels that had contact with your vaccine site or scab in the laundry and wash your hands well.
- Make sure that pets are not able to get into the trash containers that have used bandages in them. Cover trash containers tightly and put them in an area that your pets can not get to.

35) Will I still be able to take care of patients after I get the smallpox vaccine?

Yes. It is okay to continue to work after getting the smallpox vaccine as long as your vaccine site is well covered and checked by the hospital before every work shift. It is important that you use the correct type of dressing (*gauze and a semi-permeable dressing*), wear clothes with long-sleeves, and be sure to wash your hands after touching the vaccine site or the dressing, even if you are wearing gloves.

The vaccination site will be checked before every work shift by Employee Health or by other staff designated by your hospital to do these checks until your scab falls off. If you take proper care to wash your hands whenever touching the vaccination site or the dressing, and before and after seeing any patient, there should be very little risk to your patients, even to those who have weakened immune systems (*e.g., HIV infection or cancer patients*). In the past, spread of the *vaccinia* virus from the vaccine site to patients in the hospital was very rare.

However, if any of the following occur, the hospital will advise you not to come to work:

- If you are ill and physically unable to work
- If your vaccine site becomes very red, swollen with lots of pus, and can not be covered adequately with a dressing
- If you do not follow the infection control measures of washing your hands with soap and warm water (*or an approved hand hygiene disinfection product*), after touching your vaccine site or the dressing, and before and after every time you touch a patient.

Also some hospitals may, depending on your job duties, decide to temporarily re-assign you to a different job or to put you on leave until the vaccine site scab falls off. This decision will be up to each hospital and may just be applied to certain staff.

36) Why is it okay for me to work with patients who are likely to have health problems (such as HIV, cancer, pregnant women and patients with eczema) after I get the smallpox vaccine but not okay for my close household or intimate contacts to have one of these diseases or conditions?

Household or other close contacts are more likely to spend longer periods of time and to have intimate contact with the person who is vaccinated. In the hospital setting, it is much less likely for staff to have close, prolonged, or intimate contact with patients. Because of the special infection control precautions used in hospital settings (which are not as easy to follow in household settings), spread of the *vaccinia* virus (in the vaccine site) from health care providers to their patients has been low in the past.

Also, as long as the vaccine is well covered by a dressing (*gauze bandage and semi-permeable dressing*) as well as your clothing, and you are sure to wash your hands thoroughly before and after touching the vaccine site and dressing, and before and after touching your patients, the risk to your patients is thought to be low. In a recent study, no vaccine virus (the *vaccinia* virus) was found on the outside of the dressing (*gauze*

bandage and semi-permeable dressing) among almost 100% of the persons who were vaccinated.

37) I have one of the medical problems or conditions (such as HIV infection, cancer, pregnancy, or eczema) that puts me at risk for more severe side effects. Is it safe for me to work while other staff at the hospital are being vaccinated?

Yes. All staff who get the smallpox vaccine will have their vaccine site covered with both a gauze dressing and a semi-permeable membrane dressing while at work, in addition to having an outer layer of clothes covering the dressing. These vaccinated staff will also be given detailed instructions to be sure they wash their hands thoroughly after touching the vaccine site or dressing.

All vaccinated staff will be seen before they start each work shift to be sure the vaccine site is okay and well covered by the dressing. Just as there is only a low risk of spreading the vaccine virus to patients in the hospital, the risk to other staff should be low as well.

38) How safe is the smallpox vaccine? Does the smallpox vaccine have any risk of side effects (bad reactions)?

The smallpox vaccine does cause more side effects than other vaccines in use today. Most symptoms occur about one week after vaccination, when a blister begins to form at the place where the vaccination was given. This blister and the scab that soon develops is a normal reaction to the vaccine virus.

Most people do have some pain and swelling at the vaccination site. Also, fever, swollen lymph glands, fatigue, headache, nausea, redness and swelling at the vaccine site, and muscle aches are quite common. In some people, the local swelling and redness can be quite severe, although this will usually get better on its own.

In a recent study of the smallpox vaccine, persons reported the following symptoms about 7 to 9 days after the vaccination: moderate to severe pain at the vaccine site (34%), moderate to severe muscle aches (21%), moderate to severe fatigue/tiredness (20%), moderate to severe headache (14%), fever (9%) and moderate to severe nausea (4%). About one third of the people who got the vaccine were sick enough to miss work or school.

Also, it is possible if the vaccine site is not well covered and you do not wash your hands after touching the site or the dressings, that you could accidentally spread the virus from the vaccine to another site on your body, such as your eyes, or to another person.

39) For how long can the vaccinia virus in the vaccine site be spread to other persons?

The virus in the smallpox vaccine is present at the site of the vaccination until it is completely healed and the scab falls off (usually 3 weeks). Because the vaccine site contains a live virus, it can be spread to other people and other parts of the body. This can usually be prevented by not touching the vaccine site. Proper care of the vaccine site

includes covering the site with the recommended dressing and wearing clothes that cover the dressing, carefully washing your hands with soap and warm water after touching the site or the dressing, and disposing of used dressing materials in sealed or zip-locked plastic bags.

40) Are there more serious side effects (severe vaccine reactions) from the vaccine?

Yes. There can be severe side effects, although fortunately they are much less common if you do not have any of the health problems or conditions listed in Question 22 above.

This is why we will need to carefully screen any one who gets the vaccine. We want to take whatever steps we can to prevent someone from getting the vaccine if he or she has any of these medical conditions or has a household or close, intimate contact who has a medical condition that puts them at higher risk for severe reactions to the vaccine.

In the past, about 1 in 1,000 had serious, but not life-threatening complications (*primarily skin reactions involving spread of the vaccine virus to other parts of the body*). About 14-52 persons per million had potentially life-threatening reactions (*for example, more severe skin reactions or encephalitis {swelling and inflammation of the brain tissue}*) and 1-2 persons per million died as a result of the vaccine. Severe reactions have been more common among persons who were getting the smallpox vaccine for the first time compared to persons who were vaccinated in the past. It is possible that the risk of severe reactions will be less likely today than in the past because we plan on carefully screening out any persons who have any of the medical conditions listed in Question 22.

However, even with careful screening, it is possible that persons without any of the medical conditions listed in Question 22 could develop some of the more severe reactions to the vaccine (*such as encephalitis {swelling and inflammation of the brain tissue}, which most often occurs among persons who are getting the vaccine for the first time*). More detailed information on the severe side effects (reactions) from the smallpox vaccine is available from the Centers for Disease Control and Prevention's website at www.cdc.gov/smallpox.

41) What are the more severe reactions to the smallpox vaccine?

In the past, about 1,000 people for every 1 million people vaccinated for the first time had reactions that, while not life-threatening, were serious. These reactions can be more severe in those with weakened immune systems and may require medical attention:

- Accidental spread of the vaccinia virus: A vaccinia rash or outbreak of sores similar to the vaccine site rash that appears in another part of the body. This is caused by accidentally spreading the vaccinia virus after touching the vaccination site and then touching another part of the body or another person. It usually occurs on areas of the body that are most commonly touched, such as the genitals or face, including the eyes, where it can damage sight or lead to blindness. Most skin lesions will heal without any special treatment. Washing hands with soap and warm water after touching the vaccine site or the used (dirty) bandages will help prevent this.

- Generalized vaccinia: A widespread vaccinia rash. The virus spreads from the vaccination site through the blood. Fluid- or pus-filled sores break out on parts of the body away from the vaccination site. This can occur in as many as 1 per 4,000 vaccinees.
- Erythema multiforme: An allergic rash in response to the vaccine that can take various forms such as red spots, bumps, or hives.

Most Severe, Potentially Life-Threatening Reactions

Although rare, people have had very severe reactions to the vaccine. In the past, between 14 and 52 people per 1 million people vaccinated for the first time had potentially life-threatening reactions. These reactions require immediate medical attention:

- Eczema vaccinatum: A serious skin rash caused by widespread vaccinia virus infection of the skin in people with the skin diseases, eczema or atopic dermatitis. This can occur in as many as 1 per 26,000 vaccinees.
- Progressive vaccinia (or vaccinia necrosum): Ongoing infection of skin at the vaccination site with tissue destruction that can lead to death in people with immune system problems. This can occur in as many as 1 per 667,000 vaccinees, though mostly among persons with weakened immune systems.
- Post-vaccinial encephalitis: Inflammation of the brain tissues that can lead to disability or death. This can occur in as many as 1 per 83,000 vaccinees, though it is more common among young infants.
- Fetal vaccinia: Infection of the unborn child if a woman who is pregnant is vaccinated. Although rare, this can cause an infection that leads to premature delivery, a severe skin rash with scarring, stillbirth or death of the child after delivery.

People with certain medical conditions—including people with weakened immune systems or certain skin conditions—are more likely to have these reactions and should not get the smallpox vaccine unless they have been exposed to smallpox. Based on past experience, it is estimated that between 1 and 2 people out of every 1 million people vaccinated may die as a result of life-threatening reactions to the vaccine.

If after your smallpox vaccination, you develop a persistent headache or fever, confusion, seizures, difficulty staying awake, a rash or sore on other parts of your body, an eye infection, some other unexpected problem, or your vaccine site doesn't look like it is healing normally, you should seek medical attention at your hospital.

[Note: Statistical information about the more severe smallpox vaccine reactions is based on data from two studies conducted in 1968. The rates of these vaccine reactions in the United States today may be higher because there may be more people at risk from weakened immune systems (from cancer, cancer therapy, organ transplants, and illnesses such as HIV/AIDS) and eczema or atopic dermatitis.]

We hope that the number of people who die or have complications from these vaccine reactions will be less today than in the past because of advances in medical care. Also, since the rates of severe reactions are lower for persons who have gotten the smallpox vaccine at least one time in the past, if we mainly vaccinate persons who have had at least one smallpox vaccine in the past, we may see less severe reactions. And finally, as we hope to prevent anyone with a medical condition that puts them at higher risk for a vaccine reaction from getting the smallpox vaccine, these rates will also be lower among people who get the smallpox vaccine as part of this voluntary program.

42) If I get sick after the smallpox vaccine, where should I go for medical care?

Your hospital will be giving you detailed information about who to call and where to go for medical care if you have any problems with the smallpox vaccine. We strongly encourage all vaccinated persons to go to the medical clinic recommended by your hospital if you have any problems with the smallpox vaccine.

43) Since the smallpox vaccination may make me sick, will I need to use my sick days if I get vaccinated and then feel too sick to work?

As always, if you are feeling too sick to work you should stay home. Each hospital will develop its own policy on whether its employees should use sick days if they need to take time off after the vaccination.

44) If I become sick from the smallpox vaccine, who will pay for any doctor bills, hospital bills, or lost pay?

For specific details, you should talk to the benefits program at your hospital. However, if you are an employee of the hospital and have a bad reaction to the vaccine, your medical care costs and certain lost wages may be paid by your employer's Workers' Compensation insurance policy, depending on the circumstances.

Currently there is no federal program to automatically pay for any costs of hospitalization, medical consultations, other medical expenses or lost wages that may occur if you get sick from the vaccine. However, under Section 304 of the Homeland Security Act, which was just passed by the U.S. Congress and signed by President Bush, you may be able to recover money from the federal government if your illness due to smallpox vaccination was the result of negligence or a wrongful act or omission by someone other than your employer. We will provide you with any new information on whether a federal compensation program is put in place for persons who volunteer for smallpox vaccine.

45) If one of my household members or close intimate contacts becomes sick because I got the vaccine, who will pay for their doctor bills, hospital bills or lost pay?

The answer to this question depends on your insurance coverage or theirs. Please check with the insurance company involved either through your hospital's benefits program or other insurance program representatives, as appropriate.

Currently there is no federal program to automatically pay for any costs of hospitalization, medical consultations, other medical expenses or lost wages that may occur if your household members or close intimate contacts get sick as a result of you getting the vaccine.

However, under Section 304 of the Homeland Security Act, which was just passed by the U.S. Congress and signed by President Bush, your contacts may be able to recover money from the federal government if an illness related to your smallpox vaccination was the result of negligence or a wrongful act or omission. We will provide you with any new information on whether a federal compensation program is put in place for persons who volunteer for smallpox vaccine and their close contacts.

46) Will I need medical clearance to return to work if I get sick from the vaccine?

Yes. In order to return to work, you will be required to receive clearance from the Employee Health Clinic, or other designated clinic, at your hospital.

47) If I need special medicines to treat a reaction to the vaccine, who will pay for it?

There are two medications, vaccinia immune globulin and an anti-viral medication called cidofovir, which may be needed to treat certain severe reactions to the vaccine. If either of these medicines is needed, the Centers for Disease Control and Prevention will provide these medicines free of charge. However, the Centers for Disease Control and Prevention will not pay for your other medical care costs.

48) I would also like my family to be able to get the smallpox vaccine now. Can the general public get the smallpox vaccine now if they want it?

No. At this time, public health officials are not recommending smallpox vaccine for the general public since there is currently no outbreak of smallpox or a definite threat that smallpox virus might be used as a weapon. The average citizen is much less likely than a health care, public health or public safety worker to be exposed to the first smallpox cases as part of their job duties, if an outbreak occurred. For the general public, the risks of the smallpox vaccine are not worth taking if the chance that they might be exposed to a patient with smallpox is very low.

If there were an outbreak of smallpox, the federal government has enough smallpox vaccine for the entire country, if needed. However, there may be some persons who want the smallpox vaccine now, despite the recommendation that they not receive it at this time. The United States government may make smallpox vaccine available to adults in the general public once more vaccine is available and it is licensed by the Food and Drug Administration in late 2003 or early 2004.

Until then, persons in the general public who are interested in getting the vaccine can volunteer for one of the federal vaccine experimental trials using smallpox vaccines. Information on these trials can be obtained from the National Institutes of Health at <http://www.clinicaltrials.gov>.

49) Just thinking about the possibility of smallpox and the need for me to decide whether or not to get the vaccine is upsetting. Why do I feel this way?

This is a normal reaction to thinking about the possibility of terrorism. If you find that your fears or concerns about smallpox, the smallpox vaccine, or terrorism in general are affecting your ability to work or do your daily routines, it is important that you find someone to talk to. For a free referral to a mental health provider or counselor, please call the New York City Department of Health and Mental Hygiene's LifeNet program at 1-800-LIFENET (1-800-543-3638) where trained staff can assist you.

More information on smallpox and the smallpox vaccine is available on the Centers for Disease Control and Prevention's website at www.cdc.gov/smallpox.