

**New York City Department of Health and Mental Hygiene:**

**Frequently Asked Questions and Answers on the  
Implementation of Hospital Plans for the  
Vaccination of Health Care Smallpox Response Teams**

The attached Question and Answer Sheet summarizes the questions that have been raised by hospitals regarding the New York City Department of Health and Mental Hygiene’s (NYC DOHMH) plans for pre-event vaccination of health care worker smallpox response teams. This fact sheet is targeted to the hospital planning committees who are working on pre-event smallpox vaccination. The questions are divided into the following categories:

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Additional information on the NYC DOHMH’s pre-event vaccination plan for health care smallpox response teams can be found at [www.nyc.gov/health/smallpox](http://www.nyc.gov/health/smallpox), including a copy of this Question and Answer sheet that will be updated as needed. If you have additional questions, please send via electronic mail to Ms. Georgia Davidson at [gdauidso@health.nyc.gov](mailto:gdauidso@health.nyc.gov).

Additional information on the CDC’s pre-event vaccination plans is available on their website at: <http://www.cdc.gov/smallpox>.

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**Vaccination of Health Care Response Teams Against Smallpox**

**A. General Questions on Smallpox Vaccination:**

**A-1. Which smallpox vaccine will be used to vaccinate health care smallpox response teams? Will it be diluted?**

Approximately 1.7 million doses of the Dryvax<sup>®</sup> vaccine, manufactured by Wyeth Lederle in the 1980s, have been licensed by the FDA for use during this upcoming smallpox vaccination campaign of health care and public health response teams. An additional one million doses was licensed for use by the military. Although a recent study by Frey, et al (NEJM 2002; 346:1265-74) showed that the vaccine could be diluted as much as 1 to 10 and still be effective, everyone vaccinated as part of this pre-event smallpox vaccination program will receive undiluted vaccine. The FDA has licensed sufficient vaccine for the military personnel and health care and public health response teams that will be targeted during this initial phase of pre-event vaccination.

In the event of a smallpox outbreak, the existing stockpiles of Dryvax<sup>®</sup> and Aventis Pasteur vaccinia vaccines could be diluted 1:5 to provide enough vaccine for the entire country.

**A-2. Has the Dryvax<sup>®</sup> vaccine been tested against a bioengineered form of smallpox?**

According to the federal government, there is no evidence that a vaccine-resistant smallpox virus has ever been bioengineered. And while there have been some anecdotal reports that the former Soviet Union produced such strains and recent disclosures in the news media of possible smallpox stocks in at least four countries, the federal government has not confirmed that any smallpox strains exist outside of the two World Health Organization sanctioned repositories – one in the U.S. and one in Russia.

The current Dryvax<sup>®</sup> vaccine is effective against the naturally occurring smallpox virus that existed prior to the World Health Organization's successful eradication campaign. Therefore, it should be effective, if this naturally occurring smallpox strain is used as a bioweapon. As far as we know, it has not been tested against any bioengineered strains of smallpox, since there are no known existing stocks of such strains.

**A-3. Is there a new smallpox vaccine being developed?**

A new vaccinia vaccine has been developed by Acambis, using modern vaccine manufacturing techniques (cell culture as opposed to the Dryvax<sup>®</sup> and Aventis Pasteur vaccines which were derived from calf lymph). The federal government has purchased more than 200 million doses of this vaccine, and clinical trials are just beginning. It is anticipated that this vaccine will be

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available by early 2004. However, this is still a live virus vaccine and may cause the adverse events that are due to replication of the vaccinia virus.

**A-4. If someone had smallpox previously and survived, are they immune?**

Yes. If someone had smallpox disease in the past and survived, they are immune to the disease and do not need to get the smallpox vaccine.

**A-5. How do you know for sure if a health care worker has been previously vaccinated?**

The best evidence of a successful vaccine “take” is written documentation on an immunization card or medical record. Successful vaccination also should result in a scar at the site of vaccination, which could be anywhere on the upper arm or even the thigh. However, these scars are not reliable markers for previous vaccine “take,” because 1) other vaccines can cause scars (e.g., BCG), 2) scars commonly fade with time, and 3) not every vaccinee forms a scar.

Routine childhood smallpox vaccinations were discontinued in the United States in 1972 and the military stopped vaccination in 1990. Since that time, the only persons who have been routinely vaccinated with the smallpox vaccine are laboratory researchers who work with orthopox viruses.

**A-6. If a person has been vaccinated in the past, would he or she still be immune?**

Immunity can wane after 5-10 years based on previous studies. It is likely that an individual vaccinated in the past will have some immunity to smallpox but it may not be complete, and rather than protecting against infection it may just result in a less severe form of the disease. The more times that a person has been vaccinated previously, the more likely it would be that immunity to smallpox has persisted.

**A-7. Are there any serological tests that can determine whether someone who was vaccinated in the past is still immune to smallpox?**

There is no commercially available serological test that can be used to determine a person’s immunity to smallpox. Previous data on antibody titers have not shown any correlation with protection against smallpox. However, there are several research programs in NYC and NY State that will be looking at markers of immunity in past and current vaccinees, but these tests are not yet available for routine use.

**A-8. What is the approximate vaccine “take” rate?**

In a recent clinical trial described by Frey et al (NEJM 2002; 346:1265-74), the initial vaccination was successful in 665 of the 680 subjects (97.8%) being vaccinated for the first time. In this trial, people were vaccinated with different concentrations of the smallpox vaccine (undiluted vs. 1:5 vs. 1:10 dilutions). There were no significant differences in the vaccine “take” rate over the range of concentrations that were tested.

**A-9. Are the rates of vaccine “take” different between primary vaccinees and re-vaccinees?**

Yes. With proper inoculation of smallpox vaccine, nearly 100% of persons who are being vaccinated for the first time (primary vaccinees) should have a take (as demonstrated in the Frey

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study). From 70% to 100% of re-vaccinees should develop a “take,” depending on the number of previous vaccinations and the time elapsed between the last and most recent vaccination. Since most persons in the United States have not been vaccinated in over 30 years, the “take” rates may be similar between primary vaccinees and re-vaccinees who were only vaccinated during childhood. Studies are currently being done assessing the response to smallpox vaccinations in persons who were vaccinated at least once previously.

**A-10. How many times should you revaccinate an individual who does not demonstrate a vaccine “take?” What is CDC policy in this regard?**

The CDC current recommendation is to revaccinate up to two times. If there is failure to “take” after the second revaccination attempt, this person should not be allowed to serve on the hospital’s smallpox response team because it will not be possible to determine for sure if he/she is immune to smallpox. Reasons for failure to “take” may include pre-existing immunity in a re-vaccinee (especially if the vaccinee has received multiple smallpox vaccinations in the past), improper administration of vaccine, or an unrecognized defect in cellular or humoral immunity.

**A-11. If a vaccinee is vaccinated twice and it does not “take”, but was successfully vaccinated in childhood, can the vaccinee be considered immune?**

Persons with high titers of neutralizing antibody to vaccinia may not develop a vesicle after smallpox inoculation. But, since most persons born in the U.S. before 1972 have not been vaccinated in at least 30 years, it is unlikely that many people still have high levels of residual immunity to smallpox.

Presently the only proven indication of protective immunity is a vaccine “take”. Although lack of a “take” might indicate persistence of protective immunity from the childhood vaccination, we cannot be sure this is the case. Consequently, you should assume that two “non-takes” indicate that the individual is not immune regardless of the history of smallpox vaccination.

**A-12. Has the risk to a person with remote eczema or current eczema been quantified?**

No. Although we have data that identifies eczema as a risk factor for eczema vaccinatum, a potentially life-threatening adverse effect of smallpox vaccination, we do not know how many people with a history of eczema were vaccinated previously. Therefore, we cannot calculate the complication rates among vaccinees who have a history of eczema.

**A-13. What if a person was vaccinated successfully when young and then developed eczema later on in life? Can that person be vaccinated?**

No. It is recommended that persons who have *ever* had a history of eczema or atopic dermatitis not volunteer for smallpox vaccination as part of this pre-event vaccination campaign, as they are at higher risk for the severe vaccine reaction called eczema vaccinatum. In the absence of a definite threat of a smallpox attack or an actual outbreak, the risk of an adverse event from vaccination is not worth taking. On the other hand, if the same person was exposed to smallpox during an outbreak, the recommendations will change and he/she should be vaccinated as quickly as possible.

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**A-14. Is latex allergy a contraindication to smallpox vaccine?**

The vaccine vial stopper does contain dry natural rubber that may cause hypersensitivity reactions when handled by, or when the product is administered to, persons with known or possible latex allergy. The CDC has recommended that persons with severe (anaphylactic) reactions to latex not be vaccinated. However, smallpox vaccine may be administered to persons with mild hypersensitivity to latex (such as contact dermatitis to latex gloves).

**A-15. Why is the NYC DOHMH recommending that persons who have an infant less than one year in the household not get vaccinated at this time?**

The CDC 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, in the past, there was a higher risk of adverse reactions to smallpox vaccine when infants younger than one year of age were vaccinated themselves compared to older children. Therefore, as our priority is minimizing the chances of any vaccine adverse events during this pre-event vaccination campaign, the NYC DOHMH recommends that persons who live with a child less than one year of age consider not getting 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.

**A-16. Is there any particular risk for adverse reactions from people who wear contact lenses?**

Vaccinia infection of the eye is a potentially serious complication of vaccination and can lead to damaged vision. Therefore, all vaccinees need to be very careful to not inoculate the vaccinia virus into the eye. Covering the vaccine site with gauze (and semi-permeable dressing while at work), tape, and a sleeved shirt or similar clothing, as well as careful handwashing before and after touching the vaccine site and dressing, and before and after touching the contact lenses will decrease the chance of inadvertent inoculation of the vaccinia virus into the eye.

**A-17. How do the adverse event rates of re-vaccinees compare to persons who are being vaccinated for the first time?**

Based on historical data, re-vaccinees are at a 2:1 greater risk for progressive vaccinia (vaccinia necrosum) than persons who are being vaccinated for the first time (primary vaccinees). Primary vaccinees are at greater risk for all other adverse events compared with re-vaccinees, including local reactions at the vaccine site. A table comparing the rates of severe adverse events among primary and re-vaccinees is available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5010a1.htm#tab2>

**A-18. Does the same list of contraindications to smallpox vaccine apply if there is an actual outbreak and someone with a contraindication is exposed to smallpox?**

If there is an outbreak of smallpox, the recommendations on smallpox vaccine will change. If someone has direct exposure to a patient with smallpox, he/she would be offered smallpox vaccine as soon as possible, even if he or she has a known

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contraindication to the vaccine. If someone is directly exposed to a person with smallpox, the risk of serious illness or death from the smallpox virus would be much greater than the risk from the vaccine.

**A-19. If I have a household or other close contact who has contraindications, may I get the smallpox vaccine if I stay somewhere else for the 3 weeks after vaccination?**

No. Although this theoretically is an option, the NYC DOHMH would like to prioritize selecting volunteers for the health care and public health response teams who have none of the contraindications listed and have no close, personal or household contacts with any of these contraindications. As we hope to minimize the possibility of any adverse events, we do not want to take any chances that the vaccinee may have contact with his/her household or personal contact during the 3-week period after vaccination. Therefore, the safest and most conservative approach to take in the absence of an imminent smallpox outbreak is to not allow anyone to get vaccinated who has any contraindications themselves or among any household or close, personal contacts.

**A-20. Are guidelines available to assist in the recognition and management of adverse events due to smallpox vaccination?**

The CDC is finalizing protocols that address the recognition and management of vaccinia related complications that will be included in the January 24, 2002 issue of the *Morbidity and Mortality Report*. The NYC DOHMH will distribute these materials widely to NYC hospitals and clinicians. In addition, the NYC DOHMH is preparing a special edition of our *City Health Information* bulletin that will focus on smallpox vaccine, including vaccine-related adverse events. Detailed information on smallpox vaccine adverse events can be found on the CDC website at [www.cdc.gov/smallpox](http://www.cdc.gov/smallpox).

In addition, the CDC is conducting a Webcast for medical providers on the recognition and management of adverse events of smallpox vaccine that is scheduled for February 4, 2003 from 1 to 3 PM EST. Additional information on this Webcast is available on the CDC website at <http://www.phppo.cdc.gov/PHTN/smallpox0204.asp>.

Some vaccinia-related complications can be treated with vaccinia immune globulin (VIG). Cidofovir, an antiviral medication that may be effective in treating vaccinia-related complications based on in vitro data, may be recommended for certain complications as well. Both VIG and cidofovir will be made available as investigational new drugs (IND) (See Question A-18 below for more details).

**A-21. When is vaccinia immune globulin (VIG) indicated for treatment of adverse reactions to the smallpox vaccine?**

VIG does not affect the course of post-vaccinial encephalitis, and it can cause further harm if used for vaccinia keratitis. There is still debate as to the effectiveness of VIG since there have been no controlled clinical trials that tested the efficacy of VIG in treating adverse events due to smallpox vaccine. Anecdotally, VIG has had some success in the treatment of severe cases of

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eczema vaccinatum, fetal vaccinia, inadvertent inoculation, and progressive vaccinia (vaccinia necrosum).

**A-22. How can we obtain VIG or cidofovir, if indicated?**

The NYC DOHMH requests that providers report any suspected severe adverse events to the NYC DOHMH's 24-hour Provider Hotline that will be established to triage calls on vaccine related complications. For severe adverse events that may require VIG or cidofovir, the NYC DOHMH, in coordination with the treating physician, will consult with the CDC experts to determine if these medications are indicated. If the CDC agrees, VIG and/or cidofovir will be sent to the hospital free of charge, within 12 hours of approval.

Both VIG and cidofovir will be available as investigational new drugs (IND) through protocols reviewed and approved by the CDC's Institutional Review Board (IRB). IND forms and instructions for administering these medications under the IND protocols will be included with the drug shipment. The treating physician will be asked to complete paperwork that would list him or her as a co-primary investigator, through the CDC's IRB. Although hospitals' IRBs are not required to review these protocols ahead of time, the NYC DOHMH will distribute the CDC IND protocols to all NYC hospitals as soon as these are available, so that they will have the opportunity to review them.

**A-23. How will suspected vaccine-related adverse events be triaged by NYC DOHMH and/or CDC?**

The NYC DOHMH has asked all participating hospitals to identify clinical staff to serve as the initial consultants for any vaccinated hospital staff with concerns about potential adverse events. A special training for these consultants will be conducted in February 2003 (February 6, 11 and 13, 2003) to review the CDC adverse event clinical management protocols, as well as the mechanisms for consulting with the NYC DOHMH on a 24-hour, 7-day a week basis.

The NYC DOHMH requests that providers in NYC first report vaccine complications to the NYC DOHMH. A 24-hour, 7-day a week Provider Hotline will be established to facilitate consultations with medical epidemiologists at NYC DOHMH regarding any suspect adverse events. If the adverse event is one for which VIG or cidofovir is indicated (e.g., eczema vaccinatum), CDC will be consulted in order to arrange for rapid shipment of VIG or cidofovir to the hospital.

In addition to the hospital-based clinical staff who will be designated to triage adverse events for vaccinees at their institutions, all primary care providers in NYC will need to become familiar with the complications associated with smallpox vaccine because vaccinees may present anywhere for their care and not necessarily return to their hospital or vaccine clinic for evaluation. In addition to health care workers, the NYC DOHMH will be vaccinating about 3,500 city employees, including public health, emergency medical services, police officers and the medical examiner staff. Although arrangements will be made for these staff to be evaluated at designated clinical sites, these staff may present to their usual sources of medical care. Lastly,

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the U.S. military has already begun smallpox vaccinations and these persons may present to civilian providers if they become ill while on leave from their military bases.

**A-24. Do we have enough VIG to treat the expected number of adverse events?**

Currently, there is a limited amount of VIG in the U.S.; however, there is enough to cover the estimated 250 severe adverse events that would be expected from the current vaccination campaign targeting about one million people (civilian and military staff). The federal government has contracted for the production of additional VIG, which should be available soon.

**A-25. If a contact of a vaccinated staff member gets secondary vaccinia, are they immune?**

If a contact develops secondary vaccinia from a vaccinated person, they probably would become immunized against both vaccinia and smallpox if they developed a vesicle that appeared similar to a vaccine "take."

**A-26. Is there evidence that hand cleansing products, such as alcohol-based hand hygiene products, are effective against vaccinia?**

Yes. Alcohol is known to deactivate the vaccinia vaccine, which is why it is not recommended to wipe the area to be vaccinated with alcohol prior to vaccination. It is recommended that strict hand washing with soap and water and/or an approved hand hygiene product be used after contact with the smallpox vaccination site.

**A-27. Have we learned anything from the smallpox vaccinations being conducted in Israel?**

Approximately 15,000 Israeli health care workers have been vaccinated to date. There have been four reported adverse effects:

- inadvertent inoculation of an infant who was a contact of a vaccinee
- generalized vaccinia in a spouse of a vaccinee (this spouse had an underlying immunodeficiency)
- erythema multiforme in a vaccinee
- myopericarditis in a vaccinee, though it is unclear if this was directly related to or concurrent with the smallpox vaccination

There have been no reports of nosocomial transmission from vaccinated health care workers to their patients during this recent campaign in Israel. The Israelis did not recommend furlough for health care workers during the 21 days post vaccination.

It is important to note that the Israelis are using a different strain of the vaccinia virus (the Lister strain) than will be used in the United States (the NYC Board of Health strain). In addition, the Israelis continued routine smallpox vaccinations into the 1990s, so the population likely has higher levels of pre-existing immunity compared to the United States.

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**A-28. If the vaccination site is not oozing, is it necessary to take off the bandage to take a look at the site?**

Prior to each work shift, it will be important for a trained health care provider to observe the dressing site and to inspect for other adverse events that may occur. If the bandages are covering the site well and there is no evidence of excess exudates (i.e., exudates soaking through the gauze) or significant redness or swelling, it is okay to leave the bandage on until the next site check. CDC currently recommends that the semi-permeable bandage be changed at least every 3-5 days for health care workers in patient care settings. (When not at work, vaccinees may use a gauze bandage alone, in which case, the dressing should be changed at least every 1-3 days.) At seven days after vaccination, the dressing should be removed so the site can be evaluated for vaccine “take.”

For more details regarding smallpox vaccine and vaccine related adverse events, please refer to the CDC website [www.cdc.gov/smallpox](http://www.cdc.gov/smallpox)

**B. Liability and Compensation:**

**B-1. When will the Homeland Security Act become effective? Does there have to be an actual emergency for the liability protections in this act (Section 304) to be in effect?**

The Homeland Security Act will be in effect as of January 24, 2003. The liability protections for the pre-event smallpox vaccinations will become effective once the Secretary of Health and Human Services declares an “actual or potential bioterrorist incident or other actual or potential public health emergency” with circumstances that require “countermeasures” (e.g., vaccination). It is expected that Secretary Thompson will issue this declaration on or soon after January 24, 2003, when the Homeland Security Act goes into effect.

**B-2. If a vaccinee experiences an adverse event, will the federal government be liable?**

Vaccinees who experience an adverse event may be able to get money damages from the federal government if their illness was the result of negligence or a wrongful act or omission by someone other than their employer. If the adverse event resulted from neither negligence nor a wrongful act or omission, the vaccinee may be limited to whatever remedies are available to him or her under Workers’ Compensation or their hospital policy. For further information on the interpretation of Section 304, see the fact sheet on the CDC website at [www.bt.cdc.gov/agent/smallpox/vaccination/section-304-qa.asp](http://www.bt.cdc.gov/agent/smallpox/vaccination/section-304-qa.asp).

**B-3. If a household or close, personal contact gets infected from vaccinia, how would the household or close, personal contact’s medical expenses be covered?**

There is no government compensation system at present that would automatically pay for hospitalization, medical care and other costs that may occur if a household or other close,

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personal contact of a vaccinee becomes ill. If the contact has medical insurance, then his/her policy might cover medical expenses that occur in this setting. It is recommended that all persons who are considering smallpox vaccination check to be sure that their insurance policies and the policies of their household and close personal contacts will cover any medical treatment required for an adverse event associated with this voluntary smallpox vaccination program, as well as what conditions may apply (e.g., pre-authorization for medical care if an illness develops).

Under Section 304 of the Homeland Security Act, contacts who become ill from a vaccinee may be able to get money damages from the federal government if their illness was the result of negligence or a wrongful act or omission.

**B-4. When an employee declines smallpox vaccination, will he/she be required to sign a document saying that they decline, as with hepatitis B vaccine?**

No. This is a completely voluntary program and employees who decline vaccination will not be asked to explain or justify their decision.

**C. Specific Questions on the NYC DOHMH's Implementation Plans for Smallpox Vaccination of Health Care Response Teams**

**C-1. What if I represent a small hospital and we cannot meet the minimum number of staff required for a health care smallpox response team?**

There is no minimum number of staff that must be vaccinated for a hospital to participate in this program. Even if a smaller hospital is unable to identify the 100-150 personnel recommended for each institution's health care smallpox response team, it might be worthwhile to vaccinate a smaller number of hospital staff, so that a few suspected or confirmed smallpox patients could be evaluated and treated during the first days of a smallpox outbreak, until additional health care workers could be vaccinated.

**C-2. Are first time vaccinees to be excluded from this first phase of pre-event vaccination and should we only select individuals who were previously vaccinated?**

We are strongly encouraging that the volunteers for your hospital's health care smallpox response team be persons who were vaccinated at least once in the past, since the risk of adverse events and secondary transmission is likely to be less in these individuals. However, the NYC DOHMH will not exclude any potential volunteers based on the absence of a prior smallpox vaccination, unless he/she has a vaccine contraindication or his/her household or close, personal contacts have a contraindication.

**C-3. What is the role of the Smallpox Vaccine Administrative Liaisons?**

The smallpox vaccine administrative liaisons should be a senior level hospital administrator who can function as the hospital's primary liaison to the NYC DOHMH. The NYC DOHMH will send all new information, materials and updates to participating hospitals through the designated smallpox vaccine administrative liaisons.

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**C-4. Does the Smallpox Vaccine Administrative Liaison need to be vaccinated?**

Not necessarily. If the person assigned to be the administrative liaison is either (1) volunteering to be on the health care smallpox response team based on their usual job duties (e.g., hospital epidemiologist) or (2) going to be involved in either learning to administer smallpox vaccine or conducting the vaccine site care checks, then he/she should receive smallpox vaccine. Otherwise, this person does not need to receive smallpox vaccine or be vaccine-eligible (i.e., without any contraindications to vaccine) to be the administrative liaison. The primary risk of inadvertent inoculation during the vaccine clinic is to the person who is administering the vaccine, which is why the vaccinator needs to be pre-vaccinated.

**C-5. Do allied health staff (e.g., receptionists) in the clinics need to be vaccinated?**

No. There is an extremely low risk of inadvertent inoculation to others in the vaccine clinic who are not involved in administering the vaccine.

**C-6. Why are we being asked to develop a health care smallpox response team to care for only the first 5 patients that present to our hospital? Isn't it more likely that in the event of a smallpox outbreak, more than 5 patients would be presenting to each city hospital?**

This initial pre-event vaccination effort is to ensure that each hospital has a core health care response team available to provide care to a small number of smallpox cases for the first 7-10 days until other staff can be vaccinated. The public health teams that are also being vaccinated during this initial phase will be used to rapidly implement mass vaccination to vaccinate those most at risk in the event of a smallpox outbreak, including health care workers who have not yet been vaccinated and are at risk for exposure.

**C-7. Laboratory personnel were not included in the ACIP (Advisory Committee for Immunization Practices) and HICPAC (Hospital Infection Control Practices Advisory Committee) recommendations. Why not?**

The ACIP and HICPAC discussions concluded that laboratorians were not at increased risk for smallpox transmission, since the amount of smallpox virus in routine clinical specimens most likely would be low and good laboratory safety practices should protect laboratory staff from exposure. However, hospitals can include laboratorians in their health care smallpox response team at their discretion.

Although pathologists who might handle tissue specimens from suspected smallpox patients could be considered for vaccination, it is unlikely that a hospital-based pathologist would be asked to conduct diagnostic testing on suspected smallpox case, as confirmatory testing currently is available only at the CDC. The NYC DOHMH will have our laboratory staff available to assist in the collection and packaging of clinical specimens from the initial suspected smallpox case(s) and arrange shipment to CDC. Therefore, the hospital pathologists would be very unlikely to be involved in the diagnosis of the initial cases in NYC.

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**C-8. Should we include our ambulance staff in this first phase?**

The NYC DOHMH will be offering vaccine to EMS teams in the Fire Department, so vaccinated staff will be available to provide pre-hospital care and transport for suspect smallpox cases if an outbreak is recognized in NYC. Nevertheless, hospitals may still choose to offer vaccine to their own EMS staff, as part of the hospital's smallpox response team. However, hospitals need to ration their allotted vaccine carefully in order to ensure that their health care smallpox response team is able to evaluate and provide in-hospital care for the initial smallpox patients that may present to each hospital.

**C-9. Should dental clinics and dental schools be involved in this first phase of pre-event vaccination?**

No. The current target group for health care response teams are those hospital staff that would be needed for the evaluation and medical care of the initial smallpox patients at each hospital.

**C-10. Is HIV testing mandatory?**

HIV testing is not mandatory, but is strongly encouraged for potential vaccinees prior to receiving the smallpox vaccine. As many as 25% of persons with HIV infection are unaware of an exposure risk, so it is prudent for anyone considering the smallpox vaccine to be tested for HIV if they are unaware of their HIV status.

The NYC DOHMH will provide a list to all potential vaccinees of clinics that offer free, confidential or anonymous HIV testing. Information on these clinic sites will be provided during the first educational sessions for potential vaccinees, so that they have adequate time to get tested before the vaccinations start. At clinic sites that use the NYC DOHMH Public Health Laboratory for testing, we will expedite testing for persons who are considering smallpox vaccination to ensure that they get the results back in time to decide whether or not to volunteer for their hospital's health care smallpox response team.

Information on the locations and hours of the NYC DOHMH's free, confidential and anonymous HIV testing sites is available through the AIDS Hotline at 1-800-TALK HIV (1-800-825-5448 or TTY/TDD: 212-676-2388) or on the DOHMH website at [www.nyc.gov/health](http://www.nyc.gov/health).

**C-11. Where will hospital staff be vaccinated and who will monitor them?**

Most health care workers will be vaccinated in clinics that will be set up in their hospitals, though some facilities may decide to have their employees vaccinated in another hospital within their network. Daily monitoring of health care worker vaccination sites needs to take place in the hospitals where vaccinees work. Prior to each work shift, hospital staff trained by NYC DOHMH will check whether the dressing needs to be changed and whether vaccine "take" or any side effects have occurred.

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**C-12. How often will vaccine clinics be held at my hospital?**

The NYC DOHMH expects to hold clinics at each participating hospital during half-day sessions occurring weekly for approximately 3 to 4 weeks. It is expected that approximately one-third of the hospital's health care smallpox response team will be vaccinated at each clinic. The first group vaccinated at each hospital will include those hospital staff who will be trained to administer smallpox vaccine, as well as designated staff to conduct site checks and bandage changes.

**C- 13. Do vaccination clinics need to have negative pressure rooms? Do staff performing the vaccinations need to wear masks during the administration of smallpox vaccine?**

No. Vaccination clinics do not need to have negative pressure rooms because there is no risk that vaccinia virus will be aerosolized and inhaled and cause an infection among clinic staff. The risk for transmission is through direct contact with the vaccine itself. Therefore, vaccinators and staff conducting site checks need to use standard precautions, but they do not need to be masked.

**C-14. Will hospitals be responsible for vaccine storage or handling at the hospital vaccination clinic sites?**

No. NYC DOHMH will be responsible for storing and delivering smallpox vaccine to all facilities for each vaccine clinic. Unused vaccine will be returned by the NYC DOHMH staff on-site at the vaccine clinic to the NYC DOHMH at the end of each day. Hospitals will not be asked to store vaccine on-site, and vaccine can be kept at room temperature during each half-day vaccination session.

**C-15. Are you recommending that smallpox vaccinations be segregated from other Employee Health activities?**

During the several half-day vaccine clinic sessions that will be held at your hospital, the smallpox vaccine clinic should be set up in an area that is not being used for other clinical activities. This does not necessarily have to be in the Employee Health Clinic, and the decision on the best location for your particular hospital can be made in consultation with the NYC DOHMH Hospital Liaison assigned to your hospital. After completion of each day's vaccination clinic activities and before resumption of normal clinic activities, surface areas where vaccinations occurred should be cleaned with EPA-registered hospital disinfectants (e.g., quaternary ammonium compounds) or sodium hypochlorite (1:10 dilution of household bleach).

**C-16. When will the CDC education materials, fact sheets and consent forms be available for us to see?**

These materials are now available on the CDC website at [www.bt.cdc.gov/agent/smallpox/vaccination/infopacket.asp](http://www.bt.cdc.gov/agent/smallpox/vaccination/infopacket.asp).

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**C-17. Should hospitals begin recruiting staff now?**

No. The NYC DOHMH recommends that hospitals hold off on actively recruiting volunteers until after the training sessions that will be held by the NYC DOHMH for the hospitals' planning teams in early February. At these sessions, we will review the finalized CDC educational and consent materials, as well as provide training materials that can be used to educate hospital staff.

In the meantime, hospitals can provide general information on the smallpox vaccine and the vaccination campaign for health care response teams, using the template letter and fact sheet provided by the NYC DOHMH in the mailing sent on December 24, 2002. A copy of this fact sheet is available on our website at [www.nyc.gov/health/smallpox](http://www.nyc.gov/health/smallpox). In addition, the CDC patient education materials are also available at [www.bt.cdc.gov/agent/smallpox/vaccination/infopacket.asp](http://www.bt.cdc.gov/agent/smallpox/vaccination/infopacket.asp). CDC has also developed general informational sheets for potential volunteers and their close contacts that are available at <http://www.bt.cdc.gov/agent/smallpox/reference/resource-kit.asp>.

**C-18. When it is time to begin recruiting volunteers, how does the NYC DOHMH recommend that we solicit individual volunteers?**

Hospitals should first decide on the job category composition of their hospital's health care response teams (*The template for each hospital's team {Appendix B from the NYC DOHMH mailing on December 24, 2002} was due to the NYC DOHMH by January 17, 2003 and should have been used to provide information on the proposed composition of your hospital's health care response team*).

It is recommended that hospitals provide information to all staff on the smallpox vaccination campaign of health care response teams. Interested staff should be invited to first attend a general information session for potential vaccinees and other staff who may want to learn more about the vaccine program, including which job categories have been targeted for inclusion on their hospital's smallpox health care response team.

After these general information sessions, hospitals should recruit staff from the targeted job categories who are interested in volunteering for their hospital's smallpox health care response team. These potential volunteers will be required to attend at least one more detailed educational session prior to the start of the vaccination clinics. The objectives of this educational session will be to review the goals of the vaccine campaign, the expected roles of persons on the health care response team, and information on the smallpox vaccine, emphasizing the contraindications to vaccination among potential vaccinees and their contacts. This session is mandatory for any one who volunteers for vaccination and a record of attendance will be required. These educational sessions should be held at least one week before the vaccine clinics start to allow time for staff to consult their health care providers, and to obtain testing if indicated (*e.g., HIV and pregnancy testing*). The NYC DOHMH will send staff to attend these mandatory educational sessions to help answer questions, if needed.

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The NYC DOHMH will be providing all hospitals with the teaching slides to be used for both the general informational session and the required educational session for potential vaccinees during our upcoming training program in early February 2003 (February 6, 11 and 13, 2003).

After these sessions, hospitals are encouraged to actively recruit volunteers from the attendees at these educational sessions who remain interested in volunteering for vaccination. If more staff volunteer than are needed, hospitals should select persons who have been vaccinated at least once previously, as the risk of adverse events is less among re-vaccinees.

**C-19. Why is the NYC DOHMH recommending that we have a digital camera? Will instructions be provided on how to transmit photographs to the NYC DOHMH?**

The NYC DOHMH has recommended that all hospitals have at least one digital camera, with staff trained in its proper use (*including downloading of the images for electronic mail transmission*) to facilitate rapid consultation on patients presenting with cutaneous diseases of potential public health concern, including suspect smallpox cases.

For this upcoming pre-event smallpox vaccination program, digital photographs will also allow the NYC DOHMH to evaluate patients who have equivocal “take” reactions, as well as any vaccinia-related dermatologic complications (*such as eczema vaccinatum*). The NYC DOHMH will provide hospitals with instructions on how to transmit digital photographs to the staff who will be available for consultation on vaccine “take”, as well as suspected adverse events.

**C-20. Does the consent form have a section for the patient to consent to be photographed to document vaccine “take” and/or to facilitate consultation of a suspected adverse event?**

The NYC DOHMH is developing a supplemental consent form, as the CDC consent form does not address this issue.

**C-21. Should hospitals draw blood from employees who get vaccinated, in case there is a need to check for an antibody response to the vaccination?**

No. We currently are not asking for routine blood specimens during the vaccination clinics because these serologic tests are not available, except through research studies or national reference laboratories.

**C-22. What will be expected during the site care check?**

All hospitals will be expected to include a site care component to their smallpox vaccination program. Designated staff should also receive smallpox vaccine. These staff will need to assess the dressing for all vaccinated staff (whether involved in direct patient care or other duties), determine if the semi-permeable dressing needs changing (e.g., at least every 3-5 days or if accumulated exudates is visible on the gauze), and change the

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dressing if needed. (When not at work, vaccinees may use a gauze bandage alone, in which case, the dressing should be changed at least every 1-3 days.)

These staff will also assess the vaccination site for local adverse reactions as well as determine if the vaccine “take” was successful at 7 days after vaccination. At each site care visit, the vaccinated staff should be reminded about the need for strict handwashing before and after all patient care activities, and before and after touching the vaccine site or used dressings.

Staff should not be allowed to work if (a) they are physically unable to due to illness, (b) have extensive skin lesions at the vaccine site or elsewhere that can not be adequately covered, or (s) if they are unable to adhere to the recommended infection control precautions.

**C-23. Does the person who does site care (including dressing changes) and “take” checks have to be vaccinated? Are standard infection control precautions sufficient if the vaccinated “checker “ is not available to do checks and someone else has to do the job?**

Ideally, the staff person assigned to do the site care and “take” checks should be vaccinated, though the risk of transmission is low as long as persons are adherent to standard infection control precautions (e.g., wearing gloves during all dressing changes and washing hands with soap and running water or hand hygiene disinfectant products, after touching the site or dressing). If there is no one else available, unvaccinated staff can perform these duties as long as they adhere strictly to these infection control precautions and are vaccine-eligible themselves (i.e., staff who themselves have contraindications to smallpox vaccine should not perform site care checks).

**C-24. Will dressing supplies be provided by the CDC or NYC DOHMH?**

No. The hospital will need to supply all dressing materials for its staff.

**C-25. How should site care be performed for the first health care workers to be vaccinated - since the success of the “take” will not immediately be known?**

As mentioned above, while pre-vaccination of persons conducting site care and “take” checks is recommended, good infection control procedures such as wearing gloves, and proper disposal of medical waste should be adequate to protect the person doing the site check. Among the initial group of vaccinees, arrangements should be made to have one or more of these persons perform the vaccine site checks for the rest of this group.

**C-26. For people who work at two hospitals, who will check their vaccination sites?**

Hospitals will need to plan for this possibility. One system that might work would be for the employee to have the vaccination site checked at the hospital clinic where the employee is working that day, and for the clinic to fax a progress note describing the evaluation to the hospital where the employee’s vaccination chart is maintained.

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**C-27. Who should do site checks for staff that work nights or weekends?**

Each hospital will need to determine the best staffperson(s) to do this. Options include the nurse administrator on-call, medical or nursing staff in the emergency department or other appropriate clinical staff (nursing or medical).

**C-28. How should used dressings be disposed of at the hospital and at home?**

The bandages or dressings should be disposed of as infectious waste in the hospital. At home, vaccinees will be instructed to place all used dressings into a plastic bag that can be sealed and discarded in the trash. All vaccinees will receive detailed instructions on caring for the vaccination site before being discharged from the vaccination clinic.

**C-29. Do vaccinees who do not have direct patient care have to wear the semi-permeable occlusive dressing?**

The need for a semi-permeable occlusive dressing is dependent on the probability of direct contact between the worker's vaccination sites and patients, especially those at high risk for adverse events. All vaccinees who work in patient care settings should use a gauze dressing covered by a semi-permeable occlusive dressing while at work.

For vaccinees who do not work in-patient care settings (*e.g., public health staff who are office based and do not have patient care responsibilities*), plain gauze held in place by tape or an adhesive strip should be sufficient. These persons also should be instructed to wear long-sleeved clothing over their dressings.

All vaccinees need to be educated on the importance of good hand hygiene after touching the vaccine site or used dressing materials in preventing inadvertent inoculation of vaccinia virus to another site on their body or to another person.

**C-30. How should we handle cleaning hospital uniforms used by vaccinated staff?**

As per current OSHA requirements for prevention of exposure to bloodborne pathogens, hospital laundry staff or workers at laundries that wash hospital linen should adhere to standard precautions when opening and sorting laundry. Similar to other hospital laundry, used uniforms worn by recently vaccinated staff should be laundered in warm water with detergent and/or bleach.

**C-31. If a vaccinated employee calls in indicating that he/she is ill, how should this be addressed? Does the individual have to come in to be evaluated or can this be handled by phone? Should they come in to their hospital where the vaccination was administered or go to their personal physician?**

It will depend upon the symptoms. If the person reports mild fever, swollen glands, and/or mild swelling and redness at the vaccine site, it may be okay to have them stay home and simply treat the symptoms. However, if there are symptoms that suggest more severe complications, such as high fevers, a vesicular or pustular rash in areas removed from the vaccine site, formation of an ulcerative lesion at the vaccine site, or either eye or

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neurologic symptoms, the patient should be evaluated by someone on the hospital's adverse event smallpox consultation team.

The NYC DOHMH prefers that vaccinees be seen at the hospital where they work and not by their private medical care providers, since each hospital should have pre-selected and pre-trained (by DOHMH) specialty consultants to provide care to vaccinees with suspected adverse events at their hospital. For more severe complications, the NYC DOHMH will contact the CDC for expert consultation, and to determine if VIG and/or cidofovir are indicated.

The CDC and NYC DOHMH will provide more detailed information on the criteria for reporting suspect adverse events before this vaccination program starts, as well as provide the CDC protocols for clinical management of these vaccine related complications once they are available.

In addition, the CDC is planning a Webcast for medical providers on the recognition and management of adverse events of smallpox vaccine that is tentatively scheduled for February 4, 2003. Additional information on this Webcast will be provided, as soon as it is available from the CDC.

**C-32. Should staff who may be caring for patients with vaccinia-related complications be pre-vaccinated?**

Physicians, such as infectious disease specialists or dermatologists, who may act as consultants for severe adverse reactions are also good candidates for a hospital's health care smallpox response team. Although, vaccination is not required for these clinicians, they should be vaccine eligible (i.e., have no contraindications to smallpox vaccine themselves).

If the treating physician for a patient with a suspected adverse event is not pre-vaccinated, the best means to protect against inadvertent vaccinia infection would be the use of appropriate infection control practices (e.g., contact precautions). Masks are not necessary because vaccinia is not contagious by the aerosol route.

**C-33. If there is an adverse event due to spread of vaccinia virus (e.g., *generalized vaccinia*, *progressive vaccinia*, *eczema vaccinatum*) will laboratory testing for vaccinia virus be available?**

Yes. The NYC DOHMH Public Health Laboratories will be offering vaccinia testing by polymerase chain reaction testing to help diagnose an adverse event due to the spread of vaccinia virus. Rapid testing is also available for varicella and herpes simplex to help rule out infection due to these other viruses.

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## **D. Communication Issues**

### **D-1. Does NYC have plans to educate the public about this pre-event smallpox vaccination program?**

Yes. The NYC DOHMH is developing many new resources that will be used to explain the smallpox vaccination campaign and other bioterrorism-related issues to the general public. The public will be kept informed through the media, the NYC DOHMH public website, written materials and a speakers bureau.

In addition, special outreach to the HIV/AIDS community is planned, in close coordination with the NY State DOH. Several community forums are planned starting in January 2003 to address the concerns of the HIV/AIDS community.

### **D-2. How will the news media and NYC deal with the publicity that will occur after the first severe vaccine adverse events occur?**

The news media will follow this vaccination campaign closely, and it will report adverse effects and their implications. The NYC DOHMH will continue to prepare potential vaccinees and the general public for the likelihood of adverse events, given what we know from previous use of the smallpox vaccine. As adverse events occur and are reported, the NYC DOHMH will address them with the best scientific knowledge available and provide additional public health recommendations as warranted.

The NYC DOHMH will only provide the media with summary data for the city (*e.g., total number of vaccinees*); no individual, hospital or agency-level data will be provided during this campaign.

### **D-3. How will we be kept updated with regards to discussions with unions (*e.g., 1199 and NYSNA*)?**

The NYC DOHMH has had preliminary meetings with the officials at the major labor unions in the city. The primary concerns expressed to date have been: (1) ensuring that this program is conducted voluntarily and safely, (2) that liability and compensation issues are adequately addressed, and (3) the safety of the bifurcated needles that will be provided by CDC (*See Question F-2*). A meeting is planned with the 1199 union members on January 23, 2003, with presentations planned by representatives from the NYC DOHMH and NY State Department of Health, as well as academic experts from area hospitals. Any updated information will be provided, when available, through the smallpox vaccine administrative liaison at each hospital.

We expect that unions will continue to communicate their thoughts about the vaccination campaign with their membership. The Services Employee International Union (SEIU) has posted information on the smallpox vaccine on their web page at <http://www.seiu.org/health/smallpox.cfm>

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## **E. General Issues of Concern to Hospitals**

### **E-1. Any suggestions on how to promote volunteerism during this pre-event vaccination campaign?**

This pre-event vaccination program has been recommended by the President, the U.S. Secretary of Health and Human Services, the CDC, the New York State Department of Health (NYS DOH), the NYCDOHMH and the Greater New York Hospital Association as a means to ensure preparedness in our hospitals in the event of a smallpox attack. Based on the experience in Europe during prior smallpox outbreaks, more than 50% of secondary cases occurred among health care workers caring for smallpox victims. (Mack T. Smallpox in Europe, *J Infect Dis* 125(2);161-169:1972.). Therefore, if smallpox did recur due to a terrorist attack, health care providers would be on the front lines and would be at higher risk for secondary infection. Given this, those who volunteer to be on health care smallpox response teams need to be offered protection ahead of time.

New York City has recently been the target of two major terrorist attacks. After the events of September 11<sup>th</sup> and the anthrax outbreak in October 2001, New Yorkers responded with a consistent willingness and interest in helping with the recovery and response activities. That clearly was experienced throughout the hospital sector. While some persons may be more interested in the personal protection that smallpox vaccination could afford, other health care workers may be more interested in contributing to the City's ongoing efforts to become better prepared to respond to a future terrorist attack. Efforts can be made to appeal to persons interested in volunteering for either of these reasons. A template fact sheet for potential health care worker volunteers has been sent to all hospitals and is available on the NYC DOHMH website at [www.nyc.gov/health/smallpox](http://www.nyc.gov/health/smallpox).

### **E-2. Have any surveys addressed the likely vaccine refusal rate that may occur?**

We are not aware of published surveys that have looked directly at health care worker perceptions. However, two studies that have not been published have shown acceptance rates between 50% and 75% among medical specialists. We have heard that during Israel's recent health care vaccination program, approximately half of those offered vaccine declined, although the reasons for declining (*e.g., presence of a contraindication versus not interested in volunteering*) are not known.

Also, recent nationwide polls have shown that there is broad support for voluntary smallpox vaccination among the general public.

### **E-3. What will be the public health fallback position if the refusal rate for smallpox vaccinations among health care workers is too high?**

Since this vaccination program is strictly voluntary, no one will be forced to take the vaccine, even if the refusal rate is high. We will continue to try to address the concerns raised by persons who are considering or who have declined vaccinations. We will also

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continue to raise those issues that are best addressed at a national level to federal public health authorities and elected officials (*e.g., need for a compensation program for vaccinia related complications among vaccinees and their contacts*).

If at the end of this first phase of pre-event vaccination there are insufficient volunteers, hospitals are still expected to have plans in place for responding to a suspected or confirmed smallpox case, including having pre-designated teams of health care providers to care for the initial suspect or confirmed cases. Written guidelines have been distributed to all city hospitals in the document entitled, “*New York City Department of Health and Mental Hygiene and New York State Department of Health Guidelines for Management of a Suspect Case of Smallpox in Acute Care Hospitals in New York City*”, which is available at [www.nyc.gov/health/smallpox](http://www.nyc.gov/health/smallpox).

At hospitals that are not able to recruit sufficient staff to volunteer for smallpox vaccinations, these pre-designated teams should consist of persons who have received at least one smallpox vaccination in the past. In the event that smallpox does occur, all staff who had exposure to the case-patient(s) will be prioritized for smallpox vaccination within 3 days of their exposure.

**E-4. As I think it is unlikely that smallpox will ever occur, are the benefits to my hospital for participating really worth the risks to my staff from the vaccine?**

All hospitals need to be prepared for bioterrorism, including the threat of a smallpox outbreak. The primary goal of this pre-event vaccination program is to prepare hospitals for the immediate responses needed in the event of a smallpox outbreak and to protect their frontline staff given that health care workers are at increased risk of secondary transmission from smallpox patients. Based on the experience in Europe during prior smallpox outbreaks, more than 50% of secondary cases occurred among health care workers caring for smallpox victims. (Mack T. Smallpox in Europe, *J Infect Dis* 125(2);161-169:1972.). Given this, those that volunteer to be on health care smallpox response teams need to be offered protection ahead of time.

There are other potential benefits as well. Although we all hope that we never see smallpox again, we continue to have “false alarms” (reports of “suspect cases” that are later determined not to be smallpox). To ensure the ability to rapidly and calmly respond to a suspect case, it would certainly help to have pre-vaccinated staff available to evaluate and provide care for a suspect case-patient until the diagnosis is confirmed or ruled-out by testing or clinical examination. In several instances, both here in NYC and elsewhere, the presence of a suspect case generated some initial panic in the involved institution as well as a media response. Most hospitals would benefit by having a team ready and willing to care for these patients in the event a suspect case presented, regardless of whether the diagnosis is confirmed as smallpox.

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**E-5. Are there expectations that volunteer vaccinees would be available to other hospitals that do not participate in this pre-event vaccination program or to hospitals that do not have sufficient pre-vaccinated staff if a smallpox outbreak occurred?**

For planning purposes, all hospitals should assume that smallpox response teams at other institutions would be busy treating suspected or confirmed patients at their own facilities, or may not be willing to share these staff during an emergency. However, hospital networks may be more capable of sharing personnel resources between hospitals. Hospitals are encouraged to implement mutual aid agreements with other facilities that provide for sharing of needed personnel and material resources during public health emergencies.

**E-6. Can a health care worker elect not to take care of a smallpox patient?**

A health care worker may have valid reasons for refusing to care for smallpox patients (*such as an underlying immunodeficiency*), but these cases will need to be dealt with on a case-by-case basis. For more specific guidance, we recommend that you consult your hospital's legal department.

**E-7. Can a hospital refuse to take care of a smallpox patient?**

The New York State Department of Health (NYSDOH) has specific provisions of law and regulations governing a hospital's responsibility to care for patients arriving at its hospital. For more specific guidance, we recommend that you consult your hospital's legal department.

**E-8. If my hospital decides not to participate in this program, and a suspect smallpox patient is seen at our emergency department or clinic, can we expect that the NYC DOHMH will arrange to transfer the patient to another hospital where there are pre-vaccinated health care smallpox response teams?**

No. The NYC DOHMH and NYSDOH expect that all acute care hospitals have plans in place for the management of suspect or confirmed smallpox (*See NYC DOHMH and NYSDOH guidelines at [www.nyc.gov/health/smallpox](http://www.nyc.gov/health/smallpox)*). Hospitals' smallpox plans should address the following issues: training staff to recognize patients with smallpox; rapid triage and isolation of suspect cases; pre-identification of health care worker teams to provide care for the initial victims; ensuring staff are trained in appropriate infection control precautions and that personal protective equipment is available; and that airborne infection isolation rooms are functioning, as described below:

**Airborne infection isolation rooms** are defined as negative pressure isolation rooms with a minimum of 6-12 air exchanges per hour and direct exhaust to the outside, which are located more than 25 feet from an air intake and from where people may pass (if air cannot be exhausted directly to the outside more than 25 feet from an air intake and from where people may pass, then air should be filtered through an appropriately installed and maintained HEPA filter). These

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rooms should be tested monthly (and daily when in use) to verify negative airflow.

If there were a smallpox outbreak in NYC, it is likely that there would be more than a few cases. Since 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 and willing to take care of these patients until other staff could be vaccinated.

If a hospital does not have sufficient pre-vaccinated staff in place for whatever reason, and there is a large outbreak in NYC with cases presenting to hospitals citywide, all hospitals will need to protect their staff by ensuring strict adherence to airborne and contact precautions until all other staff can be vaccinated.

Within a network, it may be decided to only pre-vaccinate staff at one or a few hospitals. Such networks should have plans in place to ensure the ability to transfer any suspect smallpox cases, once stabilized to a receiving hospital with a prevaccinated team in place, in accordance with all applicable laws and regulations (for example, the federal Emergency Medical Treatment and Active Labor Act). Such plans should be made in advance, and ideally in written form.

If networks decide to vaccinate health care smallpox response teams in some but not all of their facilities, they still need to ensure that all of their acute care hospitals are prepared to identify, isolate, and treat suspect smallpox patients, as indicated in the “*New York City Department of Health and Mental Hygiene and New York State Department of Health Guidelines for Management of a Suspect Case of Smallpox in Acute Care Hospitals in New York City*” available at [www.nyc.gov/health/smallpox](http://www.nyc.gov/health/smallpox).

**E-9. If a hospital decides not to participate, can staff at that hospital still elect to get vaccinated elsewhere?**

No. Smallpox vaccinations will be offered through participating hospitals and first responder agencies only. Individuals will not be able to get vaccinated unless their employers are participating in this phase of the pre-event vaccination program.

**E-10. What will the financial costs be for hospitals to implement this program?**

We do not know. However, we suggest that all institutions keep track of these costs, in case future funding becomes available for re-imbursement (for example, through the HRSA Hospital Bioterrorism Preparedness Cooperative Agreement). During this and future vaccination waves, major costs to the health care, public health, and public safety sectors will occur in light of the staff time allotted for planning, education, training, vaccination, site monitoring, and responses to and costs of any adverse events. These costs may be offset by the smallpox response resources that the hospital will gain. When comprehensive vaccination of the health care, public health, and public safety sectors is completed, the City’s ability to withstand a smallpox outbreak will be significantly

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improved.

**E-11. Why is furlough not being recommended for vaccinated health care workers due to the potential concerns about secondary transmission of vaccinia to patients at higher risk for complications?**

The ACIP and HICPAC advisory groups determined that this was not necessary because of (1) the low historical risk of transmission from health care worker to patients, (2) data that the semi-permeable dressings over a gauze bandage greatly reduced or eliminated viral shedding, (3) that hospitals will be expected to check workers before every shift to be sure that the dressing was intact and covering the site, and to reinforce the need for strict adherence to infection control practices, including handwashing with soap and water before and after contact with patients, (4) that workers will be expected to wear long sleeves over the dressing, and (5) the planned emphasis on vaccinating previously vaccinated health care workers, at least during this initial phase of pre-event vaccination (Revaccinated persons will likely have fewer side effects and less risk of transmission to others.) The CDC is preparing to publish the final ACIP recommendations in an issue of the *Morbidity and Mortality Weekly Report* at the end of January 2003.

**E-12. Does a vaccinated health care worker need to inform his/her patients of the vaccination?**

The risk of transmission of vaccinia from vaccinated hospital personnel to their patients is thought to be much less than to household or close, personal contacts. In the hospital setting, it is much less likely for vaccinated staff to have close, prolonged, personal contact with patients or colleagues than with household or other close, personal contacts

In Israel, to date, 4 suspected serious adverse events have occurred following the recent vaccination of approximately 15,000 health care workers. All involved either vaccinees themselves (n=2) or their household contacts (n=2). The Israelis did not recommend furlough of health care workers and no secondary transmission to hospital patients was documented. The site care checks and other measures that will be used in the hospital setting (i.e., use of a semi-permeable dressing in addition to the gauze bandage), as well as the more strict adherence to infection control precautions than is usually possible in the home, should minimize the potential for vaccinia transmission to patients.

This question was also considered at the most recent Advisory Committee for Immunization Practices meeting at the CDC, and the discussion from this meeting was that health care workers do not need to inform patients of their vaccination status. Each institution should follow the procedures they use for other infections in health care workers that can be transmitted to and present a potential risk to patients (e.g., hepatitis B and HIV infection). For more specific guidance, we recommend that you consult your hospital's legal department.

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**E-13. Do healthcare workers who have been vaccinated need to wear masks when working with immunocompromised patients?**

No. The vaccinia virus in the smallpox vaccine is spread by direct contact. Vaccinia has not been shown to spread through airborne or droplet transmission.

**E-14. If a hospital cannot provide intensive care for patients with severe adverse events, should it defer from participation in smallpox vaccination?**

Each hospital must make its own decision regarding participation in this voluntary smallpox vaccination program. But whether or not a facility can provide intensive care should not be a determining factor, since referrals to hospitals that can provide the level of care needed to treat such patients should be possible in most locations. Participating hospitals will be encouraged to make arrangements for initial clinical consultations for their staff members with suspected adverse events. If hospitals are not able to provide these services on-site through hospital-affiliated clinical staff, they will be asked to make arrangements through another hospital, ideally an affiliated hospital within their institutional network.

**F. Other Issues**

**F-1. Will the military be sharing information on their vaccination campaign?**

The military has just started its pre-event vaccination campaign and there are military bases in upstate New York and New Jersey that will be offering smallpox vaccine to military personnel, including military reservists and the National Guard. The Department of Defense has stated that it will share information on their experiences with the CDC, as well as with the civilian medical community.

**F-2. Have the concerns regarding the safety of the bifurcated needle included in the vaccine kit been addressed?**

The bifurcated needle that is included with the smallpox vaccine kit does not contain a safety cover. However, it is the only needle licensed by the FDA to be used during administration of the vaccine. A written statement addressing this issue is on the CDC website at <http://www.bt.cdc.gov/agent/smallpox/vaccination/vaccination-program-ga.asp>.