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Information for Health Care and Public Health Workers Considering Voluntary Pre-Event Smallpox Vaccination for Participation in Public Health or Health Care Response Teams
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Why should health care and public health workers consider volunteering to receive smallpox vaccination?

Although smallpox no longer occurs, its causative agent, variola virus, still exists. There is uncertainty as to whether or not smallpox virus has been obtained by persons who might use it to cause intentional infections. If an outbreak of smallpox was to occur, several factors could contribute to a more rapid spread of smallpox than was routinely seen before this disease was eradicated. These factors include: 1) virtually no one currently has immunity to smallpox due to the absence of naturally occurring disease and the discontinuation of routine vaccination in the United States in the early 1970s, 2) potentially delayed recognition of smallpox by health personnel who are unfamiliar with the disease, and 3) increased mobility and crowding of the population. Because of these factors, a single case of smallpox would require an immediate and coordinated public health and medical response to contain the outbreak and to prevent further infection of susceptible individuals.

On June 20 and on October 21 2001 the Advisory Committee on Immunization Practices (ACIP) issued new revised recommendations regarding smallpox vaccine. ACIP consists of 15 experts in fields associated with immunization who have been selected by the Secretary of the U.S. Department of Health and Human Services to provide advice and guidance to the Secretary, the Assistant Secretary for Health, and the Centers for Disease Control and Prevention (CDC) on the most effective means to prevent vaccine-preventable diseases.

Information provided to the ACIP indicated that the risk for smallpox occurring as a result of a deliberate release by terrorists is considered low, and the population at risk for such an exposure cannot be determined. In order to provide a quick and effective medical and public health response to the initial smallpox cases, ACIP has recommended that smallpox vaccine be offered to persons pre-designated to provide direct patient care and conduct public health disease control activities for the initial suspected or confirmed cases of smallpox. Persons eligible for these teams would be at highest risk for contact with the initial suspected or confirmed cases of smallpox in the community based on their work duties. Specifically, the ACIP recommended voluntary vaccination of people serving on what subsequently have been designated as

1. “Smallpox Public Health Response Teams” and
2. “Smallpox Health Care Teams”

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Smallpox Health Care Teams

The ACIP recommends that in the first stages of a pre-event smallpox vaccination program each acute care hospital identify a group of healthcare workers who would be vaccinated and trained to provide in-room medical care for the first few smallpox patients requiring hospital admission and to evaluate and manage patients who present to the Emergency Department with suspected smallpox. For the first 7-10 days after patients with smallpox have been identified, this team would be hospital-based and provide care 24 hours a day, using 8-12 hour shifts. Non-essential workers would be restricted from entering into the rooms of patients with smallpox.

Suspected smallpox patients are likely to present at the hospitals and health care facilities which are their usual source of care, and not only at designated hospitals. Therefore, health and bio-terrorism officials indicated it was preferable to offer all acute care hospitals the opportunity to establish Smallpox Health Care Teams. Hospitals in King County have established criteria for the types of positions that should be included on their health care teams based on the ACIP recommendations. Persons who volunteer to serve on smallpox health care teams must agree to perform designated job functions in responding to suspected or confirmed smallpox cases. Health care workers who are not part of pre-designated smallpox response teams are not being offered smallpox vaccination at this time. It is possible that additional health care workers may be offered voluntary smallpox vaccination after smallpox response teams are established.

Smallpox Public Health Response Teams

To enhance public health preparedness and response for smallpox control, specific teams at the federal, state and local level are being established to investigate and facilitate the diagnostic work-up of the initial suspect case(s) of smallpox and initiate control measures. In Washington State, Smallpox Public Health Response Teams will include medical rapid assessment teams, persons conducting case and contact investigations (medical epidemiologists and disease investigators), diagnostic laboratory scientist, personnel who would administer smallpox vaccines (nurses), and security/law enforcement personnel.

The ACIP vaccination policy (described in the National Smallpox Vaccination Program) is designed to protect the people who would be at highest risk in a smallpox outbreak or attack without causing unnecessary harm from a vaccine that can have serious side effects. The goal is to have initial teams of skilled personnel in the public health and medical systems prepared to rapidly respond to the initial smallpox cases. Smallpox vaccination for participation in pre-event smallpox response teams is completely voluntary. To become a volunteer, eligible persons must agree to perform specific pre-designated functions on the response team, confirm that they have no contraindications to receiving smallpox vaccination, and sign a consent form for smallpox vaccination. Persons potentially interested in volunteering should carefully review the following information about smallpox vaccine and vaccine contraindications.

Adverse Reactions Following Smallpox Vaccination

Smallpox vaccination (vaccinia) is generally a safe and effective means of preventing smallpox. However, in a number of individuals, smallpox vaccination can result in untoward effects and adverse reactions. Most are totally benign, but may be alarming in appearance. Some are serious, but treatable. A few, which rarely occur, are serious, life

threatening and can be fatal. Severe adverse reactions are more common in persons receiving smallpox vaccine for the first time (primary vaccination) compared to those being revaccinated.

Local Reactions

- Primary vaccination can produce swelling and tenderness of regional lymph nodes beginning 3 to 10 days after vaccination and in some cases persisting up to 2 to 4 weeks after the skin lesion has healed.
- Other normal local reactions can include
  - local satellite lesions (which appear similar to the primary lesion),
  - considerable local edema,
  - what may be confused with bacterial cellulitis, but is simply intense inflammation accompanying the vaccination (viral cellulitis).
- In a recent study of adult primary vaccinees, 36% were sufficiently ill to miss work, school, or recreational activities or to have trouble sleeping.

Systemic Reactions

- In a recent study, 17% of adult primary vaccinees experienced fever of at least 100°F within two weeks of vaccination; 7% had a fever of 101°F or more, and 1.4% experienced a fever of 102°F or more. Beyond two weeks, fever was recorded in 0.3% of vaccinees.
- Other expected systemic reactions include malaise, soreness at the vaccination site, myalgia, local lymphadenopathy, and intense erythema ringing the vaccination site.
- A variety of erythematous or urticarial rashes occur approximately 10 days after primary vaccination in one person per 3700 vaccinated.
  - Vaccinees who develop these rashes are usually afebrile and the rash resolves spontaneously within 2 to 4 days.
  - Rarely, a more serious rash, called bullous erythema multiforme (or Stevens-Johnson syndrome) occurs.
- In a recent study of adult primary vaccinees, 36% were sufficiently ill to miss work, school, or recreational activities or to have trouble sleeping.

Inadvertent Inoculation

- Successful vaccination produces a lesion at the vaccination site. Beginning about four days after vaccination, the florid site contains high titers of vaccinia virus. This surface is easily transferred to the hands and to fomites, especially since itching is a common part of the local reaction.
- Accidental implantation occurs due to transfer of vaccinia virus from the primary site to other parts of the body, or to other individuals.
  - This is the most frequent complication of smallpox vaccination (529 per million primary vaccinees), accounting for approximately half of all complications of primary vaccination and revaccination.*
  - Lesions of inadvertent inoculation can occur anywhere on the body, but the most common sites are the face, eyelid, nose, mouth, genitalia, and rectum. Lesions in eczematous skin, in disrupted skin and in the eye pose special hazards, as the infection can be extensive in skin lesions and a threat to eyesight in the eye.
  - Most lesions heal without specific treatment.

Generalized Vaccinia

- Generalized vaccinia consists of vesicles or pustules appearing on normal skin distant from the vaccination site.
- In the past, it was estimated to occur in 242 per million primary vaccinees.*
- It is believed to result from a vaccinia viremia with skin manifestations.
- Most rashes labeled as generalized vaccinia produce only minor illness with little residual damage.
- The rash is generally self-limited and usually requires only supportive therapy. However, patients with underlying immunosuppressed illnesses may have a toxic course and require Vaccinia Immune Globulin (VIG).

Eczema Vaccinatum

- Eczema vaccinatum is a localized or systemic spread of vaccinia virus.
- In the past, it was estimated to occur in 10-39 per million primary vaccinees.*
- Transfer of vaccinia virus can occur from autoinoculation or from contact with a vaccinee whose lesion is in the florid stages.
- Individuals with eczema or atopic dermatitis are at increased risk. Eczema vaccinatum can occur regardless of whether the eczema/atopic dermatitis is active at the time of vaccination.
- Virus implanted in disrupted skin (may be at multiple sites) spreads from cell to cell producing extensive lesions dependent on extent of abnormal skin.
- Treatment should include hospitalization and urgent treatment with VIG. Mortality has been prevented in patients treated promptly and adequately.
- Severe cases and fatalities have been observed after contact of recently vaccinated persons with persons who have active eczema/atopic dermatitis or a history of eczema/atopic dermatitis.

Vaccinia Keratitis

- Vaccinia keratitis results in lesions of the cornea due to accidental implantation of vaccinia virus, and is potentially threatening to eyesight.
- Symptoms appear ten days after transfer of vaccinia virus.
- Left untreated, considerable corneal scarring may result as lesion heals resulting in significant impairment of vision.
- Topical antiviral agents are the treatment of choice; therapy should be determined in immediate consultation with an experienced ophthalmologist.

Progressive Vaccinia

- Progressive vaccinia, also known as vaccinia necrosum, is a severe, potentially fatal illness characterized by progressive necrosis in the area of vaccination, often with metastatic lesions (e.g., lesions at places other than the vaccination site).
- In the past, it was estimated that progressive vaccinia occurred in approximately 1 to 2 per million primary vaccinations, and was almost always fatal before the introduction of VIG and antiviral agents.*
- Rare in the past, it may be a greater threat today, given the larger proportion of susceptible persons in the population and the greater number with immunocompromise. Nearly all instances have been in people with defined cell-mediated immune defect (T-cell deficiency).

- Prompt hospitalization and aggressive use of VIG are required.
- Massive doses of VIG are necessary to control viremia. Up to 10 ml per kg of intramuscular VIG has been used.
- There is no proven antiviral therapy. Preliminary studies with cidofovir show some antiviral effect in vitro; studies in animals are pending.
- Immediate consultation with the CDC is recommended to determine if any experimental antiviral drugs are available.

Post-Vaccinial Encephalitis

- Encephalitis or meningoencephalitis following vaccination has been reported in about 3 to 12 per million primary vaccinees; how many such cases are coincidental in time and how many are related to the vaccination itself is impossible to know.*
- Because many different infectious agents and non-infectious processes can be responsible, it is often impossible to establish the etiology. Most cases are believed to result from autoimmune or allergic reactions rather than direct viral invasion of the nervous system.
- In general, post-vaccinial encephalitis is a severe disease with high mortality and morbidity. Approximately 15-25% percent of affected vaccinees with this complication die, and 25% develop permanent neurological sequelae.
- There is no specific therapy. Supportive care, anticonvulsants and hospitalization in intensive care may be required in individual cases.
- VIG is not effective and is not recommended.

Fetal Vaccinia

- Fetal vaccinia is a rare complication of smallpox vaccination.
- Fewer than 50 cases of fetal vaccinia infection have been reported, usually after primary vaccination of the mother in early pregnancy.
- Fetal vaccinia usually results in stillbirth or death of the infant soon after delivery.
- Smallpox vaccine is not known to cause congenital malformations.

Death

- Death resulting from smallpox vaccination is rare, in the past approximately 1 to 2 primary vaccinees died per million vaccinated.*
- Death is most often the result of postvaccinial encephalitis or progressive vaccinia.

**Adverse event rates presented here are primarily from data collected in the 1960s. Rates in the United States today may be higher because there may be more persons at risk from 1) immune suppression from cancer, cancer therapy, organ transplantation, and other illnesses, such as HIV/AIDS, and 2) eczema or atopic dermatitis. Rates may be lower for persons previously vaccinated.*

Smallpox (Vaccinia) Vaccine Contraindications – Please Read Carefully
Because the vaccinia virus used in smallpox vaccine can be spread to others from the vaccine site of an immunized person, the contraindications below apply to both potential vaccinees and their household contacts. If you or someone you live with has any of the following conditions, you should not receive the smallpox vaccine at this time. There are no contraindications to the smallpox vaccine if someone has been exposed to the smallpox virus.

- Eczema or atopic dermatitis and other acute, chronic, or exfoliative skin conditions
  Persons who have ever been diagnosed with eczema or atopic dermatitis should not be vaccinated, even if the condition is not currently active. These patients are at high risk of developing eczema vaccinatum, a potentially severe and sometimes fatal complication. Additionally, persons with household contacts that have a history of eczema or atopic dermatitis, irrespective of disease severity or activity, should not be vaccinated.

  If the potential vaccinee or any of their household contacts have other acute, chronic, or exfoliative skin conditions (e.g., burns, impetigo, chicken pox, contact dermatitis, shingles, herpes, severe acne, or psoriasis), they are at risk for inadvertent autoinoculation of the affected skin with vaccinia virus and should not be vaccinated until the condition(s) resolves.
  The literature also reports that persons with Darier's disease can develop eczema vaccinatum and therefore should not be vaccinated.

  If you, or a member of your household has ever been diagnosed with eczema or atopic dermatitis you may NOT receive voluntary pre-event smallpox (vaccinia) vaccine. Eczema/atopic dermatitis usually is an itchy red, scaly rash that lasts more than 2 weeks and often comes and goes. If you or a member of your household have <u>ever</u> had a rash like this—you should NOT receive the smallpox (vaccinia) vaccine at this time unless you and a healthcare provider are sure that this rash is not atopic dermatitis or eczema.

- Diseases or conditions which cause immunodeficiency or immunosuppression
  If a potential vaccinee or any of their household contacts have conditions such as HIV/AIDS, solid organ or stem cell transplant, generalized malignancy, leukemia, lymphoma, agammaglobulinemia, or autoimmune disease, they should not be vaccinated. People with these conditions are at greater risk of developing a serious adverse reaction resulting from unchecked replication of the vaccine virus (progressive vaccinia).

  HIV testing should be readily available to all persons considering smallpox vaccination. **HIV testing is recommended for persons who have any history of a risk factor for HIV infection and who are not sure of their HIV infection status. Anyone who is concerned that they could have HIV infection also should be tested.** HIV testing should be available in a confidential or, where permitted by law, anonymous setting with results communicated to the potential vaccinee before the planned date of vaccination. Persons with a positive test result should be told not to present to the vaccination site for immunization.

- Treatments which cause immunodeficiency or immunosuppression
  If a potential vaccinee or any of their household contacts are undergoing treatment with radiation, antimetabolites, alkylating agents, corticosteroids (high dose prednisone: ≥2mg/kg/day or ≥20 mg/d for 14 days or longer), chemotherapy agents, or organ transplant medications, they should not be vaccinated. People who are receiving these therapies are at greater risk of serious adverse reactions to the smallpox vaccine.
- Pregnancy
  Live virus vaccines are generally contraindicated during pregnancy. Pregnant women who receive the smallpox vaccine are at risk of fetal vaccinia. Although this is a very rare condition (fewer than 50 cases have ever been reported), it usually results in stillbirth or death of the infant shortly after delivery.

  Before vaccination, people should be asked if they or any of their household contacts are pregnant or intend to become pregnant in the next 4 weeks; those who respond positively should not be vaccinated. In addition, women who are vaccinated should be counseled not to become pregnant during the 4 weeks after vaccination. Routine pregnancy testing of women of child-bearing age is not recommended.

  Any woman who thinks she could be pregnant or who wants additional assurance that she is not pregnant should perform a urine pregnancy test using a "first morning" void urine on the day scheduled for vaccination.

  If a pregnant woman is inadvertently vaccinated or if she becomes pregnant within 4 weeks after vaccinia vaccination, she should be counseled regarding the basis of concern for the fetus. However, vaccination during pregnancy should not ordinarily be a reason to terminate pregnancy.

The contraindications above apply to potential vaccinees and their household contacts (if you or any of your household contacts have any of the conditions mentioned above, you should not receive voluntary pre-event smallpox vaccination). The following additional contraindications apply only to potential vaccinees:

- Previous allergic reaction to smallpox vaccine or any of the vaccine's components
  Vaccinia vaccine (Dryvax®) contains small amounts of polymyxin B sulfate, streptomycin sulfate, chlortetracycline hydrochloride, neomycin sulfate, and phenol. Anyone who has experienced an anaphylactic reaction to these components should not be vaccinated.
  In addition, anyone who has experienced a previous allergic reaction to the smallpox vaccine should not be vaccinated.

- Moderate or severe acute illness
  Moderate or severe acute illness is generally a contraindication to vaccination. Vaccination should be deferred until the acute illness has resolved.

- Smallpox vaccine is contraindicated for children less than 12 months of age and ACIP recommends it not be administered to persons under 18 years of age in nonemergency circumstances.

- Breastfeeding
  Breastfeeding mothers should not receive the smallpox vaccine. The close physical contact that occurs during breastfeeding increases the chance of inadvertent inoculation.

Careful screening is essential to minimize complications from the smallpox vaccine. If you have any questions about whether or not you should receive the smallpox vaccine, discuss your concerns with your health care provider, contact the smallpox response team organizers at your hospital and/or visit the CDC website at www.cdc.gov/smallpox. **The above adverse event and contraindication information was reproduced from the CDC smallpox web site. Additional information about smallpox and smallpox vaccine is available from the CDC web site at:**
http://www.bt.cdc.gov/agent/smallpox/reference/resource-kit.asp

The October 21, 2002 AICP recommendations are available at:
http://www.bt.cdc.gov/agent/smallpox/vaccination/acip-recs-oct2002.asp

Vaccinia (Smallpox) Vaccine: Recommendations of the Advisory Committee on Immunization Practices (ACIP) has additional information about smallpox vaccine and is available at: http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5010a1.htm

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