Complete Summary

GUIDELINE TITLE

Recommendations for using smallpox vaccine in a pre-event smallpox vaccination program. Supplemental recommendations of the Advisory Committee on Immunization Practices (ACIP) and the Healthcare Infection Control Practices Advisory Committee (HICPAC).

BIBLIOGRAPHIC SOURCE(S)

Wharton M, Strikas RA, Harpaz R, Rotz LD, Schwartz B, Casey CG, Pearson ML, Anderson LJ. Recommendations for using smallpox vaccine in a pre-event vaccination program. Supplemental recommendations of the Advisory Committee on Immunization Practices (ACIP) and the Healthcare Infection Control Practices Advisory Committee (HICPAC). MMWR Recomm Rep 2003 Apr 4;52(RR-7):1-16. [56 references] PubMed

GUIDELINE STATUS

This is the current release of the guideline.

** REGULATORY ALERT **

FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory information has been released.

On November 10, 2005, the U.S. Food and Drug Administration (FDA) notified physicians, nurses, medical technologists, pharmacists and other healthcare professionals of the potential for life-threatening falsely elevated glucose readings in patients who have received parenteral products containing maltose or galactose, or oral xylose, and are subsequently tested using glucose dehydrogenase pyrroloquinolinequinone (GDH-PQQ) based glucose monitoring systems. There have been reports of the inappropriate administration of insulin and consequent life-threatening/fatal hypoglycemia in response to erroneous test results obtained from patients receiving parenteral products containing maltose. Cases of true hypoglycemia can go untreated if the hypoglycemic state is masked by false elevation of glucose readings. A preliminary listing of U.S. products that may cause glucose test interference is provided. See the FDA Web site for more information.

COMPLETE SUMMARY CONTENT

** REGULATORY ALERT **
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SCOPE

DISEASE/CONDITION(S)

Smallpox

GUIDELINE CATEGORY

Evaluation
Management
Prevention
Treatment

CLINICAL SPECIALTY

Infectious Diseases
Internal Medicine
Preventive Medicine

INTENDED USERS

Advanced Practice Nurses
Allied Health Personnel
Health Care Providers
Hospitals
Nurses
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

- To supplement and update the 2001 Advisory Committee on Immunization Practices (ACIP) recommendations for vaccination of persons designated to respond or care for a suspected or confirmed case of smallpox
- To clarify and expand the primary strategy for control and containment of smallpox in the event of an outbreak

Note: Recommendations for vaccination of laboratory workers who directly handle recombinant vaccinia viruses derived from non-highly attenuated vaccinia

strains, or other orthopoxviruses that infect humans (e.g., monkeypox, cowpox, vaccinia, and variola) as presented in the 2001 ACIP guideline remain unchanged.

TARGET POPULATION

- *Smallpox Response Teams*: Persons designated by the appropriate terrorism and public health authorities to conduct investigations and follow-up of initial smallpox cases that might necessitate direct patient contact, as well as persons responsible for administering smallpox vaccine in the pre-event vaccination program. This might include: persons designated as medical team leaders, public health advisors, medical epidemiologists, disease investigators, diagnostic laboratory scientists, nurses, personnel who would administer smallpox vaccines, and security or law enforcement personnel, and other medical personnel to assist in evaluating suspected smallpox cases.
- *Smallpox Health Care Teams*: Acute care hospital healthcare workers expected to provide direct medical care for the first few smallpox patients requiring hospital admission, and those who would evaluate and manage patients who are examined at emergency departments with suspected smallpox. These teams include:
    - Emergency room staff, including physicians and nurses caring for children and adults
    - Intensive care unit staff, including physicians, nurses, and in hospitals that care for infants and children, pediatricians and pediatric intensive care specialists
    - General medical unit staff, including nurses, internists, pediatricians, hospitalists (i.e., physicians whose practice emphasizes providing care for hospitalized patients), and family physicians in institutions where these individuals are the essential providers of primary medical care
    - Primary care house staff (i.e., medical, pediatric, and family physicians)
    - Medical subspecialists, including infectious disease specialists (Note: This may involve the creation of regional teams of subspecialists [e.g., local medical consultants with smallpox experience, dermatologists, ophthalmologists, pathologists, surgeons, anesthesiologists in facilities where intensivists are not trained in anesthesia] to deliver consultative services.)
    - Infection control professionals
    - Respiratory therapists
    - Radiology technicians
    - Security personnel
    - Housekeeping staff (e.g., those staff involved in maintaining the health care environment and decreasing the risk of fomite transmission)

Note: Clinical laboratory workers are not recommended for inclusion in the initial phase of pre-event smallpox vaccination.

INTERVENTIONS AND PRACTICES CONSIDERED

Pre-Release Vaccination Program

1. Medical history including assessment for contraindications to vaccination and screening for precautions such as inflammatory eye disease, simultaneous vaccination with varicella vaccine, recent tuberculosis skin test (PPD)
2. Calf-lymph derived vaccine, Dryvax®
3. Use of correct vaccination technique
4. Patient education to prevent contact transmission
5. Monitor vaccination response
6. Revaccination as indicated
7. Follow-up of adverse reactions as indicated.
8. Medication, such as vaccinia immune globulin (VIG) and cidofovir (Note: VIG and cidofovir are available under Investigational New Drug [IND] protocols)

Smallpox Outbreak

1. Report suspected smallpox to local/state health departments
2. Clinical consultation through Centers for Disease Control
3. Laboratory confirmation
4. Infection control strategies including isolation, vaccination and surveillance

MAJOR OUTCOMES CONSIDERED

- Effectiveness of infection control strategies such as vaccination and isolation to contain smallpox outbreak
- Effectiveness of infection control practices (i.e., proper care of vaccination site, proper hand hygiene and decontamination procedures) to reduce contact transmission
- Rate and types of adverse events/complications following vaccination

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases
Searches of Unpublished Data

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Not stated

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Not stated

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not stated

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Smallpox Transmission and Control

The primary strategy to control a smallpox outbreak and interrupt disease transmission is surveillance and containment, which includes isolation of smallpox cases and vaccination of persons at risk of contracting smallpox. This strategy involves identification of infected persons through intensive surveillance, isolation of smallpox patients to prevent further transmission, vaccination of household contacts and other close contacts of infected persons (i.e., primary contacts), and vaccination of close contacts of the primary contacts (i.e., secondary contacts who would be exposed should disease develop in the primary contacts). This strategy was instrumental in the ultimate eradication of smallpox as a naturally occurring disease even in areas that had low vaccination coverage.

Smallpox Vaccines and Vaccinia Immune Globulin Availability

The only smallpox vaccine currently licensed in the United States is Dryvax® (manufactured by Wyeth Laboratories, Inc., Marietta, Pennsylvania), which is a lyophilized preparation of live vaccinia virus grown on the skin of calves. On October 25, 2002, the Food and Drug Administration (FDA) approved a labeling supplement and a manufacturing supplement to Wyeth's biologics license application for Dryvax®. The manufacturing supplement provides for a new kit that includes lyophilized vaccine in a 100- dose vial, a new supply of diluent (one prefilled diluent syringe), one transfer needle, and 100 individually wrapped bifurcated needles. With the approval of this supplement, Dryvax® can again be distributed and used as a licensed product. Licensed lots have to meet lot-release specifications, which include recent testing to demonstrate that the vaccine retains its potency. Further information regarding the supplement approval and labeling for Dryvax® can be found at www.fda.gov/cber/products/smalwye102502.htm. As of December 16, 2002, two lots consisting of a total of 2.7 million doses of Dryvax® had full approval for use as a licensed product. Additional lots of Dryvax® are expected to be released by the FDA under the license.

Licensed Dryvax® vaccine for civilian use will only be available through the Centers for Disease Control (CDC). Licensed vaccine will be used for vaccinating laboratory or healthcare workers who directly handle cultures, animals, or contaminated materials containing nonhighly attenuated vaccinia or recombinant vaccinia viruses, or other orthopoxviruses that infect humans. Requests for smallpox vaccine for vaccinating laboratory workers involved in vaccinia or orthopoxvirus research activities should be directed to the CDC (see the original guideline document for contact information).

State Health Departments are developing plans for vaccination of smallpox public health and health care teams and will be responsible for making vaccine requests to CDC to support the vaccination of these teams.

CDC's National Pharmaceutical Stockpile (NPS) has protocols for rapid, simultaneous delivery of smallpox vaccine to every state and U.S. territory within 12-24 hours. State and local terrorism-response plans should provide for the rapid distribution of vaccine within their jurisdictions.

Vaccinia immune globulin (VIG) is available from CDC only under Investigational New Drug (IND) protocols (i.e., protocols for products that are not yet licensed). As of January 31, 2003, enough VIG was available under an IND protocol to treat more than 4,000 serious adverse events, which is enough VIG doses to treat the expected number of adverse reactions resulting from vaccination of 40 million persons, on the basis of previously observed rates of adverse reactions.

Surveillance

Cases of febrile rash illnesses, for which smallpox is considered in the differential diagnosis, should be immediately reported to local or state health departments. After evaluation by the health departments, if smallpox laboratory diagnostics are considered necessary, CDC's Rash Illness Evaluation Team should be consulted at 770-488-7100. Because smallpox was officially certified as eradicated in 1980 and no longer occurs naturally, an initial case of smallpox must be laboratory

confirmed, which is available only at CDC. Clinical consultation and a preliminary laboratory diagnosis can be completed within 8-24 hours.

To assist medical and public health personnel in evaluating the likelihood of smallpox in patients with febrile rash illnesses, CDC has developed a rash illness assessment algorithm. Poster copies of this algorithm are available from state health departments and on the World Wide Web (www.bt.cdc.gov/agent/smallpox/diagnosis). Orders for copies of the poster can be made over the Internet at www2.cdc.gov/nchstp_od/PIWeb/niporderform.asp. Surveillance activities, including notification procedures and laboratory confirmation of cases, will change if smallpox disease is confirmed in one or more patients. Additional information regarding surveillance activities following laboratory confirmation of a smallpox outbreak can be found in the CDC Smallpox Response Plan and Guidelines (http://www.bt.cdc.gov/agent/smallpox/prep/cdc-prep.asp).

Preoutbreak Vaccination of Selected Groups to Enhance Smallpox Response Readiness

Smallpox Response Teams

Smallpox vaccination is recommended for persons designated by appropriate terrorism and public health authorities to conduct investigations and follow-up of initial smallpox cases that might necessitate direct patient contact. Additionally, persons responsible for administering smallpox vaccine in the pre-event vaccination program should be vaccinated (see Vaccination of Persons Administering Smallpox Vaccine in the Pre-Event Smallpox Vaccination Program, below).

To enhance public health preparedness and response for smallpox control, specific teams at the federal, state, and local level should be established to investigate and facilitate the diagnostic evaluation of initial suspected cases of smallpox and to initiate control measures. These smallpox response teams might include persons designated as medical team leaders, public health advisors, medical epidemiologists, disease investigators, diagnostic laboratory scientists, nurses, personnel who would administer smallpox vaccines, and security or law enforcement personnel, and other medical personnel to assist in evaluating suspected smallpox cases. The Advisory Committee on Immunization Practices (ACIP) recommends that each state and territory establish and maintain at least one smallpox response team. Considerations for additional teams should include population and geographic concerns and should be developed in accordance with federal, state, and local terrorism-response plans.

Smallpox Health Care Teams

ACIP and the Healthcare Infection Control Practices Advisory Committee (HICPAC) recommend that in the first stage of the pre-event smallpox vaccination program, each acute care hospital identify groups of healthcare workers who would be vaccinated and trained to provide direct medical care for the first smallpox patients requiring hospital admission and to evaluate and manage patients who are examined at emergency departments with suspected smallpox. This team should provide care 24 hours a day for the first 2 or more days after patients with

smallpox have been identified, until additional healthcare personnel are vaccinated. Nonvaccinated workers should be restricted from entering the rooms of smallpox patients or, under emergency conditions, should wear personal protective equipment.

ACIP and HICPAC recommend that smallpox health care teams include: 1) emergency department staff, including physicians and nurses caring for children and adults; 2) intensive care unit staff, including physicians, nurses, and in hospitals that care for infants and children, pediatricians and pediatric intensive care specialists; 3) general medical unit staff, including nurses, internists, pediatricians, hospitalists (i.e., physicians whose practice emphasizes providing care for hospitalized patients), and family physicians in institutions where these individuals are the essential providers of inpatient medical care; 4) primary care house staff (i.e., medical, pediatric, and family physicians); 5) medical subspecialists, including infectious disease specialists;* 6) infection control professionals; 7) respiratory therapists; 8) radiology technicians; 9) security personnel; and 10) housekeeping staff (e.g., those staff involved in maintaining the health care environment and decreasing the risk of fomite transmission).

*This might involve creating regional teams of subspecialists (e.g., local medical consultants with smallpox experience, dermatologists, ophthalmologists, pathologists, surgeons, anesthesiologists in facilities where intensivists are not trained in anesthesia) to deliver consultative services.

ACIP and HICPAC anticipate that the size and composition of smallpox healthcare teams will vary according to the institutions and their patient populations, but each hospital would ideally have enough vaccinated personnel from each occupational category to ensure continuity of care. When feasible, the first stage vaccination program should include previously vaccinated healthcare personnel to further decrease the potential for adverse events, because adverse events occur less commonly in previously vaccinated individuals.

Clinical laboratory workers are not recommended for inclusion in the initial phase of pre-event smallpox vaccination because the quantity of smallpox virus likely to be in clinical specimens of blood and body fluids is low. Consistent adherence to Standard Precautions and biosafety protocols for protection of laboratory workers will prevent exposure to smallpox virus in clinical specimens.

Vaccination Method

The skin over the insertion of the deltoid muscle or the posterior aspect of the arm over the triceps muscle is the preferred site for smallpox vaccination. Skin preparation for vaccination is not required unless the area is grossly contaminated, in which case soap and water should be used to clean the site. If alcohol or another chemical antiseptic is used, the skin must be allowed to dry thoroughly to prevent inactivation of the vaccine virus by the antiseptic. The multiple-puncture technique uses a pre-sterilized bifurcated needle that is inserted vertically into the vaccine vial, causing a small droplet of vaccine (approximately 0.0025 ml) to adhere between the prongs of the needle. The droplet contains the recommended dosage of vaccine, and its presence within the prongs of the bifurcated needle should be confirmed visually. Holding the bifurcated needle perpendicular to the skin, punctures are made rapidly, with strokes vigorous

enough to allow a trace of blood to appear after 15-20 seconds. According to the product labeling, 2-3 punctures are recommended for primary vaccination and 15 punctures for revaccination. If no trace of blood is visible after vaccination, an additional three insertions should be made by using the same bifurcated needle without reinserting the needle into the vaccine vial. If no evidence of vaccine take is apparent after 7 days, the individual may be vaccinated again. Any remaining vaccine should be wiped off the skin with dry sterile gauze and the gauze disposed of in a biohazard waste container.

Vaccinating Persons Administering Smallpox Vaccine in the Pre-Event Vaccination Program

Historically, vaccinators were administering smallpox vaccine as part of a disease control or eradication program, and were revaccinated frequently. No data exist regarding the risks for inadvertent inoculation of vaccinia among susceptible vaccinators, but they are assumed to have a certain level of risk. The risk might be analogous to that observed among laboratory workers handling nonhighly attenuated vaccinia strains; ACIP recommends that these workers be vaccinated. Prior vaccination likely confers substantial protection, but local reactions can occur among revaccinees; thus, protection from clinically significant inadvertent inoculation cannot be considered absolute.

ACIP and HICPAC recommend that persons administering smallpox vaccine in the pre-event vaccination program be vaccinated to minimize clinical effects of inadvertent inoculation, if inadvertent inoculation occurs. Ideally, vaccinators should have a confirmed vaccine take before vaccinating others, but administering vaccine to vaccinators immediately before beginning work in vaccination clinics is acceptable. Vaccination of this group will also contribute to preparedness for smallpox response. If a smallpox release occurs, experienced vaccinators could immediately be deployed for terrorism response.

Preventing Contact Transmission of Vaccinia Virus

After primary smallpox vaccination, vaccinia virus can be isolated from the vaccination site, beginning with development of a papule (i.e., 2 to 5 days after vaccination) until the scab separates from the skin lesion (i.e., 14 to 21 days after vaccination), with maximal shedding at 4 to 14 days after vaccination. Viral shedding may be of shorter duration among re-vaccinees. During the interval in which vaccinia virus is shed, inadvertent inoculation can occur from the vaccination site to another area of the body, most commonly the face, eyelid, nose, lips, genitalia, or anus. In addition, transmission could occur to another nonimmune person, leading to self-limited infections or to more serious complications, particularly among persons with medical contraindications to vaccination. The risk for mortality from eczema vaccinatum may be higher among contacts than among vaccinees.

After considering historical data and caveats related to the current situation (refer to the original guideline document for details), ACIP and HICPAC concluded that optimal infection control practices should essentially eliminate the risk of vaccinated healthcare workers transmitting vaccinia to patients, and that placing healthcare workers on administrative leave could create staffing shortages that would be a risk to patients.

Consequently, the Advisory Committee on Immunization Practices (ACIP) and Hospital Infection Control Practices Advisory Committee (HICPAC) recommend that, after smallpox vaccination, healthcare personnel providing direct patient care should keep their vaccination sites covered with gauze or a similar absorbent material in combination with a semipermeable dressing to absorb exudates that develop and to provide a barrier for containment of vaccinia virus to minimize the risk of transmission. Alternatively, products combining an absorbent base with an overlying semi-permeable layer can be used to cover the site. Semipermeable dressings provide an effective barrier to vaccinia virus, but use of a semipermeable dressing alone is associated with maceration of the vaccination site and increased irritation and itching at the site, thereby causing touching, scratching and possible contamination of the hands. The vaccination site should be covered with gauze, a semipermeable dressing, and a layer of clothing during direct patient care until the scab separates. Dressings used to cover the site should be changed frequently (e.g., every 3-5 days or more frequently if exudates accumulate) to prevent buildup of exudates and consequent maceration.

The most critical measure in preventing contact transmission is consistent hand-hygiene with antimicrobial soap and water or an approved alcohol based hand-rub (i.e., one that contains $\geq$60% alcohol) after any contact with the vaccination site or with materials that have come into contact with the site and before patient contact. In addition, care should be taken to prevent contact with the site or contaminated materials from the site.

Hospitals should include a site-care component to their smallpox vaccination programs in which designated staff assess dressings for all vaccinated healthcare workers daily (whether involved in direct patient care or in other duties), determine if dressings need changing (e.g., when accumulation of purulent material is visible or the integrity of the dressing has been disrupted), and change the dressing, if indicated. These designated staff should assess the vaccination site for local reactions and for vaccine take; reinforce education of vaccinees about the need for meticulous hand hygiene; and record and report serious adverse events following vaccination (See Reporting and Management of Adverse Events). When feasible, staff responsible for dressing changes for teams should be vaccinated, but having nonvaccinated staff change dressings is acceptable. All persons handling bandages should observe contact precautions.

Persons outside the patient care setting (e.g., members of public health response teams not involved in patient care, or health care workers who are not at work) can keep the site covered with a porous dressing (e.g., gauze); hand hygiene remains critical in preventing inadvertent inoculation. In nonpatient care settings in which transmission of vaccinia is a concern because of close personal contact with children or other persons, the vaccination site should be covered with gauze or a similar absorbent material and covered with clothing. Hypoallergenic tape should be used for persons who experience tape hypersensitivity.

The vaccination site should be kept dry, although normal showering or bathing can continue. A waterproof dressing might decrease the risk of autoinoculation while washing; if the site is uncovered, care should be taken to avoid touching it. After showering, if the vaccination site is wet it should be blotted dry with gauze which is then discarded; if a towel is used to dry the site it should not be used to dry the rest of the body. Alternatively, the site can be allowed to air dry before

replacing the bandage. No salves, creams, or ointments should be placed on the site. Contaminated bandages and, if possible, the vaccination site scab, after it has fallen off, should be placed in sealed plastic bags before disposal in the trash to further decrease the potential for inadvertent transmission of the live virus contained in the materials. Clothing, towels, and other cloth materials that have had contact with the site can be decontaminated with routine laundering in hot water.

Administrative Leave for Vaccinated Health Care Workers

Administrative leave is not required routinely for newly vaccinated healthcare personnel unless they: 1) are physically unable to work because of systemic signs and symptoms of illness; 2) have extensive skin lesions that cannot be adequately covered, or 3) are unable to adhere to the recommended infection control precautions. The close contact required for transmission of vaccinia to household contacts is unlikely to occur in the healthcare setting.

Vaccination and Blood Donation

FDA has recommended that vaccinees be deferred from donating blood for 21 days or until the scab has separated. Contacts of vaccinees, who have inadvertently contracted vaccinia also should be deferred from donating blood for 14 days after complete resolution of their complication. FDA guidance can be found at www.fda.gov/cber/gdlns/smpoxdefquar.htm.

If a substantial number of persons are vaccinated within a short time period, the resulting donor deferrals could impact blood availability. Blood supply shortages can be serious. Blood and platelet donors can help sustain blood supplies by donating immediately before being vaccinated and donating again after they are eligible. Because the donor deferral period needs to be documented carefully, all vaccinees should save the written record of their vaccination. Saving this record also will help to determine vaccination status and donor eligibility in the event of a smallpox outbreak.

Contraindications for Use of Smallpox Vaccine in the Pre-Event Smallpox Vaccination Program

The conditions discussed in this section are contraindications in the pre-event vaccination program. No absolute contraindications exist to defer vaccination for persons with high-risk exposure to smallpox; persons at greatest risk for experiencing serious vaccination complications are also at greatest risk for death if they become infected with the smallpox virus. If a relative contraindication to vaccination exists in the setting of a terrorism threat or exposure, the risk of experiencing serious vaccination complication must be weighed against the risk of experiencing a potentially fatal smallpox infection.

In the pre-event vaccination program, smallpox vaccination is contraindicated for persons with a history or presence of eczema or atopic dermatitis; that have other acute, chronic, or exfoliative skin conditions; who have conditions associated with immunosuppression; who are pregnant or breastfeeding; are aged <1 year; or who have a serious allergy to any component of the vaccine (See Table 1 below). According to the package insert, the vaccine may contain trace amounts of

polymyxin B, streptomycin, tetracycline, and neomycin, and the diluent contains glycerin and phenol.

Atopic dermatitis, irrespective of disease severity or activity, is a risk factor for developing eczema vaccinatum after smallpox vaccination in either vaccinees or their close contacts, but no data exist to predict the absolute risk for this population. Because the majority of primary care providers do not distinguish between eczema and atopic dermatitis, including when describing chronic exfoliative skin conditions among infants, ACIP recommends that smallpox vaccine should not be administered to persons with a history of eczema or atopic dermatitis, irrespective of disease severity or activity.

Persons with other active acute, chronic, or exfoliative conditions (e.g., burns, impetigo, varicella zoster, herpes, severe acne, severe diaper dermatitis with extensive areas of denuded skin, or psoriasis) are at higher risk for clinically severe inadvertent inoculation and should not be vaccinated until the condition resolves. Additionally, persons with Darier disease (keratosis follicularis) can develop eczema vaccinatum and therefore should not be vaccinated.

Replication of vaccinia virus can be enhanced among persons with cellular or humoral immunodeficiencies and among those with immunosuppression (e.g., including HIV [human immunodeficiency virus]/AIDS [acquired immune deficiency syndrome], leukemia, lymphoma, generalized malignancy, solid organ transplantation, or therapy with alkylating agents, antimetabolites, radiation, or high-dose corticosteroids [i.e., $\geq$2 mg/kg body weight or 20 mg/day of prednisone for $\geq$2 weeks]). Persons who are taking or have taken high dose corticosteroids should not be vaccinated within one month of completing corticosteroid therapy, and persons treated with other immunosuppressive drugs within the previous 3 months should not be vaccinated. Persons with immunosuppression also include hematopoietic stem cell transplant recipients who are <24 months posttransplant, and hematopoietic stem cell transplant recipients who are $\geq$24 months posttransplant, but have graft-versus-host disease or disease relapse. Patients with severe clinical manifestations of some autoimmune diseases (e.g., systemic lupus erythematosis) may have some degree of immunocompromise as a component of the disease. Although no data exist to indicate that a person is at risk from live-virus vaccines because of severe autoimmune disease in the absence of immunosuppressive therapy, persons with immunodeficiency as a clinical component of their autoimmune disease should not receive smallpox vaccine during the pre-event vaccination program.

According to the product labeling, smallpox vaccine is not recommended for use in breastfeeding women; whether vaccine virus or antibodies are excreted in human milk is unknown. ACIP does not recommend smallpox vaccination of children and adolescents <18 years of age in the pre-event vaccination program, and smallpox vaccine is contraindicated for infants <1 year of age.

Pre-event vaccination is also contraindicated among persons with household contacts who have a history or presence of eczema or atopic dermatitis, irrespective of disease severity or activity; who have other acute, chronic, or exfoliative skin conditions; who have conditions associated with immunosuppression (see above); or who are pregnant. For purposes of screening for contraindications for pre-event vaccination, household contacts include

persons with prolonged intimate contact with the potential vaccinee (e.g., sexual contacts), including the potential for direct contact with the vaccination site.

The presence of an adolescent or child (including an infant) in the household is not a contraindication to vaccination of adult members of the household; the risk for serious complications from transmission from an adult to a child is limited. Nonetheless, ACIP recognizes that some programs may defer vaccination of household contacts of infants <1 year of age because of data suggesting a higher risk of adverse events among primary vaccinees in this age group, compared with that among older children. The presence of a breastfeeding woman or a person with a vaccine component allergy in the household is also not a contraindication to vaccination of other household members (See Table 1 below).

Table 1: Contraindications to Using Smallpox Vaccine Among Vaccinees and Their Household Contacts in the Pre-Event Vaccination Program

Among Vaccinees:

- History or presence of eczema or atopic dermatitis
- Other acute, chronic, or exfoliative skin conditions*
- Immunosuppression[#]
- Pregnancy
- Breastfeeding
- Aged <1 year**
- Vaccine component allergy

Among Their Household Contacts[##]:

- History or presence of eczema or atopic dermatitis
- Other acute, chronic, or exfoliative skin conditions*
- Immunosuppression[#]
- Pregnancy

*Conditions include burns, impetigo, varicella zoster, herpes, severe acne, severe diaper dermatitis, or psoriasis. Persons with these conditions should not be vaccinated until the dermatologic condition resolves.

[#]Conditions include human immunodeficiency virus, acquired immune deficiency syndrome, leukemia, lymphoma, generalized malignancy, solid organ transplantation, cellular or humoral immunodeficiencies, or therapy with alkylating agents, antimetabolites, radiation, or high-dose corticosteroids.

**Vaccination of infants <1 year of age is contraindicated. Additionally, ACIP does not recommend vaccinating children and adolescents aged <18 years in the pre-event smallpox vaccination program.

[##]For purposes of screening for contraindications, household contacts include persons with prolonged intimate contact with the potential vaccinee (e.g., sexual contacts), including the potential for direct contact with the vaccination site.

Precautions for Smallpox Vaccination

Persons with inflammatory eye diseases may be at increased risk for inadvertent inoculation due to touching or rubbing of the eye. Therefore it may be prudent to defer vaccination of persons with inflammatory eye diseases requiring steroid treatment until the condition resolves and the course of therapy is complete.

Screening for Atopic Dermatitis as a Contraindication for Vaccination

To assist providers in identifying persons that should defer smallpox vaccination, ACIP recommends using two screening questions (refer to Figure in the original guideline document). Although sensitive, this approach to screening might preclude vaccination of persons who could otherwise be safely vaccinated. Certain organizations (e.g., the military or CDC) might elect to develop more precise screening tools for persons among whom the dermatologic risk factor of diagnosis is uncertain. These secondary screening tools should weigh the person's risk of developing an adverse event with the requirement of occupational readiness through safe smallpox vaccination.

Screening for Pregnancy as a Contraindication for Vaccination

Fetal vaccinia is a rare, but serious, complication of smallpox vaccination during pregnancy or immediately before conception. Infection, which can be spread to the fetus if viremia occurs after vaccination, is manifested by typical skin lesions, organ involvement, and fetal or early neonatal death. Smallpox vaccination of pregnant women has not been associated with an increased risk of congenital malformations.

Because of the limited risk but severe consequences of fetal infection, smallpox vaccine should not be administered in a pre-event setting to pregnant women or to women who are trying to become pregnant. Before vaccination, women of childbearing age should be asked if they are pregnant or intend to become pregnant in the next 4 weeks; women who respond positively should not be vaccinated. To further reduce the risk of inadvertently vaccinating a woman who is pregnant, at the time of prescreening women of childbearing age should be educated regarding what is known about fetal vaccinia. Women should be counseled to avoid becoming pregnant until $\geq$4 weeks after vaccination, and abstinence or highly effective contraceptive measures should be recommended to reduce the risk of pregnancy before or within four weeks after vaccination. Any woman who believes she might be pregnant or who wants additional assurance that she is not pregnant should perform a urine pregnancy test by using her first-morning-void urine on the day scheduled for vaccination. Such tests could be made available at the prescreening and vaccination sites to avoid cost or other barriers to testing. However, women should be informed that a negative urine pregnancy test cannot exclude a very early pregnancy, and therefore, they and their healthcare providers should not base a decision about their pregnancy status solely on a urine pregnancy test result.

If a pregnant woman is inadvertently vaccinated or if she becomes pregnant within 4 weeks after smallpox vaccination, she should be counseled regarding the basis of concern for the fetus. Smallpox vaccination during pregnancy should not ordinarily be a reason to terminate pregnancy. To expand understanding of the risk for fetal vaccinia and to document whether other adverse pregnancy outcomes might be associated with vaccination, CDC has established a pregnancy

registry to prospectively follow the outcome of such pregnancies and facilitate the investigation of any adverse pregnancy outcome among pregnant women who were inadvertently vaccinated.

Screening for HIV Infection as a Contraindication for Vaccination

Persons with HIV infection or AIDS might have an increased risk for severe adverse reactions with live-virus vaccines. Because the HIV epidemic began after the cessation of routine smallpox vaccination, data are limited regarding the risk from vaccination among HIV-infected persons.

An estimated 850,000 to 950,000 HIV-infected persons are living in the United States (prevalence, 0.3%), and of these, an estimated 180,000 to 280,000 are unaware that they are infected. Estimates of the number of HIV-infected health care workers range from about 21,000 to 48,000, and the proportion of these infected health care workers who remain undiagnosed is unknown. Risk assessment followed by counseling and testing is useful in identifying many persons with HIV infection. However, substantial numbers of HIV-infected persons might not recognize or acknowledge their risk during risk-assessment screening.

Smallpox vaccine should not be administered to persons with HIV infection or AIDS as part of a pre-event program because of their increased risk of progressive vaccinia (vaccinia necrosum). Before vaccination, potential vaccinees should be educated regarding the risk for severe vaccinial complications among persons with HIV infection or other immunosuppressive conditions; persons who think they might have one of these conditions should not be vaccinated.

ACIP does not recommend mandatory HIV testing prior to smallpox vaccination, but recommends that 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 unsure of their HIV infection status. Because known risk factors cannot be identified for certain persons with HIV infection, anyone who is concerned that they could have HIV infection also should be tested. HIV testing should be available in a confidential or anonymous setting, as allowed by local laws and regulations, with results communicated to the potential vaccinee before the planned date of vaccination. Persons with a positive test result should be advised not to be vaccinated. Information about local testing options should be provided to all potential vaccinees, including sites where testing is performed at no cost. The recently licensed rapid HIV test may facilitate availability of HIV testing to potential vaccinees.

Simultaneous Administration of Smallpox Vaccine with other Vaccines

Simultaneously administering the most widely used live and inactivated vaccines has produced seroconversion rates and rates of adverse reactions similar to those observed when the vaccines are administered separately. Inactivated vaccines do not interfere with the immune response to other inactivated vaccines or to live vaccines. An inactivated vaccine can be administered either simultaneously or at any time before or after a different inactivated vaccine or live vaccine. The immune response to one live-virus vaccine might be impaired if administered within 30 days of another live-virus vaccine, if not administered simultaneously.

To minimize the potential risk for interference, parenterally administered live vaccines not administered on the same day should be administered ≥4 weeks apart whenever possible. If parenterally administered live vaccines are separated by <4 weeks, the vaccine administered second should not be counted as a valid dose and should be repeated. The repeat dose should be administered ≥4 weeks after the last, invalid dose.

Smallpox vaccine can be administered at the same time as certain other vaccines, with levels of safety and efficacy comparable to those observed when the vaccines are given separately. Vaccines that have been documented to be effective when administered simultaneously with smallpox vaccine include oral polio vaccine, bacille of Calmette and Guérin (BCG) vaccine, yellow fever vaccine, measles vaccine, and diphtheria and tetanus toxoids and whole-cell pertussis vaccine. However, no data exist regarding simultaneous administration of smallpox vaccine with other vaccines now routinely administered to children and adults in the United States.

Varicella vaccine virus lesions could be confused with vaccinia lesions if the vaccines were administered simultaneously. In uncontrolled trials of persons ≥13 years of age, approximately 1,600 vaccinees who received one dose and 955 who received two doses of varicella vaccine were monitored for 42 days for adverse events. After the first and second doses, a nonlocalized rash consisting of a median number of five lesions developed in 5.5% and 0.9% of vaccinees, respectively, and occurred at a peak of 7-21 days and 0-23 days postvaccination, respectively.

Smallpox vaccine may be administered simultaneously with any inactivated vaccine (e.g., influenza vaccine) to encourage appropriate receipt of all indicated vaccines (e.g., among such populations as health care workers). With the exception of varicella vaccine, smallpox vaccine may be administered simultaneously with other live-virus vaccines. To avoid confusion in ascertaining which vaccine might have caused postvaccination skin lesions or other adverse events, and facilitate managing such events, varicella vaccine and smallpox vaccine should only be administered ≥4 weeks apart.

Timing of Tuberculosis Screening and Smallpox Vaccination

Suppression of tuberculin skin test (purified protein derivative [PPD]) reactivity has been demonstrated after administration of smallpox vaccine, as has been observed following administration of other parenteral live virus vaccines. Healthcare workers scheduled to receive an annual PPD skin test should not receive the skin test for one month after smallpox vaccination to prevent possible false negative reactions.

Reporting and Management of Adverse Events

Persons with progressive vaccinia, eczema vaccinatum, and severe generalized vaccinia or inadvertent inoculation might benefit from therapy with VIG or cidofovir, although the latter has not been approved by FDA for this indication. Suspected cases of these illnesses or other clinically significant adverse events after smallpox vaccination should be reported immediately to state health departments. VIG and cidofovir are available from CDC for treatment of adverse

events among smallpox vaccine recipients and their contacts under IND protocols. Recommendations regarding treatment of adverse events have been published recently. See the National Guideline Clearinghouse summary of the CDC's recommendations Smallpox Vaccination and Adverse Reactions. Guidance for Clinicians.

Additionally, serious adverse events after smallpox vaccination should be reported to the Vaccine Adverse Event Reporting System (VAERS). Reports can be submitted through a secure Internet-based system at https://secure.vaers.org/VaersDataEntryintro.htm. Printable VAERS forms are located online at http://www.vaers.org/pdf/vaers_form.pdf or postage-paid forms may be obtained by calling 1-800-822-7967. Submission of VAERS reports by Internet is encouraged to expedite processing and data entry. Completed forms can be faxed to 877-721-0366 (toll-free) or mailed to P.O. Box 1100, Rockville, MD 20894-1100. Additional information on VAERS reporting can be obtained by calling 800-822-7967 or by email at info@vaers.org.

CLINICAL ALGORITHM(S)

An algorithm on screening for eczema and atopic dermatitis among potential recipients of smallpox vaccine is provided in the original guideline document.

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The evidence supporting the recommendations is stated throughout the body of the guideline document.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Effective control and containment of smallpox in event of an outbreak
- Appropriate pre-release vaccination of selected groups to enhance smallpox response readiness
- Appropriate infection control practices to reduce contact transmission in the healthcare setting

POTENTIAL HARMS

Complications of Smallpox Vaccination

- Fetal vaccinia is a very rare, but serious, complication of smallpox vaccination during pregnancy or shortly before conception. Infection, which may spread to the fetus if viremia occurs after vaccination, is manifested by typical skin lesions, organ involvement, and fetal or early neonatal death.
- The presence of inflammatory eye disease presents an increased risk of inadvertent inoculation following smallpox vaccination.

- Smallpox vaccine should not be administered to persons with human immunodeficiency virus (HIV) infection or acquired immune deficiency syndrome (AIDS) as part of a pre-event program because of their increased risk of progressive vaccinia (vaccinia necrosum).

Other Considerations

- Smallpox vaccine should not be administered simultaneously with varicella vaccine.
- Suppression of tuberculin skin test (purified protein derivative [PPD]) reactivity has been demonstrated following administration of smallpox vaccine.

CONTRAINDICATIONS

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Contraindications to Using Smallpox Vaccine Among Vaccinees and Their Household Contacts in the Pre-Event Vaccination Program

Among Vaccinees:

- History or presence of eczema or atopic dermatitis
- Other acute, chronic, or exfoliative skin conditions*
- Immunosuppression[#]
- Pregnancy
- Breastfeeding
- Aged <1 year**
- Vaccine component allergy

Among Their Household Contacts[##]:

- History or presence of eczema or atopic dermatitis
- Other acute, chronic, or exfoliative skin conditions*
- Immunosuppression[#]
- Pregnancy

*Conditions include burns, impetigo, varicella zoster, herpes, severe acne, severe diaper dermatitis, or psoriasis. Persons with these conditions should not be vaccinated until the dermatologic condition resolves.

[#]Conditions include human immunodeficiency virus, acquired immune deficiency syndrome, leukemia, lymphoma, generalized malignancy, solid organ transplantation, cellular or humoral immunodeficiencies, or therapy with alkylating agents, antimetabolites, radiation, or high-dose corticosteroids.

**Vaccination of infants <1 year of age is contraindicated. Additionally, ACIP does not recommend vaccinating children and adolescents aged <18 years in the pre-event smallpox vaccination program.

[##]For purposes of screening for contraindications, household contacts include persons with prolonged intimate contact with the potential vaccinee (e.g., sexual contacts), including the potential for direct contact with the vaccination site.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

Multiple factors and assumptions were used in developing these supplemental recommendations, as follows:

- **Level of Disease Risk and Threat.** Information provided to the Advisory Committee on Immunization Practices (ACIP) indicated that a risk for smallpox occurring as a result of a deliberate release by terrorists exists; however, this risk is low, and the population at risk for such an exposure cannot be determined. ACIP also assumed that, regardless of the mode, magnitude, or duration of a terrorism release, the epidemiology of subsequent person-to-person transmission would be consistent with prior experience. These recommendations also are based on the assumption that, in addition to vaccination, health care workers and others would be afforded some protection from infection through appropriate infection control measures, including use of appropriate personal protective equipment.
- **Expected Severe Adverse Reactions to Vaccination.** ACIP assumes that appropriate screening for contraindications to vaccination will be implemented and will include both the vaccinated persons as well as their household contacts. ACIP further assumes that recommended precautions will be taken to minimize both the risk for adverse events among vaccinees as well as the risk of transmission of vaccinia to their contacts (e.g., patients or household members) and resulting adverse events in those contacts.
- **Smallpox Vaccine and Vaccinia Immune Globulin (VIG) Supply.** ACIP assumes that both smallpox vaccine and vaccinia immune globulin (VIG) will be available for use, in sufficient supply, handled and administered according to standard protocols, and that any pre-event use of smallpox vaccine would be voluntary.
- **State and Local Vaccination Capacity and Capability.** State and local health departments should be able to conduct surveillance and containment, including ring vaccination, as the primary strategy for the controlling and containing smallpox. In addition, state and local health departments should be able, if necessary, to expand immunization to additional groups, including entire populations, in a timely manner. CDC has recently issued large-scale vaccination clinic guidelines to assist state and local health departments in developing this capacity.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Clinical Algorithm
Patient Resources

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness
Safety

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Wharton M, Strikas RA, Harpaz R, Rotz LD, Schwartz B, Casey CG, Pearson ML, Anderson LJ. Recommendations for using smallpox vaccine in a pre-event vaccination program. Supplemental recommendations of the Advisory Committee on Immunization Practices (ACIP) and the Healthcare Infection Control Practices Advisory Committee (HICPAC). MMWR Recomm Rep 2003 Apr 4;52(RR-7):1-16. [56 references] PubMed

ADAPTATION

Not applicable: The guideline was not adapted from another source.

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GUIDELINE DEVELOPER(S)

Centers for Disease Control and Prevention - Federal Government Agency [U.S.]

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ACIP Bioterrorism Working Group
Healthcare Infection Control Practices Advisory Committee (HICPAC)
HICPAC Bioterrorism Working Group

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available from the Centers for Disease Control and Prevention (CDC) Web site:

- HTML format
- Portable Document Format (PDF)

Print copies: Available from the Centers for Disease Control and Prevention, MMWR, Atlanta, GA 30333. Additional copies can be purchased from the

Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402-9325; (202) 783-3238.

AVAILABILITY OF COMPANION DOCUMENTS

Additional information regarding smallpox preparation and response activities is available from the Centers for Disease Control and Prevention (CDC) Web site.

PATIENT RESOURCES

The following are available:

- Fact sheets: smallpox basics for the general public. Atlanta (GA): Centers for Disease Control and Prevention (CDC); 2003 Jan.
- Smallpox pre-vaccination information packet. Atlanta (GA): Centers for Disease Control and Prevention (CDC); 2003 Jan. 34 p.
- Vaccine information statement. What you need to know. Atlanta (GA): Centers for Disease Control and Prevention (CDC); 2003 Jan. 3 p.

Electronic copies of these and other related materials are available from the CDC Web site.

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC STATUS

This summary was prepared by ECRI on February 26, 2003. It was not verified by the guideline developer. This summary was updated by ECRI on November 17, 2005, following the U.S. Food and Drug Administration advisory on parenteral maltose/parenteral galactose/oral xylose-containing products.

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