SMALLPOX VACCINE (BIOTERRORISM)

I. DEFINITION:

Smallpox vaccine is a live vaccinia virus vaccine. ACAM2000™ is the current vaccine available to civilian laboratory personnel, the military and state public health preparedness programs. ACAM2000™ expires 18 months after release from the CDC Strategic National Stockpile.

II. ETIOLOGY AND EPIDEMIOLOGY:

Smallpox is an acute, viral illness caused by Variola, an Orthopox virus. Smallpox was declared eradicated from the world in 1980. Because smallpox no longer occurs as a naturally acquired infection, the most likely cause for its reintroduction into the population would be an intentional release as an act of bioterrorism.

NOTE: A SINGLE SUSPECTED CASE OF SMALLPOX MUST BE TREATED AS A HEALTH EMERGENCY AND MUST IMMEDIATELY BE BROUGHT TO THE ATTENTION OF THE STATE HEALTH DEPARTMENT, WHO WILL THEN CONTACT THE CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC).

III. MANAGEMENT PLAN:

A. Criteria for administration

1. Recommendations for vaccine usage:

a. Pre-event vaccination:

In the event of a smallpox attack, prior vaccination of front-line healthcare workers would sharply reduce the disproportionate burden of disease among healthcare workers and their families. This action would help maintain staffing levels at healthcare facilities making more front-line healthcare workers available to assist the public.

Persons included in this pre-event vaccination plan to be voluntarily vaccinated will be:

1) Certain military personnel
2) Health care teams within hospitals expected to care for any cases or suspected cases of smallpox.
3) Emergency room personnel expected to come in contact with suspected cases of smallpox.
4) Public health nurse vaccinators.
5) Public health response teams.

Persons administering the vaccine must have already received the vaccine. (They may begin administering the vaccine on the same day they receive the vaccine.) Healthcare workers with a contraindication to vaccination should not handle or administer the vaccine.

b. Post-event vaccination:

Following the identification of a case of smallpox, the rules regarding who gets vaccinated and contraindications to be considered would change.

If contacts can be vaccinated within 3 days of their contact with a smallpox case, they are protected from developing the disease or may at least develop a less severe illness.

There are no contraindications for vaccination in a person with close contact to a smallpox case.

B. Patient Medical History

1. Have you received chickenpox (varicella) vaccination in the last month?
If yes, you should not get the smallpox vaccine at this time.

2. Are you currently taking medication?
If yes, please list medications (also see questions 3, 4, and 17 below):

3. Are you sick today?
If yes, please describe your illness, you may need to wait to get the vaccine.

4. Do any of the following apply to YOU?

a. Weakened Immune System
1) Do you have any conditions that weaken the immune system such as HIV/AIDS; leukemia, lymphoma, or most other cancers; organ transplant; or primary immune deficiency disorders?
2) Do you have a severe autoimmune disease such as lupus that may weaken the immune system?
3) Are you now taking, or have you recently taken, drugs that can weaken the immune system like steroids (e.g. prednisone), some medicines for autoimmune disease, or medicines taken after an organ transplant?
4) Are you now taking cancer treatment with drugs or radiation or have you taken such treatment in the past 3 months?

b. Skin Problems
1) Do you now have, or have you ever had atopic dermatitis, often called eczema (even as a baby or child and even if the condition is mild)?
2) Do you now have other skin problems that have made many breaks in your skin such as a rash, severe burn, impetigo, chickenpox, shingles, herpes, psoriasis, or severe acne?
3) Do you have Darier's disease (a skin problem that usually begins in childhood)?

c. Heart Problems
1) Have you ever been diagnosed by a doctor as having a heart condition with or without symptoms such as previous myocardial infarction (heart attack), angina (chest pain caused by lack of blood flow to the heart), congestive heart failure, or cardiomyopathy?

2) Have you ever had a stroke or transient ischemic attack (a "mini-stroke" that produces stroke-like symptoms but no lasting damage)?
3) Do you have chest pain or shortness of breath when you exert yourself (such as when you walk up stairs)?
4) Do you have any other heart condition for which you are under the care of a doctor?
5) Do you have three or more of the following risk factors?
   a) You have been told by a doctor that you have high blood pressure
   b) You have been told by a doctor that you have high blood cholesterol.
   c) You have been told by a doctor that you have diabetes or high blood sugar.
   d) You have a first degree relative (for example mother, father, brother, or sister) who had a heart condition before the age of 50.
   e) You smoke cigarettes now.

d. Pregnant or Breastfeeding
1) Are you pregnant, might be pregnant, or might become pregnant in the next month?
2) In the past month, have you had sex without using effective birth control or do you think you will have sex without using effective birth control during the month after vaccination?
3) Are you currently breastfeeding or pumping and then bottle-feeding breast milk?

e. Other
1) Have you ever had a life-threatening allergic reaction to smallpox vaccine, latex or the antibiotics polymixin B, streptomycin, chlortetracycline, or neomycin?
2) Are you now being treated with steroid eye drops?

f. If you answered yes to any of the questions above, you should not get the smallpox vaccine at this time. If you answered NO, please continue with the following questions about your close contacts.

5. Do any of the following apply to your CLOSE CONTACTS?
(A close contact is someone you live with or have close physical contact with, such as a sex partner. Close contacts do not include friends or co-workers.)

a. Weakened Immune System
1) Do any of your close contacts have conditions that weaken the immune system such as HIV/AIDS, leukemia, lymphoma, or most other cancers; organ transplant; or primary immune deficiency disorders?
2) Do any of your close contacts have a severe autoimmune disease such as lupus that may weaken the immune system?
3) Are any of your close contacts now taking, or have they recently taken, drugs that can weaken the immune system like steroids (e.g. prednisone), some medicines for autoimmune disease, or medicines taken after an organ transplant?

4) Are any of your close contacts taking cancer treatment with drugs or radiation or have they taken such treatment in the past 3 months?

b. Skin Problems

1) Do any of your close contacts now have, or have they ever had atopic dermatitis, often called eczema (even as a baby or child and even if the condition is mild)?

2) Do any of your close contacts now have other skin problems that have made many breaks in their skin such as a rash, severe burn, impetigo, chickenpox, shingles, herpes, psoriasis, severe diaper rash, or severe acne?

3) Do any of your close contacts have Darier's disease (a skin problem that usually begins in childhood)?

c. Pregnancy

Are any of your close contacts pregnant, might be pregnant, or might become pregnant in the next month?

d. If you answered yes to any of the questions above, you should not get the smallpox vaccine at this time.

NOTE: The OSDH Immunization Service will provide updated screening criteria as needed.

NOTE: Healthcare providers or vaccinators who themselves have a contraindication to vaccination should not handle or administer vaccine.

NOTE: In the event of an actual exposure to smallpox, vaccination may be considered for individuals who otherwise have contraindications, because the benefits of vaccination would most likely outweigh the risks.

C. Directions for Reconstitution of the Vaccine

1. Follow directions closely for reconstitution of the vaccine provided by the manufacturer.

2. Label the vial with the time and date of reconstitution just prior to opening as the vaccine may be used for up to 30 days post reconstitution.

3. Label the vial with the batch number provided by the OSDH Immunization Service.

D. Vaccine Administration- Administer smallpox vaccine using the following procedure:

1. Gloves should be worn when handling opened vaccine vials, used bifurcated needles, administering vaccine, or evaluating a vaccination site. Care should be taken to prevent bacterial contamination of the opened vaccine vial or vaccination site, or self-inoculation of virus to other sites.

2. The site of vaccination should be one that is easily accessible for vaccination and evaluation of the vaccine take on post-vaccination day 7. The outer aspect of the upper right arm over the insertion of the deltoid muscle should be used as the standard vaccination site in order to prevent confusion with

the vaccination site from a previous vaccination. Do not vaccinate over a scar including a previous smallpox vaccination scar.

3. Cleaning the vaccination site is not necessary unless grossly contaminated. If cleaning is deemed necessary, clean the site with soap and water and let dry thoroughly. It is essential the site be allowed to **dry thoroughly** in order to avoid inactivation of the vaccine deposited on the skin.

4. Remove the bifurcated needle from its packaging. The needle is sterile, so be careful not to touch the bifurcated, pointed end.

5. Dip the bifurcated end of the sterile needle into the vial of reconstituted vaccine and withdraw the needle perpendicular to the floor. The needle will pick up a drop of the vaccine in the space between the two prongs. Inspect the needle tip after dipping to assure that vaccine is present between the prongs. DO NOT shake the needle after it has been dipped into the vaccine vial. If no vaccine is between the prongs of the needle, and the needle has not touched the skin of the vaccinee (i.e., it is still sterile), it may be dipped again. DO NOT dip more than one needle into a vaccine vial at a time.

6. Do not re-dip the needle into the vaccine vial if the needle has touched the skin.

7. Holding the skin of the upper arm taut, the vaccinator should place his/her wrist firmly on the arm. Holding the needle at a 90 ° angle (perpendicular) to the skin, perform insertions up-and-down (perpendicular) strokes rapidly within a 5mm diameter area (about the size of a standard pencil eraser).

    a. A number of perpendicular insertions are made in rapid order in an area approximately 5 mm in diameter. The number of insertions should be in accordance with the package insert, using 15 insertions for all vaccinees. A trace of blood should appear at the site of vaccination within 15-20 seconds.

    b. Revaccination: 15 insertions of the bifurcated needle.

    c. Apply sufficient pressure to visibly push down the skin. The strokes should be made rapidly, and be sufficiently vigorous to illicit a trace of blood at the vaccination site. If a trace of blood does not appear, the strokes have not been sufficiently vigorous and the procedure should be repeated using the same bifurcated needle without reinserting the needle into the vaccine vial. The intention is to break the skin and introduce the vaccine into the skin. This method allows the live vaccinia virus to penetrate the superficial layers of the skin so that viral multiplication can occur and produce immunity.

8. Dispose of the needle immediately into a sharps container. The bifurcated needle should never be reused.

9. The site should be covered with a dry sterile dressing to prevent dissemination of the virus. The dressing should consist of a dry sterile 2 x 2 gauze pad and then covered with micropore tape. In the case of healthcare workers involved with patient care, the gauze pad should be covered with a semi-permeable occlusive dressing. Semi-permeable occlusive dressings should not be used alone because it causes skin maceration and may increase the risk of secondary bacterial cellulitis. Vaccinia virus may be

recovered from the site of vaccination beginning at the time of development of a papule (2-5 days post-vaccination) until the scab separates from the skin (14-21 days post-vaccination). The dressing should be changed every 1-2 days and when wet or soiled. Used dressings may be disposed of in a zipper type plastic bag in the household trash. The site should be kept dry, however normal bathing can occur. (It is not necessary for the vaccinees to return for dressing changes on their days off, unless assistance is needed.)

10. If vaccine is to be stored for subsequent use, recap vial with the sterile rubber stopper and store the capped vial at 2-8ºC or 35.6-46.4 degrees Fahrenheit.

E. The following medications may be recommended to assist with itching:

Claritin 10 mg by mouth every 24 hours as needed for itching

OR

Benadryl 50 mg by mouth every 6 hours as needed for itching

F. Recognition of Expected Vaccine Reactions/Take:

1. Successful vaccination is normally associated with tenderness, redness, swelling, and a lesion at the vaccination site. Primary vaccination may also be associated with fever for a few days and enlarged, tender lymph nodes in the axilla of the vaccinated arm. These symptoms are more common in persons receiving their first dose of vaccine (15-20%) than in persons being revaccinated (0-10%). A primary (major) reaction results from successful primary vaccination of a non-vaccinated individual. It is expected that the majority of individuals will exhibit this type of reaction as most have never received vaccination or were vaccinated over 20 years ago. Reactions other than a primary or major reaction/take in an individual receiving their first-ever vaccination or revaccination after many years should be interpreted as an unsuccessful vaccination, and the individual should be revaccinated.

2. Primary (major) reaction – The inoculation site becomes reddened and pruritic 3-4 days after vaccination. A vesicle surrounded by a red areola then forms which becomes umbilicated and then pustular by the 7th to 11th day after vaccination. The red areola has enlarged by this time. The pustule begins to dry, the redness subsides, and the lesion becomes crusted between the 2nd and 3rd week. By the end of the 3rd week, the scab falls off leaving a permanent scar that at first is pink in color but eventually becomes flesh-colored. See CDC website for visual examples of takes/non-takes. Example: http://www.bt.cdc.gov/agent/smallpox/vaccination/takes-non-takes.asp

3. Initial Vaccination
   a. Vesicular or pustular lesion
   b. Area of definite palpable induration surrounding a central crust or ulcer

4. Revaccination
   a. Less pronounced and more rapid progression
   b. Pustular lesion or induration surrounding a central crust or ulcer

5. Equivocal Reaction: the absence of a pustular lesion or an area of definite induration or congestion surrounding a central lesion, including a scab or an ulcer

   a. May result from a person being sufficiently immune to suppress viral replication
   b. May result from subpotent vaccine or improper technique
   c. May be the result of a hypersensitivity reaction to components of the vaccine
   d. Vaccination should be repeated using vaccine from another vial when possible

6. Vaccinees who do not exhibit the type of “major” reaction at the vaccination site on day 7 should be revaccinated.

G. Complications

1. Reactions following smallpox vaccination, such as fever, erythematous rashes, and autoinoculation are common but generally self-limited. Pain, induration, and erythema at the site of vaccination can be dramatic but are also generally self-limited.

2. Three complications of smallpox vaccination are rare but can be very severe or fatal.

   a. Eczema vaccinatum
      1) Generalized spread of vaccinia on the skin of a vaccinated person with eczema or atopic dermatitis, or a history of eczema or atopic dermatitis.
      2) Believed to result from either blood dissemination of vaccinia virus or by direct skin inoculation of vaccinia on skin affected by eczema or atopic dermatitis.
      3) Vaccinia Immune Globulin (VIG) has been shown to be effective for the treatment of this complication.

   b. Progressive vaccinia (vaccinia necrosum)
      1) Characterized by a non-healing vaccination site with progressive necrosis.
      2) Occurs almost exclusively among persons with cellular immunodeficiency, but can occur in persons with humoral immunodeficiency.
      3) Can occur following revaccination of people who have become immunosuppressed since their primary vaccination.
      4) VIG has variable effectiveness in treating this complication.

   c. Post-vaccinial encephalitis
      1) In the majority of cases, affects primary vaccinees 12 months of age or younger, and adolescents and adults receiving a primary vaccination.
      2) Presents with any of a variety of central nervous system signs, such as ataxia, confusion, paralysis, seizures, or coma.
      3) Most cases are believed to result from autoimmune or allergic reactions, similar to other post-viral CNS syndromes rather than direct viral invasion of the nervous system.
      4) Treatment is supportive care as VIG is not effective.

H. Client Education

1. Wear a long-sleeved shirt in addition to the dressing to help cover the site.

2. Thorough hand washing with soap and water or disinfecting agents should be performed after ANY direct contact with the site or contact with materials that have come in contact with the site.

3. Care must be taken to prevent any other persons from coming into contact with the site or contaminated materials from the site.

4. As the vaccination site heals it will itch. The recipient must make a conscious effort NOT to scratch the lesion. The recipient should consider wearing a sleeved shirt to bed in addition to the dressing to avoid scratching the lesion or contaminating the bedding while sleeping.

5. Bandages used to cover the vaccination site should be changed every day to prevent maceration of the vaccination site caused by fluid buildup.

6. Contaminated bandages should be disposed of in a manner that would prevent others from coming into direct contact with them. This may be done by placing the dressings in sealed plastic bags before disposal in the trash.

7. The site scab should also be appropriately disposed of after it has fallen off.

8. The vaccination site should be kept dry, although normal bathing can continue. A waterproof bandage can be used while bathing but should be changed back to a porous bandage such as gauze after bathing.

9. No salves or ointments should be placed on the vaccination site.

10. Clothing or other cloth materials, such as bedding, that have had contact with the site can be cleaned with routine laundering in hot water. Individuals should wash their hands after handling any contaminated clothing or bedding.

IV. FOLLOW-UP:

A. Successful take of vaccination is contingent upon the presence of a pustular lesion in previously unvaccinated persons. Following revaccination of a previously vaccinated person, a pustular lesion or area of definite induration or congestion surrounding a central lesion should develop in 7 days. Vaccinees who do not exhibit the type of “major” reaction at the vaccination site on day 7 should be revaccinated.

B. If a major reaction or “take” does not occur after the second vaccination, advise the vaccinee to seek follow-up with their primary care physician. Notify the District Nurse Manager (or designee) and the Immunization Division, 405-271-4073. The presence of a pattern of ‘non-takes’ should be reviewed.

C. Successful vaccination should be documented in the client’s OSIIS record and on the client’s personal Smallpox Vaccination “Take” card.

REFERENCES:

CDC. Notice to Readers: *Newly Licensed Smallpox Vaccine to Replace Old Smallpox Vaccine*, MMWR, February 29, 2008/ 57(08);207-208. http://www.cdc.gov/mmwr/PDF/wk/mm5708.pdf

Food and Drug Administration. ACAM2000 (Smallpox [Vaccinia] Vaccine, Live). (package insert). Updated 2009. http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM142572.pdf

Heymann, D.L. (Ed.), 19th ed., 2008, *Control of Communicable Diseases Manual*, American Public Health Association, Washington, DC. Pages 560 – 563.

Smallpox Vaccine Administration Training, December 17, 18, 19, 2002, Atlanta, Georgia. Correspondence, Dennis J. Foley, Ph.D., Wyeth Pharmaceuticals, December 23, 2002.

Smallpox Vaccination **Wound Care**

You've been vaccinated, now what?

- If successful, a **red itchy bump** develops at the site of vaccination in 3-4 days.
  - In the first week, the bump becomes a **blister**, fills with pus, and begins to drain.
  - During the second week, the blister begins to dry up and a **scab** forms.
  - The **scab** falls off in the third week, leaving a small scar.

- *Vaccinia Virus* is present at the site from the time of vaccination until the scab that forms **falls off on its own** between 2 and 3 weeks after vaccination. The scab is also infectious.

- Keep vaccination site clean and dry.
  - **Working in client care setting**:
    - Cover site with 2x2 gauze and semipermeable dressing (i.e., Tegaderm)
    - Change dressing at least every 3-5 days to prevent buildup of exudates.
    - Wear clothing that covers the vaccination site at all times
    - Semipermeable dressing is not required except during client care.
  - **Working in office setting and while at home**:
    - Cover site with 2x2 gauze pad and surgical paper tape
    - Change the dressing every 1-3 days
    - Wear clothing that covers the vaccination site at all times
  - Place **contaminated bandages** in sealed plastic bag and discard in trash.
  - **Bathing:**
    - Cover site with waterproof bandage (i.e., Tegaderm)
    - Or cover site with plastic wrap (i.e., Saran Wrap) and tape edges
    - Change dressing after bathing.
  - **Do not put salves** or ointments on the vaccination site. Keep it dry.
  - **Do not scratch** or pick at the site/scab.
  - When scab falls off, discard it in a sealed plastic bag.

- **Wash hands with soap and water** thoroughly after direct contact with the vaccination site, contaminated dressings, clothing, towels or sheets.

- **Laundry concerns**:
  - Place clothing, towels, bedding or other such items that may come in contact with the vaccination site or drainage from the site in a **separate laundry hamper**.
  - Wash clothing or other material that comes in contact with the vaccination site using hot water with detergent and/or bleach.

The following medications may be used to assist with itching:

Claritin 10 mg by mouth every 24 hours as needed for itching

OR

Benadryl 50 mg by mouth every 6 hours as needed for itching

Above all else: Wash hands with soap and water after caring for vaccination site.

SMALLPOX

SMALLPOX FACT SHEET – *Information for Clinicians*

Smallpox Vaccination Method

Multiple Puncture Vaccination

During the global smallpox eradication effort, the bifurcated needle was used along with a technique called multiple puncture vaccination. Today, this is still the recommended method for administering smallpox vaccine.

Each bifurcated needle is sterile and individually wrapped. The bifurcated needle is for one-time use only and should be discarded in an appropriate biohazard container immediately after vaccinating each patient.

Step-by-Step Instructions

1. **Review patient history for contraindications.**

2. **Choose the site for vaccination.**
   The deltoid area on the upper arm is recommended.

3. **Skin preparation.**
   No skin preparation is required. Under no circumstances should alcohol be applied to the skin prior to vaccination as it has been shown to inactivate the vaccine virus.

4. **Dip needle.**
   The needle is dipped into the vaccine vial and withdrawn. The needle is designed to hold a tiny drop of vaccine of sufficient size and strength to ensure a take if properly administered. The same needle should never be dipped into the vaccine vial more than once, in order to avoid contamination of the vaccine vial.

5. **Make perpendicular insertions within a 5-mm diameter area.**
   The needle is held perpendicular to the site of insertion. The wrist of the vaccinator should be maintained in a firm position by resting on the arm of the vaccinee or another firm support.
   - A number of perpendicular insertions are made in rapid order in an area approximately 5 mm in diameter. The number of insertions should be in accordance with the package insert, using 3 insertions for primary vaccination and 15 insertions for revaccination with the Dryvax vaccine. A trace of blood should appear at the site of vaccination within 15-20 seconds. During primary vaccination, if no trace of blood is visible after 3 insertions, an additional 3 insertions should be made using the same bifurcated needle without reinserting the needle into the vaccine vial.
   - The bifurcated needle is for one-time use only and should be discarded in an appropriate biohazard container immediately after vaccinating each patient.

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6. **Absorb Excess Vaccine**
   After vaccination, excess vaccine should be absorbed with sterile gauze. Discard the gauze in a safe manner (usually in an infection control receptacle) in order not to contaminate the site or infect others who may come in contact with it.

7. **Cover vaccination site.**
   It is important that the vaccination site be covered to prevent dissemination of virus. Recommended coverings include the following:
   - Gauze loosely secured by first aid adhesive tape (taking care to obtain history of tape sensitivity).
   - When working in a health care setting, vaccinees should keep their vaccination site covered with gauze or a similar absorbent material. This dressing should, in turn, be covered with a semipermeable dressing. Products combining an absorbent base with an overlying semipermeable layer also can be used to cover the vaccination site. Healthcare workers do not need to be placed on leave after receiving a smallpox vaccination.
   - Vaccinees in settings where close personal contact is likely (such as parents of infants and young children) should cover the vaccination site with gauze or a similar absorbent material, wear a shirt or other clothing that would cover the vaccination site, and also make sure to practice good hand hygiene.

   Note: The use of semipermeable dressing alone could cause maceration of the vaccination site and increased, prolonged irritation and itching at the site, thereby increasing touching, scratching, and contamination of the hands. Thus, only persons working in healthcare settings should use semipermeable dressings (over gauze or a similar absorbent material as described above).

8. **Educate vaccinee.**
   To avoid contact transmission of the virus, vaccinees must be cautioned to do the following:
   - Do not rub or scratch the vaccination site.
   - Keep the site covered and change gauze-only dressings every 1–2 days or if wet. Change semipermeable dressings at least every 3-5 days.
   - Keep the vaccination site dry, covering it with a water-proof bandage while bathing.
   - Discard gauze carefully in plastic zip bags.
   - Set aside a laundry hamper for clothes, towels, sheets and other items that may come into contact with the vaccination site.
   - Wash clothing or other materials that come into contact with the vaccination site in hot water with detergent and/or bleach. Wash hands afterward.
   - Wash hands thoroughly with soap and hot water or with alcohol-based hand rubs such as gels or foams after touching the vaccination site, or bandages, clothing, towels, or sheets that have come into contact with the vaccination site.
   - When the scab falls off, throw it away in a plastic zip bag.
   - Report any problems by calling the phone number provided on the "Post-Vaccination and Follow-Up Information" sheet, calling your health care provider, or visiting and emergency room.
   - Return 7 days after vaccination for a "take" check (to see if the vaccination was successful).

Record the vaccination.
Record vaccination information as instructed by the CDC.

For more information, visit www.cdc.gov/smallpox, or call CDC at
800-CDC-INFO (English and Spanish) or 888-232-6348 (TTY).
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