SMALLPOX VACCINE (BIOTERRORISM)

I. DEFINITION:

In the United States, vaccinia (smallpox) virus vaccine is only available through the CDC. Smallpox vaccine is a live vaccinia virus vaccine. ACAM2000™ is the current vaccine available in the US and is recommended for routine vaccination to certain laboratory personnel and healthcare workers. ACAM2000 has been purchased by the federal government for stockpiling and will be distributed by the Department of Health and Human Services in the event of an emergency.

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 PUBLIC HEALTH EMERGENCY AND MUST IMMEDIATELY BE BROUGHT TO THE ATTENTION OF THE EPIDEMIOLOGIST-ON-CALL IN THE ACUTE DISEASE SERVICE AT THE OKLAHOMA STATE DEPARTMENT OF HEALTH (OSDH) (405-271-4060, 24/7/365),

If the OSDH is responding to an event where individuals may have been exposed to smallpox, updated/current post-exposure (PEP) guidance will be communicated through the appropriate chain of command.

III. MANAGEMENT PLAN:

A. Recommendations for vaccine usage:

1. 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:

   a. Certain military personnel.
   b. Health care teams within hospitals expected to care for any cases or suspected cases of smallpox.
   c. Emergency room personnel expected to come in contact with suspected cases of smallpox.
   d. Public health nurse vaccinators.
   e. 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.

2. 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. Obtain comprehensive medical history on client prior to vaccine administration. Include the following information to determine if the client meets criteria to receive a smallpox vaccination.

   a. Recent vaccinations including varicella and MMR
   b. Medications
   c. Current illness
   d. Previous medical history including:
      - Weakened immune system (HIV/AIDS, chemotherapy)
      - Skin conditions
      - Heart conditions
      - Pregnant or Breastfeeding
      - Allergic reactions to certain medications or using steroid eye drops

2. Obtain information about the client’s CLOSE CONTACTS. Inquire about the following information to determine if the client meets the criteria to receive a smallpox vaccination.

   a. Weakened Immune System (HIV/AIDS, chemotherapy)
   b. Skin conditions
   c. Pregnancy

Refer to current guidance to determine whether the client meets the criteria to receive a smallpox vaccine based upon patient medical history.

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

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 in accordance with the vaccine manufacturer’s instructions:**

   Special Consideration: The public health nurse must ensure that another competent employee who is CPR certified is present before any vaccinations can be administered.

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 alcohol swabs 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 2-8°C 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. Interpreting Vaccination Response:

1. Primary Vaccinees – Expected response to vaccination is the development of a major cutaneous reaction characterized by a pustule at the site of inoculation. Formation of a major cutaneous reaction by day 6-8 is evidence of a successful ‘take’ and acquisition of protective immunity. An equivocal reaction is any reaction that is not a major reaction, and indicates a non-take (vaccination failure) due to impotent vaccine or inadequate vaccination technique.

2. Previously Vaccinated Individuals (Revaccination)

a. Successful vaccination in a previously vaccinated individual is confirmed when a major cutaneous reaction is observed 6 to 8 days post-vaccination.
b. In some instances, previous vaccination may modify the cutaneous response upon revaccination such that the absence of a cutaneous response does not necessarily indicate vaccination failure.

c. Previously vaccinated individuals who do not have a cutaneous response on revaccination do not require revaccination to try to elicit a cutaneous response.

3. Vaccination Failures

a. Individuals with vaccine failure after primary vaccination may be revaccinated again in an attempt to achieve a satisfactory take.

b. If repeat vaccination fails to produce a major reaction, healthcare providers should consult the OSDH Immunization Service at 405-271-4073 before giving another vaccination.

G. Complications

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. In some instances, complications can be severe or fatal. Vaccinia Immune Globulin (VIG) may be effective for treatment in certain instances.

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 6-8 days. Individuals who are not successfully vaccinated (i.e., vaccination failures) after primary vaccination 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:


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