

INFORMATION PAPER

DHA-IHB
3 May 2016

SUBJECT: Smallpox Revaccination Policy after 10-Years

1. Purpose. To provide guidance for smallpox revaccination of Uniformed Service members.

2. Facts.

a. The Smallpox Vaccination Program (SVP) was implemented in December 2002 to protect Service members from the biological threat of smallpox based on geographic area, occupation and other designated units.

b. Smallpox vaccination is mandatory for:

(1) Uniformed personnel, emergency essential or comparable U.S. government civilian employees, and contractors traveling or assigned (or deploying within 120 days) to the Korean Peninsula for 15 or more consecutive days.

(2) All special units assigned to previously approved exceptions to policy (ETP), to include members of the USPACOM Forward Deployed Naval Forces and NORTHCOM Chemical, Biological, Radiological, and Nuclear (CBRN) Response teams.

(3) Military personnel and applicable civilians who are assigned to designated forces that constitute mission-critical capabilities or are smallpox epidemic response team members, assigned to medical teams at hospitals and clinics.

c. Screening. Screen all potential vaccine recipients for eligibility for vaccination using the Smallpox Vaccination Screening Form (dated Mar 2016) available on the DHA-IHB website at: <http://www.health.mil/smallpox>. Provide all eligible vaccinees the ACAM2000 Medication Guide and the DoD smallpox brochure titled "What You Need to Know about the Smallpox Vaccine" prior to vaccination. These documents will educate them of the risks and benefits associated with the vaccine, reasons why they may not be eligible to receive the vaccine, the expected reactions after vaccination, and how to care for their vaccination site.

d. Immunization. For both primary (naïve) vaccinees and re-vaccinees, administer a droplet of ACAM2000® by percutaneous route (scarification), on the skin of the arm just above the insertion of the deltoid muscle via 15 jabs with a bifurcated needle. Individuals originally vaccinated with Dryvax® will be revaccinated with ACAM2000®. Dryvax® is no longer licensed in the U.S.; it was replaced by ACAM2000®. After vaccination, individuals must follow specified site-care guidelines listed in the ACAM2000® Medication Guide approved by the FDA.

e. Revaccination timelines.

(1) Individuals who are deemed to be at an increased risk and are required to remain vaccinated should receive a booster dose if 10 or more years have passed since last dose. The

booster dose can be administered 120 days prior to booster dose due date or deployment to a high threat area. In the event of a smallpox outbreak, revaccination is recommended every 3 years.

(2) For certain individuals at high risk for exposure, such as research laboratory personnel handling the variola virus, revaccination is recommended every 3 years.

(3) An individual that received an initial smallpox vaccination will not be required the 10 year booster unless they continue to fall under a category in paragraph 2a. Revaccinations will not be permitted on a voluntary basis to personnel not in a required status.

f. Revaccination cutaneous response ('major reaction' or 'take').

(1) Prior vaccination may modify (reduce) the cutaneous response upon revaccination such that the absence of a cutaneous response does not necessarily indicate vaccination failure. An individual (a) born before 1972, or (b) employed as a health care worker before 1977, or (c) who travelled internationally before 1983, or (d) who was on active duty before 1991 or deployed after 2002, or (e) who has a Jennerian scar or (f) who has a documented prior smallpox vaccination and who does not have a cutaneous response ('major reaction' or 'take') following smallpox revaccination, in accordance with the ACAM2000® package insert, does not require a second vaccination attempt to try to elicit a cutaneous response. The patient is considered adequately protected against smallpox (immune) and is fit for all military-related assignments, including deployment. No further diagnostic evaluation is required.

(2) Although revaccinees' SPV vaccination site may not form a pustule or scab, because even a papule might contain infectious virus, our best advice is to keep any lesion (papule) covered, and vaccination site and dressings treated just as with primary vaccination until any lesion is gone and well-healed skin is present.

g. Caution. ACAM2000® is a live vaccinia virus that may be transmitted to persons who have close contact with the vaccinee. The risks of exposure to close contacts are the same as those stated for vaccinees. Vaccinees or their close contacts may be at risk for developing serious side effects from exposure to the vaccine so some re-vaccinees may be deferred depending upon the risk of exposure to them or their close contacts. Smallpox vaccinations should be deferred during pregnancy and until a woman has returned to full duty and is no longer breastfeeding. Screening for all known contraindications is required by DoD prior to all smallpox vaccinations.

3. Adverse Events.

a. Although the common side effects seen in primary vaccinees are generally less severe, revaccinees may experience: pain, redness, warmth, and itching at the vaccination site. Swollen lymph nodes, fatigue, fever, muscle aches, and headache may also occur. These side effects occur less frequently in revaccinated persons than persons receiving the vaccine for the first time. Inadvertent inoculation of other body sites such as the face, nose, mouth, lips, genitalia, and anus are the most frequent complication.

b. Although much less likely in the revaccinee, rare serious adverse events, such as myocarditis and pericarditis, encephalitis, encephalomyelitis, encephalopathy, progressive vaccinia, generalized vaccinia, severe vaccinia skin infections, erythema multiforme major, eczema vaccinatum, ocular complications, and fetal death, have occurred following either primary vaccination or revaccination with live vaccinia virus vaccines.

c. Any suspect adverse event, autoinoculation and/or contact transfer should be reported to the 24/7 DoD Immunization Healthcare Support Center at (877) 438-8222 for medical advice or consultation.

4. Special Considerations. Although both take and side effects are reduced in a revaccinee, the risk for contact transmission remains unchanged. Rigorous site and hand hygiene must be stressed to revaccinees. Vaccinia virus can be spread from the vaccination site to other parts of the body or to close contacts through close physical contact. This can happen for up to 30 days after vaccination in the primary vaccine. For the revaccinee, precautions are appropriate until any lesion is gone and well-healed skin is present. Do not touch a smallpox vaccination site or dirty bandages; this is the best way to avoid spreading the virus. Frequent hand washing also helps prevent spread of the virus if the vaccination site is accidentally touched.

5. References.

a. Centers for Disease Control and Prevention. Vaccinia (Smallpox) Vaccine. Recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR 2001; 50 (RR10):1-25.

b. Centers for Disease Control and Prevention. Supplemental recommendations for using smallpox vaccine in a pre-event vaccination program. Recommendations of the Advisory Committee on Immunization Practices. MMWR 2003;52(RR-7):1-16

c. Multiple resources (e.g., product insert, Vaccine Information Statements) assembled by the Defense Health Agency – Immunization Healthcare Branch:

<https://www.health.mil/Smallpox>

IHB Education Office / (877) 438-8222

Approved: Chief, Clinical Services Office