DEPARTMENT OF DEFENSE
ARMED FORCES EPIDEMIOLOGICAL BOARD
5109 LEESBURG PIKE
FALLS CHURCH VA 22041-3258

OCT 4

Armed Forces Epidemiological Board

MEMORANDUM FOR The Assistant Secretary of Defense (Health Affairs)
The Surgeon General, Department of The Army
The Surgeon General, Department of The Navy
The Surgeon General, Department of The Air Force

SUBJECT: Draft Clinical Policy Guidance - Smallpox Vaccinations (2003 – 02)

1. References:

a. Department of Defense (DoD) Directive 6205.3, "DoD Immunization Program for Biological Warfare Defense," dated November 26, 1993.

b. Memorandum, AFEB 2002-08, 19 Jul 2002, DoD Immunization Program for Biological Warfare Defense.

c. Memorandum, OASD(HA)/FHP&R, 20 Sep 2002, Draft Clinical Policy Guidance – Smallpox Vaccinations.

2. On 19 July 2002, the Armed Forces Epidemiological Board (AFEB) issued recommendation 2002 - 08, "DoD Immunization Program for Biological Warfare Defense." The AFEB endorsed the development of policies and contingency plans for use of smallpox vaccine in military personnel. While the AFEB felt that DoD policies should be consistent with Advisory Committee for Immunization Practices (ACIP) recommendations, the Board recognized that there are unique features within the military, especially concerning circumstances where post-exposure prophylaxis would not be feasible from an operational, logistical, or combat readiness point of view that should be considered. In addition, the Board felt that the side effect profiles from smallpox vaccine were likely to be lower in military personnel since they are repeatedly screened for immune-compromising conditions that predispose to complications from smallpox vaccination. On 20 September 2002, the AFEB was asked to review and provide comment on draft clinical policy guidance on the medical aspects of smallpox vaccinations, focusing on the draft policies for covering vaccination sites and employment of recently vaccinated health-care workers.

3. The Board finds the overall quality of the Clinical Policy Guidance for Smallpox Vaccinations to be excellent. There are a number of issues in the guidance, however that require clarification and the Board suggests additional detail be provided so that variation in execution of the policy be minimized among the Military Services.

- The policy should be clarified to reference its applicability to the expected FDA-approved DryVax® smallpox vaccine and the appropriate dilution should be specifically mentioned.

- An automated record of vaccination should be centrally maintained for all military personnel receiving smallpox vaccination and a system of quality assurance should be developed and implemented to assure validity of the data.

- A standard DoD form for documentation of education and screening of individuals for contraindications before immunization should be developed and included in the individual medical record. The form should include the screening questions that the potential vaccinee completes with a section for the screener to review, finalize, and classify the patient. The form should include a requirement for signature of both the individual being vaccinated and the individual administering the vaccine.

- The terminology used in the draft clinical guidance for pregnancy screening is ambiguous. The question "Do you think you are pregnant?" is generally recognized to underestimate the number of women who are pregnant. Determination of pregnancy may better be accomplished by asking if the last menstrual period was on time and normal and verify no sexual activity since the last menstrual period, medically evaluating those for pregnancy who report otherwise.

- Detailed guidelines on Dryvax® shipping, reconstitution, administration, and storage should be included or a reference provided as part of the clinical policy guidance. The clinical guidance for smallpox vaccination should also include or provide a reference for indications and dosage for Vaccine Immune Globulin (VIG).

- The DoD might want to utilize or refer to some of the checklists, guidelines, etc. recently published by the CDC: http://www.bt.cdc.gov/documentsapp/SmallPox/RPG/index.asp

- Although not considered standard, the 10-year rule for prior vaccination appears at this time to be appropriate. Additionally, the ACIP in the June 22, 2002 recommendations for Vaccina (Smallpox) Vaccine has suggested a 10-year, not 3-year interval for revaccination of persons working with vaccinia virus, recombinant vaccinia viruses, or other nonvariola Orthopoxviruses. ACIP has recommended empiric revaccination every 3 years be considered only for persons working with the more virulent nonvariola Orthopoxviruses (e.g. monkeypox).

- The term "privileged" and "credentialed" health care provider should be clarified. The Board assumes reference is to a credentialed health care provider with defined privileges for the practice of medicine within the Military Health System.

- The draft clinical policy gives Commanders an option of scheduling vaccinations during preparation for or during a deployment to potentially minimize exposing household members. As mentioned in AFEB recommendation 2002-08 dated 19 July 2002, from an operational, logistical, or combat readiness point of view, pre-deployment or pre-exposure vaccination is preferred.

- Except in the case of an emergency situation, recently vaccinated health care workers who still have an open pox due to vaccination should not be allowed to work with patients at high risk of severe morbidity or mortality due to inadvertent transmission of the vaccine virus. Requiring them to defer from caring for such patients is a more prudent course of action. If deferral is not possible, covering the vaccination site with dry gauze, covered by a semi-permeable membrane (such as Op Site), and strict attention to aseptic technique should be required.

- Page 3, paragraph 5, Vaccination-Site Selection: Consider inserting "left" before "deltoid". Traditionally smallpox vaccination has been given on the left arm and BCG on the right.

- Page 6, Medical Exemption Codes: under MI, Explanation or Example, modify to say: "Evidence of immunity (e.g. smallpox antibody test associated with an immune skin reaction on rechallenge with smallpox vaccine within the previous 3 years); documented previous smallpox infection. This is based on the lack of correlation between serologic assays and clinical protection.

- Regarding enclosure 1 - the question (c) should read "people with HIV or acquired immune deficiency syndrome.

4. The above recommendation was unanimously approved.

FOR THE ARMED FORCES EPIDEMIOLOGICAL BOARD:

STEPHEN M. OSTROFF, MD
AFEB President

JAMES R. RIDDLE, DVM., MPH
Colonel, USAF, BSC
AFEB Executive Secretary

Armed Forces Epidemiological Board
SUBJECT: Draft Clinical Policy Guidance - Smallpox Vaccinations (2003 – 02)

2. Encls
1. Memorandum, OASD(HA)/FHP&R, 20 September 2002, Draft Clinical Policy Guidance - Smallpox Vaccinations
2. Memorandum, AFEB 2002-08, 19 Jul 2002, DoD Immunization Program for Biological Warfare Defense

CF:
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HEALTH AFFAIRS

SEP 20

MEMORANDUM FOR EXECUTIVE SECRETARY, ARMED FORCES EPIDEMIOLOGICAL BOARD

SUBJECT: Draft Clinical Policy Guidance - Smallpox Vaccinations

The Armed Forces Epidemiological Board (AFEB) annually provides recommendations to the DoD Executive Agent on vaccines and immunization protocols necessary to enhance protection against validated biological warfare threat agents. In July of 2002, the AFEB provided the Department with a recommendation for implementation of smallpox vaccinations among Armed Forces personnel.

In this regard, I would like the AFEB to convene a select subcommittee to review and provide comment on draft clinical policy guidance on the medical aspects of smallpox vaccinations, focusing on the draft policies for covering vaccination sites and employment of recently vaccinated health-care workers. I request the Board provide formal comment on the draft DoD clinical policy guidance no-later-than 7 October 2002.

Ellen P. Embrey
Deputy Assistant Secretary of Defense
(Force Health Protection and Readiness)

Attachments
As stated

MEMORANDUM FOR SECRETARIES OF THE MILITARY DEPARTMENTS
CHAIRMAN OF THE JOINT CHIEFS OF STAFF
UNDER SECRETARIES OF DEFENSE
ASSISTANT SECRETARIES OF DEFENSE
GENERAL COUNSEL, DEPARTMENT OF DEFENSE
INSPECTOR GENERAL, DEPARTMENT OF DEFENSE
DIRECTORS OF DEFENSE AGENCIES
COMMANDANT OF THE US COAST GUARD

SUBJECT: Policy on Clinical Issues Related to Smallpox Vaccination

This memorandum establishes policy on medical issues involving smallpox vaccination: dosing; education materials; medical screening before immunization; pregnancy screening; vaccination-site selection; medical exemptions; and adverse-event management.

Dosage

Screening for contraindications before vaccination is essential. Smallpox vaccination shall consist of 2-3 punctures with a bifurcated needle for a primary vaccination or 15 punctures for a revaccination, as detailed in the vaccine's package insert. Accurate documentation in both individual medical records and automated immunization tracking systems is required.

Other than laboratory staff working with orthopox viruses, prior smallpox vaccination within the preceding 10 years will be accepted for personnel warranting smallpox vaccinations. For orthopox laboratory workers, smallpox vaccination intervals of 3 years will be observed.

There are no specific data evaluating the simultaneous administration of smallpox vaccine with other live-virus vaccines. General recommendations from the Advisory Committee on Immunization Practices accept administration of live and inactivated vaccines simultaneously or at any interval. Multiple live-virus vaccines should either be given simultaneously or separated by 4 weeks or more.

In most settings, smallpox vaccine will be administered by a licensed health-care worker (e.g., LPN, RN) who has been trained in scarification and in reading smallpox vaccination responses.

Care of the Vaccination Site

The most important measure to prevent inadvertent contact spread from smallpox vaccination sites is thorough hand washing after any contact with the vaccination site.

Appropriate care will be taken to prevent the spread of vaccinia virus from the vaccination site. The following standard precautions will be observed. In general, it is appropriate to leave most vaccination sites unbandaged, especially when alone. Airing will help speed healing of the vaccination site. Wearing long-sleeve clothing and/or using a loose, porous bandage (e.g., gauze) can reduce the opportunity for contact transfer (i.e., a touch-resistant barrier), until the scab falls off on its own. Bandaging may be appropriate in confined spaces (e.g., ships, aircraft) to help reduce contact spread and accidental infection (i.e., auto-inoculation). If bandages are used, dispose of contaminated bandages and the vaccination scab as biohazardous waste. If this is not feasible, dispose of these items in sealed plastic bags, double-bagged if possible. Clothing or other cloth materials that have had contact with the site can be decontaminated with routine laundering in hot water with bleach. The vaccination site should be kept dry, although normal bathing can continue.

If somebody in the vaccine recipient's household has eczema, an immune-suppressing condition, or another reason to avoid vaccinia virus, take reasonable precautions for physical separation until the scab falls off. This separation will include not allowing the vaccine recipient to share sleeping or close living space (e.g., bedroom, sleeping bay, tent) with susceptible people. Washing hands before changing a child's diapers (or having someone else change the diapers) is prudent.

Commanders will provide on-base housing to Service Members who wish to avoid exposing family members or other close contacts to vaccinia virus until the vaccination-site scab falls off. Scheduling vaccinations just before or during deployments or family separation is another option. Wearing long-sleeve clothing during the day and at night can further reduce the opportunity for contact transfer. Further instructions on infection control will be provided in Service implementation plans.

Recently vaccinated health-care workers should avoid contact with unvaccinated patients, particularly those with immunodeficiencies, until the scab falls off. However, if contact with unvaccinated patients is unavoidable, health-care workers can continue to have contact with patients, including those with immunodeficiencies, as long as the vaccination site is well-covered and thorough hand-hygiene is maintained. In this setting, a more occlusive dressing might be appropriate. Semipermeable polyurethane dressings (eg, Opsite®) are effective barriers to vaccinia and recombinant vaccinia viruses. However, exudate may accumulate beneath the dressing, and care must be taken to prevent viral contamination when the dressing is removed. In addition, accumulation of fluid beneath the dressing may increase the maceration of the vaccination site. To prevent accumulation of exudates, cover the vaccination site with dry gauze, then apply the dressing over the gauze. The dressing should also be changed at least once a day, such as at the beginning of each duty shift. Wearing long-sleeve clothing can further reduce the opportunity for contact transfer. The most critical measure in preventing inadvertent contact spread is thorough hand-hygiene after changing the bandage or after any other contact with the vaccination site. For high-risk-density assignments (e.g., intensive-care, transplant, oncology, burn units), medical commanders should consider staggering staff vaccinations to allow reassignment to other duties, taking into account local staffing, case mix, and workload.

After smallpox vaccination, commanders and noncommissioned officers will direct physical activities so that vaccination sites are not subject to undue pressure (pressure reasonably likely to burst a pustule), rubbing, or immersion. For example, clothing and load-bearing equipment will be arranged in a manner to avoid excessive pressure or rubbing at the vaccination site.

Educational Materials

Educational materials provided to all personnel before smallpox vaccination shall address the benefits, side effects, and other medical information concerning the vaccine.

Medical Screening Before Immunization

The national standard of practice for all immunizations shall be adhered to when immunizing. This includes medical screening before immunization. Education and screening shall be conducted for medical conditions for which immunization deferral or further medical evaluation before immunization is indicated. A sample screening questionnaire is provided at Enclosure 1.

Pregnancy Screening

DoD policy is to defer routine smallpox vaccinations until after pregnancy, except in emergency situations. In accordance with FDA and ACIP recommendations, all efforts will be taken to avoid unintended vaccination during pregnancy. All immunization clinics and providers will display in a prominent place written warning against unintentionally vaccinating pregnant women. This warning shall be visible during the screening process. Women of childbearing potential are to be questioned/screened for pregnancy before receiving immunizations. Women who are uncertain about pregnancy status shall be medically evaluated for pregnancy before immunization IAW service policies.

Vaccination-Site Selection

The skin over the insertion of the deltoid muscle is the preferred site for smallpox vaccination. An alternate site is the posterior aspect of the arm over the triceps muscle. As always, appropriate clinical judgement is warranted. Avoid tattooed skin and skin folds.

Medical Exemptions

Some individuals will have either acute or chronic pre-existing conditions that may warrant medical exemption from smallpox vaccination. Furthermore, a small proportion of individuals will develop a more serious reaction after vaccination that may warrant medical exemptions, temporary and permanent, from further smallpox vaccination.

In a smallpox emergency, there are no absolute contraindications regarding vaccination of a person with a high-risk exposure to smallpox. People at greatest risk for experiencing serious vaccination complications are often those at greatest risk for death from smallpox. If a relative contraindication to vaccination exists, the risk for experiencing serious vaccination

complications must be weighed against the risks for experiencing a potentially fatal smallpox infection.

Granting medical exemptions is a medical function performed by a privileged health-care provider. The provider will grant individual exemptions when medically warranted, with the overall health and welfare of the patient clearly in mind, balancing potential benefits with the risks while taking into consideration the threat situation.

The two most common medical exemptions utilized are medical temporary (MT) and medical permanent (MP).

Temporary medical exemptions are warranted when a provider has a concern about the safety of continued immunizations. Examples of situations that warrant a temporary medical exemption are listed below:

1. Immunosuppressive Therapy or Conditions. Individuals receiving systemic corticosteroid therapy, other immunosuppressive drug therapies, or radiation therapy may be in a state of temporary immunodeficiency. Because of the risk of progressive vaccinia, defer these individuals from receiving the smallpox vaccine until immune function returns, as clinically appropriate.

2. Acute Situations. Serious acute diseases, post-surgical situations, or acute injuries potentially may warrant temporary vaccination deferment, if immune response to vaccination might be impaired or adverse events affected. This includes acute febrile illnesses. Vaccinations may resume when clinically appropriate.

3. Pregnancy. Under normal circumstances, defer smallpox vaccine until after pregnancy. Smallpox vaccination is largely based on occupational risk; therefore vaccination should resume with full assumption of duties following pregnancy, unless a longer postpartum interval is clinically indicated. On rare occasions, typically after primary vaccination, vaccinia virus has been reported to cause fetal infection. Fetal vaccinia usually results in stillbirth or death of the infant shortly after delivery. Vaccinia vaccine is not known to cause congenital malformations. In a smallpox emergency, pregnancy is not an absolute contraindication to vaccination of a pregnant woman with a high-risk exposure to smallpox.

4. Breast-feeding is not a medical contraindication to any immunization, but attention is needed to prevent exposing the infant to vaccinia virus at the vaccination site.

5. Other Conditions. In situations where a medical condition is being evaluated or treated, a temporary deferral of smallpox vaccination may be warranted, up to 12 months. This would include significant vaccine-associated adverse events that are being evaluated or while awaiting specialist consultation. The attending physician will determine the deferral interval, based on individual clinical circumstances.

Medical permanent exemptions are generally warranted if the medical condition or adverse reaction is so severe that the risk of continued immunization is not justified. In the case of smallpox vaccine, these permanent exemptions could be lifted if the individual had prolonged

face-to-face contact with someone in the contagious phases of smallpox. Examples of situations otherwise warranting a permanent medical exemption are listed below:

1. Severe reaction after a previous smallpox vaccination or to a vaccine component, such that additional doses would pose an undue risk to the vaccine recipient (e.g., life-threatening allergy to polymyxin B sulfate, dihydrostreptomycin sulfate, chlortetracycline hydrochloride, and neomycin sulfate).

2. Eczema or a past medical diagnosis of eczema. Persons with other acute, chronic, or exfoliative skin conditions (e.g., atopic dermatitis, burns, impetigo, or varicella zoster) might also be at higher risk for eczema vaccinatum and should not be vaccinated until the condition resolves. *[The first sentence mimics the package insert. The second sentence mimics the 2001 ACIP recommendations.]*

3. Human immunodeficiency virus (HIV) infection or other chronic immune deficiencies.

4. For individuals with immunosuppression (e.g., leukemia, lymphomas of any type, generalized malignancy, solid organ transplantation, hematopoietic stem-cell transplantation, cellular or humoral immunity disorders, agammaglobulinemia, or other malignant neoplasms affecting the bone marrow or lymphatic systems).

5. Evidence of immunity based on surviving previous smallpox infection.

If the situation changes, a provider experienced in vaccine-safety assessment can remove a permanent medical exemption.

If an individual's clinical case is complex or not readily definable, consult an appropriate medical specialist with vaccine safety assessment expertise, before a permanent medical exemption is granted. In addition, the original health care provider may consult with physicians working with the Vaccine Healthcare Center Network, DoD's vaccine centers of excellence. If a permanent medical exemption is indicated, appropriate DoD and Service policies will be pursued for granting such exemptions. Service Members who disagree with a given provider or consultant's recommendations regarding an exemption may be referred for a second opinion to a provider experienced in vaccine adverse-event management. Medical records will be accurately and appropriately annotated pertaining to any temporary or permanent medical exemptions. When no longer clinically warranted, medical exemptions will be revoked.

If a patient disagrees with an initial medical decision or diagnosis, he or she may request a second opinion at the next higher medical treatment facility. If the second opinion is one with which the patient again disagrees, he or she may be referred directly to the Vaccine Healthcare Center Network.

Each military treatment facility will assist Service Members in obtaining appropriate specialty consultations expeditiously and assist in resolving patient difficulties. Specialists may grant permanent medical exemptions. Return of the patient to his or her primary-care provider is not required if the referring specialist deems a permanent medical exemption is warranted. The following medical exemption codes relate to all vaccines. A Vaccine Adverse Event Reporting System (VAERS) report should be filed for any permanent medical exemption due to a vaccine related adverse event.

Medical Exemption Codes:

Code	Meaning	Explanation or Example	Duration
MI	Medical, Immune	Evidence of immunity (e.g., serologic antibody test); documented previous smallpox infection.	Indefinite
MR	Medical, Reactive	Severe adverse reaction after immunization (e.g., anaphylaxis). Code can be reversed if an alternate form of prophylaxis is available. Usually warrants VAERS report.	Indefinite
MT	Medical, Temporary	Pregnancy, hospitalization, temporary immune suppression, convalescent leave, any temporary contraindication to immunization.	Specified period
MP	Medical, Permanent	HIV infection, pre-existing allergy, permanent immune suppression. Can be reversed if the condition changes.	Indefinite
MD	Medical, Declined	Declination of optional vaccines, religious waivers.	Indefinite
MS	Medical, Supply	Exempt due to lack of vaccine supply.	Indefinite

Adverse-Event Management

As with any vaccine, some individuals receiving smallpox vaccine will experience side effects or adverse events. In addition, smallpox vaccine exhibits a unique adverse-event profile involving encephalitis, progressive vaccinia, eczema vaccinatum, and other conditions.

The attached clinical guidelines (Enclosure 2) offer advice for managing adverse events that may occur after vaccination with any vaccine. These clinical guidelines are also available on the DoD military vaccine web site at www.vaccines.mil and soon at the Vaccine Healthcare Center web site at www.vhcinfo.org.

Adverse reactions from DoD-directed immunizations are line of duty conditions.

Immunizations are provided as part of the Department's Force Protection program. At the time of immunization, personnel are to be provided documentation that identifies date and location of immunization, general information on expected adverse events, location of the nearest military treatment facilities (MTFs), a toll-free 24-hour medical provider assistance line, and the toll free telephone number of the Military Medical Support Office, in the event medical treatment is required from non-military treatment facilities. Emergency-essential DoD civilian employees and contractor personnel carrying out mission essential services are entitled to the same treatment and necessary medical care as given to the Service Members. This includes follow-up and/or emergency medical treatment from the MTF or treatment from their personal healthcare providers or non-military treatment facilities for emergency medical care as a result of immunizations required by their DoD employment.

Whenever a Service Member presents at an MTF, expressing a belief that the condition for which treatment is sought is related to an immunization received during a period of duty, the

member must be examined and provided necessary medical care. Once treatment has been rendered or the individual's emergent condition is stabilized, a Line of Duty and/or Notice of Eligibility will be determined as soon as possible. Reserve Component members, who seek medical attention from their personal healthcare providers, or any non-military treatment facility, must ensure that the Military Medical Support Office is notified as soon as possible.

In the case of Emergency-Essential civilian employees presenting to a military treatment facility or occupational health clinic, the initial assessment and any needed emergency care should be provided consistent with applicable occupational health program procedures. In the case of contractor personnel covered by the vaccination policy presenting to a military medical treatment facility or occupational health clinic, Secretarial-designee authority shall be used, consistent with applicable Military Department policy, to allow an initial assessment and any needed emergency care. This policy will facilitate awareness by our medical professionals of adverse events and provide to the patient medical expertise regarding vaccine events not necessarily available in the civilian medical community. This use of Secretarial-designee authority does not change the overall responsibility of the contractor under workers' compensation program for all work-related illnesses, injuries, or disabilities.

A privileged health-care provider and any specialists, as indicated, should immediately evaluate any serious adverse event temporally associated with receipt of a dose of smallpox vaccine.

Vaccine Adverse Event Reporting System (VAERS) reports shall be filed using Service reporting procedures for those events resulting in hospital admission or lost duty time or work of 24 hours or more or from those events suspected to have resulted from contamination of a vaccine vial. Further, health-care providers are encouraged to report other adverse events that in the provider's professional judgment appear to be unexpected in nature or severity. In other situations in which the patient wishes a VAERS report to be submitted, the health-care provider will work with the patient to submit one. VAERS report forms may be obtained by accessing www.vaers.org or by calling VAERS at 1-800-822-7967.

Adverse-event management should be thoroughly documented in medical records. A copy of the VAERS report will be filed in an individual's medical record after submitting the original form through DoD reporting channels, as discussed above. Providers are encouraged to provide a copy of the VAERS report to the patient.

These policies are effective immediately and should be communicated to appropriate commanders, health-care providers, and others involved in implementation.

William Winkenwerder, Jr., MD

Attachments:
As stated

cc:
Chief of Staff of the Army
Chief of Naval Operations
Commandant of the Marine Corps
Chief of Staff of the Air Force
Surgeon General of the Army
Surgeon General of the Navy
Surgeon General of the Air Force

Enclosure 1

Screening for Bars (Contraindications) to Smallpox Vaccination.

1. How are you today? Do you have a fever, diarrhea, or vomiting today?

2. Have you ever had a reaction to a vaccine? If so, please describe it.

3. Do you have any drug allergies?

Note: People who have had serious, life-threatening allergies to the antibiotics polymyxin B, streptomycin, tetracycline, or neomycin should talk with a physician before vaccination.

4. Are you being treated by a doctor for a disease?

Note: People treated for arthritis or Crohn's disease may be taking medications that affect their immune system (e.g., etanercept/*Enbrel*, infliximab/*Remicade*). Other people in similar situations may include those treated with interferon alfa (e.g., *Intron-A, Roferon-A*; for hepatitis B or hepatitis C infection), interferon beta (e.g., *Avonex, Betaseron, Rebif*; for multiple sclerosis), or interferon gamma (e.g., *Actimmune* for chronic granulomatous disease).

5. Do you or anyone in your household have any form of cancer, leukemia, or immune system problem? For example:

a. People taking anticancer drugs, x-ray treatments, cortisone, prednisone, or other steroids (other than inhalers).

b. People with leukemia, lymphoma, or generalized cancers (malignancy).

c. People with acquired immune deficiency syndrome (AIDS).

d. Have you had an organ or bone-marrow transplant?

e. Do you have any chronic problem with your skin (eczema or history of eczema)?

f. Have you been told you or a family member has a problem with the immune system?

Note: People with AIDS have suppressed immune systems. People infected with HIV who also have high counts of CD4+ white blood cells may not develop special problems after smallpox vaccination, but this is not known for sure. There is no requirement for an HIV blood test before smallpox vaccination. People uncertain about their HIV status may be interested in an HIV blood test; MTF commanders will assist these people according to the availability of resources.

d. People with other immune deficiencies, such as agammaglobulinemia, immune suppression for organ transplants.

Note: People with certain medical conditions can have a higher risk of developing severe complications after they receive smallpox vaccination themselves. There is also a risk if someone in their household gets smallpox vaccine and then viruses at the vaccination site spread by touch to a member of the household.

7. Regarding skin disorders, people who have been diagnosed with eczema, even if the condition is mild or not presently active, could be at higher risk of complications of smallpox vaccine. Positive responses to two or more of the following questions suggest a diagnosis of atopic dermatitis:

a. Has a doctor ever diagnosed eczema in the patient?

b. Has the patient had itchy rashes that lasted more than two weeks?

c. Has the patient ever had itchy rashes in the folds of the arms or legs?

d. Did the patient have eczema or food allergies during infancy and childhood?

e. Has a doctor ever diagnosed asthma or hay fever in the patient?

8. People with other acute or chronic skin conditions, such as atopic dermatitis, burns, impetigo, or varicella zoster (shingles), should not routinely be vaccinated against smallpox until the condition resolves.

9. For women: Are you pregnant or is there a chance that you could become pregnant in the next month?

Note: As with most vaccines, vaccination of pregnant women should be deferred unless it is clearly needed. Live-viral vaccines are usually barred (contraindicated) during pregnancy. But if you have been exposed to smallpox, you would probably be vaccinated against it. Smallpox vaccine is not known to cause birth defects. On very rare occasions, vaccinia infection of the fetus has been reported after vaccinating the mother. This fetal vaccinia infection may result in stillbirth or death of the infant soon after delivery. About 50 of these fetal cases have been recorded after vaccinating literally billions of women around the globe. Smallpox infection among pregnant women has been reported to result in a more severe infection than among nonpregnant women.

10. Have you received a transfusion of blood or plasma or any medicine containing antibodies (immune or gamma globulin) in the past 12 months?

If so, you may be slightly less likely to develop a take from smallpox vaccination. Watch the vaccination site carefully and seek revaccination if no take is evident on day 6 to 8 after vaccination.

Note: Household members of contacts with bars to vaccination should consider housing themselves separately from vaccinated household members, until the vaccination site heals, to decrease the risk of contact transmission of virus.

Enclosure 2

Clinical Guidelines for Management of Adverse Events After Vaccination

August 2002 edition

(same content as at http://www.anthrax.mil/media/pdf/cpguidelines.pdf)

DEPARTMENT OF DEFENSE
ARMED FORCES EPIDEMIOLOGICAL BOARD
5109 LEESBURG PIKE
FALLS CHURCH, VA 22041-3258

REPLY TO
ATTENTION OF

JUL 19 2002

AFEB (15-1a) 2002-08

MEMORANDUM FOR The Assistant Secretary of Defense (Health Affairs)
The Surgeon General, Department of The Army
The Surgeon General, Department of The Navy
The Surgeon General, Department of The Air Force

SUBJECT: DoD Immunization Program for Biological Warfare Defense

1. References:

a. Department of Defense Directive 6205.3, "DoD Immunization Program for Biological Warfare Defense," dated November 26, 1993.

b. Memorandum, AFEB 94-07, 3 Aug 1994, Biological Warfare Vaccines.

c. Memorandum, AFEB 96-04, 8 Nov 1996, Recommendation for Biological Warfare (BW) Vaccines.

d. Memorandum, AFEB 99-05, 25 May 1999, Armed Forces Epidemiological Board Recommendations for Biological Warfare Vaccines.

e. Memorandum, AFEB 00-07, 3 Aug 2000, Armed Forces Epidemiological Board (AFEB) Comments and Recommendations Concerning the JCS BW threat List for 2000.

f. Memorandum, AFEB 01-05, 27 Sep 2001, DoD Immunization Program for Biological Warfare Defense.

g. Memorandum, AFEB 01-06, 27 Sep 2001, Medical Risk Assessment of the Biological Threat.

2. On 21 and 22 May 2002 the Armed Forces Epidemiological Board (AFEB) met to consider the DoD Immunization Program for Biological Warfare Defense as required by Department of Defense Directive 6205.3, "DoD Immunization Program for Biological Warfare Defense," dated November 26, 1993. Specifically, the AFEB is tasked to identify to the Assistant Secretary of Defense for Health Affairs (ASD(HA)) vaccines available to protect against biological threat agents designated by the Chairman of the Joint Chiefs of Staff, and recommend appropriate immunization protocols.

3. The Board received briefings on the current intelligence based biological warfare threat, the Medical Risk/Threat Matrix, the Medical Biological Defense Research Program, and the Joint Vaccine Acquisition Program. The Board noted that the current intelligence based biological warfare threat list had not been formally validated by the Chairman of the Joint Chiefs of Staff.

4. Although there has not been an updated and approved Chairman of the Joint Chiefs of Staff Validated Threat List for 2002, there have been significant changes in the availability of vaccines to protect against biological warfare threat agents since the AFEB last reviewed this issue in 2001. These include a greater supply of licensed anthrax vaccine (adsorbed) (AVA) and an acceleration of efforts to develop a sufficient stockpile of licensed vaccinia (smallpox) vaccine. Previous AFEB recommendations on administration of anthrax vaccine remain current. Two previously licensed smallpox vaccines are now available, Dryvax® made by Wyeth and the Aventis Pasteur vaccine, however both would currently have to be administered under investigational new drug (IND) protocols because of changes in diluent composition (Dryvax®) and testing for potency and sterility (Aventis Pasteur vaccine). Recent studies have demonstrated that Dryvax® can undergo a fivefold dilution and still produce "take" rates, which indicate a successful immunization, equivalent to full strength vaccine. New generation cell-culture derived smallpox vaccine is being procured by the Department of Defense and Department of Health & Human Services, but is not currently available or licensed.

5. In June 2002, the Advisory Committee on Immunization Practices (ACIP) recommended against routine smallpox vaccination of U.S. civilians due to the perceived low threat, the known complication profiles of the vaccine, and the readily available option for postexposure prophylaxis. However, the ACIP did endorse preexposure vaccination of designated smallpox response teams that would be called upon to respond to a smallpox incident, and medical and emergency response personnel at risk of coming into early contact with a smallpox case.

6. Because of these changing circumstances, including a changing threat assessment, the AFEB endorses the development of policies and contingency plans for use of smallpox vaccine in military personnel. While these policies should be consistent with ACIP recommendations, the Board recognizes that there are unique features within the military, especially concerning circumstances where postexposure prophylaxis would not be feasible from an operational, logistical, or combat readiness point of view that should be considered. In addition, the side effect profiles from smallpox vaccine are likely to be lower in military personnel since they are repeatedly screened for immune-compromising conditions that predispose to complications from smallpox vaccine. Therefore, DoD policies are likely to diverge from those used in the civilian sector. Regarding smallpox vaccine, the Board makes the following recommendations:

a. UNTIL LICENSED PRODUCT IS AVAILABLE, ANY USE OF INVESTIGATIONAL SMALLPOX VACCINE SHOULD BE DONE ON A VOLUNTARY BASIS WITH FULL INFORMED CONSENT UNLESS ADMINISTERED PER 10 U.S.C. 1107.

b. PREFERENCE SHOULD BE GIVEN TO THE USE OF LICENSED OVER UNLICENSED PRODUCT WHENEVER POSSIBLE.

c. THE DOD SHOULD MOVE TOWARDS DEVELOPMENT OF A STOCKPILE, OR READY ACCESS TO SUPPLIES OF LICENSED SMALLPOX VACCINE AND VACCINIA-IMMUNE GLOBULIN ADEQUATE FOR FULL-FORCE PROTECTION IF NECESSARY.

d. CONSISTENT WITH ACIP POLICY, THE DOD SHOULD IDENTIFY SMALLPOX RESPONSE TEAMS, MEDICAL EVACUATION PERSONNEL AND DESIGNATED MEDICAL CARE FACILITIES THAT WOULD HANDLE SMALLPOX CASUALITIES AND DEVELOP POLICIES FOR PRE- AND POST-EXPOSURE VACCINATION.

e. THE DOD SHOULD DEVELOP POLICIES THAT MINIMIZE THE POTENTIAL FOR SECONDARY TRANSMISSION OF VACCINIA FROM VACCINATED PERSONNEL.

f. THE DOD SHOULD IDENTIFY CIRCUMSTANCES, E.G. SPECIAL FORCES PERSONNEL AND DEPLOYMENTS WHERE THREAT ASSESSMENTS INDICATE A POTENTIAL HIGHER RISK OF SMALLPOX EXPOSURE, IN WHICH POST-EXPOSURE PROPHYLAXIS WOULD EITHER NOT BE FEASIBLE OR (DUE TO THE KNOWN LOCAL SIDE EFFECTS OF THE VACCINE) MIGHT DEGRADE OPERATIONAL READINESS, AND DEVELOP OPTIONS FOR PRE-EXPOSURE PROPHYLAXIS OF THESE PERSONNEL. OF NOTE, SMALLPOX PROTECTION REQUIRES ONLY A SINGLE DOSE OF VACCINE AND GENERALLY OCCURS WITHIN 7-DAYS OF ADMINISTRATION, MAKING A JUST-BEFORE DEPLOYMENT OPTION POSSIBLE.

g. THE DOD SHOULD DEVELOP TRACKING SYSTEMS FOR ADMINISTRATION OF VACCINE AND THE OCCURRENCE OF COMPLICATIONS AND SIDE EFFECTS FROM ANY USE OF THE SMALLPOX VACCINE IN MILITARY PERSONNEL.

7. The above recommendations were unanimously approved.

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