THE ASSISTANT SECRETARY OF DEFENSE

WASHINGTON, D. C. 20301-1200

HEALTH AFFAIRS

NOV 26 2002

MEMORANDUM FOR CHAIRMAN OF THE JOINT CHIEFS OF STAFF
UNDER SECRETARIES OF DEFENSE
GENERAL COUNSEL, DEPARTMENT OF DEFENSE
INSPECTOR GENERAL, DEPARTMENT OF DEFENSE
DIRECTORS OF DEFENSE AGENCIES
SECRETARY OF THE ARMY
SECRETARY OF THE NAVY
SECRETARY OF THE AIR FORCE
COMMANDANT OF THE U.S. COAST GUARD

SUBJECT: Clinical Policy for the DoD Smallpox Vaccination Program (SVP)

This memorandum establishes policy on medical issues involving smallpox vaccination: education, medical screening before immunization, pregnancy screening, vaccination-site selection, vaccine delivery, medical exemptions, and adverse-event management. The guidance provided in this policy is consistent with guidance provided in the DoD Smallpox Response Plan.

This memorandum applies primarily to the Dryvax-brand smallpox vaccine manufactured by Wyeth Laboratories, when administered in its original full-strength concentration. Dryvax was re-licensed by the Food and Drug Administration (FDA) on October 25, 2002. Supplemental policies will be issued, if warranted, for other circumstances or other vaccine formulations.

Education

All personnel will be educated about smallpox and smallpox vaccination before vaccination. Educational materials provided shall address the rationale, contraindications, criteria for medical exemptions for Service members or their household contacts, benefits, expected response at the vaccination site, side effects, risks to household contacts, vaccination-site care, and other medical information concerning the vaccine.

Healthcare providers will remain alert to modifications in clinical recommendations as the smallpox vaccination program progresses. Personnel involved in this program should regularly review the following web sites for new clinical information and educational resources: www.vaccines.army.mil and www.cdc.gov/smallpox. However, nothing in this memorandum will be superseded except by subsequent memoranda from the Assistant Secretary of Defense (Health Affairs).

Medical Screening Before Immunization

Medical screening before vaccination for contraindications in vaccine recipients and their household contacts is essential to prevent serious complications. Prescreening questionnaires for contraindications to vaccinations will be placed in the medical record. Screening must be conducted in a manner that allows Service members to freely ask questions and get reliable answers. The standard of practice for all immunizations includes medical screening before immunization. Unique for smallpox vaccine is the need to screen for risks among household contacts. Education and screening shall be conducted to document medical conditions for which immunization exemption (temporary or permanent) or further medical evaluation before immunization is indicated. A sample screening and follow-up questionnaire is provided (Attachment 1). Standardized screening tools will be provided at a later date.

Infection with human immunodeficiency virus (HIV) is a contraindication to smallpox vaccination. Service members will be up-to-date with Service HIV-screening policies before smallpox vaccination. Service members who are concerned that they could have HIV infection may request additional HIV testing. DoD civilian employees and contractors to be vaccinated against smallpox will be offered HIV testing in a confidential setting, with results communicated to the potential vaccinee before vaccination. HIV testing is recommended for anyone who has a history of a risk factor for HIV infection, especially since his or her last HIV test, and who is not sure of his or her HIV-infection status. Because known risk factors cannot be identified for some people infected with HIV, people concerned that they could be infected should be tested.

Pregnancy Screening

DoD policy is to defer routine smallpox vaccinations until after pregnancy, except in emergencies where personal benefit from vaccination outweighs the risks. In a smallpox outbreak, pregnancy is not a contraindication to vaccination of a pregnant woman with a high-risk exposure to smallpox, because the benefits of vaccination would outweigh its risks.

In accordance with FDA and Advisory Committee on Immunization Practices (ACIP) recommendations, all appropriate efforts will be taken to avoid unintended vaccination during pregnancy. On rare occasions, typically after primary (first) vaccination, vaccinia virus has been reported to cause fetal vaccinia infection. Fetal vaccinia usually results in stillbirth or death of the infant shortly after delivery. Vaccinia vaccine is not known to cause congenital malformations.

All immunization clinics will prominently display a written warning against unintentionally vaccinating pregnant women. This warning must 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. Because the requirement for smallpox vaccination is based largely on occupational risk, defer vaccination for pregnant women at least until the resumption of full duties following pregnancy, or later as postpartum care may require.

In addition, all women receiving a smallpox vaccination will be instructed to avoid becoming pregnant for at least four weeks after their smallpox vaccination.

Vaccination-Site Selection

The skin over the insertion of the deltoid muscle (non-dominant preferred) is the preferred site for smallpox vaccination. Other optional sites are described in the vaccine's package insert (Attachment 2). As always, appropriate clinical judgment is warranted. Do not vaccinate near the site of an active skin lesion or rash. Avoid tattooed skin where vaccination-site evaluation could be impaired. Avoid skin folds where drying is impeded. Any skin condition that may interfere with the immune response to vaccination should be carefully evaluated before vaccination.

Vaccination

Appropriately trained and qualified medical personnel, upon the order of an appropriately privileged health care provider, will administer smallpox vaccine. People who administer smallpox vaccine must be vaccinated themselves. The preference to vaccinate smallpox vaccinators is based on the risk of inadvertent inoculation from repetitive handling of the vaccine. People may administer smallpox vaccine promptly after being personally vaccinated.

Smallpox vaccination shall consist of 3 punctures (jabs) with a bifurcated needle for a primary (first) vaccination or 15 punctures (jabs) for a revaccination (see package insert). When in doubt, give 15 punctures. Evidence of prior smallpox vaccination includes medical documentation or a characteristic Jennerian scar. Presumptive evidence includes entry into U.S. military service before 1984, or birth in the United States before 1970 (roughly in descending order of reliability). People vaccinated with smallpox vaccine in the past 10 years do not require revaccination, except specific laboratory workers involved with orthopox virus research, who may require more frequent vaccination.

Assessment of vaccine take is required for health care workers and members of smallpox response teams who will travel into a smallpox outbreak area. Other persons receiving vaccine should also have vaccine take assessed. To assess vaccine take, medical personnel trained in vaccination evaluation will inspect the vaccination site at six to eight days after vaccine administration. Reactions will be categorized as "Major Reaction" or "Equivocal" in accordance with the World Health Organization criteria (Attachment 3). To accommodate individuals for whom take assessment is not feasible, all persons receiving smallpox vaccine will be instructed to report to the vaccination clinic if they do not develop a characteristic smallpox vaccination reaction.

Accurate documentation of both vaccination and take is required. Vaccination will be documented in both individual health records and automated immunization tracking systems. In addition, vaccination take will be documented in individual health records immediately beneath the vaccination entry by writing the date of the assessment and the type of reaction: Major Reaction or Equivocal.

Persons administering vaccines will follow necessary precautions to minimize risk of spreading diseases. Because of the nature of the vaccine container and method of administration, vaccinators' hands should be washed with soap and water or cleansed with an alcohol-based waterless antiseptic solution after each patient contact. Glove use is not routinely recommended when administering vaccinations, unless persons administering vaccinations are likely to come into contact with potentially infectious body fluids or have open lesions on their hands. Even vaccinated vaccinators may develop vaccinia skin lesions on the fingers, known as "whitlow," if vaccine touches their skin, particularly near abrasions or dry skin.

Needles should be discarded in labeled, puncture-proof containers to prevent inadvertent needle-stick injury or reuse. Standard needle-stick-injury procedures will be followed if a vaccinator is inadvertently stuck with a used bifurcated needle.

Cleansing of the vaccination site may be performed with soap and water, followed by water only, and then drying. Acetone or alcohol may be used only if adequate time is allowed for it to evaporate or if the site is wiped dry with (non-sterile) gauze to prevent unintentional inactivation of the live virus vaccine. Acetone may be preferred over alcohol, because acetone evaporates more quickly.

Revaccination

If a person does not manifest a characteristic vaccination reaction six to eight days after smallpox vaccination, that person should receive a single revaccination with 15 punctures (jabs) at a separate site. People previously vaccinated, especially if they have received multiple doses, may not respond to smallpox vaccine because of current immunity. Revaccination should be repeated once. People who do not respond with a visible skin lesion after two attempts should be referred for immunologic evaluation.

People should be revaccinated if more than 10 years have elapsed since the last smallpox vaccination. Laboratory workers working with orthopox viruses will observe appropriate revaccination intervals, based on their individual situation.

Quality Assurance

Medical commanders will use standardized materials to train smallpox vaccinators. Medical commanders will assess vaccination technique by evaluating the vaccination take rates among the first cohort of people (e.g., 50 to 100) vaccinated by each vaccinator. Recent published studies found take rates > 95% with appropriate technique.

Medical commanders will assure that proper screening of vaccine recipients occurs before vaccination and access to providers experienced in risk-benefit assessment are available to both vaccine recipients and vaccinators. Medical commanders will facilitate prompt evaluation of vaccine recipients with adverse events or side effects that interfere with the ability to work. The Clinical Guidelines for Managing Adverse Events after Vaccination should be used.

Timing and Spacing of Other Vaccinations

General recommendations from the ACIP allow administration of live and inactivated vaccines simultaneously or at any interval. The only major restriction to combining vaccinations is with multiple live-virus vaccines, which should either be given simultaneously or separated by 28 days or more. There are limited data evaluating the simultaneous administration of smallpox vaccine with other live-virus vaccines. It may be desirable to separate varicella (chickenpox) and smallpox (vaccinia) vaccinations by 28 days, because of the small potential to confuse attribution of lesions that may result in vaccine recipients.

Do not administer other vaccines near the smallpox vaccination site.

Care of the Vaccination Site

Vaccinia virus can be cultured from the site of primary vaccination beginning at the time of development of a papule (i.e., two to five days after vaccination) until the scab separates from the skin lesion (i.e., 14 to 21 days after vaccination). During that time, care must be taken to prevent spread of the virus to another area of the body or to another person by inadvertent contact. Disease transmission from intact scabs is unlikely, but high-risk individuals may be vulnerable to scab particles. Historically, the rate of spread of vaccinia virus to contacts is quite rare, about 27 cases per million vaccinations. The DoD's goal is to reduce the risk as much as possible.

The most important measure to prevent inadvertent contact spread from smallpox vaccination sites is thorough hand washing (e.g., alcohol-based waterless antiseptic solution, soap and water) after any touching of the vaccination site.

To avoid secondary infection, commanders and noncommissioned officers will direct physical activities so that smallpox vaccination sites are not subject to undue pressure (likely to burst a pustule), rubbing, or immersion sufficiently prolonged to cause tissue breakdown or secondary infection. Activities that complicate vaccine site care and cleanliness should be avoided during the post-vaccination healing period. For example, clothing and load-bearing equipment will be arranged in a manner to avoid excessive pressure or rubbing at the vaccination site. Avoid contact sports, such as wrestling. Avoid immersion in public pools or spas.

Appropriate care should be taken to prevent the spread of vaccinia virus from the vaccination site. The following special precautions will be observed. In general, it is reasonable to leave most vaccination sites unbandaged, especially when not in close contact with other persons. Airing will help speed healing of the vaccination site. Wearing clothing with sleeves covering the vaccination site and/or using a loose, porous bandage (e.g., standard Band-Aid®, a piece of gauze attached with adhesive or paper tape around each edge) to make a touch-resistant barrier can reduce the opportunity for contact transfer 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., inadvertent inoculation).

If bandages are used in a medical setting, dispose of contaminated bandages and the vaccination scab as biohazardous waste. In other settings, dispose of these items in sealed plastic bags (e.g., Zip-Loc® bag). Clothing, towels, sheets, or other cloth materials that have had contact with the site can be decontaminated with routine laundering in hot water with detergent or bleach. Normal bathing can continue, but the vaccination site should otherwise be kept dry. Avoid rubbing the vaccination site. Vaccinia virus is inactivated by sunlight.

Minimizing close physical contact with infants less than one year of age is prudent until the scab falls off. If unable to avoid infant contact, wash hands before handling an infant (e.g., feeding, changing diapers) and ensure that the vaccination site is covered with a porous bandage and clothing. It is preferable to have someone else handle the infant. Smallpox vaccine is not recommended for use in a nursing mother in non-emergency conditions.

Recently vaccinated healthcare workers should minimize contact with unvaccinated patients, particularly those with immunodeficiencies, until the scab falls off. Even patients vaccinated in the past may be at increased risk due to current immunodeficiency. If contact with unvaccinated patients is essential and unavoidable, healthcare 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. Semi-permeable polyurethane dressings (e.g., Opsite®, Tegaderm®) 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, and then apply the dressing over the gauze. The dressing should also be changed daily or every few days (according to type of bandaging and amount of exudate), such as at the start or end of a duty shift. Military treatment facilities should develop plans for site-care stations, to monitor workers' vaccination sites, promote effective bandaging, and encourage scrupulous hand hygiene. Wearing long-sleeved clothing can further reduce the risk 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.

Medical Exemptions

Some individuals will have either acute or chronic pre-existing conditions that may warrant medical exemption from smallpox vaccination. In some cases, vaccination should be withheld if the individual cannot avoid household contact with another person with contraindicating conditions. 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 to vaccinating people with a high-risk exposure to an infectious case of smallpox (e.g., face-to-face contact). Prior

contraindications to vaccination could be overshadowed by personal risk of smallpox disease. Smallpox vaccine would be made available for people exempted during pre-outbreak vaccination programs. 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 individually weighed against the risks for experiencing a potentially fatal smallpox infection.

Granting medical exemptions is a medical function performed by a privileged healthcare 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. Medical exemptions are not based on preferences of the prospective vaccinee for or against vaccination.

The two most common annotated medical exemption categories are Medical Temporary (MT) and Medical Permanent (MP). Annotate Service member records in immunization tracking systems with these codes, and update them as appropriate. In the event of a confirmed smallpox outbreak, permanent exemptions could be lifted, based on individual risk.

People who have household contact with a person who has a contraindication to smallpox vaccination (e.g., immune-suppressed people, people with atopic dermatitis or eczema, pregnant women) shall either have alternative housing arrangements or be exempted from smallpox vaccination until the household contact situation is no longer applicable. Scheduling vaccinations shortly before or during 21-day or greater deployments or family separation is an option. This avoidance of contact should continue until the vaccination scab falls off on its own.

Military-unique berthing settings require similar precautions. Exempt individuals should be physically separated and exempt from duties that pose the likelihood of contact with potentially infectious materials (e.g., clothing, towels, linen) from recently vaccinated people. This separation will include not having the vaccine recipient share or alternate use of common sleeping space (e.g., cot, bunk, berth) with people with contraindications to vaccination.

Temporary medical exemptions are warranted when a provider has a concern about the safety of immunizations in people with certain clinical conditions. The vaccine's package insert contains examples of situations that warrant a temporary medical exemption (e.g., immune-suppressed people, pregnant women). The ACIP notes that people with acute, chronic, or exfoliative skin conditions (e.g., burns, impetigo, varicella zoster, herpes, psoriasis, severe or uncontrolled acne) may also be at higher risk for inadvertent inoculation and should not be vaccinated until the condition resolves or a provider affirms it is under maximal control.

In situations where a medical condition is being evaluated or treated, a temporary deferral of smallpox vaccination may be warranted, up to a maximum 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 or unremitting that the risk of subsequent immunization is not justified. In the case of smallpox vaccine, these permanent exemptions could be lifted if the individual had face-to-face contact with someone contagious with smallpox. Examples of situations otherwise warranting a permanent medical exemption appear in the vaccine's package insert (e.g., life-threatening allergy to vaccine component, immune-suppressed people, people infected with human immunodeficiency virus, people with atopic dermatitis or eczema or a past history of those disorders; Attchment 2). People with contraindicated skin conditions who received smallpox vaccine earlier in life may be revaccinated after medical consultation for individual risk-benefit decision making.

If a permanent medical exemption is indicated, follow appropriate DoD and Service-specific policies for granting such exemptions. If the situation changes, an appropriate medical specialist can remove a medical exemption.

If an individual's clinical case is complex or not readily definable, healthcare providers should consult an appropriate medical specialist with vaccine safety-assessment expertise, before granting a permanent medical exemption. In addition, providers may consult with physicians in the Vaccine Healthcare Center Network. In such cases, providers will document specialty consultation in the individual's health record, including the considerations and reasons why a temporary or permanent medical exemption is or is not granted. A table to assist providers in determining medical exemptions will be provided at a later date.

An individual who disagrees with a provider's recommendation regarding an exemption may request a referral for a second opinion. In such cases, the individual will be referred to a provider experienced in vaccine adverse-event management who has not been involved in the decision-making to this point. This provider may be at the same facility or, when applicable, at a referral facility. If the patient disagrees with the second opinion, he or she may be referred directly to the Vaccine Healthcare Center Network. Medical commanders retain authority to review all appealed exemption determinations and may delegate this authority to individuals with appropriate expertise within their organization.

Each military treatment facility commander will assist in obtaining appropriate specialty consultations expeditiously and 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. A Vaccine Adverse Event Reporting System (VAERS) report should be filed for any permanent medical exemption due to a vaccine-related adverse event. The following medical exemption codes relate to all vaccines.

Military Medical Exemption Codes

Code	Meaning	Explanation or Example	Duration
MI	Medical, Immune	Evidence of immunity. For smallpox, documented infection (indefinite exemption) or documented confirmed take in medical records within the past 10 years.	Up to 10 years
MR	Medical, Reactive	Severe adverse reaction after immunization (e.g., anaphylaxis). Code can be reversed if an alternate form of prophylaxis is available. File VAERS report.	Indefinite
MT	Medical, Temporary	Pregnancy, hospitalization, temporary immune suppression, convalescent leave, any temporary contraindication to immunization (e.g., smallpox vaccine and household-contact situation).	Specified period
MP	Medical, Permanent	HIV infection, atopic dermatitis, 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. Adults vaccinated for the first time may develop a clinical illness with injection-site inflammation, muscle aches, and fatigue, most often on days eight to nine after vaccination. This illness may interfere with work. In addition, smallpox vaccine exhibits a unique adverse-event profile including encephalitis, progressive vaccinia, eczema vaccinatum, and other conditions.

DoD Clinical Guidelines for Management of Adverse Events After Vaccination offer useful advice. These clinical guidelines are available on the DoD military vaccine web site at www.vaccines.army.mil and at the Vaccine Healthcare Center web site at www.vhcinfo.org. Specific guidance for management of adverse reactions unique to smallpox vaccination will be published at a later date.

Specific information about treatment with vaccinia immune globulin (VIG) appears in the DoD Smallpox Response Plan and in ACIP recommendations. In summary, VIG is available under investigational new drug (IND) protocol to treat progressive vaccinia, eczema vaccinatum, severe generalized vaccinia, and ocular vaccinia. Providers may request use of VIG for a named patient by telephoning the U.S. Army Medical Research Institute of Infectious Diseases at 1-888-USA-RIID (1-888-872-7443) 24 hours a day. Additionally, after duty hours, one can call the USAMRIID Security Desk at 301-619-2257, or page the USAMRIID staff duty officer at 301-631-4393. IND-specific procedures must be followed carefully.

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 typical responses to vaccination, common and serious adverse events, location of the nearest military treatment facilities (MTFs), and the toll-free telephone number of the Military Medical Support Office (MMSO), 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 vaccine recipient 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 person must be examined and provided necessary medical care. Once treatment has been rendered or the individual's emergent condition is stabilized, Line of Duty and/or Notice of Eligibility will be determined as soon as possible. Reserve Component members and their family members who seek medical attention as a result of adverse reactions from DoD-directed immunizations should 1) immediately seek medical attention if an emergency and contact MMSO and their command as soon as possible, or 2) contact MMSO and their unit command for referral to the nearest treatment facility and to ensure payment for care and entitlements.

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 healthcare provider and any specialists, as indicated, should immediately evaluate any vaccinee with a serious adverse event temporally associated with receiving smallpox vaccination.

Vaccine Adverse Event Reporting System (VAERS) reports shall be filed using Service reporting procedures for those events resulting in hospital admission, lost duty time or work of 24 hours or more, adverse event suspected to result from contamination of a vaccine vial, or death. Further, healthcare providers are encouraged to report other adverse events that in the

provider's professional judgment appear to be unexpected in nature or severity. This is to include autoinoculations (or inadvertent infections). In other situations in which the patient wishes a VAERS report to be submitted, the healthcare provider will work with the patient to submit one without regard to causal assessment. VAERS report forms may be obtained by accessing www.vaers.org or by calling 1-800-822-7967.

Adverse-event management should be thoroughly documented in medical records. Medical record coders should use precision in coding medical encounters, noting specific codes listed in Attachment 3. 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.

Blood Donor Deferral

Because there is a significant donor deferral period associated with smallpox vaccination, it is critical that vaccination schedules be closely coordinated with local military and civilian donor center collection schedules to reduce the impact on the readiness and availability of the military blood supply. Individuals who receive the vaccination and have no complications will be deferred from donating blood until the scab spontaneously separates (14 – 21 days after vaccination). In cases where a scab is otherwise removed, the donor may be deferred for two months after vaccination. Individuals with vaccine complications will be deferred until 14 days after all vaccine complications have completely resolved.

Policy

These policies are effective immediately and should be communicated to appropriate commanders, healthcare providers, and others involved in implementation. If the FDA-approved labeling for smallpox vaccine changes, corresponding aspects of these policies will be superceded. Any recommendations from the ACIP will be taken into account in providing vaccination and clinical care.

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
Director of Health & Safety, U.S. Coast Guard

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Initial Smallpox Vaccine Immunization Note

This page to be completed by potential vaccine recipient

Today's Date (M M / D D / Y Y Y Y) ☐☐ / ☐☐ / ☐☐☐☐

BIRTH YEAR ☐☐☐☐

1st Year in Military ☐☐☐☐

GENDER ○ Male ○ Female

FEMALES: Was your last menstrual period normal and on time? ○ Yes ○ No ○ Unsure

Are you currently breastfeeding? ○ Yes ○ No ○ Unsure

Could you or someone you live with be pregnant? ○ Yes ○ No ○ Unsure

Did you ever receive smallpox vaccine? ○ Yes ○ No ○ Unsure

IF YES: Were you vaccinated within 10 years? ○ Yes ○ No ○ Unsure

Have you ever had a serious problem after being vaccinated? ○ Yes ○ No ○ Unsure

IF YES or UNSURE: Name the vaccine and describe the problems (may use additional page)

For the following questions, check ALL that apply

Do you have, or ever had, any of the following skin conditions?

- ☐ Eczema/Atopic Dermatitis (type of itchy skin rash)
- ☐ Psoriasis (scaly skin rash)
- ☐ Burns (other than mild sunburn)
- ☐ Impetigo (skin infection)
- ☐ Uncontrolled Acne
- ☐ Shingles (herpes infection, painful blisters, chickenpox)
- ☐ Other skin condition (explain below)
- ☐ I have none of these skin conditions

Do you LIVE WITH someone with any of the following skin conditions?

- ☐ Eczema/Atopic Dermatitis
- ☐ Psoriasis
- ☐ Burns (other than mild sunburn)
- ☐ Impetigo
- ☐ Uncontrolled Acne
- ☐ Shingles or Chickenpox
- ☐ Other skin condition (explain below)
- ☐ No one I live with has one of these conditions

Eczema and Atopic Dermatitis usually involve an itchy, red, scaly rash that lasts more than 2 weeks. It often comes and goes.

Do you, or anyone you live with, have a problem or take a medication that affects the immune system?

○ Yes ○ No ○ Unsure **IF YES or UNSURE: Check ALL that apply**

Do you have or take medications for:

- ☐ HIV/AIDS, leukemia, lymphoma, a generalized cancer
- ☐ arthritis, Crohn's disease, an immune system disease, or hepatitis
- ☐ a signficant exposure to X-rays or radiation treatment
- ☐ organ/bone marrow transplant
- ☐ another problem requiring steroids or prednisone

Do you LIVE WITH someone who has or takes medications for:

- ☐ HIV/AIDS, leukemia, lymphoma, a generalized cancer
- ☐ arthritis, Crohn's disease, an immune system disease, or hepatitis
- ☐ a signficant exposure to X-rays or radiation treatment
- ☐ organ/bone marrow transplant
- ☐ another problem requiring steroids or prednisone

Do you think you might be allergic to any of these antibiotics:

- ☐ Tetracycline
- ☐ Neomycin
- ☐ Streptomycin
- ☐ Polymyxin B
- ☐ Other (which ones)
- ☐ I don't know
- ☐ I have no known allergies to antibiotics

I have other concerns I'd like to discuss. ○ Yes ○ No

Explain "other" or additional concerns (may use additional page)

NOTE: If you think you might have one of the many risk factors for HIV infection, we can arrange for HIV testing before vaccination. FOR FEMALES: If you would like to be tested for pregnancy, we can arrange for that before vaccination. Please tell us.

LAST NAME ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐ FIRST NAME ☐☐☐☐☐☐☐☐ MI ☐

Social Security Number ☐☐☐ - ☐☐ - ☐☐☐☐

Initial Smallpox Vaccine Immunization Note Continuation Page 2

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This page to be completed by a health care provider

Reason for Vaccination

- O Pre-outbreak: disease prevention
- O Post-outbreak: not exposed to virus
- O Post-outbreak: exposed to virus
- O Other reason (Describe)

Assessment: Check

Yes	No	Unsure	
O	O	O	Recipient understands vaccination reason
O	O	O	Recipient is concerned about vaccination risk
O	O	O	Recipient has a contraindication for immunization
O	O	O	There is reason not to immunize at this time

Contraindications for immunization EXCEPT under emergent conditions in which there has been possible exposure to smallpox virus include:
History of presence of eczema (either recipient or in others living with recipient);
Other acute, chronic or exfoliative skin conditions (either recipient or in others living with recipient - vaccination may be given after condition resolves);
Immunosuppression (either recipient or in others living with recipient - to include HIV, AIDS, leukemia, lymphoma, generalized malignancy, solid organ transplantation, cellular or humoral immunodeficiencies, or therapy with alkylating agents, antimetabolites, radiation, or high dose corticosteroids)
Pregnancy (either recipient or in others living with recipient - vaccination may be given after pregnancy)
Age <18 yrs
Vaccine component allergy

Provider Assessment - indicate any concerns about contraindications, need to defer, or need to consult

Action Taken (Indicate One)

- O Immunized: Left upper arm - primary
- O Immunized: Right upper arm - primary
- O Immunized: Left upper arm - revaccination
- O Immunized: Right upper arm - revaccination
- O Immunization deferred: pending consult or lab test
- O Immunization deferred: Temporary contraindication
- O Immunization contraindicated unless exposed
- O Immunization not given (other reason)

Other reasons or actions taken

Please assure that all actions taken and deferrals are updated into your service's Immunization Tracking System (ITS) as soon as possible.

IF IMMUNIZED: Check all that apply

- ☐ Information sheet given to recipient
- ☐ Recipient advised about post-vaccination reaction and care
- ☐ Reasons for follow-up clinic visit described

IF NOT IMMUNIZED Check all that apply

- ☐ Reason for non-immunization explained
- ☐ Lab test requested
- ☐ Consult request written/sent
- ☐ Follow up appointment planned

Provider Signature

Social Security Number of Recipient

___ - __ - ____

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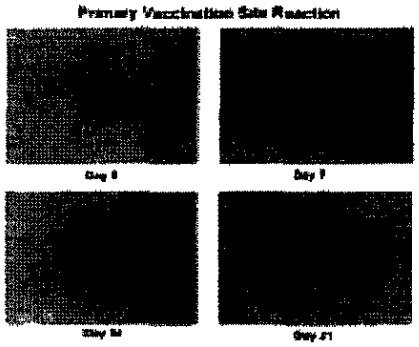
Smallpox Immunization Follow up Note

Today's Date (M M / D D / Y Y Y Y)

☐☐ / ☐☐ / ☐☐☐☐

These pictures show what can normally happen over the next few weeks following a smallpox immunization.



Since you received the smallpox immunization on your arm, what have you noticed?

(Check all that apply)

☐ local redness ☐ scab

☐ pimple ☐ nothing appeared

☐ blister ☐ do not remember

☐ pus

Check anything else you experienced after the smallpox immunization.

☐ headache ☐ eye infection

☐ fever ☐ Muscle aches

☐ generalized rash ☐ Feeling lousy

☐ generalized itching ☐ other (describe)

Please note any other reactions or problems following vaccination

Did you put a bandage on the vaccination site?

O Yes O No

IF YES: How many days did you use the bandage? ☐☐

Any problems following immunization?

☐ Little trouble

☐ Restricted activity How many days? ☐☐

☐ Limited Duty How many days? ☐☐

☐ Missed work How many days? ☐☐

☐ Took medication How many days? ☐☐

☐ Visited clinic or emergency room

☐ Hospitalized

☐ other (describe)

Do you believe anyone living near you might have become ill as a result of your immunization? O Yes O No O Unsure

Provider evaluation and action (check all that apply)

☐ Fully Immunized (major response)

☐ Equivocal response

☐ No response

☐ Re-immunization indicated

☐ Consultation request

☐ Follow-up for events described above

☐ No further follow up planned

☐ Other action (describe)

Provider Notes and Signature

LAST NAME FIRST NAME MI

Social Security Number ☐☐☐ - ☐☐ - ☐☐☐☐

VACCINATION-RESPONSE INTERPRETATION

Inspect the vaccination site 6 to 8 days after vaccination. Interpret the response at that time. The World Health Organization (WHO) Expert Committee on Smallpox defined two types of responses:

a) major reaction: virus replication took place and vaccination was successful; or

b) equivocal reaction: a possible consequence of immunity adequate to suppress viral multiplication or allergic reactions to an inactive vaccine without production of immunity.

Major Reaction:

A vesicular (blistery) or pustular (pus-filled) lesion or area of definite palpable induration or congestion surrounding a central lesion that might be a crust or an ulcer.

After primary (first) vaccination, the vaccination site usually progresses as follows:

- The inoculation site becomes reddened and pruritic 3 to 4 days after vaccination.
- A vesicle surrounded by a red areola then forms, which becomes umbilicated (collapsed center) and then pustular by days 7 to 11 after vaccination.
- The pustule begins to dry; the redness subsides; and the lesion becomes crusted between the second and third week. By the end of about the third week, the scab falls off, leaving a permanent scar that at first is pink in color but eventually becomes flesh-colored.
- After revaccination, skin reactions might be less pronounced with more rapid progression and healing than those after primary vaccination. Revaccination is successful if a pustular lesion or area of definite induration or congestion surrounding a central lesion (i.e., scab or ulcer) appears 6 to 8 days after revaccination.

Equivocal Reaction:

Equivocal reactions, including accelerated, modified, vaccinoid, immediate, early, or immune reactions, are all responses other than major reactions. If an equivocal reaction is observed, check vaccination procedures and repeat vaccination using another vial or vaccine lot, if available. A response to smallpox vaccination may be blunted by immunity, insufficiently potent vaccine, or vaccination technique failure. If repeat vaccination using vaccine from another vial fails to elicit a major reaction, consult public-health authorities before attempting another vaccination of that person.

Sources: Fenner et. al, 1988 (pp 296, 312-314); ACIP, 2001.