ANNEX B TO SMALLPOX RESPONSE PLAN 29 September 2002
VACCINATION GUIDELINES.

REFERENCES.

a. CDC Smallpox Response Plan, Guide B, Vaccination Guidelines for State & Local Health Agencies, 23 September 2002. http://www.bt.cdc.gov/DocumentsApp/Smallpox/RPG/.

b. CDC Smallpox Response Plan, Annex 2, Guidelines for Smallpox Vaccination Clinics, 23 September 2002. http://www.bt.cdc.gov/DocumentsApp/Smallpox/RPG/.

c. CDC Smallpox Response Plan, Annex 3, Vaccine Adverse Events Reporting, 23 September 2002. http://www.bt.cdc.gov/DocumentsApp/Smallpox/RPG/.

d. Army Regulation 40-562; Navy Bureau of Medicine & Surgery Instruction 6230.15; Air Force Joint Instruction 48-110; Coast Guard Commandant Instruction M6230.4E. Immunizations & Chemoprophylaxis. Washington, DC, 1 November 1995. http://www.e-publishing.af.mil/pubfiles/af/48/afji48-110/afji48-110.pdf.

e. US Army Medical Department. Managing Adverse Events After Vaccination, June 2002. http://www.anthrax.mil/media/pdf/cpguidelines.pdf and http://www.anthrax.mil/media/pdf/algorithm.pdf.

f. US Army Medical Command. “How To” Guide for Command Surgeons: Implementation Guidelines for Investigational New Drug (IND) Protocols. Falls Church, VA, May 2002.

g. US Army Medical Command. “How To” Guide for Unit Leaders and Unit Health Care Providers: Implementation Guidelines for Investigational New Drug (IND) Protocols. Falls Church, VA, May 2002.

h. US Army Medical Command. “How To” Guide for Investigational New Drug (IND) Protocols, Supplement: Smallpox Vaccination (IND # 10664). Falls Church, VA, publication pending.

i. National Vaccine Advisory Committee. Adult immunization programs in nontraditional settings: Quality standards and guidance for program evaluation. *MMWR* 2000;49(RR-1):1-13. ftp://ftp.cdc.gov/pub/Publications/mmwr/rr/rr4901.pdf.

j. Advisory Committee on Immunization Practices. Vaccinia (smallpox) vaccine. *MMWR* 2001;50(RR-10):1-25. http://www.cdc.gov/mmwr/PDF/rr/rr5010.pdf.

1. General. This DoD Annex augments CDC Guide B. Appendix B-1 summarizes CDC Guide B and this DoD Annex on one page.

a. Mission. Military treatment facilities (MTFs) will prepare to administer smallpox vaccinations to military personnel and healthcare beneficiaries, according to policies directed by the Secretary of Defense. On order and with vaccine provided from higher headquarters, MTFs will be capable of beginning emergency smallpox vaccinations within 24 to 48 hours of notification. The magnitude of local smallpox vaccination programs could range from a few dozen members of smallpox response teams to hundreds of thousands of people in a metropolitan area in a post-outbreak scenario. MTFs will thoroughly screen for bars (contraindications) to vaccination (Appendix B-11). If directed by higher headquarters, DoD personnel will be dispatched to assist with vaccination programs in civilian communities. In addition to quality vaccine delivery, MTFs will develop education programs to inform healthcare workers, military personnel, and beneficiaries about the benefits and risks of smallpox vaccination. MTFs will conduct quality programs to manage adverse events after vaccination, including detailed adverse-event reporting.

b. Background. Few U.S. service members have been vaccinated since 1990. Routine smallpox vaccinations of civilians in the United States ceased around 1972. Military personnel received routine periodic smallpox vaccination until 1984. Between 1984 and 1990, vaccination of military recruits was intermittent. In 1990, the Defense Department suspended routine vaccination of military recruits.

c. Assumptions.

(1) License Status. The smallpox vaccine (consisting of live vaccinia viruses) may be either (a) licensed by the Food & Drug Administration (FDA) at the time of vaccination or (b) unlicensed but permitted by FDA to be used under Investigational New Drug (IND) provisions of the Food Drug & Cosmetic Act. If smallpox vaccine is used as an IND medication, additional education, documentation, and consent requirements apply, compared to use of licensed vaccines (Appendix B-17). This document is written in a manner to take advantage of smallpox vaccine regardless of its IND status, recognizing the additional requirements of fulfilling IND regulations.

(2) No Presidential Waiver. This document assumes that the Department of Defense will not seek a Presidential waiver of consent to administration of IND smallpox vaccine, under provisions of 10 USC 1107, Executive Order 13139, 21 CFR 50.23(d), and DoD Directive 6200.2. Even if a waiver were granted, a Presidential waiver cannot diminish DoD's responsibility to educate Service Members about IND medications and to document IND administration in individual health records.

(3) Concentration. Smallpox vaccine will be administered in the standard full-strength concentration (as per original labeled reconstitution instructions), unless the CDC, FDA, or other responsible health authority issues explicit instructions to the contrary. Recent data demonstrate that 1:5 dilutions of *Dryvax* (Wyeth Laboratories)

produce an immune response comparable to full-strength Dryvax. Because these data are still being assembled as this document is being written, this document will await specific recommendations from CDC and FDA at the time vaccine is to be used.

(4) Bifurcated Needles. Sufficient sterile bifurcated needles will be available for single patient use before discarding. If not, refer to Guide B and CDC Annex 2 for resterilization considerations.

d. Planning Factors.

(1) Magnitude. A smallpox outbreak could be contained to a limited geographic area, in which case DoD resources (including vaccinated personnel) can go to that area to render assistance (e.g., smallpox vaccination, care of adverse events after vaccination). If a smallpox outbreak is dispersed widely, involving multiple MTFs, DoD experts will use telemedicine and other telecommunication tools to enhance the skills of local medical personnel.

(2) Contact Defined. Smallpox vaccination may be warranted for contacts of people infected with smallpox (Annex A). For this purpose, contact is defined as prolonged face-to-face contact with a suspected, probable, or confirmed case of smallpox. Risk of disease transmission increases with close contact ($\leq$ 6 feet), increasing time of exposure (e.g., > 3 hours), and presence of rash or cough. Consider smallpox cases potentially infectious from date of onset of fever > 101°F (38.3°C).

(3) VHC. The DoD Vaccine Healthcare Center (VHC) Network, developed in 2001, serves as a clinical resource for DoD healthcare providers and vaccine recipients regarding the value of vaccinations, reporting of adverse events after vaccination, and clinical management of adverse events after vaccination (Appendix B-19). The VHC Network is DoD's counterpart to the Clinical Immunization Safety Assessment (CISA) Centers being developed by CDC.

(4) Expected Adverse Events. The overall risk of serious complications following smallpox vaccination is low. Complications occur more frequently in people receiving their first dose of smallpox vaccine, and among children younger than 5 years of age. The first (primary) smallpox vaccination can produce swelling and tenderness of regional lymph nodes, beginning 3 to 10 days after vaccination, persisting for 2 to 4 weeks after the vaccination site heals. A fever is common after smallpox vaccination. About 70% of children experience 1 or more days with temperatures $\geq$ 100ºF for 4 to 14 days after primary vaccination, and 15% to 20% of children experience temperatures $\geq$ 102ºF. After revaccination, 35% of children experience temperatures $\geq$ 100ºF, and 5% experience temperatures $\geq$ 102ºF. Fever is less common among adults after vaccination or revaccination. Erythematous or urticarial rashes can occur ~ 10 days after primary vaccination and can be confused with generalized vaccinia. However, the vaccine recipient is usually afebrile with this reaction, and the rash resolves spontaneously within 2 to 4 days. Rarely, bullous erythema multiforme (i.e., Stevens-Johnson syndrome) occurs. The most frequent serious complications of smallpox vaccination are

described in detail in Appendix B-15. Common significant symptoms and signs after primary smallpox vaccination appear in Appendix B-15.

(5) Adequate Care. If a serious adverse event after smallpox vaccination occurs, encourage vaccine recipients to seek medical care promptly. Military health-care providers should contact infectious-disease, dermatology, or allergy-immunology specialists for consultation about managing adverse events. In appropriate cases (e.g., eczema vaccinatum, progressive vaccinia, ocular vaccinia, afebrile-pruritic-"toxic" generalized vaccinia), vaccinia immune globulin (VIG) treatment may be appropriate, for individual patient treatment under IND protocol (Annex H). Although its use is somewhat speculative, the antiviral agent cidofovir may be offered to treat vaccination reactions, if the supply of VIG dwindles or is exhausted (Annex H).

(6) Bars. Contraindications (bars to vaccination) and special handling of people at increased risk of vaccine complications are the subject of national discussion among subject-matter experts. DoD smallpox vaccination programs will take into account evolving guidelines and recommendations from the CDC, public-health advisors, and medical specialty associations.

(7) Auto-Inoculation. The most frequent complications of smallpox vaccination are inadvertent inoculation (transfer) of vaccinia viruses from the vaccination site to other sites of the body. This complication accounts for about half of all complications following primary vaccination (a person's first smallpox vaccination) and re-vaccination (booster doses of smallpox vaccine). Auto-inoculation (i.e., accidental infection) occurs at a rate of about 1 in 2,000 primary vaccinations, usually involving transfer by hand to places that itch, such as the face, eyelid, nose, mouth, genitalia, or rectum. Children may be more likely to need a covering over the vaccination site, if they are less able to adhere to instructions not to touch the site. Washing the hands after touching the vaccination site can prevent inadvertent inoculation. Using alcohol-based rinses also may be helpful for hand cleaning. Most of the resulting lesions heal without specific therapy, but vaccinia immune globulin (VIG) may be useful in treating some cases of ocular inoculation. VIG is a solution of human antibodies that neutralize vaccinia viruses, acting as a kind of antidote.

e. Coordinating Instructions.

(1) Civil Support. Installations and MTFs will give priority to the protection and well-being of military personnel and DoD healthcare beneficiaries. With concurrence of higher headquarters, an installation with excess capacity to administer vaccinations may provide support to health authorities in surrounding communities. Under normal circumstances, requests for military support services should be formally submitted to the Directorate of Military Support (DOMS, see also Appendix 2).

(2) VAERS. As with any medication, vaccinations can produce side effects or adverse reactions. Good clinical care is important to treat adverse events after any vaccination. Adverse events involving hospitalization, loss of 24 or more hours of duty

time, or symptoms suggesting contamination of a vaccine vial must be reported to the Vaccine Adverse Event Reporting System (VAERS) as described in reference d and detailed below. DOD encourages submission of VAERS reports for other adverse events by health care providers. Any patient who believes that he or she may have had a severe or unusual reaction to a vaccine is welcome to submit one, as well. Submitting VAERS reports adds to the safety database on each vaccine.

(3) VHC. The DoD Vaccine Healthcare Center (VHC) Network offers clinical consultation to healthcare providers regarding symptoms and conditions that may be related to any vaccination (Appendix B-18). The VHC will refer vaccine recipients who contact the VHC directly to the vaccine administration site (e.g., MTF, public-health facility) or primary-care treatment facility (e.g., military or Tricare) for individualized evaluation, management, and reporting of the adverse event. VHC staff will assist providers and vaccine recipients in case management, if specialty services are required and not locally available.

(4) IND Coordination. VIG investigators and cidofovir investigators will coordinate with the Walter Reed National Vaccine Healthcare Center (VHC, Appendix B-18) on status of individuals treated with VIG or cidofovir under IND protocol. Specialized treatment teams, investigators, and the VHC will assist in centralized tracking and case management and provide coordination with CDC's Clinical Immunization Safety Assessment (CISA) centers of excellence.

f. Legal Considerations. Any medications administered under Investigational New Drug provisions of U.S. law or regulation will be carefully documented and administered with appropriate education, as detailed in references f, g, and h.

2. Execution.

a. Concept of Operations. Depending on the magnitude of a smallpox outbreak, regional teams with medical, logistic and administrative expertise may be assigned to assist with post-outbreak vaccination programs. These teams should include infectious disease, dermatology, allergy-immunology, neurology, nursing and pharmacy representation, plus coordination with vaccine-safety expertise. If a smallpox outbreak becomes widely distributed, involving multiple MTFs, it may not be possible to dispatch augmenting teams to every location. In such cases, DoD experts will use telemedicine and other telecommunication tools to coach and consult local medical personnel. If the smallpox vaccine is to be administered as an investigational new drug (IND), the US Army will support with teams that help train local health-care providers in implementing IND protocols in contingency settings.

b. Tasks and Responsibilities.

(1) Site Planning. Before a smallpox outbreak, MTF commanders will identify controlled vaccination sites other than normal hospital or clinic locations at which mass vaccinations can be effectively delivered. Sites will take into consideration security;

appropriate ventilation, workflow, and other factors addressed in Appendix B-2, Appendix B-3, and Appendix B-6.

(2) IND Planning. Before a smallpox outbreak, MTF commanders will identify health-care providers willing to serve as local principal investigators (PIs), in case investigational new drugs (INDs) need to be administered in the course of implementing this document. MTFs will arrange training in Good Clinical Practices in advance for these likely PIs (see also Appendix B-17).

(3) Training. The military medical departments will develop standardized training programs with provision for competency assessment for healthcare staff. Considerations in impromptu staffing and training appear in Appendix B-4 and Appendix B-5. The Vaccine Healthcare Center Network and the Military Vaccine Office will coordinate this effort. The VHC Network and the Military Vaccine Office will also develop educational materials to help the public understand smallpox and smallpox vaccination.

(4) Implementation.

(a) Vaccination Coordinator. The MTF commander will designate one person to be responsible for vaccine administration during a smallpox outbreak. This person will work with Federal and other state emergency-management authorities to implement vaccine-administration strategies.

(b) IND Coordinator. The MTF commander will identify a health-care provider to serve as local principal investigator (PI) for any investigational new drug (IND) needed to implement this document. MTFs will arrange training in Good Clinical Practices in advance for these likely PIs (see also Appendix B-17).

(c) Thorough Screening. All MTFs will institute thorough prevaccination screening to identify possible contraindications to smallpox vaccination (e.g., skin disorders, immunodeficiencies). When large numbers of people need to be vaccinated quickly, self-screening tools will be important. An annotated guide to screening questions appears in Appendix B-11.

(d) Individual Education. Before vaccination, recipients or parent/guardian will receive information about vaccine benefits and risks, plus instructions on how to contact a DoD provider or the nearest military or Tricare treatment facility if the vaccine fails to take or if an adverse event develops (e.g., Military Medical Support Office, 888-647-6670). MTFs will use tools to help vaccine recipients recognize adverse events (e.g., colored diagrams showing expected site reactions, Appendix B-13), so they know when to report for additional care. Tools to help vaccine recipients avoid auto-inoculation will be emphasized. Efforts will be made to help people with low competency in English.

(e) Information Resources. The Military Vaccine Office will provide educational materials to help the public understand smallpox and smallpox vaccination (Appendix E-

2). Information about smallpox vaccine for the general public also will be available from other sources, including the CDC's National Immunization Hotline (800-232-2522, www.cdc.gov/nip) and others

(f) Documentation.

(i) Vaccination sites will employ the Services' immunization tracking systems to document administration of smallpox (vaccinia) vaccine (e.g., Medical Protection System (MedPROS), Air Force Complete Immunization Tracking Application (AFCITA), Shipboard Automated Medical System (SAMS)). Both contemporary and historical smallpox vaccinations should be entered into these tracking systems. These applications relay immunization data daily to the Defense Eligibility Enrollment Reporting System (DEERS), operated by the Defense Manpower Data Center (DMDC), Monterey, California. The Department of Defense standard is for vaccinations to be entered into the immunization-tracking system on the day of vaccination. If automated systems are temporarily unavailable, a manual system of documentation must be employed (e.g., SF 601, PHS Form 731). DD Form 2766C (Computer Generated)-AFCITA, Vaccine Administration Record, complies with article 80 of the WHO international health regulations and can be used in place of the PHS 731 when traveling outside the United States.

(ii) Appendix B-8 provides a list of recipient-specific documents required in a smallpox vaccination operation and a summary of the information to collect. One copy of each of the documents must be available (and in appropriate languages) for each vaccine recipient. CDC is developing a web-based application as part of an electronic smallpox data management system (SDMS). Guidance on use of this system will be provided at a later date. In the ideal scenario, all person-specific documents will be printed on-site for each vaccine recipient. However, paper copies of all documents must be available in sufficient quantities so that clinic operations can continue if the computer system fails. Whether during the clinic or later, electronic entry of critical data will be necessary.

(g) International Travel. Because smallpox vaccination may become an important factor in passage of international boundaries in the future, vaccination clinics will maintain the ability to issue Public Health Service (PHS) Form 731, International Certificate of Vaccination ("yellow shot records").

(h) Vaccination-Site Care.

(i) Background. National consensus has not yet fully formed on how to most appropriately prevent transfer of vaccinia virus from vaccination sites to other parts of the recipient's body or transfer to family members or other contacts. Options include occlusive, non-occlusive, or no bandaging. During the 1980s, during routine smallpox vaccination programs for recruits, military policy called for no routine covering with any bandages immediately after inoculation, with the vaccination site being allowed to air-dry instead. Sites were to be covered with a loose dressing only if an individual would

be in close contact with unvaccinated people (e.g., a recruit departing on emergency leave).

(ii) DoD Guidance. 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 bandage 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.See Appendix B-14 for specific instructions on vaccination-site care.

(i) Isolation of Vaccine Recipients.

(i) Background. National consensus on the degree to which vaccinated people should be separated from people with contraindications (bars) to vaccination has not fully formed. Most recommendations call for voluntary efforts by vaccinated people to avoid contact with those for whom vaccinia virus could be a risk. In the case of household contacts of contacts contraindicated from vaccination, CDC recommends separate housing until the vaccination scab falls off. During the 1980s, during routine smallpox vaccination programs for recruits, only basic trainees remaining at the training site for at least 4 weeks would receive smallpox vaccine. This policy was intended to reduce the risk of transmission of vaccinia virus to unvaccinated civilian contacts. In the current era, about two-thirds of military personnel entered service since 1990 and thus have never been vaccinated against smallpox. Similarly, most of the civilian population is unvaccinated against smallpox.

(ii) DoD Guidance. MTF staff will provide verbal and written counseling to vaccine recipients to avoid contact with people for whom vaccinia virus could be a risk. This counseling will be reinforced with training to avoid auto-inoculation or otherwise touching the vaccination site. If somebody in the vaccine recipient’s household has eczema, atopic dermatitis, 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 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.

(iii) Health-care Workers. 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. However, exudates can accumulate beneath the dressing, and care must be taken to prevent viral contamination when the dressing is removed. 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.

(j) Clinical Care and Consultation. MTF commanders will provide for education of primary-care providers regarding recognition of adverse events after vaccination, and the need for prompt referral of patients for specialized care. Information on how to access VAERS will be prominently featured in this education, with instructions for submitting VAERS reports displayed at every immunization clinic.

(k) Vaccine Safety Surveillance. Depending on the extent of vaccine administration, a variety of surveillance activities may be conducted.

(i) Active surveillance for adverse events may be conducted when the number of vaccine doses administered is limited. Vaccine recipient would receive a diary report card to document their response to the vaccine (e.g., prototype shown in CDC Annex 3).

(ii) To identify serious adverse events, active surveillance will be conducted for people receiving vaccinia immune globulin (VIG) or cidofovir, pharmaceutical agents indicated for the treatment of certain severe vaccine complications (Annex H). Active surveillance for VIG and cidofovir use will not be limited based on the number of vaccine doses administered.

(iii) Stimulated passive surveillance (i.e., requests that people report if they recognize an adverse event) and follow-up of serious adverse events will be conducted whether limited or large numbers of vaccine doses are administered. The Vaccine Adverse Events Reporting System (VAERS) is considered a passive surveillance system because reports are not actively solicited. However, with enhancements to VAERS marketing, such as informing every vaccine recipient how to contact VAERS, options for web-based reporting, and follow-up of all smallpox reports, the passive system can be enhanced.

(iv) If widespread vaccination is conducted, DoD's Defense Medical Surveillance System and CDC's Vaccine Safety Datalink can be used to compare and contrast vaccinated and unvaccinated people.

(v) Other safety assessment programs according to the circumstances of vaccine use. The Military Vaccine Office and the VHC will coordinate with CDC, FDA, and other relevant parties to stay abreast of advances in understanding of the side-effect profile of smallpox vaccination in the current era.

(vi) The Military Vaccine Office will work with CDC and FDA personnel to obtain copies of VAERS reports (redacted of personal identifiers) involving smallpox vaccine and military personnel or DoD beneficiaries, to enable DoD-specific vaccine-safety surveillance.

(l) Security. The installation commander will provide sufficient personnel to maintain order and preserve the security of personnel, clients, property, supplies, and equipment, and enforcing any restriction of movement rules. The security plan will include designated entrances and exits for staff use, a list of authorized staff for each clinic site, staff check-in and check-out procedures, methods and locations to safeguard vaccine and other clinic supplies, and maintaining a system to vaccinate clients in their order of arrival.

(m) Workplace Safety. Healthcare workers will observe good infection prevention and control procedures (Annex C, Annex F). Vaccination clinic procedures will address disposal of used or contaminated supplies.

(n) Confirmation of Take. Successful smallpox vaccination results in a pustular lesion in previously unvaccinated people 6 to 8 days after vaccination (Appendix B-13). In previously vaccinated people, either a pustular lesion or an area of definite induration or congestion around a central lesion develops by 6 to 8 days after vaccination. Take will be individually confirmed for all contacts and contacts of contacts. Take will also be individually confirmed for members of smallpox response teams vaccinated pre-outbreak, with documentation in occupational-health records. Based on availability of labor, take can be individually confirmed in some or all of the following groups: healthcare workers, other occupational groups, other medically defined groups, and every vaccine recipient.

(o) Inadequate Take. Equivocal reaction, including accelerated, modified, vaccinoid, immediate, early, or immune reactions, are defined as all responses other than major reactions. If an equivocal reaction is observed, check vaccination procedures and repeat the vaccination by using vaccine from another vial or vaccine lot, if available. The reaction was blunted due to immunity, insufficiently potent vaccine, or vaccination technique failure. If the repeat vaccination by using vaccine from another vial or vaccine lot fails to elicit a major reaction, health-care providers should consult public-health authorities before attempting another vaccination.

(p) Blood Donation. People vaccinated against smallpox would likely be deferred from donating blood for 30 days after vaccination, according to evolving standards of the Armed Services Blood Program Office (www.tricare.osd.mil/asbpo/asb_immu.html).

(q) Vaccine-Vaccine Interactions. In general, administer live-virus vaccines either on the same day or separated by 30 days, to prevent inhibition of viral replication. Simultaneous administration of live poliovirus, measles, and yellow fever vaccines with smallpox vaccine is permissible, if 30-day intervals are not feasible.

c. Reporting.

(1) During a smallpox outbreak, DoD vaccination sites will report the number of smallpox vaccinations administered daily to higher headquarters and to the CDC reporting system.

(2) Report adverse events after smallpox vaccination through usual channels, with one exception. Usual channels involve service reportable-disease channels (reference d) and the Vaccine Adverse Events Reporting System (VAERS). There is no need to report adverse events to VAERS that involve smallpox vaccine treated with vaccinia immune globulin (VIG) or cidofovir under IND protocol. The FDA will review all clinical data for patients treated with VIG or cidofovir under IND protocol under separate report filings. Filing reports to the Vaccine Adverse Event Reporting System (VAERS) in cases involving VIG or cidofovir under IND protocol is inappropriate, because filing a VAERS report will lead to double-counting of the case.

3. Operational Constraints. Space and patient flow must be adequate to allow storage, screening, education, documentation, vaccination, infection control, and other essential functions.

4. Administration and Logistics.

a. Because the supply of smallpox vaccine is limited and the demand for vaccine may be extremely high, take care to protect the vaccine supply from theft and fraud.

b. Because each vaccine vial contains 100 to 500 doses, plan carefully to minimize vaccine wastage that may result from discarding partially used vials. Storage and handling considerations appear in Appendix B-10.

c. Because of these factors, each dose and vial must be accounted for before and after each clinic session.

d. If DoD’s or CDC’s electronic immunization tracking systems are used, and data is entered on-line in “real time” as vaccine recipients are being processed, the number of doses administered will automatically be counted. CDC’s system will automatically

record doses administered on a Daily Smallpox Vaccine Tracking Report. If CDC smallpox data management system (SDMS) is not used or not operational, manually tally the number of doses administered from the paper copies of the Clinic Vaccination Records of people receiving vaccine that day and enter the data on the Daily Vaccine Tracking Record.

e. Assure adequate quantities of consumable supplies (Appendix B-9).

f. Assure proper infection-control and prevention procedures (Annex C).

5. Special Situations.

a. Ships Underway. Ships that have been completely isolated for 18 days without development of a smallpox case, and which can maintain this isolation, will be provided smallpox vaccine for unvaccinated crewmembers with a lower priority than ships that have not been isolated in this manner. Vaccine supply, if needed acutely, will be conducted by replenishment while underway.

b. Air crews on missions away from home base. Aircrews will be vaccinated either at their current location or upon return to home base, depending on vaccine distribution.

c. Troops deployed outside CONUS in theater. Deployed troops will receive priority for vaccination, depending on distance from recognized smallpox cases, relative isolation from potentially infected groups, and the tactical situation in theater.

d. Troops deployed outside CONUS Returning to CONUS. Once a smallpox outbreak develops, troops will not return to CONUS until they have been vaccinated against smallpox. Returning troops with medical contraindications to vaccination will be exempted from smallpox vaccination, but may need to be isolated for an appropriate interval of time to assure they are not incubating a case of smallpox. Troops returning to CONUS unable to be vaccinated abroad may receive smallpox vaccine at port of entry and then be isolated until confirmation of vaccine take, according to instructions from preventive-medicine officials.

e. Child-care centers. MTF commanders will provide advice to installation child-care centers regarding prevention of contact transmission of vaccinia from vaccination sites.

APPENDIX B-1
Vaccination Guidelines – Summary.

1. Priority for Post-Outbreak Vaccination:
   a. People exposed to an initial release of smallpox virus, if known.
   b. People with prolonged face-to-face or household contact (≤ 2 m or 6 feet) with a confirmed/suspected smallpox patient after fever and before all scabs fell off.
   c. People selected for direct evaluation, care, or transport of confirmed/suspected cases (including selected laboratory, laundry, and waste-handling personnel).
   d. Household contacts of the contacts in group b above.
   e. People essential to support of response activities (e.g., selected law enforcement, emergency response, military personnel).
   f. Based on risk analysis and extent of exposure, vaccinate people present in a hospital when a smallpox case was present and not appropriately isolated.

2. Bars or Warnings Before Pre-Outbreak Vaccination. Note: For face-to-face contact with a smallpox case, bars are usually waived. Household members with these conditions should house themselves separately from vaccinated people until site heals.
   a. People ever diagnosed with eczema or atopic dermatitis (see Appendix B-16).
   b. People with acute or chronic skin conditions (e.g., burns, impetigo, varicella zoster (shingles)), psoriasis, or uncontrolled acne, until the condition resolves (Appendix B-16).
   c. Immunodeficiency diseases (e.g., AIDS, cancer, agammaglobulinemia).
   d. Life-threatening allergies to polymyxin B, streptomycin, tetracycline, neomycin.
   e. Women who are pregnant.

3. Vaccination Clinic Procedures.
   a. Leave most vaccination sites uncovered. Alternately, loosely cover site with porous bandage (e.g., gauze), until scab separates on its own. Wear long-sleeve clothing.
   b. Counsel vaccine recipients to avoid contact with people for whom vaccinia virus could be a risk. Offer separate on-base housing, to avoid exposing family members to vaccinia virus until the vaccination-site scab separates.
   c. Teach vaccinees to avoid touching the vaccination site, to prevent spreading vaccine virus to eyes, nose, mouth, genitals, or rectum. Reemphasize this point.
   d. Teach: Wash hands with soap and water if you touch vaccination site by accident.
   e. Double-bag bandages and scab and discard in the trash.
   f. During an outbreak, report vaccination counts daily to headquarters.

4. Reporting. Report adverse events after vaccination to allow for monitoring vaccine safety. Detailed instructions on adverse-event reporting appear in CDC Annex 2.

5. Care. If a serious adverse event after smallpox vaccination occurs, seek medical care promptly. Military health-care providers should contact infectious-disease, dermatology, or allergy-immunology specialists for consultation on managing adverse events. In appropriate cases (e.g., eczema vaccinatum, progressive vaccinia, ocular vaccinia,

generalized vaccinia), vaccinia immune globulin or cidofovir treatment may be appropriate, for individual patient treatment under IND protocol (Annex H).

APPENDIX B-2
Planning for Vaccine Delivery.

1. Understand vaccination strategy. The immediate response to confirmed or probable cases of smallpox would be vaccination of first responders on the scene (i.e., medical personnel who attend the infected people and vaccinate contacts of the cases). Local smallpox plans should include localized lists of job categories that must receive vaccine immediately if a case of smallpox occurs. In addition, all face-to-face contacts of the cases must be vaccinated. Because the rapidity with which this can be accomplished will determine the ultimate extent of the outbreak, organizing a separate vaccination operation (e.g., clinic site, staff, supplies) for each group is recommended.

2. Determine resource needs. Based on the vaccination strategy, calculate the number of clinics, duration of clinics, and number of staff required. The number of personnel needed for any one clinic will vary depending on the size and layout of clinic facilities, location of clinic, geographic area being served by the clinic, and estimated number of vaccine recipients at each clinic (Appendix B-4).

3. Identify potential clinic sites. The size and type of the facilities needed for smallpox immunization clinics will vary depending on the number of people to be served. Very small clinics, such as those to immunize first responders or primary contacts, can be conducted in almost any available space. Larger clinic sites could be industrial locations, office buildings or apartment complexes. Schools are the preferred location for any clinic larger than can be held in the local health department. Schools have parking lots, long corridors, large classrooms, cafeterias, private offices, and other immediately available resources such as tables and chairs, and offer an ideal physical structure that can meet most clinic needs. Elementary schools are preferable if staffing is adequate, because they are numerous and serve fairly well defined neighborhoods convenient to the public. Using the largest number of locations that staffing permits will minimize parking and crowding problems. Use of middle or high schools may also be considered. If smallpox cases expose many people in locations such as schools and office buildings, these locations may be sites where vaccine clinics can offer vaccine quickly and efficiently to many contacts. However, to avoid wasting reconstituted vaccine, clinics should be selected and organized to administer one vaccine vial –or multiples thereof – each day. In selecting clinic sites, allow for a smooth flow of clients, accessibility of the facility to major streets, restroom facilities, parking, refrigeration, heating/air conditioning, and protection from elements if lines will form outside. Before final selection, a visit should be made to the location to ensure that the facility meets the needs of the vaccination operation.

4. Obtain prescriber authorization or standing orders. If the vaccine is in IND status, identify the principal investigator (PI) who signed the FDA Form 1572 and is responsible for vaccine delivery. Before a clinic can begin vaccinating, obtain standing orders to vaccinate from the public-health authority (e.g., chief of preventive medicine) or the principal investigator. Standing orders are also needed for responding to medical

emergencies that occur during vaccination clinics (e.g., epinephrine). In addition to providing standing orders, the health officer or designee must approve the content of informational materials and serve as medical consultants for nursing staff.

5. Plan training for vaccination staff. All health-care workers involved in smallpox vaccination efforts should receive training in screening for contraindications and in proper administration of smallpox vaccine. Training should also include procedures for reporting suspected cases. Large numbers of clinic staff can be trained through a train-the-trainer approach through satellite-based courses, web pages, videocassettes, CD-ROM courses and written training materials. A supplemental chapter on smallpox is included in CDC's "Pink Book" (*Epidemiology & Prevention of Vaccine-Preventable Diseases*, 7th edition, http://www.cdc.gov/nip/publications/pink/#download). Educational materials should provide detailed medical information about smallpox and the smallpox vaccine, and should highlight potential vaccine side effects and their clinical management. Impromptu training elements appear in Appendix B-5.

6. Publicize the clinic. Public education materials should be presented in multiple languages, reproduced in appropriate quantities. After a smallpox vaccination clinic site and recipient populations are determined, release public announcements with information about the clinic as expediently as possible. The information disseminated must clearly describe the groups for whom the clinic is intended (and not intended). Specific zip codes or alphabetic letters may be designated for a specific date and timeframe. Certain language groups may be asked to come at a specific time when translator resources are available. Also state the clinic location and directions, dates and times of operation, length of time the vaccination process may take, type of clothing to wear, and culturally appropriate information in as many languages as needed. State that those who do not meet the defined criteria will not be accepted for vaccination. In addition to information about the specific clinic being publicized, a concerted effort should be made to provide information to the public that emphasizes (a) the rationale of the vaccination strategy, (2) disease-containment measures are effective, (3) multiple measures are being taken to prevent the further spread of the disease, and (4) cooperation with efforts to isolate cases and contacts will speed control of the outbreak.

APPENDIX B-3
Vaccination Clinic Process.

Step 1: Orientation and Paperwork. As vaccine recipients arrive, security personnel handle outside traffic flow and route people to the clinic entrance. Upon entering the building vaccine recipients are directed to a location where a greeter-educator briefs groups (up to 30 people) about what is going to take place during the clinic process, provides required paperwork (preferably in a packet form) and instructs the vaccine recipients how to complete the necessary paperwork. If the vaccine is in IND status, this will include informed-consent documents. Allow time for reading and filling in the required personal information (e.g., name, address). The number of people in the orientation briefings can vary to accommodate the rate at which people arrive. Multiple educator-greeters locations may be necessary, so that people arriving after an orientation has begun can be directed to another location where another orientation will soon begin. Orientation locations can also serve as holding locations if bottlenecks occur along the clinic line. This method will ensure a steady flow of vaccine recipients to the next step.

Step 2: Registration. After orientation and completion of the paperwork, the clinic-flow coordinators direct vaccine recipients to registration tables where staff members check each vaccine recipient's form for completeness and accuracy.

Step 3: Medical Assessment. After ensuring that paperwork is completed appropriately, vaccine recipients are directed by clinic-flow controllers to the medical assessment area. Here medical screening personnel discuss with each vaccine recipient individually the medical conditions that might would prevent receipt of the vaccine and determine if any such conditions are present. They also review the common reactions to the vaccine with each vaccine recipient. People with possible medical contraindications are directed to a separate station for more in-depth evaluation. Each vaccine recipient is asked to sign the consent form before proceeding further.

Step 4: Vaccination. After medical assessment, vaccine recipients with no medical contraindications are directed to the vaccination area. This area is a screened area that affords privacy to people who find it necessary to remove clothing to expose the vaccination site. A vaccination assistant helps vaccine recipients expose their upper arm and cleanses the vaccination site, if necessary. The vaccine recipient then proceeds to the vaccine administrator who administers the vaccine and completes the necessary documentation. Immediately thereafter, a vaccination assistant applies a bandage to the vaccination site (if applicable) and instructs the vaccine recipient on post-vaccination care of the vaccination site.

Step 5: Forms Collection and Exit. Before leaving the clinic, vaccine recipients move to a forms collector stationed near the exit. This individual collects all required paperwork, answers any remaining questions and informs vaccine recipients that they are finished with the process.

APPENDIX B-4
Vaccination Clinic Staffing.

1. The official responsible for over-all direction of the vaccination operation assigns a clinic manager, responsible for overall clinic operation. The clinic manager is the primary decision-maker for the site, and supervises all non-medical personnel. If the vaccine is in an IND status, the clinic manager must know who is the principal investigator responsible for vaccine administration. All staffing assignments should be documented on a clinic assignment sheet.

2. Management and Coordination Functions. To assist the manager with large clinic operations, coordinators should be identified for the various clinic functions as outlined below:

a. Nurse Coordinator: Oversees nursing staff assigned to the clinic; assists clinic manager in making clinic assignments for nursing staff; assists on-duty nurses as needed.

b. Supply Officer/Vaccine Manager: Ensures clinic supplies are on site and available in sufficient quantities during clinic operations; maintains an inventory of supplies; oversees distribution of supplies to appropriate locations in the clinic; ensures that sufficient vaccine is available, that the cold chain is maintained through proper handling and storage; ensures that vaccine is stored in a secure manner at the clinic site and that unused vaccine is returned and accounted for; and maintains adequate vaccine and other supplies at the vaccination station.

c. Security Coordinator: Oversees personnel assigned to security activities at the clinic site; assists the clinic manager in making duty assignments of security personnel; determines appropriate number of security staff necessary according to clinic size and location; maintains a list of authorized clinic staff and their phone numbers; assigns and coordinates use of cell phones and pagers; establishes staff check-in and check-out procedures; ensures that all staff wear identification badges; maintains communication with local law enforcement officials.

d. Volunteer Coordinator: Oversees volunteer activity at the clinic site. Assists the clinic manager in making duty assignments of volunteer staff; maintains roster of people available for volunteer duty; and maintains a schedule of times that volunteers will be available to work.

3. Staff Functions. Following is a summary of suggested responsibilities of the staffing roles as outlined in the operational concept above:

a. Greeter-Educators: Greet and conduct initial orientation of potential vaccine recipients upon their arrival; provide basic information (verbally or with a video presentation) about the vaccine and the vaccination process; distribute informational

material and clinic document; explain how to complete the documents and answers questions. Greeter-educators must be able to explain the purpose of receiving the vaccine, outline the vaccination clinic process, and distribute and explain the clinic documents to vaccine recipients individually and in groups.

b. Registration Staff: Review each vaccine recipient's documents for completeness and accuracy; assist clients with completing documents. The registration staff must be familiar with each form distributed. They must be able to follow instructions on how to respond to exceptional situations, such as non-English speaking patients or patients who are anxious, hostile, or disoriented. If the form has not been completed correctly or completely, registration staff must be able to address and correct these problems. They should be prepared to read the forms to illiterate or semi-literate people needing their assistance.

c. Medical Screeners: Assess clients for contraindications to vaccination; when necessary perform physical examination of patients who state that they have dermatological conditions that may constitute contraindications; and answer medical questions. This role should be filled by a physician, nurse or paraprofessional who has good interviewing skills and is well-versed in the technical information regarding exposure risks, medical contraindications to vaccination, risks of vaccination, and risk-benefit analysis. Medical screeners will review the list of normal or expected reactions to the vaccine with each vaccine recipient. If necessary, medical screening personnel will contact a designated physician consultant to assist in making a final decision about whether or not to vaccinate. If the vaccine is still in Investigational New Drug status, medical screening personnel ensure that the consent form has been read, understood, and signed by each potential vaccine recipient.

d. Vaccination Assistants: Assist the vaccine administrator with all aspects of pre- and post-vaccination activities; prepare vaccine with diluent, ensure that vaccination station maintains adequate supplies; instruct recipients on location of vaccination; assist vaccine recipients in preparing the vaccination site (e.g., roll up sleeve, remove arm from shirt/blouse); clean vaccination site with quick-drying acetone, if necessary; apply dressing to the vaccination site; instructs clients about care and changing of the dressing. Vaccination assistants must have a thorough understanding of the vaccination process and the necessary supplies, proper technique for reconstituting the vaccine with diluent, proper care and handling of vaccine in the clinic, how to disinfect contaminated surfaces and dispose of soiled materials, and where to access additional supplies. Vaccination assistants are also responsible for entering the vaccine and diluent lot numbers on the patient's consent form and clinic record and providing the vaccine recipient with a vaccination card that documents when and where the vaccine was administered.

e. Vaccine Administrators: Oversee the vaccination process; administer the vaccine; sign the clinic record; observe vaccine recipients for immediate reaction or complications. Vaccine administrators can be nurses, physicians, pharmacists, or designated paraprofessionals who have received technical training in administration of

smallpox vaccine. Vaccinators must have the ability to quickly develop a high level of skill in vaccinating with a bifurcated needle (Appendix B-12). They must have in-depth understanding of proper vaccination techniques, methods to prevent contamination of the vaccine, exposure risks, the medical conditions that constitute contraindications for vaccinations, the risks of vaccination, preparation of the vaccination site, normal and abnormal post vaccination responses, and proper follow-up care of the vaccination site. Vaccinators must also be prepared to respond to medical emergencies that may occur within the vaccination area. Vaccinators should not have any personal contraindications to smallpox vaccination.

f. Forms Collectors: Verify that forms are correctly completed; collect all necessary forms from recipients before departure. The forms collector is responsible for checking that the vaccination staff signs the clinic record and entered the lot numbers on the appropriate documents. As the last staff member to talk with vaccine recipients, the forms collector must have the ability to ensure a response by the appropriate staff to any remaining concerns that clients may have.

g. Clinic-Flow Controllers: Direct vaccine recipients through the clinic process and monitor clinic flow. Clinic-flow coordinators are responsible for continuously monitoring and directing client activity throughout the facility. They must be able to calmly manage and assist people who may be anxious or unable to follow directions. When congestion (backlog) arises, flow controllers determine if staff at other locations are less busy and request assist in the congested area. They are also responsible for feeding back information about the number and rate of “upstream” clients to the vaccination assistants, to enable them to maximize use of all vaccine doses in opened vaccine vials. Flow controllers may be in a position to provide early alert of situations that that may require additional security personnel.

h. Security Staff: Ensure an orderly flow of traffic and parking at the clinic site; assist in maintaining orderly movement of vaccine recipients through the clinic process; provide necessary control if people become unruly; assist supply officer in maintaining security of vaccines and other clinic supplies. Security staff can be off-duty law enforcement officers, professional security personnel, or volunteers experienced and trained in crowd control.

i. Emergency Medical Personnel: Respond to medical emergencies. Emergency personnel must be able to respond to medical emergencies, including reactions ranging from the minor to anaphylactic shock and serious medical emergencies that are incidental and unrelated to vaccination but can be expected to occur whenever large groups of people congregate. For large operations, a physician, physician assistant, nurse practitioner or emergency medical technician should be on-site at all times during clinic operations.

APPENDIX B-5
Vaccination Clinic Staff Training.

1. The staff operating a clinic site should receive a group orientation to the overall purpose, function, and flow of the vaccination clinic, as well as specific verbal and written directions for their individual roles.

2. During the orientation, a diagram with annotations should be provided to show traffic flow (see Appendix B-7), the functions of all clinic stations, and a list of staff assigned to each role and each station, if possible. The general responsibilities of each area of the vaccination clinic are reviewed with the entire staff. All staff need to know where they will work, where their supplies and resources are located, and who their consults are as well as how to summon them.

3. In small clinics, there are roles within the clinic that can be flexed to accommodate to the needs of the clinic and decrease congestion and waiting time (i.e., bottlenecks, lags) and to permit breaks for staff. In larger clinics, this can be accomplished by cross-training. Therefore, orienting staff in small, interchangeable units is suggested.

4. For training vaccine administrators and assistants, a demonstration video is available from CDC. Ideally, vaccinators should practice on each other and other staff before administering vaccine to the public. Copies of package inserts, Vaccine Information Statements (VISs), and other significant administration materials should be available during training and actual vaccine clinic. Technical references for health-care providers appear at the bottom of this appendix.

5. If time permits, a mock vaccination clinic or role-playing session should be conducted to train and evaluate the potential performance of staff. Vaccinating clinic staff as well as first responders and other health care providers is suggested as a way to provide critical training and experience for all staff, especially the vaccine administrators.

6. Emergency personnel should also attend the group orientation and be given information about smallpox and managing potential exposure to smallpox. They should be familiar with the layout of the clinic site and know where ill patients will be maintained before transport for further care.

7. Daily post-clinic debriefings should be held to assess staff performance and ascertain if additional training or clinic reconfiguration is needed.

8. References:

a. Advisory Committee on Immunization Practices. Vaccinia (smallpox) vaccine. *MMWR* 2001;50(RR-10):1-25. http://www.cdc.gov/mmwr/PDF/rr/rr5010.pdf.

b. Atkinson W, Wolfe C, Humiston S, Nelson R, ed. Chapter 18, Smallpox. In: *Epidemiology & Prevention of Vaccine-Preventable Diseases*, 7th ed. Atlanta: Centers for Disease Control & Prevention, Apr 2002. http://www.cdc.gov/nip/publications/pink/#download.

c. Breman JG, Henderson DA. Diagnosis and management of smallpox. *N Engl J Med* 2002; 346:1300-8. http://content.nejm.org/cgi/reprint/346/17/1300.pdf.

d. Henderson DA, Inglesby TV, Bartlett JG, Ascher MS, Eitzen E, Jahrling PB, Hauer J, Layton M, McDade J, Osterholm MT, O'Toole T, Parker G, Perl T, Russell PK, Tonat K, Working Group on Civilian Biodefense.Smallpox as a biological weapon: Medical and public health management. *JAMA* 1999;281:2127-37. http://jama.ama-assn.org/issues/v281n22/ffull/jst90000.html.

e. World Health Organization. Smallpox. *Weekly Epidemiologic Record* 2001;76:337-44. http://www.who.int/wer/pdf/2001/wer7644.pdf.

f. Canadian National Advisory Committee on Immunisation. Statement on smallpox vaccination. *Can Comm Dis Rep* 2002;28(ACS-1):1-12. http://www.hc-sc.gc.ca/pphb-dgspsp/publicat/ccdr-rmtc/02pdf/acs28-1.pdf.

APPENDIX B-6
Vaccination Clinic Flow.

1. Clinics should have clearly marked entrance and exit points, with adequate waiting space for queues of people seeking vaccination. Post security staff at both locations to maintain order. Control the traffic flow within the clinic so that it follows a logical path from entry to exit. A linear path of traffic flow from entry to exit on opposite sides of the facility is optimal. If time permits, provide easy-to-read signage to guide people through the clinic process. See Appendix B-7 for a sample clinic-flow diagram.

2. If the clinic is being held in response to a smallpox outbreak, some people may arrive at the clinic with a referral form indicating that they are a contact to a diagnosed case of smallpox. Give these people the highest priority and escorted them directly to a registrar who will orient them and expedite the paperwork, medical assessment, and vaccination process. Alert security personnel and greeter-educators to this possibility.

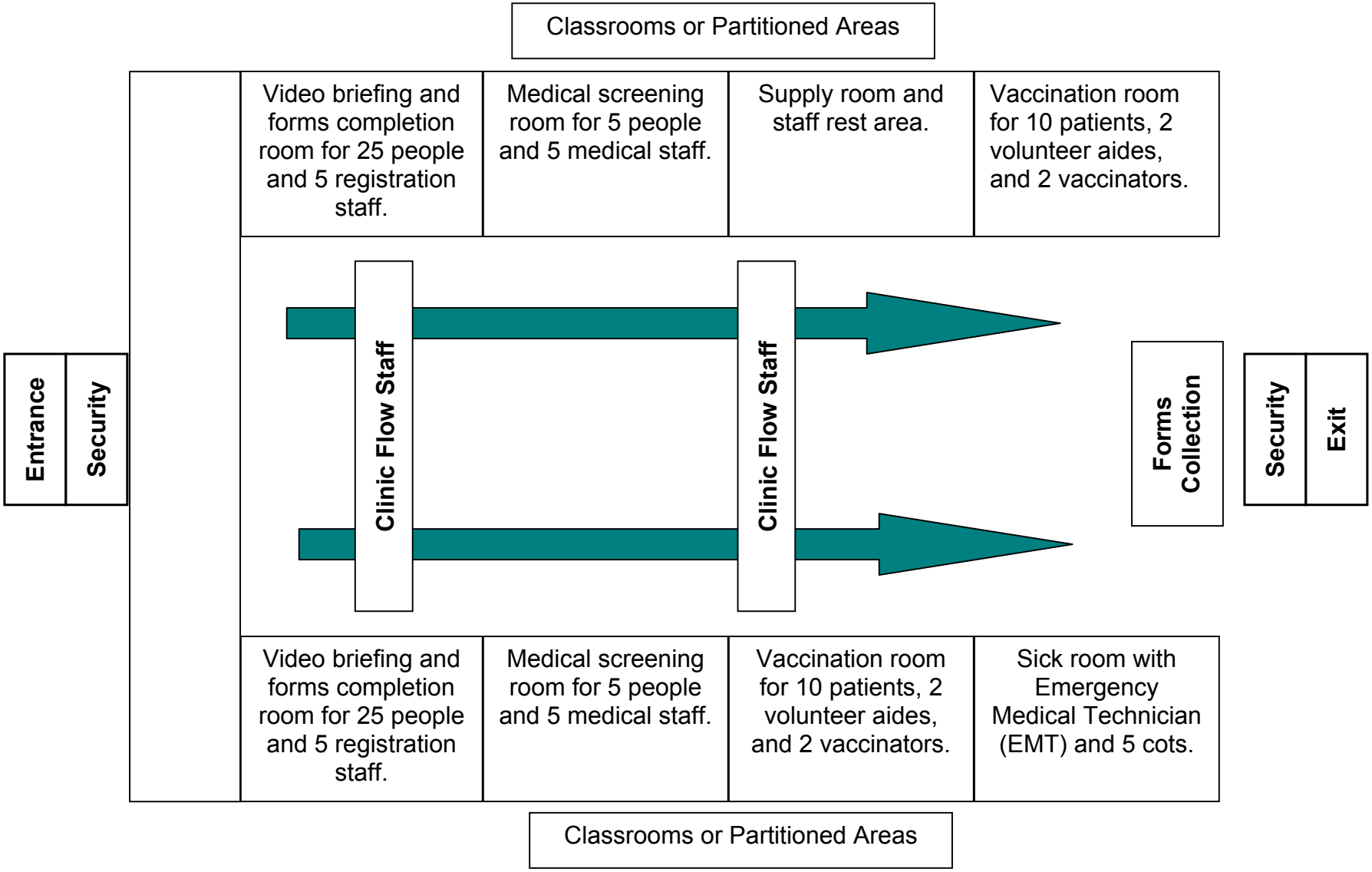
3. Ideally, locate greeter-educators and registration staff in a separate room from the vaccine administration station. This will help reduce the anxiety of people uncomfortable with viewing the vaccination process.

4. The registration and medical-screening processes probably will be the most time-consuming clinic activities. Assign sufficient staff to move people steadily through these areas, to keep a steady flow of people to the vaccination areas.

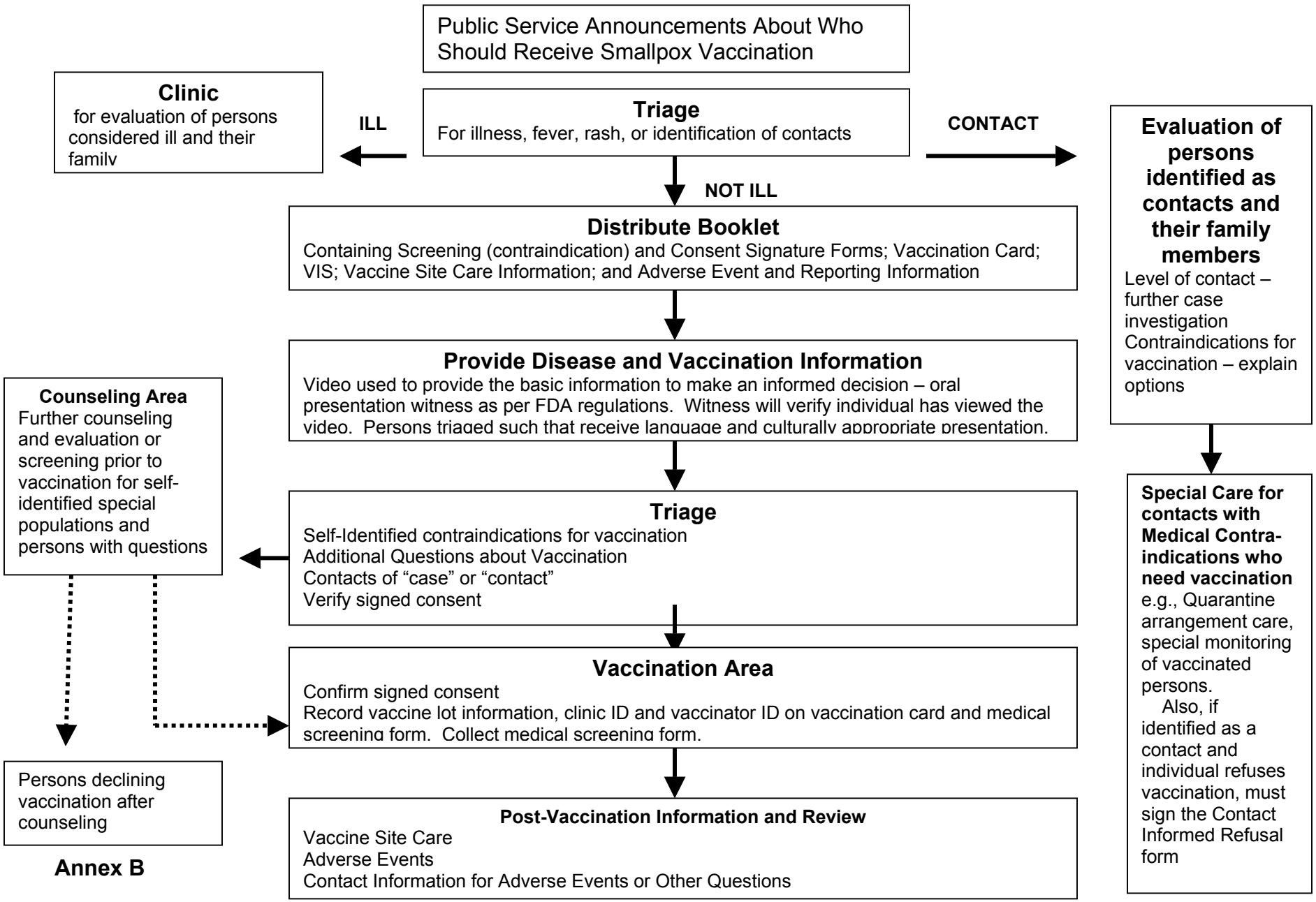
5. Keep traffic in the area where vaccine is being administered to minimum. Ideally, set up the vaccine administration tables so that staff members have their backs to the wall and patients are not congregating or walking behind them. The three steps of the actual vaccination process (i.e., site preparation, vaccination, dressing application) will all take place in a relatively small space (one or two tables) in the same area. Because some vaccine recipients may need to remove shirts or blouses to be vaccinated, use a separate, screened, private area, out of view of other people lined up for vaccination.

6. Locate the medical emergency area as close to the vaccine administration area as possible.

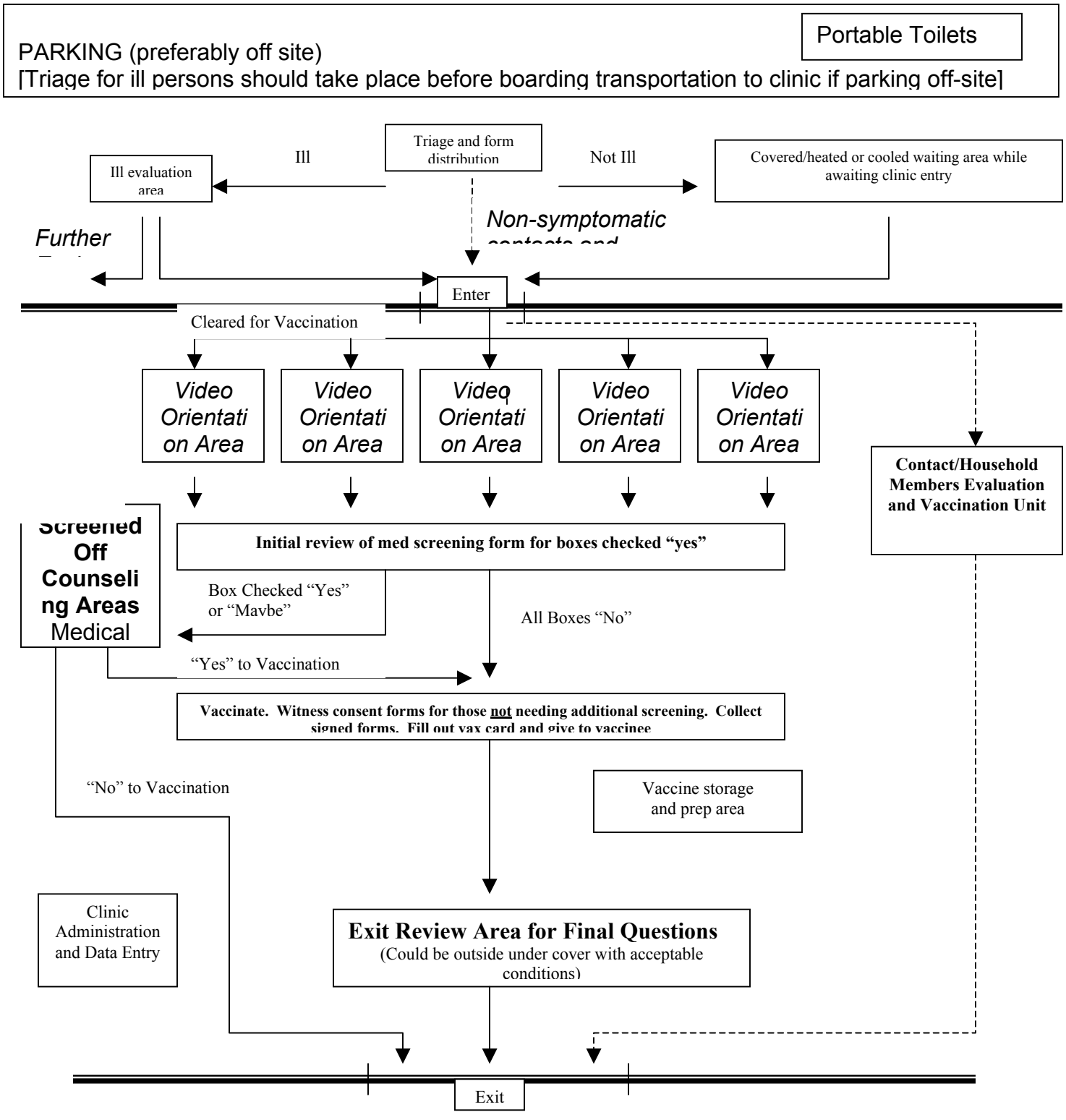
APPENDIX B-7
Vaccination Clinic Diagrams.



# Informed Consent Process Flow for Use During Emergency Smallpox Vaccination




**Annex B**


PARKING (preferably off site)
[Triage for ill persons should take place before boarding transportation to clinic if parking off-site]
Portable Toilets
Triage and form distribution
Ill
Not Ill
Ill evaluation area
Covered/heated or cooled waiting area while awaiting clinic entry
Further
Non-symptomatic
Enter
Cleared for Vaccination
Video Orientation Area
Video Orientation Area
Video Orientation Area
Video Orientation Area
Video Orientation Area
Contact/Household Members Evaluation and Vaccination Unit
Screened Off Counseling Areas Medical
Initial review of med screening form for boxes checked "yes"
Box Checked "Yes" or "Mavbe"
All Boxes "No"
"Yes" to Vaccination
Vaccinate. Witness consent forms for those not needing additional screening. Collect signed forms. Fill out vax card and give to vaccinee
"No" to Vaccination
Vaccine storage and prep area
Clinic Administration and Data Entry
Exit Review Area for Final Questions
(Could be outside under cover with acceptable conditions)
Exit

APPENDIX B-8
Vaccination Documents.

| Document | Information Collected | How Used |
|---|---|---|
| Medical/Epidemiologic Risk Screening Sheet | Medical contraindications, epidemiological risk status | Preliminary screening tool; people with potential risk routed for in-depth medical screening or priority vaccination. |
| Informed Consent Document for Investigational New Drug (IND) | Name, address, age or date of birth, gender, lot number, date, signature verifying consent | Vaccine recipient reads and signs in presence of staff. |
| Vaccine Recipient Diary | Name, address, age or date of birth, gender, lot number, date, list of contraindications, list of symptoms | Vaccine recipients take home and check off any symptoms they may have each day for 4 weeks. |
| CDC Vaccine Information Statement (VIS) | Verbal Yes/No:<br>Have you read?<br>Do you have any questions? | Given to vaccine recipients to take home. |
| Instructions on Care of the Vaccination Site | How to care for vaccination site; what vaccination site should look like; who/where to call if reaction occurs | Given to vaccine recipients to take home. |
| Clinic Vaccination Record | Name, address, age or date of birth, gender, Social Security number, lot number, date | Official clinic medical record |
| Vaccination Card | Name, address, age or date of birth, gender, lot number, date, signature/stamp | Vaccine recipient receives and keeps card to verify vaccination status. |
| Vaccination Referral | Name, physical description, gender, signature of referring case worker, case referral number, date, risk category | Presented by people referred for priority vaccination because of their epidemiological risk status (e.g., contact to a case of smallpox). |
| Expanded Vaccine Adverse Events Report | Name, address, gender, date, lot number | Documentation of adverse events for IND and the Vaccine Adverse Events Reporting System (VAERS). |

APPENDIX B-9
Vaccination Clinic Supplies & Equipment.

| General Supplies & Equipment | Vaccination Supplies | Emergency Supplies |
|---|---|---|
| Tables<br>Chairs<br>Water and cups<br>Paper<br>Pens, pencils<br>Envelopes<br>Rubber bands<br>Tape<br>Stapler, staples<br>Scissors<br>Post-it® notes<br>Clipboards<br>File boxes<br>Telephone<br>Fax machine<br>Photocopy machine<br>Paper towel<br>Kleenex® tissue<br>Table pads and clean paper to cover table for work site<br>Garbage containers and trash bags<br>Regulated medical waste red bags<br>Identification badges for staff<br>List of emergency phone numbers<br>5 or more large-screen video setups with VCRs or DVD players to show orientation video<br>7 orientation video tapes<br>Cleaning supplies (e.g., mop, bucket) | Smallpox vaccine cooler or refrigerator<br>Vaccine diluent<br>Sterilized bifurcated needles<br>Puncture-resistant (“sharps”) containers for each vaccination station<br>Latex gloves<br>Latex-free gloves<br>Antibacterial hand-washing solutions<br>Acetone pads<br>Rectangular Band-Aids®<br>Gauze<br>Adhesive tape<br>Spray bottle of bleach solution<br>Paper gowns for patients wearing clothes that do not give ready access to the arm<br>Screens, for changing, counseling, vaccination, as needed | Standing orders for emergencies<br>Epinephrine 1:1000 syringes, auto-injectors, or ampoules, subcutaneous<br>Diphenhydramine 50-mg syringes or vials, intramuscular<br>3-ml syringes with 1-inch, 25-gauge needles<br>1.5-inch needles<br>Tuberculin syringes with 5/8" needles (for epinephrine)<br>Alcohol wipes<br>Tongue depressors<br>Adult and pediatric pocket masks with one-way valves<br>Adult and pediatric airways<br>Oxygen tank with tubing<br>IV solutions and tubing<br>Sphygmomanometers (various sizes)<br>Defibrillator and pads<br>Tourniquet<br>Gurney<br>Stethoscope<br>Flashlight<br>Cots<br>Blankets<br>Pillows<br>ER report form<br>Bronchodilator inhaler<br>Thermometer<br>Emesis basin<br>Aspirin, acetaminophen, insulin, D50 |
| | Crowd Management & Triage Supplies<br><br>Signs for clinic stations and between stations and at triage area<br>Queue partitions (to keep people in lines) | Computer Equipment and Supplies<br><br>Computers<br>Printers<br>Paper<br>Internet access |

Additional Supply Considerations.

Additional Clinic Supplies and Personnel Support for Each Vaccination Clinic (VC).

- Duplication – 1 or more rapid copy machines for duplicating IND paperwork as needed; crate of duplicating paper at each VC; extra machine toner cartridges.
- Computers – 12 desktops and/or laptops for data entry (all need internet connection if Web-based database used) with appropriate software (need to standardize software, if possible).
- Centralized supplies warehouse(s) – Estimate quantity of clinic supplies needed for 1 week of operation (paper, pens, staplers, etc.) and package accordingly for single unit delivery to each VC, weekly deliveries for continued.
- Shipping – Dedicated trucks/vehicles, staff, and drivers and preplanned routes to support vaccine and supplies delivery to 20 VCs.

Communications Equipment.

- Telephones – 5 telephones/separate lines for each VC + 1 fax machine at each VC.
- Cell phones should be considered for nondata/fax needs and/or if easy access to phone lines might be difficult within the vaccination area (e.g., gymnasiums, auditoriums).
- Hand-held radio system to communicate on site without having to send a runner.

Emergency Management.

- Each VC should have clear, written procedures established to deal with emergencies caused by both vaccine adverse reactions and other reactions that could be triggered by the stress of the event (e.g., heart attacks, anaphylactic shock, asthma).

Provision of Food and Beverages for Clinic Personnel.

- Consider using resources, such as Red Cross.
- Local businesses may be willing to donate food and beverages.

Information Materials.

- Obtain 2-day supply of forms (e.g., VIS, IND forms, contraindications, vaccine take, adverse event diary, and vaccination cards) directly from national stockpile (120,000 sets to support 20 VCs for first day) or pre-print forms locally as part of planning.
- Arrange to duplicate adequate numbers of all forms for day 2, day 3, etc. (120,000/day).
- Arrange for dedicated trucks, staff, and drivers and preplanned route to support delivery to 20 VCs.
- Provide information on local clinics and laboratories that can provide HIV testing to individuals who elect to have testing done before getting vaccinated.

APPENDIX B-10
Smallpox Vaccine Handling & Storage Instructions.

*Note: Several types of smallpox vaccine might be distributed in a post-outbreak emergency. This sheet refers to Dryvax-brand smallpox vaccine. If another type of smallpox vaccine is provided, refer to information provided with that vaccine.*

1. Store smallpox vaccine in the MTF pharmacy. Vaccinia virus vaccine (Dryvax®, Wyeth Laboratories) is a live-virus vaccine that must be reconstituted with diluent. It is prepared from calf lymph.

2. Diluent. Pre-filled syringes of glycerin in water with transfer needle. Manufactured by Baxter.

3. Condition on Arrival.

a. Vaccine should be between 2° to 8°C (35° to 46°F). Refrigerate upon arrival.

b. Diluent should be between 2° to 8°C (35° to 46°F). Refrigerate upon arrival.

4. Storage requirements.

a. Powdered (unreconstituted) vaccine. Long-term storage: vaccine can be preserved indefinitely at -20°C. Short-term storage: store in the refrigerator between 2° to 8°C (35° to 46°F). Local transportation and day use. Storage in Styrofoam containers and cool packs is adequate.

b. Accompanying diluent. Store in refrigerator between 2° to 8°C (35° to 46°F).

5. Reconstitution.

a. Diluent is required for the reconstitution of the smallpox vaccine before administration. The originally licensed diluent for use with smallpox vaccine contained 50% glycerin, 0.25% phenol in Sterile Water for Injection, USP, and 0.005% brilliant green. Reconstitution of a single vial of smallpox vaccine with 0.25 mL of diluent would yield approximately 100 doses. However, this pre-packaged diluent is no longer available. The diluent that will be utilized in this protocol is similar in formulation to the licensed diluent except that it lacks the 0.005% brilliant green. This change in formulation does not affect the ability of the vaccine to produce immunity to smallpox

b. Directions. Remove vaccine vial from refrigerated storage. Allow vial to come to room temperature. Lift up tab of aluminum seal on vaccine vial just enough to expose the top of the stopper. Do not break off or tear down tab. Wipe off vial stopper with an alcohol pad and allow to dry. Place vaccine vial upright on a hard, flat surface. Remove cap from the pre-filled syringe. Take a 1 ml syringe (e.g., tuberculin syringe) and withdraw 0.25 mL

from the opening in the pre-filled diluent syringe. Inject the 0.25 mL of diluent into the vaccine vial to reconstitute the vaccine. Withdraw needle and syringe and discard in the appropriate biohazard sharps container. Allow the vaccine vial to stand undisturbed for 3 to 5 minutes. Then, if necessary, swirl vial gently to effect complete reconstitution. In the space provided on the vaccine vial label, record the date and time that the diluent vial was entered for the purpose of vaccine reconstitution. The vaccine is now ready for use.

6. Storage of Reconstituted Vaccine. Store reconstituted Dryvax in the refrigerator between 2° to 8°C (35° to 46°F). Reconstituted Dryvax may be used for 3 months if stored below 4°C (39°F), or preferably below 0°C (32°F) when not in use.

7. Vaccine Labeling and Packaging.

a. Labels. Wyeth Laboratories manufactured the existing inventory of Dryvax-brand smallpox vaccine. The vaccine vials have commercial labels reading "Smallpox Vaccine, Dried, Calf Lymph Type, DRYVAX®." However, this product is currently considered an investigational new drug (IND) product, because it is packaged with a diluent not yet approved by the Food & Drug Administration for standard use. These commercially labeled vials have lot numbers 7 digits long.

b. Packaging. Fifty vials of Dryvax vaccine are packaged in each carton (i.e., the secondary package). Up to twelve (12) cartons will fill VaxiCool® insulated shipping containers (about the size of a large Coleman®-style cooler), without further tertiary packaging or overwrap. Diluent need not be refrigerated and may be shipped outside of the VaxiCool containers.

APPENDIX B-11
Screening for Bars (Contraindications) to Smallpox Vaccination.

(Annotated Version)

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

2. Have you ever had a serious reaction to any vaccine? YES NO
If so, please describe it: _____

3. Do you have any drug allergies? YES NO
If so, please list them: _____

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

4. Have you ever received smallpox vaccination before? YES NO DON'T KNOW
Marked in records. Where? _____
Have a smallpox scar. Where? _____
Born in 19____. Where? _____
Entered US military service in 19_____

5. Are you being treated by a doctor for a disease? YES NO
If so, please describe it: _____

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).

6. 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). YES NO

b. People with leukemia, lymphoma, or generalized cancers (malignancy). YES NO

c. People who had an organ or bone-marrow transplant. YES NO

d. People with any other problem with the immune system, such as agammaglobulinemia, acquired immune deficiency syndrome (AIDS) or infected with the human immunodeficiency virus (HIV). YES NO

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. Have you ever been told by a doctor that you have eczema or atopic dermatitis? YES NO

Eczema and atopic dermatitis usually involve an itchy, red, scaly rash that lasts more than 2 weeks. It often comes and goes. You should not receive smallpox vaccine at this time unless you and a healthcare provider are sure that this rash is not atopic dermatitis or eczema.

8. Has anyone in your household ever been told by a doctor that he or she has eczema or atopic dermatitis? YES NO

Note: If the answer is yes, do not give smallpox vaccine because of the risk that the recipient or the household contact might develop eczema vaccinatum.

9. Do you have any other current skin conditions, such as burns, impetigo, varicella zoster (chickenpox or shingles), psoriasis, or severe or uncontrolled acne?

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 benefit from smallpox vaccination. Watch the vaccination site carefully and get revaccinated if no blister appears by day 6 to 8 after vaccination.

11. For women: Was your last menstrual period normal and on time? YES NO

Could you be pregnant? Or have you had unprotected sex since your last normal period?

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 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.

APPENDIX B-11 (continued)
Screening for Bars (Contraindications) to Smallpox Vaccination.

**Screening Before Smallpox Vaccination**.

| | | | |
|---|---|---|---|
| 1. How are you today? Do you have a fever, diarrhea, or vomiting today? | | | |
| 2. Have you ever had a serious reaction to any vaccine?<br>If so, please describe it: | YES | NO | |
| 3. Do you have any drug allergies?<br>If so, please list them: | YES | NO | |
| 4. Have you ever received smallpox vaccination before?<br>When? | YES | NO | DON'T KNOW |
| a. Marked in records. Where? | | | |
| b. Have a smallpox scar. Where? | | | |
| c. Born in 19 . In United States? | | | |
| d. Entered US military service in 19 . | | | |
| 5. Are you being treated by a doctor for a disease?<br>If so, please describe it: | YES | NO | |
| 6. 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). | YES | NO | |
| b. People with leukemia, lymphoma, or generalized cancers (malignancy). | YES | NO | |
| c. People who had an organ or bone-marrow transplant. | YES | NO | |
| d. People with any other problem with the immune system, such as agammaglobulinemia, acquired immune deficiency syndrome (AIDS), or infected with the human immunodeficiency virus (HIV). | YES | NO | |
| 7. Have you ever been told by a doctor that you have eczema or atopic dermatitis? | YES | NO | |
| Eczema and atopic dermatitis usually involve an itchy, red, scaly rash that lasts more than 2 weeks. It often comes and goes. You should not receive smallpox vaccine at this time unless you and a healthcare provider are sure that this rash is not atopic dermatitis or eczema. | | | |
| 8. Has anyone in your household ever been told by a doctor that he or she has eczema or atopic dermatitis? | YES | NO | |
| 9. Do you have other current skin conditions, such as burns, impetigo, varicella zoster (chickenpox or shingles), psoriasis, or severe or uncontrolled acne? | YES | NO | |
| 10. Have you received a transfusion of blood or plasma or any medicine containing antibodies (immune or gamma globulin) in the past 12 months? | YES | NO | |
| 11. For women: Was your last menstrual period normal and on time? | YES | NO | |
| Could you be pregnant?<br>Have you had unprotected sex since your last normal period? | YES | NO | DON'T KNOW |

APPENDIX B-12
How to Use a Bifurcated Needle.

Use skin over the insertion of the deltoid muscle (preferred) or the posterior aspect of the arm over the triceps muscle for smallpox vaccination. Do not use alcohol to prepare the skin, because it dries to slowly and can inactivate the vaccinia virus. If the area is grossly contaminated, use warm water. Alternately, if acetone is used, the skin must be allowed to dry thoroughly (for several minutes) to prevent inactivation of the vaccine virus.

The multiple-puncture technique uses a sterilized bifurcated needle inserted vertically into the vaccine vial, causing a droplet of vaccine to adhere between the needle prongs. The droplet contains the recommended dosage of vaccine. Confirm the presence of the droplet between the prongs visually. Holding the bifurcated needle perpendicular to the skin, make 15 punctures rapidly with strokes vigorous enough to allow a trace of blood to appear after 15 to 20 seconds. Wipe off any remaining vaccine with dry sterile gauze, then dispose of the gauze in a biohazard waste container.

Leave the site uncovered, if the individual is thoroughly counseled about the hazards of touching the vaccination site. Alternately, cover the site with a loose bandage to deter touching the site and perhaps transferring virus to other parts of the body.

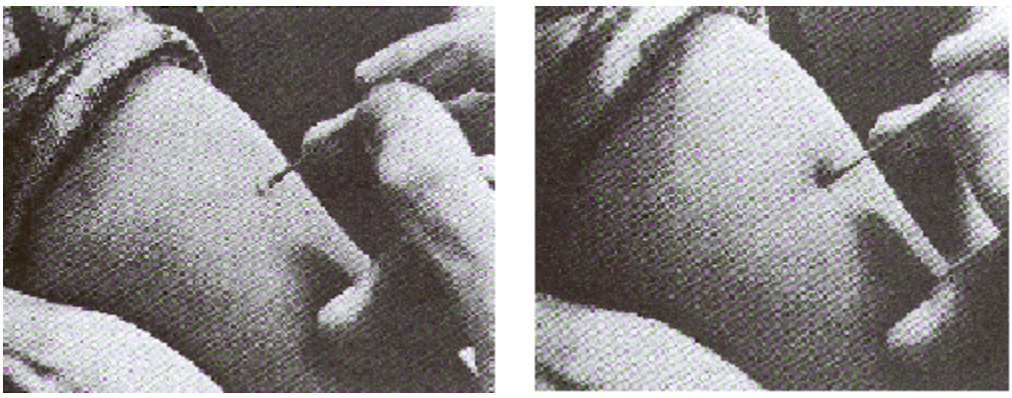
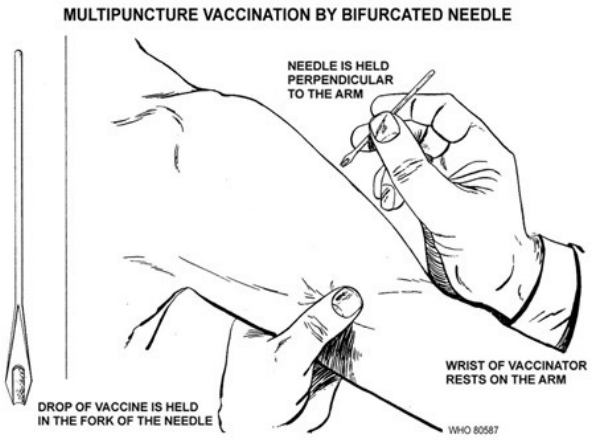


Figure – Needle held at a 90° angle to skin then rapid, up-and-down perpendicular strokes are used to administer the vaccine. [Fenner F, Henderson DA, et al. *Smallpox and its Eradication.* WHO. 1988, Reprinted with permission of WHO]



APPENDIX B-13
Response to Smallpox Vaccination.

| Day After Vaccination | Major Reaction, for primary (first) vaccination | Major Reaction, for revaccinated people * | Equivocal: Delayed Hypersensitivity Reaction | Equivocal: All Other Reactions |
|---|---|---|---|---|
| Day 1 | | | Erythema | |
| 2 | | | Erythema ** | |
| 3 | Papule (bump, pimple) | Papule | No further rxn. | |
| 4 | | | | |
| 5 | Vesicle (blister) | Vesicle | | |
| 6 | | Pustule, induration or congestion around scab or ulcer | Requires revaccination | Requires revaccination |
| 7 | Pustule -- pus-filled blister (center collapses) (if previously vaccinated, may show 'induration' (hard swelling) only) | | | |
| 8 | | | | |
| 9 | | | | |
| 10 | | | | |
| 11 | | | | |
| 12 | | | | |
| 13 | | | | |
| 14 | Scab (dark, then flesh-colored) | | | |
| 15 | | | | |
| 16 | | | | |
| 17 | | | | |
| 18 | | * greatest erythema occurs after 3d day after revaccintn; implies viral propagation. | ** vesicles infrequently | |
| 19 | | | | |
| 20 | Scab falls off (day 14 to 21) | | | |
| 21 | | | | |

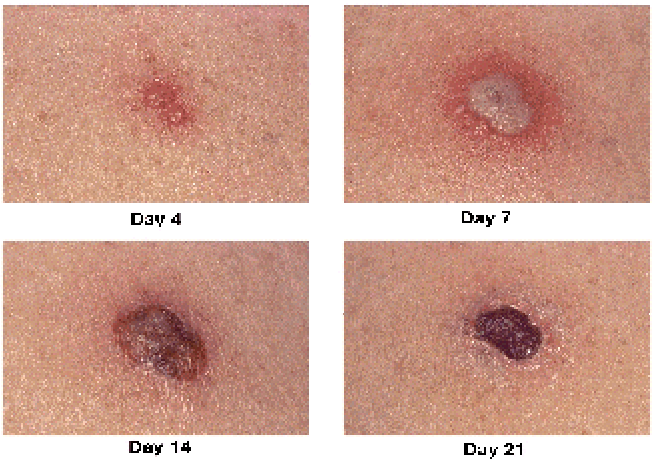



Figure. Major (primary) reaction. Expected local reaction after primary smallpox vaccination or revaccination after a prolonged period since primary vaccination.

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: possible consequence of immunity adequate to suppress viral replication or allergic reactions to 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.

**Obsolete terms**, no longer used, but included in older health records:
Accelerated reaction (Vaccinoid): Accelerated vesicular reactions appear between the fifth and eighth day inclusive, or if a typical pustular vaccinal reaction occurs.
Immediate or early reactions, peak ~ 48 h after vaccination, likely represented delayed-hypersensitivity reactions not associated with protective immunity from infection.
Immune, Reaction of immunity, Typical primary vaccinia, Modified: Terms not recommended because ambiguous or ill-defined.
Sources: Fenner et al, 1988 (pp 296, 312-314); ACIP, 2001.

APPENDIX B-14
Care of the Vaccination Site.

Three Key Points:

(a) Don't touch the vaccination site.
(b) If you touch it by accident, wash your hands right away with soap and water.
(c) Do not let others contact your vaccination site or materials that covered it.

Smallpox vaccine contains live vaccinia viruses, which grow at the vaccination site, mainly when a bump appears 3 to 5 days after vaccination. The bump becomes a vesicle (blister), then a pustule (fills with pus). It gets bigger until the 8th to 10th day after vaccination. The viruses persist until the scab falls off, 14 to 21 days later.

Spreading vaccinia virus to some other part of the body is called auto-inoculation or accidental infection. Auto-inoculation is the most common among the serious side effects of smallpox vaccination, affecting about 600 out of 1,000,000 people getting smallpox vaccine for the first time. The most common sites involved are places that itch: eyelids, nose, mouth, genitalia, and rectum.

Vaccinia virus can also be spread to a contact of the vaccinated person, especially if that other person has an immune deficiency, atopic dermatitis, or eczema. During the 1960s, the risk of spreading vaccinia virus to a contact (usually a household member) was about 8 to 27 per 1,000,000 vaccinations overall, mainly children 5 years or younger. Today, more people in the community are living with problems to their immune systems. Follow instructions about caring for your vaccination site, to minimize the chance of spreading vaccinia virus to a contact.

After vaccination, you can either leave the site uncovered or cover it with a loose, breathable dressing (e.g., standard Band-Aid®, gauze), until the scab falls off on its own. Airing will help speed healing of the vaccination site. Using a touch-resistant barrier can reduce for contact transfer. Do not use an occlusive bandage (one that doesn't breathe), because fluid could collect under the bandage, soak the skin, and damage the skin. Wearing long-sleeve clothing during the day and at night is another good idea. Minimize close contact with infants less than one year of age. Wash your hands before changing a child's diapers (or having someone else change the diapers).

If you cover the vaccination site, change bandages daily or every few days to prevent fluid buildup. Use paper (or hypoallergenic) tape, if appropriate. Dispose of contaminated bandages and the scab as biohazardous waste in a hospital. If this is not possible, dispose of bandages in sealed or double plastic bags, to keep others away from the virus. Consider adding a small amount of full-strength chlorine bleach to the bandages.

Keep the site dry. Frequent airing will speed healing. Do not use creams or ointments, to avoid softening it and prolonging healing. Long-sleeve clothing worn during the day and at night can protect the site from dirt. Rolling up sleeves in clean locations helps the site

heal. Decontaminate clothing and linens that touch the site with routine laundering in hot water with soap or bleach.

Normal bathing can continue. Dry the area carefully, so that the towel does not rub or spread virus elsewhere. Do not allow others to use that towel until after laundering. Use a waterproof adhesive bandage (e.g., Band-Aid) if you exercise enough to cause sweat to drip. Swimming can make the site soft and gooey.

Arrange clothing and load-bearing equipment to avoid excessive pressure or rubbing at the vaccination site. Avoid contact sports (e.g., wrestling). Be careful not to get sunburn, because the viruses can spread to damaged skin.

Wash your hands if you touch the vaccination site by accident. Use soap and water. Alcohol-based rinses are useful as well. Do not let others touch your vaccination site, bandages, or linen. Have them wash their hands too. It may be a good idea to wash your hands before using the bathroom.

People who live with others who have a bar (caution) against smallpox vaccination should house themselves separately, until the vaccination site heals. This will reduce the risk of spreading virus from the vaccination site to the other person.

Extra Steps for Healthcare Workers.

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 will develop plans for site-care stations, to monitor workers' vaccination sites, promote effective bandaging, and encourage scrupulous hand hygiene. Wearing long-sleeve 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.

APPENDIX B-15

Complication Rates After Vaccination with New York City Board of Health Strain of Smallpox Vaccine.

Key Points:

1. Deaths due to smallpox vaccination are of greatest concern among infants younger than 1 year old and adults receiving their first smallpox vaccination.
2. Serious complications after smallpox vaccination are relatively more common among people getting their first smallpox vaccination (primary vaccination), compared to those getting a repeat or booster smallpox vaccination, although rare for both groups.
3. An exception is that progressive vaccinia is relatively more common among adult vaccine recipients than younger vaccine recipients, although rare for both groups. The elevated rate may be due to unrecognized immunosuppression due to cancer not yet diagnosed at time of vaccination.
4. The most frequent serious complication after smallpox vaccination is accidental infection (auto-inoculation). This complication can be avoided by frequent hand washing.

| Vaccinia Complications per 1,000,000 **Primary** (First) Vaccinations | < 1 Year | 1-4 Years | 5-19 Years | 20+ Years | Overall |
|---|---|---|---|---|---|
| Death (all causes) | 5 to 14 | 0.5 | 1.5 | 1 to 5? * | 1.1 to 1.5 |
| Post-vaccinial encephalitis or other neurologic conditions (e.g., enceph-alomyelitis, transverse myelitis) | 6 to 42 | 2 to 10 | 3 to 9 | 4 | 3 to 12 |
| Progressive vaccinia (vaccinia necrosum) | 1 | 0.4 to 3 | 1 | 7 | 1 to 1.5 |
| Eczema vaccinatum | 8 to 14 | 11 to 44 | 7 to 35 | 24 to 30 | 10 to 39 |
| Generalized vaccinia | 70 to 394 | 17 to 233 | 13 to 140 | 45 to 212 | 23 to 242 |
| Accidental (inadvertent) inoculation (e.g., auto-inoculation) | 11 to 507 | 33 to 577 | 18 to 371 | 14 to 606 | 25 to 529 |
| Total (including complications not specifically mentioned) | 1,549 | 1,262 | 856 | 1,515 | 1,254 |

| Vaccinia Complications per 1,000,000 **Repeat** (Re-) Vaccinations ** | < 1 Year | 1-4 Years | 5-19 Years | 20+ Years | Overall |
|---|---|---|---|---|---|
| Death (all causes) | | | 0.23 | 0.26 | 0.23 |
| Post-vaccinial encephalitis or other neurologic conditions (e.g., enceph-alomyelitis, transverse myelitis) | | | | 4.5 | 2 |
| Progressive vaccinia (vaccinia necrosum) | | | 0.5 | 1 to 7 | 1 to 3 |
| Eczema vaccinatum | | 2 | 2 | 4.5 | 1 to 3 |
| Generalized vaccinia | | | 1 to 10 | 2 to 9 | 1 to 9 |
| Accidental (inadvertent) inoculation (e.g., auto-inoculation) | | 109 | 1 to 48 | 1 to 25 | 1 to 42 |
| Total (including complications not specifically mentioned) | | 200 | 86 | 114 | 108 |

* The number of deaths among 288,000 adults receiving primary vaccination in the 1960s was zero, but CDC extrapolates the expected rate as “5?” (the question mark originates with the CDC).

** The applicability of these revaccination data to modern circumstances is limited, because the setting of the 1960s involved a higher average number of doses per person, with shorter average intervals between vaccinations.

Rare adverse events reported after smallpox vaccination (causality consistent with other vaccines): Immediate hypersensitivity, anaphylaxis, urticaria, edema.
Rare adverse events reported after smallpox vaccination (causality undetermined): vaccinia osteomyelitis, skin cancer at site of vaccination scar, keratitis, and ocular neuritis.

Sources:
Lane JM, Ruben FL, Neff JM, Millar JD. Complications of smallpox vaccination, 1968: National surveillance in the United States. *N Engl J Med* 1969;281:1201--8.
Lane JM, Ruben FL, Neff JM, Millar JD. Complications of smallpox vaccination, 1968: Results of ten statewide surveys. *J Infect Dis* 1970;122:303--9.
Lane JM, Millar JD, Neff JM. Smallpox and smallpox vaccination policy. *Annu Rev Med* 1971;22:251--72.
ACIP. Vaccinia (smallpox) vaccine. *MMWR* 2001;50(RR-10):1-25.
Centers for Disease Control & Prevention. Smallpox Response Plan, 23 Sep 02.

| Population | Age (yrs) | Number vaccinated (millions) | | Outcomes - Rate in Cases per Million Vaccinations or (# Cases), [# deaths] | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | Deaths (all causes) | | Post-vaccinial encephalitis | | Progressive Vaccinia (V. Necrosum) | | Eczema Vaccinatum | | Generalized Vaccinia | | (Accidental) Inadvertent Inoculation | | Other[1] | | TOTAL[2] | |
| **U.S. general surveys (1968)** | | Nat'l[3] | Ten State[4] | Nat'l[3] | Ten State[4] | Nat'l[3] | Ten State[4] | Nat'l[3] | Ten State[4] | Nat'l[3] | Ten State[4] | Nat'l[3] | Ten State[4] | Nat'l[3] | Ten State[4] | Nat'l[3] | Ten State[4] | Nat'l[3] | Ten State[4] |
| Primary vaccinations | <1 | 0.614 | 0.071 | 4.9[3] | 14[1] | 6.5[3] | 42[1] | … | ... | 8.1 | 14 | 70 | 394 | 11 | 507 | 16 | 155 | 112 | 1549 |
| | 1-4 | 2.733 | 0.317 | [0] | … | 2.2 | 9.5 | 0.4 | 3.2 | 11 | 44 | 17 | 233 | 33 | 577 | 15 | 237 | 79 | 1262 |
| | 5-19 | 1.959 | 0.229 | 1.5[3] | … | 2.6[1] | 8.7 | 1.0[2] | ... | 7.1 | 35 | 13 | 140 | 18 | 371 | 5 | 214 | 46 | 856 |
| | 20+ | 0.288 | 0.033 | [0] | … | 3.5 | ... | 6.9 | ... | 24 | 30 | 45 | 212 | 14 | 606 | 17 | 636 | 111 | 1515 |
| **Total** | | **5.594** | **0.65** | **1.1[6]** | **1.5[1]** | **2.9[4]** | **12[1]** | **0.9[2]** | **1.5** | **10** | **39** | 23 | **242** | **25** | **529** | **12** | **266** | **75** | **1254** |
| Re-vaccinations | 1-4 | 0.478 | 0.055 | [0] | … | … | … | … | … | 2.1 | … | … | … | … | 109 | 2.1 | 18 | 4.2 | 200 |
| | 5-19 | 4.3 | 0.503 | 0.23[1] | … | … | … | 0.5[1] | … | 1.6 | 2.0 | 0.23 | 9.9 | 0.7 | 48 | 0.5 | 24 | 3.5 | 86 |
| | 20+ | 3.796 | 0.44 | 0.26[1] | … | … | 4.5 | 1.1[1] | 6.8 | … | 4.5 | 2.4 | 9.1 | 0.8 | 25 | 1.6 | 55 | 5.8 | 114 |
| **Total** | | **8.574** | **0.998** | **0.23[2]** | **0** | **…** | **2.0** | **0.7[2]** | **3.0** | **0.9** | **3.0** | 1.2 | **9** | **0.8** | **42** | **1** | **39** | **4.7** | **108** |
| Contacts[5] | <1 | … | ... | [0] | [0] | (0) | (0) | (0) | (0) | (4) | (0) | (0) | (0) | (9) | (1) | (1) | (1) | (14) | (2) |
| | 1-4 | … | ... | [1] | [0] | (0) | (0) | (0) | (0) | (38)[1] | (4) | (1) | (1) | (16) | (12) | (6) | (0) | (61) | (18) |
| | 5-19 | … | ... | [0] | [0] | (0) | (0) | (0) | (0) | (9) | (6) | (0) | (0) | (10) | (5) | (0) | (0) | (19) | (11) |
| | 20+ | … | ... | [0] | [0] | (0) | (0) | (0) | (0) | (9) | (3) | (1) | (0) | (9) | (11) | (0) | (0) | (19) | (14) |
| **Total** | | | | **0.07[1]** | **[0]** | **(0)** | **(0)** | **(0)** | **(0)** | **4.2[1]** | **7.9** | **0.14** | **0.6** | **3.1** | **18** | **0.5** | **0.6** | **8** | **27** |
| **Grand Totals** | | **14.17** | **1.648** | **0.6[9]** | **0.6[1]** | **1.1[4]** | **6.1[1]** | **0.8[4]** | **2.4** | **8.9[1]** | **25** | **10** | **101** | **14** | **252** | **5.9** | **129** | **40** | **587** |
| **Military** | | | | | | | | | | | | | | | | | | | |
| Israeli Recruits (1991-1996)[6] | | | > 0.300 | | (0) | | (0) | | (0) | | 15 | | 9 | | 6 | | 6 | | **40** |
| U.S. Forces WWII (1942-1945)[7] | | | ~16.4 | | 0.18[3] | | 0.48(8)[3] | | … | | … | | … | | … | | … | | **NA** |
| U.S. Recruits (1971-1975)[8] | | | ~1.97 | | (0) | | (0) | | … | | … | | 4 | | … | | 16 to 35 | | **54** |
| AD (1977-1981)[8] | | | (?) | | (0) | | (0) | | … | | | | … | | | | … | | … |
| Recruits (1981)[8] | | | ~0.322 | | (0) | | (0) | | … | | … | | 37(12) | | … | | 149(48) | | **186(60)** |

1 - "Other" includes secondary infections, miscellaneous complications, and erythema multiforme in Nat'l[3] study (with 9 cases of Stevens-Johnson syndrome). Erythema multiforme was a separate category in Ten State[4] (rate 165/M primary, 10/M re-vaccination; 1 contact case) and Israeli Recruit[6] studies (rate 3/M)).

2 - Total rates include cases with either unknown age (N=63) or vaccination status (N=31 Nat'l[3], N=65 Ten State[4]) and 118 cases of erythema multiforme (Ten State[4]).

3 - Lane et al. *NEJM;* 281(22), 1969. National surveillance of smallpox complications from seven sources (83% of reports from Red Cross VIG usage records).

4 - Lane et al. *J Inf Dis*; 122(4), 1970. Ten state direct survey of U.S. physicians regarding complications (more complete reporting, especially for minor events).

5 - Overall rate of contact complications estimated by dividing total events in category by total vaccinations (denominators for each age group unavailable).

6 - Haim et al. *Mil Med* 165(4), 2000; Note: denominator was not supplied in article but minimum estimate calculated from rates.

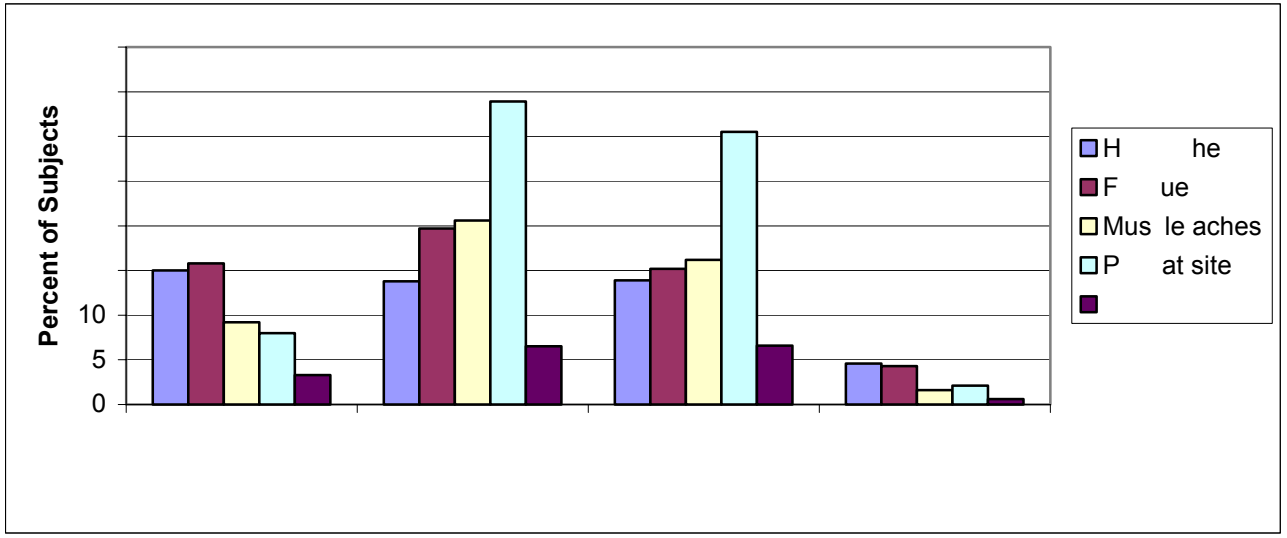
7 - Cases of PVE and deaths from Coates & Hoff. *Preventive Medicine in WWII*, Vol. III, 1955:280-7. Denominator estimate = total troops mobilized in WWII (*World Almanac*, 1998).

8 - Armed Forces Epidemiology Board Transcripts, 1977 (rates) and 1984 (cases). Recruit denominators obtained from Defense Manpower Data Center.

Frequency of Moderate to Severe Symptoms After Primary Smallpox Vaccination (n=655)

Moderate or severe symptom frequencies listed, if total frequency of reporting > 5%.
Moderate = bothersome, but did not preclude activity. Severe = precluded performance of routine activities.
Source: Frey et al. Clinical responses to undiluted and diluted smallpox vaccine. *N Engl J Med* 2002;346(17):1265-1274.

| Sy Sign | Severity | Day 0-6 | Day 7-9 | Day 10-12 | Day 13-14 |
|---|---|---|---|---|---|
| | Moderate | 12.9 | 11.7 | 11.3 | 3.8 |
| | Severe | 2.1 | 2.1 | 2.6 | 0.8 |
| **Headache** | **Total** | **15** | **13.8** | **13.9** | **4.6** |
| | | 13.4 | 17.1 | 12.6 | 3. |
| | | 2.4 | 2.6 | 2.6 | 1. |
| **Fatigue** | **T l** | **15.8** | **19.7** | **15.2** | **4.3** |
| | Moderate | 8.3 | 18 | 14.1 | 1.1 |
| | Severe | 0.9 | 2.6 | 2.1 | 0.5 |
| **Muscle aches** | **Total** | **9.2** | **20.6** | **16.2** | **1.6** |
| | Mod ate | 7 | 31.9 | 27.2 | 2.1 |
| | | 0 | 2 | 3.3 | 0 |
| | **Total** | **8** | **33.9** | **30.5** | **2.1** |
| | Moderate | 2.4 | 4.7 | 5.1 | 0.3 |
| | Severe | 0.9 | 1.8 | 1.5 | 0.3 |
| **Chills** | **Total** | **3.3** | **6.5** | **6.6** | **0.6** |



APPENDIX B-16
Skin Diseases Affecting Smallpox Vaccination.

*Adapted from the recommendations of the Ad Hoc Task Force on Bioterrorism of the American Academy of Dermatology, 2002*

1. Several skin diseases place affected people at risk for developing eczema vaccinatum after smallpox vaccination. Eczema vaccinatum is a localized or disseminated cutaneous vaccinial eruption. In some cases, the condition can be severe and life-threatening. The severe form, although uncommon, usually occurs in people who have true atopic dermatitis (see 2a). In contrast, if eczema vaccinatum develops in patients with non-atopic skin diseases (see 2b, 2c, 2d), it is usually confined to the areas of disturbed skin. This form of eczema vaccinatum is usually mild and self-limited. Many of these patients may be vaccinated once their underlying skin disease is under control.

2. Cutaneous disorders that place a person at risk are reviewed below.

a. Atopic dermatitis or a history of atopic dermatitis (often called childhood eczema). People with atopic dermatitis or a history of atopic dermatitis are at increased risk for developing adverse reactions. The risk of an adverse reaction, specifically eczema vaccinatum, is highest in people with active atopic dermatitis. The presence of active disease, treated or resolved diseases, or even a past history of atopic dermatitis, is a contraindication to vaccination. Every effort should be made to identify patients with a history of cutaneous atopic disease, and any patient with active or inactive disease should not be vaccinated. Positive responses to two or more of the following five questions should be considered consistent with the diagnosis of atopic dermatitis:

(1) Has a doctor ever diagnosed eczema or atopic dermatitis in the patient?
(2) Has the patient had itchy rashes that lasted more than two weeks?
(3) Has the patient ever had itchy rashes in the folds of the arms or legs?
(4) Did the patient have eczema or food allergies during infancy and childhood?
(5) Has a doctor ever diagnosed asthma or hay fever in the patient?

b. People with eczema or dermatitis that is not atopic dermatitis. [Note that childhood eczema is another name for atopic dermatitis and is addressed in 2a above.] Eczema, also called dermatitis, is a general term used to describe several skin conditions that exhibit eczematous skin changes (skin that is itchy, red, and scaling or oozing; vesiculating; crusting). In addition to atopic dermatitis (childhood eczema), these disorders include seborrheic dermatitis, contact dermatitis, nummular eczema, dyshidrotic eczema, and others. Although eczema is frequently used to denote atopic dermatitis, the term eczema is not synonymous with atopic dermatitis, but rather encompasses the above-mentioned disorders. Patients with dermatitis may receive smallpox vaccine when their skin condition is under good control. Such patients may occasionally auto-inoculate remaining areas of compromised skin, but this is usually mild and uncomplicated. They will also have the other usual risks for vaccine-related adverse events.

c. Other chronic exfoliative, erosive, pustular, or blistering skin disorders that disrupt the epidermis. Examples include moderate or extensive psoriasis, epidermolysis bullosa, severe acne (on face or torso), and pemphigus vulgaris. Patients with these disorders (e.g., focal psoriasis on elbows and knees only) may receive the vaccine when their skin condition is under good control. Such patients may occasionally auto-inoculate remaining areas of compromised skin, but this is usually mild and uncomplicated. They will also have the other usual risks for vaccine-related adverse events.

d. Acute, self-limited and non-relapsing skin disorders that disrupt the epidermis: Examples include (but are not limited to) impetigo, varicella, pityriasis rosea, acute contact dermatitis, or acute burns. These patients may receive the vaccine when their condition has resolved and the skin is fully re-epithelialized.

e. Some medications alter the immunity of the skin or the physical integrity of the epidermis and may theoretically increase the risks associated with smallpox vaccine. These medicines include topical immunomodulators (e.g., tacrolimus/Protopic®, pimecrolimus/Elidel®). Retinoids (both topical and oral) may dry the skin and cause numerous epidermal microfissures, possibly increasing the risk of eczema vaccinatum or focal auto-inoculation. If the medications are temporarily discontinued before vaccination, and if the epidermal barrier is restored, the patient may receive smallpox vaccination, and then resume medications once the scab or crust has separated (approximately 18 to 21 days later).

f. Smallpox vaccination involves replication of live vaccinia virus at the site of inoculation. Therefore recent vaccination sites are contagious and can potentially transmit vaccinia to bystanders until the crusts at the vaccination site have fully separated (roughly 18 to 21 days after vaccination). Patients with skin conditions described in 2a through 2e above are at particular risk. The risk for transmission to household contacts may be 27 infections per 1,000,000 vaccinations overall. The risk is higher among young children ($\leq$ 5 years of age), accounting for nearly half of cases reported. Contact transmission rarely results in postvaccinal encephalitis or progressive vaccinia. Approximately 30% of the cases of eczema vaccinatum reported resulted from contact transmission. Eczema vaccinatum may be more severe among contacts than those vaccinated, perhaps because multiple inoculations occur.

g. For these reasons, vaccination is not recommended for people who have a household member or regular close contact with an acute or active chronic skin disorder that disrupts the epidermis. Postpone vaccination until the contact's skin disorder is under control. Furthermore, if a household member or regular close contact has active atopic dermatitis or a history of atopic dermatitis, withhold the vaccination. Alternatively, if vaccination is required in such circumstances, the vaccinee should not have close household contact with at-risk individuals until the crusts at the vaccination site have fully separated, roughly 18 to 21 days after vaccination.

APPENDIX B-17
Investigational New Drugs (INDs) for Force Health Protection.

1. References. 10 USC 980, 10 USC 1107, Executive Order 13139, FDA's 21 CFR 50.23(d), FDA's 21 CFR 312, DoD Directive 6200.2.

2. Purpose. This appendix describes in general terms the tasks that need to be accomplished to administer medications (including vaccines) under the federal rules that apply to **investigational new drugs** (INDs). Documents that describe in detail how the IND medication will be administered are known as **IND protocols**. More detailed information on use of INDs is furnished in the references cited above and in "How To Guides" (references e, f, and g of this annex) developed by the US Army Medical Command. One of the core differences between IND and licensed medications involves the federal requirements for documentation, described below. If a licensed smallpox vaccine is administered, rather than IND smallpox vaccine, it will be administered with the standard record-keeping requirements applied to other licensed vaccines.

3. INDs. An IND medication is a medication that the Food and Drug Administration (FDA) allows (on a limited, voluntary basis) to be used in humans, after people receive information about benefits and risks. But an IND medication has not yet been fully accepted by the FDA as safe and effective for its intended use. The FDA requires animal data on safety and effectiveness to be collected before use in humans is allowed.

4. Standards. The FDA has very rigorous standards for licensing or approving a medication. The FDA generally requires evidence that a new drug (or vaccine) is both safe and effective in humans before they will license it. The DoD administers unlicensed medications only under the FDA's IND rules. With products such as smallpox vaccine, DoD has a vaccine nearing full FDA approval, but we must be ready to use it under IND rules, if required, before the licensing process is complete. With other products of military interest, such as nerve-agent pretreatments or antidotes, it is not ethical to expose people to a harmful substance (e.g., nerve agent) to show that the medication works in humans. So the only way DoD can use them is as INDs.

5. Informed Consent. Consent is permission to receive an IND medication, given by an individual or someone legally responsible for that individual. Consent is only considered informed if the person receives information about the potential benefits and side effects of a medication and has the opportunity to have questions answered.

6. Education. The unit commander is responsible for ensuring each service member and health-care provider in the unit receives proper education regarding the use of an IND medication, the reason why the medication is to be given, the possible side effects and risks, as well as benefits of using the medication. Unit commanders are also responsible for other tasks described below.

7. Documentation. Medical records must accurately document receipt when an IND medication or medication unapproved for its applied use is given. Medical records must also include a copy of the written notice or consent form used.

8. Responsibilities of Unit Leaders Regarding INDs. Ensure health-care providers and service members receive the appropriate education required for them to make informed decisions about whether to accept or decline an IND medication. Assign an ombudsman to assist with the informed-consent process. Assist people in finding answers to their questions about INDs. Foster an environment where people can freely choose whether or not to receive the IND medication. Foster an environment where health-care providers administer the IND medication in accordance with the approved IND protocol. Provide support for documentation of IND medication administration in health records. Ensure preservation of medical records and IND records. Refrain from discriminating, when assigning missions, against Service Members who decline to consent to participate in an IND protocol. Assist people in getting any additional necessary doses of IND product. Assist people, with health-care provider support, in reporting adverse events after IND administration, so that a complete and accurate understanding of IND product safety or side effects can be determined. Assist people in getting needed medical care.

9. Responsibilities of the Services. Services educate personnel about IND responsibilities in general, provide training to Principal Investigators, implement the requirements of DoD D 62002, provide storage, distribution, disposition, and accountability of IND products, and provide quality control/quality assurance of IND protocol documentation.

10. Responsibilities of the Combatant Commands: The Combatant Command designates an officer (or officers) to be the responsible Principal Investigator(s) within the Command. The Combatant Commanders request authority to administer IND medications for force health protection through the Chairman of the Joint Chiefs of Staff to the Secretary of Defense. If necessary, the Command may request waiver of consent (see below). The Combatant Commander is responsible for fully and carefully implementing any IND protocol.

11. Responsibilities of the Principal Investigator (PI). PIs will receive training in the rules for conducting an IND protocol, known as Good Clinical Practices (GCP). These practices emphasize detailed record keeping, informed consent, implementing the protocol as written, product accountability, and other topics. PIs must sign a FDA Form 1572, accepting responsibility for faithfully conducting the protocol according to the protocol and FDA-accepted procedures. Deviations from the protocol must be recorded and reported. Unexpected and serious adverse experiences must be noted and reported.

12. Responsibilities of Clinical Project Manager (CPM). Also trained in GCP, the Clinical Project Manager will store protocol documentation, submit safety reports to the US Army Medical Materiel Development Activity (USAMMDA), DOD's representative to the

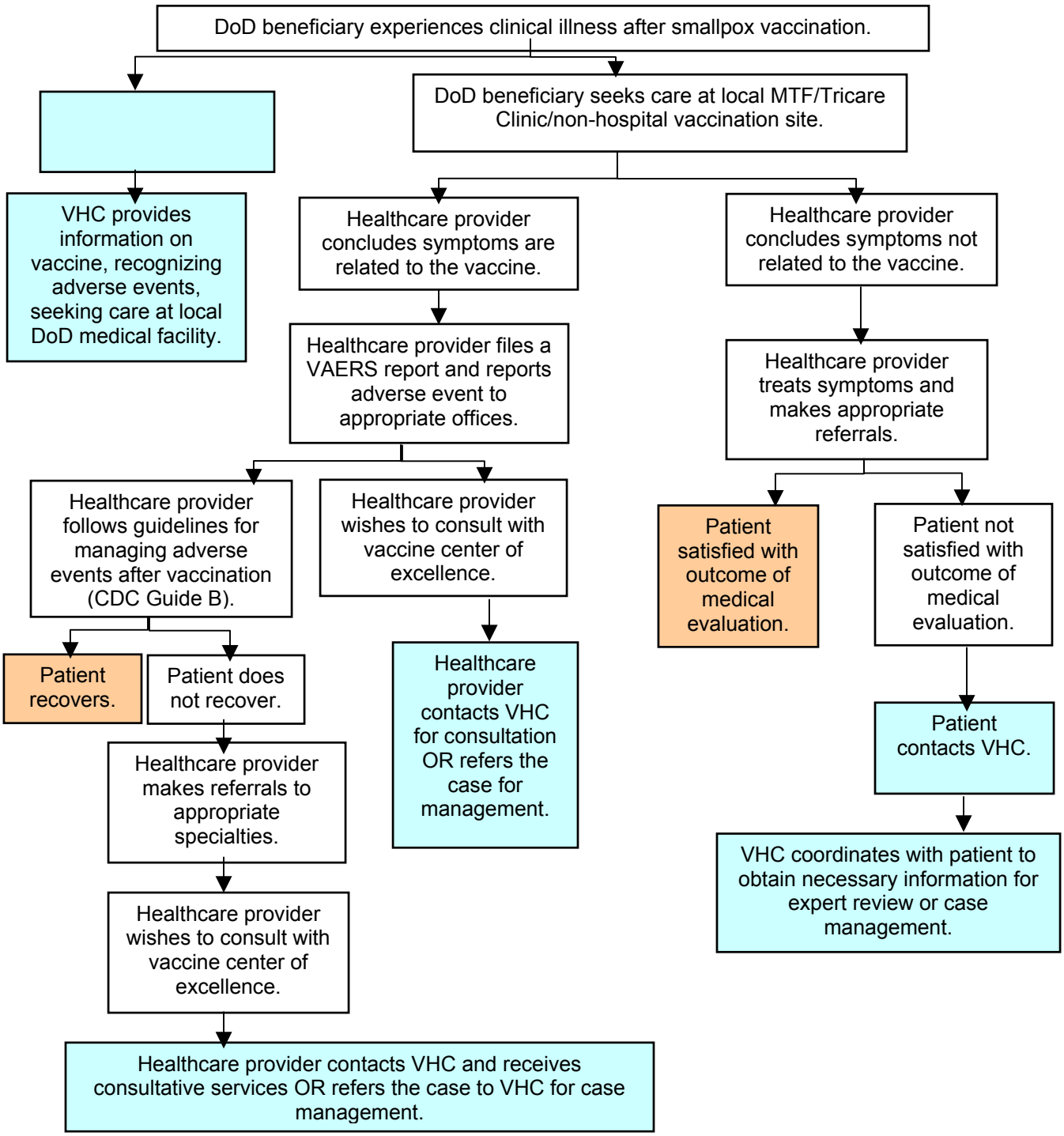
US Food and Drug Administration. The CPM will provide an annual report, track data entered into the service immunization tracking records, and retain sufficient data for subject follow up. The CPM will prepare a final report for the IND protocol.

13. Responsibilities of the Medical Monitor: The Medical Monitor will investigate all serious and unexpected adverse experiences reported to the FDA. The Medical Monitor will authorize suspension or withdrawal of volunteers from the protocol if medically appropriate.

14. Presidential Waiver. Under very limited circumstances, the President may waive requirement for consent to administration of IND medications to Service Members. To qualify for waiver, various agencies of the federal government must comply with 18 requirements specified in 21 CFR 50.23(d). If the President waives consent, use of the IND medication changes from being voluntary to being mandatory. In effect, the President issues an order directly the Service Member to receive the medication. But the President may not waive federal requirements for education or documentation in health records of IND medication administration. Federal law requires education and documentation regardless of whether consent is waived or not. In other words, the President can waive the “consent” requirement, but not the requirement for Service Members to be informed or the requirement for documentation in health records. And the Service Member must be informed of the reason for the President’s waiving of consent.

APPENDIX B-18
Vaccine Healthcare Center (VHC) Services.

Vaccine Healthcare Center, c/o Walter Reed Army Medical Center, PO Box 59605, Washington, DC 20012-0605, 202-782-0411 (DSN: 662); fax: 202-782-4658; Email: askVHC@na.amedd.army.mil; www.vhcinfo.org (pending). After duty hours, ask for the Allergist-Immunologist on call: 202-782-1000 (DSN: 662) or 202-782-7309 (DSN: 662).



APPENDIX B-19
Vaccine Adverse Event Reporting System (VAERS) Forms.

Available from:

www.vaers.org/

800-822-7967

Submit reports online at: https://secure.vaers.org/VaersDataEntryintro.htm

A blank VAERS Form-1 appears on the next page.