

# EXHIBIT 7

**Army Regulation 40-562  
BUMEDINST 6230.15B  
AFI 48-110\_IP  
CG COMDTINST M6230.4G**

**Medical Services**

# **Immunizations and Chemoprophylaxis for the Prevention of Infectious Diseases**

**Headquarters  
Departments of the Army,  
the Navy,  
the Air Force,  
and the Coast Guard  
Washington, DC  
7 October 2013**

**UNCLASSIFIED**

# ***SUMMARY of CHANGE***

AR 40-562/BUMEDINST 6230.15B/AFI 48-110\_IP/CG COMDTINST M6230.4G  
Immunizations and Chemoprophylaxis for the Prevention of Infectious Diseases

This major revision, dated 7 October 2013--

- o Changes the regulation title to "Immunizations and Chemoprophylaxis for the Prevention of Infectious Diseases" (cover).
- o Describes the responsibilities of the privileged physician with medical oversight of any clinic or activity that administers immunizations (para 1-4c(2)).
- o Describes the responsibilities of the privileged health care provider, who is under the direction of the privileged physician of any clinic or activity that administers immunizations (para 1-4c(3)).
- o Changes a reference to five-injection thresholds to reflect current evidence-based practices (para 2-1e(1)).
- o Adds a description of procedures for vaccine storage and handling (para 2-3).
- o Adds a description of military indications for required and recommended vaccines (paras 4-2 through 4-19).
- o Makes changes to chemoprophylaxis recommendations (chap 5).
- o Adds a description of procedures for documenting immunizations and immunization recordkeeping (para B-5).
- o Establishes and recommends immunization personnel training (para B-6 and table B-1).
- o Establishes criteria for determining required immunizations for military personnel (app D).
- o Makes administrative revisions (throughout).

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Medical Services

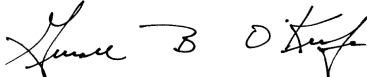
Effective 7 November 2013

## Immunizations and Chemoprophylaxis for the Prevention of Infectious Diseases

By Order of the Secretary of the Army, Navy, Air Force, and Coast Guard:

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**History.** This publication is a major revision.

**Summary.** This regulation for immunization and chemoprophylaxis updates quality standards for immunization delivery; establishes electronic immunization tracking systems as the preferred immunization record; provides guidance for lost immunization records, immunization credit for pre-existing immunity, and complying with regulations for vaccines and other products administered in investigational, new drug status or in accordance with emergency use authorization; describes dividing initial entry immunization into two clusters; and describes the role of the Military Vaccine Office.

**Applicability.** This regulation applies to the Active Army, the Army National Guard/Army National Guard of the United States, and the U.S. Army Reserve, unless otherwise stated. It also applies to the following: uniformed Departments of the Navy, Air Force, and Coast Guard (including the active and reserve components of each Service); nonmilitary persons under military jurisdiction; selected Federal employees; selected employees of Department of Defense contractors; and Family members and other health care beneficiaries eligible for care within the

military health care system. This regulation is applicable during mobilization.

**Proponent and exception authority.** The proponent of this regulation is The Surgeon General. The proponent has the authority to approve exceptions or waivers to this regulation that are consistent with controlling law and regulations. The proponent may delegate this approval authority, in writing, to a division chief within the proponent agency or its direct reporting unit or field operating agency, in the grade of colonel or the civilian equivalent. Activities may request a waiver to this regulation by providing justification that includes a full analysis of the expected benefits and must include formal review by the activity's senior legal officer. All waiver requests will be endorsed by the commander or senior leader of the requesting activity and forwarded through their higher headquarters to the policy proponent. Refer to AR 25-30 for specific guidance.

**Army internal control process.** This regulation contains internal control provisions and identifies key internal controls that must be evaluated (see appendix E).

**Supplementation.** Supplementation of this regulation and establishment of command and local forms are prohibited without prior approval from The Surgeon

General (DASG-ZA), 7700 Arlington Blvd., Falls Church, VA 22041-5143.

**Suggested improvements.** Users are invited to send comments and suggested improvements on DA Form 2028 (Recommended Changes to Publications and Blank Forms) directly to The Surgeon General (DASG-ZA), 7700 Arlington Blvd., Falls Church, VA 22041-5143. Air Force users are invited to send comments and suggested improvements on AF Form 847 (Recommendations for Change of Publication) through channels to Headquarters, AFMSA/SGOP, 7700 Arlington Blvd., Falls Church, VA 22041-5143.

**Distribution.** This publication is available in electronic media only and is intended for command levels A, B, C, D, and E for the Active Army, the Army National Guard/Army National Guard of the United States, and the U.S. Army Reserve. Navy/Marine Corps: Ships, units, and stations having medical department personnel. Air Force: Active Air Force, the Air National Guard, and Air Force Reserve. Coast Guard: Active Coast Guard and Coast Reserves.

\*This regulation supercedes AR 40-562/BUMEDINST 6230.15A/AFJ 48-110/CG COMDTINST M6230.4F, dated 29 September 2006.

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## **Glossary**



## Chapter 1 Introduction

### 1–1. Purpose

This publication provides directive requirements for the Military Vaccination Program; establishes general principles, procedures, policies, and responsibilities for the immunization program; and implements military and international health regulations and requirements.

### 1–2. References

Required and related publications and prescribed and referenced forms are listed in appendix A.

### 1–3. Explanation of abbreviations and terms

Abbreviations and special terms used in this regulation are explained in the glossary.

### 1–4. Responsibilities

*a. Command medical authority.* The command medical authority will prescribe specific immunization and chemoprophylactic requirements for their units per requirements established by this publication and additional guidance provided by the appropriate surgeon general or the U.S Coast Guard (USCG), Director of Health, Safety, and Work-Life (USCG, CG–11).

*b. Command leaders.* Combatant commanders, major command commanders, unit commanding officers, commanders of special operations and forces, and officers-in-charge will:

(1) Ensure military and nonmilitary personnel under their jurisdiction receive required immunizations and chemoprophylaxis. Ensure immunizations and immunization exemption codes (medical or administrative) are documented in an approved Department of Defense (DOD) or USCG Service Immunization Tracking System (ITS), as described in paragraph 2–7a.

(2) Maintain appropriate international, Federal, State, and local records of all immunizations and chemoprophylaxis.

(3) Ensure personnel transferred to another command or unit, including advanced instructional training or technical school, receive proper screening for, and administration of, appropriate immunizations and chemoprophylaxis for the area assigned, and are timed to provide immunity before deployment or exposure or to complete a vaccine series.

(4) Ensure immunization exemptions are documented in the Service ITS.

(5) Ensure vaccine doses or boosters are administered to complete a started series or maintain immunity.

(6) Ensure deviations from specified immunizations are cleared or authorized by the appropriate combatant commander; surgeon general; or USCG, CG–11.

(7) Observe international military standardization agreements (STANAGs).

*c. Medical commanders, commanding officers, and command surgeons.* Medical commanders, commanding officers, and command surgeons will:

(1) Ensure individuals administering immunizations are properly trained in accordance with DOD, Service, and Centers for Disease Control and Prevention (CDC) guidelines and act within their scope of practice as determined by each Service. A training checklist is found in appendix B, paragraph B–6 and table B–1.

(2) Appoint, in writing, a privileged physician with medical oversight over any clinic or activity that administers immunizations. This physician will:

(a) Complete appropriate training in immunization science in residence or via distance learning.

(b) Be available to address immunization issues, although it is not required that the privileged physician be present for administration of vaccines. The USCG requires a privileged health care provider to administer immunizations to civilians who are eligible for care in a medical treatment facility.

(c) Establish and sign vaccine and chemoprophylaxis standing orders for clinics or other locations where immunizations or chemoprophylaxis medications are administered.

(d) Ensure standard operating procedures (SOPs) are established that implement current national standards for adult and pediatric immunizations and chemoprophylactic practices and promote appropriate quality improvement mechanisms. Incorporate local practices and requirements of policies contained in references listed at appendix A.

(3) Appoint, in writing, a privileged health care provider, who is under the direction of the privileged physician appointed in paragraph 1–4c(2), to have oversight over the daily activities of any clinic or activity that administers immunizations. The privileged physician may serve as the health care provider if no one is available to assume the position of privileged health care provider.

(4) Ensure patients are evaluated for preexisting immunity, screened for administrative and medical exemptions, and/or evaluated for the need for medical exemptions to immunizations or chemoprophylaxis medications. Exemptions are granted per paragraph 2–6; document any exemptions.

(5) Monitor the immunization status of personnel and ensure compliance with policies and procedures for creating and maintaining immunization records in accordance with Title 42, United States Code, Chapter 300aa-25.

(6) Ensure emergency medical response is available and that personnel who administer immunizations receive



training on: basic cardiopulmonary resuscitation, administration of epinephrine, and emergency response to immunization-adverse events, at a minimum.

(7) Ensure health care providers are available to respond to and report adverse events resulting from immunization.

(8) Ensure patients needing evaluation of adverse events after immunization are referred to appropriate health care providers, such as medical subspecialists (including specialists in immunization health care) for evaluation, consultation, or indicated intervention.

*d. The Army, as Executive Agent for the Military Vaccination Program.* The Army, as Executive Agent for the Military Vaccination Program and in cooperation with the Military Services, will:

(1) Operate a Military Vaccine (MILVAX) Office to provide the Military Services with a coordinated source for information and education of vaccine-related activities needed in order to implement Department of Defense Directive (DODD) 6205.3, DODD 6205.02E, and Department of Defense Instruction (DODI) 6205.4.

(2) Synchronize, integrate, and coordinate immunization policies and other immunization-related activities for all DOD components.

(3) Facilitate and promote the quality of immunization policy, implementation, education, distribution, risk communication, administration, clinical services, safety surveillance, research, and program evaluation.

(4) Provide a comprehensive access point to provide information, education resources, safety surveillance, and uniform procedures to identify, report, and evaluate vaccine-associated adverse events.

(5) Maintain historical vaccine usage data as well as identify future vaccine requirements as needed.

(6) Provide primary coordination between DOD and vaccine manufacturers for all applicable post-licensure vaccine studies.

(7) Coordinate with other Secretaries of the Military Departments and the Commandant, USCG to:

(a) Establish joint clinical quality standards for immunization delivery and education and training to personnel involved in immunization healthcare. The goals of these standards are to promote clinical excellence and decrease practice variability.

(b) Assess the DOD Immunization Program by developing metrics to measure individual medical readiness, vaccine effectiveness and safety, and compliance with overall immunization policies.

(c) Regularly update the Joint Regulation on Immunization and Chemoprophylaxis for the Prevention of Infectious Diseases.

(8) Promote scholarly immunization study activities through the Army's Medical Infectious Disease Research Program using funds both from the Defense Health Program and the Research, Development, Test, and Evaluation.

*e. Each of the Military Services.* Each of the Military Services will provide an immunization health care capability to deliver medical specialty consultation, case management, and clinical investigation. The U.S. Navy provides medical services for the U.S. Marine Corps.

## Chapter 2 Program Elements and Clinical Considerations

### 2-1. Standards

*a. Department of Defense and U.S. Coast Guard policy.* The Military Service policy concerning immunizations follows the recommendations of the CDC and the Advisory Committee on Immunization Practices (ACIP) and the prescribing information on the manufacturer's package inserts, unless there is a military-relevant reason to do otherwise. Any vaccine or drug licensed by the U.S. Food and Drug Administration (FDA) or the U.S. Department of Health and Human Services (DHHS) may be used, as well as vaccines or drugs compliant with applicable DOD investigational new drug (IND) or emergency use authorization (EUA) processes. Privileged health care providers may make clinical decisions for individual beneficiaries to customize medical care or to respond to an individual clinical situation that is compliant with IND or EUA processes.

*b. Standards for delivery of military vaccines.* Standards for delivery of military vaccines are provided in appendix B. Military Services will abide by these standards in routine immunization delivery.

*c. Expiration date.* Vaccines or drugs will not be used beyond the manufacturer's potency expiration date, unless the appropriate surgeon general or USCG, CG-11, authorizes extension in exceptional circumstances.

*d. Screening for contraindications.* Screen all potential vaccines for contraindications, precautions, or warnings per the prescribing information on the manufacturer's package insert.

*e. Immunization schedules and intervals.*

(1) *Initial series.* Once an immunization series has been started, it must be completed, unless a medical or administrative exemption exists. Restarting an immunization series or adding extra doses is not necessary when an initial series of a vaccine or toxoid is interrupted; instead, give delayed doses as soon as feasible.

(2) *Doses.* Vaccine doses in an initial series will not be administered at intervals less than the recommended minimum intervals or earlier than the minimum age unless the doses are part of a CDC catch-up schedule or during an

outbreak. Doses in an initial series administered 5 or more days earlier than the minimum interval should not be counted as valid doses. The next valid dose is calculated after the last invalid dose.

(3) *Booster doses.* After the initial series of a vaccine is complete, a booster dose may be recommended for specific vaccines. For vaccines that do not provide lifetime immunity, the booster dose is usually recommended or required to increase immunity back to protective levels.

*f. Simultaneous immunizations.*

(1) When simultaneous vaccine injections are necessary, administer vaccines in different limbs. The anatomical site may depend on the age of the individual, and the degree of muscle development. If different anatomical sites are not possible, then separate the injections by at least 1 inch. Refer to the ACIP General Recommendations on Immunizations for proper needle lengths.

(2) Priority of immunization is based on the relative likelihood of various microbial threats and the existence of any vaccine-vaccine, vaccine-antibody, or vaccine-drug interactions and is best performed by the health care provider. In military training centers, contagious diseases typically represent the most imminent threats.

(3) Spacing of live and inactivated vaccines.

(a) Two or more inactivated vaccines can be administered simultaneously or at the prescribed interval and restrictions indicated in the package insert for each vaccine.

(b) Inactivated and live vaccines can be administered simultaneously or at the prescribed interval and restrictions indicated in the package insert for each vaccine.

(c) Two or more live virus vaccines must be administered simultaneously or separated by at least 28 days (4 weeks). Refer to ACIP guidelines for exceptions.

*g. Screening for immunity.* For some vaccine-preventable diseases, serologic or other tests can be used to identify pre-existing immunity from prior infections or immunizations that may eliminate unnecessary immunizations.

*h. Live virus vaccines and tuberculosis testing.* Vaccinations with live vaccines may affect tuberculosis (TB) testing. This includes both the Mantoux tuberculin skin test and the Interferon-Gamma Release Assays test whole-blood test. To avoid interference:

(1) Administer live virus vaccines and TB test on the same day.

(2) Perform TB test 4 to 6 weeks after administration of live virus vaccines, or

(3) Administer live virus vaccines, once the TB test is read.

## 2–2. Logistics

*a. Requisitioning of immunizing and chemoprophylaxis agents.* Immunizing and chemoprophylaxis agents are requisitioned in accordance with medical supply procedures. However, vaccinia immune globulin—also known as VIG-intravenous—is available only by ordering through the MILVAX Office.

*b. Transportation, storage, and handling.* All personnel will maintain the cold chain in vaccine delivery during transportation, storage, and handling. Shipping and storage advice is available from Services medical logistics centers.

*c. Small stations, ships, and cutters.* To minimize the shipment of vaccines that must be stored at frozen temperatures, small stations, ships, and cutters may requisition these items from a nearby military medical activity stocking the items. Requisitioning procedures and reimbursement are prescribed by the supplying activity.

## 2–3. Storage and handling

*a. Safety and efficacy of vaccines.* Failure to adhere to recommended specifications for storage and handling of vaccines may reduce potency, resulting in inadequate immune responses in the recipients and inadequate protection against disease. To maintain the safety and efficacy of vaccines, ensure immunizing and chemoprophylaxis agents are stored, shipped, and handled in accordance with the pharmaceutical manufacturer's instructions as outlined in the product package insert or other guidance.

*b. Policies for maintaining vaccines.* All locations that maintain and administer vaccines will develop and implement policies and procedures for maintaining cold chain management of vaccines.

*c. Shelf-life after opening.*

(1) Administer vaccines shortly after withdrawal from single-dose or multi-dose vials, in accordance with the manufacturer's package insert.

(2) Single dose vials are meant for one-time use only. At the end of the clinic day, discard all single-dose vials without protective caps.

(3) For multi-dose vaccine vials that do not require reconstitution, doses that remain after withdrawal of a dose can be administered until the expiration date printed on the vial or vaccine packaging, so long as the vial has been stored correctly and the vaccine is not visibly contaminated and the manufacturer has not specified otherwise.

(4) Multi-dose vials that require reconstitution must be used within the interval specified by the manufacturer. After reconstitution, the new expiration date should be written on the vial.

*d. Diluents.*

(1) Diluents are not interchangeable, unless specified by the manufacturer.

- (2) Transport diluents at room temperature in validated containers, but not in direct contact with shipping gel packs.
- (3) Store diluents according to the manufacturer's package insert.
- (4) Discard diluents when stored inappropriately or expired.

*e. Filling syringes and attaching needles.*

(1) Never mix individual vaccines in the same syringe. Different vaccines should never be mixed in the same syringe unless specifically licensed for such use. Do not transfer vaccine between syringes.

(2) Use a separate needle and syringe for each injection.

(3) Label filled syringes with the type of vaccine, lot number, and date of filling, unless the vaccine is administered immediately after being drawn into the syringe by the same person administering the vaccine.

(4) Attach needles to manufactured filled syringes just prior to administration. Discard needle and syringe if the vaccine is not administered before the end of the clinic day or vaccination session in accordance with the manufacturer's package insert. If no time line is provided, discard after 8 hours.

*f. Prefilling syringes.*

(1) Prefilling syringes is highly discouraged because of the increased risk of administration errors and possible bacterial growth in vaccines that do not contain preservatives. Syringes other than those filled by the manufacturer are designed for immediate use and not for vaccine storage.

(2) In certain circumstances in which a single vaccine type is being used, such as during an influenza vaccination campaign, filling a small number of syringes may be considered.

(3) Discard unused syringes filled by the end user (that is, not filled by the manufacturer) in accordance with the manufacturer's package insert. If no time line is provided, discard after 8 hours.

*g. Storing vaccine.*

(1) Ensure that only vaccines are stored in the vaccine storage unit (refrigerator or freezer).

(2) Store refrigerated vaccines at temperatures of 35°F to 46°F (2°C to 8°C). Do not expose refrigerated vaccines to freezing temperatures.

(3) Store frozen vaccines at temperatures of 5°F (-15°C) or lower.

(4) Store all reconstituted lyophilized (freeze-dried) vaccines in accordance with the manufacturer's temperature and light condition parameters.

*h. Vaccine storage equipment.* Ensure that vaccine storage units are carefully selected, used properly, and consistently monitored to maintain recommended vaccine storage temperatures.

(1) Stand-alone refrigerators and freezers are recommended for storage of vaccines. A combination refrigerator/frost-free freezer for home use is acceptable if only the refrigerator compartment of the combination unit is used to store refrigerated vaccines. A separate stand-alone freezer should then be used to store frozen vaccine. Dormitory style refrigerators are not authorized for vaccine storage.

(2) Use certified and calibrated thermometers in all vaccine storage units. Uncertified liquid (mercury or alcohol) thermometers and uncertified dial-type household refrigerator/freezer thermometers are not authorized.

(3) Ensure alarm systems are incorporated as part of the vaccine storage unit to alert staff of power failures or indicate whether or not vaccine temperatures have been maintained.

*i. Temperature tracking.*

(1) Ensure temperatures are documented for each vaccine storage unit. Physically confirm the temperature of all vaccine refrigerators and freezers at a minimum of two times per day. Document the date, time, and temperature of the vaccine storage unit on a temperature log. Vaccine outside of a refrigerator or freezer must have the temperature checked and documented every hour.

(2) Keep temperature logs for at least 3 years. State and/or local requirements may require longer recordkeeping.

(3) Record date and time of any mechanical malfunction or power outage on the temperature log or on another equipment-tracking document.

*j. Vaccine storage alarms.*

(1) Ensure alarm systems are capable of monitoring vaccine storage 24 hours a day, 7 days per week. Ensure the system either notifies an accountable person when a failure is detected, or the system is capable of indicating that the vaccine temperature integrity was maintained during the storage period (or notes any deviations).

(2) Ensure current personnel contact information exists on auto-dialers, and that appropriate coverage occurs during periods of leave, holiday weekends, and so forth.

(3) Monitor alarms electronically and physically 24 hours a day, 7 days per week.

(4) Test the entire alarm system, to include refrigerator-freezer-unit sensor to the remote monitoring station and telephone or pager, at least monthly. Maintain test records for at least 3 years.

(5) For vaccine storage units within restricted access areas, ensure the temperature can be checked and a light or audible alarm is installed to indicate when the storage unit temperature is out of range without having to physically enter the restricted area.

*k. Transporting vaccines.*

- (1) Always transport vaccines in properly insulated containers to maintain the recommended temperatures.
- (2) Ensure containers used for transporting vaccines are capable of maintaining the vaccine at the correct temperatures. Validated storage devices include the Vaxicool, Vaxipac, manufacturer shipping containers, Styrofoam(tm) coolers with at least 2-inch thick walls, or Endurotherm insulating shipping containers.
- (3) Pack containers to appropriately maintain the proper temperature while vaccine is transported or shipped. Refrigerated or frozen packs are authorized for use to maintain the cold chain when used according to the U.S. Army Medical and Materiel Agency (USAMMA) Distribution Operations Center instructions.
- (4) Include calibrated thermometers to track temperatures in all transportation and off-site storage containers.
- (5) Pack vaccines in their original packaging. Do not remove vaccine vials from boxes.
- (6) Document vaccine type, quantity, date, time, and originating facility on the outside of the transportation containers.
- (7) Ensure temperatures are tracked during transportation and any deviations in temperature are readily identifiable.
  1. *Vaccine disposal or disposition.*
    - (1) Discard syringes or vials that contain live virus vaccines per installation policy.
    - (2) Contact the pharmacy or logistics office for specific policies regarding the disposition of unopened vials, expired vials, unused doses, and potentially compromised vaccine.
    - (3) Label potentially compromised vaccines with the words “Do not use” and place in the refrigerator or freezer based on the manufacturer’s instructions as if they were not compromised. Report all compromised anthrax, smallpox, and influenza vaccines to USAMMA for validation before destruction. Contact the manufacturer for all other potentially compromised vaccines for disposition or destruction instructions.
    - (4) Report all confirmed compromised vaccine losses through Service-specific channels to the Military Vaccine Office. The report must include the following: description of the reason for the loss, vaccines compromised, total vials/doses lost, and cost of lost or compromised vaccines.

#### **2–4. Hypersensitivity or allergy**

- a. Before administration of any medication, including vaccines, determine if the individual has previously shown any unusual degree of adverse reaction or allergy to it or any specific component of the vaccine or its packaging (for example, eggs, gelatin, preservatives, latex). Review the manufacturers’ package inserts and reference materials for product-specific information.
- b. Defer individuals with reported hypersensitivity to a particular vaccine or its components from immunization.
- c. Refer individuals with a hypersensitivity to an appropriate medical specialist for evaluation, unless the health record contains documentation of a prior consultation or a specialist’s recommendations. Document hypersensitivity and any recommended exemption(s) in the electronic ITS and the appropriate sections of the health record.

#### **2–5. Immunizing women of childbearing potential**

A pregnancy screening test for women of childbearing potential is not routinely required before administering vaccines, including live virus vaccines. Take the following precautions to avoid unintentional immunization with contraindicated products during pregnancy—

- a. Display signs asking pregnant women to identify themselves. Discreetly ask her if she is, or might be, pregnant. Document responses in the health record. If the answer is “yes,” and the ACIP does not recommend the vaccine for use in pregnancy, then defer her from immunization or refer to an obstetric healthcare provider to determine whether the benefits of immunization outweigh risks in pregnancy. If the vaccine is recommend for use in pregnancy by ACIP, the vaccine may be administered. If pregnancy status is uncertain, defer immunization until after a negative pregnancy evaluation (for example, urine, or serologic test).
- b. With regard to smallpox (vaccinia) vaccine, a specific pre-immunization screening form (available at <http://www.smallpox.mil/resource/forms.asp>) that assesses the date of the last menstrual period is required. For women whose last menstrual period was more than 28 days ago, a pregnancy test is recommended.
- c. Breastfeeding women may be immunized in accordance with the current ACIP guidelines. At present, no immunization products are medically contraindicated in breastfeeding women. Smallpox vaccine is withheld from breastfeeding women, except in an outbreak, primarily due to the potential for contact transmission of vaccinia virus to the child.
- d. If a live virus vaccine is administered, counsel her to avoid becoming pregnant for the appropriate interval as recommended by CDC or the vaccine manufacturer. Document the counseling in the health record.
- e. If she is pregnant and immunization is indicated, immunize in consultation with her obstetric health care provider.
- f. If a contraindicated vaccine is inadvertently administered to a pregnant woman, report the event upon discovery to the preventive medicine point of contact and obstetric services and complete appropriate quality assurance documents. Report such cases to any applicable registry. For assistance with registry referral procedures, contact the preventive medicine service or MILVAX.

## 2-6. Exemptions

There are two types of exemptions from immunization—medical and administrative. Granting medical exemptions is a medical function. Granting administrative exemptions is a nonmedical function.

*a. Medical exemptions.* A medical exemption includes any medical contraindication relevant to a specific vaccine or other medication. Health care providers will determine a medical exemption based on the health of the vaccine candidate and the nature of the immunization under consideration. Medical exemptions may be temporary (up to 365 days) or permanent. Standard exemption codes appear in appendix C.

(1) General examples of medical exemptions include the following—

(a) Underlying health condition of the vaccine candidate (for example, based on immune competence, pharmacologic or radiation therapy, pregnancy and/or previous adverse response to immunization).

(b) Evidence of immunity based on serologic tests, documented infection, or similar circumstances.

(c) An individual's clinical case is not readily definable. In such cases, consult appropriate medical specialists, including specialists in immunization health care.

(2) Providers who are assessing medical exemptions may seek a second opinion from a provider experienced in vaccine adverse event management, such as specialists in immunization health care at a medical center, or seek additional consultation from MILVAX.

(3) Annotate electronic ITS and paper-based service treatment records with exemption codes denoting evidence of immunity, severe adverse event after immunization (except for the Medical Readiness Reporting System), other temporary or permanent reasons for medical exemption, and other appropriate categories.

(4) Report cases warranting permanent medical exemptions due to a vaccine related adverse event to the Vaccine Adverse Events Reporting System (VAERS) at the Web site at <http://www.vaers.hhs.gov> and as discussed in paragraph 2-10.

(5) Revoke medical exemptions when they are no longer clinically warranted.

*b. Administrative exemptions.* Standard exemption codes appear in appendix C.

(1) *Separation or retirement.* Within 180 days before separation or retirement, Service personnel may be exempt from deployment (mobility) immunizations, if one of the following conditions are met:

(a) They are not currently assigned, deployed, or scheduled to perform duties in a geographical area where an immunization is indicated.

(b) The commander has not directed immunization because of overriding mission requirements. Personnel who meet separation or retirement requirements and desire an immunization exemption must identify themselves to their commander. The member must have approved retirement or separation orders. Active duty personnel continuing duty in the reserve component are not exempted on this basis.

(2) *Thirty days or fewer of service remaining.* Applies to civilian employees and contractor personnel who will leave a permanent (other than OCONUS deployments) assignment subject to immunization within 30 days or fewer.

(3) Religious exemptions.

(a) *Servicemembers.* Immunization exemptions for religious reasons may be granted according to Service-specific policies to accommodate religious beliefs of a Service member. This is a command decision made with medical, judge advocate, and chaplain input.

1. Requests for religious exemption must comply with the provisions of the applicable policy and/or regulation for the Servicemember requesting religious accommodation. For the Army, religious accommodation policy is provided in AR 600-20. For the Navy and Marine Corps, waivers are granted on a case-by-case basis by the Chief, Bureau of Medicine, and Surgery. For the Air Force, permanent exemptions for religious reasons are not granted; the MAJCOM commander is the designated approval and revocation authority for temporary immunization exemptions. For the Coast Guard, CG-122 is the designated approval and revocation authority for religious immunization exemptions. USCG requests must be forwarded through the appropriate chain to Commandant CG-122 via CG-112.

2. A military physician must counsel the applicant. The physician should ensure that the Servicemember is making an informed decision and should address, at a minimum, specific information about the diseases concerned; specific vaccine information including product constituents, benefits, and risks; and potential risks of infection incurred by unimmunized individuals.

3. The commander must counsel the individual that noncompliance with immunization requirements may adversely impact deployability, assignment, or international travel.

4. Per DODI 1300.17 and applicable service regulations will be provided whether Servicemembers with pending active requests for religious exemption are temporarily deferred from immunizations, pending outcome of their request.

5. Religious exemptions may be revoked, in accordance with Service-specific policies and procedures, if the individual and/or unit are at imminent risk of exposure to a disease for which an immunization is available.

(b) *Civilian employees.* Civilian employees submit requests for immunization exemption for religious reasons to their supervisors. Civilian requests are processed in accordance with Part 1605, Title 29, Code of Federal Regulations and component policies.

(c) *Bargaining units.* Civilian personnel affected by this document who are members of bargaining units will be

considered for exemption consistent with applicable personnel management policies and applicable labor relations obligations.

(d) *Other exemption categories.* Administrative or medical personnel will appropriately annotate electronic ITS with exemption codes denoting separation, permanent change of station, emergency leave, missing or prisoner of war, deceased, and other appropriate categories.

## 2-7. Immunization and chemoprophylaxis records

### a. *Electronic immunization tracking systems.*

(1) Document all immunizations in a DOD and USCG-approved ITS. Include date, immunization given, dose, anatomical location of administration, lot number, manufacturer, Vaccine Information Sheet (VIS) date, and the identification of the person administering the vaccine.

(2) Electronic ITS must—

(a) Comply with the requirements of the National Vaccine Injury Compensation (NVIC) Program as provided in 42 USC 300aa-25, Report and Recording of Information, and 42 USC 300aa-26. NVIC information is outlined in paragraph 2-7d.

(b) Incorporate DOD-directed levels of security, certification, and redundancy, and the requirements of the Health Insurance Portability and Accountability Act to preclude unauthorized access to personal medical information and to survive hardware or software malfunction.

(c) Be capable of generating printed reports of immunization status and exemption information on both an individual and unit basis.

(3) A printed report from the electronic ITS, in CDC Form 731 (International Certificate of Vaccination or Prophylaxis) 731, SF 601 (Health Record-Immunization Record), or DD Form 2766C (Adult Preventive and Chronic Care Flowsheet) (Continuation Sheet) format, accompanied by an official clinic stamp and the authorized signature and printed name of an authenticating official, will qualify as an official paper immunization record.

(4) A printed report as identified in preceding paragraph 2-7a(3) will suffice as a valid certificate of vaccination for international travel (except for yellow fever which is documented on the CDC Form 731) for active duty members of the Armed Forces as outlined in Article 36 (Annex 6) of the World Health Organization (WHO) International Health Regulations.

### b. *Non-electronic immunization and chemoprophylaxis records.*

(1) *Deployment records.* Transfer information regarding immunizations and chemoprophylaxis including date, product given, dose, and initials of person administering to the deployable health record (DD Form 2766) or comparable approved form, either by computer-generated report or by hand. Upon return from deployment, transfer entries on the deployment record into the appropriate ITS or other electronic record system.

(2) *Abbreviations.* Use abbreviations for vaccines and their manufacturers conforming to the nomenclature adopted by the CDC Vaccine Identification Standards Initiative. When annotating the date a vaccine is administered, the day, month, and year are listed in that order. The day is expressed in Arabic numerals, the month spelled out or abbreviated using the first three letters of the word, and the year expressed in Arabic numerals either by four digits or by the last two digits (for example, 14 June 1994 or 14 Jun 94).

(3) *Transcribed records.* Entries based on prior official records will include the following statement: “Transcribed from official records.” Alternately, the statement may cite the specific source (for example, “Transcribed from SF 601”). When entries are transcribed onto paper records, include the initials of the transcriber on each entry.

(4) *SF 601 (Navy, Marine Corps, and U.S. Coast Guard).* Prepare SF 601 in accordance with this directive and chapter 16 of NAVMED P-117.

(5) *DD Form 2766C.* Initiate DD Form 2766C for all personnel at the time of entry into Military Service.

(6) *Paper-based immunization and chemoprophylaxis records.* Individuals preparing paper-based immunization and chemoprophylaxis records will ensure that paper records match the electronic ITS. If paper-based immunization or chemoprophylaxis records are used, electronic ITS will be updated within 24 hours.

(7) *CDC Form 731.* Required for yellow fever documentation and or prepared upon request for each member of the Armed Forces and for nonmilitary personnel receiving immunizations, including date, immunization given, dose, and the initials of the person administering the vaccine. The form contains valid certificates of immunization for international travel and quarantine purposes in accordance with WHO international health regulations. CDC Form 731 remains in the custody of the individual who is responsible for its safekeeping and for keeping it in his or her possession when traveling internationally. Data are entered by hand, rubber stamp, or by typewriter.

(a) *Supply.* CDC Form 731 is obtained through normal publication supply channels.

(b) *Stamps.* Use in accordance with instructions received from the Division of Global Migration and Quarantine; the appropriate surgeon general; Chief, Bureau of Medicine and Surgery; or CG-11.

1. *Army.* USAHRC (AHRC-PDR), 1600 Spear Head Division Avenue, Fort Knox, KY 40122.

2. *Navy.* Bureau of Medicine and Surgery (BUMED), Washington, DC 20372.

3. *Air Force.* HQ AFPC/DPMDB, Randolph AFB, TX 78148.

4. *Marine Corps*. Headquarters, U.S. Marine Corps, Washington, DC 20380.

5. *Coast Guard*. Commandant, CG-11, USCG Headquarters, 2100 Second Street SW, Washington, DC 20593-0001.

(c) *Written signatures*. Written signatures must appear in appropriate spaces on each certificate; signature stamps are not valid.

c. *Lost immunization records*. If an individual's immunization records are lost, assume the individual received standard immunizations administered at entry into Military Service by the individual's accession source (for example, enlisted, Service academy, direct commission) unless there is an objective reason to believe otherwise. Do not repeat such immunizations. Base decisions for future immunizations on assumed date of last immunization (for example, individual assumed to have received tetanus-diphtheria toxoid in July 1995 would next be immunized in July 2005).

d. *National Vaccine Injury Compensation Program*.

(1) The statute 42 USC 300aa-1 to 300aa-34 (The National Childhood Vaccine Injury Act of 1986) and other regulations set standards for certain immunizations. These requirements apply to U.S. vaccines as indicated by the CDC after the DHHS Secretary publishes a notice of coverage. Document the patient's name; identifying number (for example, sponsor's SSN); type of vaccine; date of administration; manufacturer; lot number; and the name, address, and title of person administering the vaccine in a permanent health record or permanent office log or file, in either paper or electronic format. The electronic immunization tracking systems are the primary method of immunization documentation. Other records and management reports may be generated from the electronic immunization database, as described above.

(2) Personnel who administer any vaccine covered under the NVIC program, to either children or adults, will provide a written copy of the VIS to the vaccinee and allow sufficient opportunity to read the most recent VISs provided by the DHHS and an opportunity to ask questions about the vaccine. Copies of VISs are available through the CDC Web site (<http://www.cdc.gov/vaccines>). The VIS should be supplemented with an oral explanation or video presentation, or in the appropriate language, when the patient or guardian does not appear to be literate in English. Provide printed copies to any individual who requests one. Translations of VISs into languages other than English are available from nongovernmental organizations.

(3) Personnel who administer vaccines are not required to obtain the signature of the military member, patient, or legal representative acknowledging receipt of a VIS. However, to create a record that the materials were provided, health care personnel who administer vaccines will annotate each patient's health record that the VISs were provided at the time of immunization.

(4) The statute 42 USC 300aa-1 to 300aa-34 (The National Childhood Vaccine Injury Act of 1986), requires that the following events be reported to VAERS, a public health activity administered by the FDA and CDC:

(a) Any event listed in the NVIC program's vaccine injury table (at <http://www.hrsa.gov/vaccinecompensation/table.htm>) occurring within the time period specified.

(b) Any contraindicating event listed in a vaccine's package insert (product labeling).

(5) The VAERS accepts all reports by any interested party of real or suspected adverse events occurring after the administration of any vaccine.

(6) All DOD and USCG health care beneficiaries are eligible to file claims with the NVIC program, according to the program's procedures.

## **2-8. Jet-injection immunization devices**

These devices must be used in accordance with FDA-approved manufacturer's recommendations. Only vaccines with FDA approval for jet injectors use may be used in these devices.

## **2-9. Emergency response requirements**

a. *Written plan*. Clinics or activities administering immunizations will develop and maintain a written plan for emergency response, including standing orders for the management of anaphylaxis and fainting.

b. *Training*. Whenever vaccines are administered, at least one person present must be trained and current in basic cardiopulmonary resuscitation, oropharyngeal airway management, and recognition and initial treatment of anaphylaxis with epinephrine.

c. *Anaphylaxis management*. For the medical management of an anaphylaxis event whenever vaccines are administered, the following must be immediately accessible on scene: stethoscope, blood pressure cuff (sphygmomanometer), minimum of three adult doses of epinephrine (1:1000), oral airway, bag valve mask or equipment to administer oxygen by positive pressure, and the equipment and ability to activate an emergency medical system. Other equipment and/or medications (for example, injectable antihistamines, corticosteroids, vasopressors, glucagon, albuterol, and IV fluids with administration sets), depending on the clinical setting and local policy, may be included beyond the minimum requirements listed above.

d. *Observation*. The ACIP general recommendations suggest that persons be observed for 15 to 20 minutes after

being immunized. Manufacturer's guidance must be followed when the manufacturer's package insert exceeds this requirement.

## **2-10. Adverse events**

*a.* Describe in the individual's health record a detailed account of adverse events after administering immunizing agents or other medications. Mandatory information consists of identification, lot number, and manufacturer of the vaccine or other medication; date of administration; name and location of the medical facility; the type and severity of the event; treatment provided; and any exemption from additional doses. Consultation through MILVAX's Vaccine Healthcare Centers network is available 24 hours a day, 7 days a week, for providers who require additional support for clinical evaluation of possible vaccine adverse events.

*b.* Health care providers will report adverse events involving vaccines via the VAERS Web site <http://www.vaers.hhs.gov> or by faxing or mailing a VAERS-1 form. Obtain VAERS forms and information by calling 1-800-822-7967 or by accessing the VAERS Web site.

*c.* Health care providers will report adverse events involving chemoprophylaxis agents to MedWatch via the Web site at <http://www.fda.gov/Safety/MedWatch/default.htm> or on FDA Form 3500. MedWatch forms and information are available by calling 1-888-463-6332 or on the MedWatch Web site.

*d.* Reporting requirements are as follows:

(1) Report adverse events resulting in hospitalization, a life-threatening event (for example, anaphylaxis), time lost from duty more than one duty shift, or an event related to suspected contamination of a vaccine vial. Reports are also required for all events listed on the VAERS Table of Reportable Events Following Vaccination (available at <http://vaers.hhs.gov/resources/vaersmaterialspublications>).

(2) Further, health care providers are encouraged to report other adverse events considered unexpected in nature or severity.

(3) Reports of mild expected reactions are not required (for example, low-grade, self-limited fever of less than 24 hours duration, temporary local soreness, redness, or minor swelling at the site of immunization), but such reports may be submitted if the clinician or patient wishes.

*e.* Patients may also submit a VAERS or MedWatch report directly. If a patient wishes to submit a VAERS report, health care personnel will assist the patient in completing the form, regardless of professional judgment about causal association to immunization.

*f.* Record pertinent information from the recipient's health record on the VAERS or MedWatch report. Submit copies of the report within 7 days of adverse event recognition as follows:

(1) Send the original report form to the VAERS or MedWatch office.

(2) File a copy of the VAERS or MedWatch report in the patient's individual health record or annotate the relevant information on the report within the health record.

*g.* Immediately notify USAMMA or the vaccine manufacturer if contamination or other serious problem with a vaccine vial or lot is suspected. Suspend usage, but quarantine and retain all such opened or unopened vials or lots under appropriate storage conditions pending further investigation and disposition instructions.

*h.* An adverse reaction to a DOD-directed immunization in Service personnel is a line-of-duty condition.

(1) Medical treatment facility (MTF) commanders will provide full access to reserve component (National Guard and Reserve) members for evaluation and treatment of adverse events potentially related to DOD-directed immunizations.

(2) Reserve component (National Guard and Reserve) unit commanders will inform their members that they may seek medical care for such adverse events, with the unit providing assistance and information related to pay status and compensation issues. Any necessary documentation, including line-of-duty determinations, will be completed after the Reserve component Servicemember is evaluated and, if required, treated. In no case will such evaluation or treatment be denied or delayed pending line-of-duty determination. If additional health care is required after the initial visit and a line-of-duty determination has established a Service connection, a notice of eligibility must be completed in accordance with DODD 1241.01.

(3) DOD will provide an immunization health care capability to deliver medical specialty consultation, case management, and clinical investigation.

## **2-11. Program evaluation**

MTF facilities and commands storing service treatment records will review immunization and chemoprophylaxis practices at least annually to ensure compliance with current standards of care and documentation and as a measure of medical readiness and health promotion. Program evaluation includes internal and external assessments of the standards for military immunization (see app B). Program evaluation is focused at the clinic level, regardless of Service, to include both fixed facilities and field units. The Continuous Quality Immunization Improvement Process Tool is one of several tools available to assist with program evaluation and is described at <http://www.vaccines.mil/cqiip>. MILVAX



can assist with guidance and implementation of the Continuous Quality Immunization Improvement Process Tool. Other tools may be available depending on the Service.

## 2–12. Blood donation

For timing of immunization with regard to blood donations, clinicians will consider the policies of the Armed Services Blood Program Office (<http://www.militaryblood.DOD.mil>) and the specific Service Blood Program Offices. In some situations, such as accession sites where blood donations are scheduled, regularly coordinate the administration of live vaccine immunizations after scheduled blood donation activities, when possible.

## Chapter 3 Personnel Subject to Immunization

### 3–1. Military accessions

*a. Military accessions.* Accessions include Service personnel in enlisted initial entry training, Reserve Officers Training Corps (ROTC), Officer Candidate School, academy preparatory school, Service academy, Officer Indoctrination School, other officer accession programs, and officers who are directly commissioned.

(1) When determining the immunization needs of accessions, give credit for immunizations appropriately documented earlier in life (for example, data from electronic immunization registries maintained by State health departments).

(2) Immunize if the primary series is incomplete, if a booster immunization is needed, or if the Service personnel has no serologic or documented evidence of immunity. Complete multiple-dose immunization series according to the recommended schedule as soon as possible.

(3) Before immunizing, conduct serologic testing where available. At a minimum, conduct serologic testing for antibodies for measles, rubella, hepatitis A, hepatitis B, and varicella. Document medical exemptions for immunity (MI) in Service ITS. Documented medical exemptions for immunity will be accepted as evidence of immunity in lieu of vaccination.

(4) Except in an outbreak setting or for individual clinical purposes, immunization records will not be screened after completion of initial training with regard to measles, mumps, and rubella (MMR), poliovirus, or varicella vaccines.

(5) Document immunizations and immunization exemption codes (medical or administrative) in a DOD-approved Service ITS.

*b. Enlisted accessions.* Enlisted accessions may be scheduled for immunizations in two or more clusters, as long as all appropriate immunizations are administered or seroimmunity is determined. Pregnancy screening or testing for female accessions must be verified prior to administration of any live virus vaccines.

(1) *First cluster.* The first cluster of immunizations is administered, if susceptible, before or at the beginning of collective training (initial entry training, basic military training) to protect against pathogens that represent an imminent risk of contagious disease in settings of close contact: adenovirus; influenza; meningococcal; MMR; tetanus-diphtheria-pertussis; and varicella. Pneumococcal vaccine may be administered if warranted epidemiologically. Ensure live virus vaccines are given on the same day or at least 28 days apart (see ACIP guidelines for exceptions).

(2) *Second cluster.* The second cluster of immunizations may be administered, if susceptible, in the first or second half of basic military training, during advanced individual training, or upon arriving at the first duty station to protect against travel and other military risks. These immunizations include hepatitis A, hepatitis B, influenza (if not administered in first cluster), and poliovirus. Live virus immunizations follow at least 28 days after earlier live virus immunizations (see ACIP guidelines for exceptions).

*c. Reserve Officers' Training Corps cadets and midshipmen.* ROTC cadets and midshipmen and similar officer candidates who are ordered or called to active duty or active duty for training will require immunizations. Cadets and midshipmen may be scheduled for immunizations in two or more clusters:

(1) *First cluster.* Assess immunization or immunity status and administer immunizations, if susceptible, before or at the beginning of collective training to protect against pathogens that represent an imminent risk of contagious disease in settings of close contact. These immunizations include: influenza; meningococcal; MMR; tetanus-diphtheria-pertussis; and varicella. Ensure live virus vaccines are given on the same day or at least 28 days apart (see ACIP guidelines for exceptions).

(2) *Second cluster.* The second cluster of immunizations may be administered, if susceptible, in the first or second half of collective training to protect against travel and other military risks. These immunizations include hepatitis A, hepatitis B, influenza (if not administered in first cluster), and poliovirus. Live virus immunizations follow at least 28 days after earlier live virus immunizations (see ACIP guidelines for exceptions). ROTC cadets or midshipmen who travel overseas as part of their training will receive immunizations according to geographic risk assessments.

*d. Service academy cadets and midshipmen.* Service academy cadets and midshipmen will require immunizations as follows:

(1) *First cluster.* Assess immunization or immunity status and administer immunizations, if susceptible, before or at the beginning of collective training to protect against pathogens that represent an imminent risk of contagious disease in settings of close contact. These immunizations include: influenza, meningococcal, MMR, tetanus-diphtheria-pertussis, and varicella. Ensure live virus vaccines are given on the same day or at least 28 days apart (see ACIP guidelines for exceptions).

(2) *Second cluster.* The second cluster of immunizations may be administered, if susceptible, in the first or second half of collective training to protect against travel and other military risks. These immunizations include hepatitis A, hepatitis B, influenza (if not administered in first cluster), and poliovirus. Live virus immunizations follow at least 28 days after earlier live virus immunizations (see ACIP guidelines for exceptions). Cadets and midshipmen who travel overseas as part of their training will receive immunizations according to geographic risk assessments.

*e. Entry-level officers.* Upon accession, screen commissioned and warrant officers for immunization or immunity status and vaccinate as required.

### **3-2. Military personnel**

*a. Active duty personnel.* Immunize active duty personnel in accordance with appendix D or as supplemented in official notices posted at the Military Vaccine Office Web site, <http://www.vaccines.mil>. During Military Service, active duty personnel will receive or be up-to-date on adult routine immunizations.

*b. Reserve component (National Guard and Reserve).* Immunize Reserve component Servicemembers in accordance with appendix D or as supplemented in Service-specific policies and notices posted at <http://www.vaccines.mil>. Reserve component Servicemembers receive the same immunizations as active duty personnel, but must be in a duty status to receive required immunizations.

*c. Aviation personnel.* Typically, aviation personnel are grounded for 12 hours (Air Force: access to medical care 4 hours post vaccination unless operational needs dictate otherwise; Navy: refer to “Aeromedical Reference and Waiver Guide” (ARWG) for vaccine specific information) after immunization, or as specified by their flight surgeon. No formal grounding documents are required for uncomplicated immunization. Personnel who previously experienced urticaria, hypersensitivity phenomena, or other unusual phenomena after an immunization are restricted from flying duty for an appropriate interval (for example, 72 hours) as determined by the flight surgeon. Additional temporary grounding may be necessary until significant side effects resolve.

*d. Occupational risk.* Military members at occupational risk for specific disease threats will receive appropriate vaccines per appendix D or as supplemented in Service-specific policies posted at <http://www.vaccines.mil>. Immunize special populations at occupational risk for vaccine-preventable diseases not listed in appendix D per Service, Federal, State, or local occupational medicine guidance.

*e. Geographic travel requirements.*

(1) Each Service’s preventive medicine authority maintains current health threat assessments based on disease prevalence in specific geographical regions using Federal, DOD, USCG, and other relevant sources of information. These assessments are disseminated to units within their respective jurisdictions. Special Operations may determine additional area-specific immunization requirements.

(2) Installations and deployed units report disease occurrence through appropriate unit and/or medical lines of communication.

(3) Combatant commanders, in coordination with the appropriate surgeons general or CG-11, establish specific immunization requirements based on a disease threat assessment. These requirements may differ from standard Service immunization policies for personnel entering their area of responsibility to participate in exercises or other operational missions. Immunize personnel on official deployment or travel orders in accordance with the specific guidance established by the combatant commander before departure.

(4) For short notice travel or deployments requiring vaccines given in a multi-dose series, administer the first dose of the basic series. Administer as many of the subsequent doses as time permits. Completion before departure is the goal. If the series cannot be completed before departure, complete it upon arrival. Inform the patient that in order to obtain optimal immunity, the series must be completed by receiving all the required doses at the recommended intervals.

(5) For quarantine, entry, and reentry requirements, follow the provisions of the CDC, Division of Global Migration and Quarantine regulations concerning entry or reentry of military and nonmilitary personnel into the United States or its commonwealths, territories, and possessions.

*f. Other uniformed Service personnel.* Members of other uniformed Services are authorized immunizations according to their occupation, official duties, travel plans, health status, or other relevant factors.

### **3-3. Certain civilian employees**

*a. Federal civilian employees.*

(1) *General.* Federal civilian employees will receive country-specific immunizations without charge at military activities upon presentation of official orders or authorization. Area preventive medicine authorities are consulted for recommendations applicable to specific areas. People declining immunizations required for entry into foreign countries

are referred to the appropriate authority for counseling. Document counseling in the health record and note that omission of certain immunizations may have consequences under host country policies, which could include compulsory immunization, detention, quarantine, or denial of entry.

(2) *Civilian employees at occupational risk for vaccine-preventable disease.* Federal civilian employees who are at risk of exposure to an infectious disease associated with their occupation may receive appropriate immunizations, without charge, at military activities. Administer immunizations upon recommendation of the responsible occupational medicine authority.

(3) *Civilian health care employees.* Susceptible or occupationally exposed health care employees (including volunteers) who are at risk of exposure to an infectious disease (for example, influenza) associated with their occupation may receive appropriate immunizations, without charge, at military activities. This policy applies to all health care settings, regardless of age or sex of the health care employee. Employees, including volunteers, who have contact with or potential exposure to human blood or blood products (whether from patient care, laboratory, or other health care settings) are provided hepatitis B virus vaccine in accordance with the local bloodborne pathogen exposure-control plan. Refer to the Occupational Safety and Health Administration standards (29 CFR 1910.1030) for additional information. Immunizations or immune status may be a condition of employment.

(4) *Employees with potential occupational exposure to wastewater or sewage.* Employees at occupational risk of exposure to wastewater or sewage will receive tetanus-diphtheria toxoids (preferably with pertussis vaccine) per ACIP recommendations. Other vaccines are not routinely required based solely on occupational exposure for wastewater treatment system workers, including sewage generated by medical facilities.

(5) *Individuals immunized per categories above.* Individuals immunized per the civilian personnel categories above are authorized treatment and necessary medical care related to adverse events after immunization, consistent with applicable occupational health program requirements.

*b. Civilian Expeditionary Workforce.* Civilian employees and others in the Civilian Expeditionary Workforce may receive, without charge, appropriate immunizations at military activities. In accordance with DODD 1404.10, components should ensure emergency-essential and non-combat essential employees are aware of potential deployment immunizations as a condition of employment. Components should also ensure the employee completes and signs a record of notification with a signed DD Form 2365 (DOD Civilian Employee Overseas Emergency-Essential Position Agreement). Applicable vacancy announcements and position descriptions will note obligations to receive immunizations. Emergency-essential and non-combat essential employees have the same access as military personnel to treatment and necessary medical care related to adverse events after immunization, consistent with applicable occupational health program requirements.

*c. Bargaining units.* For Federal employees in a bargaining unit, local management must meet applicable labor relations obligations before implementing any changes to the bargaining unit employees' conditions of employment. Civilian personnel advisory centers provide guidance on these matters.

*d. Biological warfare defense.* Immunization of civilian employees and contracted workers for biological warfare defense are addressed in DODI 6205.4.

*e. Emergency situations.* In emergency situations, the provisions of DODD 6200.03 apply.

### **3–4. Contracted workers**

*a.* Provide immunizations to contracted workers according to the terms of the contract and as stated in the contract agreement. If the contract does not provide for provision of immunizations by the government, contractors are responsible for providing appropriate immunizations to their employees. For vaccines with limited distribution (for example, anthrax, smallpox), DOD or USCG may provide the immunizations, regardless of the terms of the contract. The contractor is responsible for work-related illnesses, injuries, or disabilities under worker-compensation programs, supplemented by existing Secretarial designee authority.

*b.* Contracted health care workers are eligible for immunizations required or offered to health care employees and are provided as stated in the contract agreement. Contracts will include specifications describing immunizations required of contracted health care workers.

*c.* Family members of contracted workers in foreign-duty settings under military sponsorship will receive country-specific immunizations without charge at military activities upon presentation of official orders or authorization. People declining immunizations required for entry into foreign countries are referred to the appropriate authority for counseling. Document counseling in the health record and note that omission of certain immunizations may subject them to adverse action according to host country policies, which could include compulsory immunization, detention, quarantine, or denial of entry.

### **3–5. Department of Defense, U.S. Coast Guard schools, childcare centers and youth programs**

*a.* As a condition of employment, schoolteachers, childcare center workers, youth program workers, and volunteers are administered appropriate vaccines against communicable diseases in accordance with ACIP adult immunization schedule recommendations, unless already immune, based on seroimmunity, physician diagnosed illness, or documented proof of immunization.

*b. Children attending DOD and USCG-sponsored primary and secondary schools, childcare centers, or similar facilities are required to be up to date on all age appropriate ACIP-recommended vaccines for children unless there is documentation of previous immunization, religious exemption, or medical contraindication. For foreign-national children outside the United States, observe host country recommendations or requirements.*

### **3-6. Other populations**

*a. Department of Defense and U.S. Coast Guard beneficiaries.*

(1) *Family members of military personnel.* Family members receive immunizations according to current ACIP recommendations. In addition, Family members may be subject to Service-specific requirements and recommendations for immunizations applicable to the country in which they will reside while accompanying military members under military sponsorship.

(2) Family members or sponsored individuals of other Federal civilian employees in foreign-duty settings under military sponsorship. These Family members will receive country-specific immunizations without charge at military activities upon presentation of official orders or authorization. People declining immunizations required for entry into foreign countries are referred to the appropriate authority for counseling. Document counseling in the health record and note that omission of certain immunizations may have consequences under host country policies, which could include compulsory immunization, detention, quarantine, or denial of entry.

*b. Foreign nationals.* Foreign nationals who come to the United States, its territories, commonwealths, or possessions under Armed Forces sponsorship receive immunizations required for entry into the United States and by local jurisdictions. When returning to their country of origin, foreign nationals receive immunizations required by international health regulations or their country of origin. These immunizations are administered without charge at military activities upon presentation of official orders or authorization.

*c. Detainees.* The installation or activity commander, upon the recommendation of the appropriate medical authority, will provide immunizations against diseases that may be a significant cause of death or illness among detainees. Such immunizations are voluntary and are administered without charge to the detainee. Annotate all immunizations and chemoprophylactic medications in the detainee's health record. Before immunization, inform detainees in their own language about the relative benefits and risks of the specific immunizations offered. Factors to consider in deciding which immunizations to offer detainees include their likely preexisting immunity, the anticipated length of detention, seasonal threat of infection, and other risk factors related to personal health status and living conditions. (Refer to DODI 2310.08E for additional guidance.)

*d. Overseas commander authority.* The overseas commander, commanding officer, or officer-in-charge, upon the recommendation of the appropriate medical authority, will provide immunizations against communicable diseases judged to be a potential hazard to the health of the command; such vaccines are administered without charge.

*e. Other than U.S. Forces.* Immunization of other than U.S. Forces for biological warfare defense are addressed in DODI 6205.4.

*f. Emergency situations.* In emergency situations, the provisions of DODD 6200.03 apply.

## **Chapter 4**

### **Specific Immunization Requirements for Department of Defense and U.S. Coast Guard Personnel**

(Also see appendix D for a chart on the required immunizations for military personnel.)

#### **4-1. Civilian applicability**

Certain civilian employees may be required to receive immunizations as a condition of their employment or participation in a particular assignment. In such cases, failure to voluntarily receive the immunizations may result in a personnel action being taken (see chap 3), but in no case will immunizations be involuntarily administered.

#### **4-2. Adenovirus types 4 and 7**

*a. Military indication.* To prevent adenovirus infection, an acute febrile respiratory disease caused by adenovirus serotypes 4 and 7. Direct contact and fecal oral transmission of the virus may result in a respiratory disease infection or outbreak of disease among an unvaccinated recruit population.

*b. Basic trainees.* Administer adenovirus vaccine to military enlisted basic trainees before or at the beginning of collective training at the same time the first live virus vaccines are administered. Routine administration in other populations is not generally recommended except when directed by preventive medicine guidance, based on disease incidence and severity.

#### **4-3. Anthrax**

*a. Military indication.* To prevent anthrax, an acute infectious disease caused by the spore forming bacterium

*Bacillus anthracis*. Direct exposure to anthrax spores may result in cutaneous, gastrointestinal, or inhalational infection. *Bacillus anthracis* has been identified as a potential biological warfare agent.

*b. Military and civilian personnel.* Administer anthrax vaccine to military personnel and applicable civilians according to DOD or USCG policy for the Anthrax Vaccine Immunization Program and Service-specific implementation plans. Immunize personnel based on geographical areas at higher risk for release of anthrax as a weapon or in occupational roles as designated by the Services, Chairman of the Joint Chiefs, or the Office of the Secretary of Defense.

*c. Occupational risk.* Administer anthrax vaccine to at-risk veterinary and laboratory workers and others at occupational risk of exposure.

#### **4-4. Haemophilus influenzae serotype b, commonly called Hib**

*a. Military indication.* To prevent invasive Haemophilus influenza disease and infection of many organ systems caused by the bacterium *Haemophilus influenzae* serotype b (Hib). The disease is transmitted via respiratory droplets. The most common types of invasive Hib disease are: meningitis, epiglottitis, pneumonia, arthritis, and cellulitis.

*b. Military and civilian personnel.* Administer Hib vaccine to those who are immunocompromised, have sickle cell disease, or do not have a spleen or a functioning spleen.

#### **4-5. Hepatitis A**

*a. Military indication.* To prevent hepatitis A, an acute infection of the liver that is acquired by consuming food or water contaminated with hepatitis A virus, particularly during deployment or travel to areas with poor food, water, and sewage sanitation. It can range in severity from a mild illness lasting a few weeks to a severe illness lasting several months. Hepatitis A infections occur worldwide.

*b. Basic trainees and other accessions.* Unless seroimmune, administer hepatitis A vaccine to trainees and accessions during initial entry training.

*c. Military and civilian personnel.* Unless seroimmune, or evidence of appropriate complete vaccination, administer hepatitis A vaccine to all military personnel, and civilian personnel when indicated.

*d. Occupational risk.* Hepatitis A vaccine is indicated per ACIP guidelines and locally designated food handlers.

#### **4-6. Hepatitis B**

*a. Military indication.* To prevent hepatitis B, an acute or potentially chronic infection of the liver that is acquired through percutaneous, sexual, and other mucosal exposure to blood and body fluids from people infected with hepatitis B virus. Chronic infections may result in cirrhosis or cancer of the liver. Hepatitis B infections occur worldwide, and some infected people maintain a chronic carrier state.

*b. Basic trainees and other accessions.* Unless seroimmune, administer hepatitis B vaccine to basic trainees and accessions during initial entry training.

*c. Military and civilian personnel.* Unless seroimmune, or evidence of appropriate complete vaccination, administer hepatitis B vaccine to all military personnel, and civilian personnel, when indicated.

*d. Occupational risk.* Administer hepatitis B vaccine to susceptible personnel who are at risk of potential exposure to bloodborne pathogens per the Occupational Safety and Health Administration standards (29 CFR 1910.1030). For military purposes, this includes occupational specialties involving health care workers, emergency medical technicians, mortuary affairs personnel, search and rescue specialists, correctional facility staff, and designated special operations forces.

*e. Serologic testing.* Conduct serologic testing of health care workers who have direct contact with patients and those who have potential occupational risk for exposure to bloodborne pathogens 1 to 2 months after completion of the hepatitis B vaccine series to determine serologic response according to CDC and ACIP recommendations.

#### **4-7. Influenza**

*a. Military indication.* To prevent influenza, an acute febrile respiratory viral infection that can cause epidemics within military populations, especially under conditions of crowding, such as initial entry training, aboard ships, extended air transport, or deployment settings. Influenza has the potential for widespread transmission through person-to-person contact and fomites.

*b. Military personnel.* Administer influenza vaccine(s) annually or as indicated to all active duty, Reserve, and National Guard personnel.

*c. Occupational risk.* Administer influenza vaccine(s) annually or as indicated to personnel who work or volunteer in DOD MTFs.

#### **4-8. Japanese encephalitis**

*a. Military indication.* To prevent Japanese encephalitis, a mosquito-borne viral disease, during deployments and travel to endemic areas in Eastern Asia and certain western Pacific Islands. Japanese encephalitis virus (JEV) can cause

an acute infection of the brain, spinal cord, and meninges with high rates of complications, chronic disability, and death.

*b. Military and civilian personnel.* Administer the JEV vaccine to military personnel and civilian personnel who have a substantial risk of exposure to the virus based on their geographic location.

*c. Temporary flying restrictions.* Impose temporary flying restrictions post-JEV immunization for aircrew personnel per Service-specific policy.

#### **4–9. Measles, mumps, and rubella (MMR)**

*a. Military indication.* To prevent MMR, primarily by boosting immunity acquired from childhood immunization. These three acute viral infections are spread by the respiratory route or person-to-person contact. In military trainee populations, each can cause disease outbreaks. Rubella usually causes a mild infection, but infection during the first trimester of pregnancy puts the fetus at high risk of congenital rubella syndrome and birth defects. Young adults may experience more severe complications from mumps infection. All three diseases occur worldwide, primarily among children.

*b. Basic trainees and other accessions.* Unless seroimmune to both measles and rubella, administer MMR vaccine to susceptible basic trainees and accessions within the first 2 weeks of training.

*c. Military and civilian personnel.* Presume immunity through infection for persons born in 1957 or earlier. Ensure personnel born after 1957 have received two lifetime doses of MMR vaccine or have positive serologic test results. Immunity against mumps is not necessary as a military requirement, but may be appropriate in exceptional clinical circumstances such as outbreaks.

*d. Occupational risk.* Ensure health care workers have received two documented doses of MMR vaccine or have positive serologic test results.

#### **4–10. Meningococcal**

*a. Military indication.* To prevent meningococcal disease or meningitis and other systemic infections caused by the bacteria *Neisseria meningitidis* serogroups A, C, W–135, and Y. No vaccine against serogroup B meningococcus, another common pathogen, is currently licensed in the United States. Basic trainees and other military populations living in crowded conditions are at an increased risk for meningococcal infection. Historically, outbreaks have occurred in training populations. Meningococcal vaccine may be indicated for deployment and travel to areas with highly endemic meningococcal disease.

*b. Basic trainees and other accessions.* Administer meningococcal vaccine to basic trainees, cadets, and midshipmen at Service academies within the first 2 weeks of training, if no evidence of vaccination within the last 5 years.

*c. Military and civilian personnel.* Administer meningococcal vaccine to personnel traveling to countries in which *N. meningitidis* is hyperendemic or epidemic and other countries as required by DOD and USCG policy or recommended by the CDC.

*d. Alert personnel.* Administer meningococcal vaccine to personnel who are designated to deploy within 10 days of notification.

*e. Other personnel.* Administer one dose of meningococcal vaccine to persons who do not have spleens or functional spleens.

#### **4–11. Pertussis**

Tetanus, diphtheria, and pertussis guidance is in paragraph 4–16.

#### **4–12. Pneumococcal**

*a. Military indication.* To prevent pneumococcal disease due to *Streptococcus pneumoniae* in personnel who fall into a high-risk category due to age or underlying health conditions (for example, persons who smoke, have asthma, or have no spleen) or who are in high-risk situations, such as certain training populations. *Streptococcus pneumoniae* may result in pneumonia, bacteremia, and meningitis.

*b. Basic trainees and other accessions.* Routine administration of vaccine is not generally practiced, but may be directed by preventive medicine guidance, based on disease incidence and severity.

*c. Military personnel.* Administer pneumococcal vaccine to military personnel who are in a high-risk category per ACIP recommendations. Administer a second dose to persons without spleens or severely immunocompromised five years after the initial dose.

#### **4–13. Poliomyelitis**

*a. Military indication.* To prevent poliomyelitis, a viral infection that affects the central nervous system resulting in paralytic symptoms, primarily by boosting immunity acquired from childhood immunization. Poliomyelitis is acquired by person-to-person transmission through the fecal-oral route. Military and civilian personnel deploying or traveling to areas with poor sanitation are at increased risk, although international immunization efforts have decreased poliomyelitis incidence worldwide. Only inactivated poliovirus vaccine (IPV) is available in the US.

*b. Basic trainees and other accessions.* Administer a single booster dose of IPV to basic trainees and accessions. Personnel who have not received the primary series must complete the series using IPV. Unless there is reason to suspect otherwise (for example, childhood spent in a developing country, childhood immunizations not administered), receipt of the primary series of IPV may be assumed.

*c. Military personnel.* Because of the high level of childhood immunization against this disease, do not screen immunization records with regard to poliovirus immunity after completion of initial entry training except in an outbreak setting or for individual clinical purposes.

#### 4–14. Rabies

*a. Military indication.* To prevent rabies, a life threatening viral disease caused by exposure to the saliva of animals or humans infected with the rabies virus, which includes bites.

(1) *Pre-exposure prophylactic immunization.* A pre-exposure immunization series may be indicated for people with potential occupational risk of exposure to rabid animals, or for forces assigned to locations where access to definitive care likely exceeds 24 hours. Pre-exposure prophylaxis should not be considered sufficient for the prevention of rabies; however, it reduces the need for human rabies immune globulin-better known as HRIG-and reduces the number of shots required for post-exposure prophylaxis.

(2) *Post-exposure prophylaxis.* Consult with a preventive medicine physician and veterinarian for guidance and to report the animal exposure. Post-exposure treatment includes immediate wound care, and may include the post-exposure vaccine series, and human rabies immune globulin in an unvaccinated patient. Post-exposure prophylaxis is safe and effective.

*b. Military personnel.* Administer pre-exposure rabies vaccine series to special operations personnel, including designated special operations enablers and the occupational risk groups listed below, in accordance with Service policy.

*c. Occupational risk.* Administer pre-exposure rabies vaccine series to veterinary workers, animal handlers, certain laboratory workers, and personnel who have animal control duties and personnel assigned long-term to regions with endemic rabies. Give booster doses every 2 years or when antibody concentrations indicate.

#### 4–15. Smallpox

*a. Military indication.* To prevent smallpox disease due to the deliberate release or spread of the smallpox virus. In 1980, the WHO declared the global eradication of naturally occurring smallpox. Nonetheless, stocks of variola virus, the causative agent of smallpox, could be used as a biological warfare agent.

*b. Military and civilian personnel.* Vaccinate designated military and civilian personnel according to DOD and other designed personnel in accordance with USCG policy and Service-specific implementation plans. These include military personnel and applicable civilians who are smallpox epidemic response team members, assigned to medical teams at hospitals and clinics, or assigned to designated forces that constitute mission-critical capabilities. Immunize personnel based on geographical areas at higher risk for release of smallpox as a weapon or in occupational roles as designated by the Services, Chairman of the Joint Chiefs, or the Office of the Secretary of Defense.

*c. Training and education.* Before administering smallpox vaccine to military or civilian personnel who are eligible to receive smallpox vaccine, provide education on the criteria for exemption from immunization, expected response at the vaccination site, vaccination-site care, risks of spreading vaccinia to close contacts, adverse events following immunizations (AEFI) such as myopericarditis, and other relevant topics per Service implementation plans.

*d. Screening.* Use the DOD-specific screening form posted at <http://www.vaccines.mil> to identify persons with personal or household contraindications to smallpox vaccination (for example heart conditions, immunosuppressed conditions, pregnancy, skin conditions such as eczema and atopic dermatitis). Screening will include assessing pregnancy status and recency of testing for human immunodeficiency virus infection. In the event of a smallpox outbreak, “permanent” exemptions may be rescinded according to individual risk of exposure to variola virus.

*e. Vaccination.* Internal MTF and command clinical quality management programs will have mechanisms to confirm that vaccinators demonstrate proper vaccination technique.

*f. Post-vaccination site care.* Take appropriate care to prevent the spread of vaccinia virus from a vaccinee’s vaccination site. MTFs will monitor the vaccination sites of vaccinated health care workers (for example, operating site-care stations), promote effective bandaging, and encourage scrupulous hand washing.

*g. Post-vaccination evaluation (“take” check).* Assessment and documentation of response (a “take”) to vaccination is required for health care workers and members of smallpox response teams who would travel into a smallpox outbreak area. Evaluate and record the vaccination response of individuals receiving smallpox vaccine in a DOD and USCG-approved electronic ITS.

#### 4–16. Tetanus, diphtheria, and pertussis

*a. Military indication.* To prevent tetanus, diphtheria, and pertussis, primarily by boosting immunity acquired from childhood immunization.

(1) Tetanus is an acute disease of the nervous system caused by the serotoxin produced by *Clostridium tetani*. The *C. tetani* spores enter the body through breaks in the skin, and the bacterium then grows at the wound site. A tetanus

infection results in generalized rigidity and convulsive spasms of the skeletal muscles. The *C. tetani* spores occur in the environment worldwide.

(2) Diphtheria is an acute disease caused by a cytotoxin of the bacteria *Corynebacterium diphtheriae*. *C. diphtheriae* is transmitted person-to-person via respiratory droplets and direct contact. Diphtheria can lead to airway obstruction, and more severe complications may result from toxin absorption into organs and tissues. Diphtheria occurs worldwide.

(3) Pertussis is a highly communicable acute respiratory illness caused by the bacteria *Bordetella pertussis*. Pertussis is spread via direct contact with respiratory secretions. Pertussis occurs worldwide.

*b. Basic trainees and other accessions.* For those individuals lacking a reliable history of prior immunization, administer one dose of Tetanus-diphtheria and acellular pertussis (Tdap) vaccine according to ACIP guidelines. Unless there is reason to suspect otherwise (for example, childhood spent in a developing country, childhood immunizations not administered), receipt of the basic immunizing series may be assumed.

*c. Military and civilian personnel.* Administer booster doses of Tetanus-diphtheria (Td) to all personnel every 10 years following the completion of the primary three-dose series. A one-time dose of Tdap in place of a Td booster during adulthood is required, regardless of interval.

*d. All personnel.* Following ACIP wound-management guidelines for the treatment of contaminated wounds. Tdap is preferred to Td for adults vaccinated 5 years earlier who require a tetanus toxoid-containing vaccine as part of wound management and who have not previously received Tdap. For adults previously vaccinated with Tdap, Td should be used if a tetanus toxoid-containing vaccine is indicated for wound care.

#### 4–17. Typhoid fever

*a. Military indication.* To prevent typhoid fever, a systemic bacterial disease acquired by consuming food or water contaminated with *Salmonella typhi*, particularly during deployment or travel to typhoid-endemic areas and other areas with poor sanitation.

*b. Military and civilian personnel.* Administer typhoid vaccine before overseas deployment to typhoid-endemic areas.

*c. Alert personnel.* Administer typhoid vaccine to alert personnel, per Service policy, who are prepared for deployment to typhoid-endemic areas or who have potential risks of exposure to contaminated local food and drink. Administer booster doses per immunization schedule. For Air Force, only units specifically identified by the MAJCOM surgeon require initial and subsequent immunization against typhoid fever.

#### 4–18. Varicella

*a. Military indication.* To prevent varicella (chickenpox), a generally mild and self-limiting viral infection caused by the varicella zoster virus. Although varicella is a common childhood disease, adults may experience more severe illness and have higher complication and case-fatality rates. Adolescents and adults are at higher risk for severe disease complications such as secondary skin infections, neurologic disease, and multi-organ involvement. Varicella zoster virus is transmitted by respiratory secretions, direct contact, and aerosolization of the virus from skin lesions. Military members at higher risk for infection include basic trainees, cadets/midshipmen at Service academies, officer trainees, and special operations personnel, and others living in military environments conducive to person-to-person spread of respiratory diseases (for example, barracks, ships).

*b. Basic trainees and other accessions.* Administer varicella vaccine to susceptible trainees and other accessions within the first 2 weeks of initial entry training. Serologic screening of trainees is the preferred means of determining those susceptible to varicella infection and in need of immunization. Identify those people who do not have a personal history of varicella disease, documentation of two prior varicella immunizations, or documentation of immunity based on serologic testing as susceptible. Document positive results of serologic testing in a DOD-approved electronic ITS. Adults and adolescents require two doses of varicella vaccine given 4 to 8 weeks apart.

*c. Health care workers.* Administer varicella vaccine to susceptible health care workers. Determine susceptibility as noted above for trainees, birth before 1980 should not be considered evidence of immunity for health care workers. Routine post-immunization testing for antibodies to varicella is not recommended.

*d. Other susceptible adults.* Offer varicella vaccine to other susceptible persons, especially nonpregnant women of childbearing age and men living in households with young children.

#### 4–19. Yellow fever

*a. Military indication.* To prevent yellow fever disease, a viral infection that may result in severe systemic disease and organ failure. Yellow fever infection is transmitted via the bite of an infected mosquito. Documented vaccination status must be verified to meet international health requirements during deployment or travel to yellow-fever-endemic areas. Areas of greatest risk are sub-Saharan Africa and tropical South America.

*b. Military personnel.* Administer yellow fever vaccine to all Marine Corps accessions and military personnel traveling to or transiting through yellow-fever-endemic areas.

*c. Alert personnel.* Administer yellow fever vaccine to alert personnel prepared for deployment to yellow-fever-endemic areas. Administer booster doses per immunization schedule. For Air Force, only units specifically identified



by the MAJCOM surgeon require initial and subsequent immunization against yellow fever. For Navy, administer to those assigned to units subject to deployment within 10 days of notification into land areas where yellow fever is endemic.

*d. Civilian and other personnel.* Administer yellow fever vaccine to personnel traveling to, or transiting through, endemic areas.

## Chapter 5 Chemoprophylaxis

### 5-1. General

*a. Chemoprophylaxis.* This section does not relate to the treatment of diseases but provides a brief review of military relevant diseases and associated chemoprophylaxis guidelines. Chemoprophylaxis is defined here as the administration of medication before, during, or after possible exposure to an infectious agent, to prevent either infection or disease. Most agents used for chemoprophylaxis are not FDA-approved for this indication and thus may not be administered to units under a force health protection strategy or policy; rather, these agents must be prescribed to individuals and documented accordingly by an appropriate health care provider. Follow instructions from the relevant combatant command surgeon who will consult with the appropriate preventive medicine authority for the use of chemoprophylactic agents. Command medical officers will review indications for use and potential adverse effects of specific chemoprophylactic medications before use. These recommendations for drugs or agents are current as of the date of this publication. Consult current information and guidance for appropriate drugs and dosing regimens (for example the CDC, the ACIP, the National Center for Medical Intelligence (NCMI), and the American Public Health Association's "Control of Communicable Diseases Manual"). The following classes of chemoprophylaxis are not addressed in this publication:

(1) Chemical warfare-related chemoprophylaxis. Consult the current version of "Medical Management of Chemical Casualties," published by the U.S. Army Medical Research Institute of Chemical Defense.

(2) Medical therapy for tuberculosis infection. Consult publications from CDC, the American Thoracic Society, the Advisory Council for the Elimination of Tuberculosis, and similar authorities.

(3) Radiation-related chemoprophylaxis (for example, potassium iodide, granisetron, or Prussian blue).

(4) Other forms of prevention involving nonbiological medications (for example, calcium, aspirin, or vitamins).

(5) Immunotherapy.

*b. Packaging.* Dispense chemoprophylaxis agents to individuals in child-resistant containers, consistent with 15 USC 1471-1476 (The Poison Prevention Packaging Act), or unit-of-use packaging. Use appropriate packaging to keep the medication clean and dry.

*c. Labeling.* Dispense chemoprophylaxis agents to individuals in packages that contain the name of the product, directions for proper use, and the name of the person to whom the medication was dispensed.

### 5-2. Anthrax

*a. Military indication.* The use of antibiotics and immunoglobulin following a possible exposure to anthrax is locally-directed and is prescribed by preventive medicine based on risk. The use of antibiotics and immunoglobulin have been shown to increase survival when used after exposure to anthrax and before onset of symptoms (post-exposure prophylaxis or empiric treatment).

*b. Chemoprophylaxis.* Recommended drugs include ciprofloxacin and doxycycline. Refer to Service-specific policies. Anthrax immunoglobulin is available through the CDC's Emergency Operation Center.

### 5-3. Group A streptococcus

*a. Military indication.* Outbreaks of group A streptococci can spread rapidly in groups in settings of close contact, such basic training and contingency operations.

*b. Chemoprophylaxis.* The primary drug used for prophylaxis is penicillin, specifically the long-acting injectable form, penicillin G benzathine. Oral penicillin VK and azithromycin have also been used effectively. Administer penicillin prophylactically, when required, to terminate disease transmission. Routine administration of penicillin for prophylaxis of basic trainees against group A streptococcal infection has been shown to be effective at some installations with historically high incidence of disease. This practice should be directed by local preventive medicine authority.

### 5-4. Influenza

*a. Military indication.* Influenza can be a significant cause of morbidity in a susceptible population and can degrade mission capability.

*b. Chemoprophylaxis.* Consider prophylactic use of antiviral therapy if available vaccine does not antigenically

match circulating strains or if an outbreak occurs early in the season before widespread immunization. For additional guidance, refer to CDC.

#### **5–5. Leptospirosis**

- a. Military indication.* Leptospirosis can cause morbidity in personnel exposed to contaminated water sources.
- b. Chemoprophylaxis.* Doxycycline is effective in preventing leptospirosis in exposed military personnel during periods of high risk of exposure. Consult an infectious diseases or preventive medicine authority for proper use and dosing.

#### **5–6. Malaria**

- a. Military indication.* Malaria has caused morbidity and mortality in military populations for centuries. It continues to be one of the most important disease threats to military and civilian personnel deployed to areas where the disease is endemic.
- b. Chemoprophylaxis.* The Services or the combatant command surgeon determine specific chemoprophylactic regimens, typically with guidance from the NCMI, for the area of operations based on degree and length of exposure and the prevalence of drug resistant strains of *plasmodia* in the area(s) of travel. Prescribe anti-malarials per package insert. Health care providers will screen individuals for contraindications to specific malaria chemoprophylaxis (for example G6PD deficiency and primaquine) and determine the appropriate malaria chemoprophylaxis. Health care providers must document malaria chemoprophylaxis prescriptions in the health record when anti-malarial medications are prescribed. Include the member's electronic medication profile (for example, Composite Health Care System II), whenever possible.

#### **5–7. Meningococcal disease**

- a. Military indication.* Meningococcal disease can result in morbidity and potential mortality in populations experiencing crowded conditions. Chemoprophylaxis has been shown to prevent disease when administered post-exposure to susceptible people.
- b. Chemoprophylaxis.* There are several drugs available for prophylaxis of close contacts of meningococcal disease cases. Consult an infectious diseases or preventive medicine authority for determination of individuals to offer prophylaxis and for assistance with drug selection and dosing.

#### **5–8. Plague**

- a. Military indication.* Plague has been identified as a potential biological warfare agent, especially if aerosolized to cause pneumonic plague. There is no licensed vaccine that is effective against pneumonic plague. Provide chemoprophylaxis to persons potentially exposed to cases of pneumonic plague.
- b. Chemoprophylaxis.* Consult an infectious diseases or preventive medicine authority for determination of individuals to offer prophylaxis and for assistance with drug selection and dosing.

#### **5–9. Scrub typhus**

- a. Military indication.* Spread by the bite of infective larval mites. Mite bites may be a source of morbidity in populations encountering field conditions.
- b. Chemoprophylaxis.* Doxycycline has been shown to be effective in preventing scrub typhus in exposed personnel. Consult an infectious diseases or preventive medicine authority for proper use and dosing.

#### **5–10. Smallpox**

- a. Military indication.* Various forms of vaccinia infections may develop following receipt of the smallpox vaccine. Chemoprophylaxis may be indicated to prevent morbidity in immunized Servicemembers or their contacts.
- b. Chemoprophylaxis.* VIG and vaccinia-specific antivirals are available through the DOD. Contact MILVAX to request and coordinate administration of these chemoprophylactic agents.

#### **5–11. Traveler's diarrhea**

- a. Military indication.* Diarrhea can cause morbidity in personnel exposed to contaminated food and water sources.
- b. Chemoprophylaxis.* Chemoprophylaxis for traveler's diarrhea is only recommended on rare occasions where diarrhea would compromise a mission. Prophylactic antibiotics may be considered for short-term travelers who are high-risk hosts (such as those who are immunosuppressed) or those taking critical trips during which even a short bout of diarrhea could significantly impact the purpose of the trip. Instead of prophylaxis travelers, should be prescribed appropriate medications and provided instructions for self-treatment of diarrhea. Consult an infectious diseases or preventive medicine authority for assistance.

## **Chapter 6 Biological Warfare Defense**

### **6-1. Responsibilities**

*a.* The combatant commanders, annually and as required, provide the Chairman of the Joint Chiefs of Staff with their assessment of the biological warfare threats to their theaters.

*b.* The President of the Defense Health Board, in consultation with the Secretaries of the Military Departments, annually and as required, identifies to the Assistant Secretary of Defense (Health Affairs) (ASD (HA)) vaccines available to protect against validated biological warfare threat agents and recommends appropriate immunization protocols and/or chemoprophylaxis.

### **6-2. Procedures**

The DOD Immunization Program for Biological Warfare Defense is conducted as follows:

*a.* The combatant commanders, annually and as required, provide the Chairman of the Joint Chiefs of Staff with their assessment of the biological warfare threats to their theater.

*b.* The Chairman of the Joint Chiefs of Staff, in consultation with the combatant commanders; the chiefs of the Military Services; and the Director, Defense Intelligence Agency, annually validates and prioritizes the biological warfare threats to DOD personnel and forwards the threat list to the DOD Executive Agent through the ASD (HA).

*c.* Within 30 days of receiving the validated and prioritized biological warfare threat list from the Chairman of the Joint Chiefs of Staff, the DOD Executive Agent, in consultation with the Secretaries of the military departments and the President of the Defense Health Board, provides recommendations to the ASD (HA) on vaccines and immunization protocols necessary to enhance protection against validated biological warfare threat agents.

*d.* Within 30 days of receiving the coordinated recommendations of the DOD Executive Agent, the ASD (HA) directs the Secretaries of the military departments to begin immunization of the specified DOD and USCG personnel against specific biological warfare threat agents. The ASD (HA) will coordinate with and obtain approval from the Secretary or Deputy Secretary of Defense before issuing the appropriate direction.

*e.* The Secretaries of the military departments will program and budget for required vaccinations, including the costs of the biological warfare defense vaccines.

## **Chapter 7 Vaccines and Other Products in Investigational New Drug Status**

### **7-1. Purpose**

For infectious disease threats for which the only available vaccine or chemoprophylaxis product is in an IND status, the IND product must be administered in full accordance with FDA regulations at 21 CFR Parts 50 and 312, as well as 10 USC 1107, Executive Order 13139, and DODD 6200.2. DOD may use products that have not been approved or licensed for commercial marketing as force health protection measures in combat settings, other military operations, peacekeeping, or humanitarian missions. DOD will provide comparable access to IND products to military personnel, civilian personnel, contracted workers, and beneficiaries based on the health risk to the people involved.

### **7-2. General guidance on investigational new drug products**

Commanders, through the appropriate chain, must request approval from the Secretary of Defense to use INDs for force health protection. If the member's use of an IND product is voluntary, the product must be administered with documented informed consent in accordance with a protocol approved by the FDA for IND product use. A vaccine, antibiotic, or other product in an IND status may be mandatory for military members, if the President of the United States has approved a waiver of the requirement for informed consent. Under 10 USC 1107, only the President has the authority to grant a waiver of the requirement that a military member provide prior consent to receive an IND or a drug unapproved for its applied use in connection with the member's participation in a particular military operation. The President must determine, in writing, that obtaining consent (1) is not feasible, (2) is contrary to the best interests of the member, or (3) is not in the interests of national security. The requirement for informed consent may not be waived for civilian personnel, contracted workers, and beneficiaries.

### **7-3. Health recordkeeping requirements for investigational new drug products**

All IND vaccines or chemoprophylaxis products that are administered, whether with the member's informed consent or with an approved waiver of informed consent, must be recorded in the individual's permanent health record or DOD and USCG-approved electronic ITS. For vaccines, the documentation is the same as that required for other vaccines with an annotation "IND" with the vaccine name. This recordkeeping requirement is in addition to any recordkeeping

requirements of the FDA-approved IND protocol. The requirement for recordkeeping applies to IND vaccines, antibiotics, and other medications in IND status.

#### **7-4. Information requirements for investigational new drug products**

Any recipient of an IND vaccine or chemoprophylaxis product must receive the information (for example, briefing, individual counseling, information statements) required by the FDA-approved IND protocol. Full compliance with this requirement is extremely important whether the IND product is voluntary or mandatory.

#### **7-5. Coordination**

The Army, as the Executive Agent for the Immunization Program for Biological Warfare Defense, maintains a program office at the U.S. Army Medical Materiel Development Activity (USAMMDA) to execute oversight and coordination of the use of IND products for Force Health Protection.

## **Chapter 8**

### **Vaccines and Other Products Used Under Emergency Use Authorization**

#### **8-1. General**

Under 21 USC 564 (The Food, Drug, and Cosmetic Act), some drugs, vaccines, or devices that have not been approved or licensed by the FDA through the regular drug approval process (or not approved for an intended use) may be used as medical countermeasures to chemical, biological, radiological, and nuclear (CBRN) agents or threats, if the FDA grants an EUA. This EUA authority is an alternative to the otherwise applicable requirement to file an IND application and follow IND rules (see chap. 7) to use such unapproved drugs as CBRN medical countermeasures.

#### **8-2. Criteria**

In general, the FDA may grant an EUA for up to 12 months, with potential renewal, based on the following:

- a. The Secretary of Defense or designee has determined that there is a military emergency or significant potential for a military emergency relating to a particular CBRN agent or threat.
- b. The Secretary of DHHS declares an emergency based on the Secretary of Defense's determination.
- c. The Secretary of DHHS determines—
  - (1) The vaccine or drug may be effective in diagnosing, treating, or preventing the disease or condition.
  - (2) The known and potential benefits of the vaccine or drug outweigh the known and potential risks.
  - (3) There is no adequate, approved, and available alternative medical countermeasure.
- d. The duration of authorization corresponds to the duration of the emergency or significant potential for an emergency.

#### **8-3. Refusal options**

The FDA may decide that potential recipients of a drug under an EUA should have the option to refuse it. The President may waive this option for military personnel.

#### **8-4. Health recordkeeping requirements for emergency use authorization products**

All EUA vaccines or chemoprophylaxis products that are administered must be recorded in the individual's permanent health record and/or DOD-approved electronic ITS.

#### **8-5. Information requirements for emergency use authorization products**

Any recipient of an EUA vaccine or chemoprophylaxis product must receive the information (for example, briefing, individual counseling, information statements) required by the FDA-approved EUA. Full compliance with this requirement is critical.

#### **8-6. Department of Defense requests for emergency use authorizations**

Requests for possible EUAs for military purposes must be submitted to ASD (HA) for consideration.

#### **8-7. Coordination**

The Army, as the Executive Agent for the Immunization Program for Biological Warfare Defense, maintains a program office at the USAMMDA. This office oversees and coordinates EUA product use for force health protection.

## **Appendix A References**

### **Section I**

#### **Required Publications**

Unless otherwise stated, all publications are available at: <http://www.apd.army.mil/>. Department of Defense regulations are available at: <http://www.dtic.mil/>.

#### **DODI 6200.03**

Public Health Emergency Management within the Department of Defense (Cited in paras 3–3*d*, 3–6*f*.)

#### **DODI 6205.4**

Immunization of Other Than U.S. Forces (OTUSF) for Biological Warfare Defense (Cited in paras 3–3*e*, 3–6*f*.)

### **Section II**

#### **Related Publications**

A related publication is a source of additional information. The user does not have to read a related publication to understand this regulation. Unless otherwise stated, all publications are available at: <http://www.apd.army.mil/>. Department of Defense regulations are available at: <http://www.dtic.mil/>. The U.S. Code and the Code of Federal Regulations are available at: <http://www.gpoaccess.gov/fdsys/>.

#### **AR 11–2**

Managers' Internal Control Program

#### **AR 25–30**

The Army Publishing Program

#### **AR 600–20**

Army Command Policy

#### **AFI 48–123**

Medical Examination and Standards (Available at <http://www.e-publishing.af.mil/>.)

#### **Control of Communicable Diseases Manual**

Communicable disease control and the international health regulations (Available at <http://www.apha.org/>.)

#### **COMDTINST M6000.1**

Medical Manual

#### **DODD 1241.01**

Reserve Component Medical Care and Incapacitation Pay for Line of Duty Conditions

#### **DODD 1404.10**

DOD Civilian Expeditionary Workforce

#### **DODI 6200.02**

Application of Food and Drug Administration (FDA) Rules to Department of Defense Force Health Protection Programs

#### **DODD 6205.02E**

Policy and Program for Immunizations to Protect the Health of Service Members and Military Beneficiaries

#### **DODD 6205.3**

DOD Immunization Program for Biological Warfare Defense

#### **DODI 1300.17**

DOD Accommodation of Religious Practices Within the Military Services

#### **DODI 1400.32**

DOD Civilian Work Force Contingency and Emergency Planning Guidelines and Procedures

**DODI 2310.08E**

Medical Program Support for Detainee Operations

**DODI 5010.40**

Manager's Internal Control (MCIP) Program Procedures

**Executive Order 13139**

Improving Health Protection of Military Personnel Participating in Particular Military Operations (Available at <http://www.archives.gov/federal-register/executive-orders/disposition.html/>.)

**NATO STANAG 2037**

Vaccination of NATO Forces(Available at <http://www.nato.int/docu/standard.htm/>.)

**NATO STANAG 2491**

NBC/MED Policy for the Immunization of NATO Personnel Against Biological Warfare Agents(Available at <http://www.nato.int/docu/standard.htm/>.)

**NATO STANAG 3474**

Temporary Flying Restrictions Due to Exogenous Factors Affecting Aircrew Efficiency (Available at <http://www.nato.int/docu/standard.htm/>.)

**10 USC 1107**

Notice of use of an investigational new drug or a drug unapproved for its applied use

**15 USC 1471**

Definitions

**15 USC 1472**

Special packaging standards

**15 USC 1473**

Conventional packages, marketing

**15 USC 1474**

Regulations for special packing instructions

**15 USC 1475**

Repealed. Section 1205(c), Act of 13 August 1981, Public Law 97-35, Title XII, Volume 95, U.S. Statute at Large, p. 716.

**15 USC 1476**

Preemption of Federal standards

**21 USC 360**

Registration of producers of drugs or devices

**42 USC 300aa**

Public Health Service

**42 USC 300aa-1 to 300aa-34**

The National Childhood Vaccine Injury Act of 1986

**42 USC 300aa-25**

Recording and Reporting of Information

**21 CFR 312**

Investigational New Drug Application

**29 CFR 1605**

Guidelines on Discrimination Because of Religion

**29 CFR 1910.1030.**

Blood borne pathogens

**Section III**

**Prescribed Forms**

This section contains no entries.

**Section IV**

**Referenced Forms**

Except where otherwise indicated below, the following forms are available as follows: DA forms are available on the APD Web site, at <http://www.apd.army.mil>; DD forms are available from the OSD Web site, at <http://www.dtic.mil/whs/directives/infomgt/forms/index.htm>; standard forms (SFs) and optional forms (OFs) are available from the GSA Web site (<http://www.gsa.gov>).

**DA Form 11-2**

Internal Control Evaluation Certification

**DA Form 2028**

Recommended Changes to Publications and Blank Forms

**DD Form 2365**

DOD Civilian Employee Overseas Emergency-Essential Position Agreement

**DD Form 2766**

Adult Preventive and Chronic Care Flowsheet (Available through normal forms supply channel.)

**DD Form 2766C**

Adult Preventive and Chronic Care Flowsheet (Continuation Sheet) (Available through normal forms supply channel.)

**FDA Form 3500**

MedWatch: The FDA Safety Information and Adverse Event Reporting System (Available at <http://www.fda.gov/Safety/MedWatch/default.htm>).

**Form VAERS-1**

Vaccine Adverse Event Reporting System (Available at <http://vaers.hhs.gov/esub/index>)

**CDC Form 731**

International Certificate of Vaccination (Available through normal forms supply channel. Also available at <http://bookstore/gpo.gov>, or toll free at 1-866-512-1800.) (Marine Corps and Navy - S/ N 0108-LF-400-0706. Available from the Navy Supply System and may be requisitioned per NAVSUP P-2002D.)

**SF 600**

Medical Record - Chronological Record of Medical Care

**SF 601**

Health Record - Immunization Record

## **Appendix B Standards for Military Immunization**

### **B–1. Standard #1: immunization availability**

- a.* Ensure immunizations are available when required to minimize disruption of deployment or training schedules.
- b.* Ensure immunizations are available at convenient times, without unnecessary barriers and are available on a walk-in basis, as staffing permits. As clinically appropriate, administer any vaccine doses required simultaneously to avoid missed immunization opportunities.
- c.* Ensure immunization services are responsive to the needs of beneficiaries.
- d.* Review the vaccination status of all beneficiaries at every health care visit to determine which vaccines are indicated.
- e.* Implement standing orders if written orders are unavailable. Standing orders must address vaccine dosage and administration, contraindications and precautions, and documentation procedures. Ensure standing orders are signed by the privileged physician who has medical oversight of the clinic.

### **B–2. Standard #2: vaccine information and vaccinee education**

- a.* Educate beneficiaries about the benefits and risks of vaccination in a culturally appropriate manner and at an appropriate education level.
- b.* Prior to vaccination, provide all parents/guardians and vaccinees the most current Vaccine Information Sheets (VISs) for each vaccine as mandated by Federal law (42 USC 300aa-26). Allow sufficient time to discuss any concerns or questions as noted by the vaccinee. Ensure VISs are accessible and visible in the patient waiting area of the clinic or activity that provides immunizations.
- c.* Prior to each vaccination provide all potential vaccinees the opportunity to read the current DOD and/or FDA mandated vaccine information brochure. Additional education requirements may be required as outlined in vaccination policy.
- d.* Ensure immunization personnel are readily available to accurately answer patients' immunization questions and concerns about vaccines. Ensure personnel have ready access to immunization information resources.

### **B–3. Standard #3: vaccine storage and handling**

- a.* Ensure staff members adhere to cold-chain management principles during administration, transportation, and storage. Ensure up-to-date, written cold-chain management protocols are accessible at all locations where vaccines are stored.
- b.* Implement temperature monitoring processes at any clinic or activity that administers immunizations. All vaccine storage devices should have a calibrated thermometer and alarm systems that are visually monitored at a minimum of twice a day.
- c.* The CDC's National Center for Immunization and Respiratory Diseases strongly recommends that providers draw vaccine only at the time of administration to ensure that the cold chain is maintained and that vaccine is not inappropriately exposed to light. Do not pre-draw doses; draw them when they are needed.

### **B–4. Standard #4: indications and contraindications**

- a.* Screen each patient for allergies, health status, recent vaccinations, and previous vaccine adverse events before immunization. Provide each patient an opportunity to ask questions about potential contraindications. Refer patients for appropriate medical evaluation, as needed.
- b.* Screen each patient's immunization record to determine vaccine needs or requirements.
- c.* Ensure staff members document any contraindication to an immunization in the health record and ITS. Screen all women for pregnancy status.

### **B–5. Standard #5: immunization recordkeeping**

- a.* Record immunizations accurately in a DOD and USCG-approved electronic ITS according to Service-specific policy at the time of immunization, or no later than 24 hours after administration of immunization. Transcribe all historical immunizations into the immunization tracking system.
- b.* Recommend any clinic or activity that administers immunizations has one or more mechanisms for notifying patients when the next dose of an immunization series is needed (a reminder system) or when doses are overdue (recall system). Reminder and recall systems may be automated or manual and may include mailed, emailed, or telephone messages.
- c.* Record all military personnel immunization information in an electronic ITS immunization record. All Services must record military immunization data into an electronic database that communicates with a centralized DOD registry.



**B-6. Standard #6: immunization personnel training**

a. Ensure all persons who administer vaccines, including immunization augmentees, are appropriately trained and work within their appropriate scope of practice as determined by Service policies.

b. Immunization training must meet a standard acceptable to the MTF commander, command surgeon, or other appropriate medical authority. Training will include vaccine storage and handling; vaccine characteristics; recommended vaccine schedules; patient screening; contraindications; vaccine administration techniques; and treatment and reporting of adverse events to include anaphylaxis, vaccine benefit and risk communication, and documentation and management.

c. Ensure personnel who administer vaccines complete a comprehensive immunization orientation and annual continuing education that addresses training standards and competency of vaccine related topics based on an individual's role in administering and/or handling vaccines. Individuals who routinely administer vaccines should complete at least 8 hours of training annually. Training resources include resident courses, self-paced online training programs, and video training (see table B-1).

**Table B-1**  
**Training standards**

Medical standard or procedure	Physicians and medical directors	Immunizers	Chapter and appendix paragraph locations
<b>Quality patient care and delivery of immunizations</b>			
Properly trained in accordance with DOD, Service, USCG, and Centers for Disease Control and Prevention (CDC) guidelines and act within their scope of practice as determined by each Service.	B <sup>1</sup> , A <sup>2</sup>	B, A	1-4c(1)
Understands standing order procedures for administering immunizations including dose, route, time indication, contraindications, and so forth.	B, A	B, A	2-1b and B-1
Demonstrates the ability and knowledge to screen individuals for contraindications, hypersensitivities, allergies, and so forth, before administering vaccines.	B	B, A	2-1d and B-4
Understands and adheres to immunization dosing and interval schedules.	B	B, A	2-1e and B-6
Understands how to properly document exemptions from further immunization in the ITS (DD Form 2766C), on the DD Form 2766 (Adult Preventive and Chronic Care Flowsheet), and/or in other relevant paper-based immunization records.	B	B, A	2-6, 2-7, and B-4
<b>Patient information and education before immunization</b>			
Understands the purpose of and legal requirements for making VISs available to vaccine recipients.	B	B, A	2-7d(2) and B-2
Understands how to document the date of the VIS in the ITS when documenting an immunization given.	B	B, A	2-7d(3) and B-2
<b>Vaccine storage and handling</b>			
Trained in cold-chain management principles and procedures.	B, A	B, A	2-3 and B-3
Demonstrates how to read a vaccine package insert for storage and handling requirements.	B	B, A	2-3 and B-3
Understands proper reporting procedures for vaccine storage and handling losses.	B, A	B, A	2-3f and B-3
<b>Emergency care and adverse-event reporting</b>			
Basic cardiopulmonary resuscitation and the administration of epinephrine.	B, R <sup>3</sup>	B, R	2-9b and B-6
Knows how to use the emergency equipment available for treating an anaphylactic reaction. Ensures medications in kit are not expired.	B	B, A	2-9c and B-6
Demonstrates the ability to initiate anaphylactic reaction treatments per protocol.	B	B, A	2-9c and B-6
Understands the procedure for documenting an adverse event after an immunization.	B	B, A	2-10d and B-7

**Table B-1**  
**Training standards—Continued**

Knows how to submit a Vaccine Adverse Event Reporting System (VAERS) Form 1.	B	B, A	2-10d and B-7
Comprehends DOD's Clinical Guidelines for Managing Adverse Events after Immunization.	B, A	B	2-10 and B-7
<b>Understands how to handle and administer specific vaccines</b>			
Military and civilian personnel eligible to receive smallpox vaccine will be educated before immunization regarding criteria for exemption from immunization, expected response at the vaccination site, vaccination-site care, risks of spreading vaccinia to close contacts, and other relevant topics.	B, A	B, A	4-15
<b>Immunization record keeping (documentation)</b>			
Trained to accurately document immunizations, historical immunization data, and medical exception codes in ITS.	B	B, A	2-6a and b, 2-7, and B-5
<b>Training</b>			
Demonstrates understanding of and ability to follow this multi-Service publication and other pertinent references such as DOD, USCG, and CDC guidance in the performance of duties.	B, A	B, A	1-5
Notes:			
<sup>1</sup> B=baseline or initial training			
<sup>2</sup> A=annually			
<sup>3</sup> R=as required			

d. Ensure persons who administer vaccines have ready access to information resources regarding current recommendations for childhood, general adult, travel, and military-specific immunizations.

**B-7. Standard #7: adverse events after immunization**

a. Epinephrine (such as auto-injectable epinephrine) must be properly stored and readily available at all vaccination locations along with other supplies determined locally to manage adverse events (see para 2-9). Ensure all immunization personnel are trained to administer epinephrine.

b. Provide easy access to telephones or radios to persons who administer vaccines for summoning emergency medical personnel. Medical providers document adverse events in the health record at the time of the event or as soon as possible thereafter.

c. Report all clinically significant adverse events after vaccination to VAERS. Provide staff members with ready access to reporting options for the VAERS.

d. Develop a quality improvement process to assure adverse events are reported to VAERS promptly.

**B-8. Standard #8: vaccine advocacy to protect the military Family**

a. Develop a mechanism at the MTF level to determine the extent of influenza and pneumococcal immunization coverage among its high-risk patients. Develop a plan to optimize vaccination uptake and coverage.

b. Implement a plan to optimize immunization rates among cardiac, pulmonary, diabetic, asplenic, and other patient groups at elevated risk of complications from vaccine-preventable infectious diseases.

c. Conduct a quality improvement program to optimize the performance in immunizing children, adolescents, and adults against the preventable infections that most threaten them.

d. Ensure commanders use immunization databases to identify and resolve the vulnerabilities of their units.

e. All health care providers (not just those in any clinic or activity that administers immunizations) should routinely determine the immunization status of their patients, offer vaccines to those for whom they are indicated, and maintain complete immunization records.

## Appendix C

### Medical and Administrative Exemption Codes

This appendix gives details about medical and administrative exemption codes, as well as information on duration.

#### C-1. Medical exemption codes

Medical exemption codes appear in table C-1.

Code	Meaning	Explanation of example	Duration
MD	Medical, declined	Declination of optional vaccines (not applicable to military required vaccinations).	Indefinite
MA	Medical, assumed	Prior immunization reasonably inferred from individual's past experiences (for example, basic military training), but documentation missing. Code used to avoid superfluous immunization. Code can be reversed upon further review.	Indefinite
MI	Medical, immune	Evidence of immunity (for example, by serologic antibody test ); documented previous infection (for example, chickenpox infection); natural infection presumed (for example, measles, if born before 1957).	Indefinite
MP	Medical, permanent	HIV infection, prolonged or permanent immune suppression, upper age limit, other contraindication determined by physician. Can be reversed if the condition changes. For tuberculosis, positive tuberculosis test.	Indefinite
MR	Medical, reactive	Permanent restriction from receiving additional doses of a specific vaccine. Use only after severe reaction after vaccination (for example, anaphylaxis). Report such reactions to VAERS. Code can be reversed if an alternate form of prophylaxis is available. Do not code mild, transient reactions as MR. code events referred for medical consultation as MT.	Indefinite
MS	Medical, supply	Exempt due to lack of vaccine supply.	Up to 90 days
MT	Medical, temporary	Pregnancy, hospitalization, events referred for medical consultation, temporary immune suppression, convalescent leave, pending medical evaluation board, any temporary contraindication to immunization.	Up to 365 days

#### C-2. Administrative exemption codes

Administrative exemption codes appear in table C-2.

Code	Meaning	Explanation of example	Duration
AD	Administrative, deceased	Individual is deceased.	Indefinite
AL	Administrative, emergency leave	Individual is on emergency leave.	Up to 30 days
AM	Administrative, missing	Missing in action, prisoner of war.	Indefinite
AP	Administrative, PCS	Permanent change of station.	Up to 90 days
AR	Administrative, refusal	Personnel involved in actions under the Uniformed Code of Military Justice, religious waiver. (Indefinite and revocable. May be revoked at any time. See paragraph 2-6b(2).	Until resolution
AS	Administrative, separation	Pending discharge, separation (typically within 60 days), and retirement (typically within 180 days).	Until 180 days
AT	Administrative, temporary	Absent without leave, legal action pending (other than code AR).	Until 90 days
NR	Not required	Individuals who received immunization while eligible, subsequently changed occupational category and now serve as civilian employees or contract workers not otherwise required to be immunized.	Indefinite

## Appendix D Immunizations for Military Personnel

### D-1. Text citations

Paragraphs 4-2 to 4-19 provide additional information on immunizations for military personnel.

### D-2. Required immunizations

This table provides a listing of required immunizations for military personnel.

**Table D-1  
Immunizations for military personnel**

Name of vaccine	Army	Navy	Air Force	Marine Corps	Coast Guard
Adenovirus <sup>1</sup>	Acc <sup>2</sup>	Acc	Acc	Acc	Acc
Anthrax	Risk	Risk	Risk	Risk	Risk
Haemophilus influenzae type b	Risk	Risk	Risk	Risk	Risk
Hepatitis A	Acc, Rou <sup>3</sup>	Acc, Rou	Acc, Rou	Acc, Rou	Acc, Rou
Hepatitis B	Acc, Rou	Acc, Rou	Acc, Rou	Acc, Rou	Acc, Rou
Influenza	Acc, Rou	Acc, Rou	Acc, Rou	Acc, Rou	Acc, Rou
Japanese encephalitis	Risk <sup>4</sup>	Risk	Risk	Risk	Risk
Measles, mumps, rubella	Acc, Rou	Acc, Rou	Acc, Rou	Acc, Rou	Acc, Rou
Meningococcal	Acc, Rou	Acc, Rou	Acc, Rou	Acc, Rou	Acc, Rou
Pneumococcal	Risk	Risk	Risk	Risk	Risk
Poliovirus <sup>5</sup>	Acc, Rou	Acc, Rou	Acc, Rou	Acc, Rou	Acc, Rou
Rabies	Risk	Risk	Risk	Risk	Risk
Smallpox (vaccinia)	Risk	Risk	Risk	Risk	Risk
Tetanus-diphtheria (preferably with pertussis vaccine)	Acc, Rou	Acc, Rou	Acc, Rou	Acc, Rou	Acc, Rou
Typhoid fever	Risk	Risk	Risk	Risk	Risk
Varicella	Acc, Rou	Acc, Rou	Acc, Rou	Acc, Rou	Acc, Rou
Yellow fever	Risk	Risk	Risk	Acc, Risk	Risk

Notes:

<sup>1</sup> Initial entry and basic training accessions only

<sup>2</sup> Acc=accessions

<sup>3</sup> Rou=adult routine

<sup>4</sup> Risk=special, risk-based, and occupational

<sup>5</sup> Refer to paragraph 4-13.

## **Appendix E**

### **Internal Control Evaluation Process**

#### **E-1. Function**

The function covered by this checklist is immunization and chemoprophylaxis.

#### **E-2. Purpose**

The purpose of this checklist is to assist in evaluating key management controls and is not intended to address all controls. The evaluation is focused at the clinic level, regardless of Service, to include both fixed facilities (MTFs, TDA units) and TOE field units. The checklist serves as a clinical quality improvement tool and is described at <http://www.vaccines.mil/cqiip>.

#### **E-3. Instructions**

Answers must be based on the actual testing of key management controls (for example, document analysis, direct observation, interviewing, sampling, or simulation). Answers that indicate deficiencies must be explained and corrective action indicated in supporting documentation. These key management controls must be formally evaluated at least once every 5 years. Certification that this evaluation has been conducted must be accomplished on DA Form 11-2-5 (Internal Control Evaluation Certification Statement).

#### **E-4. Test questions**

Test questions are available directly via a link at the Web site address in paragraph E-2, above.

#### **E-5. Supersession**

This evaluation replaces the evaluation for immunization and chemoprophylaxis previously published in AR 40-562, dated 29 September 2006.

## **Glossary**

### **Section I**

#### **Abbreviations**

**ACIP**

Advisory Committee on Immunization Practices

**AFI**

Air Force Instruction

**AFJI**

Air Force Joint Instruction

**ASD (HA)**

Assistant Secretary of Defense (Health Affairs)

**CBRN**

chemical, biological, radiological, and nuclear

**CDC**

Centers for Disease Control and Prevention

**CFR**

Code of Federal Regulations

**CG-11**

Coast Guard, Director, Health, Safety, and Work-Life

**COMDTINST**

Commandant Instructions

**DCJI**

disposable-cartridge jet injectors

**DD**

Department of Defense Form

**DHHS**

Department of Health and Human Services

**DODD**

Department of Defense Directive

**DODI**

Department of Defense Instruction

**EUA**

emergency use authorization

**FDA**

Food and Drug Administration

**G6PD**

glucose-6-phosphate dehydrogenase

**Hib**

Haemophilus influenzae type b

**HQ**

headquarters

**HQDA**

Headquarters, Department of the Army

**IND**

investigational new drug

**IPV**

inactivated poliovirus vaccine

**ITS**

immunization tracking systems

**JTF CapMed**

Joint Task Force - National Capital Region/Medical

**JEV**

Japanese-encephalitis vaccine

**MAJCOM**

major command (Air Force)

**MILVAX**

Military Vaccine Office

**MMR**

measles, mumps, rubella

**MTF**

medical treatment facility

**NCVIA**

National Childhood Vaccine Injury Act

**NVIC**

National Vaccine Injury Compensation (Program)

**OTUSF**

other than U.S. Forces

**RC**

reserve component

**ROTC**

Reserve Officers' Training Corps

**SF**

Standard Form

**SOP**

standard operating procedure

**SSN**

social security number

**STANAG**

standardized agreement

**TB**

tuberculosis

**Td**

Tetanus-diphtheria

**Tdap**

Tetanus-diphtheria and acellular pertussis (vaccine)

**USAMMDA**

U.S. Army Medical Materiel Development Activity

**USC**

United States Code

**USCG**

United States Coast Guard

**VAERS**

Vaccine Adverse Events Reporting System

**VIS**

vaccine information statement

**WHO**

World Health Organization

**Section II**

**Terms**

This section contains no entries.

**Section III**

**Special Abbreviations and Terms**

**Accession**

The attainment of rank or dignity.

**Alert personnel**

Specified forces maintained (alert force) in a special degree of readiness.

**Antigen**

A substance that, when introduced into the body, stimulates the production of an antibody.

**Contraindication**

A factor that renders the administration of a drug or the carrying out of a medical procedure inadvisable.

**Hyperendemic**

Equally endemic, at a high level, in all age groups of a population.

**Neisseria meningitides**

The bacteria that is the causative agent of cerebrospinal meningitis.

**Plasmodia**

A genus of apicomplexan protozoa, in the family Plasmodiidae parasitic, in the blood cells of animals and humans; the malarial parasite.

**Primaquine**

An ant malarial agent especially effective against Plasmodium vivax.

**Seroimmunity**

Immunity conferred by administration of an antiserum.



**Serologic**

The scientific study of blood serum and other bodily fluids.

**Toxoid**

A bacterial toxin (usually an exotoxin) whose toxicity has been weakened or suppressed either by chemical (formalin) or heat treatment, while other properties, typically immunogenicity, are maintained.

**Urticaria**

A skin condition characterized by intensely itching welts and caused by allergic reactions.

**Variola virus**

The causative agent of smallpox.

**UNCLASSIFIED**

**PIN 000011-000**