IMMUNIZATIONS AND CHEMOPROPHYLAXIS FOR THE PREVENTION OF INFECTIOUS DISEASES

BUMEDINST 6230.15B (07NOV2013)

BUMEDINST 6010.13 (19AUG91)
STANDARDS:

• The Department of Defense will follow the recommendations of the CDC (Center for Disease Control), Advisory Committee on Immunization Practices (ACIP) and the prescribing information on the manufacturer’s package insert, unless there is a military-relevant reason to do otherwise.

• The Department of Defense will follow the manufacturer’s recommendations for expiration dates, standards of delivery, dosing, and screening for contraindications.
ADMINISTRATION:

• Once an immunization series has been started, it must be completed, unless a medical or administrative exemption exists.

• Simultaneous immunizations; when required administer in different limbs. If unable to use different sites, separate the injections by at least ONE inch.

• Inactive vaccines; two or more may be administered simultaneously or at the prescribed interval and restrictions indicated in the package insert for each vaccine.

• Inactive and active vaccines; may be administered simultaneously or at the prescribed interval and restrictions indicated in the package insert for each vaccine.

• Active vaccines; MUST be administered simultaneously OR separated by at least 28 DAYS.
ADMINISTRATION AND TUBERCULOSIS TESTING:

• Vaccinations with live vaccines may affect tuberculosis testing.

• To avoid interference:
  • Administer live virus vaccine and TB test on the same day.
  • Perform TB test 4 to 6 weeks AFTER administration of live virus .
  OR
  • Administer live virus vaccines, once the TB test has been read.
LOGISTICS AND STORAGE/HANDLING:

• All immunizing and chemoprophylaxis agents are requisitioned in accordance with (IAW) medical supply procedures, EXCEPT vaccinia immune globulin (VIG intravenous) which is only available by ordering through MILVAX office.

• All personnel will maintain the cold chain in vaccine delivery.

• Small stations, ships and cutters may requisition vaccines that are stored at frozen temperatures from nearby military medical activities.

• Administer vaccines shortly after drawn from vial.

• Single dose vials are meant for one time use only. At the end of clinic day discard all single-dose vials without protective cap.

• Multi-dose vials that do not require reconstitution, dose drawn up are good until expiration date.
LOGISTICS AND STORAGE/HANDLING:

• Multidose vials which were reconstituted, must be used within the interval specified by the manufacturer. After reconstitution the new expiration should be written on the vial.

• Diluents are not interchangeable. Normal Saline and Sterile Water are NOT the same thing. Follow the manufacturer’s directions.

• Discard diluents that have not been stored correctly or expired.

• Store vaccines in vaccine only storage, do not cohort with food.

• Refrigerated vaccines are stored at 35-46 degrees F (2-8 degrees C).

• Frozen vaccines are to be stored at 15 or less degrees F (-15 degrees C).

• Store all reconstituted lyophilized (freeze-dried) vaccines IAW manufacturer’s temperature AND light condition parameters.
REFRIGERATION AND TEMPERATURE TRACKING:

• Dormitory style refrigerators are not authorized for vaccine storage.
• Combination refrigerator/freeze units may ONLY store refrigerated vaccines, a stand alone freeze must be used to store frozen vaccines.
• Use only certified and calibrated thermometers in all vaccine storage units.
• Ensure there is an alarm system to notify staff of power failures or indicated whether or not vaccine temperatures have been maintained.
• Temperatures are DOCUMENTED for EACH vaccine storage unit, physically confirmed TWICE A DAY (minimally) on all vaccine storage units. Date, time and temperature.
• Vaccines outside of a refrigerator/freezer must be checked HOURLY.
• Temperature logs are kept for 3 years.
ALARM SYSTEMS:

• Temperature alarm systems are 24 hours, 7 days a week.
• Ensure all information (current personnel contact) for those who are to be covering the alarm system in clinical area is correct regardless of the day or time.
• Monitor alarms physically and electronically 24 hours, 7 days a week.
• TEST the entire alarm system MONTHLY and maintain test records for 3 years.
• If refrigerator/freezer is in a restricted area, ensure there is a visual (light) or audible alarm.

• If contamination or other serious problem with a vaccine vial or lot is suspected, suspend usage, but quarantine and retain all vial/lots (open or unopened) AND immediately notify USAMMA (United States Army Medical Material Development Activity)
TRANSPORTATION:

- Transporting vaccines have very specific rules:
- Always transport in properly insulated containers, valid storage devices are:
  - Vaxicool
  - Vaxipac
  - Manufacturer’s shipping container
  - Styrofoam ™ coolers with 2 inch thick walls
  - Endurotherm insulating shipping containers
- Include thermometers in all transport and off site storage.
- Pack vaccines in original packing.
- Document vaccine type, quantity, date, time, and originating facility on the outside of the transportation container.
VACCINE DISPOSAL AND DISPOSITION:

• Discard syringes and vial the contained LIVE vaccines IAW INSTALLATION POLICY.

• Contact either Pharmacy or Logistics for proper disposition of expired, unopened, unused doses and potentially compromised vaccines.

• Label “DO NOT USE” on potentially compromised vaccines.

• Report all confirmed compromised vaccine losses through the Navy to the Military Vaccine Office. The report must include description of the reason for the loss, vaccines compromised, total vial/doses lost and cost of lost or compromised vaccines.
SYRINGES:

• NEVER mix individual vaccines in the same syringe.
• Use a separate needle and syringe for each injection.
• Label filled syringe with:
  • Type of vaccine
  • Lot number
  • Date drawn
• Attach needle just prior to administration.
• Discard needle and syringe if vaccine not administered before end of the clinic day or vaccination session IAW manufacturer’s package insert.
• If no time is provided in the manufacturer’s insert, DISCARD AFTER 8 HOURS.
PREFILLING SYRINGES:

• This practice is HIGHLY discouraged. There is an increase risk of administration and possible bacterial growth in vaccines that do not contain preservatives.

• Discard unused syringes, which were prepared by end user (not manufacturer) IAW manufacturer’s package insert, if no time limit is given then discard vaccine after 8 hours.
PRE INJECTION:

• Prior to the administration determine if the patient has previously shown any unusual degree of adverse reaction or allergy to it or any specific component of the vaccine or its packaging.

• Defer patients who have reported a hypersensitivity to a particular vaccine or its components.

• Refer the patient with reported hypersensitivity to an appropriate medical specialist for evaluation, unless already done and record contains documentation of the consultation.
WOMEN OF CHILDBEARING AGE AND IMMUNIZATIONS:

• Signs should be displayed to remind the patient to inform staff if they are pregnant.

• Staff should be discreet in asking the patient if she is or maybe pregnant. Document the patient’s response.

• If the patient answers “yes” when asked, cross reference the immunizations due to the recommendations of ACIP (Advisory Committee on Immunization Practices) if ACIP does not recommend vaccine, then defer to an OBSTETRIC healthcare provider.

• Breast feeding women may be vaccinated IAW ACIP.

• Advise women who received a live vaccine to follow the guidelines of CDC (Center for Disease Control) or the manufacturer’s guidelines.
WOMEN OF CHILDBEARING AGE AND IMMUNIZATIONS:

- Small pox vaccinia (vaccine) has a specific pre-immunization screening form, this form 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 first prior in administration of vaccine.

- If a contraindicated vaccine is inadvertently administered to a pregnant woman:
  - Report the event upon discovery to the Preventive Medicine Point of Contact.
  - Obstetric services.
  - Complete the appropriate quality assurance documents. (See BUMEDINST 6010.13 – Quality Assurance Program, 19 Aug 91)
  - Report such cases to any applicable registry, see Preventive Medicine service or MILVAX for referral assistance.
**Sample of The Smallpox PreScreening Form:**

**Note:** This is an example of an overprint SF 600 – Chronological Record of Medical Care.

**Chronic Medical Care Case:**

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
<th>Unsure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Do you have a current illness with fever?</td>
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<tr>
<td>Are you allergic to any of these products: aluminum, benzamethonium?</td>
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<tr>
<td>Are you allergic to antibiotics?</td>
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<td>Are you allergic to any of these products: penicillin?</td>
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<td>Are you allergic to any of these products: sulfa?</td>
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<tr>
<td>Are you allergic to any of these products: tetracycline?</td>
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</tbody>
</table>

Please answer the following questions to the best of your knowledge.

**Chronic Medical Care Case:**

<table>
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<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
<th>Unsure</th>
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<tbody>
<tr>
<td>Do you currently receive any prescription medications?</td>
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This is an example of an overprint SF 600 – Chronological Record of Medical Care.
TRAINING REQUIREMENT, EMERGENCY RESPONSE REQUIREMENTS:

- Clinics and activities administering immunizations will have a written plan for emergency response, including standing orders for management of Anaphylaxis and Syncope (fainting).
- Wherever vaccines are administered, at least one person must be:
  - Trained and current in basic cardiopulmonary resuscitation.
  - Oropharyngeal airway management.
  - Recognition and initial treatment of anaphylaxis with epinephrine.

- Equipment for Anaphylaxis management:
  - Stethoscope
  - Blood pressure cuff
  - 3 doses of Epinephrine (1:1000)
  - Oral airway
  - Bag valve mask or positive pressure oxygen equipment
  - Ability to activate Emergency Medical System (EMS)
EXEMPTIONS, ADMINISTRATIVE:

• General
  • Granting administrative exemptions is a NON-medical function.
  • Physicians do NOT make this decision.
EXEMPTIONS, ADMINISTRATIVE:

• Religious exemptions
  • This decision is made by the Chief, Bureau of Medicine and Surgery, with input from:
    • Physician, who will counsel the patient to ensure an informed decision is being made.
    • Commander, MUST counsel the patient that noncompliance with immunization requirements by adversely impact deployability, assignment, and international travel.
    • Legal – Judge Advocate, to comply with DODI 1300.17.
    • Chaplain
  • Religious exemptions may be REVOKED if the patient is at IMMINENT risk of exposure to a disease which there is an immunization available.
EXEMPTION CODES, ADMINISTRATIVE:

• Administrative, deceased (AD) The patient is deceased. – Indefinite.

• Administrative, emergency leave (AL) The patient is on emergency leave. Up to 30 days.

• Administrative, missing (AM) The patient is missing in action, or prisoner of war. – Indefinite.

• Administrative, PCS (AP) The patient is in the process of PCS (Permanent Change of Station). – Up to 90 days.

• Administrative, refusal (AR) Personnel involved in actions of UCMJ (Uniform Code of Military Justice), religious wavier. – Until resolution.
EXEMPTION CODES, ADMINISTRATIVE:

• Administrative, separation (AS) Pending discharge, separation (typically within 60 days) and retirement (typically within 180 days). – Until 180 days.

• Administrative, temporary (AT) Absent without leave, legal action pending other than personnel involved in actions under the UCMJ, religious waiver. – Until 90 days.

• Not required (NR) 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.
EXEMPTIONS, MEDICAL:

• General
  • Granting medical exemptions is a medical function, must be done by a Health Care Provider, (I.E. Physician).
  • Providers who are assessing medical exceptions may seek a second opinion or seek additional consultation from MILVAX.
  • Annotate electronic ITS (Immunization tracking systems) and paper-based service treatment records (SF 601 or PHS 731).
  • Revoke medical exemptions when they are no longer clinically warranted.
EXEMPTION CODES, MEDICAL:

• Medical, declined (MD) Declination of optional vaccines (NOT applicable to military required vaccinations). – Indefinite.

• Medical, assumed (MA) Prior immunization reasonably inferred, but documentation missing. – Indefinite but can be reversed.

• Medical, immune (MI) Evidence of immunity; documented previous infection; natural infection presumed. – Indefinite.

• Medical, permanent (MP) HIV infection, prolonged or permanent immune suppression, upper age limit, other contraindication determined by physician. – Indefinite but can be reversed.
EXEMPTION CODES, MEDICAL:

- Medical, reactive (MR) Permanent restriction from receiving additional doses of a specific vaccine. Use only after SEVERE reaction (I.E. Anaphylaxis). Report such reactions to VAERS (Vaccine Adverse Event Reporting System). – Indefinite may be reversed if an alternate form of prophylaxis is available.

- Medical, supply (MS) Exempt due to lack of vaccine supply. – Up to 90 days.

- Medical, temporary (MT) Pregnancy, hospitalization, temporary immune suppression, convalescent leave, pending MEB (Medical Evaluation Board), any temporary contraindication to immunization and mild/transient reactions while referred for medical consultation. – Up to 365 days.
PERSONNEL SUBJECT TO IMMUNIZATION:

- Enlisted Personnel are given shots in clusters upon entry into the military system.
  - Cluster 1: Adenovirus, Influenza, Meningococcal, MMR, Tetanus-Diphtheria-Pertussis and Varicella.
  - Cluster 2: Hepatitis A, Hepatitis B, Influenza (if not previously given) and Poliovirus.
- Ensure all live vaccines are given on the same day or at least 28 days apart.

- Reserve Officer’s Training Corps Cadets and Midshipmen are given shots in cluster when called to Active Duty.
  - Cluster 1: Influenza, Meningococcal, MMR, Tetanus-Diphtheria-Pertussis and Varicella.
  - Cluster 2: Hepatitis A, Hepatitis B, Influenza (if not previously given) and Poliovirus.
- Ensure all live vaccines are given on the same day or at least 28 days apart.
ACTIVE DUTY PERSONNEL:

• During military service, active duty personnel will receive or be up-to-date on adult routine vaccines.

• Aviation personnel will be grounded for 12 hours. Naval aviation personnel will refer to “Aeromedical Reference and Waiver Guide” (ARWG) for vaccine specific information.

• Occupational risk, military members at occupational risk for specific disease threats will receive appropriate vaccines.

• Special Operations, may determine additional area-specific immunization requirements.
CIVILIANS AND CONTRACTORS:

- Civilians (Federal Employees) will receive country-specific immunizations and/or immunizations in which their occupation places them at risk (working with waste water, in health care settings, etc) without charge at military activities.

- Family member(s) will receive country-specific immunizations without charge at military activities IAW ACIP recommendations.

- Contractors will receive immunizations IAW with their contact.
LIST OF IMMUNIZATIONS:

- Immunizations:
  - Adenovirus
  - Anthrax
  - Haemophils Influenza serotype B (Hib)
  - Hepatitis A
  - Hepatitis B
  - Influenza
  - Japanese Encephalitis

- Measles, Mumps and Rubella (MMR)
- Meningococcal
- Pneumococcal
- Poliomyelitis
- Rabies
- Smallpox
- Tetanus, Diphtheria and Pertussis
- Typhoid Fever
- Varicella
- Yellow Fever
CHEMOPROPHYLAXIS:

- Chemoprophylaxis is defined here as the administration of medication before, during, and after possible exposure to an infectious agent, to prevent either infection or disease.

List of Chemoprophylaxis:

- Anthrax
- Group A Streptococcus
- Influenza
- Leptospirosis
- Malaria
- Meningococcal
- Plague
- Scrub Typhus
- Smallpox
- Traveler’s Diarrhea
BIOLOGICAL WARFARE DEFENSE AND INVESTIGATIONAL NEW DRUG:

• Biological Warfare Defense:
  • Combatant Commanders annually and as required, provide the Chairman of the Joint Chiefs of Staff with their assessment of biological warfare threats to their theater.
  • Within 30 days of receiving the coordinated recommendations will begin immunization of DoD personnel against specific biological warfare threat agents.

• Investigational New Drug (IND):
  • The member’s use of IND is voluntary.
  • All IND vaccines or chemoprophylaxis products that are administered must be recorded in the patient’s health record.
EMERGENCY USE AUTHORIZATION (EUA):

- Under Emergency Use Authorization (EUA):
  - Under 21 USC (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 may be used as medical countermeasures to chemical, biological, radiological, and nuclear agents or threats.
  - Patient’s may refuse it, but the President may waive this option.
  - Any patient 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.
DOCUMENTATION, GENERAL:

- Documentation must have:
  - Date
  - Immunization given
  - Dose
  - Anatomical location of administration
  - Lot number
  - Manufacturer
  - Vaccine Information Sheet (VIS) date
  - Identification of the person who administered the vaccine
DOCUMENTATION, ELECTRONIC:

• Printed report from the ITS maybe on:
  • CDC Form 731 – International Certificate of Vaccination or Prophylaxis (FORMERLY PHS-731, this form is referenced in the NAVEDTRA 14295B).
  • SF 601 – Health Record – Immunization Record.
  • DD Form 2766C – Adult Preventive and Chronic Care Flowsheet.
• A printed copy of any of the previous forms will suffice as valid certificate of vaccination, EXCEPT for YELLOW FEVER which must be documented on CDC Form 731 for active duty members of the ARMED FORCES IAW WHO (World Health Organization) International Health Regulations.
DOCUMENTATION, PAPER (NON-ELECTRONIC):

- This is used for DEPLOYMENT. Transfer from the ITS to DD Form 2766.
- When documenting date use 2 Arabic numbers for day, 3 letters for month, and last 2 digits of the year. I.E. “18 Jun 16” which is June 18, 2016.
- Entries based on prior official records will include, “Transferred from official records” or “Transferred from SF 601”.
- Prepare SF 601 IAW NAVMED P-117 (Manual of the Medical Department) Chapter 16.
- Yellow Fever vaccination must be documented on CDC Form 731 (Formerly PHS 731). This form may be obtained through the normal supply channels.
DOCUMENTATION, ADVERSE REACTION:

• What needs to be reported:
  • Adverse events requiring hospitalization.
  • A life-threatening event (I.E. Anaphylaxis).
  • Time lost from duty more than one duty shift.
  • An event related to a suspected contamination of a vaccine vial.

• Recommended to report, other adverse events considered unexpected in nature or severity.
DOCUMENTATION, ADVERSE REACTION:

What information must be included on the report:

- Lot number.
- Manufacturer of the vaccine or medication.
- Date of administration.
- Name and location of the medical facility.
- The type and severity of event.
- Treatment provided.
- Any exception from additional doses.

Consultation with MILVAX’s Vaccine Healthcare Centers network is available 24 hours a day, 7 days a week.
DOCUMENTATION, ADVERSE REACTION:

• Who may file a report:
  • Physicians (Health care providers)
  • Patients, health care personnel will assist patients in completing the form.

• Who gets the report:
  • VACCINES – VAERS (Vaccine Adverse Events Reporting System) Web site (http://www.vaers.hhs.gov) 1-800-822-7967
  • CHEMOPROPHYLAXIS – MedWatch (http://www.fda.gov/Safety/MedWatch/default.htm) 1-888-463-6332

• Reports will be filed within 7 days, originals to either VAERS or MedWatch and a copy in the patient’s health record.
TAKE A WAY:

• **KNOW** BUMEDINST 6230.15B is Immunization and Chemoprophylaxis for the Prevention of Infectious Diseases.

• FOLLOW the MANUFACTURER’S RECOMMENDATIONS and INSTRUCTIONS.

• Smallpox requires special documentation.

• Patient’s may refuse but must be counseled and the patient’s refusal may be overturned by emergency/Presidential decisions.

• For access to package inserts and immunization information (electronically) go to: vaccines.mil (IHB – The DoD Immunization Information and Training Portal).
TERMINOLOGY:

• Cold chain; is a temperature-controlled supply chain.