



Defense Health Agency - Immunization Healthcare Branch Continuous Quality Immunization Improvement Process Customer “Reference Guide”



Thank you for completing the Defense Health Agency’s (DHA’s)- Immunization Health Branch (IHB) Continuous Quality Immunization Improvement Process (CQIIP) Tool. The CQIIP Customer reference guide is available to sites upon completion of the CQIIP tool. This guide includes references for the questions asked on the CQIIP tool. If you have any questions, please contact your DHA-IHB Immunization Healthcare Specialist (IHS) using the following link: www.health.mil/ContactYourIHS.

References:

1. Joint Instruction (AR 40-562, BUMEDINST 6230.15B, AFI 48-110_IP, CG COMDTINST M6230.4G), Immunizations and Chemoprophylaxis for the Prevention of Infectious Diseases: www.health.mil/vaccines
2. Centers for Disease Control and Prevention (CDC) Advisory Committee on Immunization Practices (ACIPs) General Recommendations on Immunization: www.cdc.gov/mmwr/pdf/rr/rr6002.pdf
3. Centers for Disease Control and Prevention (CDC); Epidemiology and Prevention of Vaccine-Preventable Diseases (Pink Book); Atkinson W, Wolfe S, Hamorsky J, eds. 12th ed. Washington DC: Public Health Foundation, 2011. <http://www.cdc.gov/vaccines/pubs/pinkbook/index.html>

Standard 1: Immunization Availability

Question:	References:
<p>1. Are records reviewed routinely for required immunizations and immunizations given at appropriate intervals?</p> <p>If yes, do you administer the vaccine during the same patient visit?</p> <p>If no, do you require the patient to return at a later date?</p>	<p>Joint Instruction (pg 25), Appendix B, B-1, a - d. a. Ensure immunizations are available when required to minimize disruption of deployment or training schedules.</p> <p>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.</p> <p>c. Ensure immunization services are responsive to the needs of beneficiaries.</p> <p>d. Review the vaccination status of all beneficiaries at every health care visit to determine which vaccines are indicated.</p> <p>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.</p> <p>Joint Instruction (pg 27), Appendix B, B-6, d. Ensure persons who administer vaccines have ready access to information resources regarding current recommendations for childhood, general adult, travel, and military-specific immunizations.</p> <p>Joint Instruction (pg 27), Appendix B, B-8, 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.</p> <p>ACIP General Recommendations (pg 6), Simultaneous Administration: Simultaneously administering all vaccines for which a person is eligible at the time of a visit increases the probability that a child, adolescent, or adult will be vaccinated fully by the appropriate age.</p> <p>Pink Book (pg 41), Reduction of Missed Opportunities: A missed opportunity is a healthcare encounter in which a person is eligible to receive a vaccination but is not vaccinated completely. Missed opportunities occur in all settings in which immunizations are offered, whether routinely or not.</p>
<p>2. Has a privileged “physician” with medical oversight over any site/clinic that provides</p>	<p>Joint Instruction (pg 1), section 1-4 c. (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.</p>

<p>vaccinations been appointed in writing and a privileged healthcare provider [e.g. physician, nurse practitioner, physician assistant, Independent Duty Corpsman (IDC), Independent Duty Medical Technician (IDMT)] under the privileged physician been appointed in writing to oversee daily site/clinic activities?</p>	<p>(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.</p> <p>(c) Establish and sign vaccine and chemoprophylaxis standing orders for clinics or other locations where immunizations or chemoprophylaxis medications are administered.</p> <p>(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.</p> <p>Joint Instruction (pg 1), section 1-4 c. (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.</p>
<p>3. Standard Operating Procedures (SOPs)/Operating Instructions (OIs):</p> <p>Are SOPs/ OIs available, and signed by the privileged “physician”?</p> <p>Has the privileged physician approved, annually reviewed, and signed SOP/OIs?</p>	<p>Joint Instruction (pg 1), section 1-4 c. (2) (d). Ensure standard operating procedures (SOPs/OIs) 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 in Appendix A (pg 22).</p> <p>Joint Instruction (pg 1), section 2-11. 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.</p>
<p>4. Standing Orders:</p> <p>Are standing orders used in place of a physician’s prescription?</p> <p>Has privileged physician annually reviewed/approved/signed all standing orders?</p>	<p>Joint Instruction (pg 1), section 1-4 c. (2) (c). Establish and sign vaccine and chemoprophylaxis standing orders for clinics or other locations where immunizations or chemoprophylaxis medications are administered.</p> <p>Joint Instruction (pg 8), section 2-9 a. 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.</p> <p>Joint Instruction (pg 25), Appendix B, B-1, 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. http://www.immunize.org/standing-orders/</p> <p>Pink Book (pg 42), Standing Orders: These are protocols whereby non-physician immunization personnel may vaccinate clients without direct physician involvement at the time of the immunization. Standing orders are implemented in settings such as clinics, hospitals, and nursing homes. When used alone or in combination with other interventions, standing orders have had positive effects on immunization rates among adults and children.</p>
<p>5. Do you provide travel and/or deployment immunizations?</p>	<p>Joint Instruction (pg 1), section 1-4 b. (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.</p> <p>Joint Instruction (pg 11), section 3-2 e. (1)-(5). (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</p>

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.

Joint Instruction (pg 11), section 3-2 f. Members of other uniformed Services are authorized immunizations according to their occupation, official duties, travel plans, health status, or other relevant factors.

Joint Instruction (pg 11-12), section 3-3 a. (1). 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.

Joint Instruction (pg 12), section 3-4 a-c. *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.

Joint Instruction (pg 13), section 3-6 a – c. *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.

Joint Instruction (pg 13), section 4-1. 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.

Joint Instruction (pg 13-14), section 4-3 a-b. 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.

Joint Instruction (pg 14), section 4-7 a. 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 & fomites.

Joint Instruction (pg 14-15), section 4-8 a-b. 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.

Joint Instruction (pg 15), section 4-10 a-d. 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.

Joint Instruction (pg 15), section 4-13 a. *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.

Joint Instruction (pg 16), section 4-14 a-b. *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.

Joint Instruction (pg 16), section 4-15 b. *Military and civilian personnel.* Vaccinate designated military and civilian personnel according to DOD and other designated 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.

Joint Instruction (pg 17), section 4-17 a-c. *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.

Joint Instruction (pg 17-18), section 4-19 a-d. *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.

	<p>Joint Instruction (pg 25), Appendix B, B-1, a. Ensure immunizations are available when required to minimize disruption of deployment or training schedules.</p> <p>Joint Instruction (pg 27), Appendix B, B-6, d. Ensure persons who administer vaccines have ready access to information resources regarding current recommendations for childhood, general adult, travel, & military-specific immunizations.</p> <p>ACIP General Recommendations (pg 6), Simultaneous Administration: Simultaneous administration also is critical when preparing for foreign travel and when a health-care provider is uncertain that a patient will return for additional doses of vaccine.</p>
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Standard 2: Vaccine Information and Vaccinee Education

Questions:	References:
<p>1. Vaccine Information Statements (VISs):</p> <p>Are VISs available for all vaccines provided?</p> <p>Are all VISs current?</p>	<p>Joint Instruction (pg 8), section 2-7 d. (2). (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.</p> <p>Joint Instruction (pg 25), Appendix B, B-2, 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.</p> <p>ACIP General Recommendations (pg 11), Benefit and Risk Communication: The National Childhood Vaccine Injury Act of 1986 requires that vaccine information materials be developed for each vaccine covered by the act. These materials, known as vaccine information statements (VISs), must be provided by all public and private vaccination providers each time a vaccine is administered. Copies of VISs are available from state health authorities responsible for vaccination and from CDC (http://www.cdc.gov/vaccines).</p>
<p>2. What process is in place for patients/parents who ask for additional information beyond what is on the VIS or refuse vaccination?</p>	<p>Joint Instruction (pg 25), Appendix B, B-2, a. Educate beneficiaries about the benefits and risks of vaccination in a culturally appropriate manner and at an appropriate education level.</p> <p>Joint Instruction (pg 25), Appendix B, B-2, c-d. 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.</p> <p>ACIP General Recommendations (pg 11-12), Benefit and Risk Communication: Parents, guardians, legal representatives, and adolescent and adult patients should be informed about the benefits of and risks for vaccines in language that is culturally sensitive and at an appropriate educational level. Opportunity for questions should be provided before each vaccination. Discussion of the benefits of and risks for vaccination is sound medical practice and is required by law. Certain parents or patients question the need for or safety of vaccinations and want to discuss the risks from and benefits of certain vaccines. Some refuse certain vaccines or reject all vaccinations for personal or religious reasons. Having a basic understanding of how patients and parents view vaccine risk and developing effective approaches to address vaccine safety concerns are imperative for vaccination providers. Each person understands and reacts to vaccine information on the basis of different factors, including previous experience, education, personal values, method of data presentation, perceptions of the risk for disease and perceived ability to</p>

	<p>control these risks, and risk preference. Increasingly, decisions about vaccinations are based on inaccurate information about risk provided by the media and certain websites. Websites and other sources of vaccine information might be inaccurate or incomplete. Health-care providers can be a pivotal source of science-based credible information by discussing with parents and patients the risks from and benefits of vaccines, which helps patients make informed decisions. When a parent or patient initiates a discussion about a perceived vaccine adverse reaction, the health-care provider should discuss the specific concerns and provide factual information, using appropriate language. Effective, empathetic vaccine risk communication is essential in responding to misinformation and concerns, with health-care providers recognizing that risk assessment and decision-making can be difficult and confusing. Certain vaccines might be acceptable to a parent who is resistant to other vaccines. This partial acceptance can be used to facilitate additional communication. Their concerns can be addressed using the VIS and offering other resource materials (e.g., vaccination information from CDC: http://www.cdc.gov/vaccines). The American Academy of Pediatrics (AAP) does not recommend that providers exclude from their practice patients whose parents or guardians question or refuse vaccination. A limited number of providers might exclude patients on this basis; however, an effective public strategy is to identify common ground and discuss measures that need to be followed if the decision is to defer vaccination. Health-care providers should reinforce key points about each vaccine, including safety, and emphasize risks for disease among unvaccinated children. Parents should be advised of state laws regarding entry to school or child-care facilities, which might require that unvaccinated children be excluded from the facility during outbreaks. These discussions should be documented in the patient's record; including the refusal to receive certain vaccines (i.e., informed refusal).</p> <p>Pink Book (pg 42), Provider education: Anyone responsible for administering immunizations should be knowledgeable about principles of vaccination and vaccination scheduling, to the extent required for their position. Providers are largely responsible for educating their patients, so an investment in provider education will result in a higher level of understanding about immunizations among the public in general. Numerous educational materials, in a variety of formats, are available from CDC, the Immunization Action Coalition, and some state health departments, hospitals, or professional organizations.</p>
<p>3. Are current mandatory DOD brochures and educational materials available for the smallpox and anthrax vaccine?</p> <ul style="list-style-type: none"> - Anthrax brochure - Smallpox brochure - ACAM2000 Medication Guide - Smallpox screening form 	<p>Joint Instruction (pg 8), section 2-7 d. (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.</p> <p>Joint Instruction (pg 13-14), section 4-3 b. <i>Military and civilian personnel.</i> 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.</p> <p>Joint Instruction (pg 16), section 4-15 c. 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.</p> <p>Joint Instruction (pg 27), Appendix B, B-6, d. Ensure persons who administer vaccines have ready access to information resources regarding current recommendations for childhood, general adult, travel, & military-specific immunizations.</p> <p>Clinical Policy for the Administration of Anthrax Vaccine Absorbed (dated 31 Jul 09) (pg 3), Medical Screening & Educational Materials: <u>Military treatment facilities will distribute the anthrax vaccine brochure to vaccinees</u> www.health.mil/anthrax) and use it for education sessions. Brochures are shipped with vaccine orders through the United States Medical Materiel Agency or they can be ordered by</p>

	<p>email usarmy.detrick.medcom-usamma.mbx.doc@mail.mil.</p> <p>Update to Clinical Policy for the Department of Defense Smallpox Vaccination Program (dated 1 Apr 2008), (pg 1-2) Education: http://www.health.mil/smallpox Personnel will be educated about smallpox & smallpox vaccination before vaccination. Educational materials provided shall address the rationale, contraindications, criteria for medical exemptions for SM or their household contacts, benefits, side effects, expected response at the vaccination site, risk to household contacts, vaccination-site care & other medical information concerning the vaccine. The ACAM 2000-brand smallpox medication guide and the most current DoD version of the Smallpox Vaccine brochure will be provided to vaccinees.</p>
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Standard 3: Vaccine Storage and Handling

Questions:	References:
<p>1. What is the approximate cost of vaccine(s) in your refrigerator and/or freezer?</p>	<p>Joint Instruction (pg 2), section 1-4 d. (5) Maintain historical vaccine usage data as well as identify future vaccine requirements as needed.</p> <p>Pink Book (pg 61), Vaccine Storage and Handling: Vaccines exposed to temperatures outside the recommended ranges can have reduced potency and protection. Storage and handling errors can cost thousands of dollars in wasted vaccine and revaccination.</p> <p>Pink Book (pg 65), Freezers & Refrigerators: Using the correct freezer and/or refrigerator can help prevent costly vaccine losses & the inadvertent administration of compromised vaccines.</p>
<p>2. Is your thermometer certified and calibrated?</p>	<p>Joint Instruction (pg 4), section 2-3 h. (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.</p> <p>Joint Instruction (pg 5), section 2-3 k. (4). Include calibrated thermometers to track temperatures in all transportation and off-site storage containers.</p> <p>Joint Instruction (pg 25), Appendix B, B-3 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 a minimum of twice a day.</p> <p>ACIP General Recommendations (pg 18), Temperature Monitoring: Thermometers should be placed in each compartment near the vaccines. Different types of thermometers can be used, including standard fluid-filled, minimum-maximum, and continuous chart recorder thermometers (Table 12). Standard fluid-filled thermometers are the simplest and least expensive products. Product temperature thermometers are encased in biosafe liquids and generally reflect refrigerator temperature more accurately than standard fluid-filled thermometers. Minimum-maximum thermometers monitor the temperature range. Continuous chart recorder thermometers monitor temperature range and duration. All thermometers used for monitoring vaccine storage temperatures should be calibrated and certified by an appropriate agency (e.g., National Institute of Standards and Technology or the American Society for Testing and Materials). Because all thermometers are calibrated as part of the manufacturing process, this recommendation refers to a second calibration process that occurs after manufacturing but before marketing and is documented with a certificate that comes with the product. Some products (e.g. continuous chart recorder thermometers) usually include a manufacturer-defined schedule for additional recalibration. For many types of thermometers, replacement might be less expensive than recalibration.</p> <p>Pink Book (pg 66), Thermometers: Thermometers are a critical part of good storage and handling practice. The freezer and the refrigerator unit or compartment should each have its own</p>

	<p>thermometer. There are a variety of types, including digital, bio-safe liquid, continuous graphic, and minimum/maximum thermometers. For measuring vaccine storage unit temperatures, CDC recommends using only calibrated thermometers with a Certificate of Traceability and Calibration. The traceability declaration is to confirm that the measurement standards and instruments used during calibration of the product are from an International Organization of Standardization accredited testing laboratory, to NIST, or to another internationally recognized standards agency. Because all thermometers are calibrated as part of the manufacturing process, this recommendation refers to a 2nd calibration process that occurs after manufacturing but before marketing & is documented with a certificate that comes with the product. Periodic recalibration is necessary. Manufacturer guidelines should be consulted for specific information on recalibration. For many types of thermometers, purchasing a replacement thermometer may be less expensive than recalibration. Immunization programs are often excellent resources for information on calibrated thermometers.</p>
<p>3. How often do you visually check and manually document refrigerator and/or freezer temperatures on a temperature log?</p>	<p>Joint Instruction (pg 4), section 2-3 i (1-2). (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.</p> <p>Joint Instruction (pg 25), Appendix B, B-3 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 a minimum of twice a day.</p> <p>ACIP General Recommendations (pg 18), Temperature Monitoring: Temperature monitoring is a critical component of temperature management. All office and clinical staff members should be aware of vaccine vulnerabilities and storage requirements. Assigning one person in the office as primary responsibility for maintaining and reviewing temperature logs generally is most effective, with a second person assigned as backup. Temperatures for both the refrigerator and freezer should be documented twice a day and recorded. The backup person should review the log at least once each week. Temperature logs should be maintained for 3 years unless state or local statutes require a longer time. An automated monitoring system that alerts staff when a temperature deviation occurs is optimal. However, even if an automated monitoring system is used, temperatures still should be manually checked and recorded twice each day.</p> <p>Pink Book (pg 63), Personnel, Training, and Education: A primary vaccine coordinator who is responsible for ensuring that vaccines are stored and handled correctly should be assigned at each facility. At least one, backup vaccine coordinator who can perform these responsibilities in the absence of the primary coordinator should be designated. These responsibilities include, but are not limited to the following tasks: Ordering vaccines; overseeing proper receipt and storage of vaccine shipments; organizing vaccines within the storage unit(s); temperature monitoring of the storage unit(s) at least twice daily; recording temperature readings on a log; etc.</p> <p>Pink Book (pg 66-67), Temperature Monitoring: Regular temperature monitoring is vital to proper cold chain management. Temperatures in both the freezer and refrigerator units should be read twice each day, once in the morning and once before leaving at the end of the workday. A temperature log should be posted on the door of the storage unit where the twice-daily temperature readings are recorded. CDC recommends keeping these temperature logs for at least 3 years unless state statutes or rules require a longer period.</p> <p>Army Medical Department Supply Bulletin (SB 8-75-11) dated 20 Nov 13, section 3-57, Temperature Sensitive Medical Products (TSMP) Storage and Handling a. (1), (pg 59): (1) Vaccines and Mission Essential TSMP: V&ME TSMP storage refrigerators and freezers will be connected to an emergency or backup power source to ensure proper storage conditions are maintained during commercial power interruption. The commander must outline inspection and recording requirements for V&ME storage units. Each refrigerator and freezer must be labeled as “Refrigerator” or “Freezer” and must be labeled for “Vaccines & Mission Essential Temperature Sensitive Medical Product storage” on the outside of the unit. Exceptions to these requirements are outlined in para f below. Ensure that vaccine temperatures are documented for each vaccine</p>

	<p>storage unit. Physically confirm the temperature of all vaccine refrigerators and freezers at a minimum of two times per day, Physical checks should be performed at the beginning and end of shift changes. Vaccines kept outside of a refrigerator or freezer must have the temperature checked and documented every hour.</p> <p>Pink Book (Chapter 5), Vaccine Storage and Handling (pg 61-74): http://www.cdc.gov/vaccines/pubs/pinkbook/vac-storage.html</p> <p>DHA-IHB, Storage and Handling webpage: http://www.health.mil/coldchain</p> <p>USAMMA website: http://www.usamma.amedd.army.mil/net/Pages/doc/coldChainManagement.aspx</p>
<p>4. Do you have a continuous (24-hr/7) temperature monitoring alarm system that notifies staff if the refrigerator and/or freezer temperature(s) fall outside the normal ranges?</p> <p>Is the alarm system plugged into back-up or battery power?</p> <p>Is the refrigerator and/or freezer plugged into back-up or battery power?</p>	<p>Joint Instruction (pg 4), section 2-3 h. Vaccine Storage Equipment. Ensure that vaccine storage units are carefully selected, used properly, and consistently monitored to maintain recommended vaccine storage temperatures.</p> <p>Joint Instruction (pg 4), section 2-3 h. (3) Ensure alarm systems are incorporated as part of the vaccine storage unit to alert staff of power failure or indicate whether or not vaccine temperatures have been maintained.</p> <p>Joint Instruction (pg 4), section 2-3 j. (1)–(5). (1) Ensure alarm systems are capable of monitoring vaccine storage 24 hours, 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 a 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.</p> <p>Joint Instruction (pg 25), Appendix B, B-3 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 a minimum of twice a day.</p> <p>ACIP General Recommendations page (18), Temperature Monitoring: An automated monitoring system that alerts staff when a temperature deviation occurs is optimal. However, even if an automated monitoring system is used, temperatures still should be manually checked and recorded twice each day.</p> <p>Pink Book (pg 67), Temperature Monitoring: Some providers have purchased alarmed, continuous, automatic, temperature monitoring devices. CDC's recommendation is to continue manual temperature monitoring at least twice daily. Although they may help to minimize human error, the alarmed & continuous monitoring temperature devices have not proven fail safe. CDC continues to receive reports of automatic electronic monitoring system failures & undetected, unresolved vaccine temperature excursions using these as the sole temperature monitor.</p> <p>Pink Book (pg 67), Temperature Monitoring: It is inevitable that manual temperature monitoring may not be accomplished when a provider's office is closed, however. In that case, the electronic monitoring system can provide a backup for assurance that storage temperatures remain within vaccine manufacturers' recommended ranges and that corrective action can be taken quickly if they go out of range. Providers should determine how they are to be notified in the event of an emergency (e.g. a power outage) during hours when the clinic is not open.</p> <p>Pink Book (pg 63), Storage and Handling Plans: Every clinic should also have an emergency</p>

	<p>vaccine retrieval and storage plan. The plan should be easily accessible to staff and identify a backup location where the vaccine can be stored. Considerations when choosing this site include appropriate storage units, temperature monitoring capability and a backup generator. Potential backup locations might include a local hospital, pharmacy, long-term care facility, or the Red Cross.</p>
<p>5. Are all vaccines stored IAW manufacturer's recommendations in original packaging and properly rotated (e.g. b expiration date)?</p>	<p>Joint Instruction (pg 5), section 2-3 l (5). Pack vaccines in their original packaging. Do not remove vaccine vials from boxes.</p> <p>ACIP General Recommendations (pg 18), Expiration Dates and Windows: All vaccines have an expiration date determined by the manufacturer that must be observed. Providers should record the vaccine expiration dates and lot numbers on a stock or inventory record for each vaccine vial when a shipment is received. When vaccines are removed from storage, clinicians and other health-care providers should note whether an expiration window exists for vaccine stored at room temperature or at an intermediate temperature.</p> <p>ACIP General Recommendations (pg 46), Table 11. Vaccine Storage temperature recommendations (states certain vaccines must be protected from light).</p> <p>Pink Book (pg 68), Vaccine Placement and Labeling: Vaccines should be kept in their original packaging with the lids in place until ready for administration and stacked in rows with vaccine of the same type. Bins, baskets, or some other type of uncovered containers with slotted sides or openings can be used to store the vaccines. There should be space between the vaccine stacks or containers.</p> <p>Pink Book (pg 69), Vaccine Storage Troubleshooting: In addition to temperature monitoring, a physical inspection of the storage unit should be performed daily. An inspection should include the following: Are the vaccines placed properly in the unit? Are the vaccines in their original boxes? Are vaccines being stored away from the walls, coils, and vent and not being stored in the doors?</p> <p>Pink Book (pg 70), Vaccine Inventory Control: It is also important to avoid overstocking vaccine supplies, which could lead to vaccine wastage or having outdated vaccine on hand. Vaccine and diluent expiration dates should be closely monitored. Rotate stock so that vaccine and diluent with the shortest expiration date are used first to avoid waste from expiration. The expiration date or time might change once the vaccine is opened or reconstituted. This information is provided in the manufacturer's product information. Expired vaccine and diluent should never be used and should be promptly removed from the storage unit.</p>
<p>6. Are all diluents current (not expired) and stored IAW manufacturer's package insert?</p>	<p>Joint Instruction (pg 4), section 2-3 d (1)-(4). 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 manufacturers' package inserts. (4) Discard diluents when stored inappropriately or expired.</p> <p>ACIP General Recommendations page (46), Table 11. Vaccine Storage temperature recommendations.</p> <p>Pink Book (pg 68), Vaccine Placement and Labeling: Vaccines that must be reconstituted are shipped with diluent specific to that vaccine. Vaccine diluents are not all the same, some contain vaccine antigen. As with vaccines, diluents should be stored according to the guidelines in the manufacturer's product information. When feasible, diluents that require refrigeration should be stored with their corresponding vaccines. Never store any diluent in the freezer because the vials are not designed for freezer storage and could crack.</p>
<p>7. Do you pre-fill/pre-draw vaccine in syringes?</p>	<p>Joint Instruction (pg 4), section 2-3 f (1)-(4). (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</p>

	<p>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 (i.e., not filled by the manufacturer) IAW manufacturer's package insert. If no time line is provided, discard after 8 hours. (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 IAW manufacturer's package insert. If no time line is provided, discard after 8 hours.</p> <p>Joint Instruction (pg 28) =25, Appendix B, B-3 c. The CDC's National Center for Immunization and Respiratory Diseases (NCIRD) 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 exposed to light. Do not pre-draw doses before they are needed.</p> <p>ACIP General Recommendations (pg 14), Needles and Syringes: ACIP discourages the routine practice of prefilling syringes because of the potential for administration errors and vaccine wastage. Because the majority of vaccines have a similar appearance after being drawn into a syringe, prefilling might result in administration errors. In certain circumstances in which a single vaccine type is being used (e.g. in preparation for a community influenza campaign), filling a small number of syringes may be considered. Vaccine doses should not be drawn into a syringe until immediately before administration. When the syringes are filled, the type of vaccine, lot number, and date of filling must be labeled on each syringe, and the doses should be administered as soon as possible after filling. Unused syringes filled by the end user (e.g. not filled by the manufacturer) should be discarded at the end of the vaccination session. In addition to administration errors, prefilling of syringes is a concern because FDA does not license administration syringes for vaccine storage. Unused syringes that are prefilled by the manufacturer and activated (e.g. syringe cap is removed or needle attached) should be discarded at the end of the clinic day. CDC Multi-dose Vial Recommendations: The National Center for Immunization and Respiratory Diseases (NCIRD), Centers for Disease Control and Prevention 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 before they are needed.</p>
<p>8. Are all vaccines handled IAW CDC/ACIP Storage and Handling guidelines?</p>	<p>Joint Instruction (pg 4),=3 section 2-3 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 manufacturers' instructions as outlined in the product's package insert or other guidance.</p> <p>Joint Instruction (pg 4)=3, section 2-3 c (1)-(4). Shelf-life after opening. (1) Administer vaccines shortly after withdrawal from single dose or multidose vials IAW 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) Multidose vaccine vials that do not require diluents (reconstitution). For multidose vials that do not require diluents, withdraw single dose of vaccine into separate sterile needle and syringe for each immunization. Unused portions of multidose vials should be refrigerated at 35° to 46°F (2° to 8°C) and used until marked expiration date or according to manufacturers' package insert. Mark multidose vials with the date it was first opened. (4) Multidose vaccine vials that require diluents. For multidose vials that require diluents, mark reconstituted vaccine with the date and time it was reconstituted. Discard vaccines based on the manufacturer's package insert, the expiration date on the vaccine or vial, or per installation policy.</p> <p>ACIP General Recommendations (pg 14), Needles and Syringes: Different vaccines should never be mixed in the same syringe unless specifically licensed for such use, and no attempt should be made to transfer between syringes. Single-dose vials and manufacturer-filled syringes are designed for single-dose administration and should be discarded if vaccine has been withdrawn or reconstituted and subsequently not used within the time-frame specified by the manufacturer. This typically is no longer than the same clinic day (typically recommended as a</p>

maximum for inactivated vaccines).

ACIP General Recommendations (pg 17), Storage and Handling of Immunobiologics:

Failure to adhere to recommended specifications for storage and handling of immunobiologics can reduce or destroy their potency, resulting in inadequate or no immune response in the recipient. Recommendations in the product package inserts, including methods for reconstitution of the vaccine, should be followed carefully.

ACIP General Recommendations (pg 17), Storage Temperatures: Vaccines licensed for refrigerator storage should be stored at 35°F–46°F (2°C–8°C). Liquid vaccines containing an aluminum adjuvant permanently lose potency when exposed to freezing temperatures. Live, attenuated virus vaccines that should be frozen lose potency when exposed to higher temperatures because the viruses degrade more quickly at storage temperatures that are warmer than recommended (Table 11).

ACIP General Recommendations (pg 19), Multidose Vials: Certain vaccines (i.e., quadrivalent meningococcal polysaccharide vaccine [MPSV4], PPSV, TIV, IPV, and yellow fever) are available in multidose vials. Because several doses are withdrawn from the same vial, proper technique must be followed to prevent contamination. For multidose 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 if the vial has been stored correctly and the vaccine is not visibly contaminated, unless otherwise specified by the manufacturer. Multidose 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.

ACIP General Recommendations (pg 46), Table 11. Vaccine Storage temperature recommendations.

Pink Book (pg 61), Vaccine Storage Temperatures: Vaccines are fragile. They must be maintained at the temperatures recommended by vaccine manufacturers and protected from light at every link in the cold chain. Potency can be adversely affected if vaccines are left out too long or exposed to multiple temperature excursions that can have a cumulative negative effect. It is a good idea to post a sign on the front of the storage unit(s) indicating which vaccines should be stored in the freezer and which should be stored in the refrigerator.

Pink Book (pg 68), Vaccine Placement and Labeling: A storage unit should be big enough so that vaccines can be placed away from the walls, coils, and vents in the part of the unit best able to maintain the constant, required temperature. Vaccines should be kept in their original packaging with the lids in place until ready for administration and stacked in rows with vaccine of the same type. Bins, baskets, or some other type of uncovered containers with slotted sides or openings can be used to store the vaccines. There should be space between the vaccine stacks or containers. These measures will help to avoid confusion between vaccines, provide for air circulation around and through vaccine stacks for even cooling, and protect vaccines from unnecessary light exposure. Not only live attenuated vaccines, but also some inactivated vaccines must be protected from light. The manufacturer's product information indicates if the vaccine must be protected from light.

Pink Book (pg 70), Vaccine Inventory Control: It is also important to avoid overstocking vaccine supplies, which could lead to vaccine wastage or having outdated vaccine on hand. Vaccine and diluent expiration dates should be closely monitored. Rotate stock so that vaccine and diluent with the shortest expiration date are used first to avoid waste from expiration. If the date on the label has a specific month, day, and year, the vaccine can be used through the end of that day. If the expiration date on the label is a month and year, the vaccine can be used through the end of that month. A multidose vial of vaccine that has been stored and handled properly and is normal in appearance can be used through the expiration date printed on the vial unless otherwise stated in manufacturer's product information. Mark a multidose vial with the date it is first opened. Mark a reconstituted vaccine with the date and time it is reconstituted. The expiration date or time might change once the vaccine is opened or reconstituted. This information is provided in the manufacturer's product information. Expired vaccine and diluent should never be

	used and should be promptly removed from the storage unit.
9. Do you receive annual cold chain management training?	<p>Joint Instruction (pg 1), section 1-5=4, c. (1). Ensure individuals administering immunizations are properly trained in accordance with Department of Defense (DoD), Service, and Centers for Disease Control and Prevention (CDC) guidelines and act within their scope of practice as determined by each Service.</p> <p>Joint Instruction (pg 29)=26, Appendix B, B-6 a-b. 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; treatment and reporting of adverse events to include anaphylaxis; vaccine benefit and risk communication; and documentation and management.</p> <p>Pink Book (pg 64), Training and Education: Vaccine storage and handling training should be provided to all new personnel who handle or administer vaccines, including temporary staff. Continuing education for staff is essential when new vaccines are stocked and when there are any changes to the storage and handling guidelines for a particular vaccine. Immunization programs often have good resources for staff training.</p>
10. Do you receive vaccine specific Medical Materiel Quality Control (MMQC) messages?	<p>Joint Instruction (pg 4)=3, section 2-3 a. To maintain the safety and efficacy of vaccines, ensure immunizing and chemoprophylaxis agents are stored, shipped, and handled in accordance with the pharmaceutical manufacturers' instructions as outlined in the product's package insert or other guidance.</p> <p>MMQC Messages: http://www.usamma.amedd.army.mil/net/Pages/doc/mmqcmmi.aspx</p>
11. Are step-by-step emergency procedures included in site's/clinic's SOPs/OIs to help prevent a vaccine cold chain compromise?	<p>Joint Instruction (pg 4)=3, section 2-3 a. To maintain the safety and efficacy of vaccines, ensure immunizing and chemoprophylaxis agents are stored, shipped, and handled in accordance with the pharmaceutical manufacturers' instructions as outlined in the product's package insert or other guidance.</p> <p>Joint Instruction (pg 4), =3section 2-3 b. All locations that maintain and administer vaccines will develop and implement policies for maintaining cold chain management of vaccines.</p> <p>Joint Instruction (pg 4),section 2-3 g =pg 5 l(2). Contact the pharmacy or logistics office for specific policies regarding the disposition of unopened vials, expired vials, unused doses and potentially compromised vaccine.</p> <p>ACIP General Recommendations (pg 14),=18 Response to Out-of-Range Temperature Reading: An out-of-range temperature reading should prompt immediate action. A plan should be developed ahead of time to address various types of emergencies that might require removal of vaccine from the original storage unit. Transfer of vaccines to a pre-designated alternative emergency storage site might be necessary if a temperature problem cannot be resolved immediately (e.g., plugging in an unplugged unit or closing a door that has been left open). Vaccine should be marked "do not use" and moved to the alternate site after verifying that the alternate unit is at the proper temperature. After the vaccine has been moved, determine whether the vaccine is still useable by contacting the state or local health department or manufacturer.</p> <p>Pink Book (pg 64), Training and Education: All personnel who handle or administer vaccines should be familiar with the storage and handling policies and procedures for their facility. This includes not only those who administer vaccines, but also anyone who delivers or accepts vaccine shipments and anyone who has access to the unit(s) where vaccines are stored. These policies and procedures should be available in writing as a reference for all staff members.</p>
12. Does site/clinic have a process for reporting a	Joint Instruction (pg 4),=5 section 2-3g= l (3)-(4). (3) Label potentially compromised vaccine with the words "Do not use" and place in the refrigerator or freezer based on the manufacturer's

<p>potential vaccine or Temperature Sensitive Medical Product (TSMP) compromise?</p>	<p>instructions as if it was not compromised. Report all compromised anthrax and smallpox vaccines to US Army Medical and Materiel Agency (USAMMA) for validation before destruction. Report all other potentially compromised vaccines to the Defense Logistics Agency –Troop Support (DLA-TS) for disposition or destruction instructions. (4) Report all confirmed compromised vaccine losses through Service specific channels to the DHA-IHB IHS for your installation. 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.</p> <p>Joint Instruction (pg 28),=25 Appendix B, B-3, a. Ensure staff members adhere to cold-chain mgt principles during administration, transportation, and storage. Ensure up-to-date, written cold-chain management protocols are accessible at all locations where vaccines are stored.</p> <p>ACIP General Recommendations (pg 18), Response to Out-of-Range: A plan should be developed ahead of time to address various types of emergencies that might require removal of vaccine from the original storage unit.</p> <p>Pink Book (pg 67), Temperature Monitoring: If at any time it is discovered that stored vaccines have been exposed to temperatures outside the recommended ranges, these vaccines should remain properly stored, but segregated and marked “Do NOT Use” until guidance can be obtained. Protocols after an event will vary depending on individual state or agency policies. Contact the immunization program, vaccine manufacturer(s), or both for guidance.</p>
<p>13. Do staff know the proper packing protocol for transporting or shipping vaccines and/or other TSMP?</p>	<p>Joint Instruction (pg 5), section 2-3 I (1)-(7). =k (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™ 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 USAMMA Distribution Operations Center (DOC) instructions. (4) Include calibrated thermo-meters 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.</p> <p>Joint Instruction (pg 25), Appendix B, B-3, a. Ensure staff members adhere to cold-chain management principles during administration, transportation & storage. Ensure up-to-date, written cold-chain mgt protocols are accessible at all locations where vaccines are stored.</p> <p>Pink Book (pg 72), Vaccine Transport to Off-Site Clinics: The number of times vaccines are handled and transported should be minimized. If vaccine transportation to another location is required, it is critical that vaccine potency is protected by maintaining the cold chain at all times. Some immunization programs may recommend or require different vaccine transport practices and procedures. Providers should contact their immunization program for details on how to pack vaccine and diluent for transport and procedures for maintaining the cold chain in the field.</p>
<p>14. Does site/clinic have a process for redistribution of vaccines that will expire and not be used within 90 days?</p>	<p>Joint Instruction (pg 4)= 5, section 2-3 g (2) I. Contact the pharmacy or logistics office for specific policies regarding the disposition of unopened vials, expired vials, unused doses and potentially compromised vaccine.</p> <p>ACIP General Recommendations (pg 8), Vaccine Supply: Potential advantages of stocking a limited number of vaccines include 1) reducing confusion and potential errors when staff members must handle redundant products and formulations, 2) minimizing waste when less commonly used products expire, 3) decreasing cold storage capacity requirements, and 4) minimizing administrative costs related to accounting, purchasing, and handling.</p> <p>Pink Book (pg 70), Vaccine Inventory Control: It is also important to avoid overstocking vaccine supplies that could lead to vaccine wastage or having outdated vaccine on hand. Vaccine and diluent expiration dates should be closely monitored. Rotate stock so that vaccine and diluent</p>

	with the shortest expiration date are used first to avoid waste from expiration. The expiration date or time might change once the vaccine is opened or reconstituted. This information is provided in the manufacturer's product information. Expired vaccine and diluent should never be used and should be promptly removed from the storage unit.
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Standard 4: Indications & Contraindications

Questions:	References:
<p>1. Are patients screened for all indicated vaccinations based on age, health status, occupation, etc, during their visit?</p> <p>If yes, how are records screened and when does this occur?</p> <p>If no, how do you know what immunizations a patient requires?</p>	<p>Joint Instruction (pg 1), section 1-4 b (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 a DoD-approved Service Immunization Tracking System (ITS).</p> <p>Joint Instruction (pg 1), section 1-4 b (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, timed to provide immunity before deployment or exposure, or to complete a vaccine series.</p> <p>Joint Instruction (pg 1), section 1-4 c (5). Monitor the immunization status of personnel and ensure compliance with policies and procedures for creating and maintaining immunization records in IAW 42 USC 300aa-25.</p> <p>Joint Instruction (pg 11), section 3-2 d. 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.</p> <p>Joint Instruction (pg 12), section 3-3 a (2). Federal civilian employees who are at risk of exposure to an infectious disease associated with their occupation will receive appropriate immunizations without charge at military activities unless a current immunization, a protective titer, or a medical or religious exemption is documented. Administer immunizations upon recommendation of the responsible occupational medicine authority.</p> <p>Joint Instruction (pg 12), section 3-5. As a condition of employment or attendance at these facilities, schoolteachers, childcare center workers, volunteers, and children attending DoD and USCG-sponsored primary and secondary schools, childcare centers, or similar facilities are administered appropriate vaccines against communicable diseases unless already immune (based on documented receipt of vaccine series or physician-diagnosed illness) or medically/administratively exempt. For rubella, immunity is based only on documentation of immunization or laboratory evidence of immunity. Administer influenza vaccine annually to schoolteachers, daycare workers, and volunteers. In addition, all other age appropriate ACIP-recommended vaccines for children are required unless there is documentation of previous immunization, religious exemption, or medical contraindication.</p> <p>Joint Instruction (pg 13), section 3-6 a (1). Family members receive immunizations according to current ACIP recommendations. In addition, family members may be subject to Service-specific requirements/ recommendations for immunizations applicable to the country in which they will reside while accompanying military members under military sponsorship.</p> <p>Joint Instruction (pg 25), Appendix B, B-1, d. Review the vaccination status of all beneficiaries at every health care visit to determine which vaccines are indicated.</p> <p>Joint Instruction (pg 25), Appendix B, B-4, b. Screen each patient's immunization record to determine vaccine needs or requirements.</p> <p>Joint Instruction (pg 27), Appendix B, B-6, d. Ensure persons who administer vaccines have ready access to information resources regarding current recommendations for childhood, general</p>

	<p>adult, travel, & military-specific immunizations.</p> <p>Joint Instruction (pg 27), Appendix B, B-8, e. All health care providers (not just those in any clinic or site 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.</p> <p>ACIP General Recommendations (pg 27), Persons Vaccinated Outside the United States: Clinicians have a limited ability to determine whether persons are protected based on their country of origin and their records alone. Vaccines administered outside the United States generally can be accepted as valid if the schedule (i.e., minimum age and intervals) is similar to that recommended in the United States. With the exception of the influenza vaccine and PPSV, only written documentation should be accepted as evidence of previous vaccination. Written records are more likely to predict protection if the vaccines, dates of administration, intervals between doses, and age at the time of vaccination are comparable to U.S. recommendations.</p> <p>ACIP General Recommendations (pg 30), Records of Health-Care Providers: Appropriate and timely vaccination documentation helps ensure not only that persons in need of recommended vaccine doses receive them but also that adequately vaccinated patients do not get excess doses.</p> <p>ACIP General Recommendations (pg 30), Immunization Information Systems: IISs (formerly referred to as immunization registries) are confidential, population-based, computerized information systems that collect and consolidate vaccination data from multiple health-care providers within a geographic area. IISs are a critical tool that can increase and sustain vaccination coverage by consolidating vaccination records from multiple providers, generating reminder and recall vaccination notices for each person, and providing official vaccination forms and vaccination coverage assessments.</p> <p>ACIP General Recommendations (pg 31), Vaccination of Children and Adolescents: Physicians and other pediatric vaccination providers should adhere to the standards for child and adolescent vaccination practices (8). These standards were published by the National Vaccine Advisory Committee and define appropriate vaccination practices for both public and private sectors. The standards provide guidance on practices that eliminate barriers to vaccination, including eliminating unnecessary prerequisites for receiving vaccinations, eliminating missed opportunities to vaccinate, improving procedures to assess vaccination needs, enhancing knowledge about vaccinations among parents and providers, and improving management and reporting of adverse events. In addition, the standards address the importance of recall and reminder systems and using assessments to monitor clinic or site vaccination coverage levels.</p> <p>ACIP General Recommendations (pg 31), Adolescents: To ensure vaccine coverage, clinicians and other health-care providers who treat adolescents must screen for a complete vaccination history on every occasion that an adolescent has an office visit.</p>
<p>2. Do you have standardized questions for screening patients prior to vaccination?</p>	<p>Joint Instruction (pg 1), section 1-4 c (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.</p> <p>Joint Instruction (pg 2), section 2-1 d. Screen all potential vaccinees for contraindications, precautions, or warnings per the prescribing information on the manufacturers' package insert.</p> <p>Joint Instruction (pg 3), section 2-1 g. 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.</p> <p>Joint Instruction (pg 5), section 2-4 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.</p>

	<p>Joint Instruction (pg 5), section 2-5. A pregnancy screening test for women of childbearing potential is not routinely required before administering vaccines, including live-virus vaccines.</p> <p>Joint Instruction (pg 25), Appendix B, B-4 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.</p> <p>Joint Instruction (pg 25), Appendix B, B-4 c. Ensure staff members document any contraindication to an immunization in the health record and ITS. Screen all women for pregnancy status.</p> <p>ACIP General Recommendations (pg 10), Contraindications and Precautions: Persons who administer vaccines should screen patients for contraindications and precautions to the vaccine before each dose of vaccine is administered. Screening is facilitated by consistent use of screening questionnaires, which are available from certain state vaccination programs and other sources (e.g., the Immunization Action Coalition, http://www.immunize.org).</p> <p>Pink Book (pg 27), Screening for Contraindications and Precautions: The key to preventing serious adverse reactions is screening. Every person who administers vaccines should screen every patient for contraindications and precautions before giving the vaccine dose. Effective screening is not difficult or complicated and can be accomplished with just a few questions. Every person should be screened for contraindications and precautions before vaccination. Standardized screening forms for both children and adults have been developed by the Immunization Action Coalition and are available on their web site at http://www.immunize.org.</p>
<p>3. What do you do if a patient states they have an allergy to a component of a vaccine?</p>	<p>Joint Instruction (pg 5), section 2-4 a-c. 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.</p> <p>Pink Book (pg 28), Screening for Contraindications and Precautions: A history of anaphylactic reaction to a previous dose of vaccine or vaccine component is a contraindication for subsequent doses. A history of encephalopathy within 7 days following DTP/DTaP is a contraindication for further doses of pertussis-containing vaccine. Precautions to DTaP (not Tdap) include (a) seizure within 3 days of a dose, (b) pale or limp episode or collapse within 48 hours of a dose, (c) continuous crying for 3 hours within 48 hours of a dose, and (d) fever of 105°F (40°C) or higher within 48 hours of a previous dose. Other adverse events that might have occurred following vaccination constitute contraindications or precautions to future doses. Usually vaccines are deferred when a precaution is present. However, situations may arise when the benefit outweighs the risk (e.g., during a community pertussis outbreak). A local reaction (redness or swelling at the site of injection) is not a contraindication to subsequent doses.</p>
<p>4. Are signs posted in the area where vaccines are administered asking pregnant woman to identify themselves?</p> <p>What is your process for pregnancy screening?</p>	<p>Joint Instruction (pg 5), section 2-5 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: (1) 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 "no", then immunize her. If the answer is "yes", then defer her from immunization until her pregnancy ends, the vaccine is recommended for use in pregnancy by ACIP or refer to an obstetric care provider to determine whether the benefits of immunization outweigh risks in pregnancy. If pregnancy status is uncertain, defer immunization until after a negative pregnancy evaluation (for example, urine, or serologic test). (2) With regard to smallpox (vaccinia) vaccine, a specific pre-immunization screening form (http://www.health.mil/smallpox) that</p>

	<p>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. (3) 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. (4) 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 counseling in the health record. (5) If she is pregnant and immunization is indicated, immunize in consultation with her obstetric health care provider. (6) If a contraindicated vaccine is inadvertently administered to a pregnant woman, report the event upon discovery to preventive medicine POC 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 the Military Vaccine Agency.</p> <p>Joint Instruction (pg 25), Appendix B, B-4 c. Ensure staff members document any contraindication to an immunization in the health record and ITS. Screen all women for pregnancy status.</p> <p>ACIP General Recommendations (pg 10), Contraindications and Precautions: Persons who administer vaccines should screen patients for contraindications and precautions to the vaccine before each dose of vaccine is administered.</p> <p>ACIP General Recommendations (pg 27), Vaccination During Pregnancy: Because of the importance of protecting women of childbearing age against rubella and varicella, reasonable practices in any vaccination program include asking women if they are pregnant or might become pregnant in the next 4 weeks; not vaccinating women who state that they are or plan to become pregnant; explaining the theoretical risk for the fetus if MMR, varicella, or MMRV vaccine were administered to a woman who is pregnant; and counseling women who are vaccinated not to become pregnant during the 4 weeks after MMR, varicella, or MMRV vaccination.</p>
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Standard 5: Immunization Recordkeeping

Questions:	References:
<p>1. Which DOD-approved Immunization Tracking System (ITS) is utilized to document immunizations?</p> <p>Check all that apply:</p> <p>MRRS SAMS MEDPROS ASIMS Non Active Duty – AHLTA Active Duty - AHLTA Other No ITS utilized</p>	<p>Joint Instruction (pg 7), section 2–7 a. a. Electronic immunization tracking systems. (1) Document all immunizations in a DoD-approved immunization tracking system (ITS) including date, immunization given, dose, lot number, manufacturer, and the identification of the person administering the vaccine. (2) Electronic ITS must — (a) Comply with the requirements of both the National Vaccine Injury Compensation (NVIC) Program, 42 USC 300aa-25. Report and Recording of Information and 42 USC 300aa-26. Vaccine information outlined in paragraph d, below. (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, SF 601 (Health Record-Immunization Record), or DD Form 2766C (Adult Preventive and Chronic Care Flow sheet) (Continuation Sheet) format, accompanied by an official clinic or site 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 paragraph (3) above will suffice as a valid certificate of vaccination for international travel (except for yellow fever that 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.</p> <p>Joint Instruction (pg 8), section 2–7 d (1). The National Childhood Vaccine Injury Act (NCVIA) of 1986 and other regulations set standards for certain immunizations. These requirements apply to US vaccines as indicated by the CDC after the Secretary DHHS 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</p>

	<p>of immunization documentation.</p> <p>Joint Instruction (pg 10), section 3-1 a (5). Document immunizations and immunization exemption codes (medical or administrative) in a DoD-approved Service ITS.</p> <p>Joint Instruction (pg 25), Appendix B, B-5 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.</p> <p>Joint Instruction (pg 25), Appendix B, B-5 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.</p> <p>ACIP General Recommendation (pg 30), Immunization Information Systems: IISs (formerly referred to as immunization registries) are confidential, population-based, computerized information systems that collect and consolidate vaccination data from multiple health-care providers within a geographic area. IISs are a critical tool that can increase and sustain vaccination coverage by consolidating vaccination records from multiple providers, generating reminder and recall vaccination notices for each person, and providing official vaccination forms and vaccination coverage assessments (214). A operational IIS also can prevent duplicate vaccinations, limit missed appointments, reduce vaccine waste, and reduce staff time required to produce or locate vaccination records or certificates. Most IISs have additional capabilities, such as vaccine management, maintenance of lifetime vaccination histories, and interoperability with other health information systems. The National Vaccine Advisory Committee strongly encourages development of community- or state-based IISs and recommends that vaccination providers participate in these systems when possible.</p> <p>Pink Book (pg 39), Immunization Information Systems: The Task Force on Community Preventive Services recommends immunization information systems based on strong evidence of effectiveness in increasing vaccination rates. Specifically, the Task Force concluded that IIS are directly related to increasing vaccination rates through their capabilities to create or support effective interventions such as client reminder/recall systems, provider assessment and feedback, and provider reminders; generate and evaluate public health responses to outbreaks of vaccine-preventable disease; facilitate vaccine management and accountability; determine client vaccination status for decisions made by clinicians, health departments, and schools; and aid surveillance and investigations on vaccination rates, missed vaccination opportunities, invalid dose administration, and disparities in vaccination coverage.</p>
<p>2. What process(es) is/are in place for notifying patients when immunizations are due? (Check All that Apply)</p> <p>Hit list Reminder cards Readiness Web-site Unit correspondence Recall roster Deployment list Automated notification system Mailed/emailed Telephone notification During routine visits Health record verification In/Out Processing</p>	<p>Joint Instruction (pg 25), Appendix B, B-5 b. Recommend any clinic or site 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, e-mailed, or telephone messages.</p> <p>ACIP General Recommendations (pg 30), Immunization Information Systems: IISs (formerly referred to as immunization registries) are confidential, population-based, computerized information systems that collect and consolidate vaccination data from multiple health-care providers within a geographic area. IISs are a critical tool that can increase and sustain vaccination coverage by consolidating vaccination records from multiple providers, generating reminder and recall vaccination notices for each person, and providing official vaccination forms and vaccination coverage assessments.</p> <p>Pink Book (pg 39), Recommendations to Parents and reinforcement of the need to Return: Regardless of their child's true immunization status, many parents believe the child is fully vaccinated. Parents may not have been told or may not have understood that return visits are necessary. It is useful for patients to have the next appointment date at the time they leave the provider's office. An additional reminder strategy is to link the timing of the return visit to some calendar event, e.g., the child's birthday or an upcoming holiday. Even with written schedules or reminders, a verbal encouragement and reminder can be an incentive for a patient's completing</p>

	<p>the immunization series and can ultimately result in higher coverage levels. Both the Standards for Child and Adolescent Immunization Practices and the Standards for Adult Immunization Practices call upon providers to develop and implement aggressive tracking systems that will both remind parents of upcoming immunizations and recall children who are overdue. ACIP supports the use of reminder/recall systems by all providers. The National Center for Immunization and Respiratory Diseases provides state and local health departments with ongoing technical support to assist them in implementing reminder and recall systems in public & private provider sites.</p>
<p>3. How and when do you document immunizations?</p>	<p>Joint Instruction (pg 1), section 1-4 b (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 a DoD-approved Service Immunization Tracking System (ITS).</p> <p>Joint Instruction (pg 7), section 2–7 a. Electronic immunization tracking systems. (1) Document all immunizations in a DoD and USCG approved immunization tracking system (ITS) including date, immunization given, dose, lot number, manufacturer, and the identification of the person administering the vaccine. (2) Electronic ITS must —(a) Comply with the requirements of both the National Vaccine Injury Compensation (NVIC) Program, 42 USC 300aa-25. Report and Recording of Information and 42 USC 300aa-26. Vaccine information outlined in paragraph d, below. (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, SF 601 (Health Record-Immunization Record), or DD Form 2766C (Adult Preventive and Chronic Care Flow sheet) (Continuation Sheet) format, accompanied by an official clinic or site 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 paragraph (3) above will suffice as a valid certificate of vaccination for international travel (except for yellow fever that 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.</p> <p>Joint Instruction (pg 7), section 2-7 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) 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 initials of person administering. 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/her possession when traveling internationally. Data are entered by hand, rubber stamp, or by typewriter. (a) Abbreviations. Use abbreviations for vaccines and their manufacturers conforming to the nomenclature adopted by the CDC Vaccine Identification Standards Initiative (VISI). When writing, 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).</p> <p>Joint Instruction (pg 7), section 2-7 b. (6). 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.</p> <p>Joint Instruction (pg 8), section 2–7 d (1). The National Childhood Vaccine Injury Act (NCVIA) of 1986 and other regulations set standards for certain immunizations. These requirements apply to US vaccines as indicated by the CDC after the Secretary DHHS publishes a notice of coverage. Document the patient's name; identifying number (for example, sponsor's SSN); type of vaccine;</p>

	<p>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.</p> <p>Joint Instruction (pg 25), Appendix B, B-5 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.</p> <p>ACIP General Recommendations (pg 30), Records of Health Care Providers: Appropriate and timely vaccination documentation helps ensure not only that persons in need of recommended vaccine doses receive them but also that adequately vaccinated patients do not receive excess doses. Curtailing the number of excess doses administered to patients controls costs incurred by patients, providers, insurers, vaccination programs, and other stakeholders. In addition, excess doses of inactivated vaccines might increase the risk for an adverse reaction. Health-care providers who administer vaccines covered by the National Childhood Vaccine Injury Act are required to ensure that the permanent medical record of the recipient (or a permanent office log or file) indicates the date the vaccine was administered, the vaccine manufacturer, the vaccine lot number, and the name, address, and title of the person administering the vaccine. In addition, the provider is required to record the edition date of the VIS distributed and the date those materials were provided. This information should be kept for all vaccines, not just for those required by the act. Providers and staff members also should systematically update patient's permanent medical records to reflect any documented episodes of adverse events after vaccination and any serologic test results related to vaccine-preventable diseases (e.g., rubella screening & antibody to HBsAg).</p>
<p>4. What process is in place for patients who present with no written documentation of previous vaccinations?</p>	<p>Joint Instruction (pg 3), section 2-1 g. 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.</p> <p>Joint Instruction (pg 8), section 2-7 c. 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).</p> <p>Joint Instruction (pg 8), section 2-7 d (1). The National Childhood Vaccine Injury Act (NCVIA) of 1986 and other regulations set standards for certain immunizations. These requirements apply to US vaccines as indicated by the CDC after the Secretary DHHS 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.</p> <p>ACIP General Recommendations (pg 10), Unknown or Uncertain Vaccination Status: Vaccination providers frequently encounter persons who do not have adequate documentation of vaccinations. With the exception of influenza vaccine and PPSV, providers should only accept written, dated records as evidence of vaccination; self-reported doses of influenza vaccine and PPSV are acceptable (49,68). Although vaccinations should not be postponed if records cannot be found, an attempt to locate missing records should be made by contacting previous health-care providers, reviewing state or local IISs, and searching for a personally held record. If records cannot be located within a reasonable time, these persons should be considered susceptible and started on the age-appropriate vaccination schedule. Serologic testing for immunity is an alternative to vaccination for certain antigens (e.g., measles, rubella, hepatitis A, and tetanus). However, commercial serologic testing might not always be sufficiently sensitive or standardized for detection of vaccine-induced immunity (with the exception of hepatitis B vaccination at 1-2 months after the final dose), and research laboratory testing might not be readily available.</p>

<p>5. CDC 731 (Yellow Shot Record): Do you have form CDC 731s (formerly PHS 731) available?</p> <p>Is DOD International Certification stamp (known as Yellow Fever stamp) available?</p>	<p>Joint Instruction (pg 7), section 2-7 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) 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 initials of person administering. 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/her possession when traveling internationally. Data are entered by hand, rubber stamp, or by typewriter. (a) Abbreviations. Use abbreviations for vaccines and their manufacturers conforming to the nomenclature adopted by the CDC Vaccine Identification Standards Initiative (VISI). When writing, 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 (i.e., 14 June 1994 or 14 Jun 94).</p> <p>To order CDC 731 (formerly known as PHS 731) forms: U.S. Government Printing Office, Washington, D.C., http://bookstore.gpo.gov/ telephone 866-512-1800. The stock # is 017-001-00567-3 for 25 copies and 017-001-00566-5 for 100 copies.</p> <p>To order Official DoD Certificate of Vaccination Stamp contact your DHA-IHB Immunization Healthcare Specialist (IHS) at www.health.mil/ContactYourIHS</p>
<p>6. Do you transcribe immunization records?</p>	<p>Joint Instruction (pg 7), section 2-7 b (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 initials of person administering. 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/her possession when traveling internationally. Data are entered by hand, rubber stamp, or by typewriter.</p> <p>Joint Instruction (pg 7), section 2-7 b. (2). Use abbreviations for vaccines and their manufacturers conforming to the nomenclature adopted by the CDC Vaccine Identification Standards Initiative (VISI). When writing, 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).</p> <p>Joint Instruction (pg 5), section 2-7 b. (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.</p> <p>Joint Instruction (pg 9), section 2-7 b. (6). Individuals preparing paper-based immunization & chemoprophylaxis records will ensure that paper records match electronic ITS. If paper-based immunization or chemoprophylaxis records are used, electronic ITS will be updated within 24 hours.</p>

Standard 6: Immunization Personnel Training

Questions:	References:
1. How many hours of	Joint Instruction (pg 1), section 1-4, c. (1). Ensure individuals administering immunizations are

<p>immunization specific training are required during orientation and annually for staff members?</p> <p>Is the training documented in the staff's training record(s)?</p>	<p>properly trained in accordance with Department of Defense (DoD), Service, and Centers for Disease Control and Prevention (CDC) guidelines and act within their scope of practice as determined by each Service.</p> <p>Joint Instruction (pg 26), Appendix B, B-6. 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; 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 eight (8) hours of training annually. Training resources include resident courses, self-paced online training programs, and video training. See table B-6. d. Ensure persons who administer vaccines have ready access to information resources regarding current recommendations for childhood, general adult, travel, & military-specific immunizations.</p>
<p>2. Are immunization specific competencies utilized for immunizer's training records?</p>	<p>Joint Instruction (pg 1), section 1-4, c. (1). Ensure individuals administering immunizations are properly trained in accordance with Department of Defense (DoD), Service, and Centers for Disease Control and Prevention (CDC) guidelines and act within their scope of practice as determined by each Service.</p> <p>Joint Instruction (pg 26), Appendix B, B-6, Table B-1. 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; 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 eight (8) hours of training annually. Training resources include resident courses, self-paced online training programs, and video training. See table B-6. d. Ensure persons who administer vaccines have ready access to information resources regarding current recommendations for childhood, general adult, travel, & military-specific immunizations.</p> <p>AFI 44-102, Chapter 13 Allergy and Immunization Services</p>
<p>3. Which of the following immunization resources do you utilize? (Check All that apply)</p> <p>DHA-IHB CDC/ACIP Service Specific COCOM MAJCOM Pink Book Yellow Book Immunization Toolkit Other:</p>	<p>Joint Instruction (pg 26), Appendix B, B-6. a. Ensure all persons who administer vaccines, including immunization augmentees, are 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; 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 eight (8) hours of training annually. Training resources include resident courses, self-paced online training programs, and video training. See table B-6. d. Ensure persons who administer vaccines have ready access to information resources regarding current recommendations for childhood, general adult, travel, & military-specific immunizations.</p> <p>Joint Instruction (pg 27), Appendix B, B-6, d. Ensure persons who administer vaccines have</p>

<p>4. Which training resources does your site/clinic utilize (check all that apply)</p> <p>DHA-IHB on-line training (e.g. ImzU, PIR)</p> <p>Live training (e.g. IBC/ILC, Pink Book course, National Immunization Conference, etc.)</p> <p>CDC</p> <p>Immunization Action Coalition (IAC)</p> <p>Other:</p>	<p>ready access to information resources regarding current recommendations for childhood, general adult, travel, & military-specific immunizations. DHA-IHB Website: www.health.mil/vaccines</p> <p>Joint Instruction (pg 1), section 1-5, c. (1). Ensure individuals administering immunizations are properly trained in accordance with Department of Defense (DoD), Service, and Centers for Disease Control and Prevention (CDC) guidelines and act within their scope of practice as determined by each Service.</p> <p>CDC: http://www.cdc.gov/vaccines/default.htm</p> <p>Cold Chain Mgmt: www.health.mil/coldchain</p> <p>Immunization University: (On-line training, Archived webcasts, Immunization Program Leaders Course, Standards for Quality Immunization Practice Course): http://www.vaccines.mil/training</p> <p>Project Immune: https://www.projectimmunereadiness.amedd.army.mil/</p> <p>DOD Smallpox Training: http://www.vaccines.mil/MyImzU/default.aspx</p> <p>CDC Continuous Education: http://www2a.cdc.gov/TCEOnline/</p> <p>CDC's "You Call the Shots": http://www.cdc.gov/vaccines/ed/youcalltheshots.htm</p> <p>Immunization Tracking Systems: www.health.mil/ITS</p> <p>Immunization Action Coalition: http://www.immunize.org/</p> <p>Vaccine Adverse Events Reporting System (VAERS): http://vaers.hhs.gov/index</p> <p>National Immunization Conference (NIC): http://www.cdc.gov/vaccines/events/nic/</p>
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Standard 7: Adverse Events after Immunization

Questions:	References:
<p>1. Does site/clinic have medications, equipment, and supplies readily available for emergency management of anaphylaxis?</p> <p>Are a minimum of 3 vials of epinephrine 1:1,000 or Epi-pen auto-injectors available?</p>	<p>Joint Instruction (pg 8), section 2-9 c. 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 (e.g., 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.</p> <p>Joint Instruction (pg 27), Appendix B, B-7 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 paragraph 2-9). Ensure all immunization</p>

<p>Are emergency medications (e.g. Epi, Benadryl) & equipment (e.g. blood pressure cuffs, oral airways, bag valve mask, etc.) available for patient population served (e.g. infant, pediatric, adult)?</p> <p>Is ability to activate emergency response system available and tested at least monthly?</p>	<p>personnel are trained to administer epinephrine.</p> <p>Joint Instruction (pg 27), Appendix B, B-7 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.</p> <p>ACIP General Recommendations (pg 12), Managing Acute Vaccine Reactions: Although anaphylactic reactions are rare after vaccination, their immediate onset and life-threatening nature require that all personnel and facilities providing vaccinations have procedures in place for anaphylaxis management. All vaccination providers should be familiar with the office emergency plan and be currently certified in cardiopulmonary resuscitation. Epinephrine and equipment for maintaining an airway should be available for immediate use.</p>
<p>2. Is staff trained annually on the management of anaphylaxis and vasovagal (e.g. fainting) episodes?</p>	<p>Joint Instruction (pg 2), section 1-4 c. (6) Ensure emergency medical response is available; that personnel who administer immunizations are trained at a minimum in basic cardiopulmonary resuscitation, administration of epinephrine, and emergency response to immunization adverse events.</p> <p>Joint Instruction (pg 8), section 2-9 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.</p> <p>Joint Instruction (pg 26), Appendix B, B-6 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; treatment and reporting of adverse events to include anaphylaxis; vaccine benefit and risk communication; and documentation and management.</p> <p>ACIP Recommendations (pg 12) Managing Acute Vaccine Reactions Although anaphylactic reactions are rare after vaccination, their immediate onset and life-threatening nature require that all personnel and facilities providing vaccinations have procedures in place for anaphylaxis management. All vaccination providers should be familiar with the office emergency plan and be currently certified in cardiopulmonary resuscitation.</p>
<p>3. What is the site/clinic's process to report an adverse event after immunization?</p>	<p>Joint Instruction (pg 2), section 1-4 c. (7). Ensure health care providers are available to respond to and report adverse events resulting from immunization.</p> <p>Joint Instruction (pg 2), section 1-4 c. (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.</p> <p>Joint Instruction (pg 9), section 2-10 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 the VHC network is available 24/7 for providers who require additional support for clinical evaluation of possible vaccine adverse events.</p> <p>Joint Instruction (pg 9), section 2-10 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.</p> <p>Joint Instruction (pg 9), section 2-10 d. Reporting requirements are as follows: (1) Report adverse events resulting in hospitalization, a life-threatening event (for example, anaphylaxis),</p>

	<p>time lost from duty more than 24 hours (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, (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) because they are already expected, but such reports may be submitted if the clinician or patient wishes.</p> <p>Joint Instruction (pg 11), section 3-2 c. Aviation personnel. Typically aviation personnel are grounded for 12 hours (Air Force: 4 hours post vaccination access to medical care unless access to operational needs dictate otherwise) 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. Further temporary grounding may be necessary until significant side effects resolve.</p> <p>Joint Instruction (pg 27), Appendix B, B-7 c. Report all clinically significant adverse events after vaccination to VAERS. Provide staff members with ready access to reporting options for the VAERS.</p> <p>ACIP General Recommendations (pg 13), Reporting Adverse Events after Vaccination: Complete information about adverse reactions to a specific vaccine is available in the package insert for each vaccine and from CDC at http://www.cdc.gov/vaccines/vac-gen/side-effects.htm. An adverse event is an untoward event that occurs after a vaccination that might be caused by the vaccine product or vaccination process. These events range from common, minor, local reactions to rare, severe, allergic reactions (e.g., anaphylaxis). Reporting adverse events, including serious events, to VAERS is a key mechanism for identifying potential vaccine safety concerns. The National Childhood Vaccine Injury Act requires health-care providers and vaccine manufacturers to report to VAERS specific adverse events that occur after vaccination. The reporting requirements are different for manufacturers and health-care providers. Manufacturers are required to report all adverse events that occur after vaccination to VAERS, whereas health-care providers are required to report events that appear in the reportable events table on the VAERS website at http://vaers.hhs.gov/reportable.htm. In addition to the mandated reporting of events listed on the reportable events table, health-care providers should report to VAERS all events listed in product inserts as contraindications, as well as all clinically significant adverse events, even if they are uncertain that the adverse event is related causally to vaccination. Persons other than health-care providers also can report adverse events to VAERS. There are three ways to report to VAERS: 1. Submit the report online via a secure website at https://vaers.hhs.gov/esub/step1, 2. Fax a completed VAERS form to 877-721-0366, or 3. Mail a completed VAERS form: VAERS, P.O. Box 1100, Rockville, MD 20849-1100. A VAERS form can be downloaded from the VAERS website at http://vaers.hhs.gov/resources/vaers_form.pdf. VAERS forms also can be requested by e-mail (info@vaers.org), telephone (800-822-7967), or fax (877-721-0366).</p>
<p>4. Does SOPs/OIs include step-by-step procedures in the event of an anaphylaxis and/or an adverse event?</p>	<p>Joint Instruction (pg 8), section 2-9 a. Written plan. Clinics or sites administering immunizations will develop and maintain a written plan for emergency response, including standing orders for the management of anaphylaxis and fainting.</p> <p>ACIP General Recommendations (pg 12), Managing Acute Vaccine Reactions: Although anaphylactic reactions are rare after vaccination, their immediate onset and life-threatening nature require that all personnel and facilities providing vaccinations have procedures in place for anaphylaxis management. All vaccination providers should be familiar with the office emergency plan and be currently certified in cardiopulmonary resuscitation.</p>

Standard 8: Vaccine Advocacy to Protect the Military Family

Questions:	References:
<p>1. Do staff or site/clinic participate in immunization patient education, outreach events, and/or marketing?</p> <p>Immunization events include (check all that apply)</p>	<p>Joint Instruction (pg 1), section 1- 4 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.</p> <p>Joint Instruction (pg 1), section 1- 4 b. (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.</p> <p>Joint Instruction (pg 1), section 1- 4 c. (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.</p> <p>Joint Instruction (pg 9), section 2- 11 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).</p> <p>Joint Instruction (pg 25), Appendix B, B-2 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.</p> <p>Joint Instruction (pg 27), Appendix B, B-8, 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.</p>
<p>2. Does your site/clinic have a quality improvement process in your immunization practice?</p>	<p>Joint Instruction (pg 9-10), section 2- 11 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.</p>

	<p>Joint Instruction (pg 27), Appendix B, B-7, d. Develop a quality improvement process to assure adverse events are reported to VAERS promptly.</p> <p>Joint Instruction (pg 27), Appendix B, B-8, a-c. <i>a.</i> 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. <i>b.</i> 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. <i>c.</i> Conduct a quality improvement program to optimize the performance in immunizing children, adolescents, and adults against the preventable infections that most threaten them.</p>
<p>3. Are annual influenza compliance and immunization readiness rates tracked at your site/clinic?</p>	<p>Joint Instruction (pg 1), section 1- 4 b. (1) 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.</p> <p>Joint Instruction (pg 1), section 1- 4 b. (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.</p> <p>Joint Instruction (pg 27), Appendix B, B-8, 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.</p> <p>Joint Instruction (pg 27), Appendix B, B-8, a-c. <i>a.</i> 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. <i>b.</i> 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. <i>c.</i> Conduct a quality improvement program to optimize the performance in immunizing children, adolescents, and adults against the preventable infections that most threaten them.</p>
<p>4. Are ACIP recommended vaccines promoted at site/clinic for high risk groups? ACIP recommended vaccines include (check all that apply):</p>	<p>Joint Instruction (pg 27), Appendix B, B-8, a-c. <i>a.</i> 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. <i>b.</i> 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. <i>c.</i> Conduct a quality improvement program to optimize the performance in immunizing children, adolescents, and adults against the preventable infections that most threaten them.</p> <p>Joint Instruction (pg 27), Appendix B, B-8, 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.</p> <p>ACIP General Recommendations (pg 32), Vaccination of Children and Adolescents: Ensuring adolescents receive routine and catch-up vaccination and increasing vaccination coverage in this age group present challenges. In general, adolescents do not visit health-care providers frequently. Health-care providers should promote annual preventive visits (217), including one specifically for adolescents aged 11 and 12 years. The annual visits should be used as opportunities to provide routinely recommended vaccine doses, additional catch-up doses needed for lapsed vaccine series, vaccines recommended for high-risk groups, additional doses that might have been recently recommended, and other recommended health-care services.</p>