



DEPARTMENT OF THE ARMY
OFFICE OF THE SURGEON GENERAL
5109 LEESBURG PIKE
FALLS CHURCH VA 22041

REPLY TO
ATTENTION OF

Military Vaccine Agency

12 August 2011

MEMORANDUM FOR SEE DISTRIBUTION

SUBJECT: Implementation Guidance for Administration of Adenovirus Type 4 and Type 7 Vaccine Live, Oral

1. References:

a. Department of Defense (DoD) Joint Regulation (Army Regulation 40-562, BUMEDINST 6230.15A, AFJI480110, CG COMDTINST M6230.4F), Immunization and Chemoprophylaxis, 29 September 2006. Available at: <http://www.vaccines.mil/>

b. Department of Defense Directive (DODD) 6205.02E, *Policy and Program for Immunizations to Protect the Health of Service Members and Military Beneficiaries*, 19 September 2006. Available at: <http://www.vaccines.mil/documents/973Policy620502p.pdf>

c. Department of Defense, Armed Forces Epidemiological Board, Prevention/Minimization of Adenovirus Infection, Number 02-01, November 23, 2001. Available at: http://www.health.mil/dhb/afeb_gosearch_content.cfm

d. Food and Drug Administration (FDA), Center for Biologics Evaluation and Research (CBER), Adenovirus Type 4 and Type 7 Vaccine, Live Oral - Product Approval Information, 16 March 2011. Available at: <http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm247511.htm>

e. Food and Drug Administration (FDA), Center for Biologics Evaluation and Research (CBER), Package Insert, Adenovirus Type 4 and Type 7 Vaccine, Live, Oral. Available at: <http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm247508.htm>

f. Armed Forces Blood Program Office, Blood Program Letter (BPL) 11-03 Revision to the Deferral Period for Adenovirus Type 4 and Type 7 Vaccine (Draft). Available at: <http://www.militaryblood.dod.mil/Staff/bpl.aspx>

2. Purpose. To provide instructions to Service representatives for the administration of Adenovirus Type 4 and Type 7 Vaccine, Live, Oral to military recruit populations.

3. Summary. Adenovirus is a significant cause of respiratory disease in enlisted military recruits. Adenovirus Type 4 and Type 7 Vaccine Live, Oral was developed specifically for the U.S. Military by TEVA Pharmaceuticals, USA/Barr Laboratories, Inc., to prevent adenovirus type 4 and type 7 associated illnesses. The FDA approved licensure of the adenovirus vaccine on 16 March 2011 for military populations 17 to 50 years of age.

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4. Timeline. Adenovirus Type 4 and Type 7, Live, Oral will be positioned at enlisted basic training sites by early October 2011. Services will begin immunizing military enlisted basic trainees upon receipt of vaccine.

5. Adenovirus Type 4 and Type 7 Vaccine, Live, Oral Vaccination Policy. Services will administer adenovirus vaccine to all enlisted military recruits in accordance with reference a.

6. Clinical Requirements.

a. Adenovirus Type 4 and Type 7 Vaccine, Live, Oral consists of two tablets administered orally to enlisted military recruits 17 to 50 years of age. Each tablet must be swallowed whole and cannot be chewed or crushed.

b. Administer Adenovirus Type 4 and Type 7 Vaccine, Live, Oral to all military enlisted basic trainees at the earliest opportunity upon arrival to the accession site.

c. Adenovirus Type 4 and Type 7 Vaccine, Live, Oral is administered once with no booster requirement.

d. The adenovirus vaccine can be administered simultaneously or at any interval before or after other vaccines, including live vaccines.

e. The adenovirus vaccine should not be administered to individuals with known severe allergic reactions to any components (see package insert) of the vaccine; pregnant females, nursing mothers, females considering pregnancy within 6 weeks of receiving the vaccine; individuals incapable of swallowing an entire tablet whole, without chewing.

f. Postpone administration to individuals with vomiting and/or diarrhea and those with moderate to severe acute illness.

g. Prospective Blood donors immunized with Adenovirus Type 4 and Type 7 Vaccine, Live, Oral will be deferred 4 weeks from the time of vaccination (ref f).

h. Adenovirus Types 4 and Types 7 Vaccine, Live, Oral is not required for cadre working at the enlisted basic training sites.

7. Education.

a. Prior to immunization, provide vaccine recipients a copy of the vaccine information statement (VIS) for Adenovirus Type 4 and Type 7 Vaccine, Live, Oral (ref e). Display the VIS at the recruit immunization site and urge each vaccinee to read the VIS prior to immunization. The adenovirus VIS is available for download at www.cdc.gov/vaccines/pubs/vis/default.htm or www.vaccine.mil/adenovirus.

b. The manufacturer will provide a brochure to each training site which contains additional information about the adenovirus vaccine. A copy of the brochure is available for download at www.vaccine.mil/adenovirus.

c. The vaccine contains live adenovirus that is shed in the stool for up to 28 days following vaccination; therefore, instruct all vaccinees in the proper procedures for hand washing and utilization of hand sanitizer to prevent spread of the virus.

d. During the 28 day shedding interval, vaccine recipients should exercise caution when in close contact with children less than 7 years of age, immunocompromised individuals, and pregnant women.

e. Female personnel who inadvertently received the adenovirus vaccine during pregnancy, or become pregnant within 6 weeks of vaccination, should receive information concerning the Adenovirus Vaccine Pregnancy Registry for self-referral. Per the package insert, all cases in which a women receives adenovirus vaccine during pregnancy or becomes pregnant (conception occurs) within 6 weeks following vaccination should be reported to the Adenovirus Vaccine Pregnancy Registry by calling 1-866-790-4549 or text or email: adenovirus@kendle.com.

8. Vaccine Ordering, Storage, and Handling Procedures.

a. The U.S. Army Medical Materiel Agency (USAMMA) Distribution Operations Center (DOC) will coordinate the distribution of the adenovirus vaccine to supporting medical supply activities for all services. The manufacturer will ship the vaccine directly to the recruit training sites with coordination from USAMMA.

b. USAMMA will develop a Medical Materiel Quality Control Message (MMQC) detailing the ordering process for Adenovirus Type 4 and Type 7, Live Oral vaccine for the recruit training sites.

c. Adenovirus Type 4 and Type 7 Vaccine Live, Oral must be refrigerated between 2° and 8°C (35° and 46° F) and never frozen.

d. All bottles must be protected from moisture and remain tightly closed. The desiccant canister should not be removed from the bottle.

9. Immunization Record Keeping Procedures. Every vaccination must be entered into a DoD-approved electronic immunization tracking system. The assigned CVX code for Adenovirus Type 4 and Type 7 Vaccine, Live, Oral is "143".

10. Adenovirus Vaccine Post-Licensure Requirements.

a. The Military Vaccine Agency will coordinate DoD's efforts with the manufacturer in conducting a Food and Drug Administration (FDA) required Post-marking Surveillance study (Sentinel Surveillance Plan), to detect potential safety signals, and to monitor and analyze uncommon and unexpected medical events occurring within 42 days following vaccination of the first 100,000 enlisted military recruits. The Sentinel Surveillance Plan will utilize data from DoD's Defense Medical Surveillance System (DMSS).

b. The Military Vaccine Agency will coordinate DoD's efforts with the manufacturer in conducting an FDA required Pregnancy registry of pregnant women vaccinated with the

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adenovirus types 4 and 7 Oral vaccine, and their live born offspring through the first year, to monitor potential safety signals. Please refer to paragraph 7d for additional information.

c. The Naval Health Research Center (NHRC) will coordinate with the manufacturer in conducting FDA required surveillance for vaccine associated febrile respiratory illness (FRI) due to adenovirus types 4 and 7 vaccine shedding. Vaccine viral shedding will be evaluated using data from the NHRC Febrile Respiratory Illness Surveillance Program.

11. POC for this message is Ms. Traci Vactor, COM: 703-325-6538 or DSN: 221-6538.

A handwritten signature in black ink, appearing to read "Patrick M. Garman". The signature is fluid and cursive, with a long horizontal stroke at the end.

PATRICK M. GARMAN
LTC, MS
Director, Military Vaccine Agency

Distribution:

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