DEPARTMENT OF THE ARMY
HEADQUARTERS, UNITED STATES ARMY MEDICAL COMMAND
2050 WORTH ROAD
FORT SAM HOUSTON, TX 78234-6000

REPLY TO
ATTENTION OF

MCOP

12 SEP 2006

MEMORANDUM FOR Commanders, MEDCOM Major Subordinate Commands

SUBJECT: Policy for Influenza Immunization, 2006-2007 Season

1. Each year approximately 36,000 people die from influenza or its severe complications and an average of approximately 226,000 influenza-associated excess hospitalizations occur in the United States. Immunization remains the primary method for preventing influenza and its severe complications.

2. The Advisory Committee on Immunization Practices (ACIP) recommends immunization for the following groups: children ages 6 to 59 months; women who will be pregnant during the influenza season (includes women who may be pregant or become pregnant during the influenza season); people 50 years old or older; children and adolescents (6 months to 18 years) receiving chronic aspirin therapy, adults and children who have chronic conditions of the pulmonary or cardiovascular system including asthma; adults and children with chronic (requiring medical follow-up or hospitalization during the previous year) metabolic diseases, renal dysfunction, hemoglobinopathies, or immunodeficiency; adults and children who have any condition (e.g., seizure disorders, spinal cord injuries, cognitive dysfunction, or other neuromuscular disorders) that compromises respiratory function or the handling of respiratory secretions; residents of nursing homes and long-term care facilities, people who live with or care for people at high risk for influenza-related complications (including healthy household contacts and caregivers of children ages 0 to 59 months); and healthcare workers (HCWs).

3. The annual influenza immunization program will begin in October 2006, or concurrent with receipt of influenza vaccine. The primary goal of the DoD influenza immunization program is to protect all Active Duty and Select Reserve Component personnel, as well as TRICARE beneficiaries from influenza and its severe complications.

4. This season's policy places special emphasis on the use of live, attenuated, influenza vaccine-trivalent (Flumist®, manufactured by MedImmune) in healthy people 5 to 49 years old without a medical contraindication; immunization of healthcare workers (HCWs); immunization of children between the ages of 6 to 59 months; and a recommendation for concurrent pneumococcal screening/immunization of all beneficiaries 65 years of age and older not previously immunized.

5. Medical treatment facilities and immunization clinics will utilize first-available vaccine doses to immunize high priority groups, including deployed or deploying Soldiers, HCWs and high-risk groups as listed above and in accordance with ACIP recommendations (available from: www.cdc.gov/mmwr/PDF/rr/rr55e628.pdf). Large scale immunization campaigns for lower-risk groups will begin after reasonable attempts are made to immunize higher-priority groups and when vaccine supplies are adequate. Immunizations should begin as soon as vaccine is received. Immunization of basic combat training Soldiers should continue until vaccine expires. Four influenza vaccine manufacturers estimate delivery of over 100 million doses to the US market this year.

6. MTFs and immunization clinics will reserve injectable vaccine for people in whom the intranasal vaccine is medically contraindicated or where the intranasal vaccine is not available due to temperature constraints during shipping. Healthy Soldiers, 49 years old or younger, without a medical contraindication should receive the intranasal vaccine subject to shipping constraints. Intranasal vaccine is also encouraged for immunizing all healthy beneficiaries 5 to 49 years old without a medical contraindication to the live, attenuated vaccine.

7. All immunizations and medical exemptions for military personnel will be documented in the Medical Protection System (MEDPROS), the Army standard for electronic tracking of individual medical readiness. Healthcare personnel caring for beneficiaries must document immunization in individual medical records. The Military Vaccine Agency will monitor Major Command and Regional Medical Command compliance with the influenza immunization program through MEDPROS beginning 1 October 2006 or upon receipt of vaccine from DSCP.

8. Severe complications from influenza infection are potentially deadly to children less than 2 years old and people 50 years old and older. Encourage retirees, healthy family members and caregivers of young children and people 50 years old and older to receive influenza immunization each fall.

9. My point of contact at the Military Vaccine Agency is LTC Stephen Ford, (703) 681-5101, Stephen.ford1@amedd.army.mil.

Encl

JOSEPH G. WEBB, JR.
Major General
Acting Commander

MCOP
SUBJECT: Policy for Influenza Immunization, 2006-2007 Season

CF:
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Chief, US Army Reserve Command, ATTN: Surgeon, 1401 Deshler Street, South West, Fort McPherson, GA 30330-2000
Commander, US Army Training and Doctrine Command, ATTN: Surgeon, 7 Fenwick Road, Fort Monroe, VA 23651-5000
Commander, US Army Forces Command, ATTN: Surgeon, Fort McPherson, GA 30330-6000
Commander, US Army Materiel Command, ATTN: Surgeon, 9301 Chapek Road, Fort Belvoir, VA 22060-5527
Commander, US Army Test and Evaluation Command, ATTN: Surgeon, Park Center IV, 4501 Ford Avenue, Alexandria, VA 22333-0001
Commander, US Army Special Operations Command, ATTN: Surgeon, Fort Bragg, NC 28307-5200
Commander, US Army, Europe, ATTN: Surgeon, Unit 29351, APO AE 09014-9351
Commander, 8th US Army, Korea, ATTN: Surgeon, Unit 15236, APO AP 96205-0009
Commander, V Corps, US Army, ATTN: Surgeon, Unit 29355, APO AE 09014
Commander, US Army, Pacific, ATTN: Surgeon, Fort Shafter, HI 96858-5100
Chief of Staff, Headquarters, Department of the Army, ATTN: Surgeon, 200 Army Pentagon, Washington, DC 20310-0200

Enclosure. Implementation Guidance, Influenza Immunization, 2006-2007 Season

1. References:

a. Army Regulation 40-562, 1 November 1995 Immunizations and Chemoprophylaxis.

b. Army Regulation 40-3, 3 April 2006, Medical, Dental, and Veterinary Care.

c. Advisory Committee on Immunization Practices (ACIP). Prevention and Control of Influenza. *Morbidity and Mortality Weekly Report (MMWR)* 2006;54(RR-10) (Jul 28):1-42. (Available from: www.cdc.gov/mmwr/preview/mmwrhtml/rr5510a1.htm)

d. Memorandum, Assistant Secretary of Defense, Health Affairs, Subject: Policy for the Use of Influenza Vaccine for the 2006-2007 Influenza Season, 31 July 2006.

2. Distribution: Disseminate this guidance to all preventive medicine, immunization, family practice, primary care, pharmacy departments, services, and clinics, medical logistics divisions and unit or command surgeons.

3. 2006-07 Influenza Vaccine:

a. Both the inactivated and live, attenuated vaccines for the 2006-2007 season include: A/New Caledonia/20/1999 (H1N1)-like, A/Wisconsin/67/2005 (H3N2)-like, B/Malaysia/2506/2004-like antigens (for the A/Wisconsin/67/2005 [H3N2]-like antigen, manufacturers may use the antigenically equivalent A/Hiroshima/52/2005 virus, and for the B/Malaysia/2506/2004-like antigen, manufacturers may use the antigenically equivalent B/Ohio/1/2005 virus). These viruses were chosen because they are representative of influenza viruses that are anticipated to circulate in the United States during the 2006-2007 influenza season.

b. **The influenza vaccines are temperature sensitive products and activities must comply with <u>Cold Chain Management</u> when transporting and storing these vaccines. NOTE: Live, attenuated vaccine must be kept frozen and all inactivated products must be kept refrigerated prior to use.**

c. The **2006-2007 Influenza Virus Vaccines** contracted for DOD have the following characteristics:

1) **NSN: 6505-01-536-9909 - FLUZONE®**
   NOM: Influenza Virus Vaccine, USP, 0.5 ml dose, 10 dose vial; **for immunizing persons 6 months of age and older;** for Influenza Season 2006-2007
   MFR: Sanofi-Pasteur
   Unit of Issue: VI (0.5 ml dose, 10 doses per vial)
   Unit Price: $104.78
   Acquisition Advice Code: A
   Shelf Life: 12 months
   Storage: Requires refrigeration. **DO NOT FREEZE**
   Store product at 2 to 8 degrees Celsius or 36 to 46 degrees Fahrenheit. Cold Chain must be maintained when transporting and storing FLUZONE® prior to use.

2) **NSN: 6505-01-539-3595 - FLUARIX®**
   NOM: Influenza Virus Vaccine, USP, 0.5 ml dose syringe unit, Thimerosal/Preservative free tip lok syringes, **5's; for immunizing persons 18 years of age and older;** for Influenza Season 2006-2007
   MFR: GlaxoSmithKline
   Unit of Issue: PG (0.5 ml dose, 5 syringes per package)
   Unit Price: $60.16
   Acquisition Advice Code: A
   Shelf Life: 12 months
   Storage: Requires refrigeration. **DO NOT FREEZE**
   Store product at 2 to 8 degrees Celsius or 36 to 46 degrees Fahrenheit. Cold Chain must be maintained when transporting and storing FLUARIX® prior to use.

3) **NSN: 6505-01-536-9932 - FLUMIST®**
   NOM: Influenza Virus Vaccine, Attenuated, Intranasal, Trivalent, 0.5 ml dose, Live Virus, Prefilled Single Use Sprayer; 10 sprayers per package; Thimerosal/Preservative free;
   for immunizing healthy persons 5 to 49 years of age; for Influenza Season 2006-2007
   MFR: MedImmune
   Unit of Issue: PG (0.5 ml dose, 10 sprayers per package)
   Unit Price: $138.75
   Acquisition Advice Code: A
   Shelf Life: 6 months
   Storage: **MUST BE FROZEN;** Store product at or below minus 15 degrees Celsius or 5 degrees Fahrenheit. **DO NOT REFREEZE.** Thawed vaccine can be stored in refrigerator and stored at 2 to 8 degrees Celsius or 36 to 46 degrees Fahrenheit for no more than 60 hours prior to use. Cold Chain (FROZEN) must be maintained when transporting and storing FLUMIST® prior to use.

4) **NSN: 6505-01-537-4818 - FLUZONE® - Pediatric Vaccine**
NOM: Influenza Virus Vaccine, USP, 0.25 ml dose, syringe unit, 10 per package; Thimerosal/Preservative free; **for immunizing persons 6 to 35 months of age;** for Influenza Season 2006-2007
MFR: Sanofi-Pasteur
Unit of issue: PG (0.25 ml dose, 10s)
Unit Price: $127.25
Acquisition Advice Code: A
Shelf Life: 12 months
Storage: Requires refrigeration. **DO NOT FREEZE**
Store product at 2 to 8 degrees Celsius or 36 to 46 degrees Fahrenheit. Cold Chain must be maintained when transporting and storing FLUZONE® prior to use.

e. The CDC publishes separate Vaccine Information Statements (VIS) for the inactivated (injectable) and live, attenuated (intranasal) influenza vaccines. These statements must be conspicuously displayed at immunization clinics and provided to each vaccinee or their parent/guardian. The VISs can be downloaded and reproduced locally from www.cdc.gov/nip/publications/VIS/vis-flu.pdf and www.cdc.gov/nip/publications/VIS/vis-flulive.pdf. Federal law does not require written informed consent before influenza immunization.

4. Vaccine Logistics:

a. The U.S. Army Medical Materiel Agency (USAMMA) is the Inventory Control Point (ICP) for the Army for the influenza vaccine which is an acquisition advice code (AAC) Service regulated item. The Defense Supply Center, Philadelphia (DSCP), contracts with manufacturers, acquires vaccine, and distributes it to activities based on priorities submitted to them by USAMMA. USAMMA follows all requisitions until they are fulfilled.

b. Influenza vaccine is distributed to Medical Treatment Facilities (MTFs) and deployed units through pharmacy and/or logistics activities. Information and official messages regarding the distribution of influenza vaccine may be obtained from the US Army Medical Materiel Agency (USAMMA) website: www.usamma.army.mil. Questions may also be referred to MAJ Paula Doulaveris, DSN 343-4307, commercial 301-619-4307 or Ms.Teresa Bess, DSN 343-3242, commercial 301-619-3242, or email usammafluvaccine@amedd.army.mil.

5. Opportunity for Comprehensive Vaccine Review: As Soldiers process through the annual influenza immunization program, evaluate their need for additional vaccines and enter any paper-based immunizations not already recorded in MEDPROS. Units will organize the administrative and patient flow requirement according to local resources and physical setting. The core tasks will involve:

a. Evaluating immunization records to determine need for any additional doses of multi-dose vaccines; for example, a second dose of hepatitis A vaccine, or a third dose of hepatitis B vaccine.

b. Administering needed doses of multi-dose vaccines, along with influenza immunization.

c. Entering all immunizations given that day into MEDPROS. Units will begin planning now for resources (e.g., labor, computer access, MEDPROS passwords) needed to perform this thorough review, to increase immune protection of our Soldiers. Step 6(a) can be performed before troops get in line for immunization.

6. Special Considerations:

a. Basic Combat Trainees will be vaccinated until the vaccine's labeled expiration date on 30 Jun 07.

b. Individuals who deploy during off-season periods to endemic regions of the tropics and the Southern Hemisphere (where winter occurs from June through August), will be immunized before the vaccine's labeled 30 Jun 07 expiration date.

c. MTF Commanders should coordinate with supported component surgeons to distribute and administer vaccine.

7. Contraindications:

a. Vaccine should not be administered to people known to have hypersensitivity (i.e., allergic reactions including anaphylaxis) to eggs (e.g., hives, swelling of the lips or tongue, acute respiratory distress or collapse) or to other components of the influenza vaccine without first consulting a physician. Allergy to influenza vaccine should not be confused with mild systemic reactions characterized by fever, malaise, myalgia, and headache.

b. People with acute febrile illness should not be vaccinated until their symptoms have resolved. However, minor illnesses with or without fever are not contraindications to the vaccine, particularly among children with mild upper respiratory tract infection or allergic rhinitis.

c. Pregnancy and Breast-feeding. FluMist® is a live, attenuated influenza vaccine and is contraindicated for pregnant women. However, pregnant women should be vaccinated with inactivated influenza vaccine at any time during their pregnancy. Influenza vaccines (both live, attenuated and inactivated vaccines) do not affect the safety of mothers who are breast-feeding nor their infants.

8. Side Effects and Adverse Reactions: Local swelling, soreness at the injection site and headache are common side effects that are self-limiting, resolve quickly, and do

not constitute an allergic reaction. Soreness at the immunization site lasting up to 2 days, fever, malaise, myalgia, and other systemic symptoms may occur. These begin 6-12 hours after immunization and can persist for 1-2 days. Immediate allergic reactions including hives, angioedema, allergic asthma, and systemic anaphylaxis are rare. Report known or suspected adverse events related to the administration of influenza vaccine to the Vaccine Adverse Event Reporting System (VAERS). Attach pertinent information from the vaccine recipient's medical record to the VAERS report. Either file a copy of the VAERS report in the patient's individual medical record or record the relevant information on the VAERS report within the medical record. Also submit copies of these VAERS reports simultaneously to the MTF Pharmacy and Therapeutics Committee and the Reportable Medical Events System for further internal review. Reports to VAERS are required for events involving hospitalization, prolongation of hospitalization, lost duty time more than 24 hours (more than 1 duty shift), or suspected vial or lot contamination. Reports of other clinically significant events are encouraged.

9. Surveillance and Case Reporting:

a. It is important to confirm whether local increases in respiratory disease are caused by influenza and to identify specific viruses involved. MTFs should institute procedures to identify and monitor patients with influenza-like illness (ILI) and ensure that appropriate clinical specimens are collected and submitted for laboratory analysis (e.g., culture). For this purpose, ILI may be defined as fever, respiratory symptoms, sore throat, myalgia and headache with or without clinical or radiographic evidence of acute non-bacterial pneumonia. Ideally, nasopharyngeal washes should be taken from patients with ILI and from any individual with acute non-bacterial pneumonia. MTFs are requested to send samples to the US Air Force as described in paragraph 11. Results of these efforts may indicate a need for supplementary disease-control activities. Nasal or throat swabs will also be accepted by the Air Force laboratory.

b. Influenza infection is a reportable disease. All laboratory-confirmed cases of influenza infection will be reported through preventive medicine activities to the Reportable Medical Events System (RMES) at the Army Medical Surveillance Activity (AMSA). Reported cases should meet the case definition found in the Tri-Service Reportable Events List published at http://amsa.army.mil/. POC at AMSA is CPT Paul Ciminera at DSN 662-0471, commercial 202-782-0471.

c. Report outbreaks of influenza and deaths due to influenza telephonically to the Surgeon General's Proponency Office for Preventive Medicine (Mr. Paul Repaci, DSN 761-2949, commercial 703-681-2949). As a result of the number of pediatric deaths in the general population in recent years, the CDC requests that all influenza-associated pediatric deaths (less than age 18 years) be reported to the CDC through state and local health departments (www.cdc.gov/mmwr/preview/mmwrhtml/mm5253a4.htm).

10. Influenza Laboratory Surveillance:

a. The U.S. Air Force continues to be the executive agent for laboratory-based influenza surveillance and is operated out of Air Force Institute for Operational Health (AFIOH) at Brooks City Base, San Antonio, TX. Sentinel sites have already been selected, based on location, mission, and training status. However, submission of clinical samples for virus isolation is encouraged, but not from every patient seen. Information about the surveillance program, including instructions on procedures to submit samples, can be obtained at their website (https://afioh.brooks.af.mil/pestilence/influenza/). POC at AFIOH is Ms. Linda Canas at DSN 240-1679, commercial 210-536-1679, or email: linda.canas@brooks.af.mil. AFIOH provides the shipping materials free-of-charge and covers the shipping costs. In addition, AFIOH posts the DoD Weekly Influenza Surveillance Report during the influenza season at its website.

b. Samples from the following situations should especially be considered for submission to AFIOH, regardless of whether it is a sentinel site: (1) outbreaks, (2) influenza suspected in patients previously vaccinated with the current vaccine, (3) samples from installations in the Far East, and (4) based on a "sampling" procedure (every "xth" influenza patient or "x" number of samples per week). In addition, samples should be sent from patients admitted to MTFs with the diagnosis of viral pneumonia. Data from the DoD laboratory surveillance program contributes to the national program and is critical in identifying any variations or mutations in influenza viruses that may require a change in the following year's vaccine formulation. The Air Force Virology Lab looks for multiple viral causes (e.g., adenovirus, parainfluenza, RSV, herpes simplex, enteroviruses).

c. Army Medical Centers offer full clinical viral culture services for MTFs in their region. All medical centers, and many AMEDD community hospitals, also offer rapid antigen testing for influenza. Rapid diagnostic tests for influenza can aid clinical judgment and help guide treatment decisions, particularly if anti-viral therapy is considered for treatment. Nonetheless, the use of such tests requires oversight to assure appropriate use and interpretation in the clinical setting

11. Reporting Requirements for Military Immunizations:

a. Accurate records must be kept of actual vaccine usage. Detailed records will facilitate projection of vaccine requirements for the 2007-2008 influenza immunization program.

b. The status of Major Command (MACOM), Regional Medical Command (RMC), and installation compliance with the requirement to vaccinate all active-duty (AD) personnel will be tracked by OTSG through the Medical Protection System (MEDPROS) of the Military Occupational Data System (MODS).

c. Several areas require emphasis. There must be universal implementation of procedures at installation in- and out-processing stations to ensure that personnel changing stations receive immunization before departure. MEDPROS and DEERS registry of new Soldiers (i.e., accessions) must be accomplished to capture immunization data in the newest Soldiers. Special efforts must be initiated to ensure that both immunization and documentation efforts are extended to Soldiers who serve in remote locations. Screen for the need for influenza immunization at mobilization and demobilization sites, during Soldier readiness processing, and at other similar opportunities.

d. Commanders are charged with ensuring immunization data is entered into MEDPROS fully and promptly. Data entry may be accomplished using the MEDPROS web base (www.mods.army.mil), the MODS mainframe, the Remote Immunization Data Entry System (RIDES) compact disk (CD), or other systems or processes in coordination with the MODS Support Team. Data entry support may be obtained from the MODS Help Desk at DSN 761-4976, commercial 703-681-4976 or 888-849-4341.

e. MEDPROS will continue to offer command drill-down reporting capability to allow all users to track compliance. This tracking will commence during the week of 16 Oct 06. Compliance will be categorized as green (≥90% of personnel vaccinated), amber (80-89% vaccinated), and red (<80% vaccinated). The standard is for each MACOM, RMC region, and installation to achieve a green status NLT 31 Dec 06.