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

REPLY TO
ATTENTION OF

31 AUG 2005

MCCS

MEMORANDUM FOR SEE DISTRIBUTION

SUBJECT: Policy for Influenza Immunization, 2005-2006 Season

1. On average, 36,000 people die each year in the United States due to influenza infection. Last year, over 700 cases of influenza were reported at Army military treatment facilities (MTFs). Influenza immunization is the primary method for preventing severe illness and medical complications from influenza infection.

2. The annual influenza immunization program will begin in Oct 05, as influenza vaccine arrives at each installation. Additional instructions and references are contained in the enclosure. The primary goal of the program is to vaccinate the total force including all Active Duty and activated Reserve Component personnel, as well as selected TRICARE beneficiaries. It is important to ensure that Soldiers leaving basic and advanced training sites receive influenza vaccine before departure to reduce the likelihood of being infected with influenza during leave. This year, place special emphasis on influenza immunization for healthcare workers.

3. The Army will purchase no more than 90% of its influenza vaccine order from any one manufacturer. Defense Supply Center Philadelphia (DSCP) contracted with influenza vaccine suppliers to deliver a partial shipment not later than (NLT) 15 Oct 05, and the remaining supply NLT 31 Dec 05. Release of vaccine to deployed units and then fixed installations will occur as soon as possible after the depot receives the vaccine. Should there be a shortage this year, MTFs will prioritize vaccine administration in accordance with guidance provided in paragraph 13 of the Enclosure. Sufficient vaccine should be available by Dec 05 to accomplish immunization for all beneficiary populations. MTFs should advise beneficiaries desiring influenza immunization to be immunized by mid-Dec 05 or sooner, depending on local receipt of vaccine. After ample opportunity has been given for high-risk beneficiary populations to be immunized, mass immunization campaigns can be initiated.

4. All immunizations and exemptions given to military personnel will be documented in the Medical Protection System (MEDPROS), the Army standard for electronic tracking of individual medical readiness. To ensure eligible personnel receive immunization, screen all Soldiers at installation in- and out-processing stations for influenza and other needed immunizations. Healthcare personnel caring for DoD beneficiaries must

document immunization in health records, in addition to entering the transaction into the Composite Health Care System. Beginning 17 Oct 05, the Military Vaccine Agency will monitor Army Major Command and MEDCOM Major Subordinate Command compliance with the influenza immunization program through MEDPROS.

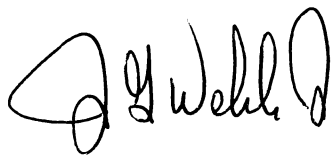
5. This year's influenza policy includes FluMist® (MedImmune), an intranasal, live, attenuated vaccine indicated for healthy people, 5 to 49 years of age. Use of FluMist® in eligible people is encouraged to increase availability of FluZone® for people in groups at high risk (e.g., young children, the elderly, those with chronic disease) for whom FluMist® is contraindicated. FluMist® can be given concurrently with other vaccines. Additional information on usage and administration is found at www.flumist.com.

6. The Centers for Disease Control & Prevention recommend inactivated influenza vaccine for pregnant women. Pregnant women have been shown to be at increased risk of hospitalization from complications secondary to influenza infection.

7. Complications from influenza infection are potentially lethal to those 50 years and older. Encourage retirees and family members 50 years and older to receive influenza immunization each fall.

8. My points of contact at the Military Vaccine Agency are CPT Allison Christ (DSN 761-0950, 703-681-0950, allison.christ@otsg.amedd.army.mil) or COL John Grabenstein (703-681-5059, john.grabenstein@otsg.amedd.army.mil).

FOR THE COMMANDER:



Encl

JOSEPH G. WEBB, JR.
Major General
Chief of Staff

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Enclosure. Implementation Guidance, Influenza Immunization, 2005-2006 Season

1. References:

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

b. Army Regulation 40-3, 12 November 2002, Medical, Dental, and Veterinary Care.

c. Centers for Disease Control & Prevention (CDC) Influenza Home Page (updated information, provider's information, supply concerns and updates, public affairs and media materials, patient education materials), www.cdc.gov/flu.

d. Advisory Committee on Immunization Practices (ACIP). Prevention and control of influenza. *Morbidity and Mortality Weekly Report (MMWR)* 2005;54(RR-8) (Jul 13): 1-40, www.cdc.gov/mmwr/preview/mmwrhtml/rr54e713al.htm.

e. Memorandum, Assistant Secretary of Defense, Health Affairs, subject: Policy Guidance Influenza Vaccine Orders for 2005-2006 Season, 19 April 2005.

f. Advisory Committee on Immunization Practices (ACIP). Tiered use of inactivated influenza vaccine in the event of a vaccine shortage. *MMWR* 2005;54(RR-30) (Aug 5):749-750, www.cdc.gov/mmwr/preview/mmwrhtml/mm5430a4.htm.

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

3. 2005-06 Influenza Vaccine:

a. The Food and Drug Administration's Vaccine and Related Biological Products Advisory Committee recommended that the 2005-2006 trivalent vaccine for the United States contain: A/New Caledonia/20/99-like (H1N1), A/California/7/2004-like (H3N2), B/Shanghail/361/2002-like viruses.

b. This year DoD contracted vaccine from two manufacturers (Sanofi Pasteur and MedImmune). The influenza vaccines are temperature-sensitive products. Activities must comply with cold-chain management principles when transporting and storing these vaccines. National Stock Numbers (NSNs) and corresponding cold-chain management instructions for the 2005-2006 influenza immunization program are below. NSNs change yearly for the influenza vaccine. It is essential that the current year's NSNs be used in the requisitioning process. NSNs requisitioned must coincide with Requirements NSNs previously submitted. If a change is required, notify the US Army Medical Material Agency's (USAMMA) Distribution Operations Center, at 301-619-3242, -3017, or -7235 or email usammafluvaccine@amedd.army.mil for assistance.

NSN: 6505-01-528-3870
NOM: Influenza Virus Vaccine, USP Trivalent Split Vaccine, 0.5-ml dose, 10-dose vial, FluZone®; for immunizing people 6 months of age and older; for influenza season 2005-2006; virus strain A/New Caledonia/20/1999 (H1N1)-like A/California/07/2004 (H3N2)-like, B/Shanghai/361/2002-like.
MFR: Sanofi Pasteur
Unit of Issue: VI (0.5 ml dose, 10 doses per vial)
Unit Price: $100.14
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 FluZone®.

NSN: 6505-01-528-3757
NOM: Influenza Virus Vaccine, USP Trivalent Split Vaccine, Thimerosal/Preservative Free, 0.5 ml dose syringe unit, 10 syringes per package, FluZone®; for immunizing people 36 months of age and older; for influenza season 2005-2006; virus strain A/New Caledonia/20/1999 (H1N1)-like, A/California/07/2004 (H3N2)-like, B/Shanghai/361/2002-like.
MFR: Sanofi-Pasteur
Unit of Issue: PG (0.5 ml dose, 10 syringes per package)
Unit Price: $130.86
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 FluZone®.

NSN: 6505-01-528-3708
NOM: Influenza Virus Vaccine, Attenuated, Intranasal, Trivalent, 0.5 ml dose, live virus, pre-filled single use sprayer; 10 sprayers per package; Thimerosal/Preservative Free, FluMist®; for healthy people ages 5-49 years of age; for influenza season 2005-2006
MFR: MedImmune, Inc.
DIST: GIV
Unit of Issue: PG (0.5 ml dose, 10 sprayers per package)
Unit Price: $167.25
Acquisition Advice Code: A
Shelf Life: 9 months
Storage: **MUST BE FROZEN.** May be stored up to 6 months in a standard (i.e., frost-free) freezer. Once thawed, thawed vaccine may be stored not more than 60 hours in a standard refrigerator between 2-8 degrees Celsius. **DO NOT REFREEZE.** Cold chain must be maintained when transporting FluMist®. People unfamiliar with FluMist® should obtain additional instructions from www.flumist.com.

c. DSCP is not contracting for the pediatric formulation for 2005-2006 influenza season from Sanofi Pasteur. Activities with requirements for this formulation may procure the product locally through Prime Vendor, NSN: 6505-01-530-1765, 0.25 ml syringe needle unit, 10 syringes per package, split surface antigen only, preservative free; for immunizing people 6-35 months of age; estimated price $130.86 per package.

d. The CDC publishes separate Vaccine Information Statements (VIS) for the inactivated (injectable) and live (intranasal) influenza vaccines. These statements must be conspicuously displayed at immunization clinics and provided to each vaccinee. 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: Influenza vaccine is distributed to 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 USAMMA website, www.usamma.army.mil. Questions may also be referred to MAJ Paula Doulaveris, DSN 343-4307, commercial 301-619-4307 or Ms. MaryJane Carty, DSN 343-3242, commercial 301-619-3242, or email usammafluvaccine@amedd.army.mil.

5. Priority for Influenza Immunization: In case of a shortage or delay in vaccine availability, a matrix for vaccine prioritization is found in paragraph 13. This matrix is consistent with guidance from the CDC. Upon receipt of influenza vaccine, MTFs will administer vaccine IAW this list.

6. Opportunity for Comprehensive Vaccine Review: As Soldiers process through the annual influenza immunization program, there is an opportunity to 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 for this requirement according to local resources and physical setting. To conduct a comprehensive immunization review:

a. Evaluate paper and electronic 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. Administer needed doses of multi-dose vaccines, along with influenza immunization.

c. Enter all immunizations given that day into MEDPROS.

d. Units should begin planning now for resources (e.g., labor, computer access, MEDPROS passwords) needed to perform this thorough review, to increase the

immune protection of our Soldiers. Step 6(a) can be performed before troops get into line for immunization.

7. Special Considerations:

a. Basic Combat Trainees will be vaccinated until the vaccine's labeled expiration date on 30 Jun 06.

b. Individuals who deploy during off-season periods to endemic regions of the tropics and the Southern Hemisphere (where winter occurs from Jun through Aug), will be immunized before the vaccine's labeled 30 Jun 06 expiration date.

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

8. 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 do **NOT** contraindicate the use of 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 <u>inactivated influenza vaccine</u> at any time in their pregnancy. Influenza vaccine does not affect the safety of mothers who are breast-feeding nor their infants.

9. Side Effects and Adverse Reactions: Local swelling and 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, time lost from duty more than 24 hours (more than 1 duty shift), or suspected vial or lot contamination. Other reports of clinically significant events are encouraged.

10. 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 encouraged to send samples to the US Air Force as described in paragraph 11. Results of these efforts may initiate supplementary disease-control activities. Nasal or throat swabs will also be accepted by the Air Force Virology Laboratory at Brooks City Base, San Antonio, TX.

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 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).

11. Influenza Laboratory Surveillance:

a. The US 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, provision 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 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. Moreover, Madigan Army Medical Center (MAMC) offers a fluorescent, non-culture method for the most common respiratory pathogens. 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.

12. 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 2006-2007 influenza immunization program.

b. The status of Army Major Command (MACOM), MEDCOM Major Subordinate Command, 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).

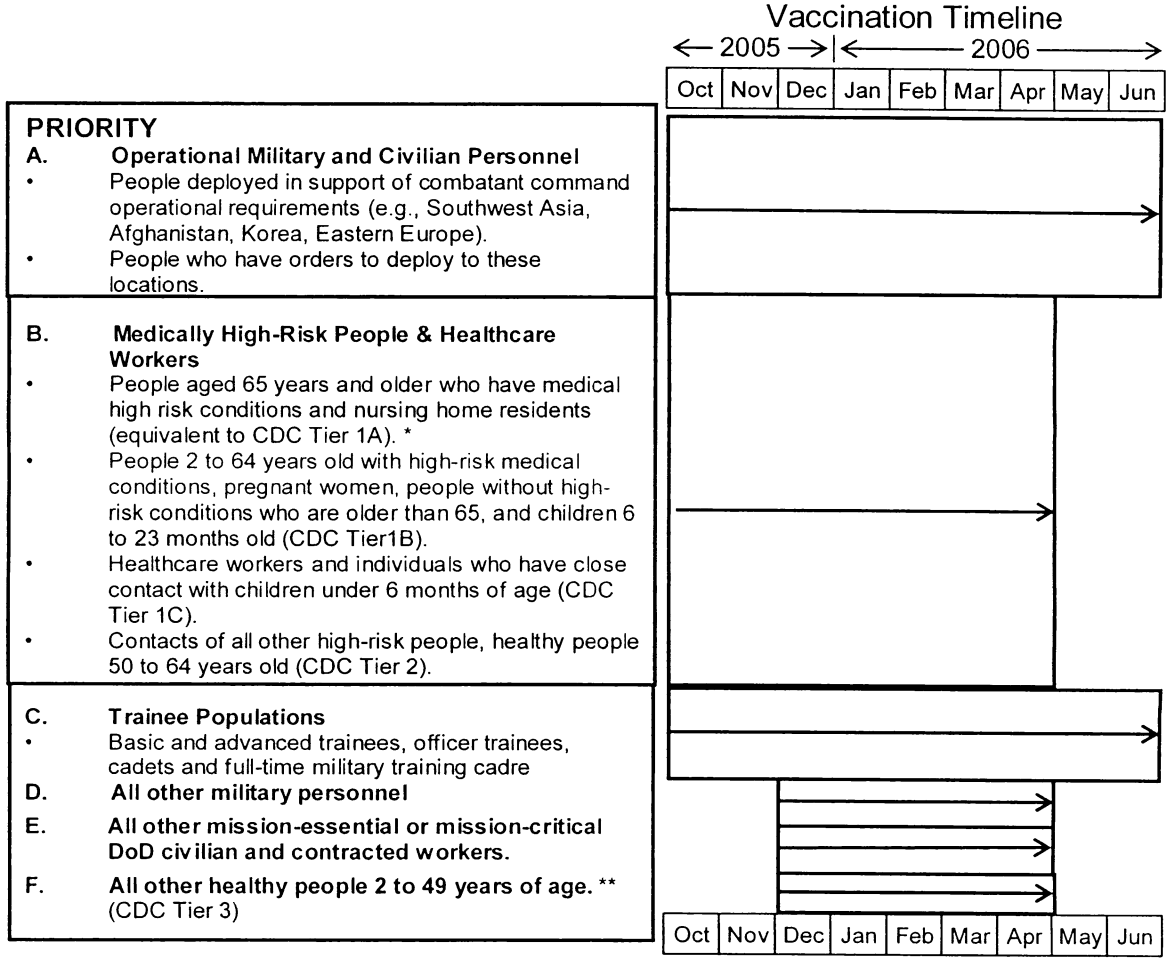
c. Several areas require emphasis. There must be universal implementation of procedures at installation in- and out-processing stations to ensure that personnel changing stations receive immunization before departure. MEDPROS and DEERS registry of new Soldiers (i.e., accessions) must be accomplished 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 a command drill-down reporting capability to allow all users to track compliance. This tracking will commence during the week of 17 Oct 05. Compliance will be categorized as green (≥90% of personnel vaccinated), amber (80-90% vaccinated), and red (<80% vaccinated). The standard is for each MACOM, MEDCOM MSC, and installation to achieve a green status NLT 31 Dec 05.

13. Priority Groups for Influenza Immunization, 2005-2006



* CDC's tiered approach encourages, during a vaccine shortage, that Tiers 1C, 2 and 3 (Army policy includes groups C, D, E and F) receive *Flumist*, unless otherwise contraindicated. This prioritization scheme can be applied as initial vaccine shipments arrive. All categories should be vaccinated as promptly as possible after clinics receive their last shipment of vaccine. Strict prioritization will be used if vaccine shortage or delay occurs.

** Children younger than 9 years old receiving influenza vaccine for the first time should begin in October, because they need a second vaccination one month later.

Adapted from:

Advisory Committee on Immunization Practices (ACIP). Prevention and control of influenza. *Morbidity and Mortality Weekly Report (MMWR)* 2005;54(RR-8) (Jul 13):1-40, www.cdc.gov/mmwr/preview/mmwrhtml/rr54e713al.htm.

Advisory Committee on Immunization Practices (ACIP). Tiered use of inactivated influenza vaccine in the event of a vaccine shortage. *Morbidity and Mortality Weekly Report (MMWR)* 2005;54(Aug 5):749-750, www.cdc.gov/mmwr/preview/mmwrhtml/mm5430a4.htm.