DEPARTMENT OF THE AIR FORCE
HEADQUARTERS UNITED STATES AIR FORCE
WASHINGTON DC

27 September 2009

MEMORANDUM FOR ALMAJCOM/SG

FROM: HQ USAF/SG
1780 Air Force Pentagon
Washington, DC 20330-1780

SUBJECT: Air Force 2009-2010 Novel H1N1 Influenza Immunization Program

This memo and attached guidance provide implementation instructions for the 2009-10 influenza immunization programs, supplementing AFJI 48-110, *Immunizations and Chemoprophylaxis*. This guidance does not address seasonal influenza, which is covered in the annual influenza guidance.

Air Force medical staff will administer influenza vaccine to all military members in accordance with AFJI 48-110. Distribution of the novel H1N1 vaccine will be along similar lines as seasonal influenza for Active Duty, Guard and Reserve personnel, and for other beneficiaries living overseas (excluding Alaska and Hawaii). Distribution of novel influenza vaccines will be different from the seasonal influenza vaccine for dependents and retirees in the United States. Upon receipt of vaccines for beneficiaries, military treatment facilities (MTFs) should offer them to eligible beneficiaries as appropriate. Refer to the attached program guidance for more details.

The success of this year's influenza program will require the earliest possible administration of the novel H1N1 influenza vaccine as supplies become available. The novel H1N1 vaccine may be administered at the same time as the seasonal influenza vaccine, but should be given in a different limb than the one in which the seasonal vaccine was placed.

Immunization personnel and health care providers should review the most recent Advisory Committee on Immunization Practices recommendations for updates and changes. MTF leadership should work to improve vaccination coverage and remove barriers to influenza vaccination. While maintaining the high level of influenza vaccine coverage previously achieved for military members, medical staff and commanders should develop programs to target beneficiaries who are at increased risk for influenza-related complications.

My point of contact for this issue is Lt Col Philip Gould, AFMOA/SG3PM, (202) 767-4268, DSN 297-4268, or philip.gould@pentagon.af.mil.

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Attachment:
Air Force 2009-2010 Novel H1N1 Influenza Immunization Program Guidance

SG Doc 09-0014

Air Force 2009-2010 Novel H1N1 Influenza Immunization Program Guidance

1. Purpose

This message provides Air Force (AF) guidance for influenza vaccination programs. Request dissemination of this message to all military treatment facilities (MTFs), MTF commanders, immunization points of service/clinics, public health offices, pharmacy services, medical logistic/supply sections, and primary care managers.

2. This message does not address the seasonal influenza immunization program. Please refer to the AF 2009-2010 Seasonal Influenza Immunization Program Guidance (available on the KX at https://kx.afms.mil/kxweb/dotmil/kjPage.do?functionalArea=OperationalPreventionDiv&cid=ctb_117356)

3. Novel H1N1 Influenza

a. Novel H1N1 influenza is a new influenza virus of swine origin that first caused illness in Mexico and the United States in April 2009. It is thought that the novel H1N1 virus spreads in the same way that regular seasonal influenza viruses spread, through coughs and sneezes of people who are sick with the virus, and by touching infected objects and then touching one's nose or mouth. On 11 June 2009, the World Health Organization (WHO) signaled that a global pandemic of novel H1N1 influenza was underway by raising the worldwide pandemic alert level to Phase 6. Since the WHO declaration of a pandemic, the novel H1N1 virus has continued to spread. In the United States, novel H1N1 influenza illness has continued into the summer, with localized, and in some cases, intense outbreaks occurring.

b. The novel H1N1 influenza virus, in conjunction with regular seasonal influenza viruses, poses the potential to cause significant illness with associated hospitalizations and deaths during the United States influenza season.

c. Immunization is the key to reducing the risk for disease.

4. General program guidance

a. **This program is different than seasonal influenza in three important ways:**

(1) Vaccine for Active Duty (AD), Guard, and Reserve personnel will be from a single manufacturer, Novartis, and will be an injectable, inactivated vaccine. This vaccine will also be made available to mission-essential civilian personnel if they choose to be vaccinated by the military. This vaccine will be shipped through the Defense Supply Center Philadelphia (DSCP), as it was centrally purchased.

(2) Vaccine for dependents and retirees located overseas excluding Alaska, Hawaii, and Guam will receive vaccine purchased by the Department of Health and Human Services (DHHS). This vaccine will be made up of a portion of some or all of the four manufacturers' vaccines, including an inactivated injectable vaccines (made by Novartis, CSL, and Sanofi Pasteur) and live attenuated vaccine (made by MedImmune: "FluMist"-like). This vaccine will be provided to the DSCP for distribution along seasonal influenza vaccine distribution.

(3) Vaccine for dependents and retirees located within the United States, including Alaska and Hawaii will receive their vaccine from the Centers for Disease Control (CDC) through the United States. This vaccine will be made up of a portion of all manufacturers' vaccines, including inactivated injectable vaccines (made by Novartis, CSL, and Sanofi Pasteur) and live attenuated vaccine (made by MedImmune: "FluMist"-like). MTFs should have worked with their States in order to procure vaccine. The States will then forward their numbers and contact information to the CDC. The CDC forwards these details to the distribution contractor hired for this purpose, McKesson, who forwards the vaccine as it comes in.

(4) Within the civilian community, there will be multiple sites offering vaccine. DoD civilians and contractors are encouraged to seek vaccine through non-DoD sources when available as this will likely result in quicker access to vaccine.

b. Influenza viruses for both novel H1N1 Inactivated Influenza Vaccine and novel H1N1 Live Attenuated Influenza Vaccine are grown in embyonated chicken eggs and might contain limited amounts of residual egg protein. Persons with a history of severe hypersensitivity to eggs, such as anaphylaxis, should not receive influenza vaccine.

c. The Food and Drug Administration (FDA) and WHO have selected A/California/07/2009 (H1N1) as the strain for the novel H1N1 influenza vaccines.

d. The package insert is an important source of information and should be referred to for additional information.

e. The DoD-contracted manufacturer for the novel H1N1 influenza vaccine is Novartis. The anticipated date of release of the first shipment of 1M doses of vaccine to DSCP is 15 October 2009. The second shipment of 1.7M doses is anticipated 3 weeks later. **Refer to the package inserts for proper storage and handling.**

f. DHHS is purchasing vaccine from three additional manufacturers CSL, Sanofi Pasteur and Medimmune (live attenuated, "FluMist"-like). These vaccines will be distributed as described in paragraphs 4.a.(2) and 4.a.(3).

g. **Due to the various influenza vaccine products available this season it is imperative that utmost care and attention is devoted to providing correct immunizations (both seasonal influenza and novel H1N1 influenza) based on age and medical conditions.**

Accurate documentation of the immunizations given is critical.

h. Mass immunization campaigns should not be organized until adequate delivery dates of appropriate vaccine are assured.

i. Flying/Special Duty populations: similar to seasonal influenza as the side effect profile is the same. Allow for 4 hours of potential medical contact time; immunize no more than 50% of a unit at any one time; schedule immunizations to limit the operational impact (e.g. Friday, to allow for the weekend).

j. 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 inappropriately exposed to light. **Do not** pre-draw doses before they are needed.

k. Although pre-drawing vaccine is generally discouraged, a limited amount of vaccine may be pre-drawn in a mass immunization setting if the following procedures are followed:

(1) Only one vaccine type may be administered at the clinic. If more than one vaccine type is to be administered, separate vaccine administration stations must be set up for each vaccine type to prevent medication errors.

(2) The type of vaccine, lot number, and date of filling must be carefully labeled on **each** syringe, and vaccine should be administered promptly (same day, preferably within the same hour as drawn), and should be kept within the manufacturer's specifications as far as temperature handling before administration.

(3) Vaccine should not be drawn up in advance of arriving at the clinic site. Because of the lack of data on the stability of vaccine stored in plastic syringes, the practice of drawing up quantities of vaccine hours or even days before a clinic is **not acceptable**.

l. As dependent and retiree vaccine will be distributed through the States, the States should order vaccine consistent with the State's own laws regarding the use of thimerosal in vaccines.

m. The CDC's Advisory Committee on Immunization Practices (ACIP) has developed recommendations for novel H1N1 influenza vaccines (see reference d).

n. AF Medical Logistics (AFMLO) is responsible for distributing DoD novel H1N1 influenza vaccine and vaccine for overseas beneficiaries. AFMLO will notify units of the quantities ordered and the document numbers being used. Questions regarding the distribution should be directed to AFMOA/SG3SLC, DSN: 343-4170, (301) 619-4170. AFMLO website: https://medlog.detrick.af.mil/index.cfm

5. Public Affairs (PA)

Given two different types of influenza vaccine as well as a different distribution system, local PA messages need to be drafted that address the vaccine program and different venues where all beneficiaries, to include Guard and Reserve personnel where appropriate, may be vaccinated. The FAQs found on the DoD Pandemic Watchboard are a good starting point: http://fhp.osd.mil/aiWatchboard/h1n1faqs.jsp. Additional PA messages are being drafted by HA and AF/SGL.

6. Timing of Novel H1N1 Influenza Immunization

a. Antibodies sufficient to achieve protection against novel H1N1 influenza infection usually develop within 2 weeks of vaccination. Novel H1N1 influenza vaccinations should begin as early as possible. Begin mass immunization programs as soon as adequate quantities of the vaccine are available. It is anticipated that the peak activity of this year's influenza will be early in the season. At this point it is unknown whether immunization against novel H1N1 influenza will be necessary through next summer, but it should be anticipated that the novel H1N1 influenza strain may persist for longer than 1 year. Vaccination of susceptible individuals into the summer months with un-expired vaccine may therefore be beneficial.

b. Novel H1N1 influenza vaccine may be given at the same time as the regular seasonal vaccine, but in a different limb. At this time, per the CDC, do not give both live attenuated seasonal influenza and live attenuated novel H1N1 influenza vaccines at the same time, but separated by at least one month. Live attenuated influenza vaccine may be given at the same time as inactivated influenza vaccine.

c. Vaccination of all military members should be completed within one month of receipt of sufficient vaccine supplies. Every effort should be made to exceed a goal of 90% of AD vaccinated by 1 December 2009.

d. Children under 10 years of age are currently recommended to have two doses of vaccine approximately one month apart, but testing in this age group is ongoing. Follow current package insert regarding appropriate dosing.

e. While the Novartis vaccine should not be used for a mass immunization campaign for dependents and retirees, high risk beneficiaries presenting for immunization should not be turned away.

7. Target groups among Active Duty, Guard, Reserve and mission essential civilians

a. Deployed or hard tasked personnel

b. Overseas (CENTCOM, USFK, PACOM, EUCOM, AFRICOM)

c. MTF personnel providing direct patient care

d. Training locations: basic military training sites, academies

e. Mission essential/mission critical civilians/contractors

8. ACIP Recommendations for the Prevention and Control of Influenza

a. **Target Groups for Vaccination.**

(1) Pregnant women

(a) Live attenuated influenza vaccine ("FluMist"-like) is contraindicated in pregnancy; however, the inactivated virus vaccine is recommended by the ACIP for pregnant women. Studies show that vaccination against influenza in pregnant women reduces influenza complications in the pregnant woman and protects the newborn.

(b) The three inactivated vaccines are pregnancy Category C, reflecting that the vaccine has not been directly tested in pregnant women.

(c) Nonetheless, ACIP recommends pregnant women be considered a target group for vaccination because they are a group at high risk of complications and death from influenza disease.

(d) Immunization clinics and health care personnel will display a prominent sign directing women to alert the technician or provider if they think they might be pregnant.

(e) All females of childbearing age will be asked about the possibility of pregnancy prior to receiving the vaccine. If women have questions or concerns, they should consult with their healthcare provider before receiving the vaccine.

(2) Children between the ages of 6 months through 24 years of age

(3) Health care and emergency medical services personnel

(4) People who live with or care for children younger than 6 months of age or other persons at risk for medical complications

(5) People from ages 25 through 64 years who are at higher risk for novel H1N1 influenza because of chronic health disorders or compromised immune systems

(a) Live attenuated influenza vaccine ("FluMist"-like) is contraindicated in persons with known immunodeficiency.

(b) Dosing of inactivated novel H1N1 influenza vaccine is not yet known. Refer to the package insert.

(c) Conditions that may fall in this category include:

1 Adults and children who have chronic pulmonary (including asthma), cardiovascular (except hypertension), renal, hepatic, hematological or metabolic disorders (including diabetes mellitus)

2 Adults and children who have immunosuppression (including immunosuppression caused by medications or by human immunodeficiency virus)

3 Adults and children who have any condition (e.g., cognitive dysfunction, spinal cord injuries, seizure disorders, or other neuromuscular disorders) that can compromise respiratory function or the handling of respiratory secretions or can increase the risk for aspiration

(6) Children and adolescents (aged 6 months-18 years) receiving long-term aspirin therapy who therefore might be at risk for experiencing Reye's syndrome after influenza virus infection

(7) Other persons for whom the ACIP recommends the seasonal influenza vaccine

(a) All children aged 2 years through 18 years

(b) All persons ≥ 65 years

(c) Residents of nursing homes and other chronic-care facilities

(d) Students or other persons in institutional settings (e.g., those who reside in dormitories)

(a) All persons who want to reduce the risk of becoming ill with influenza or of transmitting influenza to others

9. Documentation:

a. All vaccinations will be documented in AF Complete Immunization Tracking Application (AFCITA). Mass immunization and workplace vaccination campaign planning must consider this requirement for AD, Reserve Component, and DoD beneficiaries (e.g., automated methods on-site or manual lists at vaccination site compiled and used to update AFCITA). The AFCHIPS website provides base-level influenza vaccination completion data throughout influenza season and is available at https://www.afchips.brooks.af.mil/main.htm.

b. Accurate documentation of influenza vaccines given during influenza vaccine programs continues to be a challenge, and will be even more of an issue with two different influenza vaccines with multiple formulations. All influenza immunizations administered will be entered into AFCITA. MTFs are strongly encouraged to utilize the stand-alone capacity of AFCITA when giving immunizations outside the MTF. Paper "sign-in rosters" are discouraged. If paper rosters must be utilized, data must be entered into AFCITA within 24 hours.

10. Vaccine Information Statement (VIS) and Vaccine Adverse Event Reporting System (VAERS)

a. Although influenza vaccines have been used without significant adverse events for decades, theoretical considerations about the use of the novel H1N1 influenza vaccine dictate that early VAERS reporting occur for significant adverse events.

b. **VIS and Patient Information.** The VIS on influenza vaccine, published by the CDC, should be made available and provided to any individual upon request. The VIS is available at http://www.cdc.gov/vaccines/pubs/vis/default.htm.

c. **VAERS Reporting.** Health care professionals should promptly report all clinically significant adverse events after influenza vaccination of children to VAERS, even if the health care professional is not certain that the vaccine caused the event. All vaccine-related adverse events must be reported through the Vaccine Adverse Event Reporting System. The Institute of Medicine has specifically recommended reporting of potential neurological complications (e.g., demyelinating disorders such as Guillain-Barré Syndrome), although no evidence exists of a causal relationship between influenza vaccine and neurological disorders in children. The VAERS form is available at http://vaers.hhs.gov. T he form must be submitted to the FDA and it may be transmitted electronically.

d. **AF and DoD Reporting.** Vaccine adverse events are DoD reportable events and must also be submitted to the US AF School of Aerospace Medicine (USAFSAM), Epidemiology Consult Service by fax at DSN 240-6841 or (210) 536-6841. VAERS reporting will be integrated into AFRESS once the web-based version is complete.

e. **Life threatening adverse events.** Incidents that are considered life-threatening or that result in death must be reported to USAFSAM within 24 hours. Phone numbers DSN

240-5497/3471, (210) 536-5497/3471. Other reports of vaccine adverse reactions or events should be faxed or mailed within 7 days of occurrence.

11. Air National Guard (ANG) and AF Reserves (AFRES) Activities

a. ANG and AFRES will receive novel H1N1 influenza in the amounts requested for their seasonal influenza this year. The vaccine will be distributed along similar lines to seasonal influenza vaccine distribution.

b. ANG Activities: Questions should be directed to MSgt Piers Heriz-Smith, DSN 278-8577, Piers.Heriz-Smith@ang.af.mil.

c. Air Force Reserve Command (AFRC) Activities: Contact HQ AFRC/SGPH at DSN 497-2398 or (478) 327-2398 if further instruction is necessary. Individual Mobilization Augmentees will be immunized by their supporting AD MTF and should be included in requirements for the MTF.

12. Contact information

a. Influenza vaccine supply, delivery, shortage and availability issues: Contact AFMSA/SGSLC, Fort Detrick, MD. DSN 343-4170 or (301) 619-4170, fax: DSN 343-6844 or (301) 619-6844, sgslc@ft-detrick.af.mil.

b. Policy and prioritization: Contact Lt Col Philip Gould, AFMSA/SG3PM, 110 Luke Ave, Room 405, Bolling AFB, DC 20032-7050, DSN 297-5424 or (202) 767-5424, philip.gould@pentagon.af.mil.

c. VAERS: Contact USAFSAM Epidemiology Services at 2513 Kennedy Circle, Brooks City Base, Texas 78235-5116 at DSN 240-3471 or (210) 536-3471, fax DSN 240-6841. https://gumbo.brooks.af.mil/pestilence/VAERS/VAERS.cfm, vaers@brooks.af.mil.

13. References

a. AFJI 48-110, *Immunizations and Chemoprophylaxis*, 29 Sep 2006

b. Assistant Secretary of Defense, Health Affairs policy documents available at: http://www.ha.osd.mil/policies/default.cfm

c. DHHS Influenza home page contains provider's information, supply concerns and updates, public affairs and media materials, and patient education materials. http://www.flu.gov/

d. Use of Influenza A (H1N1) 2009 Monovalent Vaccine Recommendations of the Advisory Committee on Immunization Practices (ACIP), 2009 / 58; 1-8 (21 August 2009). Available at: http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5810a1.htm

e. Morbidity and Mortality Weekly Report, Use of Standing Orders Programs to Increase Adult Vaccination Rates. Volume 49, RR-01, 24 March 00. http://www.cdc.gov/mmwr/preview/mmwrhtml/rr4901a2.htm.

f. Morbidity and Mortality Weekly Report, Notice to Readers, Facilitating Influenza and Pneumococcal Vaccination through Standing Orders Programs. Volume 52, Number 4, 31 January 2003, pp.68-69. http://www.cdc.gov/mmwr/PDF/wk/mm5204.pdf

g. OSHA 3327-02N 2007, Guidance on Preparing Workplaces for an Influenza Pandemic. Available at: http://www.osha.gov/Publications/influenza_pandemic.html