# Military Vaccine Agency Communications Plan
# 2009 - 2010 Seasonal Influenza

## Issue

- The Department of Defense (DoD) has implemented the 2009–2010 Seasonal Influenza Vaccine Program (SIVP).
- Influenza immunizations are mandatory for all Active Duty, National Guard, and Reserve personnel.
- Influenza immunizations are mandatory for DoD civilian and contract healthcare personnel who provide direct patient care at military treatment facilities (MTFs).
- DoD's goal is to vaccinate ≥ 90 percent of all Active Duty, National Guard, and Reserve personnel by 1 December 2009.
- A secondary goal is to swiftly complete seasonal influenza vaccinations and begin preparations for the impending Novel Influenza A(H1N1) Vaccination Program. A vaccine that can potentially prevent infection by the novel influenza A(H1N1) virus is currently being developed and further guidance will be published detailing its use in DoD.

## Impact to Department of Defense

- Influenza is a contagious respiratory illness that would disrupt DoD's military readiness.
- Immunizing with influenza vaccine will reduce the cases of influenza infection, hospitalization, and clinic visits related to influenza.
- Distribution of influenza vaccine will begin mid-August to high priority areas including CENTCOM, Korea, Navy vessels afloat, Naval Expeditionary forces, and the remainder of PACOM.
- Shipments to CONUS sites will begin mid-August.
- DoD will follow the Health Affairs (HA) policy for mandatory seasonal influenza vaccination for civilian healthcare personnel who provide direct patient care in DoD military treatment facilities.

## Background & Environment

- In the United States, analysis during the 1990s estimated an average of 36,000 annual deaths related to influenza, resulting in large part from an aging US population.

- In the United States, the average annual number of hospitalizations associated with influenza has been estimated at 226,000.
- DoD has contracted for a total of 3.6 million doses of influenza vaccine for the 2009-2010 influenza season. This includes 1.8 million doses of inactivated (injectable) vaccine and 1.8 millions doses of live attenuated (intranasal) vaccine. It is expected that the supply of intranasal and injectable vaccines will adequately meet DoD needs. MTFs should expect several deliveries to fill requirements.
- Influenza viruses are divided into three categories: Influenzavirus A, Influenzavirus B, and Influenzavirus C based on antigenic differences in two major structural proteins.
- The 2009-2010 trivalent influenza vaccine contains A/Brisbane/59/2007 (H1N1)-like virus, A/Brisbane/10/2007 (H3N2)-like virus, and B/Brisbane/60/2008-like antigens. Only the influenza B component represents a change from the 2008-2009 vaccine formulation.
- Influenza is spread through aerosolized respiratory droplets or through contact with a contaminated object.
- Injectable vaccines should be used for those in whom intranasal vaccine is medically contraindicated, or where intranasal vaccine is unavailable due to logistical constraints.
- The influenza vaccines are temperature-sensitive products and activities must comply with cold chain management guidelines when transporting and storing these vaccines.
- Fluzone® is an inactivated trivalent influenza virus vaccine manufactured for the 2009-2010 influenza season by Sanofi-Pasteur. This vaccine contains preservative. It is used for immunizing persons 6 to 35 months of age (0.25 ml per dose) and 36 months and older (0.50 ml per dose). The unit of issue is a 5.0 ml multi-dose vial with a unit price of $90.18. It has an expiration date of 30 Jun 2010. This product requires refrigeration storage. Do not freeze. This product is stored 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.
- Fluzone® is an inactivated trivalent influenza virus vaccine manufactured for the 2009-2010 influenza season by Sanofi-Pasteur. This is a preservative (thimerosal) free vaccine. It is used for immunizing persons 36 months and older (0.5 ml per dose). The unit of issue is a package of 10 0.5 ml pre-filled syringes with a unit price of $98.82. It has an expiration date of 30 Jun 2010. This product requires refrigeration storage. Do not freeze. This product is stored 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.
- Fluzone® pediatric vaccine is an inactivated trivalent influenza virus vaccine manufactured for the 2009-2010 influenza season by Sanofi-

Pasteur. This is a preservative (thimerosal) free vaccine. It is used for immunizing persons 6 to 35 months of age (0.25 ml per dose). The unit of issue is a 5.0 ml multi-dose vial with a price of $121.53. It has an expiration date of 30 Jun 2010. This product requires refrigeration storage. Do not freeze. This product is stored 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.

- Afluria® is an inactivated trivalent influenza virus vaccine manufactured for the 2009-2010 influenza season by CSL Biotherapies. This vaccine contains a preservative. It is used for immunizing persons 18 years of age and older. The unit of issue is a 5.0 ml multi-dose vial (10 vials), in 0.50 ml doses, and has a unit price of $52.54. Its acquisition advice code is A. It has an expiration date of 30 Jun 2010. Once the stopper has been pierced, the vial must be discarded within 28 days. This product requires refrigeration storage. Do not freeze. This product is stored at 2 to 8 degrees Celsius or 36 to 46 degrees Fahrenheit. Cold chain must be maintained when transporting and storing Afluria® prior to use.
- Afluria® is an inactivated trivalent influenza virus vaccine manufactured for the 2009-2010 influenza season by CSL Biotherapies. This is a preservative (thimerosal) free vaccine. It is used for immunizing persons 18 years of age and older. The unit of issue is a package of 10 0.5 ml pre-filled syringes with a unit price of $59.95. Its acquisition advice code is A. It has an expiration date of 30 Jun 2010. Once the stopper has been pierced, the vial must be discarded within 28 days. This product requires refrigeration storage. Do not freeze. This product is stored at 2 to 8 degrees Celsius or 36 to 46 degrees Fahrenheit. Cold chain must be maintained when transporting and storing Afluria® prior to use.
- Flumist® is a live attenuated trivalent influenza virus vaccine manufactured for the 2009-2010 influenza season by MedImmune. This is a preservative (thimerosal) free vaccine. It is used for immunizing healthy persons 2 to 49 years of age. The unit of issue is a package of 10 0.20 ml pre-filled single use sprayers that has a unit price of $150.64. Its acquisition advice code is A. It has a shelf life of 18 weeks. This product is shipped frozen from the manufacturer. Do not refreeze. This product is stored at 2 to 8 degrees Celsius or 36 to 46 degrees Fahrenheit upon receipt and until use before the expiration date. Cold chain must be maintained when transporting and storing Flumist® prior to use.
- Influenza vaccines should not be administered to people with sensitivities to egg proteins (eggs or egg products), chicken proteins, or any component of the vaccine.
- Influenza vaccine should not be administered to anyone with an active nervous system disorder or a history of Guillain-Barré Syndrome.

# Key Messages

- Maintaining optimum health, safety, and well-being of Service members is our top priority.
- The DoD Influenza Vaccine Program is part of our national defense strategy to safeguard DoD personnel against influenza disease.
- Vaccination remains the cornerstone of preventing influenza.
- Vaccinations offer a layer of protection in addition to antivirals and other measures that are needed for the armed forces.
- Infection from influenza viruses can result in illness ranging from mild to severe and may cause life-threatening complications.
- Serious problems from influenza vaccinations are very rare.
- Influenza vaccinations should continue until supply is exhausted or the vaccine expiration has been reached.
- Healthcare providers should take time to screen immunization records and tracking systems for other vaccine requirements or booster immunizations.

# Talking Points

- Influenza is a contagious respiratory illness caused by influenza viruses and the best way to protect against influenza is to get vaccinated every year.
- Two forms of influenza vaccine are distributed in the United States:
  - An inactivated, protein-derived vaccine, given by intramuscular injection.
  - A live attenuated (weakened) vaccine sprayed into the nose.
- Studies have shown that both the injectable vaccine and the intranasal vaccine are safe and effective at preventing influenza.
- Vaccine Adverse Event Reporting System (VAERS) is in place for reporting vaccine related adverse events (www.vaers.hhs.gov).
- Vaccine Healthcare Centers (VHC) Network is available to assist with healthcare issues potentially resulting from vaccine-related adverse events (http://www.vhcinfo.org/).
- The Epidemiology Branch of the Air Force School of Aerospace Medicine (USAFSAM) updates the influenza surveillance website (https:/gumbo.brooks.af.mil/pestilence/influenza) and publishes laboratory surveillance results weekly.

- USAFSAM and the DoD Global Emerging Infections Surveillance and Response System will coordinate weekly summary and final reports to the Assistant Secretary of Defense for Health Affairs.
- Commanders are charged with ensuring immunization data is entered into electronic immunization tracking systems.

## Policy

- DoD policy requires immunization of all Active duty and Reserve Component personnel against influenza according to Service-specific guidelines.
- Under the current DoD policy, influenza vaccinations are mandatory for all emergency essential and equivalent civilian personnel.
- HA Policy 08-005, dated 4 April 2008, mandates all civilian healthcare personnel who provide direct care to patients in MTFs must be immunized against seasonal influenza each year as a condition of employment.
- All Services will monitor implementation using Service-specific immunization tracking systems.
- The vaccine will be offered to DoD beneficiaries during the influenza season in accordance with the Centers for Disease Control and Prevention (CDC) Advisory Committee on Immunization Practices (ACIP) guidelines.

## PAO POCs / Subject Matter Expert (SME) Resources

For more information contact the Military Vaccine (MILVAX) Agency at 1-877-GETVACC (438-8222) or at vaccines@amedd.army.mil.

## Questions and Answers

**1) When will the 2009-2010 Seasonal Influenza Vaccine Program (SIVP) begin?**

SIVP will begin immediately upon receipt of influenza vaccine to protect individuals at risk from developing influenza or its complications. All Services will follow Service–specific implementation guidelines. Influenza vaccinations should continue until supply is exhausted or the vaccine expiration has been reached.

**2) How much vaccine is available for the military this year?**

DoD has contracted with the Defense Supply Center Philadelphia to obtain influenza vaccine from three different manufacturers. For the 2009-2010 influenza season, DoD has purchased a total of 3.6 million influenza vaccine doses. This includes 1.8 million doses of inactivated (injectable) vaccine and 1.8 million doses of live attenuated (intranasal) vaccine. The distribution of injectable and intranasal vaccine will start in August. There are no expected shortages of vaccine this year.

Note: More detailed information regarding this year's influenza vaccines can be found at http://www.vaccines.mil/flu.

**3) How are injectable and intranasal influenza vaccines shipped and stored?**

All injectable vaccines are shipped and stored at 2 to 8 degrees Celsius.

Intranasal vaccine is shipped directly from the manufacturer frozen, on dry ice. Immediately after vaccine arrives at its first destination, it is placed in a refrigerator and stored at 2-8 C (35-46 F) until used before the expiration.

Note: For more information regarding storage and stability under conditions other than those recommended, call 1-877-FLUMIST (1-877-358-6478 prompt 2).

**4) Is injectable vaccine reserved for any specific population?**

The Services will reserve injectable vaccine for people in whom the intranasal vaccine is medically contraindicated or where the intranasal vaccine is unavailable due to logistical constraints.

**5) Who does the Advisory Committee on Immunization Practices (ACIP) recommend receive annual influenza vaccination?**

- All children from 6 months through 18 years of age.
- Anyone 50 years of age or older.
- Anyone who is at risk of complications from influenza, or more likely to require medical care.
- Women who will be pregnant during influenza season.
- Anyone with long-term health problems.
- Anyone with a weakened immune system.
- Anyone 6 months through 18 years of age on long-term aspirin treatment.
- Residents of nursing homes and other chronic-care facilities.

- Anyone who lives with or cares for people at high risk for influenza-related complications.
- Household contacts and caregivers of children from birth up to 5 years of age and people 50 years and older.

**6) Why do I need to get immunized against influenza every year?**

Influenza viruses change from year to year. Protection that develops after a person is infected or is immunized against the circulating viruses of one season does not provide adequate cross-protection when a new influenza strain develops.

**7) Will new strains of influenza virus circulate this season?**

Influenza viruses are constantly changing, so it is not unusual for new strains of influenza virus to emerge at any time of the year. This year's influenza vaccines were made using the following strains: A/Brisbane/59/2007 (H1N1)-like virus, A/Brisbane/10/2007 (H3N2)-like virus, and B/Brisbane/60/2008-like antigens. Only the influenza B component represents a change from the 2008-2009 vaccine formulation.

More information about influenza vaccine is available from MILVAX at www.vaccines.mil/flu and from the CDC at www.cdc.gov/flu/protect/.

**8) How soon will I get sick after being exposed to the influenza virus?**

The incubation period for influenza is commonly 2 days, but ranges from 1-4 days. This is the period when people are most contagious to others because the infected person still feels normal, and is not taking the necessary precautions to avoid spreading the disease.

**9) What is the best way to protect my family and myself from getting influenza if we do not get immunized?**

Vaccination is your best protection against influenza infection. If you are unable to receive the vaccination, avoid close contact with people who are sick. Wash your hands often and avoid touching your eyes, nose, or mouth. Germs are often spread when a person touches something that is contaminated with germs and then touches his or her eyes, nose, or mouth. If possible, stay home from work or school when you are sick. Cover your mouth and nose with a tissue when coughing or sneezing and wash your hands often. This may help prevent those around you from getting sick. Infection control recommendations for

healthcare facilities are located at www.cdc.gov/flu/professionals/infectioncontrol/index.htm.

**10) How effective is influenza immunization in protecting me from illness caused by the different strains of influenza?**

Vaccines are developed each year in an attempt to match the predicted virus strains. When they are well-matched, immunization of healthy adults is 70-90% effective in preventing influenza illness. When vaccines are not well matched to the majority of circulating strains, effectiveness has been as low as 47-77%. Vaccines may be somewhat less effective in elderly persons and very young children, but immunization can still help prevent serious complications from influenza illness.

**11) Who should not get the injectable influenza vaccine?**

- People who have a severe allergy to chicken proteins, eggs, egg products, or any components of the influenza vaccine.
- People who have had a severe reaction to an influenza vaccination in the past.
- People who developed Guillain-Barré Syndrome within 6 weeks of getting an influenza vaccination previously (unless advised otherwise by their physician).
- People who are sick with a fever. These people can get immunized once their symptoms resolve.
- Children younger than 6 months of age.

NOTE: People who have a history of a severe allergic reaction to vaccine components, but also are at high risk for complications from influenza, may be able to receive the vaccine after appropriate allergist evaluation and desensitization.

**12) What side effects can I expect when I receive the injectable influenza vaccine?**

The viruses in inactivated influenza vaccine have been killed, so you cannot get influenza from the vaccine. Side effects which could occur are:

- Soreness, redness or swelling at injection site
- Fever, weakness, headache
- Muscle aches

If these problems occur, they usually begin soon after immunization and typically last for one or two days. Most people who receive influenza vaccine experience

no serious problems. In rare instances, serious problems such as severe allergic reactions can occur.

**13) Who should receive the intranasal influenza vaccine?**

FluMist is a live intranasal vaccine approved for 2-49 year olds. For more information, see www.vaccines.mil/flu.

**14) What side effects can I expect when I receive the intranasal influenza vaccine?**

The viruses in the intranasal vaccine are weakened and do not cause severe symptoms associated with the influenza. Side effects can include: runny nose, headache, fever, cough, and sore throat.

For more information, see www.vaccines.mil/flu.

**15) Who should not receive the intranasal influenza vaccine?**

The following populations should not be immunized with the Live Attenuated Intranasal Vaccine (LAIV):

- People younger than 2 years old or those older than 49 years of age.
- People with asthma, reactive airways disease, or other chronic disorders of the pulmonary or cardiovascular systems.
- People with other underlying medical conditions, including such metabolic diseases as diabetes, renal dysfunction, and hemoglobinopathies.
- People with known or suspected immunodeficiency diseases or who are receiving immunosuppressive therapies.
- Children or adolescents receiving aspirin or other salicylates (because of the association of Reye's Syndrome with natural (wild-type) influenza virus infection).
- People with a history of Guillain-Barré Syndrome.
- Pregnant women.
- People with a history of hypersensitivity, including anaphylaxis, to any of the components of LAIV or to eggs.

**16) If I need to place a tuberculin skin test (TST) and the patient also needs their annual influenza vaccine, should I be concerned about the timing of these products?**

Yes. If you are using the intranasal influenza vaccine which is a live attenuated virus vaccine, it can suppress a reaction to the tuberculin skin test (i.e., can

cause a false-negative tuberculosis skin test result). Intranasal influenza vaccine and the TST should be administered on the same day, or if the intranasal influenza vaccine is given first, then the TST must be administered at least 28 days later. The TST can be placed first, and once the TST is read, then you can administer the intranasal influenza vaccine.

Injectable influenza vaccines and tuberculin skin test **can be administered concurrently**.

**17) What if I'm pregnant or breastfeeding? Can I still get vaccinated against influenza?**

Yes. Pregnant women, as well as lactating women and their newborn babies, are all at risk for influenza complications. The Advisory Committee on Immunization Practices (ACIP), the American College of Obstetricians and Gynecologists, and the American Academy of Family Physicians have all recommended the routine vaccination of women who are pregnant, or become pregnant during influenza season, with injectable vaccine. ACIP states that pregnant or lactating women do not need to avoid contact with persons recently vaccinated with intranasal vaccine.

**18) Are influenza vaccines harmful during my pregnancy?**

This year's influenza vaccines are labeled as Pregnancy Category C, which means that animal reproduction studies have not been conducted, and it is not known whether or not influenza vaccine can cause fetal harm or affect reproductive capacity. Package inserts state that influenza vaccines should only be given when clearly needed. ACIP recommends the use of injectable influenza vaccine for immunization of pregnant women because the benefit outweighs the risk of any adverse events. This year's ACIP recommendations for Prevention and Control of Influenza describe studies that were used to make this recommendation. See http://www.cdc.gov/mmwr/pdf/rr/rr58e0724.pdf.

**19) If I need to get other live vaccines at the same time as my annual influenza vaccine, should I be concerned about the timing of these products?**

Yes, if you are using the live intranasal influenza vaccine. If patients need a live vaccine and qualify for receipt of intranasal influenza vaccine, all live vaccines should be administered on the same day or separated by 28 days. Inactivated influenza vaccine (injectable) does not interfere with the scheduling of live or inactive vaccines.

**20) Who can I contact if I have a problem after taking my vaccine?**

Contact your healthcare provider or the clinic at which you received your vaccination. You may also contact the Military Vaccine (MILVAX) Agency, 1-877-GETVACC (438-8222) or at vaccines@amedd.army.mil; the Vaccine Healthcare Centers (VHC) Network, 1-202-782-0411 or https://askvhc.wramc.amedd.army.mil/; the 24/7 DoD Vaccine Clinical Call Center, 1-800-232-4636 are available to assist with healthcare issues potentially resulting from vaccine-related adverse events; the CDC National Immunization Hotline, 1-800-232-4636, or submit a report directly to the Vaccine Adverse Event Reporting System (VAERS) at www.vaers.hhs.gov.

**21) What documentation is required with influenza immunization?**

It is important to document immunizations properly into electronic immunization and paper-based systems. Proper documentation includes patient identification, the date the vaccine was given, the vaccine name or code, manufacturer, lot number, volume of the dose given, vaccine administration route and anatomic site, name, rank, and SSN of prescriber, vaccinator name, the date patient is given the Vaccine Information Statement (VIS), and the VIS version date. All Services monitor implementation using Service-specific electronic immunization tracking systems (Medical Protection System (MEDPROS), Air Force Complete Immunization Tracking Application (AFCITA), Medical Readiness Reporting System (MRRS), and Defense Eligibility Enrollment Reporting System (DEERS)).