## Military Vaccine Agency Communications Plan Novel A(H1N1) Influenza

### Issue

- The Department of Defense (DoD) will implement the Novel A(H1N1) Influenza Vaccine Immunization Program (NIVIP) immediately upon receipt of vaccine to protect individuals from contracting the H1N1 influenza virus.
- DoD's goal is to protect all Active Duty (AD) and Reserve Component (RC) personnel, healthcare personnel (HCP), DoD civilians, military essential contractors, and dependents from the novel A(H1N1) influenza virus and its complications.
- H1N1 immunizations will be mandatory for uniformed personnel and highly encouraged for all others.
- H1N1 influenza vaccine will be administered as a single dose for those ≥10 years of age and as a two dose regimen separated by approximately one month for those 6 months to 9 years of age.
- Vaccine availability to the DoD will be dependent on the overarching national acquisition strategy.

### Impact to Department of Defense

- Novel A(H1N1) influenza disease is a contagious respiratory illness that would disrupt DoD's military readiness.
- DoD purchased enough influenza A(H1N1) 2009 monovalent vaccine from the Department of Health and Human Services (DHHS) to ensure a basic quantity of vaccine is available for its operational forces.
- DoD will receive additional vaccine through allocations from the DHHS to cover all categories of beneficiaries.
- The novel A(H1N1) influenza vaccine is mandatory for uniformed personnel and highly encouraged for all others.
- Active Duty, National Guard, and Reserves will be immunized through DoD 2009 H1N1 vaccine allocations by priority based on operational needs and/or health risks according to DoD guidance.
- If severity of disease is similar to the spring/summer H1N1 influenza outbreak, vaccine distribution will be targeted towards deployed and deploying forces, new accessions (including Service Academies), ships afloat, and healthcare personnel.



- DoD civilians and contractors are encouraged to seek vaccine through non-DoD sources when available as this will likely result in quicker access.
- For CONUS dependents and retirees, military treatment facility (MTF) commanders, in coordination with installation public health emergency officers (PHEOs), will register through their respective states as an immunizer, compile local beneficiary population statistics, and provide those numbers to the state. The state in turn will roll those numbers into their total population and forward to the CDC. The CDC will supply vaccine to the state based on those numbers. The state will coordinate with the vaccine distributor and the installation to have the vaccine delivered to the MTF (Alaska and Hawaii are included in state allocations from CDC).
- For OCONUS beneficiaries, vaccine will be supplied according to the seasonal influenza distribution model.

### Background & Environment

- Novel A(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 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 June 11, 2009, the World Health Organization (WHO) signaled that a global pandemic of novel A(H1N1) influenza was underway by raising the worldwide pandemic alert level to Phase 6. Since the WHO declaration of a pandemic, the new H1N1 virus has continued to spread.
- In the United States, novel A(H1N1) influenza illness has continued into the summer, with localized, and in some cases, intense outbreaks occurring. The novel A(H1N1) virus, in conjunction with regular seasonal influenza viruses, poses the potential to cause significant illness with associated hospitalizations and deaths during the U.S. influenza season.
- Influenza is spread through aerosolized respiratory droplets or through contact with a contaminated object.
- Infection from the novel A(H1N1) influenza infection can result in illness ranging from mild to severe and may cause life-threatening complications.
- The FDA and WHO have selected A/California/07/2009 (H1N1) as the strain for the H1N1 vaccines. The H1N1 vaccines licensed by the FDA do not contain adjuvants. Monovalent intranasal and injectable vaccine formulations will be available.
- Novel A(H1N1) influenza vaccinations should continue until supply is exhausted or the vaccine expiration date has been reached.



- The influenza vaccines are temperature-sensitive products and activities must comply with cold chain management guidelines when transporting and storing these vaccines:
  - NSN 6505-01-577-5940 Novartis Vaccines Influenza A(H1N1) 2009 Monovalent Vaccine is manufactured by Novartis Vaccines. This vaccine contains a preservative. It is given intramuscularly to persons 4 years of age and older. The unit of issue is a package of 10 pre-filled 0.5 mL single dose syringes. Its acquisition advice code is A. 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 this product.
  - NSN 6505-01-577-5936 Novartis Vaccines Influenza A(H1N1) 2009 Monovalent Vaccine is manufactured by Novartis Vaccines. This vaccine contains a preservative. It is given intramuscularly to persons 4 years of age and older. The unit of issue is a 5.0 mL multi-dose vial. 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 this product.
  - NSN 6505-01-577-6829 Sanofi Pasteur Influenza A(H1N1) 2009 Monovalent Vaccine is manufactured by Sanofi Pasteur. This is a preservative (thimerosal) free vaccine. It is given intramuscularly to persons 6 months to 35 months of age. The unit of issue is a package of 10 pre-filled 0.25 mL single dose pediatric syringes. 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 this product.
  - NSN 6505-01-577-9973 Sanofi Pasteur Influenza A(H1N1) 2009 Monovalent Vaccine is manufactured by Sanofi Pasteur. This is a preservative (thimerosal) free vaccine. It is given intramuscularly to persons 6 months to 35 months of age. The unit of issue is a package of 25 pre-filled 0.25 mL single dose pediatric syringes. 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 this product.
  - NSN 6505-01-577-7716 Sanofi Pasteur Influenza A(H1N1) 2009 Monovalent Vaccine is manufactured by Sanofi Pasteur. This is a preservative (thimerosal) free vaccine. It is given intramuscularly to persons 36 months of age and older. The unit of issue is a package of 10 pre-filled 0.5 mL single dose syringes. 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 this product.
- NSN 6505-01-577-9975 Sanofi Pasteur Influenza A(H1N1) 2009 Monovalent Vaccine is manufactured by Sanofi-Pasteur. This is a preservative (thimerosal) free vaccine. It is given intramuscularly to persons 36 months of age and older. The unit of issue is a package of 25 pre-filled 0.5 mL single dose syringes. 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 this product.
- NSN 6505-01-577-6430 Sanofi Pasteur Influenza A(H1N1) 2009 Monovalent Vaccine is manufactured by Sanofi Pasteur. This is a preservative (thimerosal) free vaccine. The unit of issue is a 0.5 mL single-dose vial. It is given intramuscularly to persons 6 to 35 months of age (0.25mL per dose) and 36 months and older (0.5 mL per dose). 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 this product.
- NSN 6505-01-578-2138 Sanofi Pasteur Influenza A(H1N1) 2009 Monovalent Vaccine is manufactured by Sanofi Pasteur. This vaccine contains a preservative. It is given intramuscularly to persons 6 to 35 months of age (0.25mL per dose) and 36 months and older (0.5 mL per dose). The unit of issue is a 5.0 mL multidose vial (10 vials), in 0.50 mL doses. Its acquisition advice code is A. 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 this product.
- NSN 6505-01-577-7047 CSL Biotherapies Influenza A(H1N1) 2009 Monovalent Vaccine manufactured by CSL Biotherapies. This vaccine contains a preservative. It is given intramuscularly to persons 18 years of age and older. The unit of issue is a 5.0 mL multidose vial (10 vials), in 0.50 mL doses. Its acquisition advice code is A. 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 this product.
- NSN 6505-01-577-7013 CSL Biotherapies Influenza A(H1N1) 2009 Monovalent Vaccine is manufactured by CSL Biotherapies. This vaccine is a preservative (thimerosal) free vaccine. It is given intramuscularly to persons 18 years of age and older. The unit of issue is a package of 10 0.5 ml prefilled syringes. Its acquisition



- advice code is A. 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 this product.
- NSN 6505-01-578-1392 MedImmune Influenza A(H1N1) 2009 Monovalent Live, Intranasal vaccine is manufactured by MedImmune. This is a preservative (thimerosal) free vaccine. It is given intranasly to healthy persons 2 to 49 years of age. The unit of issue is a package of 10 0.2 mL prefilled single use sprayers. Its acquisition advice code is A. 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 this product.
- Ancillary supplies for DoD vaccine allocation will be accompanied by a corresponding number of syringes distributed by DSCP.
   Ancillary supplies to complement doses provided by DHHS allocations will come from the Strategic National Stockpile.
- 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.

### H1N1 Vaccine Administration

- There is a seasonal and novel H1N1 Live, Attenuated Intranasal Vaccine (LAIV) product. LAIV is administered intranasally.
- Two LAIVs e.g. seasonal LAIV and novel H1N1 LAIV should not be administered in near concurrent fashion due to theoretical concerns of viral re-assortment which could lead to a diminished immune response to both vaccines, according to CDC recommendations. If two LAIVs are mistakenly administered concurrently there is no need to revaccinate.
- H1N1 LAIV may be administered on the same day with injectable live virus vaccines. If this is not possible then separate the live virus vaccines by at least 28 days, according to CDC recommendations. H1N1 LAIV and seasonal LAIV should not be administered simultaneously.
- H1N1 LAIV may be given with any inactivated vaccine without regard to timing per CDC national recommendations.
- H1N1 inactivated vaccine (IV) (injectable) does not interfere with the scheduling of live or inactive vaccines.



### Key Messages

- Maintaining optimum health, safety and well-being of Service members is our top priority.
- The vaccine is safe and effective.
- Vaccination offers a layer of protection in addition to antivirals and other measures that are needed for the armed forces.
- The DoD NIVIP is part of our national defense strategy to safeguard DoD personnel against influenza disease.
- Vaccination remains the cornerstone of preventing novel A(H1N1) influenza disease.
- Vaccination acts as an internal body armor and offers a 24/7 layer of protection.
- Take everyday actions to stay healthy.

### **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.
- The H1N1 influenza virus is not the same as previous or current human seasonal influenza viruses. Seasonal influenza vaccine does not provide protection against the 2009 H1N1 influenza virus.
- In order to be fully protected against H1N1 virus, a separate vaccination is needed.
- Two forms of H1N1 influenza vaccine are distributed in the United States:
  - An inactivated, protein-derived vaccine, given by intramuscular injection over the deltoid.
  - A live attenuated (weakened) vaccine sprayed into the nose.
- The CSL Monovalent vaccines are used to vaccinate persons 18 years of age and older. This vaccine is not to be administered to new accessions under 18 years of age.
- Studies have shown that both the injectable vaccine and the intranasal vaccine are safe and effective at preventing influenza.
- The primary goal of the DoD NIVIP is to protect all Active Duty (AD) and Reserve Component (RC) personnel, healthcare personnel (HCP), DoD civilians, mission-essential civilians, and dependents from influenza and its severe complications.
- If severity of disease is similar to the spring/summer H1N1 influenza outbreak, vaccine will be targeted toward deployed and deploying forces, new accession sites (including Service Academies), and healthcare



- personnel. If the novel A(H1N1) influenza virus begins to cause more severe disease, vaccine will be prioritized towards protecting forces responsible for completing DoD operational missions as determined by the Joint Staff.
- Vaccine Adverse Event Reporting System (VAERS) is in place for reporting vaccine-related adverse events (www.vaers.hhs.gov).
- The Epidemiology Branch of the Air Force School of Aerospace Medicine (USAFSAM) updates the influenza surveillance website (<a href="https://gumbo.brooks.af.mil/pestilence/influenza">https://gumbo.brooks.af.mil/pestilence/influenza</a>) and publishes laboratory surveillance results weekly. Contact: <a href="mailto:influenza@brooks.af.mil">influenza@brooks.af.mil</a>.
- 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 (ITS).

### Policy

- 2009 H1N1 Vaccine Policy for Family Members and Retirees Residing in the Continental United States including Alaska and Hawaii.
   (http://www.vaccines.mil/documents/1288HAPCDOCS\_n171787\_v1\_2009\_ H1N1\_Vaccine\_Policy\_for\_Dependents\_and\_Retirees\_Residing\_in\_the\_Continental\_United\_Stat.pdf.
- Department of Defense Pandemic Vaccine Guidance for Novel Influenza A(H1N1).
   (<a href="http://www.vaccines.mil/documents/1291DoD">http://www.vaccines.mil/documents/1291DoD</a> H1N1 Policy Sep2009.pdf
   )
- Implementation Guidance for Administration of Novel A(H1N1)
   Influenza Vaccine
   (<a href="http://www.vaccines.mil/documents/1295H1N1\_Implementation\_Guidance.pdf">http://www.vaccines.mil/documents/1295H1N1\_Implementation\_Guidance.pdf</a>)
- Army Operation Order 09-75 (Novel A(H1N1) Influenza Immunization Program).
   (<a href="http://www.vaccines.mil/documents/12850PORD\_09\_75\_H1N1.pdf">http://www.vaccines.mil/documents/12850PORD\_09\_75\_H1N1.pdf</a>)
- USAF Air Force 2009-2010 Novel H1N1 Influenza Immunization Program. (<a href="http://www.vaccines.mil/documents/1287SG\_Doc\_09-0014\_Air\_Force\_2009\_10\_H1N1.pdf">http://www.vaccines.mil/documents/1287SG\_Doc\_09-0014\_Air\_Force\_2009\_10\_H1N1.pdf</a>)
- Navy Initial Policy for the Use of Novel H1N1 Influenza Vaccine for 2009-2010.
  - (http://www.vaccines.mil/documents/1283BUMED h1n1 15sep09.pdf)



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

For more information contact the Military Vaccine (MILVAX) Agency at 1-877-GETVACC (438-8222) or at <a href="mailto:vaccines@amedd.army.mil">vaccines@amedd.army.mil</a>.

### Questions and Answers

# 1) Will vaccination with the new novel A(H1N1) influenza vaccine be mandatory for Active Duty service members?

Yes. The novel A(H1N1) influenza vaccine will be mandatory for uniformed personnel and highly encouraged for all others.

# 2) Have the vaccines met the requirements by U.S. Food and Drug Administration (FDA)?

The FDA approved supplements to existing vaccine licenses to protect against the pandemic (H1N1) 2009 influenza virus. The 2009 novel A(H1N1) influenza monovalent vaccines contain an A/California/7/09-like virus.

Note: H1N1 influenza vaccine package inserts are posted at <a href="http://www.vaccines.mil/H1N1">http://www.vaccines.mil/H1N1</a>.

### 3) Do you expect any shortage of the novel A(H1N1) influenza vaccine?

No. A shortage of novel H1N1 vaccine is not expected, but availability and demand can be unpredictable. Should an unexpected vaccine shortage occur, directions regarding prioritization will be provided by ASD (HA), and will be consistent with recommendations published in subsequent issues of the CDC Morbidity and Mortality Weekly Report. The Department of Defense (DoD) purchased enough influenza A(H1N1) 2009 monovalent vaccine from the Department of Health and Human Services (DHHS) to ensure a basic quantity of vaccine is available for its operational forces. DoD will receive additional vaccine through allocations from the DHHS to cover all categories of beneficiaries.

### 4) Where will the vaccine be available?

Vaccine for operational forces will come from the Defense Supply Center Philadelphia (DSCP), following the seasonal influenza distribution model.



For CONUS (including Alaska and Hawaii) military treatment facility (MTF) commanders, in coordination with installation public health emergency officers (PHEOs), will register through their respective states as an immunizer to vaccinate dependents and retirees

(<a href="http://www.cdc.gov/h1n1flu/vaccination/statecontacts.htm">http://www.cdc.gov/h1n1flu/vaccination/statecontacts.htm</a>). The state, in turn, will incorporate this population and forward to the CDC. The CDC will supply vaccine to the state based on this population. The state will coordinate with the vaccine distributor and the installation to have the vaccine delivered to the MTF. 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.

For OCONUS dependents and retirees, vaccine will be supplied according to the seasonal influenza vaccine distribution model.

NIVIP will begin immediately upon receipt of H1N1 influenza vaccine to protect individuals at risk from developing influenza or its complications. All Services will follow Service—specific implementation guidelines.

# 5) What documentation is required with novel A(H1N1) influenza immunization?

It is important to document immunizations properly into electronic immunization tracking systems or 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 (if available). 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)).

#### 6) 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.
- Military Vaccine (MILVAX) Agency, 1-877-GETVACC (438-8222) or at vaccines@amedd.army.mil.
- Vaccine Healthcare Centers (VHC) Network, 1-202-782-0411 or https://askvhc.wramc.amedd.army.mil/.
- DoD Vaccine Clinical Call Center, 1-800-232-4636.



 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.

Note: The VHC and DoD Call Center are available to assist with healthcare issues potentially resulting from vaccine-related adverse events.

#### 7) What is novel H1N1 (swine flu)?

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 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 June 11, 2009, the World Health Organization (WHO) signaled that a pandemic of novel H1N1 influenza was underway.

# 8) Why is novel A(H1N1) influenza virus sometimes called "swine flu"?

This virus was originally referred to as "swine flu" because laboratory testing showed that many of the genes in this new virus were very similar to influenza viruses that normally occur in pigs (swine) in North America. Further study has shown that this new virus is very different from what normally circulates in North American pigs. This virus has two genes from influenza viruses that normally circulate in pigs in Europe and Asia and bird (avian) genes and human genes. Scientists call this a "quadruple reassortant" virus.

#### 9) How does the novel A(H1N1) influenza virus spread?

Spread of novel H1N1 virus is thought to occur in the same way that seasonal influenza spreads. Influenza viruses are spread mainly from person to person through coughing or sneezing by people with influenza. Sometimes people may become infected by touching something – such as a surface or object – with influenza viruses on it and then touching their mouth or nose.

# 10) Why do we need vaccination against novel H1N1 influenza this year in addition to the normal influenza vaccine we get each year?

The seasonal influenza vaccine is not expected to protect against the novel H1N1 influenza. The novel H1N1 virus is a seasonal variant, and in conjunction with regular seasonal influenza viruses, poses the potential to cause significant illness with associated hospitalizations and deaths during the U.S. influenza season. H1N1 vaccine is being developed using a different strain of influenza viruses not found in the seasonal vaccine.



# 11) Who will be recommended as priority groups by the CDC's Advisory Council for Immunization Practices (ACIP) to receive the novel A(H1N1) influenza vaccine?

Key populations include pregnant women, people who live with or care for children younger than 6 months of age, healthcare and emergency medical services personnel, persons between the ages of 6 months and 24 years old, and people ages 25 through 64 years of age who are at higher risk for novel H1N1 because of chronic health disorders or compromised immune systems. A shortage of novel H1N1 vaccine is not expected, but availability and demand can be unpredictable. There is some possibility that initially, the vaccine will be available in limited quantities. In this setting, the ACIP recommended that the following groups receive the vaccine before others: pregnant women, people who live with or care for children younger than 6 months of age, healthcare and emergency medical services personnel with direct patient contact, children 6 months through 4 years of age, and children 5 through 18 years of age who have chronic medical conditions.

The ACIP recognized the need to assess supply and demand issues at the local level. The committee further recommended that once the demand for vaccine for these prioritized groups has been met at the local level, programs and providers should begin vaccinating everyone from ages 25 through 64 years. Current studies indicate the risk for infection among persons age 65 or older is less than the risk for younger age groups. Therefore, as vaccine supply and demand for vaccine among younger age groups is being met, programs and providers should offer vaccination to people over the age of 65.

#### 12) How will H1N1 vaccinations effect our TRICARE population?

In an effort to support TRICARE Prime enrollees obtaining the H1N1 immunization, and avoid Point of Service (POS) charges, a temporary suspension of the requirement that the Prime enrollee obtain a referral from their Primary Care Manager (PCM) to receive the H1N1 immunization from a non-network, TRICARE authorized provider is in place effective October 1, 2009, through April 30, 2010. To read the memorandum, click <a href="http://www.tricare.mil/customerservicecommunity/documents/HAPCDOCS\_n170">http://www.tricare.mil/customerservicecommunity/documents/HAPCDOCS\_n170</a> 878 v2B Temporary Suspension of H1N1 Immunization Authorizations.pdf.

The availability of the vaccine will be limited across the country, so beneficiaries may still experience a delay in getting the H1N1 vaccine. In the meantime, they should be encouraged to get the seasonal influenza vaccination in accordance with (IAW) TRICARE Policy. To stay current on issues pertaining to influenza, go to <a href="http://www.tricare.mil/flu/">http://www.tricare.mil/flu/</a> or to the official DoD WatchBoard at <a href="http://fhp.osd.mil/aiWatchboard/index.jsp">http://fhp.osd.mil/aiWatchboard/index.jsp</a>.



#### 13) What are the symptoms of H1N1?

Symptoms are like seasonal influenza and include the following:

- Fever
- Cough
- Sore throat
- Body aches
- Headaches
- Chills and fatigue
- · Sometimes diarrhea and vomiting

# 14) Will the seasonal influenza vaccine also protect against the novel A(H1N1) influenza?

No. The 2009 H1N1 influenza virus is not the same as previous or current human seasonal influenza viruses. Seasonal influenza vaccine does not provide protection against the novel 2009 H1N1 influenza virus. Although the currently licensed seasonal trivalent influenza vaccines contain an H1N1 subtype, the subtype differs from the novel 2009 H1N1 influenza virus, which is a new viral strain.

# 15) Can the seasonal vaccine and the novel A(H1N1) influenza vaccine be given at the same time?

According to the ACIP, simultaneous administration of inactivated vaccines against seasonal and novel A(H1N1) viruses is permissible if different anatomic sites are used. Two LAIVs e.g. seasonal LAIV and novel H1N1 LAIV should not be administered in near concurrent fashion due to theoretical concerns of viral reassortment which could lead to a diminished immune response to both vaccines. If two LAIVs are mistakenly administered concurrently, there is no need to revaccinate.

# 16) If I need to get other live vaccines at the same time as novel A(H1N1) influenza vaccine, should I be concerned about the timing of these products?

H1N1 LAIV may be administered on the same day as other injectable live virus vaccines. If this is not possible then the vaccinations should be separated by at least 28 days, according to CDC recommendations. Inactivated influenza vaccine (injectable) does not interfere with the scheduling of live or inactive vaccines.



#### 17) How many doses will an individual receive?

Adults will be administered 1 dose, as will children and adolescents 10 years of age and older, as we expect that they will respond similarly to adults. Currently available data suggest that children 6 months to 9 years of age have little or no evidence of protective antibodies to the pandemic (H1N1) 2009 virus (<a href="http://www.cdc.gov/mmwr/pdf/rr/rr5810.pdf">http://www.cdc.gov/mmwr/pdf/rr/rr5810.pdf</a>). Those 6 months to 9 years of age, will receive a two dose regimen separated by approximately one month. Clinical studies are underway and will provide additional information about the optimal number of doses.

## 18) What are the expected side effects of the 2009 novel A(H1N1) influenza monovalent vaccines?

The expected side effects will be similar to those of the seasonal vaccine, potentially including a mild fever, body aches, and fatigue for a few days after the vaccine, and soreness at the injection site. The most common side effects seen with administration of the nasal vaccine include runny nose or nasal congestion in recipients of all ages; fever more than 100 degrees Fahrenheit in children two to six years of age, and sore throat in adults. As with any medical product, serious adverse events may occur.

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.

### 19) What can I do to protect myself, and my family?

Take these everyday steps to help prevent the spread of germs and protect your health:

- Cover your nose and mouth with a tissue when you cough or sneeze, or sneeze into your sleeve. Throw the tissue in the trash after you use it.
- Wash your hands often with soap and warm water, especially after you cough or sneeze. Alcohol-based gel hand cleaners are also good to use.
- Avoid touching your eyes, nose, or mouth. Germs spread this way.
- Try to avoid close contact with sick people. (If you are pregnant and you
  live or have close contact with someone who has H1N1 influenza, talk to
  your doctor about medicines to prevent influenza.)
- Have a plan to care for sick family members.
- Stock up on household, health, and emergency supplies, such as water, Tylenol®, non-perishable foods.



#### 20) What should I do if I get sick?

- If you get sick with influenza-like symptoms, stay home, limit contact with others, and call your doctor. Your doctor will decide if testing or treatment is needed. Tests may include a nasal swab which is best to do within the first 4-5 days of getting sick. Like regular influenza, H1N1 influenza may make other medical problems worse.
- If you are alone at any time, have someone check in with you often if you are feeling ill. This is always a good idea.
- If you have close contact with someone who has H1N1 influenza or is being treated for exposure to H1N1 influenza, contact your doctor to discuss whether you need treatment to reduce your chances of getting influenza.

#### 21) How is novel A(H1N1) influenza treated?

- Treat any fever right away. Tylenol® (acetaminophen) is the best treatment of fever in pregnant women.
- Drink plenty of fluids to replace those you lose when you are sick.
- Your doctor will decide if you need antiviral drugs such as Tamiflu®
   (oseltamivir) or Relenza® (zanamivir). Antiviral drugs are prescription
   pills, liquids or inhalers that fight against the influenza by keeping the
   germs from growing in your body. These medicines can make you feel
   better faster and make your symptoms milder.
- These medicines work best when started soon after symptoms begin (within two [2] days), but they may also be given to very sick or high risk people (like pregnant women) even after 48 hours. Antiviral treatment is taken for 5 days.
- Tamiflu® and Relenza® are also used to prevent H1N1 influenza and are taken for 10 days.
- There is little information about the effect of antiviral drugs in pregnant women or their babies, but no serious side effects have been reported. If you do think you have had a side effect to antiviral drugs, call your doctor right away.

