Influenza - H1N1 Vaccination Program
Questions and Answers

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Adapted from the Immunization Action Coalition (with permission) and the Centers for Disease Control and Prevention (CDC).

Policy and Management

Department of Defense (DoD) Novel A(H1N1) Influenza Vaccination Program

1) Will vaccination with the new novel A(H1N1) influenza vaccine be mandatory for Active Duty service members?
Yes. The novel A(H1N1) influenza vaccination is mandatory for uniformed personnel and highly encouraged for all others.

2) Have the vaccines been approved by U.S. Food and Drug Administration (FDA)?
Yes, on September 15, 2009, the FDA approved supplements to existing vaccine licenses to protect against the novel A(H1N1) 2009 influenza virus. The 2009 novel A(H1N1) influenza monovalent vaccines contain the A/California/7/09-like virus strain.

Note: H1N1 influenza vaccine package inserts are posted at http://www.vaccines.mil/H1N1.

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 Centers for Disease Control and Prevention (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) How will the H1N1 vaccine be distributed?
Vaccine for operational forces will come from the Defense Supply Center Philadelphia (DSCP), and will be distributed following the seasonal influenza vaccine model. Operational forces will only receive the Novartis injectable vaccine.

For OCONUS dependents and retirees, vaccine will be supplied according to the seasonal influenza vaccine distribution model. Sanofi Pasteur Injectable multi-dose vials will be distributed to military treatment facilities overseas.

For CONUS beneficiaries (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. The state, in turn, will submit this request to the CDC. The CDC will supply vaccine to the state. The state will coordinate with the vaccine distributor and the installation to have the vaccine delivered to the MTF. Beneficiaries will receive the CSL Biotherapies, Sanofi Pasteur, or MedImmune vaccine.

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. (http://www.cdc.gov/h1n1flu/vaccination/statecontacts.htm).

H1N1 vaccinations should 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. 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.

The Disease

General Information

1) What is novel A(H1N1) influenza (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.

2) 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.

3) 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.

4) Why do we need a vaccination against the novel A(H1N1) influenza virus this year in addition to the yearly seasonal influenza vaccine?
The seasonal influenza vaccine is not expected to protect against the novel A(H1N1) influenza. The novel A(H1N1) influenza virus is a new 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 monovalent vaccine was developed using the strain of H1N1 influenza virus isolated from the April 2009 outbreak, this strain is not found in the 2009-10 seasonal influenza vaccine.

Prevention

1) 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).
- Stay home from work or school if you are not feeling well.
- Have a plan to care of sick family members.
- Stock up on household, health, and emergency supplies, such as water, Tylenol®, and non-perishable foods.

2) 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. 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.

3) What are the symptoms of H1N1influenza?
- Fever
- Cough
- Sore throat
- Body aches
- Headaches
- Chills and fatigue
- Sometimes diarrhea and vomiting

4) Who are the priority groups recommended 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.

5) 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 and seasonal influenza vaccine does not provide protection against the 2009 H1N1 influenza virus. Although the currently licensed seasonal trivalent influenza vaccines contain an H1N1 subtype, the subtype differs from the 2009 H1N1 influenza virus, which is a new or (novel) virus strain that has never before circulated among humans.

6) Can the seasonal influenza and the novel A(H1N1) influenza vaccines be administered at the same time?
According to the ACIP, simultaneous administration of two inactivated (injectable) vaccines against seasonal and novel A(H1N1) influenza or the use of one live and one inactivated virus vaccine is permissible if different anatomic sites are used. However, simultaneous administration of two live, attenuated (intranasal) vaccines against seasonal and novel A(H1N1) influenza virus is not recommended.

7) 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 Live, Attenuated Intranasal Vaccine (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.

8) 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 (http://www.cdc.gov/mmwr/pdf/rr/rr5810.pdf). 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.

9) 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.

The Vaccine

General Questions

1) What is the definition of a "monovalent" vaccine?
A monovalent vaccine is made from one strain of virus. In contrast, the seasonal influenza vaccine is made of three strains of virus each year. It is called a trivalent vaccine.

2) How did the H1N1 vaccine come about?
The FDA and WHO selected A/California/07/2009 (H1N1) as the strain for the H1N1 vaccines. The H1N1 vaccines licensed by the FDA do not contain adjuvants. Both monovalent intranasal and injectable H1N1 vaccine formulations are available.

3) Who is in the target group to receive H1N1 influenza vaccine?
Groups recommended to receive H1N1 influenza vaccine first are:

- Pregnant women.
- People who live with or care for infants younger than 6 months of age.
- Healthcare and emergency medical personnel.
- Anyone from 6 months to 24 years of age.
- Anyone from 25 through 64 years of age with certain chronic medical conditions or a weakened immune system.

As more vaccine becomes available, these groups should also be vaccinated:

- Healthy adults 25 through 64 years.
- Adults 65 years and older.

4) What type of H1N1 vaccines are available?
Two forms of H1N1influenza vaccine are distributed in the United States:

- An inactivated, protein-derived vaccine, administered by intramuscular injection over the deltoid.
- A live attenuated (weakened) vaccine sprayed into the nose.

Note: H1N1 influenza vaccine package inserts are posted at http://www.vaccines.mil/H1N1.

5) Who manufactures the H1N1 vaccines?
The three manufacturers of H1N1 inactivated injectable vaccine licensed in the US are Novartis, CSL Biotherapies, and Sanofi Pasteur. MedImmune is the only manufacturer of the intranasal vaccine.

6) What are the expected side effects of the 2009 novel A(H1N1) influenza monovalent vaccine?
The expected side effects will be similar to those of the seasonal vaccine, including a mild fever, body

aches, fatigue, and soreness at the injection site. Symptoms may last for 2-3 days after vaccination. 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.

7) Who should not be vaccinated with H1N1 vaccine?
H1N1 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. H1N1 influenza vaccine should not be administered to anyone with a history of Guillain-Barré Syndrome.

Intranasal Vaccine – 2009 H1N1 Monovalent (MedImmune product)

1) What is the H1N1 intranasal vaccine?
H1N1 intranasal vaccine is a monovalent live, attenuated influenza vaccine developed from the live strain of the virus that is sprayed into the nostrils. This product is a preservative (thimerosal) free single dose vaccine.

2) Who should receive H1N1 intranasal vaccine?
H1N1 intranasal vaccine is approved for all healthy people 2-49 years old. For more information, see http://www.vaccines.mil/H1N1.

3) What side effects can I expect when I receive H1N1 intranasal vaccine?
The virus in the intranasal vaccine is weakened and will not cause severe symptoms associated with the influenza. Common side effects may include runny nose, headache, fever, cough, and sore throat. Other possible side effects are chills, cough, decreased activity, decreased appetite, headaches, irritability, muscle aches, and tiredness/weakness. For more information, see http://www.medimmune.com/h1n1.aspx.

4) Who should not receive H1N1 Live, Attenuated Intranasal Monovalent Vaccine?
The following populations should not be immunized with the Live, Attenuated Intranasal Vaccine.

- People less than 2 years old or those 50 years old or older.
- 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 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.
- Persons who have received a live vaccine in the last 28 days

5) If a child 6 months - 9 years of age is receiving an H1N1 influenza vaccination for the first time and requires two doses, does the same type of vaccine have to be used for both doses?
No. The first and second doses do not have to match. Either an inactivated or live vaccine may be

used to complete the 2 dose series.

6) How are H1N1 injectable and intranasal influenza vaccines shipped and stored?
Novel A(H1N1) influenza vaccine is heat and cold sensitive. All H1N1 injectable vaccines are shipped and stored at 2 to 8 degrees Celsius. H1N1 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 the expiration date on the package.

Note: The USAMMA website provides additional guidance on handling, storage, transportation, and administration of the influenza vaccine. http://www.usamma.army.mil/cold_chain_management.cfm.

7) If I need to place a tuberculin skin test (TST) and the patient also needs their H1N1 influenza vaccine, should I be concerned about the timing of these products?
Yes. There is one other special circumstance related to the administration of LAIV. LAIV may suppress a positive response to tuberculin skin testing (TST or PPD) in a person who has tuberculosis (TB). This suppression might result in a false negative skin test in a person who is infected with TB. If a person needs TB skin testing and LAIV, you can correctly administer both in one of three ways:

- Give the TST (PPD) and the LAIV simultaneously.
- Give the TST (PPD) first. When the person returns to have the skin test results interpreted, give the LAIV.
- Give the LAIV and then delay administration of the TST (PPD) for 28 days.

Injectable H1N1 influenza vaccines and tuberculin skin test **can be administered concurrently.**

8) Can I receive other live vaccines on the same day as my live H1N1 influenza vaccine?
Yes, you can receive other live vaccines in addition to your live intranasal H1N1 vaccine but you should not receive two live intranasal vaccines on the same day. If you have recently received any live vaccines you should wait at least 28 days before receiving the live intranasal H1N1 vaccine. Inactivated influenza vaccines (injectable) do not interfere with the scheduling of live or inactive vaccines.

Injectable Vaccine – 2009 H1N1 Monovalent (Novartis, CSL Biotherapies, and Sanofi Pasteur products)

1) What is H1N1 inactivated vaccine?
H1N1 inactivated vaccine is a monovalent vaccine produced from a killed form of the H1N1 virus strain. It is injected into the muscle, like the annual influenza vaccination. Multi-dose vials of H1N1 inactivated vaccine contain a preservative called thimerosal. All single dose syringes and single dose vials are preservative free.

2) Which one of the H1N1 injectable vaccines will be used for the uniformed Services?
All uniformed personnel will receive one dose of H1N1 influenza vaccine produced by Novartis.

3) Who is in the target group to receive H1N1 influenza vaccine?
Groups recommended to receive H1N1 influenza vaccine first are:

- Pregnant women.
- People who live with or care for infants younger than 6 months of age.

- Healthcare and emergency medical personnel.
- Anyone from 6 months to 24 years of age.
- Anyone from 25 through 64 years of age with certain chronic medical conditions or a weakened immune system.

As more vaccine becomes available, these groups should also be vaccinated:

- Healthy adults 25 through 64 years.
- Adults 65 years and older.

4) When should I get vaccinated with H1N1 influenza vaccine?
Get vaccinated as soon as the vaccine is available. Adults and children 10 years or older need only one dose. Children 6 months through 9 years of age should get two doses of vaccine at least 4 weeks apart for protection.

5) Who should not be vaccinated with H1N1 vaccine?
H1N1 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. H1N1 influenza vaccine should not be administered to anyone with an active nervous system disorder or a history of Guillain-Barré Syndrome.

6) Can pregnant or breastfeeding women be vaccinated with H1N1 influenza vaccine?
Pregnant or breastfeeding women are highly recommended to receive H1N1 inactivated vaccine.

7) What are the expected side effects of novel A(H1N1) influenza injectable vaccine?
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.

8) Can H1N1 inactivated vaccine be given with other vaccines?
Yes. H1N1 inactivated vaccine may be given at the same time as other vaccines, including seasonal influenza vaccine.

Myths and Facts

Myths and Facts about Influenza - H1N1 vaccine

1) Myth: Last year's influenza vaccine will protect you from getting H1N1 influenza.
Fact: The 2009 H1N1 influenza is a new influenza virus. It is very different from seasonal influenza viruses of the past. Most people have little or no immunity to this new influenza virus. You should receive the 2009-10 seasonal influenza vaccine, to be protected against seasonal influenza.

2) Myth: All of the H1N1 vaccines are experimental.
Fact: All of the vaccines on the market today have been approved by the FDA. These vaccines were made and approved just like the seasonal influenza vaccines. They are expected to be as safe and effective as seasonal influenza vaccines. They will not prevent "influenza-like" illnesses caused by other viruses.

3) Myth: I can wait until after winter to be immunized against H1N1 influenza virus.
Fact: Get vaccinated as soon as the vaccine is available. The H1N1 virus is unpredictable so the best

prevention is to be vaccinated against it.