

October 14, 2009
H1N1 Q&A

The first doses of 2009 H1N1 vaccine have arrived in Louisiana in very limited amounts. Large volume pediatric clinics began receiving on October 6, 2009. The earliest vaccine shipments came in the form of a nasal spray, which is appropriate for the priority group of young children. Both the nasal spray and the injectable form of the vaccine are now arriving. . Additional pediatric clinics, OB/GYN clinics and Tier 1 hospitals have begun receiving vaccine beginning on October 13, 2009. Tier 1 hospitals will prioritize staff to receive these initial vaccines. Additional vaccines will be shipped weekly to an ever increasing number and types of providers. Please remember this is the beginning of a campaign expected to continue over the next several months. The choice was made to deliver vaccine as soon as it became available, rather than to wait until large quantities were ready to be shipped. This presents challenges and requires on-going communication.

Louisiana is allocated 1.4% of manufactured vaccine. The OPH Immunization Program will order the full allocation of vaccine available and direct vaccine to priority groups through targeted provider distribution based on provider profiles. Receiving sites should vaccinate as many persons as possible as quickly as possible with an emphasis on priority groups and available vaccine. Over 2200 sites have registered in Louisiana Immunization Network for Kids Statewide (LINKS) to become vaccinators.

Q: What is the difference between the two flu vaccines?

A: The 2009 H1N1 vaccine contains only the novel H1N1 virus. This year's seasonal vaccine contains three influenza viruses — one A (H3N2) virus, one regular seasonal A (H1N1) virus unrelated to the swine flu strain and one B virus.

Q: With a “relatively mild” flu, should children be vaccinated?

A: It became clear last spring that the pandemic H1N1 strain was not as deadly as once feared, health officials reassured a nervous public that most H1N1 infections had been “relatively mild.” It created the false perception that H1N1 is not a life-threatening illness. While most people who get H1N1 are sick for three or four days and then recover, a recent *New England Journal of Medicine* study showed that among Americans hospitalized with swine flu last spring, one in four ended up in intensive care and 7 percent of them died. In the Southern Hemisphere, 14 percent of flu patients in intensive care died.

Since Aug. 30, at least 936 Americans have died of flu symptoms or flu-associated pneumonia from H1N1. It appears 2009 H1N1 flu will be at least as deadly as seasonal flu, which kills about 36,000 people annually.

Q: How is this flu season different from every other flu season?

A: The new flu strain is preying on children and young adults and appears to have a disproportionately high fatality rate in pregnant women. Older people, typically most

vulnerable to flu, appear to have some immunity. Since April, 81 children have died of H1N1 according to the federal Centers for Disease Control and Prevention. During the first four months of the outbreak, 100 pregnant women were hospitalized with the virus, and 28 died. The C.D.C. reports that 37 states now have widespread influenza activity, highly unusual this early in the season. Hospitalization rates for influenza also are higher than expected for this time of year.

Q: What's the difference between the seasonal flu that occurs every winter and this new H1N1 flu virus?

A: Seasonal flu comes back in slightly different forms each year. But the 2009 H1N1 is an entirely new combination of four genetic elements: a bird flu, some human flu genes and two types of swine flu. The 2009 H1N1 virus, which has spread worldwide, was surprisingly robust during the spring and summer months. Right now, over 90 percent of the circulating flu is H1N1, although seasonal flu, which typically peaks in winter, has also been detected.

Q: Since the vaccine for H1N1 is new, how do we know it is safe?

A: Every year, the seasonal flu vaccine is tailored to match the viruses circulating at the time, and the H1N1 vaccine was made exactly the same way.

Q: Was the H1N1 vaccine subjected to the same testing and clinical trials as seasonal flu vaccine?

A: The F.D.A. does not require a new round of human clinical trials to study minor changes in the flu vaccine each year. However, clinical trials were conducted on the 2009 H1N1 vaccine to determine the adequate dose. In addition, because H1N1 is a pandemic, we now have more information from other countries. Of the first 39,000 Chinese to get shots, only four had minor side effects, including muscle cramps and headaches.

Q: Were manufacturing shortcuts taken to rush this vaccine to market?

A: It typically takes five to six months to make flu vaccine, and that is about how long it took to produce the 2009 H1N1 vaccine. The H1N1 virus itself grows more efficiently than some past flu strains. "We have cut no corners," Dr. Thomas R. Frieden, the C.D.C. director, said at a news conference on October 6, 2009. "This flu vaccine is made as flu vaccine is made each year, by the same companies, in the same production facilities with the same procedures, with the same safety safeguards."

Q: How is flu vaccine made?

A: The C.D.C. identifies and tests a viral strain, then distributes a version of it to vaccine manufacturers, who inject it into millions of eggs, where it multiplies. Then the virus is harvested, purified and developed into a vaccine.

Q: What is the difference between the nasal spray and the flu shot?

A: The injectable vaccine or flu shot is made from a killed influenza virus that is highly purified and broken into tiny pieces. It cannot recombine in the body to produce flu, but it can still stimulate the immune system to evoke a protective response.

The nasal vaccine, called FluMist, is made of an attenuated live virus. This is a weakened version of the virus that has been tamed in the laboratory so it cannot cause illness. (The measles and chicken pox vaccines also are made from a live attenuated virus.) The attenuated virus can multiply only in the cooler temperatures of the nasal passages, and cannot survive in the higher temperatures of the respiratory tract. When the vaccine is sprayed into the nose, it multiplies on the mucous membranes in the nose and throat, triggering the body's immune response without causing any illness. Some studies suggest the nasal mist is more effective than the traditional flu shot.

FluMist is not approved for people with asthma, pregnant women or people with chronic medical conditions like heart disease and diabetes.

About 2 weeks after vaccination, antibodies that provide protection against 2009 H1N1 influenza virus infection will develop in the body. The 2009 H1N1 vaccine will not protect against seasonal influenza viruses.

Q: How long after vaccination does the body develop immunity to the 2009 H1N1 virus?

A: In general, immunity to 2009 H1N1 beings in about seven to eight days after the vaccine, slightly faster than the 10 to 14 days typical of seasonal flu vaccine. However, a child below the age of 10 will need two doses of the H1N1 vaccine, spaced about a month apart, and full immunity will not occur until about a week after the final dose.

Q: Can seasonal flu vaccine and 2009 H1N1 vaccine be taken at the same time?

A: It depends on the formulation. A patient can receive two flu shots or a combination of nasal spray and flu shot. But patients who want both vaccines in nasal spray form must wait at least 28 days between vaccinations so the attenuated viruses do not compete against each other.

Q: If I've already had the flu this year, do I need either flu shot?

A: Unless your case was officially confirmed by a laboratory test as 2009 H1N1, there is no way to be sure you are protected. If you did have confirmed H1N1, you are still vulnerable to seasonal flu.

Q: Can you get vaccinated against flu if you have a fever or a cold?

A: The flu vaccine is typically not recommended for patients with any signs of moderate to severe illness, so that symptoms are not wrongly misdiagnosed as side effects of a flu shot.

Q: Can people who are allergic to eggs get the flu vaccine?

A: The vaccine typically is not given to people with egg allergy. People at high risk for flu complications may be able to work with an allergist to be desensitized so they tolerate the vaccine.

Q: Why are pregnant women at higher risk of complications from H1N1 flu?

A: A woman's immune system is compromised during pregnancy. Late in the pregnancy, the fetus pushes up against the thoracic cage and decreases a woman's lung capacity,

putting her at risk for respiratory complications if she contracts flu. A *New England Journal of Medicine* study found that pregnant women with swine flu were nine times more likely to be in intensive care.

Q: Is flu vaccination an option for people with suppressed immune systems?

A: A flu vaccine works by stimulating the body's immune system to produce antibodies against the virus. A person with a suppressed immune system cannot generate an immune response and does not benefit from vaccination. This includes many cancer patients undergoing chemotherapy, asthma patients who require large doses of steroids and those taking immune-suppressing drugs after an organ transplant. Patients who are immune-compromised should talk to their doctor about whether they should get a flu shot.

Q: Do adjuvants added to flu vaccine increase risk of an autoimmune reaction?

A: This is a myth. Although substances called adjuvants are sometimes added to vaccines to make them more effective, no flu vaccine sold in the United States, including the 2009 H1N1 vaccine, contains any adjuvants.

Q: Does the new vaccine contain the mercury compound thimerosal?

A: Flu vaccine packaged in a multidose vial contains thimerosal, a preservative that prevents contamination of the vial during repeated use. One dose from a multiuse vial contains about 25 micrograms of mercury. By comparison, a tuna fish sandwich contains about 28 micrograms of mercury. Repeated studies have shown thimerosal to be safe. However, people who want to minimize mercury exposure can ask for a vaccine in a single-dose package, which has only trace amounts. Thimerosal is not used in the production of FluMist.

Q: What about the severe complications associated with the 1976 swine flu vaccine?

A: A 1976 swine flu vaccine was associated with Guillain-Barré syndrome (pronounced ghee-YAN bah-RAY), in which the body damages its own nerve cells, causing weakness and sometimes paralysis. The data on flu vaccine and Guillain-Barré syndrome are not conclusive. One study suggested the 1976 vaccine posed a 1 in 100,000 risk. Another study found flu vaccine in general carries a 1 in one million risk for Guillain-Barré syndrome. By comparison, 1 in 8,300 Americans dies of flu each year.

Q: If people think they have 2009 H1N1, should they see a doctor?

A: Most people will recover without needing a doctor. H1N1 Flu Self Evaluation at www.flu.gov may be helpful, but it is not a substitute for evaluation and treatment by a healthcare professional. High-risk persons should consult with their health care provider prior to or at the onset of flu symptoms so treatment with the antiviral medications can be considered.

Q: Are antiviral medications available?

A: Antiviral medications are plentiful in most pharmacy retailers in Louisiana. In addition, over 265 pharmacies in Louisiana have agreed to provide antiviral medication at low or no cost to uninsured and underinsured persons with a prescription for an antiviral. Most healthy persons who develop an illness consistent with influenza, or persons who

appear to be recovering from influenza, do not need antiviral medications for treatment or prophylaxis. However, persons presenting with suspected influenza and more severe symptoms such as evidence of lower respiratory tract infection or clinical deterioration should receive prompt empiric antiviral therapy, regardless of previous health or age.

- Treatment with oseltamivir or zanamivir is recommended for all persons with suspected or confirmed influenza requiring hospitalization.
- Early empiric treatment with oseltamivir or zanamivir should be considered for persons with suspected or confirmed influenza who are at higher risk for complications including:
 - Children younger than 2 years old;
 - Persons aged 65 years or older
 - Pregnant women
 - Persons of any age with certain chronic medical or immunosuppressive conditions (see page 3); and,
 - Persons younger than 19 years of age who are receiving long-term aspirin therapy.
- Children 2 year to 4 years old are more likely to require hospitalization or urgent medical evaluation for influenza compared with older children, although the risk is much lower than for children younger than 2 years old. Children aged 2 years to 4 years without high risk conditions and with mild illness do not necessarily require antiviral treatment.
- Treatment, when indicated, should be initiated as early as possible because studies show that treatment initiated early, usually within 48 hours of illness onset is more likely to provide benefit.
- A list of participating pharmacies is available under the Clinician sidebar on the www.fighttheflu.com web site. If additional information is required please contact the DHH OPH Pharmacy at 504-568-5022.