Key Messages
Seasonal and H1N1 Influenza Vaccines

September 30, 2009

2009 H1N1 Influenza Vaccine

- All manufactures of the 2009 H1N1 vaccines are using the same processes that they use for making the seasonal flu vaccines, which have a long record of producing safe seasonal influenza vaccines.

- States will be able to place their first orders for the 2009 H1N1 vaccine on Wednesday, September 30, 2009**.** Kansas will receive approximately 16,000 doses in that first allocation. The initial doses will be of the H1N1 live Attenuate Influenza Vaccine (LAIV), a nasal-spray flu vaccine, which can be given to healthy individuals 2-49 years of age.

- Each week KDHE allocates Kansas' share of the vaccine among each of the counties in the state. KDHE's intent is to base the initial allocation of vaccines on the 2008 census data for individuals aged 0-24 years. The rationale for use of this age-adjusted data is to better assure that the vaccine is allocated in a way that reflects the primary target populations of children and young adults.

- Once KDHE concludes that the uptake of vaccine in these populations is saturated, KDHE will change to allocation based on the total population of each county.

- After KDHE allocates the vaccine to each county, the local health department will make the decision on how the vaccine is administered locally. Local health departments may choose to partner with public and private providers in their county (such as hospitals, doctor's offices or retail pharmacies) to

help administer the H1N1 vaccine. (See the attached flow chart for more details on how the H1N1 vaccine will be distributed in the state of Kansas.)

- It is important to keep in mind that while some doses of vaccine will be distributed beginning the first week of October, initial supplies are small and it will take several days for those doses to reach clinics and doctors offices.

- During the upcoming weeks more vaccine will be available to the public in more places. We expect additional doses of vaccine to be available for distribution each week after the first week in October. The federal government has purchased enough vaccine to provide a total of 250 million doses.

- It is likely that children younger than 10 years will need two doses of 2009 H1N1 flu vaccine. This is slightly different from CDC's recommendations for seasonal influenza vaccination which state that children younger than 9 who are being vaccinated against seasonal influenza for the first time need to receive two doses. Infants younger than 6 months of age are too young to get the 2009 H1N1 and seasonal flu vaccines. CDC recommends that the two doses of 2009 H1N1 vaccine be separated by 4 weeks. However, if the second dose is separated from the first dose by at least 21 days, the second dose can be considered valid.

<u>H1N1 Vaccine Priority Groups and People age 65 and over</u>

- Initially, the vaccine will be made available to individuals in the federally-identified target groups. These priority groups include pregnant women, household contacts and caregivers of infants younger than 6 months of age, all children and young adults ages 6 months through 24 years, healthcare and emergency medical services (EMS) personnel, and people aged 25-64 years with certain high-risk medical conditions.

- Because early supplies will be very limited, KDHE strongly recommends that local health departments prioritize this initial vaccine for health care workers with direct patient contact and healthy children between the ages of two and nine years.

- Because the initial LAIV allocation is not adequate to vaccinate all persons in the two targeted groups, local health departments are asked to vigilantly monitor vaccine uptake and to assure it is being managed in accordance to these recommendations and their best clinical judgment.

- Younger people are more likely to get infected with the 2009 H1N1 influenza virus than those 65 years and older. Therefore, younger persons are recommended to receive the first available doses of 2009 H1N1 influenza vaccine before persons 65 years and older.

- Current studies indicate the risk for infection among persons age 65 or older is much 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 will offer vaccination to people over the age of 65.

- While people 65 and older aren't included in the high risk groups to be prioritized for 2009 H1N1 influenza vaccination, they can get the 2009 H1N1 influenza vaccine as soon as the high-risk groups have had the opportunity to be vaccinated and should not delay in seeking medical treatment if they develop symptoms of influenza.

- CDC's priority for people 65 and older is to have them get their seasonal influenza vaccine as soon as it is available.

H1N1 Vaccine Safety

- All four manufacturers of the 2009 H1N1 vaccines are using the same processes that they use for making the seasonal flu vaccines, which have a long record of producing safe seasonal influenza vaccines.

- CDC expects that any serious side effects following vaccination with the 2009 H1N1 influenza vaccine would be rare.

- The types and frequencies of side effects from the 2009 H1N1 vaccine will likely be similar to those experienced following seasonal influenza vaccines which are mild, localized reactions.

H1N1 Vaccine Safety Monitoring

- The CDC and FDA closely monitors the safety of all vaccines licensed for use in the United States including seasonal influenza vaccines in

cooperation with state and local health departments, healthcare providers, and other partners. Additional special monitoring is occurring to assure that any rare side effects of the 2009 H1N1 vaccine detected as soon as possible.

Seasonal Influenza Vaccine

- The new 2009 H1N1 influenza virus is a reminder of the unpredictable nature of influenza, and the importance of prevention.

- While the 2009 H1N1 influenza virus has been the focus of attention since the spring, it is important that we do not forget the risks posed by seasonal influenza viruses. As always, seasonal flu viruses will circulate this season.

- We hope that people, especially those at high risk for serious complications and their close contacts, will seek seasonal flu vaccines now or as soon as vaccine is available in their communities.

- The seasonal influenza vaccine will be available earlier than the 2009 H1N1 influenza vaccine. The usual seasonal influenza viruses are still expected to cause illness this fall and winter.

- Seasonal flu vaccine is now available in various areas. Individuals are encouraged to get their seasonal flu vaccine as soon as it becomes available in their community.

Adjuvants

- Some vaccines contain “adjuvants,” which are ingredients that help boost the vaccine’s potency. As a result, a smaller amount of vaccine is needed per person, and therefore, the vaccine supply can be used to reach more people.

- According to current federal plans, only unadjuvanted vaccines will be used in the United States during the 2009-10 flu season.

- This includes all of the 2009 H1N1 and seasonal influenza vaccines that will be available for children and adults in both the injectable and nasal spray formulations. None of these influenza vaccines that will be used in the U.S. during the 2009-10 season will contain adjuvants.

- Studies of 2009 H1N1 influenza vaccines with adjuvants are being conducted to determine if 2009 H1N1 influenza vaccines with adjuvants meet safety and efficacy requirements for use in the United States.

Thimerosal

- Thimerosal is a mercury-based preservative that is used in some influenza vaccines to keep them free from contamination of microorganisms.

- The 2009 H1N1 influenza vaccine is being manufactured in several formulations.
  - Several vaccine manufacturers will be producing some of the 2009 H1N1 influenza vaccine in single-dose units, which will not require the use of thimerosal as a preservative.

  - The live-attenuated version of the vaccine, which is administered intranasally (through the nose), is produced in single-units and will not contain thimerosal.

  - Some vaccine will come in multi-dose vials and will contain thimerosal as a preservative, as is the case with seasonal influenza vaccines in multi-dose vials.

- Multi-dose vials of seasonal influenza vaccine contain thimerosal to prevent potential contamination after the vial is opened. Seasonal flu vaccines that do not contain thimerosal are available.

Guillain-Barré syndrome (GBS)

- Guillain-Barré syndrome (GBS) is a medical condition in which the body damages its own nerve cells, causing muscle weakness and sometimes paralysis. Most people who develop GBS fully recover, but in some cases, death can result, usually from difficulty breathing.

- It is not fully understood why some people develop GBS, but it often occurs following infection. It is believed that stimulation of the body's immune system may play a role in its development.

- The infection that most commonly precedes GBS is caused by a bacterium called *Campylobacter jejuni.* Influenza virus infection has also been associated with GBS.

- In 1976, there was a small risk of GBS following influenza (swine flu) vaccination (approximately 1 additional case per 100,000 people who received the swine flu vaccine). That number of GBS cases was slightly higher than the background rate for GBS. Since then, numerous studies have been done to evaluate if other flu vaccines were associated with GBS. In most studies, no association was found, but two studies suggested that approximately 1

additional person out of 1 million vaccinated people may be at risk for GBS associated with the seasonal influenza vaccine.

- FDA and CDC and several partners will be closely monitoring reports of serious vaccine adverse events, including GBS, following the 2009 H1N1 influenza vaccination.