



For Information Contact:

Andrew T. Jewett, Director
Hospital Preparedness Program
Iroquois Healthcare Association
315-410-6470 / ajewett@iroquois.org

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New and updated information relating to H1N1

FDA Approves High Dose Seasonal Influenza Vaccine for People Ages 65 and Older

The U.S. Food and Drug Administration has approved Fluzone High-Dose, an inactivated influenza virus vaccine for people ages 65 years and older to prevent disease caused by influenza virus subtypes A and B. Fluzone High-Dose is administered as a single injection in the upper arm and is available in single dose pre-filled syringes without preservative. People with hypersensitivity to egg proteins or life-threatening reactions after previous administration of any influenza vaccine should not be vaccinated with Fluzone High-Dose.

Fluzone High-Dose was approved via the accelerated approval pathway. FDA's accelerated approval pathway helps safe and effective medical products for serious or life-threatening diseases become available sooner. In clinical studies, Fluzone High-Dose demonstrated an enhanced immune response compared with Fluzone in individuals 65 and older. As part of the accelerated approval process, the manufacturer is required to conduct further studies to verify that the Fluzone High-Dose will decrease seasonal influenza disease after vaccination.

Fluzone High-Dose, manufactured by Sanofi Pasteur Inc., is formulated so that each 0.5 mL dose contains a total of 180 micrograms (mcg) of influenza virus hemagglutinin (HA) which is made up of 60 mcg of each of the three influenza virus strains. Other currently licensed seasonal influenza vaccines for adults are formulated to contain a total of 45 mcg of influenza virus hemagglutinin (15 mcg HA from each of the three influenza strains per dose). Sanofi Pasteur, also manufactures Fluzone, a seasonal vaccine for the United States approved for use in individuals ages 6 months and older.

As expected, because of the higher HA content, non-serious adverse events were more frequent after vaccination with Fluzone High-Dose compared with Fluzone. Common adverse events experienced during clinical studies included pain, redness and swelling

at the injection site and headache, muscle aches, fever and malaise. The rate of serious adverse events was comparable between Fluzone High-Dose and Fluzone.

Fact Sheet: <http://multivu.prnewswire.com/mnr/sanofipasteur/41724/docs/41724-FluzoneHighDoseFactSheet.pdf>

Journal of Infectious Disease Study:

<http://www.journals.uchicago.edu/doi/abs/10.1086/599790>

H1N1 Poses Grave Risk to Pregnant Women, New Moms

Infection with H1N1 influenza poses a grave danger to pregnant women and those who have just delivered, and the risk increases when they do not receive antiviral treatment very rapidly, California and Atlanta researchers report online in the *New England Journal of Medicine*: <http://content.nejm.org/cgi/content/full/NEJMoa0910444>

Weekly FluView Map and Surveillance Report

Updated CDC FluView for 2009-2010 Influenza Season Week 50 ending December 19, 2009. All data are preliminary and may change as more reports are received.

<http://www.cdc.gov/flu/weekly/>

Influenza and Pneumonia-Associated Hospitalizations and Deaths from August 30 to December 19, 2009

Flu activity continued to decline in the United States during the week of December 13-19, 2009, as reported in FluView. The number of states reporting widespread flu activity decreased from 11 to 7. Visits to doctors for influenza-like illness, flu-associated hospitalizations, and flu-associated deaths all declined from the previous week.

<http://www.cdc.gov/h1n1flu/updates/us/#totalcases>

Summary of 2009 Monovalent H1N1 Influenza Vaccine Data – Vaccine Adverse Event Reporting System

CDC and FDA provide weekly updates on vaccine safety monitoring activities. The information summarizes adverse event reports to VAERS after the administration of 2009 H1N1 monovalent influenza vaccine.

http://vaers.hhs.gov/resources/2009H1N1Summary_Dec17.pdf

Thimerosal-Free Vaccine Recall

Some priority groups may not be able to find thimerosal-free H1N1 flu vaccine due to a recent recall of pre-filled, pediatric 0.25ml single-dose syringes by Sanofi Pasteur licensed for children 6-35 months old:

http://www.cdc.gov/h1n1flu/vaccination/syringes_ga.htm

Intent to Receive Influenza A (H1N1) 2009 Monovalent and Seasonal Influenza Vaccine

On September 15, 2009, the Food and Drug Administration approved the manufacture of four influenza A (H1N1) 2009 monovalent vaccines. To measure intent to receive H1N1 and seasonal influenza vaccines among children and adults, during August 28--29, 2009, the North Carolina Center for Public Health Preparedness, with state and local public health officials, conducted a community assessment in two counties. This report summarizes the results of that assessment, which determined that 64% of adults reported intent to receive H1N1 vaccine.

<http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5850a1.htm> and
<http://www.cdc.gov/mmwr/>

Immunogenicity of a Monovalent 2009 Influenza A (H1N1) Vaccine in Infants and Children

Recently released in the *Journal of American Medical Association* (JAMA), this article describes a study that found that one dose of 2009 H1N1 vaccine stimulated a protective antibody response among most healthy infants and children. CDC has written an editorial in response to this article, which is also available in the journal issue. <http://jama.ama-assn.org/cgi/content/full/2009.1911v1>