Kentucky Fluview H1N1 Surveillance Report



Publication Date February 5, 2010 Issue # 10

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For previous issues of KY Fluview, find them at Kentucky Health Alerts: <u>http://</u> <u>healthalerts.ky.gov/</u> <u>Pages/</u> <u>KentuckyFluView.aspx</u>

This Week



The total number of doses ordered through 2/1/2010 was 1,234,500. (page 4) €

After receiving 10,008 calls, the H1N1 hotline came to a close on Jan. 24, 2010. The most frequent questions asked were related to the availability of H1N1 vaccine (27%), general questions about the H1N1 vaccine (21%), and vaccine safety and contraindications (12%). (page 8) ↑





Although close to 99.7% of the specimens that tested positive for influenza were positive for novel H1N1 influenza A, that is not all that was going on in the lab. The lab also saw circulation of other pathogens that were not influenzarelated. (page 5) \clubsuit



First Lady Jane Beshear received her H1N1 flu vaccination at the First Onsite Clinic for state employees in the Capitol Annex building. Governor and Mrs. Beshear encourage Kentuckians to also get vaccinated. (page 9) ↑ 'Public Health Works' Stories



Tell Us What You Think! Let us know what you think of the *Fluview* newsletter by taking the brief survey found on the link below: http://www.surveymonkey.com/s/HH6C3XY

Other highlights in this issue:

- Kentucky is experiencing sporadic influenza activity overall, but AL and GA continue to experience regional activity. (page 3)
- Guidelines for the Disposal of Expired H1N1 Influenza Vaccine (page 12)
- New! Voluntary non-safety recall of unused doses: Recall of pre-filled syringes and identified by the following lot numbers: UT023AA, UT023BA, UT023CA, UT023EA, UT023FA, and UT037AA. (page 13)

Page 2

When was this data updated?

ltem	Current as of:
KY Deaths	1/30/2010
US deaths	1/26/2010

Abbreviations and Acronyms

KDPH-Kentucky Department for Public Health

LHD-local health departments

CDC—Centers for **Disease Control** and Prevention

MMWR-

Mortality and Morbiditv Weekly Report published by CDC

ILI-influenza like illness

KDE—Kentucky **Department of** Education

US Pediatric Deaths with Confirmed Influenza A Subtype

Dates	Deaths
1/17/2010- 1/23/2010	5
Since Aug. 30, 2009	248

Laboratory Confirmed Kentucky Deaths - Continues to be unchanged

No additional H1N1-associated deaths were confirmed in Kentucky during the past two weeks leaving our total count at thirty-nine deaths. These deaths involved only people with lab-confirmed novel H1N1 influenza. Of the thirty-nine, twenty-four were female, and fifteen were male. The median age was forty-seven, with a range of one to eighty years. Of the thirty-nine, thirtythree had underlying medical conditions. The pattern seen in the figure, with the highest number of deaths in the 25-49 year-old age category, has been consistent throughout the pandemic in Kentucky.



Number of Deaths Attributed to H1N1 by County, August 1, 2009 – January 30, 2010



Mortality due to H1N1 influenza rose from mid-August to a peak during the last week of October and the first week of November, dropping quickly after that in Kentucky. The number of deaths attributed to H1N1 influenza has dropped precipitously since then and remains low to date. There have been no deaths reported since the first week of January.

Novel H1N1-Related Mortality by Week Kentucky 2009 8 7 6 5 4



US Deaths As Reported by Centers for Disease Control

U.S. Influenza Deaths from 8/30 - 1/26/2010	Hospitalizations	Deaths
Influenza Laboratory Test Confirmed	39,387	1,857

This data was posted on www.cdc.gov/h1n1flu/updates/us/

Weekly Influenza Activity Estimates Reported by State and Territorial Epidemiologists*

Kentucky continues to report sporadic influenza activity. States bordering KY to the north (IL, IN, and OH) also reported sporadic activity this week. VA is still experiencing regional activity, while TN is at local influenza activity. In the south, AL, and GA continue to experience regional activity.



Flu-Like Illness Trends

Percentage of Visits for Influenza-like Illness (ILI) Reported by the U.S. Outpatient Influenza-like Illness Surveillance Network (ILINet), Weekly National Summary, National Summary 2008-2009 and Previous Two Seasons: Oct. 1, 2006 – January 30, 2010.

Nationwide during the week of December 13th-19th, 2.3% of patient visits reported through sentinel providers via the U.S. Outpatient Influenza-like Illness Surveillance Network (ILINet) were due to influenza-like illness (ILI). This percentage is at the national baseline of 2.3%. Influenza-like illness (ILI) is a medical diagnosis of possible influenza or other illness causing a set of common symptoms. Symptoms commonly include fever, shivering, chills, malaise, dry cough, loss of appetite, body aches and



nausea, typically in connection with a sudden onset of illness. The Centers for Disease Control and Prevention (CDC) tracks ILI and reports ILI by week of the year.

When was this
data updated?ItemCurrent
as of:ILI out-
patient
visits1/30/10

What do you think?

We have enjoyed producing the *Fluview,* the H1N1 Surveillance Report. Now we want to hear from you. Let us know what you have enjoyed about the *Fluview,* and what we could improve on by taking the survey below:

<u> http://</u>

www.surveymonkey .com/s/HH6C3XY

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When was this data updated? Item Current as of:

Doses allocated	2/1/2010
Ordered and shipped	2/1/2010

Kentucky's Estimated Herd Immunity Against novel influenza H1N1

According to the Behavioral Risk Factor Surveillance Survey (BRFSS), an ongoing national phone survey conducted by CDC. Kentucky experienced the highest cumulative percent of ILI across the U.S. in adults at close to 45% of adults reporting they had experienced ILI during the fall wave of novel H1N1 influenza (August 2-December 13. 2009). When combining this with the fact that CDC estimates approximately 50% of influenza is asymptomatic and only 60% of ILI is H1N1, this gives a naturally acquired immunity against H1N1 of approximately 54% in Kentucky.

(Continued on right hand margin on page 5)

Vaccine Allocation

CDC sends states a weekly 2009 H1N1 allocation report which indicates how much of each formulation of 2009 H1N1 influenza vaccine Kentucky can order. CDC allocates vaccine based on the state's population. KDPH then sub-allocates vaccine to counties and health districts by population. CDC's vaccine distribution contractor ships vaccine to hospitals, clinics, doctor's offices, health departments, and other providers three or four times per week. The chart below shows the cumulative doses of vaccine allocated to Kentucky from the CDC. The total allocated to Kentucky as of 2/1/10 is 2,306,700 doses.





The total number of doses ordered through 2/1/2010 was 1,234,500. For more information about the types of vaccines ordered and shipped see page 7.

Surveillance of Virus Subtypes

KDPH works in partnership with clinicians, local health departments, and the federal Centers for Disease Control and Prevention to conduct surveillance for influenza-like illness.

A total of 4,448 specimens were submitted by providers to the state lab for testing between August 1, 2009 and January 19, 2010. Of those that tested positive for influenza, 99.7% were

	Aug.	Sept.	Oct.	Nov.	Dec.	Jan.	Feb.
Specimens Tested	327	769	1594	1106	453	189	10
Specimens positive for Flu	116	358	857	430	172	22	0
H1N1	114	358	855	430	171	22	0
Seasonal Flu subtype	2	0	2	0	1	0	0

positive for novel H1N1 influenza. The lab has received specimens from all 120 counties in Kentucky. Out of the specimens submitted, all 120 counties have had at least one positive H1N1 case. The results of tests performed by the Kentucky State Lab since August 2009 by month are summarized in the table.

*Note that tests for February do not represent a full month and are current up to 02/2/10.

Got Influenza?

The Kentucky State Laboratory was busy during the Fall 2009, testing over 4,500 specimens submitted by providers to determine lab-confirmed influenza cases. Although 99.7% of the specimens that tested positive for influenza were positive for novel H1N1 influenza A, influenza was not the only respiratory illness circulating. As seen in the chart below, the lab also received many specimens that were not determined to be influenza of any strain. In the months of August, November, and December, the specimens that tested negative for influenza outnumbered the influenza positive specimens. During September and October, there were slightly more influenza positive specimens then other viral specimens detected in the lab. Overall, approximately 40% of all specimens did not test positive for influenza, so the illnesses that gave rise to these lab submissions represented other viruses or bacteria. This indicates that 'influenza-like illness' is often caused by other etiologies than influenza.



When was this data updated?		
Item	Current as of:	
Lab counts	2/2/2010	

(Continued from left hand margin on page 4)

BRFSS data also indicated that as of mid-December, 2009, Kentucky had immunized approximately 9.5% of the population (at this time, we estimate 32% of Kentuckians have received the H1N1 vaccine).

The estimated herd immunity from vaccine and natural immunity combined is estimated to be the second highest among all other states at close to 63%. CDC's analysis of the BRFSS data indicates that the acquired immunity of Kentucky residents is most likely beyond the critical percentage of the population that has to be immune in order to reduce or prevent the ongoing spread of influenza. In other words, Kentucky may avoid a third wave of the H1N1 pandemic if these assumptions hold true.

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School Absence Data for Influenza Surveillance: A Pilot Study in the United Kingdom

School absence records have been suggested as a tool for influenza surveillance. In a British study, absence records were analyzed from six primary schools (children aged from around five to 11 years) in London during 2005 to 2007, in order to provide baseline epidemiological characteristics of illness-related school absence, and to correlate school absence with seasonal influenza. The daily average prevalence of absence due to illness was 2.9%. The incidence was 1.3% per person -day. The mean duration of absence was 1.8 days, and over 60% of absence episodes lasted for one day. In general, peaks of absenteeism coincided with peaks of influenza A and B, but several high peaks were not associated with influenza. School absence data may be useful for the detection of localized school outbreaks and as an additional surveillance tool. but are limited due to lack of data on weekends and holidays.

Source: Eurosurveillance, Volume 15, Issue 3

Date: 21 January 2010

School Absenteeism Attributed to ILI

The KDPH, in collaboration with KDE, collects self-report data on school absences and school closures attributed to ILI from Kentucky public schools. School absenteeism data is continuously updated and may change as school census updates are provided.

The following graph is the time series of ILI reporting from the Kentucky sentinel physician network for MMWR weeks 50-52 of 2009 and the first two weeks of 2010. ILI encounters are calculated as a percentage of the total patients seen by the sentinel physician during the MMWR reporting week.



Sentinel Physician Reporting of Percent of Encounters Attributed to ILI

The chart below depicts the trend in mean rate of absences attributed to ILI per 1,000 children enrolled in Kentucky public schools from 01/04/2010 - 01/29/2010, stratified by region. The maximum rate of ILI absences reported in Kentucky schools during the H1N1 epidemic was 10 per 1,000 students. As you can see, in the first full week of January the regional absence rates attributed to ILI are well below the maximum.





^{*}Please note the break in the West and East regional rates was due to missing data on Monday, January 18, MLK Holiday.

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Item

Doses by

type

When was this data updated?

Current

as of:

2/3/10



Type of Vaccine	Ordered	Shipped
Injection 36/48 months & older	759,400	707,600
Intranasal for 2-49 years	288,100	288,100
Injection 36/48 months & older preservative free	155,400	155,400
Injection 6-35 months preservative free	62,200	62,200
Injection >= 18 years	24,800	22,200
Total	1,289,900	1,235,500

Vaccine Distribution By Health District



When was this
data updated?ItemCurrent
as of:Providers
Approved2/1/10Doses
shipped2/1/10

Kentucky Fluview

H1N1 Public Telephone Hotline: Summary Report



The chart to the right describes a breakdown of subgroups that callers were inquiring about. Nearly half of the calls were not about specific groups, but of those able to be classified, the most frequent calls were about people with chronic conditions (13.66%), followed by school aged students (13.06%), and parents or guardians calling on behalf of their infant or toddler (9.34%). Of all 10,008 hotline calls, there were fewer people representing business and workplace concerns, the disabled population, and travelers.

	1,007	10.00/0
K-12 grade students	1,307	13.06%
Infants or toddlers; pre-school	965	9.64%
Older Adults	935	9.34%
Pregnant Women	286	2.86%
Healthcare workers and Clinicians	191	1.91%
Childcare	93	0.93%
University students	80	0.80%
Other	54	0.54%
Business and workplaces	51	0.51%
Disabled population	26	0.26%
Travelers	25	0.25%

The above survey results are from a study conducted by Wayne State University and the University of Kentucky Community Mitigation Task Forces.

tacts.

N=180 schools represented

Data collected from Oct. 17- Dec. 3, 2009

Referenced from a CDC/CSTE weekly surveillance conference call

Public Health Works

First Lady receives H1N1 flu shots at First Onsite Clinic

Governor and Mrs. Beshear encourage Kentuckians to also get vaccinated

First Lady Jane Beshear today received her H1N1 flu vaccination at the First Onsite Clinic for state employees in the Capitol Annex building. Most Kentucky Employees' Health Plan (KEHP) plan members can receive the H1N1 vaccine at no cost.

The 2009 H1N1 (swine flu) strain of influenza was first identified in late spring of 2009, and has since been causing a worldwide pandemic. A vaccine for the illness became available in the fall, but has only recently been in sufficient supply to expand beyond the target groups identified as being at greatest risk.

"While we have seen reduced flu activity since early December, the spread of 2009 H1N1 (swine flu) is likely to continue well into the new year. It is still important for Kentuckians to receive the H1N1 flu vaccination to help prevent its spread in the months ahead," said Mrs. Beshear.

"I want to reassure Kentuckians that the swine flu vaccine is safe and effective, and was produced using the same methods as seasonal flu vaccine," said Public Health Commissioner William Hacker, M.D. "The swine flu vaccine is now widely available in communities across the state for anyone who wishes to receive it. We especially urge those with chronic health conditions that put them at risk of serious flu-related complications to get vaccinated as soon as possible."

The target groups strongly encouraged to be vaccinated because they are at higher risk for complications from H1N1 are: pregnant women; people who live with or care for children younger than 6 months; children and young adults 6 months to 24 years of age; health care workers; and people with chronic health conditions that include asthma, neurological conditions, chronic lung and heart disease, and disorders of the kidney, liver, endocrine system and blood. However, all Kentuckians, regardless of whether they fall into any of these groups, are now encouraged to get the vaccination.

The First Lady received her vaccination at the Capitol Annex First Onsite Clinic, one of four clinics located in state office buildings now available to employees who are enrolled in the Kentucky Employees' Health Plan (KEHP), as well as employees covered by other insurance plans. In addition to the Capitol Annex, clinics are located in the Cabinet for Health and Family Services building, the Capital Plaza Tower and the Transportation Cabinet building.



The clinics are open from 8 a.m. to 4:30 p.m. Monday-Friday and are staffed by nurse practitioners and medical assistants available to assist state employees with their health and wellness needs. The medical treatment and services provided by the First Onsite Clinics are solely billed to the employees' personal health plan. Employees must present a copy of their benefits card and remit the required copayments for services they receive at the clinics.

"We are pleased that the clinics have been

visited over 1,440 times since their opening in October," stated Personnel Cabinet Secretary Nikki Jackson. "We hope the convenience of having a clinic onsite offers an opportunity to enhance the health and wellness of our employees."

Employees can use the clinic for many wellness needs, including: blood pressure monitoring; goal setting and coaching; weight management assistance, including body fat measurements; care for the common cold; allergy shots; and much more.

Every day the state, district, and local health departments in Kentucky conduct essential services in their efforts to prevent disease, promote health, and protect the citizens of Kentucky. These stories highlight how **public health**

Public Health Works

Evaluating Vaccine Campaigns in Europe

According to a risk assessment of the pandemic situation published by the European Centre for **Disease Prevention** and Control, it is currently impossible to predict the exact number of pandemic waves and the time when they will develop in an individual country. This depends on factors such as the level of symptomatic and asymptomatic infections. Other important factors potentially affecting the evolution of this pandemic include the level of pre-existing immunity in the population, social factors. and last but not least, the rate of immunized individuals.

Increasing the immunization coverage is the only way to eliminate uncertainties about future waves of pandemic influenza A (H1N1) and is anticipated to provide significant benefits in terms of protecting the health of individuals with high-risk conditions and older individuals.

Source: Eurosurveillance, Volume 15, Issue 3

Date: 21 January 2010

Clark and Montgomery County Health Departments Team Up to Provide H1N1 Vaccinations at Basketball Game

"Clark vs. Montgomery: Rivals in Basketball; Partners in Public Health" was the theme for the Point of Dispensing clinic at George Rogers Clark (GRC) High School in Winchester the evening of January 22, 2010. This was where staff from the Clark and Montgomery County Health Departments as well as Montgomery County MRC members came together to provide an opportunity for free H1N1 and Seasonal Flu Vaccinations for those attending the highly anticipated girls and boys basketball games. Games between these long time rival teams always fill a gymnasium, and Friday night was no exception.



Leading up to the game, the vaccination clinic was publicized through local media outlets and the schools in

Clark County Public Health Director, Scott Lockard and Montgomery County Public Health Director, Jan Chamness

both counties. On the evening of the game, upon entering GRC, fans were greeted by health department staff and provided information about influenza vaccination. A large, colorful banner displaying the evening's theme and promoting flu vaccination was hung just inside the entrance of the school and right outside of the vaccination clinic, which was held in the school library. Those staffing the clinic were dressed in their respective school colors.



Indian fan and Montgomery County High School student, Nathan Bailey, looks away as he receives his H1N1 vaccination.

Although both counties have seen a decline in flu illness as well as in demand for the vaccine, both health departments continue to look for ways to promote flu vaccination. According to Jan Chamness, Montgomery County Public Health Director, "This was an excellent opportunity for us to work with a neighboring health department. It provided an opportunity for individuals from both of our communities to be vaccinated that may not come out to one of our mass clinics."

Fifty-nine vaccinations were administered at the event, 18 seasonal and 41 H1N1. Although nurses and support staff were prepared to administer hundreds of doses of vaccine, they were not disappointed. Many of the individuals that came to the clinic had no definite plans to be vaccinated against H1N1 and stopped by just because the vaccinators were there. Also, both health departments held aggressive, successful school vaccination campaigns prior to the Christmas holiday.

Public Health Works

Clark and Montgomery County Health Departments Team Up (Continued)

This is the first time that the Clark and Montgomery County Health Departments have teamed up for a Point of Dispensing clinic but it is not anticipated to be the last. Both directors have discussed the possibility of teaming up in future flu seasons to promote and provide vaccinations to Cardinal and Indian fans attending the rival basketball games. "Our counties may be big rivals in basketball, but we are on the same team in public health," said Scott Lockard, Clark County Public Health Director.



Clark County Health Department nurse answers questions about H1N1 vaccine from Cardinal fans.

Garrard County Health Department Collaborations Make Garrard County Better Prepared for H1N1 and Future Emergency Responses

Prior to the H1N1 pandemic, the Garrard County Health Department (GCHD) Director and Preparedness Coordinator briefed preparedness partners in the county on capabilities and responsibilities and solicited their support during medical emergency events. This effort included signing a formal memorandum of agreement with the school superintendent for use of the school facilities. GCHD met with the superintendent of schools and his staff, physician offices, pharmacies, dentists, and long-term care facility staff and briefed the county emergency management staff.

As part of this collaboration GCHD developed emergency communications and notification systems. This included phone trees and email distribution lists for all school, medical organizations, and emergency management directors in the county. All pertinent information from the Kentucky Department for Public Health and CDC was forwarded to these organizations on a daily basis.

Once the H1N1 pandemic impacted the county, this collaboration proved to be invaluable in GCHD's ability to respond and distribute vaccine to priority group personnel in the county. GCHD was able to quickly establish points of distribution (POD) at the health department, deliver vaccine to medical facilities, and establish additional PODs at three local elementary schools. Although schools are identified as a POD back-up in the GCHD all hazards plan, they were utilized first during the H1N1 response. The system worked well and the support from the school superintendent's office, school preparedness coordinator, nursing staff, school staff and volunteers made for smooth operations and subsequently a successful vaccination campaign.

An estimated 4,000 residents are included in the established CDC priority groups; this is about 23.5% of Garrard County's population, estimated at 17,000 residents. As of December 5, approximately 2,400 people in the county were vaccinated. The majority of those vaccinated fell within the priority groups, although vaccine was not refused to anyone who requested it.

Vaccine is still available in the county and is being offered to anyone that requests it. We are still actively advertising the importance of everyone getting the H1N1 vaccine.

Kentucky Fluview

International Influenza Update

The 2009 H1N1 influenza virus continues to be the dominant influenza virus in circulation in the world. For the most recent period in which data are available. from January 10, 2009 to January 16, 2010, 64.4% were typed as influenza A and 35.6% as influenza B. Out of all subtyped influenza A viruses, 95% were 2009 H1N1 positive.

According to WHO, the majority of 2009 H1N1 influenza isolates tested worldwide remain sensitive to oseltamivir, an antiviral medicine used to treat influenza disease. Worldwide, 220 2009 H1N1 isolates tested have been found to be resistant to oseltamivir -54 of these isolates were detected in the United States.

China has reported outbreaks due to influenza B (48.8% of all influenza positive specimens). Intermittent detections of seasonal A (H1N1), A (H3N2) and influenza B viruses were also reported from Iran, Japan, the Russian Federation and Tunisia.

CDC website: <u>http://</u> www.cdc.gov/h1n1flu/ updates/international/

Retrieved on 4 Feb. 2010

Fluview Success

Aiming to change the health of the Commonwealth's citizens, the Kentucky Department for Public Health (KDHP) works hard to collect health information through effective surveillance and then disseminate this information to the public and decision makers. One of the successful communication strategies used throughout the fall wave of the novel influenza A H1N1 epidemic has been the publication the "Kentucky Fluview." The weekly production of the newsletter began as an initiative planned in the initial stages of the H1N1 response as a tool to communicate surveillance and other pertinent information to state leadership, state and local health department personnel, medical community, the media, and the public. *Fluview* developed into a collaboration of articles contributed from state epidemiologists covering topics like H1N1 mortality rates, school surveillance including school absenteeism data, vaccine allocation information from the CDC, and special public health interest stories.

The main purpose of the newsletter is to disseminate timely H1N1 surveillance information to our partners and to inform the state leadership, including Governor Steve Beshear, on the progression of the epidemic and what the public should know about protecting themselves and their families against the virus. The *Fluview* also functions as an educational tool for local health departments, professional health associations like Kentucky Medical Association (KMA) and the Kentucky Hospital Association (KHA) to better assist them in planning and decision-making in responding to the pandemic. KDPH knew the *Fluview* was reaching its target audience when a deadline was missed and the Governor's office called to asked when to expect delivery.

The Kentucky *Fluview* was highlighted as a 'Promising Practice' according to Center for Infectious Disease Research & Policy (CIDRAP) and the Pew Center on the States (PCS), which launched an initiative in 2006 to collect and review practices that can be adapted or adopted by public health stakeholders. This project is now sponsored by the Association of State and Territorial Health Officials (ASTHO) the national non-profit organization representing the 57 state and territorial public health agencies of the United States, US Territories, and the District of Columbia. You can view this and another entry for Kentucky at: http://www.cidrappractices.org/practices/list.do?state-id=21.

Guidelines for the Disposal of Expired H1N1 Influenza Vaccine

Providers are strongly encouraged to utilize unexpired H1N1 influenza vaccine and not dispose of or return vaccine before the expiration date. We encourage all providers to continue offering the H1N1 influenza vaccine to patients as the potential for additional waves of H1N1 influenza activity still exists.

Expired H1N1 influenza vaccine products may not be returned to the distributor; therefore providers are asked to dispose of the vaccine appropriately. KDPH has produced a document which outlines steps to take for the proper disposal of expired H1N1 influenza vaccine and unused ancillary supplies.

To summarize:

- Multi-dose vials should be disposed of in a sharps container.
- Pre-filled Syringes and intranasal spray (LAIV) (without needles attached) should be disposed of in a medical waste container (red bag) or a sharps container. All syringes with a needle attached must be disposed of in a sharps container.
- Ancillary supplies (needles) that were originally intended to be used for H1N1 vaccine administration may be provided other clinical services in your practice, donated or disposed of in a sharps container.
- If providers wish to donate unused ancillary H1N1 supplies to a charitable organization, KDPH recommends drafting a statement to accompany the supplies relieving the practice, the health department, and CDC of liability for any malfunctions or misuse.
- If the cost of disposing of the expired H1N1 influenza vaccine or unused supplies presents a difficulty for the provider, sharps containers containing expired H1N1 influenza vaccine and/or unused supplies may be returned to the local health department for disposal.

A record of expired vaccine and method of disposal should be kept by the practice and forwarded to the local health department for record keeping purposes.

For more specifics on proper vaccine disposal, please visit: <u>www.http://HEALTHALERTS.KY.GOV</u>

Non-Safety-Related Voluntary Recall of Unused Doses from Certain Lots of Sanofi Pasteur H1N1 Vaccine in Pre-Filled Syringes

As part of its quality assurance program, Sanofi Pasteur, Inc., performs routine, ongoing testing of influenza vaccines after the vaccine has been distributed to health care providers to ensure that the vaccine continues to meet required specifications. In recent testing of its influenza A (H1N1) monovalent vaccine, Sanofi Pasteur found five distributed lots of single dose, pre-filled syringe pediatric (0.25 mL) vaccine and one distributed lot of single-dose pre-filled syringe for older children and adults (0.5 mL) vaccine had potency below pre-specified limits. The manufacturer is conducting a non-safety related voluntary recall of any unused doses of these affected lots of vaccine. Information will be sent by Sanofi Pasteur to providers who received vaccine from the affected lots.

After performing routine tests, Sanofi Pasteur notified the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA) that the potency in five lots of pediatric pre-filled syringes and one lot of adult pre-filled syringes that had been distributed to providers was later found to have dropped below a pre-specified limit. While the potency of these lots is now below the manufacturer's specification for the product, CDC and FDA are in agreement that the small decrease in antigen content is unlikely to result in a clinically significant reduction in immune response among persons who have received the vaccine. For this reason, there is no need to revaccinate persons who have received vaccine from these lots.

Providers will be asked to return any unused vaccine from the affected lots to the manufacturer. The only vaccine affected by this recall is supplied in pre-filled syringes and is identified by the following lot numbers: UT023AA, UT023BA, UT023CA, UT023EA, UT023FA (NDC # 49281-650-25, which also may be recorded as # 49281-0650-25), 0.25 mL syringes in 10-packs UT037AA (NDC # 49281-650-90, which also may be recorded as # 49281-0650-90), 0.5 mL syringes in 25-packs.

These lots were shipped to providers between November 2009 and January 2010. Sanofi Pasteur will send directions for returning unused vaccine from these lots to providers. All vaccines are thoroughly tested prior to release and shipping for safety, purity, and potency. The affected lots met all required specifications at the time of release. CDC and FDA have determined that there are no safety concerns for people who have received these vaccines. The potency of the affected lots of vaccine is only slightly below the specification limit. Vaccine doses from these lots are still expected to be effective in stimulating a protective response. There is no need to re-administer a dose to those who received vaccine from these lots. As is recommended for all 2009 H1N1 vaccines, all children less than 10 years old should get the recommended two doses of H1N1 vaccine approximately a month apart for the optimal immune response. So, children less than 10 years old who have only received one dose of vaccine thus far should still receive a second dose of 2009 H1N1 vaccine. For children 6 months of age and older, vaccine is available in multidose vials. The vaccine in multidose vials is safe and effective vaccine for children. The standard dose for this preparation for administration to infants 6-35 months old is the same as for the pre-filled syringes, 0.25 mL. For healthy children at least 2 years of age, the nasal spray (live, attenuated influenza vaccine) is also an option. The nasal spray vaccine is produced in single units that do not contain thimerosal. Sanofi Pasteur has informed the CDC that it will be submitting a field correction to the FDA to request a change for the expiration date of the company's remaining pediatric and adult prefilled syringes. CDC will share additional information as soon as it is available.

For More Information:

Call CDC's toll-free information line, 800-CDC-INFO (800-232-4636) TTY: (888) 232-6348, which is available 24 hours a day, every day.

Tell Us What You Think!

The KY Department of Public Health has enjoyed producing the *Fluview* newsletter for you and hope it has been a helpful surveillance and communication tool. We would love to know what you have enjoyed about *Fluview* and what you think could be improved about the newsletter. Please let us know by taking the survey through the link below:

http://www.surveymonkey.com/s/HH6C3XY

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FOR THE LASTEST UPDATES ON H1N1, GO TO: WWW.HTTP:// HEALTHALERTS .KY.GOV