



OHIO DEPARTMENT OF HEALTH DEPARTMENT OPERATIONS CENTER

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SITUATION REPORT

Report Date: 1100 December 17, 2009

Event Type: Public Health Emergency

Operational Period: December 16 through December 23, 2009

Ohio Public Health Situation

Disaster/Hazard/Disease Type:	H1N1
WHO Phase:	6 - Widespread Human Infection
Governor Emergency Proclamation:	Yes, on October 7, 2009
State EOC: OPEN	CAS Level 1
ESF 8: YES	POC: Number: (419) 564-9192
OEMA Assessment Room: YES	Number: (614) 799-3903
ODH ICS activated: YES	IC: Roger Suppes Number: (614) 752-9871
ODH DOC activated: YES	POC: Dan Deskins Number: (614) 644-3435

World Health Organization:

11 December 2009 -- As of 6 December 2009, worldwide more than 208 countries and overseas territories or communities have reported laboratory confirmed cases of pandemic influenza H1N1 2009, including at least 9596 deaths.

As many countries have stopped counting individual cases, particularly of milder illness, the case count is likely to be significantly lower than the actual number of cases that have occurred. WHO is actively monitoring the progress of the pandemic through frequent consultations with the WHO Regional Offices and member states and through monitoring of multiple sources of data.

The Centers for Disease Control and Prevention:

A Summary of CDC Key Public Health Messages this Season

2009 H1N1 Influenza Vaccine Supply

- **2009 H1N1 Vaccine Allocation.** Total available as of Dec. 15 is **94.6** million doses, an increase of approximately 12 million doses from one week ago. (22.4% of nasal spray)



Non-Safety-Related Voluntary Recall of Certain Lots of Sanofi Pasteur 2009 H1N1 Pediatric (0.25 mL, for 6-35 month olds) Vaccine in Pre-Filled Syringes

- See http://www.cdc.gov/h1n1flu/vaccination/syringes_qa.htm for complete details.
- **Summary:** As part of its quality assurance program, Sanofi Pasteur, Inc., performs additional routine, ongoing testing of influenza vaccines after the vaccine has been distributed to health care providers to ensure that vaccines continue to meet required specifications. In recent testing of the amount of antigen in its influenza A (H1N1) monovalent vaccine, Sanofi Pasteur found four distributed lots of single-dose, pre-filled syringe pediatric (0.25 mL.) vaccine with antigen content lower than required potency levels. The manufacturer is conducting a non-safety related voluntary recall of these affected lots of vaccine.
- **Background:** After performing these tests, Sanofi Pasteur notified the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA) that the antigen content in one lot of pediatric syringes that had been distributed to providers was later found to have dropped below a pre-specified limit. As a result of this finding, Sanofi Pasteur tested additional lots and found that three other lots that had been distributed also had an antigen content that had fallen below pre-specified limits. This means that doses from these four vaccine lots no longer meet the specifications for antigen content.
 - Approximately 800,000 doses of vaccine in these lots were distributed to providers.
- **Recommendations:** While the antigen content of these lots is now below the specification limit 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 are being asked to return any vaccine that remains unused to the manufacturer from the specified lots (see web page for lot numbers).

Messages:

- There are no safety concerns with these recalled lots of 2009 H1N1 vaccine. All lots successfully passed pre-release testing for purity, potency and safety.
- Only specified lots of the 2009 H1N1 pediatric vaccine for children 6-35 months in pre-filled syringes are affected.
- There is no need to re-administer a dose to those who received vaccine from these lots. The vaccine potency is only slightly below the "specified" range. The vaccine in these lots is still expected to be effective in stimulating a protective response despite this slight reduction in the concentration of antigen.
- 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. Therefore, 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.
- Parents of children who received vaccine from the recalled lots do not need to take any action, other than to complete the two-dose immunization series if not already completed.
- Children should receive both doses of 2009 H1N1 vaccine from the same type of vaccine (i.e., both doses as inactivated, injectable; or both doses as live, attenuated, nasal spray vaccine).
- All vaccines are routinely tested for purity, potency and safety prior to release. The four lots of vaccine met all required specifications at the time of release and shipment to distribution



centers. The vaccine provided in multi-dose vials and the single-dose, 0.5 mL pre-filled syringes for persons 36 months and older continues to meet all specifications.

Disease Parameters:

The Pandemic strain of H1N1 2009 continues to demonstrate similar characteristics to seasonal influenza. The exception is that people age 65 and older are less likely to become infected. It is believed that immunity in this population is related to exposure to a similar virus in the past, but H1N1, like any influenza infection in the elderly, is likely to lead to more serious illness.

Individuals are encouraged to see their primary physician if they need treatment or if their illness progresses. Illness is initially asymptomatic (showing no evidence of disease); progressing to body aches, possible fever, tiredness, and decrease in appetite, upper respiratory symptoms and resolution of illness.

ODH is conducting daily surveillance on Hospitals, Outbreaks, and Deaths and reporting them to the CDC by noon Wednesdays.

As of December 14, 2009, ODH approved providers should make the H1N1 vaccine available to all individuals wishing to be vaccinated, while considering to give high risk individuals priority consideration, unless medically contraindicated.

Impact on Individuals:

- All data sources indicated that influenza activity continues to **DECLINE** in Ohio. Influenza Confirmed Hospitalizations by County, reported in the Ohio Disease Reporting System, is 3,073 as of 12/17/09.
- The report of hospitalizations in the 85 Event Counties range from 1 case to 688 persons. Seven counties reported over 100 persons hospitalized.
- Pneumonia and influenza deaths in Ohio is 1,967 (12/17/09), reported in the Ohio Disease Reporting System.
- Getting the 2009 H1N1 influenza vaccine is much safer than getting H1N1 influenza. You can prevent 2009 H1N1 influenza illness by getting the 2009 H1N1 vaccine.
- The benefits of getting the 2009 H1N1 influenza vaccine far outweigh the very small risk of serious complications from vaccination. Some people getting vaccinated will have mild side effects such as pain, redness or swelling in the arm where the shot was given or a runny nose and headache after the nasal spray vaccine.

Incident Potential:

- Ohio's influenza activity level, an indicator of geographic spread, has been downgraded to "**regional**" with "**low intensity.**"
- The number of people infected with influenza has stabilized, and surveillance data sources continue to indicate that the intensity of this activity is decreasing.
- Public health surveillance data sources indicate decreasing reports of confirmed influenza-associated hospitalizations and declining levels of influenza-like illness in outpatient settings reported by Ohio's sentinel providers.



- The percentage of emergency department visits with patients exhibiting constitutional symptoms, as well as over-the-counter drug sales (particularly thermometer sales) have returned to baseline levels statewide.

Current Status:

- As part of its quality assurance program, the manufacturer, Sanofi Pasteur, performs routine, ongoing stability testing of its 2009 influenza A (H1N1) vaccine after the vaccine has been shipped to providers. Stability testing means measuring the strength (also called potency) of a vaccine over time. It is performed because sometimes the strength of a vaccine can be reduced over time. On December 7, Sanofi Pasteur notified CDC and FDA that the potency in one batch (called a "lot") of vaccine in pre-filled pediatric syringes that had been distributed was later found to have dropped below a pre-specified limit. As a result of this finding, Sanofi Pasteur tested additional lots and found that three other lots that had been distributed also had an antigen content that, while filled at the the proper level at the time of manufacturing, was later measured to be below pre-specified limits. This means that doses from these four vaccine lots no longer meet the manufacturer's specifications for potency. Sanofi Pasteur will send providers directions for returning any unused vaccine from these lots.
- National Influenza Vaccination Week (NIVW) is a national initiative that was established to highlight the importance of continuing influenza vaccination, as well as to foster greater use of flu vaccine after the holiday season into January and beyond. This year's NIVW, originally scheduled for December 6-12, 2009, is now rescheduled to January 10-16, 2010. Updates will be provided as more information becomes available.
- The Ohio Department of Health (ODH) will continue efforts to reach high risk populations.
- ODH Leadership is meeting with African American bishops and pastors concerning reaching the African American community with information on H1N1 vaccinations. As a result of the collaborations that are forming, some churches are willing to serve as distribution sites to disseminate vaccine to interested church members and the community.
- The ODH H1N1 flu combined general/technical information line received **253** calls on **12/16/09**.
- To date 951,078 individuals have pre-registered on the ODH H1N1 Vaccine Application Site.
- Reported pre-registered providers verified and approved by local health departments are 3182 out of 4703 as of 12/15/09.
- OPHCS alert is being generated to announce the voluntary recall of certain lots of pediatric vaccine in pre-filled syringes for 6-35 months olds. In addition, emails will be sent to providers. Emails will notify providers to alert ODH if the provider is a recipient of the lots recalled.
- The vaccine unit processed the H1N1 vaccine allocation for 12/11/09. As of 12/11/09, CDC allocated a total of 570,600 doses consisting of zero doses of .25 PFS; 57,900 doses of .5 PFS; 411,100 doses of MDV; and 101,600 doses of nasal spray. The Incident Commander determined the quantities of vaccine to be sent to enrolled H1N1 vaccine providers.
- The allocation plan on 12/11/09 consisted of: the vaccine unit allocated vaccine to each approved H1N1 vaccine provider using tier 1 and non-tier 1 data in the H1N1 Vaccine Application who requested more than 100 doses in nearly all the provider groups, including the pharmacies. The only exception was that OB-Gyn providers were not allocated vaccine – these providers should contact their local health departments if vaccine is needed this next week.



- An email was sent to all H1N1 providers on 12/11/09 indicating that the vaccine was to be available to all groups of people effective 12/14/09. Additional messaging indicated that pre-registration should still be used in the ODH H1N1 Vaccine Application and that the call center can assist providers with adjustments to the requested H1N1 vaccine need.
- The vaccine unit continues communication to LHDs on the need for children <10 years of age to get second dose and remind LHDs of the availability of technology tools.
- The following issues were identified from callers: questions regarding recall and lot numbers affected; locations/sites when the shots are available; general registration questions
- No schools or child care centers are reported closed today.

Incident Objectives:

1. Order and report vaccines in accordance with ODH Vaccine Allocation and Ordering procedures, 2009
 - a. Continue allocation process distribution to general population
 - b. Implement the application for tracking and reporting of who has been vaccinated by geography and category.
 - c. Communication vaccine distribution and expansion to general population and additional provider types.
 - d. Complete action to approve providers.
2. Provide general information to the public and technical assistance to providers/patient registration.
 - a. Implement communication plan for vaccine to hard-to-reach populations.
 - b. Continue communication to LHDs on need for children <10 years of age to get second dose and remind LHDs of the availability of technology tools (i.e. e-mail notification, reminder/recall notices) to notify parents when to return for this vaccination.
 - c. Confirm that all communication channels to reflect expansion to the general population and additional providers.
3. Report critical information to CDC and/or EOC (as found in H1N1 Critical Information Matrix).
4. Monitor the EPI assessments on trends or associations of hospitalizations and deaths and identify interventions or next steps as necessary.
5. Distribute PPE to hospitals, up receipts of requests.
6. Develop and disseminate allocation plan for SNS ventilators.
7. Finalize plan for demobilization issues and guidance.
8. Finalize and communicate holiday schedule for EOC
9. Develop strategy for promoting vaccination of state employees

Expenditures:

The total procurement cost is \$733,162.14 and payroll cost is \$972,138.99 for 200 staff. (This reflects staff's time entered into the OSAP/MOSS portal on the ICS 252 electronic forms).

Resources:

As of December 17, 2009, **495** ODH personnel have been mobilized for the ODH H1N1 response. Of those, **195** ODH personnel are currently assigned to work during the 12/16/09-12/23/09 operational period.



Planning Updates:

ODH is working with Ohio EMA to develop a demobilization plan for the state's H1N1 response. This plan will cover the state's efforts and coordination between the Governors office, Ohio EMA and ODH. A basic outline of the plan has been discussed. ODH has a separate demobilization plan for its ICS. This ODH specific plan is expected to be implemented some time next year.

Safety Message for Public:

Dr. Jackson has released a statement to the public regarding long-lines at the various H1N1 vaccination clinics. He stated people should dress appropriately for the weather, carry hand sanitizer and gave the following preventative measures to avoid spreading germs:

- Wash your hands frequently; use alcohol-based hand sanitizers if soap and water are unavailable.
- Cover your coughs and sneezes with tissue, or cough or sneeze into your elbow.
- If you are sick, stay home until free from fever for 24 hours without taking fever-reducing medication.

Weather and Effects:

Partly Sunny on Thursday and cloudy on Friday with up to 60% chance of snow for the remainder of the week. As the week progresses, temperatures range from high 30's to low 20's, causing no delays in the transportation of vaccines and ancillary supplies.