

Maine CDC/DHHS Update on 2009 H1N1 Influenza Virus

December 23, 2009

Flu Activity in Maine and the US

Data indicate that H1N1 flu has been relatively mild in Maine compared with other states, and continues to decline. There have been no new deaths since the last update.

There were 9 new hospitalizations last week, down from 11 last week, and across all age groups. There were no new admissions to intensive care. Individuals were hospitalized in Cumberland, Franklin, Kennebec, Oxford, Penobscot, Washington, and York counties.

Outbreaks were reported in one long term care facility and two K-12 schools. The outbreaks occurred in Penobscot, Somerset, and York counties.

Flu comes in waves. Protect yourself and those you care about by getting vaccinated before the next wave.

To remind people of the importance of washing hands, covering coughs, staying home when sick, and getting vaccinated, order flu posters and magnets for your organization, workplace, or health care practice:

<http://www.maine.gov/dhhs/boh/flu-poster-orders.shtml>

H1N1 Vaccine Supply and Prioritization

To date, we have received a total of about 575,000 doses of H1N1 vaccine in Maine, and by the first week of January we expect to have about 675,000 total cumulative doses – enough for about half of the state's population. Based on recent demand, Maine CDC is now recommending that H1N1 vaccine be offered to anyone who wishes to receive it when local supplies allow.

If you are an H1N1 vaccine provider and are running short of vaccine, please contact flu.questions@maine.gov to inform us of your needs. This will help our short terming planning and distribution of vaccine.

The focus for vaccine will still be the five high priority groups as defined by US CDC, but in many places public clinics will not need to turn others away. We are encouraging health care providers with sufficient supplies to provide vaccine to all who want it, and those without sufficient vaccine to focus their vaccine supply to those in the high priority groups: pregnant and recently pregnant women; household members and caregivers of infants younger than six months old; all people ages 6 months through 24 years; people ages 25 through 64 with underlying health conditions; and health care and EMS workers.

The nasal spray vaccine is available in slightly greater quantities than injectable vaccine. **We request that nasal spray vaccine be given to anyone who is eligible to receive it. The nasal spray vaccine is a safe and effective vaccine option for healthy people ages 2 through 49 who are not pregnant.** For more information on nasal spray vaccine, please see our Fact Sheet at: http://www.maine.gov/dhhs/boh/maineflu/LAIV_factsheet.pdf

The benefits of getting the H1N1 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. US CDC and FDA carefully monitor vaccine reports. After millions of doses of H1N1 vaccine being administered in the U.S., the number, pattern and types of adverse event reports are similar to what we see for seasonal influenza vaccine. More than 90% of adverse event reports nationwide have been classified as not serious.

We expect vaccine to be more readily available in retail pharmacies over the next several weeks, in addition to public clinics, doctors' offices, and through occupational health and certain large-scale employers. To find vaccine in your area: check the clinic locator at www.maine flu.gov, call 211, or call your health care provider.

Vaccine Recall

On December 18 and 21, MedImmune notified CDC and FDA that the potency of 13 lots of monovalent 2009 (H1N1) nasal spray vaccine had decreased below a pre-specified limit or were at risk of falling below that limit in the next week. This slight decrease in vaccine potency is not expected to have an impact on the protective response to vaccination. There are no safety concerns with these lots of 2009 H1N1 vaccine. **This is not a safety recall.** All lots successfully passed pre-release testing for purity, potency and safety. However, because their potency is now or might soon be below the specified lower limit, MedImmune will send providers directions for returning any unused vaccine from these lots.

Recommendations

The potency of these lots is now or might soon be slightly below the specified range for the product. CDC and FDA are in agreement that the slight decrease in vaccine potency is not expected to have an impact on the protective response to vaccination. **For this reason, there is no need to revaccinate persons who have received vaccine from these lots.**

People who received vaccine from the recalled lots do not need to take any action. Children and adults aged 10 years and older who received the vaccine do not need any further doses of vaccine. As is recommended for all 2009 H1N1 vaccines, all children younger than 10 years old should get the recommended two doses of 2009 H1N1 vaccine approximately a month apart. Therefore, children younger than 10 years old who have only received one dose of vaccine thus far should still receive a second dose of 2009 H1N1 vaccine. It is best to use the same type of vaccine for the first and second doses.

The 13 lots subject to the recall include approximately 4.7 million doses. These doses were shipped to CDC's contract distributor in October and early November. Approximately 90 vaccine providers in Maine received these doses, primarily in late October. **Most of the doses are believed to have already been administered while fully potent and within specifications.** However, there may be some doses that have not yet been used.

The potency issue described here is specific to 13 lots of nasal spray 2009 H1N1 influenza vaccine. Subsequent lots of the vaccine were produced with a slightly higher initial potency to decrease the chance that the potency would fall "below specification" before their expiration dates. Following its routine practice, the manufacturer will continue to monitor the stability of these subsequent lots.

Maine CDC will be contacting all Maine providers who received doses from any of the 13 lots of vaccine so that they can return any unused vaccine.

- . For Questions and Answers related to the withdrawn vaccine see http://www.cdc.gov/h1n1flu/vaccination/sprayrecall_qa.htm
- . 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.
- . For manufacturer's information about the recall, see http://www.medimmune.com/pdf/H1N1_Recall_QandA_122209.pdf
- . For manufacturer's instructions to providers on actions to be taken, see http://www.medimmune.com/pdf/H1N1_Recall_letter_122209.pdf
- **Important Information for Vaccine Administrators**

- **All public clinics must be posted on Maine CDC's clinic locator:**
<http://www.maine.gov/dhhs/boh/maineflu/fluclinics/clinic-form.shtml>. If you have questions about completing this form, please e-mail flu.questions@maine.gov.

All H1N1 vaccine providers and/or administrators must submit the vaccine administration data into Maine CDC's weekly vaccine reporting system. The weekly vaccine reporting form can be found at:
<http://www.maine.gov/dhhs/boh/maineflu/h1n1/health-care-providers.shtml>.

Detailed instructions are also available at: <http://www.maine.gov/dhhs/boh/maineflu/h1n1/H1N1-Weekly-Reporting-Form-instructions.pdf>.

Vaccine Return:

The only vaccines that should be returned to McKesson are those that arrive non-viable or appear to be damaged during transit. **Providers with concerns about vaccine viability during transit from McKesson should call 877-836-7123 immediately upon receipt of the package.**

Once a provider takes receipt of the vaccine as a usable product, it is that provider's responsibility to ensure proper disposal of any damaged, expired, or un-used vaccine unless it has been recalled.

Vaccinating Small Children:

Due to national production delays and the recent recall of .25 mL pre-filled syringes, Maine CDC makes the following recommendations for vaccinating small children:

Use the Sanofi or CSL multidose vial for all children ages 6 months to 2 years of age

Use the nasal spray vaccine for healthy children ages two and older, when available and appropriate

Use the Sanofi or CSL multidose vial for children ages two and older who are not eligible to receive nasal spray vaccine, or when nasal spray is unavailable

Vaccine Dose Spacing and Administration:

Those who have questions about H1N1 vaccine dose spacing and administration with seasonal flu or other vaccines should consult this table from US CDC:

http://www.cdc.gov/H1N1flu/vaccination/dosespace_admin.html.

Additional vaccine-related information for health care providers can be found on our web site at:

<http://www.maine.gov/dhhs/boh/maineflu/h1n1/hc-providers/vaccine-info-hcp.shtml>

Updates from Federal Partners

US CDC has updated its recommendations for clinicians regarding H1N1 and severely immunosuppressed patients: <http://www.cdc.gov/h1n1flu/immunosuppression/index.htm>

US CDC has updated its H1N1 Fact Sheet for people age 65 and older:

<http://www.cdc.gov/h1n1flu/65andolder.htm>

If you think 2009 H1N1 flu can't affect you, your family, or your friends—think again. Take 60 seconds to watch this reminder on why vaccination is so important. All of the excuses any of us make don't stand a chance against this serious disease. <http://www.cdc.gov/CDCTV/INever/>

This USDA study (http://www.usda.gov/documents/ARS_STUDY_H1N1_Pork_12-16-09.pdf) confirms that people cannot get H1N1 from eating or preparing pork from pigs exposed to the H1N1 virus.

From the US Department of Health and Human Services: H1N1 Year in Review:
<http://www.flu.gov/about/h1n1yearreview.html>

CDC has **not** implemented a state vaccination program requiring registration on www.cdc.gov. Users who click on e-mails directing people to create a personal H1N1 vaccination profile are at risk of having a computer virus installed on their system. For more information: http://www.cdc.gov/hoaxes_rumors.html

How to Stay Updated

· **Flu News:** View current Maine CDC press releases, Thursday weekly updates, and urgent updates from our Health Alert Network (HAN) by visiting: <http://www.maine.gov/dhhs/boh/maineflu/flu-news.shtml>. RSS feeds are available for the weekly updates and HAN.

Follow Maine CDC's Social Media Updates:

- **Facebook** (search for "Maine CDC")
- **Twitter** (<http://twitter.com/MEPublicHealth>)
- **MySpace** (www.myspace.com/mainepublichealth)
- **Maine CDC's Blog** (<http://mainepublichealth.blogspot.com>)

· **Please note that weekly conference call updates will not be held for the next several weeks.** Any future calls will be listed in advance in these updates.

· **For clinical consultation, outbreak management guidance,** and reporting of an outbreak of H1N1 call Maine CDC's toll free 24-hour phone line at: 1-800-821-5821.

For general questions:

- Call **2-1-1** from 8 a.m. to 8 p.m. seven days per week
- E-mail flu.questions@maine.gov