



DOH H1N1Influenza Guidance Updates For District of Columbia Healthcare Providers: Update #3

November 30, 2009

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TAB 1

Information for Pregnant Women Working in Education, Child Care, and Health Care Settings Concerning 2009 H1N1 Influenza Virus

Information for Pregnant Women Working in Education, Child Care, and Health Care Settings Concerning 2009 H1N1 Influenza Virus

November 9, 2009, 6:30 PM ET

Recommendations for workplace infection control and prevention strategies related to pregnant women who work in education, child care and healthcare can be found at the following websites:



- [CDC Guidance for State and Local Public Health Officials and School Administrators for School \(K-12\) Responses to Influenza during the 2009-2010 School Year](#)
- [CDC Guidance on Helping Child Care and Early Childhood Programs Respond to Influenza during the 2009-2010 Influenza Season](#)
- [Interim Guidance on Infection Control Measures for 2009 H1N1 Influenza in Healthcare Settings, Including Protection of Healthcare Personnel](#)
- [What Should Pregnant Women Know About 2009 H1N1 Flu \(Swine Flu\)?](#)
- [Interim Guidance for 2009 H1N1 Flu \(Swine Flu\): Taking Care of a Sick Person in Your Home](#)

All 2009 H1N1 guidance is interim and subject to review and revision as more is learned about this novel influenza virus. This guidance may be revised in the event that the 2009 H1N1 pandemic increases in severity compared with the situation in spring/summer 2009.

The key message for employers and employees in work settings where pregnant employees are likely to be exposed to 2009 H1N1 is to take every precaution to prevent infection. Recommended strategies to decrease the likelihood of employee exposure to 2009 H1N1 influenza virus include implementation of infection control strategies in the work place and work policies that support sick employees being away from the workplace. Implementation of employee education about influenza symptoms will support early self-recognition of possible illness and may help decrease overall exposure to the virus in the workplace.

Pregnant employees can also take steps to prevent both exposure and illness. Vaccination is the [single best way to prevent influenza illness](#). As soon as possible, all pregnant women should get both 2009 H1N1 and seasonal flu shots. In addition, everyday precautions such as hand washing and covering your mouth and nose when you cough or sneeze, and encouraging others to do so, are important ways to stay healthy and to not spread germs that cause illness. Finally, pregnant women who have signs or symptoms of influenza-like illness need to call their healthcare provider right away, because they may require [prompt treatment with antiviral medications](#).

Antiviral medications are used in some situations to prevent influenza infection after close contact <http://www.cdc.gov/h1n1flu/recommendations.htm> with someone with a confirmed, probable, or suspected influenza infection. Pregnant women who believe that they may have had close contact with someone with influenza illness should call their healthcare provider for advice. More information about post-exposure antiviral medication use can be found at this website: http://www.cdc.gov/H1N1flu/pregnancy/antiviral_pregnant_qa.htm.

Schools and child care workers

Pregnant women who work in school and child care settings, such as teachers and child care professionals, should follow guidance for school and child care personnel and the general public. In these settings, ill individuals should be identified and promptly separated from healthy individuals. Pregnant women in school and child care settings should not provide care to children who have symptoms of influenza-like illness. In addition they should be familiar with recommendations for infection control in their workplace settings.

[Guidance for Schools K-12](#)

[Guidance for Child Care and Early Childhood Programs](#)

Pregnant healthcare personnel



Healthcare personnel are defined as all persons whose activities involve contact with patients or contaminated material in a healthcare, home healthcare, or clinical laboratory setting, including students, trainees and volunteers. Healthcare personnel are engaged in a range of occupations, many of which include patient contact even though they do not involve direct provision of patient care, such as dietary and housekeeping services. Pregnant healthcare personnel treating patients with suspected or known 2009 H1N1 infection should follow facility infection control policies. Current interim CDC guidance for healthcare personnel is available on the CDC website at http://www.cdc.gov/h1n1flu/guidelines_infection_control.htm. This guidance applies uniquely to the special circumstances of the 2009-2010 influenza season and will be updated as necessary as new information becomes available throughout the course of this influenza season.

All healthcare personnel, including pregnant women, who will likely be in direct contact with patients with confirmed or suspected 2009 H1N1 flu (e.g., a nurse, physician, or respiratory therapist caring for hospitalized patients), should carefully adhere to standard precautions which includes performing hand hygiene before and after all patient contact, contact with respiratory secretions, and before putting on and upon removal of personal protective equipment (PPE). Soap and water or alcohol-based hand rubs should be used. Standard precautions also state that for any activity that might generate splashes of respiratory secretions, gowns along with eye protection should be

worn. In addition to standard precautions healthcare workers should wear a fit-tested, disposable N95 respirator when within 6 feet of the patient.

No special precautions are needed for pregnant doctors and nurses to administer the nasal spray vaccine. All healthcare personnel should wash their hands or use an alcohol-based hand rub before and after giving the vaccine.

Facilities and organizations providing healthcare services should consider offering alternative work environments as an accommodation for pregnant personnel and those at high-risk for complications during periods of increased influenza activity or if influenza severity increases.

For additional guidance for health care providers at higher risk for complications of influenza infection, please visit: [Interim Guidance for Infection Control for Care of Patients with Confirmed or Suspected Swine Influenza A \(H1N1\) Virus Infection in a Healthcare Setting](#).

Information on the correct use of PPE is available on the [CDC website](#).



TAB 2

**Update: FDA Questions
and Answers for Health
Care Providers: Renal
Dosing and Administration
Recommendations for
Peramivir IV -
Questions and answers for
renal dosing and
administration for
Peramivir IV**

Emergency Use Authorization of Peramivir IV

[FDA-Issued Peramivir IV EUA Letter](#) 

[Fact Sheet for Health Care Providers](#) 

- [FDA Questions and Answers for Health Care Providers: Renal Dosing and Administration Recommendations for Peramivir IV](#)  
- [Peramivir IV Questions and Answers for Health Care Providers](#)
- **To request Peramivir IV (licensed clinicians with prescribing privileges ONLY), [CLICK HERE](#). For any questions, call 1-800-CDC-INFO (1-800-232-4636).**
- For questions relating to this Emergency Use Authorization, contact:
EUA.OCET@fda.hhs.gov

[Fact Sheet for Patients and Parents/Caregivers](#) 

- [Fact Sheet for Patients and Parents/Caregivers \(Spanish\)](#) 

[Intravenous Peramivir](#)

***Note: For information on recognizing and reporting adverse events (side effects) of Peramivir IV, please refer to the applicable Fact Sheet.

TAB 3

2009 H1N1 Pandemic Update: Pneumococcal Vaccination Recommended to Help Prevent Secondary Infections

Distributed via Health Alert Network
November 16, 2009, 13:51 EST (01:51 PM EST)
CDCHAN-00301-09-11-16-ADV-N

2009 H1N1 Pandemic Update: Pneumococcal Vaccination Recommended to Help Prevent Secondary Infections

Summary of Recommendations: CDC's Advisory Committee on Immunization Practices (ACIP) recommends a single dose of pneumococcal polysaccharide vaccine (PPSV) for all people 65 years of age and older and for persons 2 through 64 years of age with certain high-risk conditions. Among those with high-risk conditions for pneumococcal disease, most are also at high risk for severe complications from influenza. **Special emphasis should be placed on vaccinating adults under 65 years of age who have established high-risk conditions for pneumococcal disease; PPSV coverage among this group is low and this group may be more likely to develop secondary bacterial pneumonia after an influenza infection.** All children younger than 5 years of age should continue to receive pneumococcal conjugate vaccine (PCV7) according to existing recommendations.

Situation:

Streptococcus pneumoniae (pneumococcus) remains a leading cause of vaccine-preventable illness and death in the United States. Some of CDC's Active Bacterial Core surveillance (ABCs) sites have seen greater than expected numbers of cases of invasive pneumococcal disease coincident with increases in influenza-associated hospitalizations. A causal relationship between 2009 H1N1 influenza and this increase has not yet been established, but CDC is pursuing that question with state and local public health officials.

Influenza predisposes individuals to developing bacterial community-acquired pneumonia. During each of the influenza pandemics of the 20th century, secondary bacterial pneumonia was a frequent cause of illness and death and *S. pneumoniae* was reported as the most common etiology. These findings also apply to seasonal influenza. Recently, pneumococcal infections have been identified as an important complication in severe and fatal cases of 2009 H1N1 influenza virus infection. **A key difference between this pandemic and those of the past is that now we have two pneumococcal vaccines that may help to prevent these infections.**

Recommendations:

During the 2009-2010 influenza season, pneumococcal vaccines can be useful in preventing secondary pneumococcal infections and reducing illness and death among those infected with influenza viruses.

CDC's Advisory Committee on Immunization Practices (ACIP) recommends a single dose of pneumococcal polysaccharide vaccine (PPSV) for all people 65 years of age and older and for persons 2 through 64 years of age with certain high-risk conditions. For those 19 through 64 years of age, these include: having asthma or smoking cigarettes. For those 2 through 64 years of age, high-risk conditions include: chronic cardiovascular disease (congestive heart failure and cardiomyopathies), chronic pulmonary disease (including chronic obstructive pulmonary disease and emphysema), diabetes mellitus, alcoholism, chronic liver disease (including cirrhosis), cerebrospinal fluid leaks, cochlear implant, functional or anatomic asplenia including sickle cell disease and splenectomy, immunocompromising conditions including HIV infection, leukemia, lymphoma, Hodgkin's disease, multiple myeloma, generalized malignancy, chronic renal failure, nephrotic syndrome; those receiving immunosuppressive chemotherapy (including corticosteroids); and those who have received an organ or bone marrow transplant, and residents of nursing homes or long-term care facilities.

Among those with high-risk conditions for pneumococcal disease, most are also at high risk for severe complications from influenza. A single pneumococcal revaccination at least five years after initial vaccination is recommended for people 65 years and older who were first vaccinated before age 65 years. A single pneumococcal revaccination also is recommended for people at highest risk of disease, such as those who have

functional and anatomical asplenia, and those who have HIV infection, AIDS or malignancy and have at least five years elapsed from receipt of first vaccination.

All people who have existing indications for PPSV should continue to be vaccinated according to current ACIP recommendations during the 2009 H1N1 influenza pandemic. **Special emphasis should be placed on vaccinating adults under 65 years of age who have established high-risk conditions for pneumococcal disease; PPSV coverage among this group is low and this group may be more likely to develop secondary bacterial pneumonia after an influenza infection.** PPSV is available for ordering through the usual process; ordering PPSV is not linked to placing orders for monovalent 2009 H1N1 influenza vaccine.

Use of PPSV among people without current indications for vaccination is not recommended at this time.

All children younger than 5 years of age should continue to receive pneumococcal conjugate vaccine (PCV7) according to existing recommendations.

According to existing guidelines, the use of a commercially available urine antigen test (Binax NOW®) is recommended for the diagnosis of pneumococcal pneumonia in adults. Such testing, along with blood cultures and testing for influenza infection, can assist clinicians in determining whether secondary pneumococcal pneumonia is occurring.

CDC recommends a yearly seasonal influenza vaccine as the first and most important step in protecting against seasonal influenza. Annual influenza vaccination is especially important for people at high risk of serious influenza complications, including young children, pregnant women, older adults, and people with certain chronic health conditions such as asthma, diabetes, heart or lung disease, and neurologic conditions [including disorders of the brain, spinal cord, peripheral nerve, and muscle such as cerebral palsy, epilepsy (seizure disorders), stroke, intellectual disability (mental retardation), moderate to severe developmental delay, muscular dystrophy, or spinal cord injury]. Seasonal influenza vaccine also is important for health care workers and other people who live with or care for high risk people to prevent giving the influenza to those at high risk.

A new monovalent vaccine against 2009 H1N1 influenza is available and is our best option for prevention of 2009 H1N1 infection. People at greatest risk for 2009 H1N1 infection or serious complications and recommended to receive the first available doses of vaccine include children, young adults age 19-24, pregnant women, and people age 25-64 with chronic health conditions. Monovalent 2009 H1N1 influenza vaccine is important for close contacts of infants younger than 6 months of age and health care and emergency medical services personnel. While vaccine supply is currently less than demand, additional doses are becoming available daily and supply will increase through November and December.

In communities where 2009 H1N1 is circulating, treatment with influenza antiviral agents is recommended for all hospitalized patients with confirmed, probable or suspected 2009 H1N1 or seasonal influenza and for outpatients who are at higher risk for influenza-related complications. Empiric treatment of patients hospitalized with community acquired pneumonia should include both influenza antiviral agents and appropriate antibiotic therapy. For more information on treatment of influenza, see <http://www.cdc.gov/h1n1flu/recommendations.htm>.

For More Information:

- For Clinicians: Prevention Of Pneumococcal Infections Secondary To Seasonal And 2009 H1N1 Influenza Viruses Infection (http://www.cdc.gov/h1n1flu/vaccination/provider/provider_pneumococcal.htm)
- Pneumococcal Vaccine Website (<http://www.cdc.gov/vaccines/vpd-vac/pneumo/default.htm>)
- Interim guidance for use of 23-valent pneumococcal polysaccharide vaccine during novel influenza A (H1N1) outbreak (http://www.cdc.gov/h1n1flu/guidance/ppsv_h1n1.htm)
- Nov 10 Letter to Providers Promoting PPSV for Adults (<http://www.cdc.gov/h1n1flu/vaccination/provider/lettertoprovider.htm>)
- CDC's Morbidity and Mortality Weekly Report (MMWR):

Letter to Providers Promoting PPSV for Adults Polysaccharide Vaccine (Bacterial Coinfections in Lung Tissue Specimens from Fatal Cases of 2009 Pandemic Influenza A (H1N1) --- United States, May--August 2009; September 29, 2009 / 58(Early Release);1-4 (<http://www.cdc.gov/mmwr/PDF/wk/mm5838.pdf>)

- Table: ACIP Recommendations for Use of Pneumococcal Polysaccharide Vaccine (http://www.cdc.gov/h1n1flu/vaccination/provider/provider_pneumococcal.htm#table1)
- Infectious Diseases Society of America/American Thoracic Society Consensus Guidelines on the Management of Community-Acquired Pneumonia in Adults (<http://www.journals.uchicago.edu/doi/pdf/10.1086/511159?>)
- Preventing Seasonal Flu With Vaccination (<http://www.cdc.gov/flu/protect/vaccine/index.htm>)
- General Information About 2009 H1N1 Vaccines (<http://www.cdc.gov/h1n1flu/vaccination/general.htm>)
- Updated Interim Recommendations for the Use of Antiviral Medications in the Treatment and Prevention of Influenza for the 2009-2010 Season (<http://www.cdc.gov/h1n1flu/recommendations.htm>)
- Interim Recommendations for Clinical Use of Influenza Diagnostic Tests During the 2009-10 Influenza Season (http://www.cdc.gov/h1n1flu/guidance/diagnostic_tests.htm)
- Active Bacterial Core surveillance (<http://www.cdc.gov/abcs>)

Categories of Health Alert messages:

Health Alert conveys the highest level of importance; warrants immediate action or attention.

Health Advisory provides important information for a specific incident or situation; may not require immediate action.

Health Update provides updated information regarding an incident or situation; unlikely to require immediate action.

HAN InfoService provides notification of important but not urgent information related to the situation; unlikely to require immediate action.

TAB 4

H1N1 Monovalent Vaccine Return Policy

H1N1 Monovalent Vaccine Return Policy

November 20, 2009, 11:00 AM ET

Background

A question was submitted to the 2009 H1N1 Helpdesk regarding returns and/or destruction of damaged or expired 2009 H1N1 monovalent vaccines.

The manufactures will not be accepting wasted or expired 2009 H1N1 monovalent vaccine returns. This means that McKesson will not be handling wasted or expired vaccine returns from providers.

What Should be Returned to McKesson?

The only vaccines that should be returned to McKesson are those that arrive non-viable or appear to have been damaged during transit.

Please note that providers who have concerns about vaccine viability in transit from McKesson should contact McKesson Customer Service **IMMEDIATELY UPON RECEIPT OF THE PACKAGE**. The dedicated phone line is: **877-TEMP123 (877-836-7123)**.

This telephone number, which only handles provider phone calls about vaccine viability, is printed on the temperature monitors that are placed in each vaccine shipment.

Once the grantee (or provider within the grantees' jurisdiction) has taken receipt of the vaccine as usable product, it is the responsibility of the grantee to ensure proper disposal of any damaged, expired, or un-used product. After that, neither McKesson nor the manufacturers will accept returned 2009 H1N1 vaccine.

PHER Funds to Dispose of Vaccine?

PHER funds can be used to dispose of vaccine and other medical waste products as part of the 2009 H1N1 response.

TAB 5

Updated Guidance for the Use of CSL™ 2009 H1N1 Monovalent Vaccine

Updated Guidance for the Use of CSL™ 2009 H1N1 Monovalent Vaccine

November 19, 2009, 2:15 PM EDT

Background

On November 11, 2009, the FDA expanded the approved use of CSL's™ seasonal and 2009 H1N1 monovalent influenza vaccines to include children aged 6 months and older. Both vaccines had previously been approved only for use in adults, aged 18 years and older. The immediate effect on the national 2009 H1N1 monovalent flu vaccination program is that CSL's™ 0.5 mL pre-filled syringe and 5 mL multi-dose vial formulations can now be used in a substantially broader range of ages. Currently, CSL™ 0.25 mL pre-filled syringes of 2009 H1N1 monovalent influenza vaccine are not available for use in the United States. CDC is making a programmatic recommendation and issuing clarifying guidance on use of CSL™ 2009 H1N1 monovalent vaccine that takes into account practical logistical considerations of allocation, ordering, and distribution of vaccine and ancillary supply kits.

Recommendation


Both the CSL™ 2009 H1N1 0.5 mL pre-filled syringe and multi-dose vial vaccine formulations should be reserved for use in individuals aged 3 years and older if alternative products are available to administer to children aged 6-35 months.

Rationale

Pre-filled syringe presentation: In order to prevent wasting vaccine, the CSL™ 2009 H1N1 0.5 mL pre-filled syringe is not recommended for use in children aged 6-35 months. Children aged 6-35 months require two 0.25 mL doses of vaccine separated by a minimum of 28 days. Using the CSL™ 2009 H1N1 0.5 mL pre-filled syringe to vaccinate children aged 6-35 months would result in wastage of one 0.25 mL dose per syringe. Unused 0.25 mL doses should not be reserved to administer to the same patient at a later time, or to another individual. Furthermore, transfer of vaccine content from one syringe to another is not permissible. Therefore, remaining partial doses must be discarded. With the current limited availability of vaccine nationwide, CDC discourages using a half dose of CSL™ H1N1 0.5 mL pre-filled syringe vaccine in children aged 6-35 months.

Multi-dose vial presentation: Due to logistical restrictions related to ancillary supply kits, CDC recommends that the CSL™ 5 mL multi-dose vaccine formulation be used in individuals aged 3 years and older.

The quantities of ancillary supplies (needles, syringes, vaccination records, and alcohol prep pads) available with each order of multi-dose vial vaccine were intended for administration of a 0.5 mL dose per patient. Providers can choose to administer half doses (0.25 mL) from the multi-dose vial formulation to children aged 6-35 months, if

they are able to supply their own needles, syringes, alcohol prep pads, and to print out additional vaccination records from the CDC website (http://www.cdc.gov/flu/freeresources/2009-10/pdf/influenza_record_card2009.pdf ).

Questions

If you have any questions or need clarification on this guidance please contact the CDC Immunization Desk at EOCImmunization@cdc.gov.

TAB 6

2009 H1N1 Influenza Vaccine – Dose Spacing for Children 6 Months through 9 Years of Age

2009 H1N1 Influenza Vaccine - Dose Spacing for Children 6 Months through 9 Years of Age¹

	Influenza 2009 H1N1 LAIV Dose 2 ^{1,2}	Influenza 2009 H1N1 Inactivated Dose 2 ¹
Influenza 2009 H1N1 LAIV Dose 1 ²	<p>Separate the first and second dose by at least 28 days. Some experts suggest that 14 days* or longer is acceptable.</p> <p>If given 1-13 days apart, repeat the second dose at least 14 days* (preferably 28 days) from the invalid (second) dose.</p>	<p>Using the same type of vaccine for the first and second dose is preferred. If not feasible, separate the first and second dose by at least 28 days preferably, but some experts suggest that at least 21 days* is acceptable.</p> <p>If given 1-20 days apart, repeat the second dose at least 21 days* (preferably 28 days) from the invalid (second) dose.</p>
Influenza 2009 H1N1 Inactivated Dose 1	<p>Using the same type of vaccine for the first and second dose is preferred. If not feasible, separate the first and second dose by at least 28 days preferably, but some experts suggest that at least 21 days* or longer is acceptable.</p> <p>If given 1-20 days apart, repeat the second dose at least 21 days* (preferably 28 days) from the invalid (second) dose.</p>	<p>Separate the first and second dose by at least 28 days preferably, but some experts suggest that 21 days* or longer is acceptable.</p> <p>If given 1-20 days apart, repeat the second dose at least 21 days* (preferably 28 days) from the invalid (second) dose.</p>

¹Persons 10 and older require only one dose of 2009 H1N1 vaccine.

²2009 H1N1 LAIV is recommended for use in healthy people 2 years to 49 years of age who are not pregnant.

*These intervals apply ONLY to 2009 H1N1 vaccines and should NOT be applied to seasonal influenza vaccines. The Advisory Committee on Immunization Practices' 4-day "grace period" (i.e. vaccine doses that are administered 4 or fewer days before the minimum interval can be counted as valid) should NOT be applied to 2009 H1N1 intervals.

TAB 7

2009 H1N1 Influenza Vaccine - Administration with Seasonal Influenza and Other Vaccines

2009 H1N1 Influenza Vaccine - Administration with Seasonal Influenza and Other Vaccines

	Influenza Seasonal LAIV ²	Influenza Seasonal Inactivated	Other Live Vaccines (e.g. MMR)	Other Inactivated Vaccines (e.g. PPV)
Influenza 2009 H1N1 LAIV ^{1,2}	Vaccines should be separated by at least 28 days preferably, but some experts suggest that 14 days* or longer is acceptable. If given 1-13 days apart, repeat the vaccine administered second at least 14 days* (preferably 28 days) from the invalid (second) dose. Administering both doses at the same visit is not recommended but if they are given at the same visit, neither vaccine needs to be repeated.	Vaccines can be administered on the same day or any interval (one or more days) between these vaccines is acceptable.	Vaccines can be administered at the same visit. If not administered at the same visit, vaccines should be separated by at least 28 days. If administered 1-27 days apart repeat the vaccine administered second at least 28 days* from the invalid (second) vaccine.	Vaccines can be administered on the same day or any interval (one or more days) between these vaccines is acceptable.
Influenza 2009 H1N1 Inactivated ¹	Vaccines can be administered on the same day or any interval (one or more days) between these vaccines is acceptable.	Vaccines can be administered on the same day or any interval (one or more days) between these vaccines is acceptable.	Vaccines can be administered on the same day or any interval (one or more days) between these vaccines is acceptable.	Vaccines can be administered on the same day or any interval (one or more days) between these vaccines is acceptable.

¹Persons 10 and older require only one dose of 2009 H1N1 vaccine.

²2009 H1N1 LAIV and seasonal influenza LAIV are recommended for use in healthy people 2 years to 49 years of age who are not pregnant.

*These intervals apply ONLY to 2009 H1N1 vaccines and should NOT be applied to seasonal influenza vaccines. The Advisory Committee on Immunization Practices' 4-day "grace period" (i.e. vaccine doses that are administered 4 or fewer days before the minimum interval can be counted as valid) should NOT be applied to 2009 H1N1 intervals.

TAB 8

2009 H1N1 Influenza Vaccine Dose Spacing And Administration With Seasonal Influenza and Other Vaccines

2009 H1N1 Influenza Vaccine Dose Spacing¹ and Administration with Seasonal Influenza and Other Vaccines

	Influenza 2009 H1N1 LAIV Dose 2 ^{1,2}	Influenza 2009 H1N1 Inactivated Dose 2 ¹	Influenza Seasonal LAIV ²
Influenza 2009 H1N1 LAIV Dose 1 ^{1,2}	For children 2 years through 9 years, separate the first and second dose by at least 28 days preferably, but some experts suggest that 14 days* or longer is acceptable. If given 1-13 days apart, repeat the second dose at least 14 days* (preferably 28 days) from the invalid (second) dose.	For children 6 months through 9 years, using the same type of vaccine for first and second dose is preferred. If not feasible, separate the first and second dose by at least 28 days preferably, but some experts suggest that at least 21 days* is acceptable. If given 1-20 days apart, repeat the second dose at least 21 days* (preferably 28 days) from the invalid (second) dose.	Vaccines should be separated by at least 28 days preferably, but some experts suggest that 14 days* or longer is acceptable. If given 1-13 days apart, repeat the vaccine administered second at least 14 days* (preferably 28 days) from the invalid (second) dose. Administering both doses at the same visit is not recommended but if they are given at the same visit, neither vaccine needs to be repeated.
Influenza 2009 H1N1 Inactivated Dose 1 ¹	For children 2 years through 9 years, using the same type of vaccine for first and second dose is preferred. If not feasible, separate first and second dose by at least 28 days preferably, but some experts suggest that at least 21 days* or longer is acceptable. If given 1-20 days apart, repeat the second dose at least 21 days* (preferably 28 days) from the invalid (second) dose.	For children 6 months through 9 years, separate first and second dose by at least 28 days preferably, but some experts suggest that 21 days* or more is acceptable. If given 1-20 days apart, repeat the second dose at least 21 days* (preferably 28 days) from the invalid (second) dose.	Vaccines can be administered on the same day or any interval (one or more days) between these vaccines is acceptable.

	Influenza Seasonal Inactivated	Other live vaccines (e.g. MMR)	Other inactivated vaccines (e.g. PPV)
Influenza 2009 H1N1 LAIV Dose 1^{1,2}	Vaccines can be administered on the same day or any interval (one or more days) between these vaccines is acceptable.	Vaccines can be administered at the same visit. If not administered at the same visit, vaccines should be separated by at least 28 days. If administered 1-27 days apart repeat the vaccine administered second at least 28 days* from the invalid (second) vaccine.	Vaccines can be administered on the same day or any interval (one or more days) between these vaccines is acceptable.
Influenza 2009 H1N1 Inactivated Dose 1¹	Vaccines can be administered on the same day or any interval (one or more days) between these vaccines is acceptable.	Vaccines can be administered on the same day or any interval (one or more days) between these vaccines is acceptable.	Vaccines can be administered on the same day or any interval (one or more days) between these vaccines is acceptable.

¹ Persons 10 and older require only one dose of 2009 H1N1 vaccine.

² 2009 H1N1 LAIV and seasonal influenza LAIV are recommended for use in healthy people 2 years to 49 years of age who are not pregnant.

* These intervals apply ONLY to 2009 H1N1 vaccines and should NOT be applied to seasonal influenza vaccines. The Advisory Committee on Immunization Practices' 4-day "grace period" (i.e. vaccine doses that are administered 4 or fewer days before the minimum interval can be counted as valid) should NOT be applied to 2009 H1N1 intervals.

TAB 9

2009 H1N1 Monovalent Influenza Vaccine Dosage, Administration, and Storage

2009 H1N1 Monovalent Influenza Vaccine Dosage, Administration, and Storage

November 24, 2009, 7:00 PM EDT

This document has been revised to include updated information related to FDA approval of the GSK 2009 H1N1 monovalent influenza vaccine to be used in persons ages 18 years old and older and the expanded use of CSL 2009 H1N1 monovalent influenza vaccine to younger age groups.

Inactivated Vaccine: Dosage, Administration, and Storage

The composition of the influenza A (H1N1) 2009 monovalent inactivated influenza vaccine varies according to manufacturer, and package inserts should be consulted. Inactivated vaccine formulations in multidose vials contain the vaccine preservative thimerosal; preservative-free, single-dose preparations also are available. Inactivated vaccine should be stored at 35°F to 46°F (2°C to 8°C) and should not be frozen. Inactivated vaccine that has been frozen should be discarded. Dosage recommendations and schedules vary according to age group ([Table 1](#)).

The intramuscular route is recommended for administering the influenza A (H1N1) 2009 monovalent inactivated vaccine. Adults and older children should be vaccinated in the deltoid muscle. A needle length of 1 inch or longer (25 mm or longer) should be considered for persons in these age groups because needles of less than 1 inch might be of insufficient length to penetrate muscle tissue in certain adults and older children. When injecting into the deltoid muscle in children with adequate deltoid muscle mass, a needle length of 7/8" to 1.25 inches is recommended.

Infants and young children should be vaccinated in the anterolateral aspect of the thigh. A needle length of 7/8" to 1 inch should be used for children younger than 12 months of age.






Live Attenuated Influenza Vaccine (LAIV): Dosage, Administration, and Storage

The 2009 H1N1 monovalent LAIV contains the same vaccine antigen as the inactivated vaccine. However, the antigen is constituted as a live, attenuated, cold-adapted, temperature-sensitive vaccine virus. Providers should refer to the package insert, which contains additional information about the formulation of this vaccine and other vaccine components. LAIV does not contain thimerosal. LAIV is made from an attenuated virus that is able to replicate efficiently only at temperatures present in the nasal mucosa. LAIV does not cause systemic symptoms of influenza in vaccine recipients, although a minority of recipients experience nasal congestion or fever, which is probably a result of the effects of intranasal vaccine administration or local viral replication or fever.

LAIV is intended for intranasal administration only and should not be administered by the intramuscular, intradermal, or intravenous route. LAIV is not licensed for vaccination of children younger than 2 years or adults older than 49 years of age. LAIV

is supplied in a prefilled, single-use sprayer containing 0.2 mL of vaccine. Approximately 0.1 mL (i.e., half of the total sprayer contents) is sprayed into the first nostril while the recipient is in the upright position. An attached dose-divider clip is removed from the sprayer to administer the second half of the dose into the other nostril while the recipient is in the upright position. LAIV is shipped at 35°F to 46°F (2°C to 8°C). LAIV should be stored at 35°F to 46°F (2°C to 8°C) on receipt and can remain at that temperature until the expiration date is reached.

TABLE 1. Influenza A (H1N1) 2009 monovalent vaccines approved for use in the United States, November 11, 2009

Vaccine type	Manufacturer	Presentation	Mercury content ($\mu\text{g Hg}/0.5\text{ mL dose}$)	Age group	No. of doses	Route
Inactivated*	Sanofi Pasteur 	0.25 mL prefilled syringe	0	6–35 mos	2†	Intra-muscular§
		0.5 mL prefilled syringe	0	≥ 36 mos	1 or 2†	Intra-muscular
		5.0 mL multidose vial	25.0	≥ 6 mos	1 or 2†	Intra-muscular
Inactivated*	Novartis Vaccines and Diagnostics Limited 	5.0 mL multidose vial	25.0	≥ 4 yrs	1 or 2†	Intra-muscular
		0.5 mL prefilled syringe	<1.0	≥ 4 yrs	1 or 2†	Intra-muscular
Inactivated*	CSL Limited 	0.5 mL prefilled syringe	0	≥ 3 yrs§§	1 or 2†	Intra-muscular
		5.0 mL multidose vial	24.5	≥ 3 yrs§§	1 or 2†	Intra-muscular
Inactivated*	ID Biomedical  (Distributed by GSK)	5.0 mL multidose vial	25.0	≥ 18 yrs	1	Intra-muscular
LAIV¶	MedImmune LLC 	0.2 mL sprayer**	0	2–49 yrs	1 or 2††	Intranasal

* A 0.5-mL dose contains 15 μg hemagglutinin of A/California/7/2009 (H1N1)pdm.

† Two doses administered approximately 4 weeks apart (≥ 21 days acceptable) are recommended for children aged 6 months through 9 years.

§ The preferred site for infants and young children is the anterolateral aspect of the thigh.

¶ Live attenuated influenza vaccine. A 0.2-mL dose contains 106.5–7.5 fluorescent focal units of live attenuated influenza virus reassortants of A/California/7/2009

(H1N1)pdm.

**** Influenza A (H1N1) 2009 LAIV is shipped refrigerated and stored in the refrigerator at 36°F to 46°F (2°C to 8°C) after arrival in the immunization clinic. The dose is 0.2 mL divided equally between each nostril. LAIV should not be administered to persons with asthma. Healthcare providers should consult the medical record, when available, to identify children aged 2 through 4 years old with asthma or recurrent wheezing that might indicate asthma. In addition, to identify children who might be at greater risk for asthma and possibly at increased risk for wheezing after receiving LAIV, parents or caregivers of children aged 2 through 4 years of age should be asked: "In the past 12 months, has a healthcare provider ever told you that your child had wheezing or asthma?" Children whose parents or caregivers answer "yes" to this question and children who have asthma or who had a wheezing episode noted in the medical record during the preceding 12 months should not receive LAIV.**

†† Two doses administered approximately 4 weeks apart are recommended for children aged 2 through 9 years of age.

§§ Although the FDA approved the expanded use of CSL 2009 H1N1 monovalent influenza vaccine to children ages 6 months and older, the CDC recommends that if other manufacturers' vaccines are available for use in children ages 6 through 35 months, CSL vaccine should be reserved for persons ages 3 years and older. This recommendation is not related to vaccine efficacy or safety concerns. It was made to reduce vaccine wastage and to be compatible with needle/syringe distribution logistical constraints. If providers choose to immunize children ages 6 through 35 months, the dose is 0.25 mL. For additional guidance, refer to "[Updated Guidance for the Use of CSL's 2009 H1N1 Monovalent Vaccine.](#)"

TAB 10

2009 H1N1 Influenza: Resources for Pharmacists

2009 H1N1 Influenza: Resources for Pharmacists

This page was updated November 25, 2009 to include new information on antiviral availability and additional information that may be useful for pharmacists working in both outpatient and inpatient settings.



General Information for Pharmacists

CDC has issued [recommendations for clinicians](#) on the use of antiviral medications for the treatment and prevention of influenza for the 2009-2010 season. The Food and Drug Administration (FDA) has authorized emergency use of [oseltamivir \(Tamiflu®\)](#) and [zanamivir \(Relenza®\)](#) under certain circumstances not included in the FDA-approved uses or outside of the FDA-approved uses in response to the declaration of a public health emergency involving 2009 H1N1 influenza A virus made by the Secretary of Health and Human Services on April 26, 2009. Additionally, FDA has recently issued an Emergency Use Authorization for the use of an unapproved (investigational) intravenous drug ([peramivir](#)) for the treatment of 2009 H1N1 influenza virus in certain hospitalized adult and pediatric patients.

The current public health emergency has affected the nation's pharmacists as a greater number of people than usual seek to fill prescriptions for influenza antiviral drugs or antibiotics to treat secondary infections, in addition to seeking advice on over-the-counter cough and cold medications. This may have an impact on supplies and availability of antiviral medications and other materials that may be needed to fill such prescriptions.

Antiviral Availability

At this time, CDC discussions with the antiviral supply chain (manufacturers, distributors and retailers) indicate that supplies of the Tamiflu® adult capsule formulation (75 mg) and pediatric capsule formulations (30 mg and 45 mg) and Relenza® Inhalation Powder are meeting current demand for these products. However, the FDA and Roche (maker of Tamiflu®) have determined that supplies of Tamiflu® Oral Suspension are limited.

Pharmacies should be aware of the importance of providing patients with these influenza medications as quickly as possible when they are prescribed. Having product at the pharmacy store level, including doses of Tamiflu® and Relenza®, and supplies to

compound Tamiflu® Oral Suspension, will be critical to ensure that patients needing treatment receive it as quickly as possible.

- **Limited Availability of Commercial Tamiflu® Oral Suspension**
Supplies of commercially-manufactured Tamiflu® Oral Suspension are limited. In response to this, Tamiflu® Oral Suspension has been released from the CDC Strategic National Stockpile to enhance availability at state and local levels. Some of these lots of suspension product have an expired date on the label. Under the [emergency use authorization for Tamiflu®](#) FDA has authorized the use of certain lots of expired Tamiflu®. Based on scientific review, FDA found that some Tamiflu® may be used past the expiration date printed on the package. If you want to look up the lot number for your Tamiflu to see if it has been authorized for use past its expiration date, please see the [listing of antivirals at or nearing expiry](#).

When local supplies of commercially-manufactured oral suspension are limited, physicians should consider infants and children less than one year of age or less than 33 lbs to be the highest priority for receiving the commercial suspension.

- [FDA: Information for Healthcare Professionals – Authorization of Use of Expired Tamiflu for Oral Suspension](#)
- **Supply of Ingredients Needed to Compound Tamiflu® Oral Suspension**
Tamiflu® capsules (75 mg) may be compounded using either of two vehicles: Cherry Syrup (Humco) or Ora-Sweet SF (sugar-free) (Paddock Laboratories). As of October 28, 2009, these products may be in short supply in some locations if there is increased demand for compounding an oral suspension from Tamiflu® 75 mg capsules.

Humco reports that they have increased production of Cherry Syrup and that they are releasing new production weekly to wholesalers. If pharmacists are having difficulty obtaining Humco Cherry Syrup, they may contact Humco directly to locate supplies at 1-800-662-3435. Paddock Laboratories reports that they have increased production of Ora-Sweet SF and they are releasing new production daily to customers.



- [FDA: Tamiflu Oral Suspension Shortage Information](#)

CDC will provide additional information and updates regarding antiviral drug supplies as needed.






Antiviral Prescription and Dispensing Considerations

Oseltamivir (Tamiflu®)

- **Complete information for the Emergency Use Authorization for Tamiflu® is available from CDC.**
 - [CDC: Emergency Use Authorization for Tamiflu®](#)
- **Alternatives to Tamiflu® Oral Suspension for Pediatric Patients**
While commercially-manufactured Tamiflu® Oral Suspension (12 mg/mL) is the preferred product for pediatric and adult patients who have difficulty swallowing capsules or where lower doses are needed, this product may not be locally available.

- *For patients who are less than one year old, there is one alternative:*
 - a suspension compounded by a retail pharmacy (see links below)
- *For children who are at least one year old there are two alternatives:*
 - a suspension compounded by a retail pharmacy (see links below)
 - 30mg, 45mg, or 75 mg capsules, which may be mixed into a sweetened liquid by a caregiver if the child cannot swallow capsules (see links below).
- **Tamiflu® Oral Suspension Compounded by a Retail Pharmacy**
Compounding an oral suspension from Tamiflu® 75mg capsules as described in the FDA-approved manufacturer [package insert](#)   is an alternative when commercially-manufactured oral suspension formulation is not readily available. Tamiflu® 75 mg capsules may be compounded using either of two vehicles: Cherry Syrup (Humco) or Ora-Sweet SF (sugar-free) (Paddock Laboratories). Other supplies needed include mortar and pestle and a standard pharmacy bottle, such as an amber glass or amber polyethyleneterephthalate (PET) bottle.

When prescribing Tamiflu® Oral Suspension, prescribers should specify the concentration if prescribing in mL or teaspoons, or prescribe the dose in milligrams (mg).





- [FDA Drug Safety Information: Emergency Compounding of an Oral Suspension from Tamiflu® 75 mg Capsules \(Final Concentration 15 mg/mL\)](#)  
- [FDA: Guidance to Pharmacies on Advance Compounding of Tamiflu® Oral Suspension to Provide for Multiple Prescriptions](#)  
- [Institute for Safe Medication Practices Safety Alert: Tamiflu® Oral Suspension Shortage Contributing to Dosing Errors](#)  
- **Opening and Mixing Tamiflu® Capsules with Liquids**
In addition, for children who may not be able to swallow capsules, Tamiflu® capsules may be opened and mixed with sweetened liquids, such as regular or sugar-free chocolate syrup, if oral suspension is not available. Instructions for caregivers in print and video form are linked below.
 - [CDC: Q&A for Caregivers: Opening and Mixing Tamiflu® Capsules with Liquids if Child Cannot Swallow Capsules](#)
 - CDC: Caregiver Instruction Sheet: Opening and Mixing Tamiflu® Capsules with Liquids if Child Cannot Swallow Capsules (available soon)
 - [CDC: Opening and Mixing Tamiflu® Capsules with Liquids if Child Cannot Swallow Capsules](#)
- **Commercial Tamiflu® Oral Suspension – Potential Dosing Device Errors**
Pharmacists with access to Tamiflu® Oral Suspension should be aware that an oral dosing dispenser with 30 mg, 45 mg, and 60 mg graduations is provided in the manufacturer’s packaging, rather than graduations in milliliters (mL) or teaspoons (tsp). There have been cases where the units of measure on the prescription dosing instructions (mL, tsp) do not match the units on the dosing device (mg), which can lead to patient or caregiver confusion and dosing errors. When dispensing commercially-manufactured Tamiflu® Oral Suspension, pharmacists should ensure the units of measure on the dosing instructions match the dosing device provided. If dosing instructions specify administration using mL or tsp the device included in the Tamiflu® product package should be removed and replaced with an appropriate measuring device. When dispensing Tamiflu® Oral Suspension for children younger than 1 year of age or to children who are to receive a dose <30 mg, the oral dosing dispenser that is included

in the product package should always be removed and replaced with an appropriate measuring device.

When dispensing commercially-manufactured Tamiflu® Oral Suspension, please ensure that the units of measure on the dosing instructions match the dosing device provided. For children younger than 1 year of age, the oral dosing dispenser that is included in the product package should always be removed and replaced with an appropriate measuring device.

- [FDA Public Health Alert: Potential Medication Errors with Tamiflu® for Oral Suspension](#)  
- [Dear Healthcare Professional letter](#)   (Roche)

Zanamivir (Relenza®)

- **Complete information for the Emergency Use Authorization for zanamivir is available from CDC.**
 - [CDC: Emergency Use Authorization for Relenza®](#)
- **Relenza® Inhalation Powder – Warning: Powder Must Not Be Nebulized**
The commercial formulation of Relenza® Inhalation Powder is not designed or intended for reconstitution in any liquid formulation and is not recommended for use in any nebulizer or mechanical ventilator.
 - [FDA Drug Safety Alert: Relenza \(zanamivir\) Inhalation Powder](#)  
 - [Dear Healthcare Professional letter](#)   (GlaxoSmithKline)

Peramivir IV

- **Complete information for the Emergency Use Authorization for Peramivir IV is available from CDC.**
 - [CDC: Emergency Use Authorization for Peramivir IV](#)

Note on Special Populations

Pregnant Women

Pharmacists are likely to be asked many questions from their pregnant patients about the efficacy and safety of antiviral drugs and vaccinations this flu season. Pregnant women are a particularly high-risk population for serious complications and death when infected with 2009 H1N1 influenza. Vaccination and treatment guidelines specific to pregnant women are provided below.

- [CDC: H1N1 Flu \(Swine Flu\): Resources for Obstetric Health Care Providers](#)

Pregnant women, regardless of trimester of pregnancy, should receive the inactivated seasonal influenza vaccine (trivalent inactivated vaccine) and the inactivated influenza A (H1N1) 2009 monovalent vaccine. Pregnant women should not receive the seasonal or 2009 H1N1 monovalent live attenuated influenza vaccine (LAIV) (nasal spray)


- [CDC: 2009 H1N1 Influenza Vaccine and Pregnant Women: Information for Healthcare Providers](#)

Pregnant women or women up to 2 weeks postpartum (including following pregnancy loss) with suspected influenza should be treated with antiviral medications as early as

possible in the course of their illness and at any point in their pregnancy. Treatment should not wait for laboratory confirmation of influenza.

- [CDC: Updated Interim Recommendations for Obstetric Health Care Providers Related to Use of Antiviral Medications in the Treatment and Prevention of Influenza for the 2009-2010 Season](#)

Informational Materials for Patients and Parents/Caregivers

- [CDC: Q&A for Caregivers: Opening and Mixing Tamiflu Capsules with Liquids if Child Cannot Swallow Capsules](#)
- CDC: Caregiver Instruction Sheet: Opening and Mixing Tamiflu Capsules with Liquids if Child Cannot Swallow Capsules (available soon)
- [CDC: Opening and Mixing Tamiflu Capsules with Liquids if Child Cannot Swallow Capsules](#)
- [CDC: H1N1 Flu \(Swine Flu\): Resources for Pregnant Women](#)
- [FDA Drug Safety Information: Tamiflu: Consumer Questions and Answers](#) 
- [FDA Drug Safety Information: Relenza: Consumer Questions and Answers](#) 