

**2009 H1N1 Influenza
Updated Key Points
September 18, 2009**

What's New and Updated

- Activity Update
- International Situation Update
- Antiviral Supply
- 2009 H1N1 Influenza Vaccine
- 2009 H1N1 Influenza Vaccine Safety
- Seasonal Influenza Vaccine

A Summary of CDC Key Public Health Messages this Season

- **(Updated)** Flu activity is increasing in most of the United States with nearly half of all states reporting widespread influenza activity.
- CDC recommends a three-step approach to fighting the flu: vaccination, everyday preventive actions including frequent hand washing and staying home when sick, and the correct use of antiviral drugs if your doctor recommends them.
- This strategy is summarized in a "Take 3 actions" message:

#1 Take time to get vaccinated.

- CDC recommends a yearly seasonal flu vaccine as the first and most important step in protecting against seasonal flu.
- The seasonal flu vaccine protects against the three seasonal influenza viruses that research suggests will be most common during the flu season. (Note: the seasonal flu vaccine does not protect against 2009 H1N1 flu).
- People should get vaccinated for seasonal flu as soon as the vaccine is available from their health care provider.
- Annual flu vaccination is especially important for people at high risk of serious flu complications, including young children, pregnant women, people with certain chronic health conditions like asthma, diabetes or heart and lung disease, neurologic conditions and older adults.
- Seasonal flu vaccine also is important for health care workers and other people who live with or care for high risk people to prevent giving the flu to those at high risk.
- A seasonal vaccine will not protect you against 2009 H1N1 flu.
- A new vaccine against 2009 H1N1 flu is being produced and will be available in the coming months as our best option for prevention of 2009 H1N1 infection.

**2009 H1N1 Influenza
Updated Key Points
September 18, 2009**

■ 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. 2009 H1N1 flu vaccine is important for close contacts of infants less than 6 months of age and healthcare and emergency medical services personnel.

#2 Take everyday preventive actions.

- Cover your nose and mouth with a tissue when you cough or sneeze. Throw the tissue in the trash after you use it.
- Wash your hands often with soap and water. If soap and water are not available, use an alcohol-based hand rub.
- Avoid touching your eyes, nose and mouth. Germs spread this way.
- Try to avoid close contact with sick people.
- If you are sick with flu-like illness, CDC recommends that you stay home for at least 24 hours after your fever is gone, except to get medical care or for other necessities. (Your fever should be gone without the use of a fever-reducing medicine.) Keep away from others as much as possible. This is to keep from making others sick.
- While sick, limit contact with others to keep from infecting them.

#3 Take flu antiviral drugs if your doctor prescribes them.

- Some people who get seasonal or 2009 H1N1 flu will be recommended by their doctor to be treated with antiviral drugs.
- Antiviral drugs are prescription medicines (pills, liquid or an inhaled powder) that fight against the flu by keeping flu viruses from reproducing in your body.
- Antiviral drugs can make your illness milder and make you feel better faster. They may also prevent serious flu complications.
- Antiviral drugs are not sold over-the-counter. You must get them from your health care provider.
- Antiviral are different from antibiotics.
- Antiviral drugs are recommended especially for people who are very sick (hospitalized) or people who are sick with flu-like symptoms and who are at increased risk of serious flu complications, such as pregnant women, young children, people 65 and older, and people with chronic health conditions.

**2009 H1N1 Influenza
Updated Key Points
September 18, 2009**

- For treatment, antiviral drugs work best if started within the first 2 days of symptoms.

Activity Update

- Each week CDC analyzes information about influenza disease activity in the United States and publishes findings of key flu indicators in a report called [FluView](#).
- Information collected during the week of September 6-12, 2009 is reported in FluView on September 18, 2009.
- A review of the key indicators from the most recent week's data found that influenza activity continued to increase in the United States compared to the prior weeks.
- Visits to doctors for influenza-like illness (ILI) are increasing nationally. In addition, visits to doctors for influenza-like illness are higher than what is expected during this time of year and have increased for five consecutive weeks now. This is very unusual for this time of year.
- Total influenza hospitalization rates for adults and children are similar to or lower than seasonal influenza hospitalization rates depending on age group, but are higher than expected at this time of year.
- The proportion of deaths attributed to pneumonia and influenza (P&I) was low and within the bounds of what is expected at this time of year.
- Twenty-one states (Alabama, Alaska, Arizona, Arkansas, Florida, Georgia, Illinois, Kansas, Kentucky, Louisiana, Maryland, Minnesota, Mississippi, Nevada, New Mexico, North Carolina, Oklahoma, Pennsylvania, South Carolina, Tennessee, and Virginia) are reporting widespread influenza activity at this time.
- Any reports of widespread influenza activity in September are very unusual.
- Almost all of the influenza viruses identified so far are 2009 H1N1 influenza A viruses.
- These 2009 H1N1 viruses remain similar to the viruses chosen for the 2009 H1N1 vaccine, and remain susceptible to the antiviral drugs oseltamivir and zanamivir with rare exception.
- On August 29, 2009, CDC closed out reports of 2009 H1N1 hospitalizations and deaths for the 2008-09 season.

**2009 H1N1 Influenza
Updated Key Points
September 18, 2009**

- Effective August 30, 2009, CDC began compiling information from states related to **all** influenza and pneumonia-associated hospitalizations and deaths for the 2009-2010 season using new case definitions.
- The number of influenza and pneumonia-related hospitalizations and deaths reported in this new system is 4,569 hospitalizations and 364 deaths.
 - This includes 3,524 hospitalizations and 291 deaths defined by influenza and pneumonia syndrome; and
 - 1,035 hospitalizations and 73 deaths confirmed by influenza laboratory tests.
- More information on how hospitalizations and deaths are being reported this season is included below and at <http://www.cdc.gov/h1n1flu/reportingqa.htm>
- During Week 36 (the week ending September 12, 2009), two influenza-associated pediatric deaths were reported to CDC.
 - These deaths occurred in Kansas and Tennessee, and both were associated with 2009 H1N1 virus infection.
 - These deaths occurred between August 23 and September 12, 2009.
- Since September 28, 2008, CDC has received 114 reports of laboratory confirmed influenza-associated pediatric deaths that occurred during the 2008-09 influenza season, 46 of these deaths were due to 2009 H1N1 influenza virus infections.
- CDC anticipates that 2009 H1N1 influenza viruses will co-circulate with regular seasonal influenza viruses over our influenza season.
- The timing, spread and severity of 2009 H1N1 virus – in addition to our regular seasonal influenza viruses – are uncertain.

International Situation Update

- The 2009 H1N1 influenza virus is the predominant influenza virus in circulation worldwide.
- The epidemiology of the disease caused by the 2009 H1N1 influenza virus in the Southern Hemisphere is very similar to that described in the United States this past spring.

**2009 H1N1 Influenza
Updated Key Points
September 18, 2009**

- There have been no significant changes detected in the 2009 H1N1 influenza virus isolated from persons in the Southern Hemisphere as compared to viruses isolated from persons in the Northern Hemisphere.
- In August, a White House report was prepared by the Department of Health and Human Services (HHS) in coordination with the Office of the Director for National Intelligence (ODNI) and the Department of State (DoS) and describes the characteristics and impact of 2009 H1N1 influenza A virus in the Southern Hemisphere. This report is available at <http://www.flu.gov/professional/global/southernhemisphere.html>.
- Worldwide, more than 10,000 isolates of 2009 H1N1 influenza have been tested and found to be sensitive to oseltamivir, an antiviral medicine used to treat influenza disease. Only 21 2009 H1N1 isolates tested have been found to be resistant to oseltamivir –10 of these were detected in the United States.
- As of September 13, 2009, the World Health Organization (WHO) regions have reported more than 296,471 laboratory-confirmed cases of 2009 H1N1 influenza virus (2009 H1N1) with at least 3,486 deaths, which is an increase of at least 18,864 cases and 281 deaths since September 6th. The laboratory-confirmed cases represent a substantial underestimation of total cases in the world, as many countries focus surveillance and laboratory testing only on people with severe illness.
- The 2009 H1N1 influenza virus continues to be the dominant influenza virus in circulation in the world. Since April 2009, 60.7% of influenza specimens reported to WHO were 2009 H1N1 viruses. In temperate regions of the Southern Hemisphere, disease due to 2009 H1N1 is largely declining. In tropical regions, there is still substantial disease due to 2009 H1N1. In temperate regions of the Northern Hemisphere, there is some increased disease activity due to 2009 H1N1, including in parts of the United States, Canada and Europe.

Antiviral Supply

- At this time, discussions with the antiviral supply chain (manufacturers, distributors and retailers) indicate that supplies of adult formulation (75 mg) oseltamivir (Tamiflu®) and zanamivir (Relenza®) are meeting current demand for this product.
- However, the Food and Drug Administration (FDA) and Roche (maker of Tamiflu®) have acknowledged that commercial and stockpiled supplies of Tamiflu® oral suspension (pediatric liquid formulation) are limited.

**2009 H1N1 Influenza
Updated Key Points
September 18, 2009**

- FDA has posted a statement on their website at <http://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm100228.htm> to remind health care providers and pharmacists of the FDA-approved instructions for the emergency compounding of an oral suspension from Tamiflu® 75mg capsules as described in the FDA approved manufacturer package insert for oseltamivir (Tamiflu®).
- Compounding is the mixing of drugs by a health care professional to fit the unique needs of a patient.
- Compounding an oral suspension from Tamiflu® 75mg capsules provides an alternative oral suspension when commercially manufactured oral suspension formulation is not readily available.
- Alternatively, for children who may not be able to swallow capsules, Tamiflu® 30mg and 45mg capsules also may be opened and mixed with sweetened liquids, such as regular or sugar-free chocolate syrup, if oral suspension is not available.
- Over the course of this pandemic, it is possible that in areas experiencing widespread flu activity, there may be temporary limited availability of some antiviral medications.
- CDC is developing a tool to assess antiviral supply that may be used over the course of the pandemic.
- CDC has coordinated with manufacturers, distributors and retailers to gather information on available quantities of certain medical supplies, including antiviral drugs.
- CDC will use this information to get a national picture of commercial availability of certain medical supplies, including antiviral drugs.
- The goal of the tool is to improve information about the commercial supply of certain medical supplies to help inform decision-making about when the Strategic National Stockpile (SNS) should be released.
- CDC also will be working with pharmacists and clinicians to improve awareness about the option to compound adult formulation of Tamiflu to create an alternative pediatric suspension (i.e., liquid) formulation.
- In the spring of 2009, CDC deployed 25 percent of the pandemic influenza supplies in the SNS to all U.S. states and territories. These included antiviral drugs (11 million treatment courses), personal protective equipment and respiratory protection devices.

2009 H1N1 Influenza Updated Key Points September 18, 2009

- States also purchased 24 million courses of antiviral drugs for use in a pandemic from HHS subsidized contracts in addition to what was distributed through the SNS.
- There has been very modest use of the supplies deployed in the spring.
- As of September 15, 2009, the U.S. Strategic National Stockpile has 49.9 million treatment courses of antiviral drugs. This total includes the replenishment of the antiviral drugs that were deployed in April. This replenishment is nearly complete.
- SNS assets will be made available to distribute to states and territories if it becomes necessary.
- Antiviral drugs are prescription medicines (pills, liquid or an inhaled powder) that fight against the flu by keeping flu viruses from reproducing in your body.
- Antiviral drugs can make illness milder and shorten the time you are sick. They can also prevent serious flu complications.
- For treatment, antiviral drugs work best if started within the first 2 days of symptoms.
- It's important for the public to remember that most people sick with 2009 H1N1 influenza have recovered without medical care or antiviral drugs, and the same is true of seasonal flu.
- The priority use for antiviral drugs this season is to treat people who are very sick (hospitalized) or people who are sick with flu-like symptoms and who are at increased risk of serious flu complications, such as pregnant women, very young children, people 65 and older and people with chronic health conditions.

2009 H1N1 Influenza Vaccine

- **(New)** The U.S. Food and Drug Administration announced the approval of four vaccines against the 2009 H1N1 influenza virus.
- **(New)** The vaccines that are made by each manufacturer cover the following groups:

Manufacturer: Sanofi Pasteur, Inc.

Indication: Vaccination of persons 6 months of age and older against influenza disease caused by 2009 H1N1 virus.

**2009 H1N1 Influenza
Updated Key Points
September 18, 2009**

Manufacturer: Novartis Vaccines and Diagnostics Limited

Indication: Vaccination of persons 4 years of age and older against influenza disease caused by 2009 H1N1 virus.

Manufacturer: MedImmune LLC

Indication: Vaccination of individuals 2-49 years of age against influenza disease caused by pandemic 2009 H1N1 virus.

Manufacturer: CSL Limited

Indication: Vaccination of persons ages 18 years of age and older against influenza disease caused by 2009 H1N1 virus.

- **(New)** All four manufacturers of the 2009 H1N1 vaccines are using the same processes that they use for making the seasonal flu vaccines, which have a long record of producing safe seasonal influenza vaccines.
- **(New)** Data from trials among children are not available at this time, so dosing schedules for children are not yet known. Data from trials among children will be available soon and will help determine recommendations for one versus two doses in children. As with seasonal vaccine, children ages 6 months through 35 months get two doses of 2009 H1N1 flu vaccine that contains one-half the dose used for older children and adults.
- Approximately 45 million doses of licensed vaccine are expected to be available by mid-October 2009, and doses will continue to become available through December. The federal government has purchased a total of 195 million doses of the vaccine.
- The national vaccine program will be voluntary. Those interested in vaccination for themselves or their children will receive accurate information about 2009 H1N1 influenza and the vaccine's benefits and risks so they can make an informed decision.
- A report in the August 21, 2009, Morbidity and Mortality Weekly Report (MMWR) provides official recommendations by CDC's Advisory Committee on Immunization Practices (ACIP) regarding the use of vaccine against 2009 H1N1 influenza.
- The guiding principle of these recommendations is to vaccinate as many persons as possible as quickly as possible. Vaccination efforts should begin as soon as vaccine is available.
- Highlights of these recommendations include 1) the identification of five initial target groups for vaccination efforts comprising an estimated 159 million persons (pregnant women, persons who live with or provide care for infants aged <6 months, health-care and emergency medical services

2009 H1N1 Influenza Updated Key Points September 18, 2009

personnel, children and young adults aged 6 months–24 years, and persons aged 25–64 years who have medical conditions that put them at higher risk for influenza-related complications), 2) establishment of priority for a subset of persons within the initial target groups in the event that initial vaccine availability is unable to meet demand, and 3) guidance on use of vaccine in other adult population groups as vaccine availability increases.

- **(New)** The recommendations are broad and allow for flexibility to accommodate local variability in vaccine needs and demands. Providers should be aware of and follow any additional guidance provided by their state or local health departments. If no additional guidance is provided at the state or local level, providers should vaccinate among the initial target group populations on a first come, first served basis.
- Simultaneous administration of inactivated vaccines against seasonal and the 2009 H1N1 influenza viruses is permissible if different anatomic sites are used. However, simultaneous administration of live, attenuated vaccines against seasonal and 2009 H1N1 influenza viruses is not recommended.
- Because vaccine availability is expected to increase over time and the number of vaccine doses needed is yet not established for all groups, vaccine should not be held in reserve for patients who received one dose and might require a second dose.

2009 H1N1 Flu Vaccine & People age 65 and over

- **(Updated)** Younger people are more likely to get infected with the 2009 H1N1 influenza virus than those aged 65 years and older. Therefore, younger persons are recommended to receive the first available doses of 2009 H1N1 influenza vaccine before persons aged 65 years and older.
- CDC's priority for people 65 and older is to have them get their seasonal influenza vaccine as soon as it is available.
- While people 65 and older aren't included in the high risk groups to be prioritized for 2009 H1N1 influenza vaccination, they can get the 2009 H1N1 influenza vaccine as soon as the high-risk groups have had the opportunity to be vaccinated and should not delay in seeking medical treatment if they develop symptoms of influenza.

2009 H1N1 Influenza Vaccine Safety

General H1N1 Vaccine Safety

**2009 H1N1 Influenza
Updated Key Points
September 18, 2009**

- **(New)** We expect the 2009 H1N1 influenza vaccine to have a similar safety profile as seasonal flu vaccines, which have a very good safety track record.
- **(New)** CDC expects that any serious side effects following vaccination with the 2009 H1N1 influenza vaccine would be rare.
- **(New)** If side effects occur, they will likely be similar to those experienced following seasonal influenza vaccine.

Vaccine Safety Monitoring

- **(New)** The CDC and FDA closely monitor the safety of seasonal influenza and other vaccines licensed for use in the United States in cooperation with state and local health departments, healthcare providers, and other partners.
- Vaccine safety monitoring is a complex process that uses both active and passive surveillance.
- Vaccine safety monitoring includes reviewing adverse events reported by providers, manufacturers, people who were vaccinated or their caregivers, and comparing the rate of these adverse events to the background rates (the rates at which they normally occur in the population).
 - An adverse event is a medical incident that happens after an immunization.
 - Adverse events may be coincidental (meaning occurring around the same time but not related to vaccination) or caused by vaccination.
 - Adverse events can be reported by providers, manufacturers, people who were vaccinated or their caregivers.
- The purpose of vaccine safety monitoring is timely identification of any clinically significant adverse events following immunization, as well as to provide timely information to the public, vaccine providers, public health officials, and policy makers.
- CDC and its partners will use several systems to monitor the safety of 2009 H1N1 influenza vaccine. Two primary systems that will be used are the Vaccine Adverse Event Reporting System (VAERS), which is jointly operated with FDA, and the Vaccine Safety Datalink (VSD) Project.

**2009 H1N1 Influenza
Updated Key Points
September 18, 2009**

- Additionally, CDC will conduct surveillance of adverse events through partnerships with other federal agencies, professional organizations, and academic institutions.

Adjuvants

- Some vaccines contain “adjuvants,” which are ingredients that help boost the vaccine’s potency. As a result, a smaller amount of vaccine is needed per person, and therefore, the vaccine supply can be used to reach more people.
- **(New)** According to current federal plans, only unadjuvanted vaccines will be used in the United States during the 2009 flu season.
- **(New)** This includes all of the 2009 H1N1 and seasonal influenza vaccines that will be available for children and adults in both the injectable and nasal spray formulations. None of these influenza vaccines that will be used in the U.S. during the 2009-10 season will contain adjuvants.
- Studies of 2009 H1N1 influenza vaccines with adjuvants are being conducted to determine if 2009 H1N1 influenza vaccines with adjuvants meet safety and efficacy requirements for use in the United States.

Thimerosal

- Thimerosal is a mercury-based preservative that is used in some influenza vaccines to keep them free from contamination of microorganisms.
- **(Updated)** The 2009 H1N1 influenza vaccine is being manufactured in several formulations.
 - Various vaccine manufacturers will be producing some of the 2009 H1N1 influenza vaccine in single-dose units, which will not require the use of thimerosal as a preservative. In addition, the live-attenuated version of the vaccine, which is administered intranasally (through the nose), is produced in single-units and will not contain thimerosal.
 - Some vaccine will come in multi-dose vials and will contain thimerosal as a preservative.
- Multi-dose vials of seasonal influenza vaccine contain thimerosal to prevent potential contamination after the vial is opened. Seasonal flu vaccines that do not contain thimerosal are available.

**2009 H1N1 Influenza
Updated Key Points
September 18, 2009**

Guillain-Barré syndrome (GBS)

- Guillain-Barré syndrome (GBS) is a medical condition in which the body damages its own nerve cells, causing muscle weakness and sometimes paralysis. Most people who develop GBS fully recover, but in some cases, death can result, usually from difficulty breathing.
- It is not fully understood why some people develop GBS, but it often occurs following infection. It is believed that stimulation of the body's immune system may play a role in its development.
- The infection that most commonly precedes GBS is caused by a bacterium called *Campylobacter jejuni*. Influenza virus infection has also been associated with GBS.
- In 1976, there was a small risk of GBS following influenza (swine flu) vaccination (approximately 1 additional case per 100,000 people who received the swine flu vaccine). That number of GBS cases was slightly higher than the background rate for GBS. Since then, numerous studies have been done to evaluate if other flu vaccines were associated with GBS. In most studies, no association was found, but two studies suggested that approximately 1 additional person out of 1 million vaccinated people may be at risk for GBS associated with the seasonal influenza vaccine.
- FDA and CDC and several partners will be closely monitoring reports of serious vaccine adverse events, including GBS, following the 2009 H1N1 influenza vaccination.

Seasonal Influenza Vaccine

- The new 2009 H1N1 influenza virus is a reminder of the unpredictable nature of influenza, and the importance of prevention.
- While the 2009 H1N1 influenza virus has been the focus of attention since the spring, it is important that we do not forget the risks posed by seasonal influenza viruses. As always, seasonal flu viruses will circulate this season.
- **(Updated)** We hope that people, especially those at high risk for serious complications and their close contacts, will seek seasonal flu vaccines now or as soon as vaccine is available in their communities.
- The seasonal influenza vaccine will be available earlier than the 2009 H1N1 influenza vaccine. The usual seasonal influenza viruses are still expected to cause illness this fall and winter.

**2009 H1N1 Influenza
Updated Key Points
September 18, 2009**

- **(Updated)** Seasonal flu vaccine is now available in various areas. Individuals are encouraged to get their seasonal flu vaccine as soon as it becomes available in their community.

Seasonal Flu Vaccine & People age 65 and over

- People age 65 years and over are at increased risk for complications from seasonal influenza and are recommended for annual seasonal flu vaccines. This year is no exception.
- CDC's priority for people 65 and older is to have them get their seasonal flu vaccine first, before the 2009 H1N1 flu vaccine is available.

Supply and Distribution

- At the current time, six influenza vaccine manufacturers are projecting as many as 114-115 million doses of seasonal influenza vaccine will be available from currently licensed manufacturers in the United States for use during the 2009-10 influenza season.
- Manufacturers project producing approximately 50 million doses of thimerosal-free, or preservative-free, seasonal influenza vaccine.
- **(Updated)** Approximately 54 million doses of seasonal flu vaccine have been distributed, as of September 11, 2009.
- Manufacturer projections indicate that the vast majority of vaccine will be distributed by the end of October. However, some vaccine distribution may continue into November, including doses that are ordered during the fall.
- CDC's seasonal influenza web site is now live at <http://www.cdc.gov/flu> with a new design, the latest information updates, and free resources.