

Updated 2009 H1N1 key points

Source: CDC IMS JIC Public Health Workforce

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What's New and Updated

- CDC Estimates of 2009 H1N1 Cases, Hospitalizations and Deaths
- 2009 H1N1 and Diabetes
- Morbidity and Mortality Weekly Report (MMWR): Update: Influenza Activity – United States, August 30-October 31, 2009
- Morbidity and Mortality Weekly Report (MMWR): Effect of 2008-09 Seasonal Influenza Vaccination on Risk of 2009 Pandemic Influenza A (H1N1)
- 2009 H1N1 Influenza Vaccine
- 2009 H1N1 Influenza Vaccine Safety

A Summary of CDC Key Public Health Messages this Season

- Flu activity remains high in the United States. Forty-eight states are reporting widespread flu activity. Nationally, visits to doctors for influenza-like-illness declined slightly from last week, but are still very high. Flu-related hospitalizations and deaths continue to increase and are very high nation-wide compared to what is expected for this time of year
- While influenza is unpredictable, high levels of influenza activity may continue for several weeks, and even after flu activity peaks, it's possible that one or more additional waves of influenza activity may occur – caused by either 2009 H1N1 viruses or regular seasonal flu viruses.
- CDC recommends a three-step approach to fighting the flu:
 - vaccination;
 - everyday preventive actions, including covering coughs and sneezes, frequent hand washing, and staying home when sick;
 - and the correct use of antiviral drugs if your doctor recommends them.
- 2009 H1N1 vaccination has begun. Supplies are increasing daily, but remain limited. We ask members of the public who want to receive this vaccine to be patient as this program expands and more vaccine becomes available. There will be enough vaccine available for anyone who wishes to receive it.

CDC Estimates of 2009 H1N1 Cases, Hospitalizations, and Deaths

- CDC has developed a method to provide an estimated range of the total number of 2009 H1N1 cases, hospitalizations and deaths in the United States from April



through October 17, 2009 as well as a breakdown of these estimates by age groups.

- It's important to note that these figures are **estimates**.
- This method uses actual surveillance data on 2009 H1N1 hospitalizations collected through CDC's Emerging Infections Program (EIP), which conducts surveillance for laboratory-confirmed influenza-related hospitalizations in children and adults.
- This method corrects surveillance data for underreporting using previously-published multipliers.
- Throughout the remainder of the 2009 H1N1 pandemic CDC will update the range of estimated 2009 H1N1 cases, hospitalizations and deaths every three or four weeks.
- In addition, CDC will continue to provide weekly reports of influenza activity each Friday in FluView, including the number of laboratory confirmed hospitalizations and deaths, and will update the 2009 H1N1 Situation Update each Friday as well.
- It's important to note that this methodology is **not** a predictive tool and cannot be used to forecast the number of cases, hospitalizations and deaths that will occur going forward over the course of the pandemic because they are based on actual surveillance data.

The Numbers:

- Using methods to adjust for expected amounts of under-reporting, CDC estimates that between 14 million and 34 million cases of 2009 H1N1 occurred between April and October 17, 2009. The mid-level in this range is about 22 million people infected with 2009 H1N1.
- CDC estimates that between about 63,000 and 153,000 2009 H1N1-related hospitalizations occurred between April and October 17, 2009. The mid-level in this range is about 98,000 H1N1-related hospitalizations.
- CDC estimates that between about 2,500 and 6,000 2009 H1N1-related deaths occurred between April and October 17, 2009. The mid-level in this range is about 3,900 2009 H1N1-related deaths.
- *Note: Deaths have been rounded to the nearest hundred. Hospitalizations have been rounded to the nearest thousand and cases have been rounded to the nearest million.*
- While EIP data is reported weekly during influenza season, because the system is based on reviews of patients medical charts there are sometimes delays in reporting and it can take some time for all the data to fill in. That's why reporting on this will be somewhat delayed. (For example today we are



reporting on data through October 17, since most of the data through that date has filled in at this time.)

- The number of cases, hospitalizations and deaths is occurring overwhelmingly in people 64 years and younger.
- This is very different from seasonal influenza when about 60 percent of seasonal flu-related hospitalizations and 90 percent of flu-related deaths (~36,000) occur in people 65 years and older.
- The results of this method help illustrate that the burden of disease associated with 2009 H1N1 virus is greater among younger persons and relatively less among persons 65 years and older compared with seasonal flu.
- The numbers generated by this method underscore the continued importance of the 2009 H1N1 vaccination program and support the recommended target groups for vaccination.
- Since the 2009 H1N1 pandemic began in April, states have reported 2009 H1N1 hospitalizations and deaths to CDC. Also, since the 2003-04 season, states have reported laboratory-confirmed influenza-associated deaths among children younger than 18 years of age to CDC.
- Cumulative reports of laboratory-confirmed 2009 H1N1 hospitalizations and deaths for the same period used (April through October 17, 2009), are 17,283 hospitalizations and 1,004 deaths. Cumulative 2009 H1N1 laboratory-confirmed pediatric deaths is 129 as of October 31 (with another 15 deaths attributed to influenza A, unsubtype).
- CDC has noted consistently since the beginning of this outbreak that laboratory-confirmed data on hospitalizations and deaths reported to CDC is an underestimation of the true number that have occurred likely due to a combination of incomplete testing, use of influenza tests that are not highly sensitive, or diagnoses that attribute hospitalizations and deaths to other causes, for example, secondary complications to influenza.
- While it may never be possible to validate the accuracy of these figures, the estimated ranges generated by this methodology provide a sense of scale in terms of the burden of disease caused by 2009 H1N1, and can provide an estimate of changes over time.
- The numbers generated by this method underscore the continued importance of the 2009 H1N1 vaccination program.
- More information about this can be found at www.cdc.gov/h1n1flu.



2009 H1N1 and Diabetes

- November is American Diabetes Month—a time to shine a spotlight on a serious disease that leads to potentially life-threatening complications such as heart disease, stroke, kidney disease, blindness, and amputation.
- People with diabetes are at increased risk for severe complications of influenza (both seasonal and 2009 H1N1) and account for approximately 12% of 2009 H1N1 hospitalizations in the United States.
- All people with all types of diabetes who are 6 months through 64 years of age should get vaccinated with the 2009 H1N1 flu shot. As supplies of the 2009 H1N1 vaccine increase, people 65 years of age and older also should get the 2009 H1N1 vaccine. All people with diabetes who are 6 months of age and older, including people 65 years of age and older, should get the vaccine “shot” for seasonal flu
- People with diabetes should not get the live attenuated influenza vaccine (LAIV), also known as the nasal spray vaccine, for either seasonal flu or 2009 H1N1.
- People with diabetes with suspected 2009 H1N1 infection should be treated promptly with antiviral drugs oseltamivir or zanamivir. Earlier treatment, preferably within 48 hours of onset of symptoms, is most beneficial but people with diabetes who present for care even after 48 hours and who are not improving or getting worse should also be treated.
- Health providers should not wait for a confirmed laboratory diagnosis of 2009 H1N1 before starting antiviral medications.
- Any patient who is hospitalized with suspected influenza, including persons with diabetes, should be treated with antiviral medications even if they have been ill for more than 48 hours.
- Because some people with influenza can have bacterial complications of influenza infection, including pneumonia, ear and sinus infections, clinicians may also consider appropriate antibiotic treatment if clinically indicated.
- Persons with diabetes need to follow an updated diabetes management plan created with their doctor, which includes specific sick day guidelines.
- In addition to getting vaccinated, people with diabetes should also take everyday precautions to protect against the flu, such as frequent hand washing.
- For people who are ill, good health habits like covering your cough and washing your hands often can help reduce the spread of germs. Those who are ill are also reminded to stay home except to receive medical care or other necessities. They should not return to work or school until fever has been gone for at least 24 hours without the use of fever reducing medications.
- Obesity is a risk factor for some types of diabetes. Preliminary studies suggest that people who are obese (body mass index ≥ 30) and specially those who



are morbidly obese (body mass index ≥ 40) might also be at increased risk of hospitalization and death due to 2009 H1N1 influenza infection.

2009 H1N1 and Diabetes Hospitalizations

- Emerging Infections Program (EIP) data collected from April 15 – November 3, 2009, shows the following:
 - 12% of people hospitalized with 2009 H1N1 have diabetes.
 - Among adults hospitalized with 2009 H1N1, 19% had diabetes.
 - Among children hospitalized with 2009 H1N1, 2% had diabetes.
 - The following data applies to intensive care unit admissions:
 - 24% of hospitalized people with diabetes and a 2009 H1N1 infection were admitted to an intensive care unit (ICU).
 - No significant differences in the number of ICU admissions were noted between 2009 H1N1 infected people hospitalized with or without diabetes.
 - 75% of hospitalized people with diabetes were treated with influenza antiviral drugs.
 - No difference in antiviral use was observed between adults with or without diabetes who were hospitalized with influenza

BRFSS Weighted Data

- A nationwide interview from September 1 – October 26 showed that 7.05 % of persons with diabetes report influenza like illness in the last month compared to 6.69% in the general population.
 - 45.2% of those respondents with influenza like illness and diabetes report visiting a doctor, nurse, or other health professional for this illness.

Morbidity and Mortality Weekly Report (MMWR): Update: Influenza Activity – United States, August 30-October 31, 2009

Influenza activity was substantially above historic levels in all U.S. surveillance systems.



- During August 30-October 31, 672 **deaths associated with laboratory-confirmed influenza virus infections** were reported to CDC through an aggregate state-level reporting system. The 672 laboratory-confirmed deaths are in addition to the 593 laboratory-confirmed deaths from 2009 H1N1 virus that were reported by states to CDC from April through August 30, 2009. (*Note: Laboratory confirmed deaths are known to be an under-report of actual deaths that have occurred*).
- During August 30-October 31, 17,838 **hospitalizations associated with laboratory-confirmed influenza virus infections** were reported to CDC through an aggregate state-level reporting system.
- **Influenza-associated hospitalization rates** continued to trend upward in all age groups, substantially above historic rates from the same time period during previous years.
- During September-October, **cumulative influenza hospitalization rates** for persons aged <65 years were substantially elevated for this time of year and exceeded or were approaching the end-of-season cumulative rates for the last three seasons.
- The weekly percentage of **outpatient visits for influenza-like illness (ILI)** reported by the U.S. Outpatient ILI Surveillance Network (ILINet) increased from 2.9% in the week ending September 5 to 7.7% in the week ending October 31.
- Nationwide, the percentage **of visits to health-care providers** for influenza-like illness was higher than that observed at the peak of any seasonal influenza season since ILINet was implemented in its current form in 1997.
- Of the 239 viruses that CDC has antigenically characterized since September 1, a total of 238 (99.6%) were antigenically related to the A/California/7/2009 (H1N1) reference virus selected by WHO as the 2009 H1N1 vaccine virus.

Severe outcomes, including among children, continue to be prominent during the 2009 H1N1 pandemic.



- A total of 145 pediatric deaths associated with influenza infection have been reported since the week ending April 26. (In comparison, 82 deaths were reported on average during the previous five influenza seasons).
- *During August 30-October 31*, CDC received 85 reports of pediatric deaths associated with influenza infection.
 - Seventy-three of the 85 reports were associated with laboratory-confirmed 2009 H1N1 virus.
 - Seventy-eight of the 85 reports had a medical history reported.
 - Fifty-six of the 78 were reported to have one or more medical conditions associated with an increased risk for influenza-related complications.
- Pediatric hospitalization rates are higher than those of any other age group and are particularly high among children younger than 5 years of age.

The current dominant influenza virus by far is 2009 H1N1; seasonal influenza viruses continue to circulate at low levels in the U.S. and elsewhere.

- *During August 30-October 31*, WHO and National Respiratory and Enteric Virus Surveillance System (NREVSS) collaborating laboratories in the U.S. tested 163,123 respiratory specimens for influenza viruses.
 - 48,585 (30%) of the specimens were positive for influenza.
 - 48,483 (99.8%) of the 48,585 specimens were positive for influenza A.
 - 32,867 (68%) of the 48,483 specimens were subtyped by real-time reverse transcription-polymerase chain reaction (rRT-PCR) or by virus culture.
 - Of the 32,867 specimens that were subtyped, a total of 32,814 (99.8%) of these were 2009 H1N1 viruses, 18 (0.1%) were seasonal influenza A (H1), and 35 (0.1%) were influenza A (H3) viruses.

Antiviral resistance

- Since September 1, a total of 256 2009 H1N1 virus isolates collected in the United States have been tested for resistance to influenza antiviral medications.
- All but 4 isolates were susceptible to oseltamivir, which brings the total number of resistant isolates to 14 since April 2009.
 - Twelve of the 14 patients from whom the resistant isolates were collected had documented exposure to oseltamivir through either treatment or chemoprophylaxis.



- All 256 tested viruses were sensitive to zanamivir.
- One influenza (H2N2) virus isolate and 152 2009 H1N1 virus isolates also have been tested for resistance to adamantanes and all of the virus isolates were resistant.

Morbidity and Mortality Weekly Report (MMWR): Effect of 2008-09 Seasonal Influenza Vaccination on Risk of 2009 Pandemic Influenza A (H1N1)

Background

- A number of studies have been conducted or are underway to examine whether vaccination with the 2008-09 seasonal flu vaccine decreases or increases people's risk of infection with 2009 H1N1 flu. A series of five related, but still unpublished, studies conducted in Canada received media attention after reporting that vaccination with the seasonal 2008-09 influenza vaccine was associated with a 1.5- to 2-fold greater risk of medically attended 2009 H1N1 infection.
- Other studies conducted in Australia* and New York (unpublished) found no evidence that receipt of seasonal influenza vaccine influenced the risk of being diagnosed with 2009 H1N1 infection. One hospital-based, case-control study conducted in Mexico** found that the 2008-09 seasonal flu vaccine provided protection (vaccine effectiveness 73%) against 2009 H1N1 illness. However, this study used hospital-based controls, and their results have not been replicated elsewhere. Serological studies conducted at CDC have shown that seasonal flu vaccines are unlikely to provide substantial cross-protection against infection with 2009 H1N1. It is still unknown how serologic results correlate with the complex immune responses that confer clinical protection against flu infection and illness.
- To complement these existing studies and to further address the question of whether vaccination with the 2008-09 seasonal flu vaccine impacts people's risk of infection with 2009 H1N1, CDC conducted this study.



Key Points

- To address the question of whether vaccination with the 2008-09 seasonal flu vaccine impacts people's risk of infection with laboratory confirmed*** 2009 H1N1 illness, CDC conducted a vaccine effectiveness study using surveillance data provided by eight states. This study has been published in the November 12, 2009, Morbidity and Mortality Weekly Report (MMWR0).
 - States who participated in the study include: Arizona, Colorado, Connecticut, Delaware, Kentucky, Pennsylvania, Texas and Virginia.
- Results of this study suggest that 2008-09 seasonal flu vaccination had no significant effect on the risk of illness with 2009 H1N1 flu.
 - No overall effect was found for seasonal influenza vaccination against 2009 H1N1. After adjustment for age group and presence of chronic medical conditions, the estimated vaccine effectiveness (VE) against lab confirmed 2009 H1N1 was -10% (95% CI: -43%, +15%).
 - Estimates of VE varied by age group, ranging from -57% to 15% and none were statistically different from zero (i.e., the results did not suggest an effect of vaccination). The 95% confidence intervals for each age-specific VE estimate were wider than for the overall VE because of reduced sample sizes within age groups).
- This study by CDC and state partners adds to the growing body of literature examining the effects of seasonal flu vaccine on the risk of illness with the 2009 H1N1.
- The findings of CDC's study are similar to the results of vaccine effectiveness studies conducted in Australia* and New York (unpublished), which also found no evidence that vaccination with the seasonal flu vaccine influences the risk of being diagnosed with 2009 H1N1 infection.
- Additional studies using more rigorous study designs and methods are currently underway in the United States and other countries. The results of these studies will further define seasonal influenza vaccine effectiveness against 2009 H1N1 flu infection and illness.
 - In addition, studies evaluating the effects of seasonal vaccination on infection with 2009 H1N1 viruses using established animal models for influenza (such as ferrets) are also underway at CDC and elsewhere.
- This season, CDC recommends vaccination with both seasonal vaccine and 2009 H1N1 to prevent flu illness during the 2009-2010 flu season in the United States.



Methodology

- A case-cohort analysis was used to evaluate the effectiveness of 2008-09 trivalent seasonal flu vaccine in preventing laboratory-confirmed 2009 H1N1 flu infections.
 - In this study design, CDC scientists looked at seasonal 2008-09 vaccination coverage in people with laboratory-confirmed 2009 H1N1 flu infections and compared this coverage to estimates of 2008-09 vaccination coverage in the state populations that participated in the study.
 - National influenza surveillance data along with Behavioral and Risk Factor Surveillance System (BRFSS)**** data collected from May-June 2009 was used in the study.
- Reports of people aged 18 years and older with 2009 H1N1 illness identified in eight states during May–June 2009 was compared with population estimates of 2008-09 seasonal flu vaccine coverage in these states.
- Vaccination coverage for people aged 18–29 years, 30–39 years, 40–49 years and 50 years and older was estimated for the eight selected states by using preliminary 2009 BRFSS data from a telephone survey of 20,689 respondents.
 - Respondents were considered vaccinated if 1) they said “yes” to either having a flu shot or nasal spray vaccine during the past 12 months, or 2) indicated that the month and year that they were vaccinated occurred from September 2009-February 2009.
- Only cases diagnosed in a state that has reported more than five 2009 H1N1 reports of people 18 years of age and older were eligible for inclusion in this study.
 - In order to be counted in the study, cases needed to have a date of birth, illness onset date, information about their vaccination status, and information related to whether or not the person had a chronic medical condition that increased his/her risk of flu complications.
 - Because BRFSS does not routinely collect vaccination status on children younger than 18 years old, and because BRFSS used residential landline telephone numbers, CDC’s analysis was limited to non-institutionalized adults 18 years of age and older.
- Vaccination coverage estimates were then adjusted by four age groups and by whether each participant in the study had a chronic medical condition that increased their risk of complications from flu.
- Among case patients 18 years of age and older, 28% had a chronic medical condition. Within each age group, vaccination coverage estimates were adjusted for chronic medical conditions that increase the risk of complications from flu



- Vaccine effectiveness was calculated as 1- RR (relative risk), where RR was the estimated adjusted risk of 2009 H1N1 illness as a function of seasonal vaccination coverage. Statistical software was used to estimate the BRFSS age-group related vaccination coverage for the eight states that participated in the study.

* Kelly H, Grant K. Interim analysis of pandemic influenza A (H1N1) 2009 in Australia: surveillance trends, age of infection and effectiveness of seasonal vaccination. *Euro Surveill* 2009; 14(31).

** Garcia-Garcia L., Valdespino-Gomez, JL. Lazcano-Ponce E, et al. Partial protection of seasonal trivalent inactivated vaccine against novel pandemic influenza A/H1N1 2009: case-control study in Mexico City. *BMJ* 2009;339:b3928

*** Laboratory confirmation was made using real-time reverse transcriptase polymerase chain reaction (rRT-PCR).

**** The Behavioral Risk Factor Surveillance System (BRFSS) is a state-based system of health surveys that collects information on health risk behaviors, preventive health practices, and health care access primarily related to chronic disease and injury.

BRFSS was established in 1984 by the Centers for Disease Control and Prevention (CDC); currently data are collected monthly in all 50 states, the District of Columbia, Puerto Rico, the U.S. Virgin Islands, and Guam.

More than 400,000 adults are interviewed each year, making the BRFSS the largest telephone health survey in the world. For more information about BRFSS, see <http://www.cdc.gov/brfss/>

2009 H1N1 Influenza Vaccine

In this Section:

- Supply
- Recommendations
- Research

Supply

- **(New)** CDC is now posting daily updates of the national totals of 2009 H1N1 vaccine supply status (aggregate number of doses allocated, ordered, and shipped). These numbers are updated by 4pm EST every day and posted at: <http://www.cdc.gov/h1n1flu/vaccination/vaccinesupply.htm>
- **(Updated)** As of Wednesday, November 11, 2009, there were a total of 36,983,500 doses ordered.



- **(Updated)** As of Thursday, November 12, 2009, a total of 41,641,400 doses were available for ordering. Of those available doses, 30,655,100 doses were injectable (flu shots) and 10,986,300 were LAIV (nasal spray vaccine).
- The vaccine situation changes rapidly – throughout each day, vaccine is being shipped from the vaccine manufacturers to McKesson distribution centers; orders are coming into McKesson; orders are being processed and shipped; and vaccine is arriving in thousands of places across the country.
- 2009 H1N1 vaccination has begun but initial supplies are small. More doses are expected for shipment each week. We ask members of the public who want to receive this vaccine to be patient as this program expands and more vaccine becomes available. There will be enough vaccine available for anyone who wishes to receive it.
- First doses of 2009 H1N1 vaccine were administered outside of the clinical trials on Monday, October 5, 2009.
- Initial doses of 2009 H1N1 “flu shot” were shipped the week of October 12, with additional doses scheduled for shipment each week.
- The challenges associated with the U.S. influenza vaccine supply are multi-faceted. Influenza viruses change from year to year, so influenza vaccines must be updated annually to include the viruses that research indicates are most likely to circulate in the upcoming season. Once the viruses are selected for the new formulation, manufacturers operate under a very tight timeline for producing, testing, releasing and distributing the vaccine. Due to these time constraints, any problems encountered during production may cause shortages or delays, and in fact, such problems have impacted the seasonal supply during some recent influenza seasons, and can occur with any type of influenza vaccine, including the 2009 H1N1 vaccine.
- The vaccine development process is complex and forecasting how much vaccine will be available at a certain time is challenging and amounts will vary from week to week. Millions of doses of vaccine are in the pipeline and federal, state and local public health authorities are working hard to get vaccine out to the public as soon as it is received.
- A decision had to be made between waiting to distribute vaccine until large quantities were ready to be shipped versus distributing limited quantities of the vaccine sooner. The latter was chosen knowing that it would create some challenges and frustrations (for our public health partners in the states, providers, and the public), but also knowing that it would allow for people to start being protected against this disease sooner.



- It also is important to keep in mind that there will be lag times between states placing orders and vaccine actually being distributed (we are not cutting corners in terms of steps like quality control checks) - and any number of things can create lag times between time of distribution to states and when vaccine actually arrives in provider offices or clinics.
- This vaccine program is a massive and challenging undertaking and is being carried out at a time when state and local health departments have experienced severe budget cuts.
- A new video podcast is now available on the CDC website; "H1N1 Flu Vaccine- Why the Delay?" explains how flu vaccines are made, manufactured, shipped and how people can find vaccine in their area. To watch the podcast, visit <http://www2c.cdc.gov/podcasts/player.asp?f=262894#> or <http://www.cdc.gov/Features/H1N1VaccineDelay/> on YouTube.
- The federal government allocates vaccine on a pro rata basis to state health departments and some big city health departments who then make decisions about how to distribute vaccine equitably and efficiently within their jurisdictions.
- Employee or workplace health clinics (among other locations) are a legitimate—and very effective—place to administer vaccine during a time of shortage. These clinics can and do reach and target people in priority vaccination groups, including pregnant women and 18 to 64 year workers with medical conditions that put them at higher risk for influenza complications.

Recommendations

- 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. This report is available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr58e0821a1.htm>
- The guiding principle of these recommendations is to vaccinate as many persons as possible as quickly as possible with an emphasis on vaccinating certain target groups with initial doses of vaccine.
- These recommendations:
 - 1) Identify five initial target groups for vaccination efforts comprising an estimated 159 million persons (pregnant women, persons who live with or provide care for infants younger than 6 months, health care and emergency medical services personnel, children and young adults aged 6 months through 24 years, and persons aged 25 through 64 years who have medical conditions that put them at higher risk for influenza-related complications),



2) Establish a priority subset of persons within the initial target groups in the event that initial vaccine availability is unable to meet demand, and

3) Provide guidance on use of 2009 H1N1 vaccine in other adult population groups as vaccine availability increases.

- 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 serve basis.
- Simultaneous administration of inactivated vaccines (shots) against seasonal and the 2009 H1N1 influenza viruses is permissible if different anatomic sites are used (for example, one vaccine in each arm).
- CDC has no recommendation regarding the administration of acetaminophen or other antipyretic drugs following influenza vaccination. You should follow the guidance of your physician or other health care provider.

Research on Public Knowledge, Attitudes and Beliefs

- A national poll with a representative sample of 1,073 adults aged 18 and over was conducted by the Harvard School of Public Health (HSPH) on October 30 through November 1, 2009. The poll asked about people's perceptions and experiences of trying to get the H1N1 vaccine for themselves or their children.
- 91% of the polling sample who were unable to get the 2009 H1N1 flu vaccine said that they will try again this year to get the vaccine for themselves, their children or both.
 - Even though there was only a limited amount of 2009 H1N1 vaccine available in early October, more vaccine will continue to become available over the upcoming weeks and months. Therefore, individuals who were unable to initially get the vaccine and plan to try again once more vaccine is available should contact various settings such as local health departments, healthcare provider websites and hotlines, schools, and other private settings, such as pharmacies and workplaces to see if the vaccine is available.
- To view a full report of the Harvard Poll press release, visit <http://www.hsph.harvard.edu/news/press-releases/>

2009 H1N1 Influenza Vaccine Safety

In this section:

- General H1N1 Vaccine Safety
- Vaccine Safety Monitoring



- Background Rates of Medical Events

General H1N1 Vaccine Safety

- CDC expects that the 2009 H1N1 influenza vaccines will have similar safety profiles as seasonal influenza vaccines, which have very good safety track records.
- The types and frequencies of side effects from the 2009 H1N1 influenza vaccine will likely be similar to those experienced following seasonal influenza vaccines which are mild, localized reactions.
- The most common side effects of the vaccines are pain, redness, or swelling where the shot was given in the arm or a runny nose and headache after the nasal spray.

Vaccine Safety Monitoring

- HHS released a report on the Federal Plans to Monitor Immunization Safety for the Pandemic 2009 H1N1 Influenza Vaccination Program:
http://flu.gov/professional/federal/monitor_immunization_safety.html
- CDC and its partners are using several systems to monitor the safety of 2009 H1N1 influenza vaccine. Two primary systems that are in use are the Vaccine Adverse Event Reporting System (VAERS), which is jointly operated with FDA, and the Vaccine Safety Datalink (VSD) Project.
- CDC has enhanced vaccine safety monitoring efforts in several ways:
 - The Vaccine Adverse Event Reporting System (VAERS) is a voluntary reporting system that identifies potential vaccine safety signals: healthcare providers are actively reminded to report suspected issues, and medical personnel are conducting daily reviews and follow-up [<http://vaers.hhs.gov>].
 - Second, a new Web-based active surveillance system is being implemented to prospectively follow tens of thousands of vaccinated people [www.myflushot.org].
 - Third, large population-based systems that link computerized vaccination data with healthcare codes will be used to conduct rapid and ongoing analyses. This approach includes data from large managed care plans, other health plans, Department of Defense, Medicare and the Veterans' Administration.
 - Fourth, active case finding for GBS is being conducted in 10 areas of the United States (a combined population of about 50 million people).
 - Findings from all sources are cross-referenced and reviewed by government and outside scientists to be sure any concerns are rapidly addressed.
- Vaccine safety monitoring includes reviewing adverse events reported by providers, manufacturers, people who were vaccinated or their caregivers.



- An adverse event following immunization is a medical incident that occurs after someone receives 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.

Background Rates of Medical Events

- Adverse events—such as sudden deaths, spontaneous abortions, and Guillain-Barré syndrome—will occur in the population. These will occur whether or not people have been vaccinated. In the context of vaccine safety monitoring, we call these naturally occurring events “background rates.”
- Awareness of the background rates of several adverse events is critical to assessing the safety of the vaccine. This information allows public health and medical experts to identify when adverse events are occurring more frequently than would be expected in the absence of vaccination and need more detailed investigation to determine if the vaccine is causing the adverse events.
- Background rates are helpful as a tool to assess vaccine safety by comparing the expected rate of adverse events to the actual/observed rate in any given timeframe once vaccination begins.
- Some clustering – a number of cases in a limited timeframe or area – of adverse events occurs normally, and we can expect this clustering to continue during the period that 2009 H1N1 vaccinations are given.
- By comparing the expected rate of adverse events to the actual/observed rate in any given timeframe, we can put adverse event reports in proper context.
- There are some limitations of background rates. Background rates can vary widely by location, age, sex and ethnicity, and therefore these factors should be considered when using background rates to compare events that occur following vaccination.
- Background rates by themselves usually are not sufficient as a way to fully assess vaccine safety. Full analysis requires review of individual reports and carefully controlled epidemiologic study.
- While background rates tell us that we cannot jump to conclusions or assume that any vaccine caused a particular health event, CDC takes every single adverse event report seriously and individually reviews all reports of serious adverse events so that potential problems can be quickly detected and investigated.



Seasonal Influenza Vaccine

- Two systems that look at seasonal influenza vaccinations administered and billed show that many more individuals have been vaccinated this season than at the same time last year. This is most likely due to the early availability of vaccine and public interest in getting vaccinated.
- CDC continues to recommend seasonal flu vaccination. Currently the vast majority of influenza being reported to CDC is 2009 H1N1. Influenza is very unpredictable but CDC expects both 2009 H1N1 flu and seasonal flu to cause illness, hospital stays and deaths this season.

Seasonal Influenza Vaccine Supply and Distribution

- Local areas may not have received as much vaccine as they anticipated at this point in the season and providers seeking additional vaccine now may be unable to purchase it. For more information about seasonal supply, please refer to IVATS (<http://www.preventinfluenza.org/ivats/>) over the coming weeks.
- The largest supplier of seasonal flu vaccine, Sanofi Pasteur is experiencing a delay in their shipments. Currently, the company has shipped more than half of the 50.5 million doses of Sanofi Pasteur seasonal flu vaccine ordered by U.S. health care providers. It could be November before customers receive their complete orders.
- CDC is working with manufacturers, states, and immunization providers to identify existing seasonal flu vaccine and get it to providers who can administer it to people who need and want it.
- Most will be able to obtain vaccine from their usual provider, but some will have to obtain the vaccine from an alternative provider
- **(Updated)** As of November 6, approximately 93.7 million doses of seasonal influenza vaccine have been distributed (this is about 82% of doses expected this season).
- At the current time, five influenza vaccine manufacturers are projecting as many as 114 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.
- 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 at <http://www.cdc.gov/flu> with a new design, the latest information updates, and free resources.
- (New) More information about seasonal flu vaccine supply can be found at: <http://www.cdc.gov/flu/professionals/vaccination/#supply>



Flu Activity May Occur in “Waves”

- The timing, spread and severity of influenza viruses is uncertain.
- Outbreaks of influenza may occur in different places at different times.
- Outbreaks may occur in waves of about 6-12 week time periods.
- These waves of influenza may occur over a year or so after the emergence of a new influenza virus.
- In past pandemics, “waves” of activity have been observed.
- The first wave is usually a smaller wave; followed by a larger “peak” wave. Subsequent smaller waves can occur as well.
- The United States experienced its first wave of 2009 H1N1 pandemic activity in the spring of 2009.
- At this time, we are experiencing a second wave of 2009 H1N1 activity.
- Flu activity is widespread in most of the country at this time, which is highly unusual during regular seasonal flu for this time of year, but not unexpected for a pandemic.
- Nationally, activity is continuing to increase.
- It’s not possible to predict how long activity will remain high, when this wave will peak and when activity will begin to decline.
- Even after flu activity peaks during the current wave, it’s possible that other waves of influenza activity may occur – caused by either 2009 H1N1 viruses or regular seasonal flu viruses.
- Because the timing and spread of influenza viruses are unpredictable, CDC is continuing to recommend vaccination with seasonal influenza vaccine and 2009 H1N1 vaccine for those people in whom it is recommended.

