

## **What's New and Updated**

2009 H1N1 and Asthma

2009 H1N1 Vaccine

2009 H1N1 Influenza Vaccine Safety

Seasonal Influenza Vaccine Supply and Distribution

## **A Summary of CDC Key Public Health Messages this Season**

- Flu activity is widespread in 48 states and nationally, reports of influenza-like illness continue to increase sharply in the United States. In addition, flu-related hospitalizations and flu-related deaths are higher than 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 other 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, 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 and more vaccine is being shipped 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.
- It's very important that antiviral drugs be used early to treat flu in people who are very sick (for example people who are in the hospital) and people who are sick with flu and have a greater chance of getting serious flu complications, like people with asthma, diabetes or people who are pregnant.

## **2009 H1N1 and Asthma (New)**

- Asthma affects 7.9% percent of the U.S. population and is the cause of nearly a half-million hospitalizations each year.
- People with asthma are at increased risk for severe complications of influenza, including 2009 H1N1 flu.
- People with asthma account for approximately 32% of 2009 H1N1 hospitalizations in the United States, according to recent data from the

Emerging Infections Program, a CDC surveillance system that tracks influenza-related hospitalizations.

- People with asthma need have their asthma well-controlled and should have an updated asthma action plan. Medication to control asthma (usually inhaled corticosteroids) should be used as prescribed by each patient's health care provider.
- Less than half of people with asthma seek treatment promptly when they are sick with flu-like symptoms.
- Because people with asthma are at higher risk of serious flu-related complications, they should seek treatment promptly when ill with either influenza like illness (ILI) or an asthma exacerbation.
- People with asthma with suspected 2009 H1N1 infection should be treated promptly with oseltamivir (trade name Tamiflu®). Zanamivir (trade name Relenza®) is not recommended for people with asthma.
- People with asthma should get the 2009 H1N1 flu shot (injectable, inactivated formulation only).
- People with asthma also are recommended to get the seasonal flu shot (injectable, inactivated formulation only).
- People with asthma should NOT get the live attenuated influenza vaccine (LAIV), also known as the nasal spray vaccine, for either seasonal flu or 2009 H1N1.

### **2009 H1N1 Hospitalizations in People with Asthma**

- People with asthma are at higher risk for serious complications from flu, including 2009 H1N1. As a result, people with asthma are at higher risk of hospitalization.
- CDC monitors 2009-H1N1 related hospitalizations among people with asthma through the Emerging Infections Program (EIP).
- The EIP Influenza Project conducts surveillance for laboratory-confirmed influenza-related hospitalizations in children and adults in 62 counties covering 13 metropolitan areas of 10 states.
  - This includes San Francisco, CA; Denver, CO; New Haven, CT; Atlanta, GA; Baltimore, MD; Minneapolis/St. Paul, MN;

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Albuquerque, NM; Santa Fe, NM, Las Cruces, NM; Albany, NY;  
Rochester, NY; Portland, OR; and Nashville, TN.

- Cases are identified by reviewing hospital laboratory and admission databases and infection control logs for children and adults with a documented positive influenza test\* conducted as a part of routine patient care. EIP estimated hospitalization rates are reported every week during the flu season.
- Emerging Infections Program (EIP) data collected from April 15 - October 27, 2009, shows the following:
  - 32% of people hospitalized with 2009 H1N1 have asthma.
    - Among adults hospitalized with 2009 H1N1, 30% had asthma,
    - Among children hospitalized with 2009 H1N1, 35% had asthma.
  - The following data applies to intensive care unit (ICU) admissions:
    - 21% of hospitalized adults with asthma and a 2009 H1N1 infection were admitted to an ICU.
    - 18% of hospitalized children with asthma and a 2009 H1N1 infection were admitted to an ICU.
    - No significant differences in the number of ICU admissions were noted between 2009 H1N1 infected people hospitalized with or without asthma.

### **2009 H1N1 Influenza Vaccine**

- **(New)** The aggregate number of 2009 H1N1 flu vaccine doses allocated are now being posted daily by 12:00 PM ET and are available at <http://www.cdc.gov/h1n1flu/vaccination/vaccinesupply.htm>.
- **(Updated)** As of Monday, November 2, 2009, there were a total of 25,159,000 doses ordered.
- **(Updated)** As of Tuesday, November 3, 2009, a total of 31,839,200 doses were available for ordering. Of those available doses, 22,682,300 doses were injectable (flu shots) and 9,156,900 were LAIV (nasal spray vaccine).
- All states and the District of Columbia have placed orders for vaccine, and more orders are expected daily.

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- 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.
- McKesson, the distributor for the 2009 H1N1 vaccine, is increasing the number of delivery sites from 90,000 to 150,000
- Initial doses of 2009 H1N1 “flu shot” were shipped the week of October 12, with additional doses scheduled for shipment each week.
- First doses of 2009 H1N1 vaccine were administered outside of the clinical trials on Monday, October 5, 2009.
- 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.

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- Thus, we have limited but increasing amounts of vaccine for states to order at the moment. Given this situation, states will initially be conducting very targeted vaccination efforts that take into consideration their local situation with 2009 H1N1 flu.
- 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. There will likely be bumps along the way, but we are optimistic that we will achieve our goal of making the 2009 H1N1 vaccine available to all of those who need and want it.
- **(New)** 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.
- Children younger than 10 years should receive two doses of 2009 H1N1 flu vaccine. This is slightly different from CDC's recommendations for seasonal influenza vaccination which state that children younger than 9 who are being vaccinated against influenza for the first time need to receive two doses. Infants younger than 6 months of age are too young to get the 2009 H1N1 and seasonal flu vaccines.
- CDC recommends that when two doses of flu vaccine are required, the two doses should be separated by 4 weeks. However, if the second dose is separated from the first dose by at least 21 days, the second dose can be considered valid.
- The national vaccine program is voluntary. Those interested in vaccination for themselves or their children will receive accurate information about 2009 H1N1 influenza vaccine 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. 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).

## **2009 H1N1 Influenza Vaccine Safety**

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### 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.

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- CDC expects that any serious side effects following vaccination with the 2009 H1N1 influenza vaccine would be rare.
- 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 (Updated)

- **(New)** 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](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](http://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* **(New)**

- 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 are not usually sufficient 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.

Guillain-Barré syndrome (GBS) (Updated)

- **(New)** A plain language fact sheet on GBS has been posted at [http://www.cdc.gov/h1n1flu/vaccination/factsheet\\_gbs.htm](http://www.cdc.gov/h1n1flu/vaccination/factsheet_gbs.htm)
- Guillain-Barré syndrome (GBS) is a rare disorder in which a person's own immune system damages the nerves, causing muscle weakness and sometimes paralysis.
- Each year, approximately 6,000 to 9,100 people in the United States get GBS whether or not they receive a vaccination. This means that about 140 people get GBS every week
- While it is not fully known what causes GBS, it is known that about two-thirds of people who get GBS do so several days or weeks after they have been sick with a diarrhea or lung and sinus infection
- An infection with the bacterium *Campylobacter jejuni*, which can cause diarrhea, is one of the most common illnesses associated with GBS. Although uncommon, people can also get GBS after having the flu.
- Most people recover fully from GBS, but some people have nerve damage that does not go away. In rare cases, people have died of GBS, usually from not being able to breathe due to weakness of the breathing muscles.

- In 1976, there was a small risk of GBS after getting an 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 1976, many studies have been done to evaluate if other flu vaccines were associated with GBS. In most studies, no association was found, but two studies did suggest that approximately 1 additional person out of 1 million vaccinated with the seasonal influenza vaccine may develop GBS. This continues to be studied. For the most part, the risk of getting severely ill from influenza illness far outweighs the risk of getting GBS following the flu vaccine.
- Since GBS is a serious disorder that people do get every year, CDC has developed several GBS surveillance systems. These are tracking systems to identify whether some GBS cases are linked to influenza vaccinations.
- During the 2009-2010 influenza season, CDC and FDA will be closely monitoring reports of serious problems following the 2009 H1N1 influenza vaccines and the regular seasonal influenza vaccines including GBS. These surveillance systems include some existing vaccination safety systems, such as the Vaccine Adverse Event Reporting System (VAERS), and new systems, such as the CDC Emerging Infections Program and a partnership with the American Academy of Neurology, which includes doctors (neurologists) who are most likely to see persons with GBS. None of these systems existed in 1976.
- Through these systems, CDC and FDA will be able to find any possible link between GBS and seasonal or 2009 H1N1 flu vaccines early in the vaccination campaign and take appropriate action.

### **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.
- 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
- While the national picture reveals good supply and rapid 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

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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
- As of October 23, more than 89 million doses of seasonal influenza vaccine have been distributed (this is about 77% 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.
- Manufacturers project producing approximately 50 million doses of thimerosal-free, or preservative-free, seasonal influenza vaccine.
- 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.
- 2009 H1N1 vaccine production efforts currently underway are being carried out in such a way to minimize any impact upon the total amount of seasonal vaccine available. In fact, the timing of 2009 H1N1 vaccine production, as directed by the federal government, was designed to allow sufficient time for manufacturers to be able to carry out their planned production of seasonal influenza vaccine.
- Despite vaccine production estimates that exceed past usage, providers seeking to order vaccine currently and during the past several weeks have experienced challenges in doing so. There are several reasons for these challenges. First, in early June, one of the manufacturers adjusted down their seasonal flu vaccine estimates, which resulted in some customers

switching prebooked orders to other products. These switches reserved unprebooked vaccines that were still available for order, making doses that are normally available for order during the summer and early fall months no longer available. Second, there may be more providers seeking to purchase vaccine at this time of year than normally occurs due to (1) recent 2009 H1N1 disease and related coverage in the media that may have increased the demand for seasonal flu vaccination, and (2) a desire to complete seasonal flu vaccination efforts in advance of 2009 H1N1 vaccination efforts to the extent possible.

- As in past seasons, availability of seasonal vaccine may change as the season progresses because some prebooks do not materialize into purchases. Providers looking to order additional vaccine should be encouraged to use the supplies that they have now and continue to look for additional flu vaccine for purchase in the coming weeks.
- To assist providers in finding flu vaccine available for purchase, the National Influenza Vaccine Summit supports IVATS, the Influenza Vaccine Availability Tracking System, which provides information about vaccine manufacturers and distributors with vaccine available for purchase. IVATS can be found at: <http://www.preventinfluenza.org/ivats/>. The information in IVATS is updated throughout the influenza vaccination season.
- CDC's seasonal influenza web site is at <http://www.cdc.gov/flu> with a new design, the latest information updates, and free resources.

### **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.

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- 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.