

**2009 H1N1 Influenza
Updated Key Points
October 23, 2009**

What's New and Updated

- Activity Update
- International Situation Update
- Behavioral Risk Factor Surveillance System (BRFSS) Flu Modules
- Flu Activity May Occur In Waves
- 2009 H1N1 Influenza Vaccine
- 2009 H1N1 Influenza Vaccine Safety
- Seasonal Influenza Vaccine

A Summary of CDC Key Public Health Messages this Season

- Flu activity is widespread in 46 states and reports of influenza-like illness are increasing 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 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.

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 October 11-17, 2009 is reported in FluView on October 23, 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 over prior weeks.

**2009 H1N1 Influenza
Updated Key Points
October 23, 2009**

- Visits to doctors for influenza-like illness (ILI) increased sharply in the United States, and overall, are higher than what is expected for this time of year. ILI activity is now higher than what is seen at the peak of many regular flu seasons.
- Total influenza hospitalization rates for laboratory-confirmed influenza are climbing and are higher than expected for this time of year.
- The proportion of deaths attributed to pneumonia and influenza (P&I) based on the 122 Cities report has increased and has been higher than what is expected at this time of year for two consecutive weeks.
- Forty-six states are reporting widespread activity at this time (Alabama, Alaska, Arizona, Arkansas, California, Colorado, Delaware, Florida, Georgia, Idaho, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Dakota, Tennessee, Texas, Utah, Vermont, Virginia, Washington, West Virginia, Wisconsin, and Wyoming).
- Any reports of widespread influenza activity in October 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 virus chosen for the 2009 H1N1 vaccine, and remain susceptible to the antiviral drugs oseltamivir and zanamivir with rare exception.
- Information on how hospitalizations and deaths are being reported this season is available at <http://www.cdc.gov/h1n1flu/reportingqa.htm>
- During Week 41 (the week ending October 17, 2009), 11 influenza-associated pediatric deaths were reported to CDC.
 - These deaths occurred in Georgia [2], Hawaii, Louisiana, Oklahoma [2], Ohio, North Carolina, Oregon, Texas, and Virginia, and nine of these deaths were confirmed 2009 H1N1, and two were influenza A viruses, but unsubtyped.
 - These deaths occurred between June 14 and October 10, 2009. One death reported during week 41 occurred during the 2008-09 season.
- Since April 2009, CDC has received 95 reports of laboratory confirmed 2009 H1N1 associated pediatric deaths. Since August 30, 2009, CDC has received reports of 53 flu-associated pediatric deaths; 47 of these were

**2009 H1N1 Influenza
Updated Key Points
October 23, 2009**

due to 2009 H1N1, and the remaining six were influenza A viruses that were not subtyped.

- Since CDC began tracking pediatric flu-related deaths in 2003-2004, the number of pediatric deaths reported to CDC has ranged from 46 during the 2005-2006 season to 153 during the 2003-2004 season.
- **International Situation Update**
- The 2009 H1N1 influenza virus is the predominant influenza virus in circulation in most countries worldwide.
- In temperate regions of the Southern Hemisphere, disease due to 2009 H1N1 is declining or has returned to below baseline.
 - The epidemiology of disease caused by 2009 H1N1 influenza in the Southern Hemisphere has been very similar to what was described in the United States in the spring of 2009.
 - There have been no significant changes detected in the 2009 H1N1 influenza viruses isolated from persons in the Southern Hemisphere as compared to viruses isolated from persons in the Northern Hemisphere.
- In tropical regions of the Americas and Asia, influenza activity due to 2009 H1N1 remains variable.
- In temperate regions of the Northern Hemisphere, influenza-like illness (ILI) activity due to 2009 H1N1 is above baseline in many areas, including parts of Western Europe, most of the United States, and parts of Mexico and Canada.
- According to the World Health Organization (WHO), the majority of 2009 H1N1 influenza isolates tested worldwide remain sensitive to oseltamivir, an antiviral medicine used to treat influenza. Worldwide, only 39 2009 H1N1 isolates tested have been found to be resistant to oseltamivir – 14 of these isolates were detected in the United States.
- The World Health Organization (WHO) continues to report updated 2009 H1N1 flu-associated laboratory-confirmed cases and deaths on its Web page (<http://www.who.int/csr/disease/swineflu/updates/en/>). These 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.

**2009 H1N1 Influenza
Updated Key Points
October 23, 2009**

- Since April 19, 2009, more than half of all influenza positive specimens reported to WHO were 2009 H1N1.
- On September 17, 2009, several countries including the United States announced plans to donate 2009 H1N1 vaccine or funds to support vaccination campaigns in less developed countries.

Behavioral Risk Factor Surveillance System (BRFSS) Flu Modules

Background

- 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.
- States use BRFSS data to identify emerging health problems, establish and track health objectives, and develop and evaluate public health policies and programs.
- BRFSS is a source of timely data on health-related behaviors.
- For more information about BRFSS, see <http://www.cdc.gov/brfss/>.
- The Behavioral Risk Factor Surveillance System (BRFSS) is the world's largest, on-going telephone health survey and tracks health conditions and risk behaviors in the United States yearly since 1984.

Key Points

- CDC has responded to 2009 H1N1 flu by implementing BRFSS modules* related to influenza-like illness (ILI)** and 2009 H1N1 vaccination in all U.S. states and territories and the District of Columbia.

* A BRFSS module is an optional set of questions that are asked along with the standard set of questions included in the BRFSS.

** ILI in this survey is defined as an illness with reported fever and a cough and/or a sore throat

**2009 H1N1 Influenza
Updated Key Points
October 23, 2009**

- BRFSS data collected during the first 11 days of October 2009 indicated that 7% of the adult U.S. population and more than 20% of U.S. children have reported influenza-like illness (ILI) in the previous month. Because ILI can be caused by a variety of infections, CDC is currently evaluating what percentage of this ILI is likely to be the result of flu, particularly 2009 H1N1 flu.
- In the absence of testing of individuals who have ILI, it is difficult to tell what proportion of cases of ILI are due to influenza versus being caused by other respiratory pathogens, such as rhinovirus, adenovirus, RVS, etc.

The BRFSS Influenza Like Illness (ILI) Module

- The 2009 H1N1 ILI module for adults was accepted by 49 states and Puerto Rico, DC, U.S. Virgin Islands and Guam. A subset of these (32) included the module for children in their BRFSS survey.
- The ILI module has survey questions on whether survey participants or members of their household have or have recently had flu-like symptoms;
- This ILI module is able to tell us how much ILI is occurring in the participating states, regions and territories,
- Since the survey period will run from September 2009 to March 2010, CDC will be able to determine increasing or decreasing trends in influenza-like illness.
- When people taking the survey report having had influenza-like illness, they are asked follow-up questions, including whether they sought medical care, were tested for influenza, treated with antivirals, or clinically diagnosed with influenza. So the module will collect information on care-seeking behavior as well as medical testing and treatment practices.
- The module also asks about ILI-related hospitalizations in survey participants and their household members.
- These data are supplemental to the weekly routine FluView influenza surveillance systems and will not only give us additional information about ILI and hospitalizations, but will also give us information about people's behaviors related to flu. (e.g., care-seeking, prescriptions etc.)
- The data collected by the BRFSS are provided by a representative sample of adults in the United States. Once collected, the data are weighted according to the BRFSS weighting guidelines to be able to represent

**2009 H1N1 Influenza
Updated Key Points
October 23, 2009**

trends in overall and state-specific 2009 H1N1 illness and health seeking behavior in the United States.

The BRFSS Seasonal Flu and 2009 H1N1 Vaccination Module

- The BRFSS vaccination module includes questions that ask adults – including health care personnel – questions related to their uptake of both the seasonal flu vaccination and the 2009 H1N1 vaccination. Participating adults will also answer questions regarding the vaccination status of one randomly selected child in their household.
- The BRFSS survey collects data from an estimated 30,000 households a month in participating U.S. states, and the vaccine module will collect data on an estimated sample of 10,000 children each month.
- The data collected through the vaccine module will allow CDC to estimate vaccination coverage nationwide on all people aged 6 months and older, and will provide preliminary monthly information by the 3rd week of each month.
 - The vaccine module will be able to measure vaccination coverage of people who have underlying medical conditions (such as asthma, diabetes, etc.) that place them at high risk for complications from the flu.
 - The vaccine module will also be able to provide data on vaccination uptake by race and ethnicity.

Limitations

- BRFSS data have a few limitations. It's a telephone survey, so it does not reach people without phones, and because the survey exclusively is conducted among households with phones on a landline, the dataset does not include data collected from cell-phone only households.

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.

**2009 H1N1 Influenza
Updated Key Points
October 23, 2009**

- 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.
- 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.

2009 H1N1 Influenza Vaccine

- Every Friday, CDC will post updated 2009 H1N1 vaccine supply and distribution data on the web at www.cdc.gov/h1n1flu.
- Each Thursday, CDC will share vaccine supply and distribution data with state and local public health partners for their awareness prior to the data being posted to the web and discussed in CDC’s Friday press briefings. We hope this will help our state and local partners prepare for local press activity. The data include weekly aggregate totals of doses allocated, ordered, and shipped through Wednesdays. A breakdown of doses shipped by project area is also included.
- **(Updated)** As of Wednesday, October 21, 2009, there were a total of 12,533,700 doses ordered and a total of 11,282,200 doses shipped.
- **(Updated)** As of Wednesday, October 21, 2009, a total of 14,070,900

**2009 H1N1 Influenza
Updated Key Points
October 23, 2009**

doses were available for ordering. Of those available doses, 7,595,200 doses were injectable (flu shots) and 6,475,700 were LAIV (nasal spray vaccine).

- All states and the District of Columbia have placed orders for vaccine, and more orders are expected daily.
- 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.
- Initial doses of 2009 H1N1 “flu shot” were shipped the week of October 12th, 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.
- McKesson, the distributor for the 2009 H1N1 vaccine, is increasing the number of delivery sites from 90,000 to 150,000.
- 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.
- 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 we receive it.
- We had to choose between waiting to distribute vaccine until we had large quantities ready to be shipped versus distributing limited quantities of the vaccine sooner. We chose the latter 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 us to start protecting people against this disease as soon as possible.
- Thus, we only have small 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 disease.

**2009 H1N1 Influenza
Updated Key Points
October 23, 2009**

- It is important to also 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.
- On September 21, 2009, The National Institute of Health (NIH) announced that early results from a trial testing a 2009 H1N1 influenza vaccine in children look promising. Preliminary analysis of blood samples from a small group of trial participants shows that a single 15-microgram dose of a non-adjuvanted 2009 H1N1 influenza vaccine – the same dose that is in the seasonal flu vaccine – generates an immune response that is expected to be protective against 2009 H1N1 influenza virus in the majority of 10- to 17- year-olds within eight to 10 days following vaccination. These results are similar to those recently reported in clinical trials of healthy adults. Younger children generally had a less robust early response to just one dose of the vaccine.
- 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.

**2009 H1N1 Influenza
Updated Key Points
October 23, 2009**

- 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 include:
 - 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 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

In this section:

General H1N1 Vaccine Safety

Vaccine Safety Monitoring

Guillain-Barré syndrome (GBS)

Syncope

Thimerosal

Adjuvants

Latex Allergies

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

**2009 H1N1 Influenza
Updated Key Points
October 23, 2009**

safety track records.

- 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.
- (NEW) 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

- 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.
- Additionally, CDC is conducting surveillance of adverse events through partnerships with other federal agencies, professional organizations, and academic institutions.
- CDC and FDA closely monitor the safety of all vaccines licensed for use in the United States, including seasonal influenza vaccines, in cooperation with state and local health departments, health care providers, and other partners. Additional special monitoring of the 2009 H1N1 influenza vaccine is occurring to assure that any rare and serious side effects are detected as soon as possible.
- 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

**2009 H1N1 Influenza
Updated Key Points
October 23, 2009**

provide timely information to the public, vaccine providers, public health officials, and policy makers.

- As with all vaccines licensed for use in the United States, any problems detected with this vaccine will be reported to health officials, health care providers, and the public, and needed action will be taken to ensure the public's health and safety.
- When reviewing data from CDC and FDA's passive surveillance system (VAERS), please keep in mind the following limitations:
- VAERS is a passive reporting system, meaning that reports about adverse events can be submitted voluntarily by anyone, including healthcare providers, patients, or family members. Because of this, VAERS data may and often does include incorrect and incomplete information.
- Underreporting, or failure to report events, is also one of the main limitations of VAERS. Serious medical events are more likely to be reported than minor ones.
- Most importantly, **VAERS cannot determine cause-and-effect**. The report of an adverse event to VAERS does not confirm that a vaccine caused the event. It only confirms that the event occurred sometime after vaccine receipt. No proof that the event was caused by the vaccine is required in order for VAERS to accept the report.
- VAERS accepts all reports without judging whether or not the event was caused by the vaccine. Reports on the same adverse event may be accepted from different sources (provider, manufacturer). Therefore, it is possible to have more than one report on an individual patient.
- For all reports of serious adverse events, VAERS staff members collect follow-up records on each case and medical officers review them closely to determine if in-depth reviews are needed before conducting additional studies.
- VAERS defines "serious adverse events" as those involving death, hospitalization, life-threatening illness, persistent or significant disability/incapacity, or certain other medically-important conditions.
- The most reliable information about vaccine side effects can be found in the manufacturer's vaccine package insert, vaccine information statements (VISs), or the ACIP's statements on vaccines at <http://www.cdc.gov/vaccines/pubs/ACIP-list.htm>.

**2009 H1N1 Influenza
Updated Key Points
October 23, 2009**

Guillain-Barré syndrome (GBS)

- **(Updated)** 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.
- **(NEW)** 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
- **(Updated)** 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 diarrhea, or a lung and sinus infection
- **(Updated)** 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.
- **(Updated)** 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.
- **(Updated)** 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.
- **(NEW)** 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.
- **(NEW)** 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

**2009 H1N1 Influenza
Updated Key Points
October 23, 2009**

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.

- **(NEW)** 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 if it occurs and take appropriate action.

Syncope (Fainting)

- Syncope, or fainting, has been reported after vaccination with any vaccine, and is common among adolescent patients. Falls, as a result of fainting after vaccination, can sometimes result in serious injuries.
- Such injuries can be prevented by assuring that the vaccinated person is sitting in a chair or lying down and is observed for 15 minutes following vaccination.

Thimerosal

- Thimerosal is a mercury-based preservative that is used in some influenza vaccines to keep them free from contamination of microorganisms.
- The 2009 H1N1 influenza vaccine is being manufactured in several formulations.
 - Several 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.
 - The live-attenuated version of the vaccine, which is administered intranasally (through the nose), does not contain thimerosal.
 - Some vaccine will come in multi-dose vials and will contain thimerosal as a preservative, as is the case with seasonal influenza vaccines in multi-dose vials.

Adjuvants

- **(NEW)** None of the seasonal or 2009 H1N1 influenza vaccines currently licensed and distributed by the U.S. government contains adjuvants. This means that none of these influenza vaccines contains squalene or aluminum.
- This includes all of the seasonal and 2009 H1N1 influenza vaccines that are currently available for children and adults in both the injectable (flu

**2009 H1N1 Influenza
Updated Key Points
October 23, 2009**

shot) and nasal spray formulations. According to current federal plans, none of these influenza vaccines that will be used in the U.S. during the 2009-10 season will contain 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.
- Adjuvants, in the form of aluminum salts, have been used safely and effectively in the U.S in millions of doses of vaccines for decades. Adjuvants, in the form of squalene, have been used safely and effectively in more than 50 million doses of influenza vaccines in Europe.
- 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.

Latex Allergies

- **(NEW)** It is important for people who have latex allergies to make their healthcare provider aware of that allergy at every vaccination visit.
- **(NEW)** It is important for people with latex allergies to ask their healthcare provider about the vaccines and the products that will be used to administer the vaccines to them.
- **(NEW)** The currently licensed seasonal and 2009 H1N1 influenza vaccines do not contain latex.
- **(NEW)** If healthcare providers do not use the vaccine administration products provided by the vaccine manufacturers which do not contain latex, there may be a risk of latex allergy.
- **(NEW)** Latex is not an ingredient of vaccines. However, latex may be present in seal stoppers of vaccine vials or in rubber parts of syringes. Contact with the vaccine may occur particularly when it is being drawn up into the syringe before being administered, and therefore, may cause an allergic reaction to the latex.

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.

**2009 H1N1 Influenza
Updated Key Points
October 23, 2009**

- Recently there have been several media reports describing unpublished findings from seasonal influenza vaccine studies conducted in Canada suggesting that receipt of the 2008-09 seasonal influenza vaccine (given last influenza season) was a risk factor for developing influenza caused by the 2009 H1N1 virus.
- Preliminary results of studies conducted in the United States using methods similar to the Canadian studies did not indicate that receiving a seasonal influenza vaccine increased the risk of developing influenza caused by the 2009 H1N1 influenza virus.
- In addition, no other country has reported that seasonal influenza vaccine increases the risk of developing influenza caused by the 2009 H1N1 influenza virus.
- For more information on CDC's response to this study, visit <http://www.cdc.gov/media/pressrel/2009/s091007.htm> and http://www.cdc.gov/h1n1flu/vaccination/public/vaccination_qa_pub.htm#canadian .
- 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 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.

**2009 H1N1 Influenza
Updated Key Points
October 23, 2009**

- 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 October 16, 85 million doses of seasonal influenza vaccine have been distributed (this is about 74% 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 prebooks 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

**2009 H1N1 Influenza
Updated Key Points
October 23, 2009**

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.