

**2009 H1N1 Influenza
Updated Key Points
October 30, 2009**

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A Summary of CDC Key Public Health Messages this Season

- Flu activity is widespread in 48 states and nationwide, levels of influenza-like illness continue to increase sharply. 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 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 but initial supplies are limited. 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](#).

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- Information collected during the week of October 18-24, 2009 is reported in FluView on October 30, 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.
- Nationally, visits to doctors for influenza-like illness (ILI) increased sharply again over last week. Overall, visits to doctors for ILI are much higher than what is expected for this time of year. Influenza-like illness is rising most quickly in younger age groups with people 65 and older continuing to be relatively unaffected. ILI activity is now higher than what occurs during the peak of most flu seasons.
- Total influenza hospitalization rates for laboratory-confirmed influenza are climbing and are higher than expected for this time of year. Hospitalization rates continue to be highest in younger populations with the highest hospitalization rate reported in children 0-4 years old.
- 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 four consecutive weeks now.
- Forty-eight states are reporting widespread activity at this time (Alabama, Alaska, Arizona, Arkansas, California, Colorado, Connecticut, Delaware, Florida, Georgia, Idaho, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Jersey, 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. This level of activity in October is unprecedented for seasonal flu.
- 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>

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- During Week 42 (the week ending October 24, 2009), 22 influenza-associated pediatric deaths were reported to CDC.
- These deaths occurred in Arizona [3], Florida, Georgia, Guam, Montana, Ohio, South Dakota, Tennessee [2], Texas [9], Washington, and Wisconsin, and 19 of these deaths were confirmed 2009 H1N1, and three were influenza A viruses, but unsubtype.
- These deaths occurred between August 23 and October 24, 2009. One death reported this week, occurred during the 2008-09 flu season.
- The cumulative total number of laboratory-confirmed pediatric deaths related to 2009 H1N1 since April 2009 is 114. (Since August 30, 2009 when the flu season "re-set", CDC has received reports of 74 flu-associated pediatric deaths; 65 of these were due to 2009 H1N1, and the remaining nine were influenza A viruses that were not subtyped.)
- A table showing reports of flu-related pediatric deaths (including a cumulative total of 2009 H1N1 pediatric deaths since April, 2009) is available on the CDC website at <http://www.cdc.gov/h1n1flu/updates/us/#pedh1n1cases> .
- 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, little disease due to 2009 H1N1 has been reported.
 - 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.

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- In temperate regions of the Northern Hemisphere, high rates of influenza-like illness (ILI) activity due to 2009 H1N1 have been reported 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.
- Since April 19 more than half of influenza specimens reported to WHO have been 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.

Pediatric Antiviral Supply

Summary Key Points

1. CDC is releasing remaining Strategic National Stockpile quantities – around 234,000 courses - of Tamiflu® oral suspension (This is in addition to 56,000 courses of Tamiflu oral suspension released in the Spring and 300,000 courses at the beginning of October.)
2. CDC is providing information for physicians, pharmacists and parents about the availability of pediatric doses of Tamiflu® in 30mg and 45mg capsules.
3. CDC is informing parents about the option of mixing the 30mg and 45mg capsules with sweet syrup for children who cannot swallow capsules. (This is not compounding)
4. CDC is communicating with pharmacists about the option of compounding a pediatric oral suspension from adult 75mg Tamiflu® capsules.
5. CDC will continue to monitor availability of pediatric and adult doses of antivirals as well as supplies of materials that pharmacists will need to compound adult doses into a pediatric oral suspension.

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Stockpile Release

- Today, October 30, 2009, CDC announced that all remaining supplies of Tamiflu® oral suspension will be released from the Strategic National Stockpile (SNS) for use in pediatric populations in response to short supply of commercial availability of this formulation of Tamiflu®.
- In the spring, CDC deployed 11 million treatment courses of antiviral drugs, 56,000 of which were courses of Tamiflu® oral suspension.
- On October 1, 2009, HHS approved the deployment of 300,000 bottles of Tamiflu® oral suspension from the SNS to all states based on population for use in pediatric populations.
- All 300,000 bottles have been deployed with the exception of one project area that requested a delay in shipment.
- Today, SNS will begin deployment of remaining supplies of Tamiflu® oral suspension.
- This is approximately 234,000 bottles of Tamiflu® oral suspension (A bottle is a treatment course).
- CDC is coordinating with manufacturers, distributors and retailers to gather information on available quantities of certain medical supplies, including antiviral drugs to get a national picture of commercial availability.
- At this time, supplies of adult formulation (75 mg) oseltamivir (Tamiflu®) and zanamivir (Relenza®) are meeting current demand for this product.
- CDC will continue to monitor this information to help inform decision-making about whether and when remaining supplies in the Strategic National Stockpile (SNS) should be released.

Antiviral Drugs in Children

- Tamiflu® is one of two antiviral drugs recommended by CDC for the treatment of 2009 H1N1.
- Normally, Tamiflu® is approved for use in children 1 year of age and older.
- Under the terms of an Emergency Use Authorization by FDA, the drug can be used to treat 2009 H1N1 in children younger than 1 year.

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- Tamiflu® comes in an oral suspension (liquid) and in child doses of 30mg and 45mg capsules. A 75 mg capsule (adult dose) also is available. (Dose is determined by weight.)
- In addition, the other antiviral that we have is called Relenza® and it is approved for use in children 7 years of age and older, but only for people without breathing problems (such as asthma) or heart disease.
- It is an inhaled powder that comes in a disk inhaler.

What Parents Need to Know

- There are limited supplies of Tamiflu® oral suspension.
- CDC is addressing this by releasing the stockpile but there may still be limited supply.
- There are several options for an antiviral for your child if your child is sick and needs treatment.
- There are child doses of Tamiflu® that come in capsules. (30mg and 45mg)
- If your child cannot swallow capsules, these capsules can be opened and mixed with something like chocolate syrup to make a liquid for them to swallow.
- On October 20, 2009, CDC posted Questions & Answers on Opening and Mixing Tamiflu® Capsules with Liquids if Child Cannot Swallow Capsules at http://www.cdc.gov/h1n1flu/antivirals/mixing_tamiflu_qa.htm
- Also, there is something that pharmacists can do that is called compounding. Compounding is the mixing of drugs by a health care professional to fit the unique needs of a patient.
- By compounding, pharmacists can turn adult doses of Tamiflu® (75mg capsule) into a child liquid dose.
- CDC is reaching out to pharmacists and encouraging them to compound for their customers.
- Since September 23, we have been proactively reaching out to pharmacists on the issue of compounding.

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- In addition, there is a section specific to pharmacists on our website at <http://www.cdc.gov/H1N1flu/pharmacist/> .
- And on September 25, we issued a [Health Alert Network Info Service on Compounding Information for 2009 H1N1 and Seasonal Flu](http://www.cdc.gov/h1n1flu/HAN/092509.htm) (<http://www.cdc.gov/h1n1flu/HAN/092509.htm>)
- FDA has posted a statement on their website at <http://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm100228.htm> to remind health care providers and pharmacists of the FDA-approved instructions for the emergency compounding of an oral suspension from Tamiflu® 75mg capsules as described in the FDA approved manufacturer package insert for oseltamivir (Tamiflu®).
- CDC wants pharmacists to be aware of this option and to prepare to practice it by ordering the necessary supplies for compounding.

Supply of Ingredients Needed to Compound Tamiflu

- Tamiflu® capsules 75 mg may be compounded using either of two vehicles: Cherry Syrup (Humco®) or Ora-Sweet® SF (sugar-free) (Paddock Laboratories).
- These products may be in short supply in some locations if there is increased use in compounding of an oral suspension from Tamiflu® 75mg capsules.
- The FDA has posted additional information regarding supply of these products at <http://www.fda.gov/Drugs/NewsEvents/ucm130958.htm>.
- Paddock Laboratories reports that they have increased production of Ora-Sweet® SF and they are releasing new production daily to customers.
- Humco® reports that they have increased production of Cherry Syrup and that they are releasing new production weekly to wholesalers. If pharmacists are having difficulty obtaining Humco® Cherry Syrup, they may contact Humco® directly to locate supplies at 1-800-662-3435.

Medical Supplies, Including Antivirals

- Over the course of this pandemic, it is possible that in areas experiencing widespread flu activity, there may be temporary limited commercial availability of some medical supplies, including antiviral medications.
- CDC is coordinating with manufacturers, distributors and retailers to gather information on available quantities of certain medical supplies, including antiviral drugs.

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- CDC is using this information to get a national picture of commercial availability of certain medical supplies, including antiviral drugs.
- The goal of this is to improve information about the commercial supply of certain medical supplies to help inform decision-making about when the Strategic National Stockpile (SNS) should be released.
- CDC will provide additional information and updates as needed.

SNS Deployment of Pediatric Oral Suspension on October 1

- On Oct 1, 2009, HHS approved the deployment of 300,000 bottles of Tamiflu® oral suspension from the Strategic National Stockpile (SNS) to all states based on population for use in pediatric populations to ensure available supply.
- All 300,000 bottles have been deployed with the exception of one project area that requested a delay in shipment.
- Three hundred thousand bottles equals approximately 300,000 treatment courses of pediatric suspension depending on the child's weight.
- Tamiflu® oral suspension that was deployed by the CDC included lot numbers that have an expiration date that has been extended based on scientific testing done by FDA.
- The medicine has passed FDA's tests, and the expiration date of the medicine has been extended beyond the date originally printed on the bottle.
- This product can be dispensed under the current emergency use authorization (EUA) for Tamiflu® and a fact sheet for patients and parents also is provided. To check on a specific bottle's expiration date to determine if the lot has been extended and for how long, please see <http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm154962.htm>

Antiviral Drugs, General

- Antiviral drugs are prescription medicines (pills, liquid or an inhaled powder) that fight against the flu by keeping flu viruses from reproducing in your body.
- Antiviral drugs can make illness milder and shorten the time you are sick. They can also prevent serious flu complications.

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- For treatment, antiviral drugs work best if started within the first 2 days of symptoms.
- It's important for the public to remember that most people sick with 2009 H1N1 influenza have recovered without medical care or antiviral drugs, and the same is true of seasonal flu.
- The priority use for antiviral drugs this season is to treat people who are very sick (hospitalized) or people who are sick with flu-like symptoms and who are at increased risk of serious flu complications, such as pregnant women, very young children, people 65 and older and people with chronic health conditions.

Estimates of 2009 H1N1 Prevalence April-July, 2009

- On October 28, 2009 the study "Estimates of the Prevalence of Pandemic (H1N1) 2009, United States, April-July 2009" was published online by *Emerging Infectious Diseases* and is available at <http://www.cdc.gov/eid/content/15/12/pdfs/09-1413.pdf> .
- The number of cases of 2009 H1N1 influenza reported through July 2009 were known to represent only a fraction of actual total cases.
- To better estimate the prevalence of 2009 H1N1 from April-July in the United States, researchers in this study created a simple multiplier model that adjusts for the various sources of under-counting.
- Using this approach, researchers estimated that during this time period, between 1.8 million and 5.7 million people became ill with 2009 H1N1 influenza in the United States, including 9,000-21,000 hospitalizations.
- Instead of doing complete case counts, focused modeling methods, such as the one conducted in this study, may be used in conjunction with traditional surveillance systems to define where, when and what influenza viruses are circulating, and trends in this activity.

2009 H1N1 Influenza Vaccine

- **(Updated)** As of Wednesday, October 28, 2009, there were a total of 19,443,600 doses ordered and a total of 16,870,000 doses shipped.
- **(Updated)** As of Friday, October 30, 2009, a total of 26,686,400 doses were available for ordering. Of those available doses, 17,920,600 doses were injectable (flu shots) and 8,765,800 were LAIV (nasal spray vaccine).

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- 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.
- 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 will most likely 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 in many of the 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.
- 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,

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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 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.
- 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.
- 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.

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- 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

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 safety track records.
- CDC expects that any serious side effects following vaccination with the 2009 H1N1 influenza vaccine would be rare.

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- 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

- 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 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

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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. Information how how to report an adverse events is available at <http://vaers.hhs.gov/esub/index> .
- 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>.

Comment [s1]: Add in URL for VAERS reporting form?

Guillain-Barré syndrome (GBS)

- 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.

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- 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. 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 link between GBS and seasonal or 2009 H1N1 flu vaccines early in the vaccination campaign if it occurs and take appropriate action.

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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 are 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

- 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 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 being produced for use in other countries 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.

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- 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

- It is important for people who have latex allergies to make their healthcare provider aware of that allergy at every vaccination visit.
- 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.
- 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.
- **(Updated)** Latex is not an ingredient of vaccines. However, some manufacturers may use latex 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 in people with a severe (anaphylactic) allergy to 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.
- 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.

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- 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.
- 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 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.

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- 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.

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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.