

# **H1N1 FAQs**

*Updated 10-15-09*

## **Vaccination Guidance**

### **Who is recommended to receive the 2009 H1N1 Vaccine?**

The Centers for Disease Control and Prevention (CDC)'s Advisory Committee on Immunization Practices (ACIP) met in July and recommended the following groups to receive the 2009 H1N1 influenza vaccine:

- **Pregnant women** because they are at higher risk of complications and can potentially provide protection to infants who cannot be vaccinated;
- **Household contacts and caregivers for children younger than 6 months of age** because younger infants are at higher risk of influenza-related complications and cannot be vaccinated. Vaccination of those in close contact with infants younger than 6 months old might help protect infants by “cocooning” them from the virus;
- **Healthcare and emergency medical services personnel** because infections among healthcare workers have been reported and this can be a potential source of infection for vulnerable patients. Also, increased absenteeism in this population could reduce healthcare system capacity;
- **All people from 6 months through 24 years of age**
  - **Children from 6 months through 18 years of age** because cases of 2009 H1N1 influenza have been seen in children who are in close contact with each other in school and day care settings, which increases the likelihood of disease spread, and
  - **Young adults 19 through 24 years of age** because many cases of 2009 H1N1 influenza have been seen in these healthy young adults and they often live, work, and study in close proximity, and they are a frequently mobile population; and,
- **Persons aged 25 through 64 years who have health conditions associated with higher risk of medical complications from influenza.**

No shortage of 2009 H1N1 vaccine is expected, but vaccine availability and demand can be unpredictable and there is some possibility that initially, the vaccine will be available in limited quantities. So, the ACIP also made recommendations regarding which people within the groups listed above should be prioritized if the vaccine is initially available in extremely limited quantities. For more information see the CDC press release [Advisors Make Recommendations for Use of Vaccine Against 2009 H1N1](#).

### **Can a physician practice require that all personnel be vaccinated for H1N1?**

Yes, but the practice should consider possible consequences such as what steps the practice will take if an employee refuses? Create a policy and follow it if you decide to

mandate vaccinations for employees. A more important consideration to remember is that a patient always has the right to refuse treatment. See AMA Ethical Opinion 10.1 accessible at [.ama-assn.org](http://ama-assn.org) that states in part: “(2) The patient has the right to make decisions regarding the health care that is recommended by his or her physician. Accordingly, patients may accept or refuse any recommended medical treatment.”

### **Can a hospital require its non-employed medical staff to be vaccinated for H1N1?**

While the hospital does not have direct control over independent practicing physicians, the physicians are subject to medical staff bylaws and rules. It is likely that the medical staff rules include a statement that physicians must follow certain hospital rules or policies. If the hospital adopts a rule that applies to all personnel, chances are the physicians must follow the rule. Again, consider AMA Ethical Opinion 10.1 accessible at [.ama-assn.org](http://ama-assn.org) that states in part: “(2) The patient has the right to make decisions regarding the health care that is recommended by his or her physician. Accordingly, patients may accept or refuse any recommended medical treatment.”

### **Will there be requirements regarding documentation of priority group membership?**

There will be no federal requirements for vaccinators to require documentation of priority group status such as a doctor’s note documenting pregnancy or risk status.

### **Can seasonal vaccine and novel H1N1 vaccine be administered at the same time?**

Clinical trials are exploring this question. It is anticipated that seasonal vaccine and novel H1N1 vaccines may be administered together.

### **Do those that have been previously vaccinated against the 1976 swine influenza need to get vaccinated against the 2009 H1N1 influenza?**

The 1976 swine flu virus and the 2009 H1N1 virus are different enough that its unlikely a person vaccinated in 1976 will have full protection from the 2009 H1N1. People vaccinated in 1976 should still be given the 2009 H1N1 vaccine.

## ***Clinical Guidance***

### **Where can I find H1N1 clinical guidance?**

The CDC provides detailed clinical information for the general population and for specific groups at [://www.cdc.gov/h1n1flu/guidance/#a2](http://www.cdc.gov/h1n1flu/guidance/#a2).

### **Where can I find guidance on detecting H1N1 influenza?**

Complete clinical guidance from the CDC is available at [://www.cdc.gov/h1n1flu/guidance/rapid\\_testing.htm](http://www.cdc.gov/h1n1flu/guidance/rapid_testing.htm)

**Where can I find guidance on Identifying and caring for patients with H1N1 influenza?**

The CDC provides complete guidance at [://www.cdc.gov/h1n1flu/identifyingpatients.htm](http://www.cdc.gov/h1n1flu/identifyingpatients.htm)

**Where can I find guidance on the use of antiviral medications for the treatment and prevention of H1N1 influenza?**

This guidance can be found at [://www.cdc.gov/h1n1flu/recommendations.htm](http://www.cdc.gov/h1n1flu/recommendations.htm)

**Where can I find more information on emergency use authorization (EUA) of medical products and devices?**

The CDC provides this information at [://www.cdc.gov/h1n1flu/eua/](http://www.cdc.gov/h1n1flu/eua/).

**Where can I find clinical data collection forms and templates for collection of information on patients infected with H1N1 influenza?**

Forms and templates can be found at [://www.cdc.gov/h1n1flu/clinicians/clinician\\_forms\\_templates.htm](http://www.cdc.gov/h1n1flu/clinicians/clinician_forms_templates.htm)

**Are there special considerations for H1N1 influenza in obstetric settings?**

Yes, the CDC provides guidance on this at [://www.cdc.gov/h1n1flu/guidance/obstetric.htm](http://www.cdc.gov/h1n1flu/guidance/obstetric.htm)

**Where can I find H1N1 influenza guidance for homeless and emergency shelters?**

Information can be found at [://www.cdc.gov/h1n1flu/guidance/homeless.htm](http://www.cdc.gov/h1n1flu/guidance/homeless.htm)

## ***Vaccine Availability and Distribution***

**How will the H1N1 vaccine be made available to private practice physicians?**

In order to proceed with the allocations and ordering process, the Ohio Department of Health (ODH) has closed the pre-registration process for physicians to acquire H1N1 vaccine for administration in their practices. It is recommended that you advise your patients as to whether or not you will be making the vaccine available. If you are not, the ODH is asking that you direct interested individuals to the local health department.

### **If I have decided to offer the vaccine, will the public health sector send individuals to me to be vaccinated?**

ODH will be making the vaccine locations available to local health districts and those pre-registered Ohioans who need to know where to go to get their vaccinations. They can look up sites near them. The fact that locations will be made available through the local health department may cause new patients to seek out your practice for the sole purpose of obtaining the vaccine.

### **How can health care workers get vaccinated?**

The ODH is encouraging health care workers to pre-register for vaccination. According to the ODH, the pre-registration benefits include:

- Greatly reduces the amount of time spent at the facility where you receive your vaccine.
- Improves accuracy.
- Enables you to be notified when your facility has vaccines available.
- Enables you to be notified when to receive your 2nd dose.
- Enables you to retrieve your record on this system.
- Enables public health to plan for how much product is necessary for each facility.

The ODH has an on-line system for pre-registration for individuals who wish to receive the H1N1 vaccine. The pre-registration process requires a printer and the printed form should be presented when you receive your vaccine. To pre-register:

- Access the H1N1vaccine web site at <://h1n1vaccine.odh.ohio.gov/> \
- Go to the “Individual/Family Pre-Registration” section at the top of the page and scroll to the box on the far right, titled “Individual Login.” You will need to click on the link for “New Individual/Family to Pre-register” to create a login (note that this login will be used in the future to pre-register other family members).
- Create a login and password.
- Click the “Register New Individual” button on the right of the screen and enter the requested information.
- Once all information has been completed, click the “Save” button at the bottom.
- Click on the “Print Patient Form” button to print the form.
- Take the printed form with you when you present for vaccine.

## ***Vaccination Reimbursement***

### **How will novel H1N1 vaccine be purchased?**

H1N1 vaccine will be procured and purchased by the federal government and made available for vaccinators at no cost.

### **Which ancillary supplies will be provided with vaccine?**

HHS will provide needles, syringes, sharps containers and alcohol swabs.

### **How will ancillary supplies be distributed?**

Ancillary supplies will be distributed to the same project area-designated sites as vaccine. Plans for ensuring the distribution of these products are currently being developed.

### **How will Medicare reimburse physicians for administration?**

Though Medicare typically pays for one vaccination per year, if more than one vaccination per year is medically necessary (i.e., the number of doses of a vaccine and/or type of influenza vaccine), then Medicare will pay for those additional vaccinations. Medicare claims processing contractors have been notified to expect and prepare for earlier-than-usual seasonal flu claims, and there should not be a problem in getting those claims paid. Furthermore, in the event that it is necessary for Medicare beneficiaries to receive both a seasonal flu vaccination and an influenza A (H1N1) vaccination, Medicare will pay for both. Please be advised that if either vaccine is provided free of charge to the health care provider, Medicare will only pay for the vaccine's administration (not for the vaccine itself). For more information, click .

### **Will insurance plans reimburse physicians for administration?**

The Ohio Department of Insurance (ODI) has communicated with Ohio health insurance plans on reimbursement procedures for the H1N1 vaccine. It is believed that, similar to Medicare, insurance plans will provide reimbursement for administration of the vaccine but not the vaccine itself since it is free. ODI is expected to have a list of the expected reimbursement rates for administration fees from the majority of health insurance plans by early October. It is recommended that practices should determine their billed charges, have one fee schedule and charge everyone the same rate. This avoids allegations of fraud.

In addition, CDC asked America's Health Insurance Plans (AHIP) and on behalf of its members, AHIP provided this response:

"Just as health plans have provided extensive coverage for the administration of seasonal flu vaccines in the past, public health planners can make the assumption that

health plans will provide reimbursement for the administration of a novel (A) H1N1 vaccine to their members by private sector providers in both traditional settings e.g., doctor's office, ambulatory clinics, health care facilities, and in non-traditional settings, where contracts with insurers have been established."

**Will private providers be able to charge patients for vaccine administration if they are uninsured?**

Yes, providers may charge patients if they are uninsured. The administration fee cannot exceed the regional Medicare vaccine administration fee.

**Can persons be charged for vaccine administration in public health-organized large scale vaccination clinics?**

There will be no administration fee for vaccination in public-health organized large scale vaccination clinics.

## ***H1N1 Vaccine Safety***

**Will the 2009 H1N1 influenza vaccines be safe?**

The CDC expects the 2009 H1N1 influenza vaccine to have a similar safety profile as seasonal flu vaccines, which have a very good safety track record. Over the years, hundreds of millions of Americans have received seasonal flu vaccines. The most common side effects following flu vaccinations are mild, such as soreness, redness, tenderness or swelling where the shot was given. The CDC and the Food and Drug Administration (FDA) will be closely monitoring for any signs that the vaccine is causing unexpected adverse events and we will work with state and local health officials to investigate any unusual events.

**Are there any side effects to the 2009 H1N1 influenza vaccine?**

The CDC expects that any side effects following vaccination with the 2009 H1N1 influenza vaccine would be rare. If side effects occur, they will likely be similar to those experienced following seasonal influenza vaccine. Mild problems that may be experienced include soreness, redness, or swelling where the shot was given, fainting (mainly adolescents), headache, muscle aches, fever, and nausea. If these problems occur, they usually begin soon after the shot and last 1-2 days. Life-threatening allergic reactions to vaccines are very rare. If they do occur, it is usually within a few minutes to a few hours after the shot is given.

After vaccination you should look for any unusual condition, such as a high fever or behavior changes. Signs of a serious allergic reaction can include difficulty breathing,

hoarseness or wheezing, swelling around the eyes or lips, hives, paleness, weakness, a fast heart beat or dizziness. If any unusual condition occurs following vaccination, seek medical attention right away. Tell your doctor what happened, the date and time it happened, and when the vaccination was given. Ask your doctor, nurse, or health department to report the reaction by filing a Vaccine Adverse Event Reporting System (VAERS) form. Or you can file this report yourself through the VAERS Web site at [vaers.hhs.gov](http://vaers.hhs.gov). You may call 1-800-822-7967 to receive a copy of the VAERS form. VAERS is not able to provide medical advice.

**Are there some people who should not receive this vaccine?**

People who have a severe (life-threatening) allergy to chicken eggs or to any other substance in the vaccine should not be vaccinated.

**Will the 2009 H1N1 vaccines that are currently recommended contain adjuvants?**

No. The current recommendations from the Advisory Committee on Immunization Practices (ACIP) for 2009 H1N1 influenza vaccines are for vaccines without adjuvants. This includes all of the 2009 H1N1 and seasonal influenza vaccines that will be available for children and adults in both the injectable and nasal spray formulations. None of these influenza vaccines will contain adjuvants. 2009 H1N1 influenza vaccines with adjuvants are being studied to determine if they are safe and effective. Experts will review safety data from these studies when they are available. There is no plan at this time to recommend a 2009 H1N1 influenza vaccine with an adjuvant.

**Will the 2009 H1N1 influenza vaccine contain thimerosal?**

The 2009 H1N1 influenza vaccines that FDA is licensing (approving) will be manufactured in several formulations. Some will come in multi-dose vials and will contain thimerosal as a preservative. Multi-dose vials of seasonal influenza vaccine also contain thimerosal to prevent potential contamination after the vial is opened.

Some 2009 H1N1 influenza vaccines will be available in single-dose units, which will not require the use of thimerosal as a preservative. In addition, the live-attenuated version of the vaccine, which is administered intranasally (through the nose), is produced in single-units and will not contain thimerosal. [more information on thimerosal](#).

**Will there be a possibility of Guillain-Barré Syndrome (GBS) cases following the 2009 H1N1 vaccine?**

Guillain-Barré syndrome (GBS) is a rare disease in which the body damages its own nerve cells, causing muscle weakness and sometimes paralysis. It is not fully understood why some people develop GBS, but it is believed that stimulation of the body's immune system may play a role in its development. Infection with the bacterium [jejun](#), which can cause diarrhea, is one of the most common risk factors for GBS. People can also develop GBS after having the flu or other infections (such as cytomegalovirus and Epstein Barr virus). On very rare occasions, they may develop GBS in the days or weeks following receiving a vaccination.

In 1976, there was a small risk of GBS following influenza (swine flu) vaccination (approximately 1 additional case per 100,000 people who received the swine flu vaccine). That number of GBS cases was slightly higher than what is normally seen in the population, whether or not people were vaccinated. Since then, numerous studies have been done to evaluate if other flu vaccines were associated with GBS. In most studies, no association was found, but two studies suggested that approximately 1 additional person out of 1 million vaccinated people may be at risk for GBS associated with the seasonal influenza vaccine. FDA and CDC will be closely monitoring reports of serious problems following the 2009 H1N1 influenza vaccines, including GBS

## Preparing Your Office for an H1N1 Outbreak

### How can I get my office ready for an H1N1 outbreak?

Several resources are available to help you prepare your office for an H1N1 outbreak. These resources can help you come up with a plan so your office is ready **before** such an occurrence.

- The Columbus Medical Association (CMA) in coordination with the Central Ohio Trauma System, and through a grant provided by the ODH, has developed the Influenza Pandemic Guidelines for Independent Medical Practices over the past year. These guidelines are for physicians to consider as they prepare their practices for the onslaught of pandemic flu, hurricanes, tornadoes, floods, extensive power outages or other possibilities. In light of H1N1 flu pandemic, the OSMA feels it is important to share resources like this with you. To access the CMA's guidelines, click [or](#) for a presentation from the CMA click [.](#)
- The CDC provides 10 steps for preparation:  
[://www.cdc.gov/h1n1flu/10steps.htm](http://www.cdc.gov/h1n1flu/10steps.htm).
- Guidance for small businesses is available at  
[://www.flu.gov/professional/business/smallbiz.html](http://www.flu.gov/professional/business/smallbiz.html)

### How can I prepare my family and myself for an H1N1 outbreak?

- Visit [://www.flu.gov/individual/index.html](http://www.flu.gov/individual/index.html) for information about what you should do to prepare your family.

### Where can I find more information on H1N1 influenza?

- [://www.flu.gov/](http://www.flu.gov/)
- [://www.cdc.gov/h1n1flu/general\\_info.htm](http://www.cdc.gov/h1n1flu/general_info.htm)
- [://www.odh.ohio.gov/landing/phs\\_emergency/panflu/panflumain.aspx](http://www.odh.ohio.gov/landing/phs_emergency/panflu/panflumain.aspx)

- [://www.osma.org/i4a/pages/index.cfm?pageID=4845](http://www.osma.org/i4a/pages/index.cfm?pageID=4845)