

Novel Influenza A H1N1 (2009) Vaccine

Questions & Answers for Providers / Vaccine Administrators

Who is recommended to receive the 2009 H1N1 vaccine?

CDC's Advisory Committee on Immunization Practices (ACIP) has recommended that certain groups of the population receive the 2009 H1N1 vaccine when it first becomes available. These target groups include:

- 1) pregnant women,
- 2) people who live with or care for children younger than 6 months of age,
- 3) healthcare and emergency medical services personnel,
- 4) persons between the ages of 6 months and 24 years old,
- 5) people ages of 25 through 64 years of age who are at higher risk for 2009 H1N1 because of chronic health disorders or compromised immune systems.

We do not expect that there will be a shortage of 2009 H1N1 vaccine, but availability and demand can be unpredictable. There is some possibility that initially the vaccine will be available in limited quantities. In this setting, the committee recommended that the following groups receive the vaccine before others: pregnant women, people who live with or care for children younger than 6 months of age, health care and emergency medical services personnel with direct patient contact, children 6 months through 4 years of age, and children 5 through 18 years of age who have chronic medical conditions.

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.

Why will persons aged over 65 year-old not be offered vaccine? Are my patients "too old for this vaccine"?

First, **everyone is eligible for the 2009 H1N1 flu vaccine**, although some people may have health issues that would be affected by a vaccine and therefore should not take it. The *goal* of the pandemic influenza vaccination program is to **vaccinate all persons in the United States who choose to be vaccinated**. Because the vaccines may be released gradually beginning in October, a priority list was developed to focus on immediate immunization.

Decisions about expanding vaccination to include additional populations beyond the five initial target groups should be made at the local level because vaccine availability and demand might vary considerably by area. Once vaccination programs and providers are meeting the demand for vaccine among the persons in the five initial target groups, vaccination should be expanded to all persons aged 25-64 years. Decisions about expanding or establishing priorities for vaccination should be made in accordance with local circumstances based on the judgment of state and local health officials and health-care providers. CDC and other public health agencies will assess the vaccine supply on a continuing basis throughout the manufacturing period. CDC and state and local health authorities will inform providers and the general public if any indication exists of a substantial delay or an inadequate supply.

Current studies indicate the risk for infection among persons aged ≥ 65 years is less than the risk for persons in younger age groups. Expanding vaccination recommendations to include adults aged ≥ 65 years is recommended only after assessment of vaccine availability and demand at the local level. Once demand for vaccine among younger age groups is being met, vaccination should be expanded to all persons aged ≥ 65 years. This recommendation might need to be reassessed as new epidemiologic, immunologic, or clinical trial data warrant and in the context of global need for vaccine.

Here are the statistics on who is most vulnerable to the novel H1N1 flu:

- The infection rate was progressively lower in adults as their age increased.
- The infection rate for people 5-24 years of age is 26.7 per 100,000.
- The infection rate for people 25-49 years of age is 6.9/100,000.
- The infection rate for people 50-64 years of age is 3.9/100,000.
- The infection rate for people 65 years and older is 1.3/100,000 (or twenty times lower than in those 5-24 years age group).

When will 2009 H1N1 Vaccine be available?

The 2009 H1N1 vaccine is expected to be available in the fall. More specific dates cannot be provided at this time as vaccine availability depends on several factors including manufacturing time and time needed to conduct clinical trials

Where will 2009 H1N1 Vaccine be available?

Every state is developing a vaccine delivery plan.

In Macomb County, H1N1 Vaccine will be available to the public in a combination of settings such as vaccination clinics organized by local health departments, healthcare provider offices, schools, and other private settings, such as pharmacies and workplaces.

What is the recommended dose of the 2009 H1N1 vaccine?

This will be determined during the clinical studies. It could be one dose, like the seasonal vaccine, but it could be two doses since the population has little or no immunity to the 2009-H1N1 virus, which has not infected humans previously.

Vaccines against novel influenza A (H1N1) virus infection are being produced using methods similar to those used for seasonal influenza vaccines. Licensure of vaccines against novel influenza A (H1N1) virus will be based on the same licensure standards used for seasonal influenza vaccines, as is done routinely each year when strains are changed in the seasonal vaccine. Both live, attenuated and inactivated influenza A (H1N1) 2009 monovalent vaccine formulations will be available initially; as with seasonal influenza vaccines, neither of these vaccines will contain adjuvants.

Will the 2009 H1N1 vaccine come in vial or syringes?

H1N1 Vaccine will be available in all formulations as for the seasonal flu vaccines – multi-dose vials, and pre-filled syringes, and intra-nasal application.

Is the 2009 H1N1 vaccine administered in one dose? How many doses of vaccine will a patient need?

The number of doses of vaccine required for immunization against novel influenza A (H1N1) has not been established. Because vaccine availability is expected to increase over time, vaccine should not be held in reserve for patients who already have received 1 dose but might require a second dose.

In previously unvaccinated persons aged <9 years, 2 doses of seasonal influenza vaccine are required to induce immunity because young children typically have had limited exposure to influenza viruses and are not immunologically primed (i.e., they do not have preexisting antibodies). The lack of preexisting antibody cross-reactive with the novel influenza A (H1N1) virus among children and younger adults raises the possibility that 2 doses of vaccine (typically separated by ≥ 21 days) also will be needed to provide protection for persons in these age groups. Ongoing studies will provide additional information about the immune response vaccine, including which groups might need 2 doses. Updated information will be published by CDC in MMWR or will be available at <http://www.cdc.gov/flu>.

What is the maximum order? What is the maximum number of doses of H1N1 vaccine that any doctor's practice can order?

There is no established maximum order, and allocations will initially be dependent on vaccine supply.

Will I be able to order more doses, and if so what do I need to do if I want to order more vaccine?

Approval of additional orders of H1N1 vaccines by providers will be dependent on vaccine supply, allocations to the county and utilization patterns based on Inventory management information in MCIR.

Which ancillary supplies will be provided with vaccine?

Department of Health and Human Services will provide needles, syringes, sharps containers and alcohol swabs.

Do we have a time period between injection of seasonal flu vaccine and H1N1 2009 vaccine? Or can they be given at the same time?

Simultaneous administration of inactivated vaccines against seasonal and novel influenza A (H1N1) viruses is permissible if different anatomic sites are used. However, simultaneous administration of live, attenuated vaccines against seasonal and novel influenza A (H1N1) virus is not recommended.

Will the private providers give both injections?

It is preferable that Private Providers administer both shots to their patients. The patient should however be given a vaccination card (which will be supplied along with the vaccine and other supplies) which will indicate which dose they have received, and the return date for the second dose.

Will it be necessary for the first and second dose to be the same product?

Ideally, first and second doses would be from the same product. However, practical considerations make this difficult to implement. Planners should assume they will be interchangeable.

How quickly will I be able to have my order filled or refilled?

The shipping timelines for 2009 H1N1 vaccine are currently being established by CDC and McKesson. Information will be provided as soon as it is available.

Will insurance plans reimburse private providers for administration?

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

"Every year health plans contribute to the seasonal flu vaccination campaign in several ways:

a) Health plans communicate directly with plan sponsors and members on the current ACIP recommendations and encourage immunization; they also provide information on where to get vaccinations, and who to contact with any questions.

b) 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.

Will there be a liability waiver for Providers if they administer this vaccine?

Public Readiness and Emergency Preparedness (PREP) Act: Part of the Public Health Service Act, 42 USC Sec. 247d-6d, provides broad and strong protection to individuals and entities that are engaged in activities related to the use of covered pharmaceutical countermeasures. This includes, for example, entities and individuals involved with manufacturing, labeling, distributing, packaging, marketing, selling, purchasing, donating, dispensing, prescribing, administering, licensing, or using of such countermeasures. Requires a PREP Act Declaration from the Secretary of Dept of Health & Human Services.

§ 247d-6d. Targeted liability protections for pandemic and epidemic products and security countermeasures

(a) Liability protections.

(1) In general. Subject to the other provisions of this section, a covered person shall be immune from

suit and liability under Federal and State law with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a covered countermeasure if a declaration under subsection (b) has been issued with respect to such countermeasure.

What is the proposed timing/ spacing between seasonal flu and H1N1 vaccine? Can the seasonal vaccine and the 2009 H1N1 vaccine be given at the same time?

Simultaneous administration of inactivated vaccines against seasonal and novel influenza A (H1N1) viruses is permissible if different anatomic sites are used. However, simultaneous administration of live, attenuated vaccines against seasonal and novel influenza A (H1N1) virus is not recommended.

What are other ways to prevent the spread of illness, which I can recommend to my patients?

Advise all patients to take everyday actions to stay healthy:

- Cover their nose and mouth with a tissue when they cough or sneeze. Throw the tissue in the trash after they use it.
- Wash their hands **often** with soap and water, especially after they cough or sneeze. Alcohol-based hands cleaners are also effective.
- Avoid touching their eyes, nose or mouth. Germs spread that way.
- Stay home if they become sick. CDC recommends that they stay home from work or school and limit contact with others to keep from infecting them.

Follow public health advice regarding school closures, avoiding crowds and other social distancing measures. These measures will continue to be important after a 2009 H1N1 vaccine is available because they can prevent the spread of other viruses that cause respiratory infections.

Which influenza antiviral drugs should be used for treatment this season?

At this time, treatment with oseltamivir (trade name Tamiflu®) or zanamivir (trade name Relenza®) is recommended for all people with suspected or confirmed influenza **who require hospitalization**. The recommended duration of treatment is five days. However, hospitalized patients with severe infections might require longer treatment courses.

Who is prioritized for treatment with influenza antiviral drugs?

Most people ill with influenza will recover without complications.

Some people are at increased risk of influenza complications and are prioritized for treatment with influenza antiviral drugs this season. They include:

- People **hospitalized** with suspected or confirmed influenza
- People with suspected or confirmed influenza who **are at higher risk for complications**
 - Children younger than 5 years old (children under 2 years old are at higher risk for complications than older children)
 - Adults 65 years and older
 - Pregnant women
 - People with certain chronic medical or immunosuppressive conditions

- **People younger than 19 years of age who are receiving long-term aspirin therapy**

Physicians may also decide not to treat some people in these groups and/or treat people who are not in these groups based on their clinical judgment.

As answers to the following questions are received, the Q&A will be updated.

How will my practice staff get training on MCIR?

We have a multi-physician practice. Does every provider have to register individually into MCIR or as a practice?

We have a multi-physician practice. Does every provider have to individually sign a Provider Agreement or as a practice?

We operate multiple sites in the County. Can we administer to patients at all different locations under one signed Agreement?

Send any questions you may have to:

h1n1@macombcountymi.gov or

Fax questions to (586) 307-8259 – ATTN: H1N1