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H1N1 Clinicians Questions and Answers

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Recommendations for the 2009 H1N1 Vaccine

Who is recommended to receive the 2009 H1N1 flu vaccine?

When vaccine is first available, the CDC Advisory Committee on Immunization Practices (ACIP) has recommended the 2009 H1N1 vaccine for the following 5 **target** groups (approximately 159 million persons nationally):

- Pregnant women
- Household and caregiver contacts of children younger than 6 months of age (e.g. parents, siblings, and daycare providers)
- Health care and emergency medical services personnel
- Persons from 6 months through 24 years of age
- Persons aged 25 through 64 years who have medical conditions associated with a higher risk of influenza complications

Once providers meet the demand for vaccine among persons in these initial target groups, vaccination is recommended for all persons 25 through 64 years of age. Current studies indicate that the risk for infection among persons age 65 or older is less than the risk for younger age groups. However, once vaccine demand among younger age groups has been met, programs and providers should offer vaccination to people 65 or older.

What should a 2009 H1N1 vaccination provider do if there are people requesting 2009 H1N1 vaccine who are not in the initial target groups?

The [ACIP recommendations on 2009 H1N1 vaccination](#) are not intended to deny 2009 H1N1 vaccine to anyone who wishes to be vaccinated. The U.S. government has purchased enough 2009 H1N1 vaccine for all those who choose to get vaccinated. The challenge, especially during the first few weeks of the vaccination program, is to try to provide vaccine to people in the highest risk groups, while vaccine supply may not be adequate to meet total demand. Many state and local health departments have prioritized vaccine orders so that providers who serve mainly people in high risk groups may get vaccine first. However, in any given location, the availability of -- and demand for --

vaccine may vary. Some providers may have enough doses of vaccine right away to meet their patient demand without turning anyone away. In other cases, this may not be true. If a provider does not have sufficient vaccine to meet demand and people who are not in the initial target groups are requesting vaccination, the provider may wish to explain their local plan and rationale for vaccination among the initial target groups and ask others to wait to get vaccinated later. However, until local supply of, and demand for, 2009 H1N1 flu vaccine balance out, the decision regarding who should get vaccinated is one that should be made between the provider and the patient, weighing whether there are enough doses available for those at greatest risk for infection and serious complications as well as the likelihood that patients turned away will come back for vaccine at a later date.

When will vaccine be available for those who aren't in the 5 initial target groups?

The availability of 2009 H1N1 flu vaccine will differ by state or jurisdiction based on several factors, including the total number of people recommended for initial doses in that particular area, the quantity of vaccine available and local demand for vaccine. [ACIP recommendations on 2009 H1N1 vaccination](#) were that vaccination of other people not in the initial target groups begin after local demand for vaccine among the target groups had been met. This will vary across locality and is difficult to predict. However, once the demand for vaccine for the initial target groups has been met at the local level, programs and providers should begin vaccinating everyone from the ages of 25 through 64 years, then followed by vaccination of people 65 years and older. (See also: summary of recommendations at <http://www.cdc.gov/h1n1flu/vaccination/acip.htm>) Overall, it is expected that vaccine supply should increase quickly in late October and early November.

Will the 2009 H1N1 vaccine be recommended for patients who had influenza-like illness since spring 2009?

All people in a recommended vaccination target group who did not have 2009 H1N1 virus infection confirmed by real-time reverse transcriptase-polymerase chain reaction (rRT-PCR) test should be vaccinated with the 2009 H1N1 vaccine. **People who had an illness confirmed by rRT-PCR to be 2009 H1N1 virus earlier in 2009 can be considered to be immune and do not need to be vaccinated this year.** However, most people with respiratory illnesses since this spring have not had testing with the rRT-PCR test, which is the only test that can confirm infection specifically with the 2009 H1N1 virus. Tests such as rapid antigen detection assays and diagnoses based on symptoms alone without rRT-PCR testing, cannot specifically determine if a person has 2009 H1N1 influenza. Although people who were not tested, but who became ill within 1-4 days after close contact with a person with lab confirmed 2009 H1N1 influenza might have been infected with 2009 H1N1, they cannot be certain since many pathogens can cause respiratory illness. These people should get the 2009 H1N1 vaccine as recommended for their age and risk group.

People who were infected with the 2009 H1N1 virus and who are not severely immune compromised will likely have immunity to subsequent infection with 2009 H1N1 virus. However, vaccination of a person with some existing immunity to the 2009 H1N1 virus will not be harmful, and patients who are uncertain about how they were diagnosed should get the 2009 H1N1 vaccine. In addition, people recommended for seasonal vaccine should get a seasonal vaccine because infection with the 2009 H1N1 virus does not provide protection against seasonal influenza viruses.

Supply and Distribution

How will the 2009 H1N1 vaccine flow from manufacturers to providers?

The Federal Government will allocate vaccine to states based on population size. States are responsible for identifying providers who will participate in administration of 2009 H1N1 vaccine. Vaccine will be shipped to participating providers through a centralized distribution process. Through this process, placing of orders is facilitated by the state/local health department, and this information sent to CDC to be transferred to the distributor for processing. Because of limitations related to the number of sites to which the distributor can directly ship vaccine, some project areas (includes all states, territories, Chicago, DC, NYC, and LA county) may develop additional means of distributing vaccine to providers which will be communicated to providers on a local level.

How can providers obtain vaccine?

State/Local public health departments will be responsible for directing the flow of vaccine to providers within every state. They will determine which providers will receive vaccine, and will allocate vaccine among providers as it becomes available to them. Public health departments are in the process of ascertaining which providers are interested in administering vaccine. For more information go to your state's public health department website or to the [CDC 2009 H1N1](#) website for information on how to become a 2009 H1N1 vaccine provider. Participating providers will sign a Provider Agreement assuring they intend to meet state requirements

Will vaccine be distributed equitably across providers?

Public health departments will strive to ensure equitable distribution, taking into account which target groups are seen by different types of providers as well as their internal resources for possible re-distribution of vaccine.

What supplies will be included with the 2009 H1N1 vaccine shipments?

The Federal Government will purchase vaccine and supplies (syringes, alcohol swabs, sharps containers, and vaccine record cards) and distribute these at no cost to healthcare providers who make agreements with state and local public health authorities to provide the 2009 H1N1 vaccine. Supplies will be shipped separately from vaccine and are expected to arrive before or on the same day as vaccine.

Will the 2009 H1N1 vaccine supplies include safety-engineered needles to protect clinicians against needlesticks?

Yes. The Federal Government has specified that the 2009 H1N1 vaccine supplies include safety-engineered needles.

Administration

How can providers determine what percentage of their patients plan on getting the 2009 H1N1 vaccine in a physician's office?

It is difficult to predict where individuals will go to receive the 2009 H1N1 vaccine. However, based on unpublished data from the Adult National Immunization Survey, during the 2006-2007 influenza season, among 19-49 year olds who were vaccinated, approximately 38% of persons at increased risk of complications from influenza reported receiving influenza vaccine in a physician's office.

Approximately 26% of persons with household contact with a high risk person and 25% of persons with no specific indications for influenza vaccine were vaccinated in a physician's office.

What are some possible approaches a practice might take to administer the 2009 H1N1 vaccine?

Options include holding special clinics, integrating the 2009 H1N1 vaccination into usual care, providing walk-in immunizations, or coordinating with local public health clinics if unable to administer 2009 H1N1 vaccine themselves. In determining the best option, each practice should consider several factors, including availability of vaccine, practice resources and patient demand.

If my patients are vaccinated outside of my practice, how will that information be available for inclusion in the patient's permanent medical record?

Recipients of the 2009 H1N1 vaccine will be provided with a hand-held card to serve as a record of vaccination and a source of information should a report to the Vaccine Adverse Event Reporting System (VAERS) be needed. Vaccine recipients will be encouraged to bring the hand-held card at their next visit to their primary care provider so that vaccination information can be transcribed into the patient's permanent medical record.

Can seasonal influenza vaccine and 2009 H1N1 vaccine be given at the same visit?

Both seasonal and 2009 H1N1 vaccines are available as inactivated and live attenuated (LAIV) formulations. The simultaneous and sequential administration of seasonal and 2009 H1N1 inactivated vaccines is currently being studied. However, existing recommendations are that two inactivated vaccines can be administered at any time before, after, or at the same visit as each other (General Recommendations on Immunization, MMWR 2006;55[RR-15]). Existing recommendations also state that an inactivated and live vaccine may be administered at any time before, after or at the same visit as each other. Consequently, providers can administer seasonal and 2009 H1N1 inactivated vaccines, seasonal inactivated vaccine and 2009 H1N1 LAIV, or seasonal LAIV and inactivated 2009 H1N1 at the same visit, or at any time before or after each other. Live attenuated seasonal and live 2009 H1N1 vaccines should NOT be administered at the same visit until further studies are done. If a person is eligible and prefers the LAIV formulation of seasonal and 2009 H1N1 vaccine, these vaccines should be separated by a minimum of four weeks.

Can 2009 H1N1 vaccine be administered at the same visit as other vaccines?

Inactivated 2009 H1N1 vaccine can be administered at the same visit as any other vaccine, including pneumococcal polysaccharide vaccine. Live 2009 H1N1 vaccine can be administered at the same visit as any other live or inactivated vaccine EXCEPT seasonal live attenuated influenza vaccine.

The age for two doses is different for seasonal (6 months through 8 years) and 2009 H1N1 monovalent vaccine (6 months through 9 years) in the package inserts. Does CDC recommend that clinicians follow the recommendation in the package inserts?

CDC recommends that clinicians follow the guidance in the manufacturer package inserts. For 2009 H1N1 monovalent vaccines, that means that clinicians should administer two doses of 2009 H1N1 monovalent vaccine to children 6 months through 9 years of age. Persons 10 years and older should receive one dose.

The interval between 2009 H1N1 monovalent vaccine doses, for children 6 months through 9 years, is stated as "approximately 1 month" in the package inserts. What does "approximately 1 month" mean?

CDC recommends that the two doses of 2009 H1N1 monovalent vaccine 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 to be valid. If the interval separating the doses is less than 21 days the second dose should be repeated four weeks after the first dose was given.

If seasonal live attenuated influenza vaccine (LAIV) and 2009 H1N1 LAIV are given during the same visit, do either or both doses need to be repeated, and if so, when?

There are no data on the administration of seasonal and 2009 H1N1 LAIV during the same visit. CDC's Advisory Committee on Immunization Practices (ACIP) recommends that seasonal and 2009 H1N1 LAIV not be administered during the same visit. However, if both types of LAIV are inadvertently administered during the same visit, neither vaccine needs to be repeated.

If seasonal and 2009 H1N1 LAIV are not administered during the same visit, but are separated by less than 4 weeks, do either or both doses need to be repeated, and if so, when?

Seasonal LAIV and 2009 H1N1 LAIV should not be administered during the same visit, and should be separated by at least 4 weeks. However, if the interval between administration of seasonal LAIV and 2009 H1N1 vaccine is less than 4 weeks, neither vaccine needs to be repeated.

Can patients who are allergic to eggs receive the 2009 H1N1 flu vaccine?

Asking persons if they can eat eggs without adverse effects is a reasonable way to determine who might be at risk for allergic reactions from receiving influenza vaccines. Persons who have had symptoms such as hives or swelling of the lips or tongue, or who have experienced acute respiratory distress after eating eggs, should consult a physician for appropriate evaluation to help determine if influenza vaccine should be administered. Persons who have documented (IgE)-mediated hypersensitivity to eggs, including those who have had occupational asthma related to egg exposure or other allergic responses to egg protein, also might be at increased risk for allergic reactions to influenza vaccine, and consultation with a physician before vaccination should be considered. A regimen has been developed for administering influenza vaccine to asthmatic children with severe disease and egg hypersensitivity (*J Pediatr* 1985;106:931-3.).

Can a person who has received LAIV test positive on a rapid influenza diagnostic test?

The live attenuated influenza vaccine viruses in LAIV (seasonal vaccine and 2009 H1N1 monovalent vaccine) can cause a positive result on a rapid influenza diagnostic test. The tests are designed to detect influenza viruses and cannot differentiate between live attenuated and wild-type influenza viruses. A positive test in a person who recently (in the previous 7 days) received LAIV and who also has an influenza-like illness could be caused by either LAIV or wild-type influenza virus.