

Update on 2009 H1N1 influenza vaccine issues

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Influenza activity has increased sharply throughout the country, as reflected by rising numbers of physician visits for influenza-like illnesses, hospitalizations for severe influenza and its complications, and deaths. Virtually all influenza viruses identified to date are 2009 H1N1 influenza (swine flu), which is widespread in nearly all 50 states.



Dr. Bernstein

Vaccination is the best way to protect against influenza. Millions of doses of the 2009 H1N1 influenza monovalent vaccine are being distributed weekly.

Initial priority groups targeted for vaccination

The intent of the federal government is to vaccinate as many people as possible, as quickly as possible. Unfortunately, the 2009 H1N1 influenza monovalent vaccine initially will be in limited supply, making it difficult to meet early demand.

Therefore, the following “special groups” are recommended as top priority for 2009 H1N1 influenza monovalent vaccine:

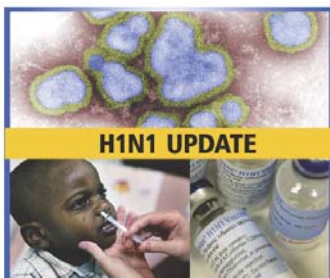
- children 5 through 18 years of age with chronic medical conditions (e.g., asthma and neurological disorders; details at www.aap.org/new/H1N1pdf.htm) that increase their risk for complications from the flu;
- household contacts of infants under 6 months of age;
- health care workers and emergency services personnel who provide direct patient care or have contact with infectious substances;
- all children 6 months through 4 years of age; and
- pregnant women.



Dr. Bocchini

Vaccine supply is anticipated to improve over the next month or so. As more vaccine becomes available, all persons 6 months through 24 years of age and all 25- through 64-year-olds with chronic medical conditions that increase the risk of complications of influenza should be vaccinated.

Since the vaccine is not approved for infants younger than 6 months of age, vaccinating everyone who lives with or cares for young infants is the



best way to protect them from being exposed to influenza.

Live attenuated influenza vaccine (LAIV) can be given by nasal inhalation to all healthy people 2 through 49 years of age. Pregnant women and children and adults with chronic medical conditions that increase the risk of complications from influenza should receive the inactivated influenza vaccine (TIV) by injection, not the live attenuated vaccine.

However, both vaccine types are safe for women who have just given birth and/or are breastfeeding.

None of the influenza vaccines licensed and distributed in the United States contain an adjuvant. The current vaccines are being made the same way that seasonal influenza vaccines have been made for years.

Number of doses, intervals between them

Children 10 years (10th birthday) and older should receive one dose of the 2009 H1N1 influenza monovalent vaccine. This is in slight contrast to seasonal influenza vaccine, where children 9 and older need only one dose. Harmonizing these two recommendations is being explored.

Children younger than 10 years should receive two doses of 2009 H1N1 influenza monovalent vaccine, separated by four weeks.

- An interval of at least 21 days between doses of the inactivated 2009 H1N1 vaccine is considered acceptable. If the interval separating the inactivated 2009 H1N1 vaccine doses is less than 21 days, the second dose should be repeated at least 21 days after the first dose.
- Twenty-eight days is the appropriate valid interval between doses of 2009 H1N1 live attenuated vaccines.
- Additional information about intervals for both types of 2009 H1N1 vaccines (inactivated and live attenuated) from ongoing clinical trials will be considered when available.
- When feasible, the same type of H1N1 vaccine (live attenuated or inactivated) should be used in a two-dose schedule, but mixed schedules are preferable to not completing the series.

The table (above) summarizes the current guidelines for administering seasonal and H1N1 vaccines. The inactivated 2009 H1N1 vaccine can be administered with any other vaccine, and anytime before or after other vaccines. The live attenuated monovalent influenza vaccine can be administered along with any other live vaccine except seasonal live attenuated influenza vaccine. Doses of

live viral vaccines should be separated by one month.

Seasonal trivalent inactivated vaccine and the 2009 H1N1 inactivated vaccine may be given at the same time, but seasonal LAIV and 2009 H1N1 LAIV vaccines must not be administered at the same visit.

Based on previous studies of LAIV replication and immune response, as little as 14 days (two weeks) might be sufficient to allow for an appropriate immune response to both vaccines. Therefore, an interval of two weeks or more between seasonal LAIV and 2009 H1N1 LAIV may be acceptable, although an interval of 28 days is preferred. If the interval between seasonal LAIV and 2009 H1N1 LAIV is less than 14 days, the vaccine more recently administered should be repeated.

Vaccines should be administered in accordance with Food and Drug Administration (FDA)-approved labeling. Precautions and contraindications for H1N1 monovalent vaccine can be found on the Centers for Disease Control and Prevention (CDC) Web site (www.cdc.gov/h1n1flu/vaccination/) and the FDA Web site (www.fda.gov/NewsEvents/PublicHealthFocus/ucm150305.htm).

Safety monitoring

The CDC has systems in place to monitor the safety of 2009 H1N1 influenza vaccine — Vaccine Adverse Event Reporting System (VAERS), the Vaccine Safety Datalink Project and the CDC Emerging Infections program.

VAERS is a passive surveillance system, so under-reporting is a known limitation. In addition, none of the reports collected can determine cause and effect.

Supply and distribution

This year, the demand for the influenza vaccine is predicted to be higher than last year. It is estimated that 114 million doses of seasonal influenza vaccine have been made, of which more than three-quarters have been distributed. Two systems that look at vaccinations administered and billed show that many more individuals have been vaccinated this season than at the same time last year. This may reflect the early availability of seasonal vaccine.

Guidelines for administering seasonal and H1N1 vaccines at the same visit

	Injected		Inhaled	
	H1N1 TIV	Seasonal TIV	H1N1 LAIV	Seasonal LAIV
H1N1 TIV	N/A	Can be given together	N/A	Can be given together
Seasonal TIV	Can be given together	N/A	Can be given together	N/A
H1N1 LAIV	N/A	Can be given together	N/A	Must separate by 2 weeks (preferably by 4 weeks)
Seasonal LAIV	Can be given together	N/A	Must separate by 2 weeks (preferably by 4 weeks)	N/A

Actual numbers will depend on the manufacturers' abilities to meet production goals. If the demand for the seasonal influenza vaccine exceeds the supply, the extra demand will not be met. Unfortunately, manufacturers are not able to produce more seasonal influenza vaccine for this season. The same facilities are being used to produce the H1N1 vaccine, which takes several months to produce.

The CDC recommends that providers check the National Influenza Summit Web site (www.preventinfluenza.org), which lists available vaccine by distributor.

Health care worker (HCW) immunization

Most of the H1N1 vaccine currently being distributed is LAIV, with only modest amounts of TIV available. HCWs under 50 years of age with no underlying medical conditions may receive LAIV. This vaccine does not represent any significant risk to their patients from the attenuated vaccine virus shed from the nasal mucosa, except for those who work with severely immunocompromised patients (e.g., hematopoietic stem cell transplant recipients during periods that require a protected environment) for seven days after LAIV immunization, although there have been no reports of LAIV transmission from a vaccinated person to an immunocompromised person.

Those who work in offices, clinics, hospital wards, and even neonatal and pediatric intensive care units, all may receive the H1N1 LAIV.

Continue to monitor the AAP (<http://aap.org/new/swineflu.htm>) and CDC (www.cdc.gov/h1n1flu/) Web sites, as recommendations may change.

Drs. Bernstein and Bradley are members of the AAP Committee on Infectious Diseases (COID). Dr. Bocchini is chair of COID.