

# **Top 10 frequently asked questions on use of influenza A(H1N1) 2009 monovalent vaccines (2009 H1N1 vaccines): Practical considerations for immunization programs and providers**

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Two different influenza vaccines are available this influenza season, and many people will be recommended to receive both the seasonal influenza vaccine and the 2009 influenza A (H1N1) 2009 monovalent vaccine (referred to in this document as 2009 H1N1 vaccine). Below are some practical considerations for use of influenza vaccines. They are only intended to address the current pandemic situation and might change as the situation unfolds. They are not intended to be applied to routine use during future seasonal influenza vaccination efforts.

## **1. Two Doses for Children**

Children ages 6 months through 8 years receiving seasonal influenza vaccination for the first time are recommended to receive 2 doses. However, children ages 6 months through 9 years are recommended to receive 2 doses in the prescribing information for 2009 H1N1 vaccines. Does CDC recommend that clinicians follow the recommendation in the 2009 H1N1 vaccine package inserts, or use the standard seasonal vaccine recommendations?

The recommendations for use of seasonal vaccine are unchanged. Using the 2009 H1N1 vaccine schedule presented in the prescribing information is recommended (6 months through 9 years receive 2 doses). However, if considered necessary for consistency, vaccination providers can also follow the guidance for the seasonal vaccines for both vaccines, pending additional data from ongoing studies. The ongoing vaccine immunogenicity studies might provide additional information on which children should receive 2 doses, but these data are not yet available.

## **2. Definition of 1 Month Interval**

The interval between doses stated in the 2009 H1N1 vaccine prescribing information is "approximately 1 month". What does "approximately 1 month" mean?

CDC recommends that the two doses of 2009 H1N1 vaccines be separated by 28 days (4 weeks).

## **3. Acceptable Interval for 2009 H1N1 Inactivated Vaccines**

The influenza A (H1N1) 2009 monovalent inactivated vaccine trials that are currently underway have often used a 21 day (3 week) interval between doses. Is a 21 day interval acceptable?

CDC recommends that the two doses of 2009 H1N1 vaccines be separated by 28 or more days (4 weeks). However, trials of the inactivated 2009 H1N1 vaccines have often used a 21 day interval. Administering the two doses of a

2009 H1N1 inactivated vaccine at least 21 days apart is safe. Therefore, if the second dose of an inactivated 2009 H1N1 vaccine is separated from the first dose by at least 21 days, the second dose can be considered valid. If the interval separating the doses is less than 21 days, the second dose should be repeated 28 or more days after the first dose (21 days acceptable). Trials of 2009 H1N1 live attenuated vaccines have used a 28 day interval between doses and therefore 28 days is the appropriate valid interval. Additional information about intervals for both types of 2009 H1N1 vaccines (inactivated and live attenuated) from the ongoing clinical trials will be considered when available.

#### **4. Using Seasonal Inactivated Influenza Vaccines and 2009 H1N1 Inactivated Vaccine at the Same Time.**

**Can the seasonal inactivated vaccine (trivalent inactivated vaccine or TIV) and the 2009 H1N1 inactivated vaccine be given at the same time?**

Yes.

#### **5. Use of Seasonal Live Attenuated Influenza Vaccine (LAIV) and 2009 H1N1 LAIV at the Same Visit**

**If seasonal LAIV and 2009 H1N1 LAIV are given at the same visit, do either or both doses need to be repeated, and if so, when?**

Seasonal LAIV and 2009 H1N1 LAIV should not be administered at the same visit. There are no data from studies in humans on the administration of seasonal and H1N1 2009 monovalent live attenuated vaccines at the same visit. Use of the 2 types of LAIV at the same time could result in reduced immunogenicity for one vaccine, according to some experts. However, if both types of LAIV are inadvertently administered at the same visit neither vaccine needs to be repeated.

#### **6. Minimum Interval between Different LAIV Formulations**

**What is the minimum interval between doses of seasonal LAIV and 2009 H1N1 LAIV?**

There are no data on sequential administration of the two types of LAIV (seasonal and 2009 H1N1). The ACIP General Recommendations on live attenuated vaccines indicates that 28 days (4 weeks) is the recommended minimum interval, and can be applied to use of a seasonal LAIV and a 2009 H1N1 LAIV, because these are considered 2 different vaccines. The ACIP recommendations were developed based on data from studies using attenuated live virus vaccines such as measles, mumps and rubella vaccine that are injected. However, based on previous studies of LAIV replication and immune response, as little as 14 days (2 weeks) might be sufficient to allow for an appropriate immune response to both vaccines. Therefore, an interval between the two types of LAIV of 2 weeks or more may be acceptable, although an interval of 28 days is preferred.

#### **7. Repeating Doses when Seasonal LAIV and 2009 H1N1 LAIV are Used in Shorter Intervals than is Accepted (between 1 and 13 days)**

**If seasonal and H1N1 LAIV are not administered on the same day, but are separated by less than 14 days (2 weeks), do either or both doses need to be repeated, and if so, when?**

Seasonal LAIV and 2009 H1N1 LAIV should not be administered at the same visit, and should be separated by at least 14 days and ideally by at least 28 days

based on previous studies of attenuated influenza vaccine virus replication and immune response. If the interval between administration of seasonal LAIV and 2009 H1N1 LAIV is from 1-13 days, the vaccine more recently administered should be repeated.

#### **8. Using an Inactivated Vaccine and a Live Attenuated Vaccine at the Same Time**

**Can a live attenuated vaccine be given at the same time as an inactivated influenza vaccine (e.g., seasonal LAIV and 2009 H1N1 inactivated vaccine, or 2009 H1N1 LAIV and seasonal trivalent inactivated influenza vaccine [TIV])?**

Yes, these two types of vaccines can be given at the same time, based upon ACIP's General Immunization recommendations. Any interval between the two types of vaccines is also acceptable.

#### **9. Using an Inactivated 2009 H1N1 Vaccine and a Live Attenuated 2009 H1N1 Vaccine in the Same Series**

**Can a child who requires 2 doses of a 2009 H1N1 vaccine and who received the first dose with a inactivated 2009 H1N1 vaccine complete the series with the 2009 H1N1 LAIV, or vice versa?**

When feasible, the same type of vaccine (live attenuated or inactivated) should be used in a two dose schedule, but mixed schedules are preferable to not completing the series. A 28 day interval between doses is recommended, but 21 days is acceptable. There are limited data on mixed schedules.

#### **10. Use of 2009 H1N1 Vaccines Outside Approved Age Indications Can 2009 H1N1 vaccines be used outside the age range approved by the Food and Drug Administration?**

Whenever possible, vaccines should be administered in accordance with FDA-approved labeling. Vaccines approved for an age group will have undergone the required testing for that age group. There are no known safety concerns with use of inactivated vaccines in appropriate doses outside their labeled age indications. Data on vaccine effectiveness for influenza vaccines use outside of labeled age indications are limited.

LAIV should not be used outside the approved age indications (ages 2 years through 49 years).

Inactivated influenza vaccines should not be given to infants younger than 6 months.

However, clinicians may use inactivated 2009 H1N1 vaccines for persons 6 months and older outside their labeled age range if a vaccine licensed for use in a particular age group is not available, and the need to provide vaccination is urgent. For instance, an inactivated 2009 H1N1 influenza vaccine licensed for people 18 years and older (e.g., CSL H1N1 vaccine) may be used for a child younger than 18 years if no other vaccine is available, and the alternative would be for the child to not receive a 2009 H1N1 influenza vaccine at that visit. Similarly, an inactivated 2009 H1N1 vaccine labeled for use in older children or adults (e.g., Novartis, CSL, or some Sanofi Pasteur formulations) can be given to an infant or younger child if the alternative would be for the child to not receive any influenza vaccine at that visit. For children ages 6 months through 35 months, a half dose (0.25 mL) of a vaccine licensed for older children or adults should be used. If possible, children who require 2 doses should receive at least 1 dose in a formulation approved for their age. Use of vaccines outside approved indications is a temporary measure that applies only to the special circumstances faced during the 2009 H1N1 pandemic, and should be avoided if possible.