

September 30, 2009

TO: Medical Providers and Health Care Facilities

FROM: NYSDOH Bureau of Immunization

HEALTH ADVISORY: Use of Live Attenuated Intranasal Monovalent H1N1 Influenza Vaccine (LAIV) in the 2009-10 H1N1 Influenza Vaccination Program

Please distribute to the Infection Control Department, Medical Director, Director of Nursing, Emergency Department, Employee Health, and all patient care areas

Influenza vaccination is the most effective method for preventing influenza virus infection and its complications.

During the vaccination campaign for the 2009 H1N1 influenza live attenuated intranasal monovalent vaccine (LAIV) will be one of the 5 vaccines provided by the federal government, and will be among the first vaccines to be made available. Since the national goal for the vaccination campaign is to vaccinate as many people for H1N1 influenza as quickly as possible, vaccine providers receiving 2009 H1N1 intranasal LAIV should be familiar with the indications for its use and should make every effort to vaccinate appropriate populations as soon as it is available.

Indications for use of 2009 H1N1 intranasal LAIV: This vaccine is licensed for use among non-pregnant persons aged 2-49 years who are healthy and do not have an underlying medical condition.

Priority groups for 2009 H1N1 monovalent influenza vaccination in whom 2009 H1N1 intranasal LAIV can be used:

- Otherwise healthy persons age 2 to 24 years.
- Otherwise healthy persons age 2 to 49 years who live with or provide care for infants aged <6 months (e.g., parents, siblings, and daycare providers).
- Otherwise healthy health care and emergency medical services personnel (HCP) up to age 49 years who are not contacts of severely immunosuppressed persons may receive 2009 H1N1 intranasal LAIV.
 - Severely immunosuppressed persons include, for example, patients with hematopoietic stem cell transplants during those periods in which the immunosuppressed person requires care in a protective environment (typically defined as a specialized patient-care area with a positive airflow relative to the

corridor, high-efficiency particulate air filtration, and frequent air changes). HCP caring for these patients should be vaccinated with inactivated influenza vaccine.

- LAIV transmission from a recently vaccinated person causing clinically important illness in an immunocompromised contact has not been reported. The rationale for avoiding use of LAIV among HCP or other close contacts of severely immunocompromised patients is the theoretical risk that a live, attenuated vaccine virus could be transmitted to the severely immunosuppressed person. As a precautionary measure, HCP who receive LAIV should avoid providing care for severely immunosuppressed patients requiring a protected environment for 7 days after vaccination.
- Hospital visitors who have received LAIV should avoid contact with severely immunosuppressed persons in protected environments for 7 days after vaccination but should not be restricted from visiting less severely immunosuppressed patients.
- LAIV may be used to vaccinate HCP who have close contact with persons with lesser degrees of immunosuppression (e.g., persons with diabetes, persons with asthma who take corticosteroids, persons who have recently received chemotherapy or radiation but who are not being cared for in a protective environment as defined above, or persons infected with HIV).

Personnel who can administer 2009 H1N1 intranasal LAIV:

- Severely immunosuppressed persons (as defined above) should not administer LAIV. However, all other persons can administer LAIV. These include persons with underlying medical conditions placing them at higher risk or who are likely to be at risk, including pregnant women, persons with asthma, and persons aged ≥ 50 years.

Concurrent administration of 2009 H1N1 intranasal LAIV with other vaccines:

- Inactivated or live vaccines can be administered simultaneously with LAIV. Currently, however, the seasonal LAIV (Flumist®) and the 2009 H1N1 intranasal LAIV should not be given at the same time. After administration of a live vaccine, at least 4 weeks should pass before another live vaccine is administered.

Contraindications and precautions for use of 2009 H1N1 intranasal LAIV

LAIV is contraindicated in:

- Persons with a history of hypersensitivity, including anaphylaxis, to any of the components of LAIV or to eggs;
- Persons aged < 2 years or those aged ≥ 50 years;
- Adults and children who have chronic pulmonary (including asthma), cardiovascular (except hypertension), renal, hepatic, neurological/neuromuscular, hematological, or metabolic disorders (including diabetes mellitus);
- Adults and children who have immunosuppression (including immunosuppression caused by medications or by HIV);
- Children aged 2–4 years whose parents or caregivers report that a health-care provider has told them during the preceding 12 months that their child had wheezing or asthma, or whose medical record indicates a wheezing episode has occurred during the preceding 12 months;

- Children or adolescents aged 6 months–18 years receiving aspirin or other salicylates (because of the association of Reye syndrome with wild-type influenza virus infection); or
- Pregnant women.

Precautions for LAIV are: a moderate or severe illness, with or without fever, and a history of Guillain-Barré Syndrome (GBS) within 6 weeks following a previous dose of influenza vaccine.

Efficacy of LAIV (Flumist®):

A randomized, double-blind, placebo-controlled trial among 1,602 healthy children aged 15–71 months assessed the efficacy of LAIV against culture-confirmed influenza during two seasons. This trial included a subset of children aged 60–71 months who received 2 doses in the first season. During season one (1996–97), when vaccine and circulating virus strains were well-matched, efficacy against culture-confirmed influenza was 94% for participants who received 2 doses of LAIV separated by ≥ 6 weeks, and 89% for those who received 1 dose. During season two (1997--98), when the A (H3N2) component in the vaccine was not well-matched with circulating virus strains, efficacy (1 dose) was 86%.

A recently published study found that for adults, LAIV was less effective than the influenza shot. However, this study was performed with the seasonal influenza vaccine, not the monovalent H1N1 influenza vaccine. It was hypothesized that prior exposure to related influenza strains may have reduced the efficacy of LAIV; however that situation is not expected with the 2009 H1N1 virus.

Other information about 2009 H1N1 intranasal LAIV:

- LAIV is shipped at 35° F – 46° F (2° C – 8° C).
- LAIV should be stored at 35° F – 46° F (2° C – 8° C) on receipt and can remain at that temperature until the expiration date is reached.
- LAIV does not contain thimerosal.

ACIP Statement: Prevention and Control of Seasonal Influenza with Vaccines.

<http://www.cdc.gov/mmwr/pdf/rr/rr5808.pdf>

ACIP Statement: Use Influenza A (H1N1) 2009 Monovalent Vaccine

<http://www.cdc.gov/mmwr/PDF/rr/rr5810.pdf>

Package Insert for Influenza A (H1N1) 2009 Vaccine Live, Intranasal

<http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM182406.pdf>

NYSDOH Fact sheet on Flumist®

<http://www.health.state.ny.us/diseases/communicable/influenza/flumist.htm>