

Minnesota Department of Health

Live attenuated influenza vaccine (LAIV): A safe and effective choice

Is LAIV as effective as the influenza shot?

Yes. Studies conducted before the licensure of LAIV (FluMist) show that it is very protective against influenza disease. CDC discusses the efficacy as follows: "In one large study among children aged 15-85 months, the nasal-spray flu vaccine (LAIV) reduced the chance of influenza illness by 92% compared with placebo. In a study among adults, the participants were not specifically tested for influenza. However, the study found 19% fewer severe febrile respiratory tract illnesses, 24% fewer respiratory tract illnesses with fever, 23-27% fewer days of illness, 13-28% fewer lost work days, 15-41% fewer health care provider visits, and 43-47% less use of antibiotics compared with placebo."¹ Efficacy of inactivated influenza vaccine is about 70-90% in adults <65 years, and 77-91% effective in children 1-15 years of age. Thus, LAIV is at least as effective as inactivated vaccine.

Who can receive LAIV?

Healthy non-pregnant people 2 through 49 years of age without any chronic health conditions are eligible for LAIV. This includes household contacts and out-of-home caregivers of infants under 6 months of age, health care workers, and contacts of persons who have chronic health conditions.

Is LAIV really an option for health care workers?

Yes, for healthy health care workers up through age 49, especially when there is a shortage of inactivated influenza vaccine. Choosing LAIV, currently available as FluMist, means you are helping to conserve when there is limited inactivated influenza vaccine for high-risk persons who do not have the option of live attenuated influenza vaccine. Your decision to do the right thing could possibly save a life.

What does "attenuated" mean?

Attenuated means that the influenza viruses used to make LAIV have been weakened so they cannot grow well in human tissue. Six parts of the genetic material used to make the vaccine have been modified. In order for the vaccine to become as strong as the circulating influenza virus strains, all six of these components would have to change. Throughout the clinical trials,

the stability of the virus was studied and it was found that all six of the genetic components of LAIV remained stable maintaining its attenuated, cold-adapted characteristics.

I read that LAIV is "cold adapted." What does that mean?

Cold adapted means the vaccine survives and replicates only at temperatures less than 25° Celsius. This temperature range allows the vaccine to grow well in the nose and throat. However, once the virus reaches the lower respiratory tract, the warm temperature destroys the virus. This means the vaccine, unlike influenza viruses, cannot replicate and cause disease.

Is shedding the virus a problem for health care workers?

By law the FluMist package insert must state that a person can shed the virus for up to three weeks, but shedding alone should not be equated with person-to-person transmission. In fact studies have found that it is very rare. In a study designed to maximize the chance of detecting vaccine virus transmission, conducted in a Finnish daycare, one child shed the virus for 21 days. Other children in this study shed the virus a mean of 7.6 days. Transmission rates were extremely low (0.6%-2.4%). There was actually only one documented case of LAIV transmission.² An additional small study of 40 adults conducted since licensure found that only 50% of the adults were shedding the virus from the influenza vaccine on day three after vaccination; one adult shed the virus on day seven as well. That means that half the adults had stopped shedding the virus by day three.³ Some of these post licensure studies have prompted ACIP to reduce the days a HCW should avoid contact with patients requiring protective isolation - from three weeks to seven days.

What if the shed virus is transmitted? Isn't that dangerous?

The virus is shed in lower titers than typically occur with shedding of wild-type influenza viruses. So even if transmission were to occur, there are not enough viral particles to make a person ill. It also retains its attenuated characteristics, thus cannot replicate in the lower respiratory tract. The bottom line? Shedding and



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rare subsequent transmission cannot be presumed to cause disease.

Who cannot receive LAIV?

Because no studies were completed at licensure to determine the efficacy or safety in certain persons, LAIV is not recommended for the following:

- People with medical conditions that place them at high risk for complications from influenza, including those with chronic heart or lung disease, such as asthma or reactive airways disease; people with medical conditions such as diabetes or kidney failure; or people with illnesses that weaken the immune system or who take medications that can weaken the immune system.
- Children age 2 through 4 years of age with possible reactive airway disease (recurrent wheezing or a wheezing episode within the past 12 months).
- Children or adolescents receiving aspirin therapy.
- People with a history of Guillain-Barré Syndrome, a rare disorder of the nervous system.
- Pregnant women.
- People with a history of allergy to any of the components of LAIV or to eggs.

Can contacts of the persons listed above get vaccinated with LAIV?

Yes. There is only one instance in which healthy people should consider the inactivated flu injection over the nasal spray – when they are caring for persons requiring protective isolation, e.g., post bone marrow transplant.

Can contacts of persons with weakened immune systems be vaccinated with LAIV?

Yes, LAIV can be used in contacts of persons who have HIV/AIDS, who are on chemotherapy, or who have diseases that weaken their immune system. Remember that the vaccine uses a weakened virus that doesn't contain a viral dose big enough to cause disease. Also, once the virus gets to the lower respiratory tract the warmer temperatures kill it.

Can a pregnant health care worker administer LAIV?

Yes. No special precautions (such as gloves) are necessary. Wash hands or clean them with a waterless hand sanitizer before and after administering the vaccine or having any direct contact with patients in a health care setting.

What side effects are associated with LAIV?

In children, the most common side effects can include runny nose, headache, vomiting, muscle aches, and fever. In clinical trials upper respiratory symptoms,

such as runny nose and nasal congestion, fever, or other systemic symptoms, were reported in 10%-40% of both vaccine and placebo recipients. Adults may experience a runny nose, headache, sore throat, and cough. Unlike children, fever is not a common side effect in adults receiving LAIV.

Is LAIV a safe vaccine?

The study and development of the live attenuated influenza vaccine have been going on since the 1960s. Prior to licensure, the safety of LAIV was studied in 20 clinical trials. More than 6,000 clinical trial participants were in the age range of 5-49 years and an additional 4100 children age 6-59 months were monitored. In healthy children down to age 24 months there were no significant differences between vaccine and placebo recipients. In children under age 24 months there were increased reports of wheezing and hospitalization compared to the group receiving TIV.⁴ Serious adverse reactions have been identified in less than 1% of LAIV recipients, either children or adults, since licensure.

There have been no instances of Guillain-Barré Syndrome reported among LAIV recipients.

Can LAIV be given to patients when they are ill?

Persons with mild illnesses, e.g., diarrhea or mild upper respiratory tract infection, with or without fever, may receive the nasal spray flu vaccine (LAIV). Vaccination may need to be delayed for persons who have an illness that has caused nasal congestion because of the interference of vaccine delivery.

¹ Prevention and Control of Influenza: Recommendations of the Advisory Committee on Immunization Practices (ACIP) (MMWR 28 May 2004; 53[RR06]:1-40).

² Vesikari T, Karnoven A., Karhonen T. et al. A randomized double-blind study of the safety, transmissibility, and phenotypic stability of cold-adapted influenza virus vaccine. *Ped Infec Dis J* 2006; 26:4940-6.

³ Talbot TR, Crocker DD, Peters J, et al. Duration of viral shedding after trivalent intranasal live attenuated influenza vaccination in adults. *Infec Control Hosp Epidemiol* 2005; 26:494-500.

⁴ Belshe RB, Edwards KM, Vesikari T, et al. Live attenuated versus influenza vaccine in infants and young children. *NEJM* 2007; 356:685-96.