Seasonal Influenza Immunization Program

Live Attenuated Influenza Vaccine (LAIV) (FluMist® Quadrivalent)
Questions and Answers for Health Care Providers

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1. What is live attenuated influenza vaccine (LAIV)?

FluMist® Quadrivalent is a live attenuated influenza vaccine (LAIV) that is administered by the intranasal route (i.e. nasal spray). Each pre-filled glass sprayer contains 0.2mL dose (given as 0.1mL in each nostril) of live attenuated influenza virus reassortants of four vaccine virus strains. The spray is a colorless to pale yellow, clear to opalescent liquid; small, white particles may be present.

2. Why is LAIV an intranasal spray?

LAIV (FluMist® Quadrivalent) is made from attenuated viruses that are able to replicate efficiently only at temperatures present in the nasal mucosa. LAIV is manufactured using the four influenza virus strains recommended by the World Health Organization (WHO) for the northern hemisphere. Through manufacturing processes, the four influenza virus strains become:

- **cold-adapted** so they are only able to replicate at cooler temperatures in the nasal mucosa
- **temperature sensitive** so they are unable to replicate at warmer temperatures of the lower airways and lungs
- **attenuated** so they are unable to cause influenza. Attenuation takes an infectious agent, such as the influenza virus, and alters it so that it becomes harmless or less virulent.

The cumulative effect of these properties is such that the viral strains induce protective immunity without causing disease.¹

3. Why is LAIV not indicated for use in children less than 24 months of age?

LAIV (FluMist® Quadrivalent) is contraindicated in this age group due to increased risk of wheezing.⁴ A multi-centre efficacy trial found that rates of wheezing were statistically and significantly higher among children six to 24 months of age (5.9% LAIV vs. 3.8% trivalent inactivated influenza vaccine) in the weeks following immunization.³

4. Can LAIV be administered to children with chronic health conditions?

As per the National Advisory Committee on Immunization (NACI), LAIV can be used in children 24 months and older with stable, non-severe asthma and in children with chronic health conditions (excluding those with immunocompromising conditions and severe asthma).

5. Can LAIV be administered to healthy adults 18 to 59 years of age?

Yes. As per NACI, LAIV can be used for the prevention of influenza in healthy adults up to 59 years of age. Manitoba Health, Seniors and Active Living (MHSAL) provides publicly-funded LAIV to healthy adults up to 59 years of age provided they would otherwise decline immunization if only the needle option (inactivated influenza vaccine) were offered.

6. Can LAIV be administered to adults with immune compromising conditions?

LAIV is contraindicated for children and adults with immune compromising conditions due to underlying disease, therapy or both, as the vaccine contains live attenuated virus. These individuals should be offered the inactivated influenza vaccine (needle).
7. Can LAIV be administered to adults with chronic health conditions?

LAIV is contraindicated in adults with chronic health conditions which increase the risk of influenza-related complications or hospitalizations, including:

- Cardiac or pulmonary disorders (including bronchopulmonary dysplasia, cystic fibrosis and asthma)
- Diabetes mellitus and other metabolic diseases
- Cancer, immune compromising conditions (due to underlying disease and/or therapy)
- Renal disease
- Anemia or hemoglobinopathy
- Conditions that compromise the management of respiratory secretions and are associated with an increased risk of aspiration
- Morbid obesity (BM≥40)

8. Can LAIV be administered to health care workers providing care to individuals with immunocompromising conditions?

No. NACI recommends that inactivated influenza vaccine (needle), instead of LAIV, be used for health care workers providing care to those with immune compromising conditions due to the concern that in rare instances, shed vaccine viruses can be transmitted from vaccine recipients to unvaccinated persons causing an infection.

9. When was LAIV approved and available for use in Canada?

LAIV (FluMist® - trivalent formulation) was approved in Canada in June 2010 for persons two to 59 years of age and was first used in publicly funded immunization programs in Canada for the 2012-13 influenza season. The quadrivalent formulation was approved for use in Canada for the 2014-15 season and has been in use since that time. Trivalent LAIV is no longer available in Canada.

10. Is LAIV available for use in other Countries?

LAIV (FluMist® Quadrivalent) has been approved in the United States since 2003. Since 2002, more than 60 million doses of FluMist® (trivalent/quadrivalent) have been manufactured and distributed globally. Outside of North America, countries with approval for FluMist® Quadrivalent (called Fluenz® in Europe) are: the United Kingdom, Germany, France, Sweden, Israel, Malaysia and Hong Kong.

11. Which four influenza virus strains make-up this year’s seasonal influenza vaccine?

For the northern hemisphere, the World Health Organization (WHO) recommends that the 2017-18 seasonal quadrivalent influenza vaccine (inactivated and live attenuated) contain:

- A/Michigan/45/2015 (H1N1)pdm09-like virus
- A/Hong Kong/4801/2014 (H3N2)-like virus
- B/Brisbane/60/2008-like virus
- B/Phuket/3073/2013-like virus
12. Who is LAIV publicly-funded for in 2017-18 in Manitoba?
Healthy children two to 17 years of age can be immunized with LAIV (nasal spray). A small number of healthy adults up to 59 years of age who are needle averse may also be immunized with LAIV (nasal spray) if they would otherwise refuse vaccination if only inactivated influenza vaccine (needle) were available.

13. What are the dosing schedules for administration of LAIV?
2 to less than 9 years of age: one dose given as 0.2mL (0.1mL in each nostril) intranasal spray. A second dose of influenza vaccine is recommended 4 weeks after receipt of the first dose for children who have NEVER received an influenza vaccine.
9 to 17 years of age: one dose given as 0.2mL (0.1mL in each nostril) intranasal spray. This product can be used for use in this age group as it offers the advantage of needle-free administration.
18 to 59 years of age: one dose given as 0.2mL (0.1 mL in each nostril) intranasal spray. This product is approved for use in this age group but inactivated influenza vaccine (needle) provides better protection against influenza and should be used unless the individual would otherwise decline immunization if only the inactivated influenza vaccine (needle) were offered.

14. What if a child less than 24 months of age receives LAIV?
LAIV (FluMist® Quadrivalent) is not approved for this age group due to an increased risk of wheezing found in clinical trials in this group. If FluMist® Quadrivalent is inadvertently administered to a child < 24 months of age, there is no need to offer inactivated influenza vaccine (needle) subsequently as LAIV provides protection in this age group. However, inform the parent/guardian of the risk of increased wheezing and recommend that if wheezing occurs they contact the child’s primary care provider as well as report to public health. Complete the required patient safety/vaccine error documentation within your organization.

Children under nine years of age who have not previously received seasonal influenza vaccine require two doses given four weeks apart. When a child < 24 months is inadvertently given LAIV for the first dose presents for a second dose, give by needle.

15. What if a child presents for LAIV and the product is no longer available?
If a child presents for a first or second dose of LAIV and the product is no longer available, offer inactivated influenza vaccine (needle). Children under nine years of age who have NEVER previously received seasonal influenza vaccine require two doses given four weeks apart. If the child has received one or more doses in any previous season, only a single dose is required.

16. Is the expiry date of LAIV different from inactivated influenza vaccine?
The shelf-life of LAIV is considerably shorter than that of inactivated influenza vaccine. The default expiry date of this product is NOT the last day of the month. Be sure to check the expiry date on the packaging as vaccine stock is received. All immunization service providers are asked to optimize planning of use to ensure that the quantities received are used prior to expiry.
17. What if a child receives an expired dose of LAIV?

If an expired product is given inadvertently, the dose must be repeated. To ensure that a child is protected against the four seasonal influenza strains contained in the vaccine, offer a valid dose of LAIV on the same day the expired vaccine was given or as soon as the error is discovered. There is no minimum interval between an expired and a valid dose of LAIV as it is the same product being administered and protection against influenza should not be delayed.

If the child or parent/guardian refuses to repeat LAIV administration, offer inactivated influenza vaccine (needle) as an alternative. To document the administration of an expired dose, complete the required patient safety/vaccine error documentation within your organization.

18. What are the steps for intranasal administration of LAIV?

**FLUMIST IS AN INTRANASAL SPRAY AND IS NOT FOR INJECTION.**

The product is provided in a ‘sprayer’ in a firm device that looks like a syringe with a tip protector at one end and a plunger with a dose divider clip at the other end. Details and accompanying diagram on how to administer the product are contained in the product monograph and the accompanying text is reproduced below:

1. Remove the rubber tip protector. Do not remove the dose-divider clip at the other end of the sprayer.
2. With the recipient sitting upright, place tip of the sprayer just inside a nostril to ensure vaccine is delivered into the nose.
3. In one motion depress the plunger as rapidly as possible until the dose-divider clip prevents you from going further.
4. Pinch and remove the dose divider clip from the plunger.
5. Place the tip of the sprayer just inside the other nostril and with a single motion depress the plunger as rapidly as possible to deliver the rest of the vaccine.

19. How should the sprayer be disposed of after use?

The sprayer should be disposed of according to the standard procedures for medical waste (e.g. sharps container or biohazard container).
20. Can you provide an illustration of the steps of LAIV intranasal administration?

21. What if a child sneezes right after being immunized with LAIV?

NACI\(^\circ\) supports that if the vaccine recipient sneezes immediately after administration, the dose should NOT be repeated. The binding of the virus to epithelial cells occurs very rapidly and there are
more virus particles in the vaccine than are needed to establish immunity. Therefore, sneezing or blowing your nose immediately after immunization with LAIV will not affect immunity.7

22. What if a child receives both half doses of LAIV in the same nostril?

It is recommended that LAIV be administered as two divided sprays (0.1mL into each nostril) to maximize the vaccine’s contact surface area of epithelial cells within the nasopharynx. No clinical trials have been conducted using a single-nostril administration. However, there is no need to repeat immunization as each half dose (0.1mL) contains enough viral particles to induce an immune response.10 Complete the required patient safety/vaccine error documentation within your organization.

23. What if during LAIV administration, a child is sprayed in the eye instead of the nostril?

Immediately flush the area with water or saline. If irritation persists, refer to a physician to assess for possible conjunctivitis. If at least half of the LAIV dose (0.1mL) was administered into the nostril, the client does not need further vaccine at that time.15 However, if the first half of the vaccine dose went into the eye, the second half of the dose (0.1mL) should be offered. If at that time the child or the parent/guardian does not want to attempt further administration of LAIV, offer inactivated influenza vaccine (needle). Complete the required patient safety/vaccine error documentation within your organization.

24. What if during LAIV administration, the child refuses the second half of the dose?

If a child refuses the second half of the LAIV dose, attempt to give the second half (0.1mL) of the LAIV dose in the other nostril. If you are unsuccessful, there is no need to repeat immunization as each half dose (0.1mL) of LAIV contains enough viral particles to induce an immune response.10 Complete the required patient safety/vaccine error documentation within your organization.

25. Do I have to use personal protective equipment to administer LAIV?

The use of personal protective equipment such as gloves and masks are not needed to administer FluMist® Quadrivalent. Using routine practices, as when administering any immunization, is adequate in settings where FluMist® Quadrivalent is given.12

26. What are the contraindications to receipt of LAIV?

- History of anaphylactic reaction to a previous dose of any type of influenza vaccine or to any component of FluMist® Quadrivalent (excluding eggs)
- History of Guillain-Barré Syndrome (GBS) within 6 weeks of receipt of a previous dose of influenza vaccine
- Severe asthma as defined as currently on oral or high-dose inhaled glucocorticosteroids or active wheezing, or those with medically attended wheezing in the seven days prior to immunization
- Individuals two to 17 years of age receiving Aspirin®-containing therapy because of the association of Reye syndrome with Aspirin® and wild-type influenza infection. It is recommended that Aspirin®-containing products in children less than 18 years of age be delayed for four weeks after receipt of FluMist® Quadrivalent
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- Children less than two years of age
- Individuals with immune compromising conditions
- Health care workers working with immunocompromised individuals

27. Can you provide some examples of immunocompromising conditions?

Examples of immunocompromising conditions\(^{17}\) include (but are not limited to):

- Cancer
- Immunodeficiency (including human immunodeficiency virus [HIV] infection)
- Immunosuppression due to underlying disease or therapy (e.g., severe rheumatoid arthritis requiring immunosuppressive therapies)

28. Can you define severe asthma?

According to NACI, severe asthma is “…defined as currently on oral or high dose inhaled glucocorticosteroids or active wheezing or those with medically-attended wheezing in the seven days prior to vaccination.”\(^{93}\)

High dose systemic steroids interfere with vaccine induced immune responses (i.e. considered as persons receiving ≥ 2 mg/kg per day or ≥ 20 mg daily of prednisone for more than 14 days duration to be immune-suppressed). Topical and locally injected steroids do not have an impact on vaccines unless there is clinical or laboratory evidence of immunosuppression from such therapy.\(^{13}\)

According to the British Columbia Medical Association, high dose inhaled corticosteroids in pediatric patients are those treated with ≥ 200 ug/day fluticasone (or equivalent) because this high dosage may be associated with systemic side-effects.\(^{14}\)

In children with asthma, if a parent or guardian of a child cannot identify a child’s current dosage of oral or inhaled steroid, inactivated influenza vaccine (needle) should be offered.

29. Can a child receiving daily intranasal steroids for conditions other than asthma receive LAIV?

Yes. Intranasal steroids typically used for treatment of allergic rhinitis are not a contraindication because the effects are local and not systemic. These products do not cause immunosuppression so they are not a contraindication to LAIV. Topical and locally injected steroids do not have an impact on vaccines unless there is clinical or laboratory evidence of immunosuppression from such therapy.\(^{13}\)

30. What about the use of LAIV in pregnant and breastfeeding women?

LAIV should not be administered to pregnant women because of the lack of safety data at this time. Although LAIV has not been studied in pregnant women, no unexpected patterns of pregnancy complications or fetal outcomes have been identified after inadvertent administration of LAIV. In the event of inadvertent administration of LAIV to a pregnant woman, complete the required patient safety/vaccine error documentation within your organization. It is not known whether LAIV is excreted in human milk; however LAIV is not contraindicated in breastfeeding women.\(^{3}\)

AstraZeneca, the manufacturer of FluMist® Quadrivalent, does not maintain a registry for inadvertent administration of LAIV to pregnant women. However, they do have an adverse event reporting phone line (1-800-668-6000) and e-mail (medinfo.canada@astrazeneca.com).
31. What are the potential allergens and product components of LAIV?

The product monograph contains a full list of the contents of FluMist® Quadrivalent.

**FluMist® Quadrivalent potential allergens:** ovalbumin, gelatin hydrolysate (porcine Type A), gentamicin, arginine hydrochloride.

**FluMist® Quadrivalent other components:** sucrose, dibasic potassium phosphate, monobasic potassium phosphate, monosodium glutamate.

32. Should faith-based clients be concerned about the gelatin content in LAIV?

LAIV (FluMist® Quadrivalent) contains porcine-type gelatin. Scholars from the Muslim and Jewish faiths have determined that receipt of gelatin in vaccines is permissible and does not constitute a violation of religious practice. Religious leaders’ statements on the use of vaccines containing porcine gelatin are available from: [http://www.vaccinesafety.edu/Porcine-vaccineapproval.htm](http://www.vaccinesafety.edu/Porcine-vaccineapproval.htm)

33. Are there precautions to the receipt of LAIV?

Individuals who have experienced ORS without lower respiratory tract symptoms may be safely re-immunized with influenza vaccine. Persons who experienced ORS with lower respiratory tract symptoms should have an expert review.

Also, vaccine recipients should be informed that FluMist® Quadrivalent is a vaccine that contains a weakened strain of influenza virus and could potentially be transmitted to another person through contact with respiratory secretions. An infection with this weakened virus could cause a serious infection in a small category of patients who are severely immunocompromised and receiving care in hospital in a protected environment (e.g. post bone marrow transplant). Both health care workers and close contacts of such patients should avoid contact with these patients for two weeks after getting FluMist® Quadrivalent. If such contact cannot be avoided, offer inactivated influenza vaccine (needle) instead of FluMist® Quadrivalent.

34. Can you provide me with more information on LAIV and viral shedding?

Both children and adults can shed vaccine viruses after LAIV administration and studies have shown that younger children are more likely to shed (and shed higher titers) than older children and adults. Children may shed for a mean duration of 7.6 days and shedding is rare after day 11.³

Viral shedding is not synonymous with transmission of vaccine virus. Shedding is generally below levels needed to transmit infection, although in rare instances, shed vaccine viruses can be transmitted from vaccine recipients to unvaccinated persons. Serious illness has not been reported among unvaccinated persons inadvertently infected with vaccine virus and no transmission of vaccine virus has ever been reported in a health care setting.³

It is important to note that wild type influenza virus is a community acquired infection readily transmitted from person to person through droplet contact during influenza season, with attack rates ranging from five to 25 per cent depending on the severity of the season. The attenuated virus contained in the vaccine is a much weakened strain of influenza compared to wild influenza viruses.

35. Are there any special considerations for co-administration of LAIV and other live vaccines?

Based on expert opinion, intranasal LAIV can be administered with, or at any time before or after, live attenuated or inactivated vaccines. No interference is expected with the administration of
intranasal LAIV and parenteral live vaccines because the mucosa associated lymphoid tissue (MALT) is populated by B cells, T cells and accessory cells that are phenotypically and functionally distinct as compared to the systemic lymphoid tissue that responds to parenteral vaccines. Interference is also not expected with the administration of intranasal LAIV and live oral vaccines as mucosal immune responses also demonstrate a high level of compartmentalization between separate mucosal sites (nasal versus oral) as a result of strong restrictions on lymphoid cell recirculation.4

36. Are there any special considerations for a child taking antiviral medications?

LAIV should not be administered when taking antiviral agents because these drugs interfere with the immune response to FluMist® Quadrivalent. FluMist® Quadrivalent should not be administered to individuals while taking antiviral agents active against influenza (oseltamivir and zanamivir). Such individuals should receive inactivated influenza vaccine (needle). If antiviral agents are administered from 48 hours before two weeks after receipt of FluMist® Quadrivalent, revaccinate when antiviral agents have been discontinued for at least 48 hours.

37. What are the common side-effects of LAIV?

Most people have no reaction to the vaccine. Reactions that do occur are typically mild and last for one to three days. For children requiring two doses of vaccine, symptoms tend to be less frequent following the second dose.9 As with any immunization, unexpected or unusual side-effects can occur, including anaphylaxis.

- **Common local side-effects**: adults and children - runny nose or nasal congestion.
- **Common systemic side-effects**: children - decreased appetite, weakness, headache, fever. Adults - headache, sore throat, cough, weakness.

38. Should I ask if the vaccine recipient is allergic to any component of LAIV before administration?

No, it is unnecessary for immunization providers to list each component of the vaccine to the recipient. Instead, when confirming eligibility for all vaccines, providers must inquire about any allergies that the recipient may have. Providers then must ensure that the recipient is not allergic to any component of the vaccine.

39. Can I give LAIV to an individual who has an egg allergy?

Yes, after careful review of recently published studies, NACI concludes that egg allergic individuals may be vaccinated against influenza using LAIV. The full dose may be used without prior vaccine skin test and in settings where vaccines are routinely administered.16

As with the administration of any vaccine, an individual should remain in the office and be monitored for 15 minutes after being immunized to monitor for any severe adverse reactions.

40. How long does it take after administration of LAIV for the individual to acquire protective immunity levels?

It takes about two weeks for the body to acquire full protection. This is why it is best that people get vaccinated **before** influenza activity starts each season.
41. Can LAIV be given to children who are household contacts of someone who is immunocompromised?
Yes. LAIV is contraindicated only for those who are contacts of persons who are severely immunocompromised. Severely immunocompromised is defined by NACI, “as hospitalized and requiring care in a protected environment.”
All vaccine recipients should be informed that FluMist® Quadrivalent is a live attenuated vaccine that contains a weakened strain of influenza virus and has the potential to be transmitted to another person through contact with respiratory secretions. Vaccine recipients should therefore avoid close contact with severely immunocompromised individuals for two weeks after receiving LAIV. If such contact cannot be avoided, inactivated influenza vaccine (needle) should be used.

42. Can I give LAIV to children who have experienced common local side-effects to inactivated influenza vaccine?
Yes. If parents want their two to 17 year old child to receive LAIV, and the child meets the eligibility requirements, LAIV can be given in place of inactivated influenza vaccine (needle). This would eliminate some potential side-effects such as redness, warmth and swelling at the injection site.

43. Can the side-effects listed for LAIV occur late?
The side-effects listed for this product are (1) local: runny nose or nasal congestion; and, (2) systemic: decreased appetite, weakness, headache, fever, sore throat and cough. All of these are non-specific to the vaccine and may occur as a result of other causes such as the common cold. In clinical trials, nasal congestion was identified as the solicited event occurring most commonly. Events were solicited for the first 10 days following vaccine receipt, as this was the period deemed most plausible for such vaccine-associated adverse events.

44. Are there suggested positioning techniques parents can use with children receiving the LAIV?
For administration of LAIV, it is best that the child is seated comfortably, or positioned on the parent’s lap, if they prefer. They should not lie down nor do they need to tilt their head back. The provider should stabilize the child’s chin. Any further restraint, such as of the arms for children expected to cover their nose, should be discussed with the parent and child at the clinic. Some options are that the parent or health care provider may apply slightly more pressure to stabilize the chin, or the forehead. If a child is seated on the parent’s lap with their back and head against the parent’s chest, this should be enough to avoid the child pulling back.

45. Can a health care worker who is immunocompromised administer LAIV?
Yes. LAIV (FluMist® Quadrivalent) contains attenuated (weakened) influenza virus and is to be avoided only by those with such severe immunocompromise that they are “hospitalized and requiring care in a protected environment.” Standard precautions such as hand-washing or use of alcohol hand rubs before and after vaccine administration are recommended. Used sprayers should be discarded into a sharps container with biological waste.

46. Can a pregnant health care worker administer LAIV?
Yes. A pregnant woman can administer FluMist® Quadrivalent; no special precautions are necessary. The viruses in the nasal spray vaccine are attenuated or weakened. This means that the
vaccine viruses would not cause influenza illness, even if a person inadvertently gets vaccine viruses in their nose.

47. Is LAIV the preferred product for children?

After careful review of the available vaccine effectiveness data over the last several influenza seasons, NACI concludes that the current evidence does NOT support a recommendation for the preferential use of LAIV in children two to 17 years of age. Health care providers can offer LAIV or inactivated influenza vaccine (needle) to children two to 17 years of age.

RESOURCES

To learn more about LAIV (FluMist® Quadrivalent), please refer to the following websites:

Public Health Agency of Canada (PHAC) - Canadian Immunization Guide

Recommendations on the use of live attenuated influenza vaccine (FluMist®):

- Addendum – LAIV Use in Children and Adolescents Advisory Committee Statement (ACS) – National Advisory Committee on Immunization (NACI).

- Addendum – LAIV Use in Egg Allergic Individuals Advisory Committee Statement (ACS) – National Advisory Committee on Immunization (NACI).

Supplemental Statement on Seasonal Influenza Vaccine for 2011-2012

National Advisory Committee on Immunization (NACI) Statement on Seasonal Influenza Vaccine: www.phac-aspc.gc.ca/naci-ccni/index-eng.php

AstraZeneca Canada Inc.:
Site for Healthcare Professionals: www.astrazeneca.ca/en/Healthcare-Professionals
REFERENCES


12 Centers for Disease Control (CDC) and Prevention. (2013). The nasal-spray flu vaccine (live attenuated influenza vaccine [LAIV]) questions and answers. What personal protective equipment is recommended for health-care workers who are giving LAIV (FluMist®) [Internet]. Atlanta (GA): CDC; 2012 Aug 31 [cited 2013 Aug 2]. Available from: http://www.cdc.gov/flu/about/qa/nasalspray.htm
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