Live Attenuated Influenza Vaccine (FluMist®): Questions and Answers for Health Care Providers
June 2014

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Please Note: Content within this document has been adapted, with permission, from the BC Centre for Disease Control.
BACKGROUND

1. What is Live Attenuated Influenza Vaccine (LAIV)?

FluMist® is a live, attenuated influenza vaccine (LAIV) and is administered by the intranasal route by a health care provider. Each pre-filled glass sprayer contains 0.2 mL dose (given as 0.1 mL in each nostril) of live, attenuated influenza virus reassortants of three strains of virus. 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®) is made from attenuated viruses that are able to replicate efficiently only at temperatures present in the nasal mucosa. LAIV is manufactured using the 3 influenza virus strains recommended by the World Health Organization (WHO) for the northern hemisphere. Through manufacturing processes the 3 influenza virus strains become:

- **cold-adapted** so they are only able to replicate at cooler temperatures of the nasopharyngeal 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 clinical influenza disease

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

3. Has LAIV Been Well Studied?

LAIV (FluMist®) has been studied in over 140,000 patients in clinical trials. A number of studies (LAIV versus placebo and LAIV versus trivalent inactivated influenza vaccine (TIIV)) have been conducted in children and adults. The results of efficacy and safety studies have demonstrated that FluMist® is effective, safe and well tolerated.

4. Why is LAIV not Approved for use in Children < 24 Months of Age?

LAIV (FluMist®) is contraindicated in this age group due to increased risk of wheezing. A multi-centre efficacy trial found that rates of wheezing were statistically significantly higher among children 6 to 23 months of age (5.9% LAIV vs. 3.8% trivalent inactivated influenza vaccine (TIIV)) in the weeks following immunization.

5. Why Does NACI Recommend LAIV Over TIIV for Immunization of Healthy Children?

Based on effectiveness, efficacy and immunogenicity data, the National Advisory Committee on Immunization (NACI) recommends LAIV as the preferred product for use in healthy children and adolescents 2-17 years of age. If LAIV is not available, TIIV should be used as it is safe, efficacious and effective in this group. NACI states that LAIV has generally been shown to be equally, if not more, immunogenic than TIIV for all 3 influenza strains in children 2-17 years of age.

6. Can you Tell me More about the Studies that Support the Preferential Use of LAIV in Younger, Healthy Children?

Several clinical trials have been conducted in young children, and this literature has been systematically reviewed in two papers and also reviewed by NACI. In five randomized controlled clinical trials, the absolute vaccine efficacy of LAIV against laboratory confirmed influenza in children aged 6 years and under was 85% (95% CI 77 to 100%). Similar findings of vaccine efficacy were
made in one trial of children up to age 7 years\textsuperscript{7}. In contrast, 2 studies of TIIV in this age group found absolute vaccine efficacy of 39\% (95\% CI -8 to 66\%) against the same outcome of laboratory confirmed influenza. An additional benefit to use of LAIV is demonstrated cross-protection against mismatched strains, including greater cross-protection versus TIIV\textsuperscript{3}. This is to be expected because the attenuated virus is a more complete antigenic stimulus than the antigenic components used in inactivated vaccines.

7. Can you tell me more About the Studies that Support the Use of LAIV in Older Children?
Randomized clinical controlled trials of LAIV vaccine efficacy have not been conducted in healthy children and youth older than 7 years. Several observational studies have been done, however, in children up to 18 years old with the outcomes being medically attended acute respiratory illness. Findings have generally been consistent with those described above (see question 6) with some suggestion of declining effectiveness at older ages, but confidence intervals have been wide and findings are inconclusive. Therefore the data to support preferential use over TIIV in this age group are not as strong, but the vaccine has demonstrated effectiveness and offers the additional advantage of needle free administration and potentially improved cross-protection to other strains, as outlined above.

One randomized open label study has been conducted in asthmatic children\textsuperscript{8} aged 6 to 17 years, using either LAIV or TIIV. During the 2002-03 influenza season, the study demonstrated a significantly greater relative efficacy of LAIV compared to TIIV of 34.7\% (95\% CI 3.9\%–56.0\%). Asthma exacerbations were similar in the two groups. Those who received LAIV had higher incidence of runny nose or nasal congestion (66.2\% compared to TIIV at 52.5\%) and about 70\% of TIIV recipients reported injection site reactions.

8. Can LAIV be Administered to Children with Chronic Health Conditions?
NACI recommends that 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). Based on expert review, it is expected that LAIV should be as safe, immunogenic and efficacious in immune competent children with chronic health conditions as it is in healthy children. However, at this time there is insufficient evidence available to prefer LAIV over TIIV in children with chronic health conditions\textsuperscript{4}.

9. Can LAIV be Administered to Healthy Adults 18 to 59 Years of Age?
Yes. NACI recommends that LAIV can be used for the prevention of influenza in healthy adults 18 to 59 years of age. Manitoba Health, Healthy Living and Seniors (MH HLS) provides publicly-funded LAIV to healthy adults 18 to 59 years of age if they would otherwise decline immunization if only inactivated influenza were offered (needle option).

10. Can LAIV be Administered to Adults with Immune Compromising Conditions?
No. NACI recommends against LAIV for individuals with immune compromising conditions.

11. Can LAIV be Administered to Adults with Chronic Health Conditions?
No. At this time, NACI concludes that there is insufficient evidence to recommend LAIV in adults with chronic health conditions. Chronic health conditions which increase the risk of influenza-related complications or hospitalizations include:
12. Can LAIV be Administered to Health Care Workers providing care to Individuals with Immunocompromising Conditions?

No. NACI recommends that TIV, instead of LAIV, should be used for health care workers providing care to those with immune compromising conditions.

13. When was LAIV Approved and Where Else is it provided in Canada?

LAIV (FluMist®) was approved in Canada in June 2010 for active immunization of persons 2 to 59 years of age. Since 2010, more than 850,000 doses of FluMist® have been distributed in Canada. The following is a timeline for launch of FluMist® in Canada:

- **2013-14**: British Columbia, Alberta, Northwest Territories, Nunavut, Prince Edward Island, Quebec and Yukon.
- **2012-13**: Alberta, British Columbia (pilot project in Vancouver Coastal Health), Nunavut, Prince Edward Island and Quebec
- **2011-12**: Available in the private market only.

14. Has LAIV been Approved for use in Other Countries?

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

RESOURCES

To learn more about LAIV (FluMist®), 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®):

- 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

Astra Zeneca Canada Inc.:
- Site for Healthcare Professionals: www.astrazeneca.ca/en/Healthcare-Professionals
MANITOBA’S LAIV PROGRAM

15. Which 3 Influenza Virus Strains Make Up This Year’s Seasonal Trivalent Influenza Vaccines?

For the northern hemisphere, the World Health Organization (WHO)\(^5\) recommended that the 2014-15 Seasonal Trivalent Influenza Vaccine (inactivated and live attenuated) contain:

- an A/California/7/2009 (H1N1)pdm09-like virus;
- an A/Texas/50/2012 (H3N2)-like virus;
- a B/Massachusetts/2/2012-like virus.

16. In the 2014-15 Influenza Season, who is LAIV Publicly-Funded For?

LAIV is publicly funded in Manitoba for eligible children aged 2 to 17 years old inclusive, as per National Advisory Committee on Immunization (NACI) recommendations:

- Healthy Children 2-17 years of age: based on effectiveness, efficacy and immunogenicity data, NACI recommends LAIV for use in healthy children and adolescents 2-17 years of age. Available data indicates that LAIV would be preferred over TIIV.
- Children with Asthma: NACI recommends that LAIV can be used in children 24 months and older with stable, non-severe asthma. LAIV should not be used in those with severe asthma (as defined as currently on oral or high dose inhaled glucocorticosteroids or active wheezing) and those with medically attended wheezing in the seven days prior to vaccination.
- Children with other chronic health conditions: NACI recommends that LAIV can be used in children with chronic health conditions (excluding those with immune compromising conditions and severe asthma, as defined above).

**NOTE:** NACI recommends against LAIV for individuals with immune compromising conditions. Live vaccines have generally been contraindicated in people with immune compromising conditions, with some exceptions. NACI concludes that there is insufficient evidence supporting the use of LAIV in those with immune compromising conditions in terms of both safety and effectiveness. Based on expert opinion, NACI concludes that the use of LAIV in this population is contraindicated.

Manitoba Health, Healthy Living and Seniors (MHHLS) will publicly-fund LAIV for Manitobans aged 18 to 59 years if they would otherwise decline immunization if only TIIV were available.

- Healthy Adults 18 to 59 years of age: NACI recommends that LAIV can be used for the prevention of influenza in healthy adults 18 to 59 years of age.

**NOTE:**
- NACI recommends against LAIV for individuals with immune compromising conditions. Live vaccines have generally been contraindicated in people with immune compromising conditions, with some exceptions. NACI concludes that there is insufficient evidence supporting the use of LAIV in those with immune compromising conditions in terms of both safety and effectiveness. Based on expert opinion, NACI concludes that the use of LAIV in this population is contraindicated.
- At this time NACI concludes that there is insufficient evidence to recommend LAIV in adults with chronic health conditions 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 (BMI ≥ 40)

- NACI recommends that TIIV, instead of LAIV, should be used for health care workers providing
  care to those with immune compromising conditions.

17. What are the Dosing Schedules for Administration of LAIV?

2 to 8 years of age: 1 or 2 doses given as 0.2 mL (0.1 mL in each nostril) intranasal spray.
- This product should be preferentially offered to children in this age group. A 2nd dose of
  influenza vaccine is recommended 4 weeks later for children receiving influenza vaccine for
  the first time that season.

9 to 17 years of age: 1 dose given as 0.2 mL (0.1 mL in each nostril) intranasal spray.
- This product is recommended for use in this age group and offers the advantage of needle-
  free administration.

18 to 59 years of age: 1 dose: 0.2 mL (0.1 mL in each nostril) intranasal spray.
- This product is approved for use in this age group but TIIV provides better protection against
  influenza and should be used unless the individual would otherwise decline immunization if
  only TIIV were offered.

18. What if a Child <24 months of age Receives LAIV?

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

Children under 9 years of age who have not previously received seasonal influenza vaccine require
2 doses given 4 weeks apart. When a child < 24 months inadvertently given LAIV for the 1st dose
presents for a 2nd dose, give TIIV.

19. What if a Child Presents for LAIV and the Product is no Longer Available?

If a child presents for a 1st or 2nd dose of LAIV and the product is no longer available, offer TIIV.
LAIV is the preferred product; however, TIIV may be given interchangeably if LAIV is not available.
Children under 9 years of age who have not previously received seasonal influenza vaccine require
2 doses given 4 weeks apart. If the child has received 1 or more doses in any previous season, only
a single dose is required.

20. Is the Expiry Date of LAIV Different from TIIV?

The shelf-life of LAIV is considerably shorter than that of TIIV. The default expiry date of this product
is NOT the last day of the month. Be sure to check the expiry date as vaccine lots are received. All
immunization service providers are asked to optimize planning of use to ensure that the product
quantities allocated to your branch office are used up prior to expiry.
21. 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 3 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 TIIV as an alternative. To document the administration of an expired dose, complete the required patient safety/vaccine error documentation within your organization.

22. 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 on page 11 and 12 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.
23. How should the Sprayer be Disposed After Use?

The sprayer should be disposed of according to the standard procedures for medical waste (e.g. sharps container or biohazard container). 

24. Can you provide an Illustration of the Steps of LAIV Intranasal Administration?

1. **Check expiration date.** Product must be used before the date on sprayer label.

2. Remove rubber tip protector. Do not remove dose-divider clip at the other end of the sprayer.

3. With the patient in an upright position, place the tip just inside the nostril to ensure FluMist® is delivered into the nose.

4. With a single motion, depress plunger as rapidly as possible until the dose-divider clip prevents you from going further.

5. Pinch and remove the dose-divider clip from plunger.

6. Place the tip just inside the other nostril and with a single motion, depress plunger as rapidly as possible to deliver remaining vaccine.
25. What if a Child Sneezes Right After Being Immunized with LAIV?

Both NACI¹³ and the Advisory Committee on Immunization Practices (ACIP)¹³ support 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 immunity¹¹.

26. What if a Child Receives Both Half Doses of LAIV in the Same Nostril?

It is recommended that LAIV be administered as 2 divided sprays (0.1 mL 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 (0.1 mL) contains enough viral particles to induce an immune response¹⁴. Complete the required patient safety/vaccine error documentation within your organization.

27. 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 physician to assess for possible conjunctivitis. If at least half of the LAIV dose (0.1 mL) was administered into the nostril the client does not need further vaccine at that time.¹⁵ However, if the 1st half of the vaccine dose went into the eye, the 2nd half of the dose (0.1 mL) should be offered. If at that time the child or the parent/guardian does not want to attempt further administration of LAIV offer TIIV. Complete the required patient safety/vaccine error documentation within your organization.

28. What if During LAIV Administration, the Child Refuses the 2nd Half of the Dose?

If a child refuses the 2nd half of the LAIV dose, attempt to give the 2nd half (0.1 mL) of the LAIV dose in the other nostril. If you are unsuccessful there is no need to repeat immunization as each half dose (0.1 mL) of LAIV contains enough viral particles to induce an immune response¹⁴. Complete the required patient safety/vaccine error documentation within your organization.

29. 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®. Using routine practices, as when administering any immunization, is adequate in settings where FluMist® is being given¹⁶.

30. 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®.
- Egg allergy. Such individuals should receive TIIV.
- Severe asthma or active wheezing (on high dose inhaled or oral steroids or medically attended wheezing in the 7 days prior to vaccination).
- Adults and children with immune compromising conditions.
- Health care workers working with immunocompromised individuals.
- Individuals less than 2 years of age or ≥ 60 years of age.
- Pregnancy.
• Individuals 2-17 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 < 18 years of age be delayed for 4 weeks after receipt of FluMist®.
• History of Guillain-Barré syndrome (GBS) within 6 weeks of receipt of a previous dose of influenza vaccine without another cause being identified.

31. Can you provide some Examples of Immunocompromising Conditions?
Examples of immunocompromising conditions\(^1\) 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)

32. 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 7 days prior to vaccination.”\(^3\)

High dose systemic steroids interfere with vaccine induced immune responses (i.e., consider persons receiving \(\geq 2\) mg/kg per day or \(\geq 20\) 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\(^1\).

According to the British Columbia Medical Association, high dose inhaled corticosteroids in pediatric patients are those treated with \(\geq 200\) ug/day fluticasone (or equivalent) because this high dosage may be associated with systemic side effects\(^1\).

In children with asthma, if a parent or guardian of a child cannot identify a child’s current dosage of oral or inhaled steroid, TIV should be offered.

33. 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\(^1\).

34. 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\(^3\). Although LAIV has not been studied in pregnant women, no unexpected patterns of pregnancy complications or fetal outcomes have been identified after the inadvertent administration of LAIV to pregnant women. In the event of an inadvertent administration of LAIV to a pregnant woman complete the required patient safety/vaccine error documentation within your organization.

AstraZeneca does not maintain a registry for inadvertent administration of FluMist® to pregnant women. However, they do have an Adverse Event Reporting phone line (1-800-668-6000) and e-mail (medinfo.canada@astrazeneca.com).
It is not known whether LAIV is excreted in human milk; however LAIV is not contraindicated in breastfeeding women.

35. What are the Potential Allergens and Product Components of LAIV?

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

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

36. Should Faith-Based Clients be Concerned About the Gelatin Content in LAIV?

LAIV (FluMist®) 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

37. Are There Precautions to the Receipt of LAIV?

Severe oculo-respiratory syndrome (ORS) after previous receipt of an influenza vaccine is a precaution to the administration of LAIV.

Also, vaccine recipients should be informed that FluMist® 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 2 weeks after getting FluMist®. If such contact cannot be avoided, offer TIIV instead of FluMist®.

38. 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.

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.

It is important to note that wild type influenza virus is a community acquired infection readily transmitted person to person through fomites and droplet contact during influenza season, with attack rates ranging from 5 to 25% 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.

39. 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.

The administration of LAIV with or at any time before or after live attenuated or inactivated vaccines is a change since the 2012-2013 influenza statement when specific timing rules applied to LAIV and other live vaccines. Note that the timing rules related to two parenteral live vaccines still apply.

40. 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®. FluMist® should not be administered to individuals while taking antiviral agents active against influenza (oseltamivir and zanamivir). Such individuals should receive inactivated influenza vaccine. If antiviral agents are administered from 48 hours before to 2 weeks after receipt of FluMist®, revaccinate when antiviral agents have been discontinued for at least 48 hours.

41. Are there any Special Considerations for Administration of LAIV and a Tuberculosis (TB) Skin Test?

No information on the effect of FluMist® on a tuberculosis (TB) skin test is available. It is prudent to do TB skin testing on the same day as FluMist® immunization, or delay TB skin testing ≥ 4 weeks, to avoid having a false negative TB skin test result. This advice is extrapolated from the experience with measles vaccine.

42. 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 1 – 3 days. For children requiring 2 doses of vaccine, symptoms tend to be less frequent following the 2nd dose. 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.

**Oculo-respiratory syndrome (ORS):** Fewer than 1 in 20 people may develop ORS and symptoms include: red eyes, a cough, and/or sore throat and/or hoarseness.

43. Is there a list of Screening Questions for the Contraindications, Precautions and Special Considerations for LAIV?

Yes, a list of LAIV (FluMist®) screening questions is available for your use (see APPENDIX A).

44. Should I ask if the Vaccine Recipient is Allergic to all the Components of the 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.
45. How long does it take After Administration of LAIV for the Individual to Acquire Protective Immunity Levels?

It takes about 2 weeks for the body to acquire full protection. This is why it is best that people get vaccinated before influenza activity starts each season.

46. Can LAIV be given to Children who are Household Contact of Someone who is Immunocompromised?

Yes. LAIV is contraindicated only for those who are contacts of persons who are severely immunocompromised. Such severe immunocompromise is defined by NACI, “as hospitalized and requiring care in a protected environment.”

As indicated in the health file, all vaccine recipients should be informed that LAIV (FluMist®) 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 2 weeks after receiving LAIV. If such contact cannot be avoided, the injectable TIIV should be used.

47. Can I give the LAIV to Children who have Experienced Common Local Side Effects to TIIV?

Yes. If parents want their 2-17 year old child to receive LAIV, and the child meets the eligibility requirements, LAIV can be given in place of the TIIV. This would eliminate some potential side effects such as redness, warmth and swelling at the injection site.

48. Can the Side Effects Listed for LAIV Occur Late?

The side effects listed for this product are: Local: runny nose or nasal congestion. 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.

49. Are there Suggested Positioning Techniques Parents can use with Children Receiving the LAIV?

For administration of the LAIV, it is best that the child is seated comfortably, or positioned on a 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.

50. Can a Health Care Worker who is Immunocompromised still Administer LAIV?

Yes. LAIV (FluMist®) 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.

51. Can a Pregnant HCW Administer LAIV?
Yes. A pregnant woman can administer FluMist®; 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.

52. Where can the Public Access LAIV?
LAIV (FluMist®) is available both publicly and privately. For individuals who are eligible for the publicly funded LAIV, it is available through public health units and doctors offices. For those not eligible, it can be purchased privately.
REFERENCES


16 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


APPENDIX A: Live Attenuated Influenza Vaccine (LAIV) Screening Questions:
Questions to ask the parent/guardian of the child or vaccine recipient prior to administration of live attenuated influenza vaccine.

CONTRAINDICATIONS

1. Do you have a history of anaphylactic reaction to a previous dose of any type of influenza vaccine or to any component of LAIV?
LAIV is contraindicated for those with a history of anaphylactic reaction to a previous dose of any type of influenza vaccine or to any component of LAIV.

2. Do you have an allergy to eggs?
LAIV is contraindicated for individuals with an egg allergy. The National Advisory Committee on Immunization (NACI) has concluded that egg-allergic individuals may be vaccinated against influenza using inactivated influenza vaccine, without prior influenza vaccine skin test and with the full dose. Health care providers should review the pertinent section of the NACI influenza statement on egg allergic individuals before proceeding with vaccination. Data are not currently available to support this recommendation for LAIV.

3. Do you have severe asthma (on high dose inhaled or oral steroids) or active/medically attended wheezing in the 7 days?
LAIV is contraindicated for individuals with severe asthma (as defined as currently on oral or high dose inhaled glucocorticosteroids or active wheezing) or medically attended wheezing in the 7 days. These individuals and those who cannot identify their current dosage of glucocorticosteroids should be offered inactivated influenza vaccine. High dose inhaled glucocorticosteroids in pediatric patients are those treated with $\geq 200$ ug/day fluticasone (or equivalent). High dose oral glucocorticosteroids are those treated with $\geq 2$ mg/kg per day or $\geq 20$ mg daily of prednisone for more than 14 days.

4. Are you immunocompromised due to disease or treatment?
LAIV is contraindicated for individuals immunocompromised due to disease or treatment. They should be offered inactivated influenza vaccine.

5. Are you a health care worker (HCW) working with immunocompromised individuals?
NACI recommends that inactivated influenza vaccine, instead of LAIV, should 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.

6. Are you less than 2 years?
LAIV is recommended for eligible children 2 to 17 years of age inclusive and is not approved for children < 24 months of age.

7. Are you pregnant or could become pregnant in the next month?
LAIV is contraindicated for pregnant women because of the lack of safety data. They should be offered inactivated influenza vaccine.

8. Are you currently/have you received Aspirin® containing therapy in the last 4 weeks?
LAIV is contraindicated for children <18 years of age receiving Aspirin®-containing therapy. They should be offered inactivated influenza vaccine. It is recommended that use of Aspirin®-containing products in children <18 years of age be delayed for 4 weeks after receipt of LAIV.
9. Do you have a history of Guillain-Barré syndrome (GBS) within 6 weeks of receipt of a previous dose of influenza vaccine without another cause being identified?

LAIV is contraindicated for individuals with a history of GBS within 6 weeks of receipt of a previous dose of influenza vaccine.

PRECAUTIONS

1. Do you have a history of severe oculo-respiratory syndrome (ORS) after previous receipt of an influenza vaccine?

A history of severe ORS after previous receipt of an influenza vaccine is a precaution to the receipt of LAIV.

2. Are you in contact with someone who is severely immunocompromised and receiving care in hospital in a protected environment? (e.g. post bone marrow transplant)

LAIV 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. Both health care workers and close contacts of such patients should avoid contact with these patients for 2 weeks after getting LAIV. If such contact cannot be avoided they should be offered inactivated influenza vaccine.

SPECIAL CONSIDERATIONS

1. Have you recently received a tuberculosis (TB) skin test that has not been read, or require one in the next 4 weeks?

Do TB skin testing on the same day as LAIV immunization, or delay TB skin testing ≥ 4 weeks to avoid having a false negative TB skin test result.

2. Are you currently/have you received anti-viral medications in the past 2 weeks?

LAIV should not be administered when taking antiviral agents because they interfere with the immune response to LAIV. They should be offered inactivated influenza vaccine. LAIV should not be administered to individuals while taking antiviral agents active against influenza (oseltamivir and zanamivir). If antiviral agents are administered from 48 hours before to 2 weeks after receipt of LAIV, revaccinate when antiviral agents have been discontinued for at least 48 hours.