



Public Health
England

Protecting and improving the nation's health

The national childhood flu immunisation programme 2015/16

Information for healthcare practitioners

About Public Health England

Public Health England exists to protect and improve the nation's health and wellbeing, and reduce health inequalities. It does this through world-class science, knowledge and intelligence, advocacy, partnerships and the delivery of specialist public health services. PHE is an operationally autonomous executive agency of the Department of Health.

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Background

Following a recommendation in 2012 by the Joint Committee on Vaccination and Immunisation (JCVI) that the annual influenza vaccination programme should be extended to include all children aged two to under 17 years of age, the phased introduction of this extension began in 2013. In 2013, flu vaccine was offered to all two and three year old children, and those aged four to 10 years (up to and including pupils in school year 6) in seven different geographical pilot areas.

In the 2014/15 flu season, flu vaccine was offered to all two, three and four year old children. The seven geographical pilots of primary school aged children started in 2013/14, continued and there were several different geographical pilots in secondary school aged children in school years 7 and 8.

In the 2015/16 flu season, flu vaccine should be offered to all children who are two, three and four years old on 31 August 2015 and to all children of school years 1 and 2 age.

Why vaccinate children?

Extending the flu vaccination programme to all children aims to lower the public health impact of flu by:

- providing direct protection to children, thus preventing a large number of cases of flu in children
- providing indirect protection by lowering flu transmission from children to other children, adults and to those in the clinical risk groups of any age thus averting many cases of severe flu and flu-related deaths in older adults and people with clinical risk factors

Studies commissioned by JCVI¹ suggested that, despite the high cost, extending the flu vaccination programme to all children is highly likely to be cost effective and well below the established cost effectiveness threshold when indirect protection to the whole population is taken into account, particularly over the longer term.

The role of healthcare professionals

Healthcare professionals have a key role in promoting increased uptake of flu vaccination in children through:

- understanding the benefits and evidence base relating to the use of the vaccine against flu
- promoting the use of vaccine to parents/carers of children who are eligible to receive the flu vaccination
- safely administering flu vaccines in accordance with the vaccine schedule
- ensuring any adverse effects are managed and reported appropriately

¹ Pitman RJ, Nagy LD and Sculpher MJ (2013) Cost-effectiveness of childhood influenza vaccination in England and Wales: Results from a dynamic transmission model. *Vaccine* 31(6): 927-42.

Influenza

What is flu?

Flu is a highly infectious, acute, viral infection of the respiratory tract. It is transmitted by the inhalation of infected droplets and aerosols and by hand-to-mouth/eye contamination from an infected surface. The incubation period can be 1–5 days (average 2–3 days).

There are three types of influenza virus. Influenza A causes epidemics and pandemics. This virus is found in many different animals and may spread between them. Birds, particularly wildfowl, are the main animal reservoir. Influenza B tends to cause less severe disease and smaller outbreaks. It is predominantly found in humans and the burden of disease is mostly in children. Influenza C causes minor respiratory illness only.

Who does it affect?

Flu can affect anyone, but it is a more serious illness in babies, pregnant women, older people and those with certain underlying conditions.

What are the symptoms of flu?

In healthy individuals, flu is usually an unpleasant but self-limiting illness with recovery in five to seven days. Common symptoms include the sudden onset of fever, chills, headache, myalgia (muscle aches) & severe fatigue. Sufferers can also experience a dry cough, sore throat and stuffy nose. In young children, gastrointestinal symptoms such as vomiting and diarrhoea may be seen.

Possible complications of flu

Common complications may include bronchitis, otitis media (middle ear infection) in children and sinusitis. Other less common complications include secondary bacterial pneumonia, viral pneumonia, meningitis and encephalitis.

Flu vaccination programme for children

Live attenuated influenza vaccine (LAIV)

Which vaccine should be used?

The flu vaccine that should be offered to most children in the eligible cohort groups is a live attenuated intranasal vaccine (LAIV). It contains an attenuated (weakened) vaccine virus that is also cold adapted so that it cannot cause the disease that it protects against.

LAIV is manufactured by AstraZeneca/Medimmune and has been sold in many countries for over 10 years. Only one LAIV vaccine is available, marketed as Fluenz Tetra for the UK and EU market, and FluMist Quadrivalent for the US market. Fluenz Tetra and FluMist Quadrivalent are the same product but in different packaging. For more information about these two vaccines and why both are being used in the 2015/16 flu season, please see [Use of live attenuated influenza vaccine \(LAIV\) FluMist Quadrivalent: Frequently asked questions for healthcare workers](#)

LAIV may not be suitable for all children who are eligible for the flu vaccine (please refer to contraindications question below). For those children in whom LAIV is contraindicated, an injectable inactivated influenza vaccine should be offered.

How is LAIV presented?

LAIV is supplied as a box containing 10 single-use, prefilled nasal applicators. Each applicator contains 0.2ml nasal suspension. The nasal applicator is ready to use. No reconstitution or dilution is required. The nasal suspension is colourless to pale yellow, clear to opalescent. Small white particles may be present.

The virus in the LAIV is cold adapted - what does this mean?

A cold adapted virus is designed not to reproduce well at body temperature (37°C). So it will not replicate in the lungs but will reproduce at the cooler temperatures found in the nose (nasal mucosa). This allows the child to produce antibodies which then protect against infection. These antibodies work in the lining of the airways and are not produced in response to the inactivated flu vaccine. By limiting viral reproduction to the nose, the worst symptoms of flu are avoided.

As LAIV is a live vaccine, can the vaccine virus be passed on to others?

There is the theoretical potential for transmission of the live attenuated flu virus in LAIV to very severely immunosuppressed contacts (for example bone marrow transplant patients requiring isolation). This risk is for the period of one to two weeks following vaccination. In the US, where there has been extensive use of LAIV, there have been no reported instances of illness or infections from the vaccine virus among immunocompromised patients inadvertently exposed. Where close contact with very severely immunosuppressed contacts (for example household members) is likely or unavoidable however, consideration should be given to using an appropriate inactivated flu vaccine.

To assist healthcare workers and headteachers who are asked this question in relation to the safety of the LAIV being given in schools, please read the specifically prepared information about this:“ [Information for head teachers and health care workers about the nasal flu vaccine and ‘viral shedding’](#)”

Vaccine recommendations

Who is LAIV recommended for?

In England, all children aged 2, 3 and 4 years on the 31 August 2015 and of school year 1 and 2 age should be offered LAIV. Additionally, LAIV should be offered to children aged between 2 and 18 years in clinical risk groups unless contraindicated (please refer to contraindications question below). For further information about the childhood flu immunisation programme 2015/16, please refer to the annual flu letter from DH/PHE/NHS England: ‘[The national flu immunisation programme 2015/16: supporting letter](#)’.

How many doses are required?

Children NOT in clinical risk groups only require one dose of LAIV. A single dose is 0.2ml (administered as 0.1ml per nostril).

The marketing authorisation holder’s Summary of Product Characteristics² (SPC) states that, for children who have not previously been vaccinated against seasonal flu, a second dose should be given after an interval of at least four weeks. The JCVI have considered this issue and have recommended that as a second dose of the vaccine provides only modest additional protection, children who are not in a clinical risk group should be offered a single dose of LAIV.

Healthcare professionals are reminded that in some circumstances, the recommendations regarding vaccines given in the Green Book chapters may differ from those in the SPC for a particular vaccine. When this occurs, the recommendations in the Green Book are based on current expert advice received from the JCVI and this advice should be followed. The Green Book recommendations and/or further advice from the Department of Health/Public Health England should be reflected in PGDs.

Children aged two years to less than nine years who are in a clinical risk group and who have not received flu vaccine before should receive two doses of LAIV. The second dose should be given at least four weeks after the first.

Which flu vaccine should be offered to a partially immunised child when all LAIV has expired?

In the event that eligible children who have previously received one dose of LAIV require a second dose (ie those in clinical risk groups who have never received flu vaccine before and are aged between two and less than nine years) but all LAIV stock has expired, a suitable inactivated injectable flu vaccine should be offered as an alternative, allowing a four week minimum interval period between the two doses. It is recommended that children aged two to less than three years should receive an inactivated trivalent flu vaccine, whilst children aged

² Fluenz Tetra® Summary of Product Characteristics (SPC) available at <https://www.medicines.org.uk/emc/medicine/29112> [last accessed 27 July 2015].

three to less than nine years should receive the quadrivalent inactivated flu vaccine (Fluarix™ Tetra). If the quadrivalent vaccine cannot be obtained, the trivalent vaccine should be used as an alternative rather than delay immunisation.

Contraindications and precautions

What are the contraindications to LAIV?

There are very few children who cannot receive any flu vaccine. When there is doubt, appropriate advice should be sought promptly from the local NHS England Screening and Immunisation team, local Health Protection Team or a consultant paediatrician to minimise the period the child is left unvaccinated.

LAIV should not be given to a child or adolescent who:

- is under 24 months or 18 years or older
- has had a confirmed anaphylactic reaction to a previous dose of flu vaccine
- has had a confirmed anaphylactic reaction to any component of the vaccine
- is clinically severely immunodeficient due to conditions or immunosuppressive therapy such as: acute and chronic leukaemias; lymphoma; HIV infection not on highly active antiretroviral therapy (HAART); cellular immune deficiencies; and high dose corticosteroids
- is currently taking or has been prescribed oral steroids in the last 14 days
- is receiving salicylate therapy
- is pregnant

The Green Book³ chapter on 'contraindications and special considerations' (chapter 6) gives further advice on the use of live vaccines in individuals who are severely immunosuppressed. Where LAIV is contraindicated, consideration should be given to the use of inactivated flu vaccine instead.

What are the precautions to LAIV?

LAIV is not recommended for children and adolescents with severe asthma or active wheezing, for example those who are currently taking oral steroids or who have been prescribed oral steroids in the last 14 days for respiratory disease. There is limited safety data on children who are currently taking a high dose of an inhaled steroid – Budesonide >800 mcg/day or equivalent (e.g. Fluticasone >500 mcgs/day) so such children should only be given LAIV on the advice of their specialist. As these children are a defined risk group for flu, those who cannot receive LAIV should receive an inactivated flu vaccine.

Vaccination with LAIV should be deferred in children with a history of active wheezing in the past 72 hours or those who have increased their use of bronchodilators in the previous 72 hours. If their condition has not improved after a further 72 hours then, to avoid delaying protection in this high risk group, these children should be offered an inactivated flu vaccine.

³ Public Health England (2013) Immunisation against infectious disease. Contraindications and Special Considerations. <https://www.gov.uk/government/publications/contraindications-and-special-considerations-the-green-book-chapter-6>

If a child is acutely unwell, immunisation may be postponed until they have fully recovered. This is to avoid confusing the differential diagnosis of any acute illness by wrongly attributing any signs or symptoms to the adverse effects of the vaccine. However, minor illnesses without fever or systemic upset are not valid reasons to postpone immunisation.

What should be done if an individual experiences a side effect?

As with all vaccines and other medicines, healthcare professionals and patients are encouraged to report suspected adverse reactions using the yellow card reporting scheme at <http://mhra.gov.uk/yellowcard>.

Can anaphylaxis occur following administration of LAIV?

As with all vaccines, there is a very rare possibility of this vaccine causing a severe allergic reaction (anaphylaxis). All health care professionals responsible for vaccination should be trained to recognise and treat anaphylaxis.

Can LAIV be given in pregnancy?

There are limited data on the use of live attenuated flu vaccine in pregnancy. Whilst there is no evidence of risk with live attenuated influenza vaccine, inactivated flu vaccines are preferred for those who are pregnant. There is no need, however, to specifically test eligible girls for pregnancy or to advise avoidance of pregnancy in those who have been recently vaccinated. There are no specific precautions regarding pregnant women who are exposed to children who have been vaccinated with LAIV as the likelihood of onward transmission is considered very low.

Which vaccine should be given to children with egg allergy?

JCVI has advised⁴ that, except for those with severe anaphylaxis to egg which has previously required intensive care, children with an egg allergy can be safely vaccinated with LAIV in any setting (including primary care and schools). Those with clinical risk factors that contraindicate LAIV (e.g. immunosuppression) should be offered an inactivated injectable flu vaccine with a very low ovalbumin content (less than 0.12 µg/ml).

Children with a history of severe anaphylaxis to egg which has previously required intensive care, should be referred to specialists for immunisation in hospital. LAIV is not otherwise contraindicated in children with egg allergy. Egg-allergic children with asthma can receive LAIV if their asthma is well-controlled (please see the advice on severe asthma in the precautions question above).

Inactivated vaccines with ovalbumin content more than 0.12 µg/ml (equivalent to 0.06 µg for 0.5 ml dose) or where content is not stated should not be used in egg-allergic children. The ovalbumin content of the flu vaccines for 2015/16 is available in a table on the PHE website (see [Influenza vaccines: 2015 to 2016 flu season](#)).

⁴ Joint Committee on Vaccination and Immunisation Minutes of the February 2015 meeting. Available at : <https://www.gov.uk/government/groups/joint-committee-on-vaccination-and-immunisation#minutes>

The use of inactivated flu vaccine when LAIV is contraindicated

Where LAIV is contraindicated, children may be offered inactivated flu vaccine. Inactivated flu vaccines suitable for children are presented as prefilled syringes for intramuscular injection. The preferred site for injection is the anterolateral aspect of the thigh for infants under one year. Children over one year of age can receive the vaccine in the deltoid region of the upper arm.

Some inactivated flu vaccines are restricted to use in particular age groups or are not suitable for those with an egg allergy. Professionals must be familiar with and refer to the manufacturer's SPC for individual brands when administering inactivated flu vaccines.

An inactivated quadrivalent vaccine (Fluarix™Tetra) is now authorised for those children aged three years and older for whom LAIV is unsuitable. The quadrivalent vaccine contains both influenza B strains so may be better matched (and therefore provide better protection) to the circulating B strain(s) than trivalent inactivated flu vaccines.

Inactivated flu vaccine has a similar systemic adverse reaction profile to LAIV. They may also cause injection site reactions (redness, swelling, tenderness). These usually disappear after one or two days.

How many doses of inactivated flu vaccine are required?

When children cannot receive LAIV due to a contraindication and where the child is aged six months to less than nine years and has not received any flu vaccine before, they should receive two doses of inactivated flu vaccine, with the second dose at least four weeks after the first. The inactivated flu vaccines are interchangeable – the second dose does not have to be the same vaccine given for the first dose.

Children who have received one or more doses of any flu vaccine before should be considered as previously vaccinated. Two doses are only required the first year the child receives any flu vaccine. In subsequent years, they can be given a single dose as their immune system will already have been primed.

What if the child is unwell on the day of vaccination?

If the child has an acute severe febrile illness, LAIV administration should be deferred until recovered. Minor illnesses without fever or systemic upset are not valid reasons to postpone vaccination.

Vaccine constituents

Does LAIV contain latex?

The LAIV is supplied in a single use nasal applicator (type 1 glass) with nozzle (polypropylene with polyethylene transfer valve), nozzle tip-protector (synthetic rubber), plunger rod, plunger stopper (butyl rubber) and dose divider clip, none of which should affect latex sensitive individuals.

Does LAIV contain any preservatives such as thiomersal?

No – LAIV does not contain any preservatives such as thiomersal.

Does LAIV contains ingredients that come from pork ?

The nasal flu vaccine contains hydrolysed gelatine derived from pork as one of its additives. Gelatine is commonly used in a range of pharmaceutical products, including many capsules and some vaccines. The gelatine used in LAIV is a highly purified product used to stabilise live viral vaccines.

Is it permissible for those of certain faiths to receive the vaccine?

This statement from representatives of the Jewish community may help some patients/parents/carers to reach a decision about having the vaccine:

Rabbi Abraham Adler from the Kashrus and Medicines Information Service, said:

“It should be noted that according to Jewish laws, there is no problem with porcine or other animal derived ingredients in non-oral products. This includes vaccines, including those administered via the nose, injections, suppositories, creams and ointments”.

However, we acknowledge that some groups within the British Muslim community may consider the porcine product to be forbidden. In this circumstance, the individual would be unable to accept many pharmaceutical products unless there was no suitable alternative and/or the product was considered life-saving.

Is there an alternative live vaccine that does not contain porcine products?

No. Fluenz Tetra® and FluMist Quadrivalent® are the only live attenuated flu vaccines available in Europe.

Public Health England’s statement⁵ on vaccines and gelatine can be found [here](#). PHE have also published a specific Q&A document⁶: [Children’s flu vaccination programme, the nasal flu vaccine and porcine gelatine](#).

Ordering, storage and handling

How should LAIV be ordered?

All flu vaccines for children are purchased centrally by PHE. This includes vaccine for all children aged two to four years, for children of school years 1 and 2 age and for children in risk groups aged six months to less than 18 years.

For children in risk groups under 18 years of age where is contraindicated, suitable inactivated influenza vaccines will be provided centrally and should be offered. The quadrivalent inactivated influenza vaccine (Fluarix™ Tetra) is authorised for children aged from three years and is preferred because of the additional protection offered. Children aged from six months to less than three years should be given inactivated influenza vaccine (Split Virion) BP®.

⁵ Public Health England (2013) Vaccines and Gelatin: PHE’s response. <https://www.gov.uk/government/news/vaccines-and-gelatine-phe-response> [last accessed 27 July 2015].

⁶ Public Health England (2014). The children’s flu vaccination programme, the nasal flu vaccine Fluenz and porcine gelatin. <https://www.gov.uk/government/publications/childrens-flu-vaccination-programme-nasal-flu-vaccine-and-porcine-gelatine> [last accessed 27 July 2015].

LAIV and inactivated injectable flu vaccines for children can be ordered through the ImmForm website: www.immform.dh.gov.uk as for other centrally purchased vaccines. Please also read [Vaccine update: issue 235, October 2015](#).

How should LAIV be stored?

LAIV must be stored in accordance with manufacturer's instructions. It should be stored between +2°C and +8°C in its original packaging and protected from light. It must not be frozen and like most other vaccines, heat speeds up the decline in potency reducing vaccine shelf life. LAIV may be left out of the refrigerator for a maximum period of 12 hours at a temperature not above 25°C as indicated in the Summary of Product Characteristics² (SPC). If the vaccine has not been used after this 12 hour period, it should be disposed of. For further information about stability of LAIV and what do to in the event of a cold chain failure where LAIV is involved, please see [Responding to cold chain failures involving the live attenuated influenza vaccine \(LAIV\) \(Fluenz Tetra®/Flumist®\)](#)

What is the shelf life of LAIV?

LAIV has an expiry date 18 weeks after manufacture – this is much shorter than inactivated injectable flu vaccines. Expiry dates should be checked regularly and all efforts should be made to vaccinate children before the Christmas holidays if possible.

Vaccine safety and efficacy

Is LAIV safe?

LAIV has been used in the USA for over 10 years. Millions of doses have been given and it has a good safety profile in children aged two years and older. In the 2013/14 and 2014/15 flu seasons, thousands of doses of LAIV were given to children in the UK and no significant adverse reactions were reported.

Why is LAIV the vaccine of choice for most children aged two years and older?

LAIV has been shown to be more effective in children compared with inactivated flu vaccines, particularly after only a single dose, and it may also offer some additional protection against influenza strains not contained in the vaccine as well as to those strains that are. Thus it has potential to offer better protection against strains that have drifted from those contained in the vaccine.

Since this vaccine is comprised of weakened whole live virus, it imitates natural flu exposure /infection which induces better immune memory. This means it should also offer better long-term protection to children than they would get from the inactivated vaccines.

Additionally, as it is administered intranasally, rather than as an injection, it is likely to be more acceptable to children and their parents and carers.

What are the potential side effects of LAIV?

Nasal congestion/runny nose (rhinorrhoea), reduced appetite, weakness and headache are common adverse reactions following administration of LAIV. Immediate reactions such as urticaria, angio-oedema, bronchospasm and anaphylaxis can occur.

Is LAIV effective?

LAIV provides greater protection for children than inactivated flu vaccine, including cross-protection against mismatched strains. By using a live attenuated virus which provides a more complete antigenic stimulus, more elements of the immune system are involved including the production of IgA, a T-cell response and cell mediated immunity.

Results from the 2013/14 child flu vaccine pilot programme suggest a positive impact on levels of flu in that flu season and that there was both a direct and indirect impact on flu indicators⁷. In pilot areas compared to non-pilot areas, there were fewer GP consultations and A&E attendances for 'influenza like' and respiratory illness, and fewer people tested positive for flu in primary care.

In the 2014/15 flu season, fewer GP influenza-like consultations, emergency department respiratory attendance, respiratory swab positivity, hospitalisation and excess respiratory mortality were again consistently lower in both vaccinated and non-vaccinated individuals in the primary school age pilot areas⁸. So vaccination of healthy primary school age children resulted in a population-level impact despite the circulation of drifted A and B influenza strains.

How long after receiving LAIV does it take for a child to acquire protective immunity levels?

It takes about two weeks for the body to acquire full protection. This is why it is best to offer vaccination as early as possible in the flu season before flu viruses start to circulate.

Vaccine administration

How is the vaccine given?

LAIV is administered by the intranasal route and is supplied in an applicator that allows 0.1ml to be administered into each nostril (total dose of 0.2ml in both nostrils). Clear diagrams showing administration are provided in the [SPC](#) and NHS Education for Scotland has made a [video for health professionals on how to administer the vaccine](#).

Can healthcare staff in clinical risk groups administer the vaccine?

In theory, healthcare workers may have low level exposure to live attenuated influenza vaccine viruses during administration of the vaccine and/or from recently vaccinated patients. The vaccine viruses are cold-adapted and attenuated however and are unlikely to cause symptomatic influenza. In the US, where there has been extensive use of LAIV, no transmission of vaccine virus in healthcare settings has ever been reported and there have been no reported instances of illness or infections from the vaccine virus among healthcare professionals inadvertently exposed. Thus, the Centers for Disease Control and Prevention has considered that the risk of acquiring vaccine viruses from the environment is unknown but is

⁷ Pebody RG, Green HK, Andrews N, et al (2014). Uptake and impact of a new live attenuated influenza vaccine programme in England: early results of a pilot in primary school-age children, 2013/14 influenza season. *Euro Surveillance*,19(22)

⁸ Pebody RG, Green HK, Andrews N, et al (2015). Uptake and impact of vaccinating school age children against influenza during a season with circulation of drifted influenza A and B strains, England, 2014/15. *Euro Surveillance*, 20 (39)

probably low⁹. As a precaution, however, very severely immunosuppressed individuals should not administer live attenuated influenza vaccine. Other healthcare workers who have less severe immunosuppression or are pregnant, should take reasonable precautions to avoid inhaling the vaccine and ensure that they themselves are appropriately vaccinated.

What happens if the child sneezes, blows their nose or has nasal dripping following administration?

Administration of the dose does not need to be repeated. 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 the nose immediately after immunisation with LAIV will not affect immunity¹⁰ and reassurance should be given that the vaccine will still be effective if any of these occur.

Can LAIV be given when the patient has a blocked or runny nose?

There are no data on the effectiveness of LAIV when given to children with a heavily blocked or runny nose (rhinitis) caused by infection or allergy. As heavy nasal congestion might impede delivery of the vaccine to the nasopharyngeal mucosa, deferral of administration until resolution of the nasal congestion should be considered or use of an appropriate alternative intramuscularly administered flu vaccine should be considered.

What happens if half of the vaccine dose cannot be given e.g because it is accidentally squirted into the child's eye?

It is not necessary to repeat the dose of vaccine as long as at least 0.1ml of the vaccine has been given intranasally¹¹ as each half dose (0.1 ml) contains enough viral particles to induce an immune response¹².

The vaccine may cause some slight irritation to the eye and eyewash/normal saline should be used to wash out the eye. The child/parent should be advised to seek medical advice if any irritation occurs and persists beyond what might reasonably be expected.

⁹ Centers for Disease Control and Prevention (2013) Prevention and Control of Seasonal Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices — United States, 2013–2014. MMWR September 20, 62(RR07);1-43 http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6207a1.htm?s_cid=rr6207a1_w#AvailableLAIV

¹⁰ Astra Zeneca. Re: FLUMIST (influenza vaccine [live attenuated]) – Re-administration of FLUMIST subsequent to sneezing [Internet] Message to: British Columbia Centre for Disease Control. 2013 July 30. Cited in: British Columbia Centre for Disease Control Live Attenuated Influenza Vaccine Questions and Answers for Health Care Providers 2013-2014 . Revised Nov 2013

¹¹ Astra Zeneca. FLUMIST® (Influenza Vaccine [Live, attenuated]) – Inadvertent Oral Administration & Inadvertent Eye Exposure [Internet] Message to: British Columbia Centre for Disease Control. 2013 July 30. Cited in: British Columbia Centre for Disease Control Live Attenuated Influenza Vaccine Questions and Answers for Health Care Providers 2013-2014. Revised Nov 2013

¹² Astra Zeneca. FLUMIST® (Influenza Vaccine [Live, attenuated]) – Single nostril Administration/Inadvertent Single Nostril Administration [Internet] Message to: British Columbia Centre for Disease Control. 2013 July 30. Cited in: British Columbia Centre for Disease Control Live Attenuated Influenza Vaccine Questions and Answers for Health Care Providers 2013-2014 . Revised Nov 2013

What happens if the child refuses the second half of the vaccine dose after the first half has been given?

As each half dose (0.1 ml) contains enough viral particles to induce an immune response⁸, it is not necessary to offer an inactivated vaccine or a repeat live vaccine on another occasion.

What if a child inadvertently receives both half doses 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 immunisation as each half dose (0.1 ml) contains enough viral particles to induce an immune response⁹.

What should you do if you inadvertently administer LAIV to a child who is aged less than 24 months?

LAIV is contraindicated in all children aged less than 24 months due to an increase in adverse events in this age group. An increase in wheezing and hospitalisation was observed in clinical trials that included children aged from six to 23 months of age. The decision not to license the vaccine for use in children aged less than 24 months was based on these observations rather than vaccine efficacy in this age group.

Children who have received LAIV at less than 24 months of age do not require a replacement dose. The inadvertently administered vaccine should count as a valid dose as LAIV will provide protection in this age group. However, the child's parents/carers should be informed of the possible adverse events in the short term and recommended to seek medical care if adverse events occur. They should be reassured that no long term effects from receiving LAIV are anticipated.

Children from six months of age in clinical risk groups who have not received a flu vaccine previously should count the inadvertently administered LAIV as the first dose. The child should also be offered the inactivated trivalent flu vaccine four weeks later to complete the two dose schedule (in line with the recommendation that children aged six months to under 9 years who have not received inactivated flu vaccine previously should be offered a second dose at least four weeks after the first dose). If the child reaches their second birthday in the four weeks between the dose of LAIV and when a second dose of flu vaccine would be due, a further dose of LAIV can be given.

Healthcare professionals should report the administration error via their local governance system(s) so that lessons can be learnt and the risk of future errors minimised.

What should you do if you inadvertently administer LAIV to a child who is immunosuppressed?

If an immunocompromised individual receives LAIV then the degree of immunosuppression should be assessed. If the individual is severely immunocompromised, antiviral prophylaxis should be considered, otherwise they should be advised to seek medical advice if they develop flu-like symptoms in the four days (the usual incubation period) following administration of the vaccine. If antivirals are used for prophylaxis or treatment, then in order to maximise their protection in the forthcoming flu season, the patient should also be offered inactivated influenza vaccine. This can be given straight away.

Healthcare professionals should report the administration error via their local governance system(s) so that the appropriate action can be taken, lessons can be learned and the risk of future errors minimised.

How can the practice/school nurse recognise if someone is severely immunosuppressed?

An individual may be considered severely immunosuppressed if they:

- are severely immunodeficient due to conditions or immunosuppressive therapy
- have acute and chronic leukaemia
- have lymphoma
- are HIV positive and not on highly active antiretroviral therapy
- have a cellular immune deficiency
- are taking a high dose of steroids

Can LAIV be administered at the same time as, or at any interval before/after other vaccines?

LAIV can be given at the same time as, or at any interval before or after other vaccines, including live vaccines. Although it was previously recommended that, where vaccines cannot be administered simultaneously, a four-week interval should be observed between live viral vaccines, JCVI have now advised that no specific intervals need to be observed between the live attenuated intranasal flu vaccine and other live vaccines. See the [Revised recommendations for the administration of more than one live vaccine](#) for more information.

Can LAIV be administered with antiviral agents against flu?

There is a potential for flu antiviral agents to lower the effectiveness of LAIV. Therefore, flu antiviral agents and LAIV should not be administered concomitantly. LAIV should be delayed for at least 48 hours after cessation of treatment with flu antiviral agents. Administration of flu antiviral agents within two weeks of administration of LAIV may adversely affect the effectiveness of the vaccine.

LAIV is not contraindicated for use in children or adolescents with stable HIV infection receiving antiretroviral therapy; those receiving topical/inhaled corticosteroids or low-dose systemic corticosteroids; or those receiving corticosteroids as replacement therapy, for example for adrenal insufficiency.

What should you do if you inadvertently administer an expired dose of LAIV?

Inadvertently administering an expired dose of LAIV is unlikely to cause harm to the child other than that the expired dose may not offer them adequate protection. Health professionals should inform the parent/carer of the error, provide reassurance where necessary and discount the expired dose. An additional dose of LAIV that is in date should be offered as soon as possible (on the same day as the expired vaccine was given or as soon as the error is discovered), to ensure satisfactory protection. There is no minimum interval between an expired and a valid dose of LAIV as it is the same product being administered. In the event that 'in date' LAIV is not available, a suitable inactivated flu vaccine should be offered as an alternative.

Inadvertently administering an expired dose of LAIV is a clinical incident that should be reported via the local governance system(s), so that appropriate action can be taken, lessons can be learnt and the risk of future errors minimised.

As some patients with learning disabilities may not accept an injected flu vaccine, can they be offered the intranasal vaccine instead?

PHE understand the difficulty with vaccinating this patient group with injectable vaccines. PHE advises that, because Fluenz Tetra is not licensed for adults, practitioners should first attempt to vaccinate the patient with an injectable vaccine. In the past, some practitioners have found, Intanza, the intradermal preparation, easier to use and less distressing in this patient group. This vaccine comes in a small auto-jet type device and is very quick to deliver. Intanza is licensed for patients from 60 years of age.

If offering injectable vaccine is not successful, although Fluenz Tetra is not licensed in adults, in the USA the same product is licensed up to 50 years. A license was not granted above this age in the UK because of some evidence of poorer efficacy against flu than the inactivated product. Nevertheless it is expected to have some efficacy, and studies suggest no additional safety issues other than a slightly higher frequency of sore throat in those over 65 years. Therefore an individual medical practitioner can choose to use Fluenz Tetra “off-label” for adults, without any other medical contra-indication, who are eligible for influenza vaccination but who cannot be vaccinated with injectable vaccines. This could include patients with learning difficulties who become seriously distressed with needles.

The legislation does allow for such situations and states that ‘prescribers can use unlicensed and off-label medicines where there is no suitable alternative.’ The responsibility for such use rests with the health professional. In this situation, a patient specific direction will be required. In these exceptional circumstances, where it has not proved possible to administer the inactivated vaccine, PHE has agreed that the national Fluenz Tetra stock can be used for this purpose.

Resources

Flu Plan and Supporting Letter detailing 2015/16 flu programme: Department of Health, Public Health England, NHS England. Published 27 March 2015. Available at: www.gov.uk/government/publications/flu-plan-2015-to-2016

Immunisation against infectious disease (the Green Book) Influenza chapter August 2015. Available at: www.gov.uk/government/organisations/public-health-england/series/immunisation-against-infectious-disease-the-green-book

Leaflets and posters prepared specifically for the childhood flu programme. Available at: www.gov.uk/government/collections/annual-flu-programme

Toolkit for childhood flu programme available at www.gov.uk/government/publications/flu-immunisation-toolkit-for-programme-extension-to-children

A video for health professionals on how to administer the vaccine produced by NHS Education for Scotland is available at www.nes.scot.nhs.uk/education-and-training/by-theme-initiative/public-health/health-protection/seasonal-flu.aspx

Fluenz Tetra[®] Summary of Product Characteristics (SPC) available at www.medicines.org.uk/emc/medicine/29112

A PGD template to support the national influenza (Fluenz Tetra[®] or FluMist[®] Quadrivalent) vaccination programme: October 2015 to August 2016 is available at <https://www.gov.uk/government/publications/influenza-vaccine-fluenz-tetra-patient-group-direction-pgd-template>

Additional flu resources available at www.gov.uk/government/collections/annual-flu-programme