Frequently asked questions **Childhood influenza vaccination programme** 2020/21

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Public Health Advice

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Contents

Contents

Overview/epidemiology

Why has the influenza vaccination programme been extended to include healthy children?

The National Immunisation Advisory Committee (NIAC) has recommended influenza vaccine, for all children aged 2 to 17 years inclusive, to prevent cases of influenza in children.

For 2020/21, the Department of Health has decided LAIV should be given to children aged 2 to 12 years inclusive.

Vaccination of children will also decrease transmission to others and so reduce morbidity and mortality in those in the clinical risk groups and older adults.

Are children at risk of influenza?

The World Health Organization recommends that children under 5 years of age are a priority group for influenza vaccination because of their greater risk of severe disease or complications.

Influenza occurs globally with an annual attack rate estimated at 20–30% in children compared to 5–10% in adults. Children contribute to the burden of influenza in all age groups because they are more likely to transmit infection to others than are adults.

Children can transmit influenza to others for 10 or more days (compared to 6 days for adults) thus increasing spread of the disease. Those attending day-care centres and schools are likely to transmit influenza in the community.

What symptoms of influenza do children have?

Common symptoms include a sudden onset of fever, chills, headache, muscle and joint pain and extreme fatigue, a dry cough, sore throat and stuffy nose. Young children may develop gastrointestinal symptoms such as vomiting and diarrhoea. Infection may be asymptomatic.

Common complications are bronchitis, otitis media, sinusitis and secondary bacterial pneumonia. Less commonly meningitis, encephalitis, meningoencephalitis and primary influenza pneumonia are seen.

What are the rates of infection in children?

It is estimated that up to 10% of children under 15 years of age attend their GP with influenza in an average season. Incidence rates are highest in the younger age groups leading to high rates of excess outpatient visits, hospital admissions and antibiotic prescriptions.

There is a considerable burden from paediatric influenza (Figure 1).

Figure 1: Burden of paediatric influenza on Irish health system 2009/10-2018/19

Source: HPSC

>11,000 notified influenza confirmed cases

4,000 sentinel GP influenza-like illness consultations

>4750 confirmed influenza hospitalisations

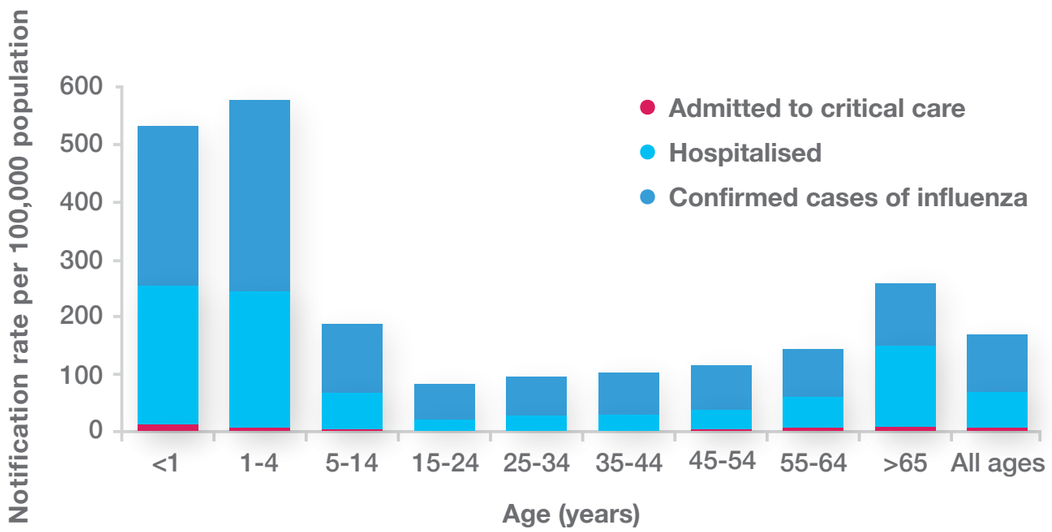
183 critical care admissions for confirmed influenza

41 notified influenza cases died

In Ireland, in 2018/19 the highest age specific rate for hospitalised influenza cases were in those aged <5 years and those aged 65 years and older (Figure 2).

Figure 2: Age specific notification rates per 100,000 population for confirmed influenza cases, by hospitalisation status, during the 2018/2019 influenza season, in Ireland

Source: HPSC



Why is it important to vaccinate children?

It is particularly important to minimise the influenza rates this season so the health service is not overwhelmed with dual outbreaks of influenza and COVID-19. Patients with influenza and COVID-19 co-infection are likely to have worse outcomes.

Influenza vaccination of as many children as possible will reduce their rates of infection and also limit the spread of infection to vulnerable people.

Live attenuated influenza vaccine

What is the live attenuated influenza vaccine (LAIV)?

Trivalent LAIV was first licensed in the USA in 2003 and quadrivalent LAIV has been licensed since 2012.

In Europe, trivalent LAIV was licensed in 2011 for children aged 2 to 17 years inclusive and replaced by quadrivalent LAIV in 2013.

The name of the quadrivalent LAIV vaccine is Fluenz Tetra and it is manufactured by Astra Zeneca. The licensed documentation can be found here https://www.hpra.ie/homepage/medicines/medicines-information/vaccines.

What are the vaccine contents?

LAIV contains the following four attenuated (weakened) influenza strains:

- an A/Guangdong-Maonan/SWL1536/2019 (H1N1)pdm09-like virus;
- an A/Hong Kong/2671/2019 (H3N2)-like virus;
- a B/Washington/02/2019 (B/Victoria lineage)-like virus; and
- a B/Phuket/3073/2013 (B/Yamagata lineage)-like virus.

These are the same virus strains as the quadrivalent inactivated influenza vaccine (QIV) recommended for those in the at risk groups.

LAIV and QIV are both egg based vaccines.

LAIV may contain residues of egg proteins (e.g. ovalbumin) and gentamicin.

LAIV contains the following excipients:

- Sucrose.
- Dipotassium phosphate.
- Potassium dihydrogen phosphate.
- Gelatin (porcine, Type A).
- Arginine hydrochloride.
- Monosodium glutamate monohydrate.
- Water for injections.

LAIV does not contain thimerosal (mercury).

Does LAIV contain latex?

The LAIV presentation does not contain any product that should affect latex sensitive individuals.

What is the ovalbumin content of LAIV?

The maximum amount of ovalbumin in LAIV is less than 0.024 micrograms per 0.2 ml dose.

NIAC recommends that influenza vaccines with an ovalbumin content less than 0.1 micrograms per dose can be given to those with an egg allergy (see section on precautions for further details).

Does LAIV contain porcine gelatin?

LAIV contains porcine gelatin as a stabiliser.

Some members of the Muslim community may have concerns about a vaccine containing porcine gelatin.

The National Immunisation Office received correspondence https://www.hse.ie/eng/health/immunisation/hcpinfo/fluinfo/ from the Imam of the Islamic Cultural Centre of Ireland and the Chairman of the Council of Imams in July 2020 which states *"medicines and vaccinations containing a percentage of gelatine made of pork are permissible."*

How long has LAIV been in use?

LAIV was first licensed in 2003 and since then millions of doses have been given to children across the world.

What other countries give LAIV to children?

In the US, annual influenza vaccine is recommended for all persons including children from 6 months of age and LAIV has been recommended since 2004.

In 2013, the UK introduced trivalent LAIV for 2 and 3 year olds with pilot programmes for primary school children. Quadrivalent LAIV was introduced in 2014/15. The programme has extended to include all children from 2 to 11 years.

In Canada, influenza vaccine was introduced for all children from 6 months to 2 years in 2011 and extended to 6 years of age in 2012. Children from 2 to 5 years can receive either LAIV or inactivated influenza vaccine.

In Finland, annual inactivated influenza vaccine was recommended for children aged 6–35 months in 2007. LAIV was introduced in 2015 to enhance vaccine uptake. Since then, all 2 and 3 year old children have been eligible for vaccination with either LAIV or inactivated influenza vaccine. The programme has recently been extended to include all children to 6 years of age.

LAIV was temporarily not recommended in the US in 2016 because of concerns about low effectiveness against 2009 H1N1 pandemic viruses. This was not seen in the UK where data from the 2015/16 influenza season showed the overall effectiveness and impact of childhood influenza vaccination. LAIV has again been recommended in the US since the 2017/18 influenza season.

How effective is LAIV?

In some studies, LAIV has been shown to be more effective in children compared with inactivated influenza vaccines. Since LAIV contains live attenuated viruses, it mimics natural infection, which induces more durable immune memory and so provides better long-term protection to children than inactivated influenza vaccine.

In addition, LAIV may offer some protection against strains not contained in the vaccine, as well as virus strains that have undergone antigenic drift.

What is the impact of LAIV?

The UK pilot primary school programme was evaluated in 2014/2015 and showed:

- 94% reduction in primary school age children GP influenza like consultations.
- 74% reduction primary school age ED attendances with respiratory complaints.
- 93% reduction in primary school age confirmed influenza hospitalisations.
- 59% reduction in adults GP influenza like illness consultations.

Who should receive LAIV?

While NIAC recommended all children aged 2 to 17 years inclusive should receive LAIV, the Department of Health has decided LAIV should be given to children aged 2 to 12 years inclusive for 2020/21.

LAIV is offered to all children age 2 to 12 years inclusive as part of the 2020/21 HSE seasonal influenza vaccination programme.

Children who are 2 years on the date of vaccination are eligible to receive LAIV.

Children who are 12 years on the date of vaccination are eligible to receive LAIV.

How many doses are required for healthy children?

Children not in a medically at risk group require one dose of LAIV.

Why is only one dose required for healthy children and not two doses as per the licensed information?

Post marketing effectiveness studies have shown:

- Adequate efficacy after one dose of LAIV.
- A second dose of LAIV is of little added benefit to healthy children.

NIAC has recommended that all healthy children should receive a single dose of LAIV.

This recommendation is concordant with Finnish and UK recommendations.

What about a child in a medically at risk group?

Children in a medically at risk group aged 2 to 8 years inclusive, who have not had any influenza vaccine before, require two doses of LAIV, 4 weeks apart.

Children in a medically at risk group aged 2 to 8 years inclusive, who have received one previous dose of **any** influenza vaccine, require one dose of LAIV.

Children in a medically at risk group aged 9 to 12 years inclusive, require one dose of LAIV regardless of their previous vaccination history.

Group	Age	Previous vaccination	Dose
Medically at risk	2 to 8 years	Have never had any influenza vaccine	Two doses 4 weeks apart
		Have had any influenza vaccine before	One dose
	9 to 12 years	N/A	One dose
Healthy	2 to 12 years	N/A	One dose

Which previously unvaccinated children need two doses of LAIV?

Previously unvaccinated children aged 2 to 8 years inclusive with the following medical conditions require two doses of LAIV, 4 weeks apart:

- Any condition that can compromise respiratory function (e.g. spinal cord injury, seizure disorder, or other neuromuscular disorder) especially those attending special schools/day centres.
- Cancer patients.
- Chronic heart disease.
- Chronic liver disease.
- Chronic neurological disease (and hereditary and degenerative disorders of the central nervous system).
- Chronic renal failure.
- Chronic respiratory disease (including cystic fibrosis and moderate or severe asthma).
- Diabetes mellitus.
- Down syndrome.
- Immunosuppression due to disease or treatment, including asplenia or hyposplenism.
- Moderate to severe neurodevelopmental disorders such as cerebral palsy and intellectual disability.
- Morbid obesity.

Who should not receive LAIV?

Contraindications

- Anaphylaxis following a previous dose of influenza vaccine or any of its constituents (other than ovalbumin – see Precautions).
- Asthma.
  - Acute exacerbation of symptoms, increased wheezing and/or additional bronchodilator treatment in the last 72 hours.
  - Seek specialist advice if on regular oral steroids or previous critical care admission.
- Children who live with severely immunosuppressed persons requiring isolation (e.g. post haematopoietic stem cell transplant).
- Concomitant use of aspirin/salicylates.
- Influenza antiviral medication within the previous 48 hours.
- Pregnancy.
- Significant immunosuppression due to disease or treatment (e.g. acute/chronic leukaemia, lymphoma, HIV positive not on highly active antiretroviral therapy, cellular immune deficiency, high dose steroids >0.5mg/kg/day in children <40kgs or on other immunosuppressive drugs).
- Those with severe neutropoenia (absolute neutrophil count $<0.5 \times 10^9$/L) to avoid an acute vaccine related febrile episode.
- Those on combination checkpoint inhibitors (e.g. ipilumumab plus nivolumab) because of a potential association with immune related adverse reactions.

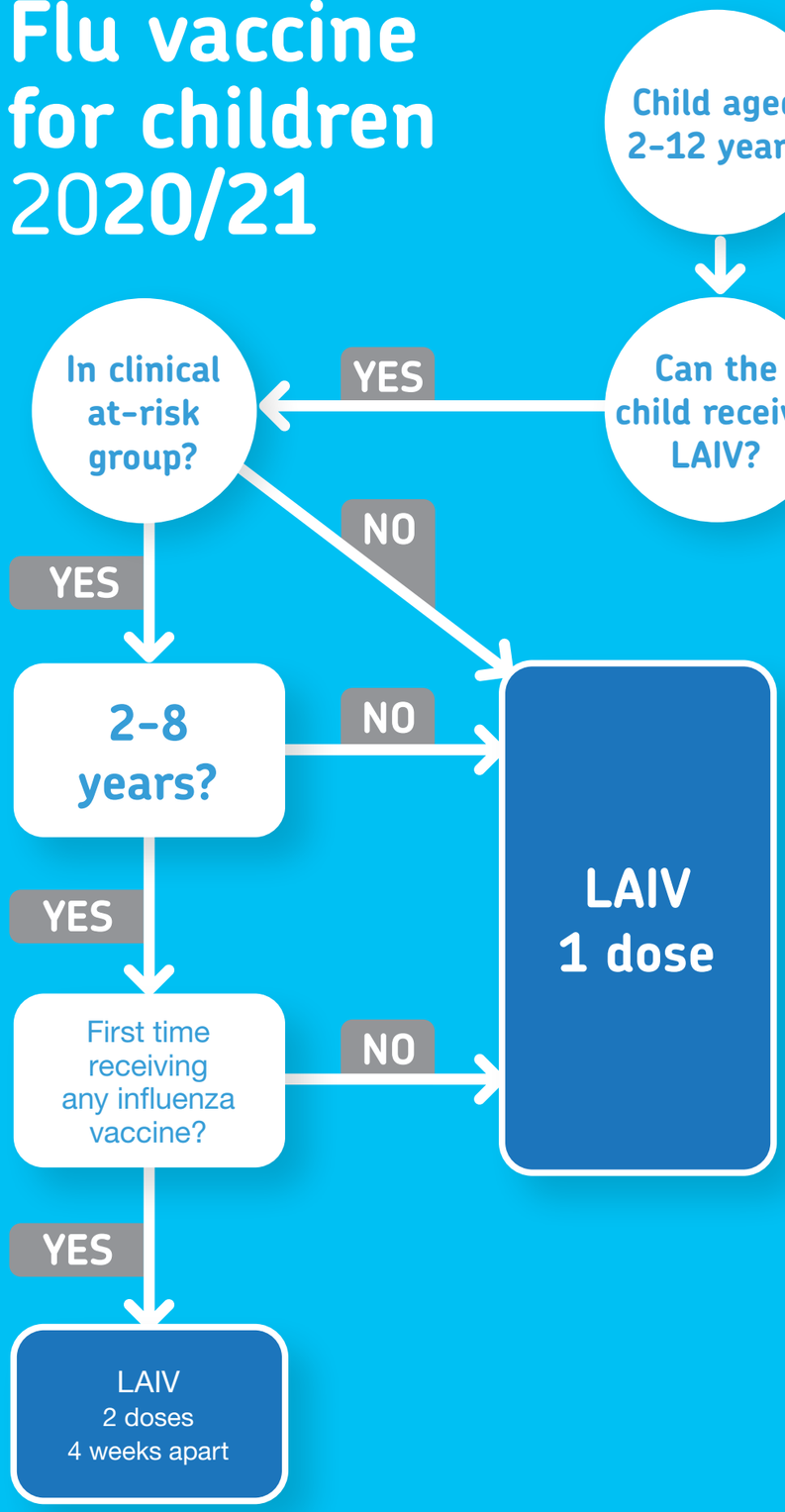
The following are NOT contraindications

- Asymptomatic HIV infection.
- Children receiving:
  - Topical or inhaled corticosteroids.
  - Low dose systemic corticosteroids.
  - Replacement therapy corticosteroids (e.g. adrenal insufficiency).

Precautions

- Defer until recovered from an acute severe febrile illness.
- As LAIV has an ovalbumin content less than 0.024 micrograms per 0.2 ml dose, it can be given to children with confirmed egg anaphylaxis or egg allergy in a primary care setting. Children who have required critical care admission to hospital for a previous severe anaphylaxis to egg should be given LAIV in hospital.
- Aspirin/salicylates should not be used for 4 weeks after vaccination unless medically indicated, as Reye's syndrome has been reported following the use of salicylates during wild-type influenza infection.
- Avoid influenza antiviral medication for 2 weeks post vaccination.

Flu vaccine for children 2020/21



PROTECT PREVENT IMMUNISE

www.hse.ie/flu
@hseimm #YourBestShot

QIV 1 dose

(2 doses 4 weeks apart
if
post transplant
or
2-8 years
and
receiving for first time)

Contraindications to LAIV

- Anaphylaxis following a previous dose of any influenza vaccine or any of its constituents (other than ovalbumin)
- Asthma
  - current acute exacerbation of symptoms/increased wheezing and/or additional bronchodilator treatment in the previous 72 hours
  - seek specialist advice for those who require regular oral steroids or who had previous critical care admission for asthma
- Current use of aspirin/salicylates
- Influenza antiviral medication within the previous 48 hours
- On combination checkpoint inhibitors
- Pregnancy
- Severe neutropoenia
- Significant immunosuppression due to disease or treatment
- Children who live with an immunosuppressed person requiring isolation (e.g. post haematopoietic stem cell transplant)

QIV: Quadrivalent influenza vaccine (split virion, inactivated)

LAIV: Live attenuated influenza vaccine. Fluenz Tetra

What if LAIV is contraindicated?

QIV should be given if LAIV is contraindicated. Check that there are no contraindications to QIV.

What if a child is taking influenza antiviral medication?

LAIV should be delayed if a child has taken influenza antiviral medication within the previous 48 hours and antiviral medication should be avoided for 2 weeks post vaccination.

How long does LAIV take to work?

Like QIV, LAIV takes about two weeks to provide protection against the four influenza strains in the vaccine.

Vaccine administration

What personal protective equipment (PPE) is required to administer LAIV?

The HSE Antimicrobial Resistance and Infection Control Division has advised the following:

- Medical Mask.

Other PPE is not required. Careful hand hygiene before and after administration of LAIV is recommended.

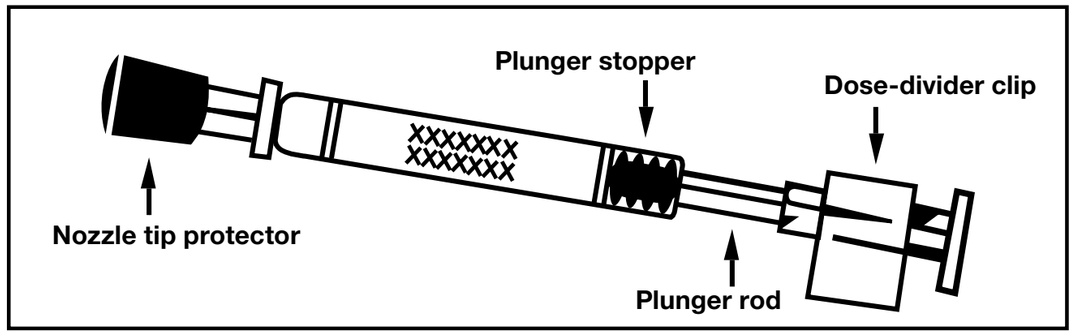
More information is available www.hpsc.ie

How is the vaccine presented?

LAIV is supplied in a box containing 10 single vaccines.

Each vaccine comes as a prefilled nasal applicator.

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.

What is the expiry date of LAIV?

LAIV has a very short shelf life of 18 weeks.

The expiry date must be checked before administration.

The expiry date is written on the side of the nasal applicator as a **day, month and year** and is the last date the vaccine can be administered.

How is LAIV administered?

LAIV is administered **intranasally** as a divided dose in both nostrils.

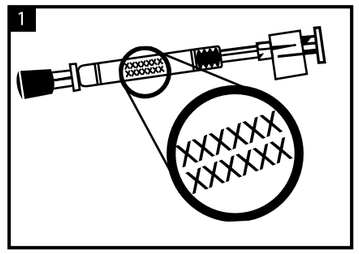
LAIV must not be injected or given orally.

What is one dose of LAIV?

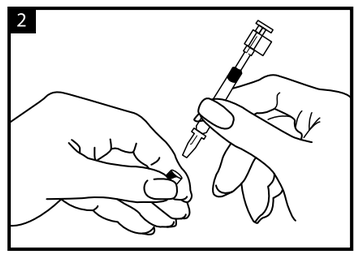
One dose of LAIV is 0.2ml administered in divided doses into each nostril i.e. 0.1ml in each nostril.

Step 1: Only remove 1 vaccine at a time from the box of 10 in the fridge.

Check the expiry date – this is written as a date, month and year on the side of the applicator.

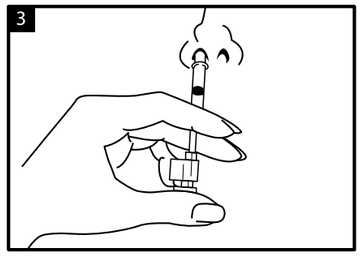


Step 2: Remove nozzle tip protector. Do not remove dose divider clip.

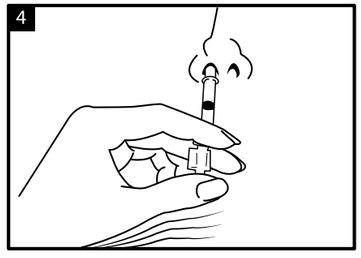


Step 3: Place tip inside the RIGHT nostril (with child in upright sitting position and head titled slightly backwards).

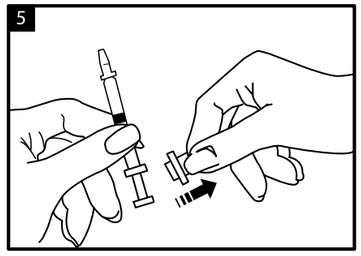
Advise the child to breathe normally. There is no need to inhale or sniff.



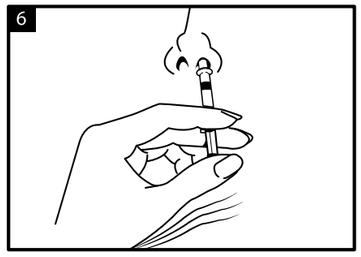
Step 4: Depress plunger as quickly as possible until dose divider clip prevents further administration.



Step 5: Pinch and remove dose divider clip.



Step 6: Insert tip inside the LEFT nostril. Depress plunger as quickly as possible until all vaccine has been given.



Step 7: Dispose of applicator in sharps bin.

What are the side effects of LAIV?

Very common or common (More than 1 in 10 to 1 in 100):

Nasal congestion/rhinorrhoea, decreased appetite, malaise, fever, headache, myalgia. These symptoms usually take a day to develop. In post marketing surveillance, overall rates of fever were similar to the rates following other childhood vaccines and were generally mild and of short duration.

Very rare (less than 1 in 10,000):

Immediate allergic reactions.

Very rare cases of Guillain-Barré syndrome (GBS) have been observed in the post-marketing setting following influenza vaccination. The risk of GBS following influenza infection is significantly greater than that following influenza vaccination.

How long should a child be monitored after LAIV administration?

NIAC recommends that “when possible, patients should remain in the vicinity for up to 15 minutes after vaccination”. This applies after any child or adult vaccination because of the very rare possibility of anaphylaxis. In addition, syncope may occur with most cases occurring less than 5 minutes after vaccine administration.

In most instances, following vaccination there is a period of at least 5 minutes when the record card is being completed before the vaccinated person leaves the room.

To reduce the risk of possible exposure to coronavirus, the child may leave the premises and remain in the vicinity for the remaining minutes provided the parent/guardian is given post vaccination advice and the vaccinated child is accompanied by an adult.

Is there post immunisation advice related to COVID-19?

NIAC has issued the following advice:

“Symptoms associated with the administration of LAIV usually take about 24 hours to develop and usually resolve without treatment within 72 hours.

Further investigation is not required if the very common or common mild symptoms develop as above, within 72 hours after LAIV, unless COVID-19 is suspected.”

What advice should be given after vaccination?

The child can be given paracetamol or ibuprofen to alleviate common symptoms.

Aspirin or salicylates should not be used for 4 weeks after vaccination unless medically indicated, as Reye’s syndrome has been reported following the use of salicylates during wild-type influenza infection.

Influenza antiviral medication should be avoided for 2 weeks post vaccination.

What about virus shedding?

Vaccinated children can shed the attenuated virus for a few days after vaccination but the virus does not survive for long outside the body.

Can LAIV cause influenza?

The attenuated vaccine viruses in LAIV are cold adapted. They can replicate at the lower temperatures found in the nose but cannot replicate efficiently at body temperature elsewhere in the body.

Can influenza be transmitted from LAIV to health care workers or any close contact?

There have been no reported cases of live vaccine virus transmission in health care workers who administer the vaccine or in close contacts, including those who are pregnant.

What if the child has a heavy cold/blocked or runny nose?

If a child has a heavy cold or blocked or runny nose, vaccination should be deferred as this may hinder absorption of the vaccine or else QIV administration should be considered.

What if a child is living with/in close contact with someone who is immunocompromised?

LAIV is contraindicated in a child living with someone who is severely immunocompromised and requires isolation such as a person who has had a haematopoietic stem cell transplant. Such a child should be given QIV.

Can a child taking daily steroids for conditions other than asthma receive LAIV?

Yes. Children receiving topical or inhaled corticosteroids, low dose systemic corticosteroids or replacement therapy corticosteroids can be given LAIV.

What if a child sneezes or blows their nose after vaccination?

If the child sneezes or blows their nose after vaccination, the vaccine dose does not need to be repeated. The vaccine is immediately absorbed after administration.

Sneezing or blowing the nose after immunisation with LAIV will not affect immunity and parents and guardians should be reassured the vaccine is still effective if these occur.

What if the child's nose drips after vaccination?

If the child's nose drips after vaccination, the vaccine dose does not need to be repeated. The vaccine is immediately absorbed after administration.

Nose dripping after immunisation with LAIV will not affect immunity and parents and guardians should be reassured the vaccine is still effective if this occurs.

What if LAIV squirts into the child's eye?

If the vaccine inadvertently squirts into the child's eye, this should be washed out with normal saline or eyewash as it may cause some slight irritation. The parent or guardian should be advised to seek medical advice if this persists.

What if LAIV is only given into only one nostril (i.e. only half the dose is given)?

If a 0.1 ml dose has been given into only one nostril, it is not necessary to repeat the dose of vaccine as this contains enough attenuated viral particles to induce an immune response.

Can LAIV be given at the same time as other vaccines?

Yes, LAIV can be given at the same time or at any time before or after any other live (e.g. MMR or varicella) or non-live vaccine.

Is influenza vaccine recommended for younger children?

QIV is recommended for children aged 6 months to less than 2 years in a medically at risk group. See section in this booklet.

LAIV is only licensed for children from 2 years of age because of the increased risk of wheezing and hospitalisation in younger children. NIAC does not recommend universal QIV for younger children.

What about children who were pre-term what age should they receive LAIV?

Yes. As for all childhood vaccines, children who were pre–term should be vaccinated at their chronological age. All children between 2-12 years of age should receive LAIV unless contraindicated.

Is influenza vaccine recommended for older children?

QIV is recommended for children aged 13 and older in a medically at risk group. See section in this booklet.

What if a child aged 2-12 years presents for vaccination after LAIV has expired?

If a healthy child presents for vaccination after LAIV has expired, no further action is required. They are not eligible to receive QIV.

If the child is in an at risk group, QIV should be given – 1 or 2 doses as required.

What if LAIV is given inadvertently to a child who is immunocompromised?

If LAIV is inadvertently given to a child who is immunocompromised, the level of immunosuppression should be assessed and if severe, antiviral prophylaxis should be considered. The parent/guardian should be advised to seek medical advice if the child develops flu-like symptoms a few days after vaccine administration.

The Health Products Regulatory Authority should be notified of any suspected adverse reaction.

If antivirals are used for prophylaxis or treatment, QIV should be offered to provide protection. No interval is required between antiviral medication and QIV administration.

What if LAIV is inadvertently given to child less than 2 years of age?

LAIV is contraindicated in children aged less than 2 years of age because of an increase in wheezing and hospitalisation.

If LAIV is inadvertently given to a child less than 2 years of age the parent/guardian should be informed and advised about possible adverse events and to seek medical care if they occur.

The Health Products Regulatory Authority should be notified of any suspected adverse reaction.

A dose of QIV should be given 4 weeks later if the child is in a medically at risk group and requires a second dose of vaccine. If the child has reached 2 years of age in the interim, a second dose of LAIV can be given.

What if LAIV is inadvertently given to a child aged 13 or older?

If LAIV is inadvertently given to a child less aged 13 or older, no further action is needed as the vaccine is licensed to 17 years of age.

Reporting adverse events

Reporting suspected adverse reactions to vaccines is important to ensure continuous monitoring of safety. Healthcare professionals are encouraged to report any suspected adverse reaction to the Pharmacovigilance section of the Health Products Regulatory Authority (HPRA).

A report can be made using the online reporting form (https://www.hpra.ie/homepage/about-us/report-an-issue/human-adverse-reaction-form) or alternatively using email (medsafety@hpra.ie) or phone (+353 1 676 4971).

The name of the vaccine and batch number, where known, should be included. For serious or severe suspected adverse reactions, as much information as possible is requested.

Vaccine ordering and storage

How can LAIV be ordered?

LAIV can be ordered from the HSE National Cold Chain Service using the online ordering system.

How should LAIV be stored?

LAIV should be stored in a pharmaceutical fridge which maintains temperature between +2°C to +8°C.

Seasonal influenza vaccination programme 2020/21

Quadrivalent live attenuated influenza vaccine (LAIV) and Quadrivalent inactivated influenza vaccine (QIV)

	LAIV	QIV
Name	Fluenz Tetra (egg based)	Quadrivalent Influenza Vaccine (split virion, inactivated) (egg based)
Manufacturer	Astra Zeneca	Sanofi Pasteur

Who	2 to 12 years (at the time of vaccination)	• In a risk group
		  - 6 months to less than 2 years
		  - 13 to 64 years
		• 65 and older
		• 2 to 12 years if LAIV is contraindicated

What	• 1 dose (healthy children)
	• 2 doses if
	  - in a risk group
	  - and 2 to 8 years
	  - and never had any influenza vaccine before
		• 1 dose
		• 2 doses if
		  - post HSCT or solid organ transplant
		  - or 2 to 8 years
		  - and never had any influenza vaccine before

How	**Intranasal**	**Intramuscular**
Contra-indications	• Anaphylaxis following a previous dose of influenza vaccine or any of its constituents (except ovalbumin) • Severe neutropoenia (absolute neutrophil count less than 0.5 x 10^9/L) • On combination checkpoint inhibitors (e.g. ipilumumab plus nivolumab)	
	• Asthma - acute exacerbation of symptoms, increased wheezing and/or additional bronchodilator treatment in the last 72 hours	

	LAIV	QIV
Contra-indications	• Seek specialist advice if on regular oral steroids or previous critical care admission • Concomitant use of aspirin/ salicylates • Influenza antiviral medication in the previous 48 hours • Pregnancy • Significant immunosuppression due to disease or treatment • Children who live with severely immunosuppressed persons requiring isolation (e.g. post HSCT)	
Precautions	Acute severe febrile illness, defer until recovery	
	• Children who required critical care admission for a previous severe egg anaphylaxis should be given LAIV in hospital • No aspirin/salicylates for 4 weeks after vaccine due to risk of Reye's syndrome • Avoid antiviral medication for 2 weeks after vaccine	• Seek specialist assessment for those who required critical care admission for a previous severe egg anaphylaxis • Separate QIV from PCV vaccine by at least 1 week for children aged 12-23 months
Adverse reactions	*Very common or common:* Nasal congestion/rhinorrhoea, decreased appetite, malaise, fever, headache and myalgia. (Fever rates similar to those after other childhood vaccines; generally mild and of short duration)	*Very common:* Injection site pain and swelling fever, fatigue, myalgia, and irritability in young children. *Common:* Drowsiness, sweating and arthralgia
	Very rare: Immediate allergic reactions. Guillain-Barré syndrome (risk of GBS following infection is much greater than that post vaccination)	

FLU VACCINE

Protect yourself.
Protect others.

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