Frequently asked questions

Seasonal influenza vaccination programme 2021/2022

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Public Health Advice

FLU VACCINE

Protect yourself.
Protect others.

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Facts about Influenza

Influenza causes hundreds of deaths and thousands of hospitalisations every year in Ireland.

Influenza is a very infectious illness and can cause serious illness and make chronic health problems worse.

It's especially important this influenza season that we prevent morbidity and mortality from influenza, and reduce the burden on our health services from influenza.

Influenza vaccine is the best protection against influenza for at-risk groups and health care workers.

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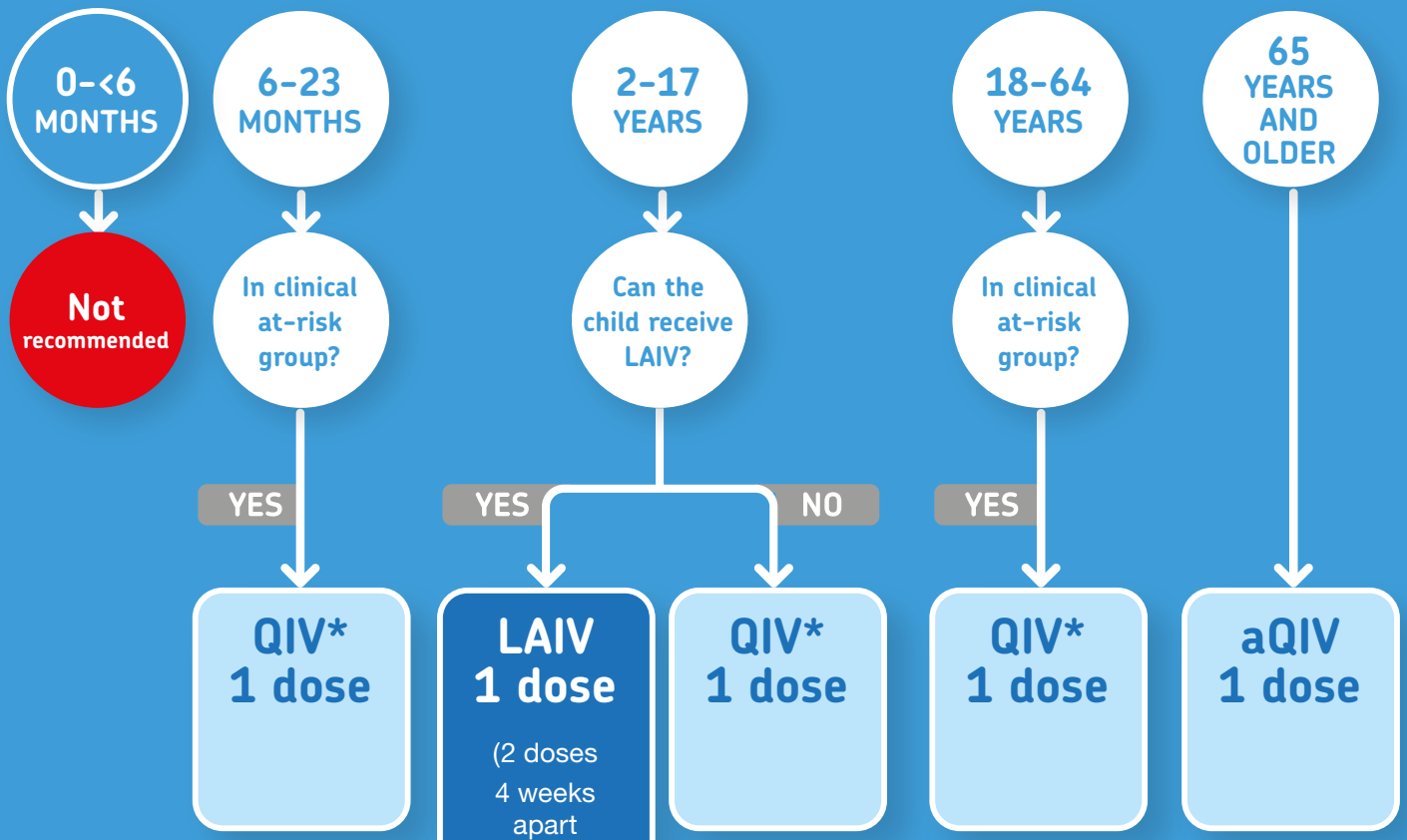
Flu Vaccine 2021/22



*For QIV:

- 2 Doses four weeks apart for children aged 6 months to <9 years if receiving influenza vaccine for the first time.
- 2 Doses four weeks apart if post haematopoeitic stem cell or solid organ transplant and receiving influenza vaccine for the first time post-transplant.
- Cancer patients who receive the vaccine while on chemotherapy and who complete their treatment in the same season require two doses with the 2nd dose at least 4 weeks after completion of chemotherapy and at least 4 weeks after 1st dose (regardless of influenza vaccination in previous seasons).

QIV: Quadrivalent influenza vaccine (split virion, inactivated)

LAIV: Live attenuated influenza vaccine. Fluenz Tetra

aQIV: Adjuvanted Quadrivalent influenza vaccine. Fluad Tetra

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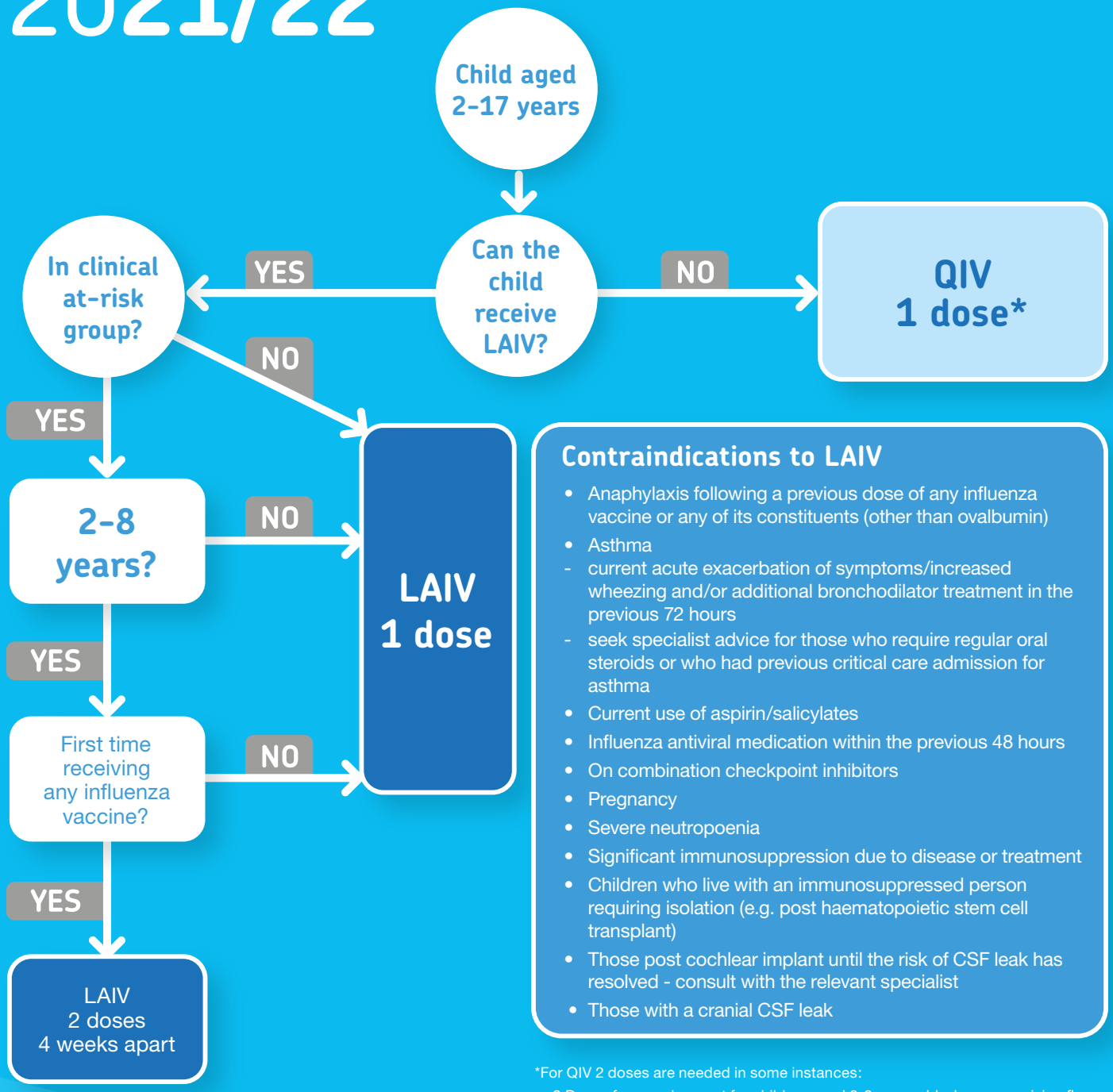
Flu Vaccine for children 2021/22



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)
- Those post cochlear implant until the risk of CSF leak has resolved - consult with the relevant specialist
- Those with a cranial CSF leak

QIV: Quadrivalent influenza vaccine (split virion, inactivated)

LAIV: Live attenuated influenza vaccine. Fluenz Tetra

*For QIV 2 doses are needed in some instances:

- 2 Doses four weeks apart for children aged 2-8 years old who are receiving flu vaccine for first time.
- 2 Doses four weeks apart if post haematopoeitic stem cell or solid organ transplant and receiving influenza vaccine for the first time post-transplant.
- Cancer patients who receive the vaccine while on chemotherapy and who complete their treatment in the same season require two doses with the 2nd dose at least 4 weeks after completion of chemotherapy and at least 4 weeks after 1st dose (regardless of influenza vaccination in previous seasons).

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Section 1: General Information Seasonal influenza vaccination programme 20210/221

How long does the influenza season last?

The influenza season usually starts at the beginning of October and lasts until the end of April.

What seasonal influenza vaccines will be available this year?

Quadrivalent Influenza Vaccine (QIV)

This year the HSE has procured Quadrivalent Influenza Vaccine (split virion, inactivated) (QIV) manufactured by Sanofi Pasteur for the seasonal influenza programme. This is a not a live vaccine.

Adjuvanted Quadrivalent Influenza Vaccine (aQIV)

This year the HSE has procured a new flu vaccine for adults aged 65 years and over. The adjuvated quadrivalent influenza vaccine is called Fluad Tetra and is manufactured by Seqirus. This is a not a live vaccine.

Live attenuated influenza vaccine (LAIV)

This year the Live Attenuated Influenza Vaccine (LAIV) will be offered to children aged 2-17 years old. This vaccine is given intranasally. LAIV contains a weakened vaccine virus that is also cold adapted so that it cannot cause the disease that it protects against. The Live Attenuated Influenza Vaccine (LAIV) is called Fluenz Tetra and is manufactured by AstraZeneca.

What is the composition of this year's seasonal influenza vaccines?

The World Health Organization (WHO) has recommended that this year's influenza vaccines contains protection against the following strains:

- an A/Victoria/2570/2019 (H1N1)pdm09-like virus;
- an A/Cambodia/e0826360/2020 (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 strains estimated by the World Health Organization to be the strains most likely to be circulating this influenza season.

Is influenza vaccine effective?

Influenza vaccine effectiveness varies from year-to-year among different age and risk groups and according to different types of influenza vaccine. It can depend on the match between the predicted vaccine virus used to produce the vaccine and the viruses that will circulate this season. In general, current influenza vaccines tend to work better against influenza B and influenza A (H1N1) viruses and offer lower protection against influenza A (H3N2) viruses.

Influenza vaccines usually reduce the risk of infection by 40-60%. Influenza vaccines also reduce the severity of illness, complications from influenza, reduce influenza-related hospitalisations, and admissions to critical care units.

See factsheet at **https://www.cdc.gov/flu/about/qa/vaccineeffect.htm**

How long does it take influenza vaccine to work?

The vaccine starts to work within 2 weeks.

Who should receive influenza vaccine?

The HSE recommended influenza vaccine for:

- People aged 65 years or older. They should be offered Fluad Tetra (aQIV). QIV should be given if aQIV is not suitable
- All pregnant women at any stage of pregnancy
- Children aged 2-17 years. Children aged 2-17 years should receive LAIV. QIV should be given if LAIV is contraindicated
- Those aged 6-23 months and 13 to 64 years who are at increased risk of Influenza- related complications:
    - Those with chronic illness, e.g. chronic heart disease (including acute coronary syndrome), chronic liver disease, chronic neurological disease (where the neurological condition compromises clearance of respiratory secretions), chronic renal failure, chronic respiratory disease (including chronic obstructive pulmonary disease, cystic fibrosis, moderate or severe asthma, and bronchopulmonary dysplasia), diabetes mellitus, or haemoglobinopathies
    - Those with immunosuppression due to disease or treatment, including asplenia or hyposplenism, and all cancer patients
    - Those with 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
    - Children and adults with Down syndrome
    - Children with moderate to severe neurodevelopmental disorders such as cerebral palsy and intellectual disability
    - Those with morbid obesity (Body mass index >40)
- Residents of nursing homes, old people's homes, and other long stay facilities where rapid spread is likely to follow introduction of infection
- Healthcare workers
- Household contacts of people with underlying chronic health condition or Down syndrome
- Out-of-home care givers for people who have an underlying chronic health condition or have Down syndrome. A carer is someone who provides ongoing significant level of care to a person who is in need of care in the home due to illness or disability or frailty.
- People in regular contact with pigs, poultry or waterfowl

Section 2A: Quadrivalent Influenza Vaccine (QIV)

Who should NOT receive QIV?

QIV should **NOT** be given to:

- Those with a history of anaphylaxis to a previous dose of influenza vaccine or any of its constituents.
- Patients on combination checkpoint inhibitors (e.g. ipilimumab plus nivolumab) because of a potential association with immune-related adverse reactions.
- People with severe neutropoenia (absolute neutrophil count $<0.5 \times 10^9$/L) to avoid an acute febrile episode.

Precautions:

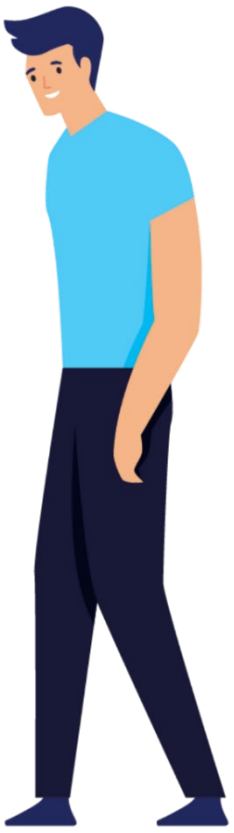
- Acute severe febrile illness (temperature ≥38°C) – defer until recovery.
- QIV should be separated from pneumococcal conjugate vaccine (PCV13) by at least 1 week for children aged 12-23 months because of a slightly increased risk of febrile convulsions if the vaccines are given at the same time in this age group.

Visit www.hpra.ie to read the licensed information) about the vaccine: Summary of Product Characteristics (SmPC) and Patient Information Leaflet (PIL).

Can people with egg allergy receive QIV?

QIV is a low ovalbumin vaccine with an ovalbumin content of ≤0.06 micrograms per dose. Those with confirmed egg anaphylaxis or egg allergy can be given this influenza vaccine in a primary care or school setting with the exception of those who have required admission to ICU for a previous severe anaphylaxis to egg.

Those requiring non-live influenza vaccine who have had a previous ICU admission for a severe anaphylaxis to egg should be referred for specialist assessment with regard to vaccine administration in hospital.



How many doses of QIV are required?

Table 1 summarises the doses of quadrivalent inactivated influenza vaccine required.

Table 1: Dose of QIV

Group	Dose
Children aged 6 months to <9 years**	Two doses 4 weeks apart, if • receiving influenza vaccine for the firsttime or • vaccination history is unknown
post hematopoietic stem cell or post solid organ transplant	Two doses 4 weeks apart, if • receiving influenza vaccine for the firsttime post-transplant
Cancer patients who receive the vaccine while on chemotherapy and who completetheir treatment in the same season*	Two doses 2nd dose on completion of treatment at least 4 weeks after 1st dose (regardless ofinfluenza vaccination in previous seasons)
All others	One dose

* If the lymphocyte count is ≥1.0 x109/L

** Note that children aged 2-17 years will be offered LAIV; only those for whom LAIV is contraindicated should receive QIV.

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

Influenza vaccine can be given at the same time as other vaccines e.g. PPV23 and Tdap. The only exception is with PCV13 for children aged 12-23 months. See next question for further details.

Why can QIV not be given at the same time as PCV13 in children aged 12-23 months?

In children aged 12-23 months of age PCV13 and influenza vaccines should be separated by an interval of at least one week to decrease the risk of febrile seizures occurring.

This is because vaccine safety data from the United States in 2011 reported a small but increased risk of febrile convulsions among children aged 12-23 months who received PCV13 at the same time as inactivated influenza vaccine in the 2010-2011 season (risk approximately 1 in 1,640 vaccinees).

Are there any side effects from QIV vaccination?

The most commonly reported adverse reactions are pain at the injection site, localised redness and swelling at the injection site, myalgia and headache (³ 1 in 10).

Serious allergic reactions are very rare.

Further details are available from the Summary of Product Characteristics (SmPC) available at www.hpra.ie

Where is QIV available?

The influenza vaccine is available from participating GP practices or pharmacies.

Section 2B: QIV and Pregnancy

Why do pregnant women need influenza vaccine?

Influenza vaccination protects women during and after pregnancy.

- Pregnancy increases the risk of complications from influenza due to alterations in heart rate, lung capacity and immunological function.
- Influenza in pregnancy is associated with miscarriage, premature birth, and reduced foetal growth and stillbirth.
- Premature birth can lead to long-term medical and social consequences.
- Vaccination during pregnancy provides passive immunity to infants up to the first 6 months of life, when babies are too young to receive the influenza vaccine. Infants under 6 months have the highest rates of hospitalisation and death from influenza.

Is it safe to give QIV to pregnant women?

Yes. Pregnant women are advised the QIV vaccine. The QIV is an inactivated influenza vaccine; it is not a live vaccine and is considered very safe in pregnancy.

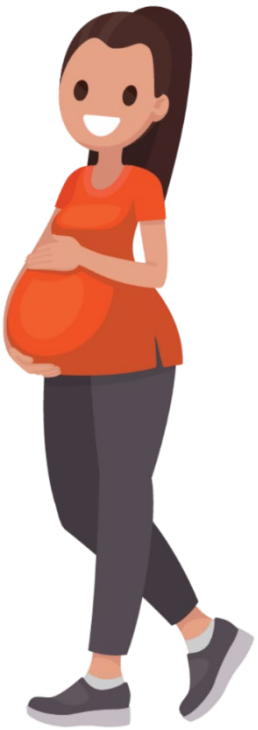
It has been given to millions of pregnant women and has not caused any harm to women or their babies.

At what stage of pregnancy should women receive QIV?

The vaccine can be given to pregnant women at any stage of pregnancy.

Should a woman who was pregnant at the end of the 2020-21 campaign, who received influenza vaccine then, and who has not yet delivered her baby receive 2021-2022 influenza vaccine now?

Yes – the National Immunisation Advisory Committee (NIAC) has recommended that in these instances that the pregnant woman receives a further dose of influenza vaccine. This is because there is a new strain in this season's vaccine and immunity from the first dose could have waned.



Can pertussis vaccine be given at the same time as influenza vaccine in Pregnancy?

Yes. Both vaccines can be given at the same time.

Note: Pertussis vaccine is recommended between 16-36 weeks of pregnancy

Section 3A: Adjuvanted Quadrivalent Inactivated Influenza Vaccine

Why is the flu vaccine important for people aged 65 years and over?

Influenza (or flu) is a serious illness caused by the seasonal flu virus. People aged 65 years and over have an increased likelihood of severe illness, being admitted into hospital or dying from flu when compared to the general population. Although the severity of the flu season can vary, we know that people aged 65 years and over are most likely to impacted. The flu vaccine is the best protection against flu this winter.

What is Fluad Tetra?

Fluad Tetra is an injectable flu vaccine that is available to adults aged 65 years and over. It protects against four strains of the flu virus expected to circulate this flu season as recommended by experts. The flu vaccine changes every year to match the expected circulating strains - therefore you need a flu vaccine every year. It is an inactivated vaccine- meaning it does not contain any live virus. The flu vaccine cannot give you flu. It also contains an adjuvant (an ingredient) to improve its effectiveness.

How do adjuvanted vaccines improve the effectiveness of the vaccine?

As we get older our immune system may not respond to vaccines to the same extent. Therefore, the adjuvanted flu vaccine called Fluad Tetra is being recommended in adults aged 65 years and over. Adjuvants are substances added to vaccines to help generate a greater and longer immune response. Adjuvants have been added to vaccines for many years to improve their effectiveness.

In Fluad Tetra the adjuvant used is MF59. MF59 is mainly made from squalene oil – a natural oil found in humans, plants and animals. A similar adjuvanted trivalent flu vaccine has been used in other countries across Europe and Northern America for a number of years. The adjuvanted quadrivalent flu vaccine has also been used by the United States as part of their 2020-21 flu vaccination programme.

Has Fluad Tetra been associated with narcolepsy?

No. There has been no known association between Fluad Tetra and narcolepsy.

Fluad Tetra has been used by the United States (marketed as FLUAD Quadrivalent) as part of their 2020-2021 flu vaccination programme. A similar adjuvanted flu vaccine (Fluad which is the trivalent version which also contains MF59) has been used in up to 29 countries for over 20 years. MF59 is used as an adjuvant in Fluad Tetra and is squalene based.

The EMA has licensed Fluad Tetra vaccine as it has a favourable safety profile.

What flu vaccines are available for people aged 65 years and over?

Fluad Tetra is the recommended flu vaccine for those aged 65 years and over.

Fluad Tetra is only licensed for use in those aged 65 years and over and offers the best protection against flu for this age group.

Although adults in this cohort may choose to receive either of the vaccines licensed in adults including the 'Quadrivalent Influenza Vaccine'.

All flu vaccines offer protection against flu and reduce the impact of flu if you were to catch it.

What are the known side effects after the Fluad Tetra?

Most side effects are mild to moderate and short lived. After Fluad Tetra very common side effects (affecting more than 1 in 10 people) include: injection site pain, fatigue and headache.

Common side effects (affecting more than 1 in 100 people) include: bruising, redness or inflammation at the injection site, loss of appetite, nausea, diarrhoea, flu-like symptoms including chills, muscle aches and joint pain. Some people may get a fever after the vaccine.

Serious side effects such as a severe allergic reaction (anaphylaxis) are rare.

Who should not get the Fluad Tetra?

You should not get the flu vaccine if you have had a severe allergic reaction (anaphylaxis) to a previous dose of the flu vaccine or the ingredients in the vaccine (including polysorbate 80). Read the manufacturer's Patient Information Leaflet to see the list of ingredients.

Patients on combination checkpoint inhibitors (e.g. ipilumumab plus nivolumab) which are used to treat cancer should not receive any influenza vaccines.

Those with severe neutropoenia should not receive any vaccine.

If you are unwell with a high temperature (greater than 38°C) vaccination should be delayed until after recovery.

Can Fluad Tetra be given to people with an egg allergy?

Adjuvanted QIV vaccine has an ovalbumin content equal to or less than 1 microgram per dose.

Those with confirmed egg anaphylaxis or egg allergy can be given this influenza vaccine in a primary care or school setting with the exception of those who have required admission to ICU for a previous severe anaphylaxis to egg.

Those requiring this vaccine who have had a previous ICU admission for a severe anaphylaxis to egg should be referred for specialist assessment with regard to vaccine administration in hospital.

Can Fluad Tetra be given to people with a latex allergy?

The safety of Fluad Tetra in people who are sensitive to latex has not been determined.

Can Fluad Tetra be given to people with a history of allergy to antibiotics?

People with a history of allergy to Kanamycin and/or Neomycin sulphate should not be given Fluad Tetra. This is because Fluad Tetra may contain residues of these antibiotics as part of the vaccine manufacturing process.

If the Quadrivalent Influenza Vaccine (split virion, inactivated) has been given a person aged 65 years and over, do they need to be revaccinated with the recommended Fluad Tetra vaccine?

No, if someone has already received a dose of standard QIV they do not need revaccinating with Fluad Tetra.

Is COVID-19 different from flu?

Yes, COVID-19 is caused by the SARS-CoV-2 virus. Influenza (or flu) is caused by the influenza virus.

Although some of the symptoms of COVID-19 and how it is spreads might be similar to flu - these are two different diseases caused by two different viruses.

Older adults are significantly more impacted by COVID-19 and flu. You still need your flu vaccine to protect you against flu. We do not know the impact of having COVID-19 and flu at the same time - it is likely that it will be much worse.

Can you get the COVID-19 vaccine at the same time as Fluad Tetra?

COVID-19 vaccines and other vaccines (such as Fluad Tetra) may be given at the same time or at any interval.

To reduce any local side effects it is recommended that each vaccine is given in different arms if possible.

If more than one vaccine has to be injected in the same muscle then each vaccine should be separated by at least 2.5cm.

How to use Fluad Tetra?

Fluad Tetra comes in pre-filled syringes in packs of ten with attached needles. 25 gauge 1-inch needles are provided with Fluad Tetra.

The normal appearance of Fluad Tetra is a milky-white suspension (due to the adjuvant added).

A single dose (0.5ml) of Fluad Tetra is administered intramuscularly into the deltoid muscle using a 1-inch needle.

How many doses of Fluad Tetra are required?

Only 1 dose of Fluad Tetra vaccine is recommended per season, regardless of medical conditions.

A second dose is not required for those post haematopoietic stem cell transplant, post solid organ transplant or cancer patients who receive aQIV while on chemotherapy and who complete their treatment in the same season.

Can Fluad Tetra vaccine be given to those under the age of 65 e.g. immunocompromised people?

No. Fluad Tetra is only licensed for use in adults age 65 and over. It should not be used in persons under the age of 65.

People under the age of 65 in should be offered the age appropriate flu vaccine.

What if Fluad Tetra is inadvertently given those under the age of 65?

Fluad Tetra is only licensed for use in adults age 65 and over. If it is inadvertently given to those under the age of 65 it should be reported to the HPRA. The vaccine recipient should be informed that the vaccine is licensed in those aged 65 and over only. Furthermore they should be should be advised regarding the common adverse events expected after vaccination including that they may experience more local side effects due to the adjuvant in the vaccine.

Although Fluad Tetra is not indicated for use in children the manufacturer's summary of product characteristics (section 5.1) for Fluad Tetra does contain information on safety data from clinical trials done in paediatric populations (6months to under 6 years). Children less than 3 years of age received 0.25 ml vaccine, older children received 0.5 ml vaccine. In the paediatric clinical trail safety data was collected up to 12 months after receipt of the last vaccination. A higher incidence of local and systemic reactions was reported in subjects who received Fluad Tetra compared to the non-adjuvanted comparator influenza vaccine. The most commonly reported adverse reactions (>10%) were tenderness (43.2%), irritability (27.1%), sleepiness (26.3%), change in eating habits (22.5%), fever (19.1%), diarrhoea (12.3%) and vomiting (10.3%).

Where can I get the adjuvanted flu vaccine?

It is available from participating pharmacies and GP surgeries for adults aged 65 years and over.

What is the normal appearance of Fluad Tetra vaccine?

Gently shake before use.

After shaking, the normal appearance of the vaccine is a milky-white suspension.
Visually inspect the contents of each pre-filled syringe for particulate matter and/or variation in appearance prior to administration.

If either condition is observed, do not administer the vaccine.

Section 3B: Adults aged 65 years and over and the pneumococcal vaccine

How often is vaccination with pneumococcal vaccine (PPV23) required?

The pneumococcal vaccine protects you against pneumococcal infection caused by the streptococcus pneumoniae bacteria. Pneumococcal infection can cause serious complications such as pneumonia, sepsis and meningitis. Routinely adults aged 65 years and over are recommended one dose of the pneumococcal vaccine (pneumococcal polysaccharide vaccine, PPV23). Generally, for older adults one dose of the pneumococcal vaccine after the age of 65 provides life-long protection - you do not need to the vaccine every year.

Revaccination is not normally required. Revaccination with PPV23 can produce severe local reactions especially if given within 5 years of previous injection.

Aged 65 years and older

Those aged 65 years and older who have never previously received PPV23 require one dose only. No further doses are required regardless of immune status. For those who received a previous dose of PPV23 at less than 65 years of age, a once only booster vaccine is recommended 5 years after the first vaccine.

Less than 65 years of age

One booster vaccine is recommended 5 years after the first PPV23 vaccine for those whose antibody levels are likely to decline rapidly e.g. asplenia, hyposplenism, immunosuppression including HIV infection, chronic renal disease, nephrotic syndrome or renal transplant.

If PPV23 was given during chemotherapy or radiotherapy a further dose of PPV23 vaccine is recommended 3 months after treatment.

When is a 3rd dose of PPV23 required?

Adults whose antibodies are likely to decline rapidly should receive two doses of PPV23 while aged less than 65.

They will need a third dose of PPV23 when they turn 65 provided at least five years have passed since their last dose of PPV23.

Can PPV23 vaccine be given at the same time as influenza vaccine?

Yes. PPV23 may be given at the same time as influenza vaccine but at a different site. As there is considerable overlap in the target groups for both vaccines, it is appropriate to offer the PPV23 to patients (if indicated) when they attend for their influenza vaccine.

No interval is required if both vaccines are not given on the same day.

Section 4: Live attenuated influenza vaccine (LAIV)

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 2021/22, the Department of Health has decided LAIV should be given to children aged 2 to 17 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.

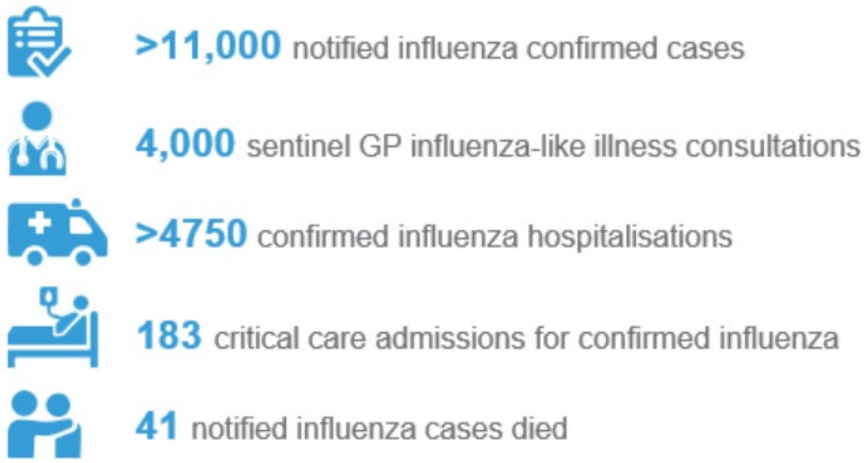
Less commonly meningitis, encephalitis, meningoencephalitis and primary influenza pneumonia are seen.

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.

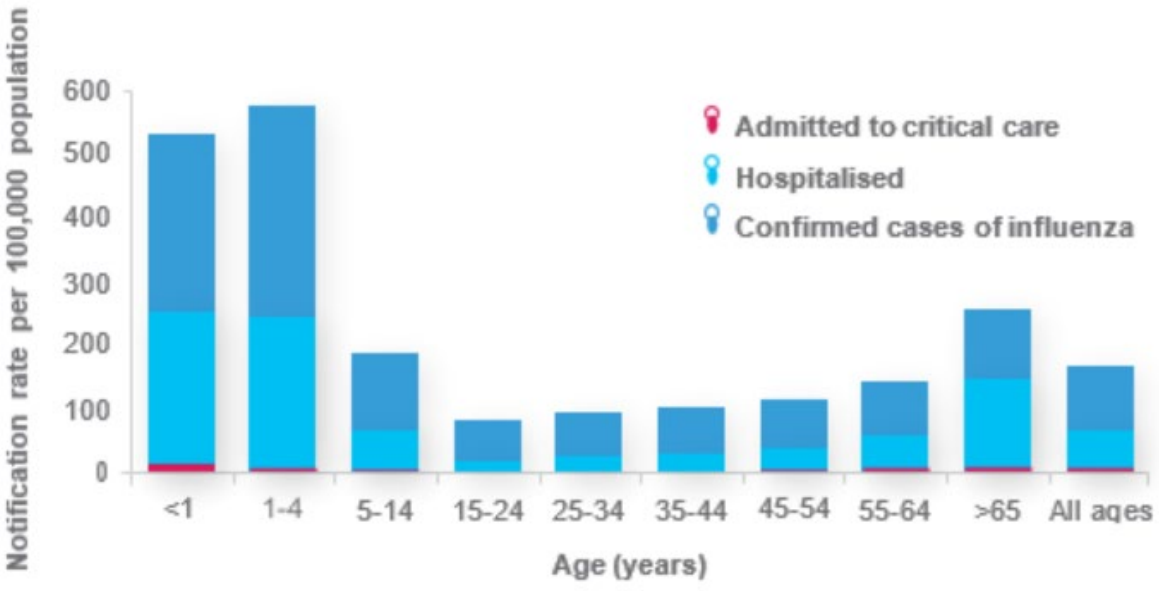
There is a considerable burden from paediatric influenza (Figure 1).

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



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.

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 on **https://www.hpra.ie**.

What are the vaccine contents?

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

- an A/Victoria/2570/2019 (H1N1)pdm09-like virus;
- an A/Cambodia/e0826360/2020 (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 is an egg based vaccine.

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 those with confirmed egg anaphylaxis or egg allergy can be given influenza vaccine in a primary care or school setting with the exception of those who have required admission to ICU for a previous severe anaphylaxis to egg (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/flufaq/fatwa-gelatin-irish-council-of-imams-2020.pdf 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?

LAIV is offered to all children age 2 to 17 years inclusive as part of the 2021/22 HSE seasonal influenza vaccination programme in line with Department of Health policies.

- Children who are 2 years on the date of vaccination are eligible to receive LAIV.
- Children who are 17 years on the date of vaccination are eligible to receive LAIV.

For all children aged 2-17 LAIV is the recommended flu vaccine for this age group- including children medically at-risk. QIV should only be given to children aged 2-17 if LAIV is contraindicated.

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 17 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 Have had any influenza vaccine before	Two doses 4 weeks apart One dose
	9 to 17 years	N/A	One dose
Healthy	2 to 17 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 post cochlear implant until the risk of a CSF leak has resolved - consult with the relevant specialist
- Those with a cranial CSF leak
- Those with severe neutropoenia (absolute neutrophil count <0.5 × 109/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.

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

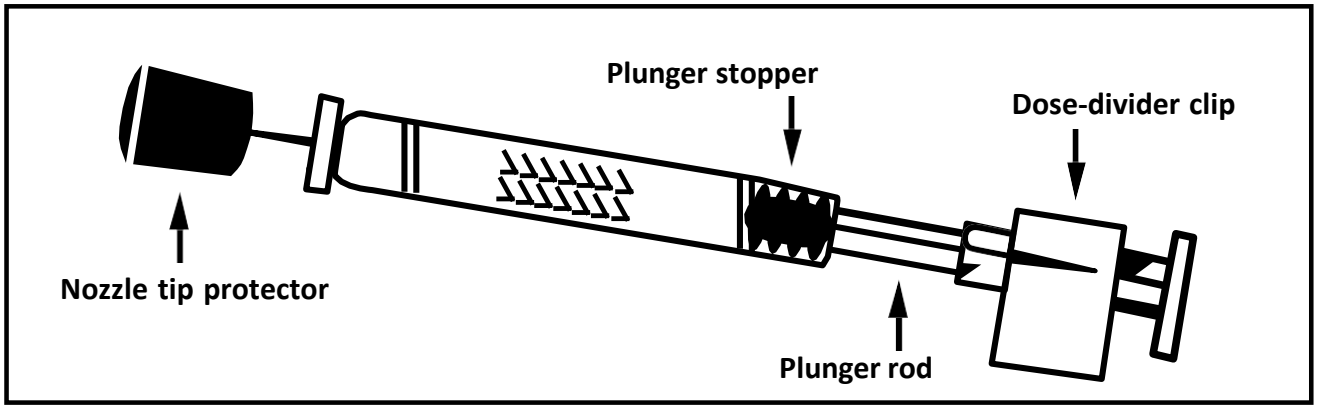
Other PPE is not required. Careful hand hygiene before and after administration of LAIV is recommended.

More information is available on 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.

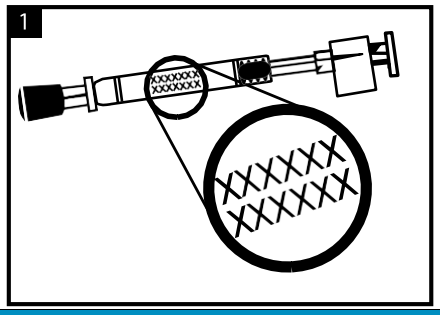
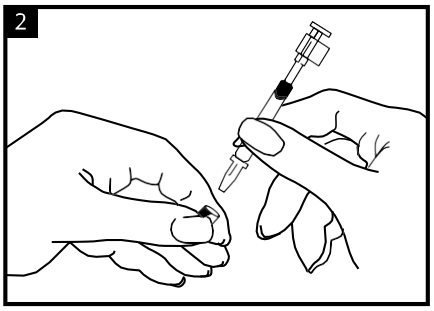
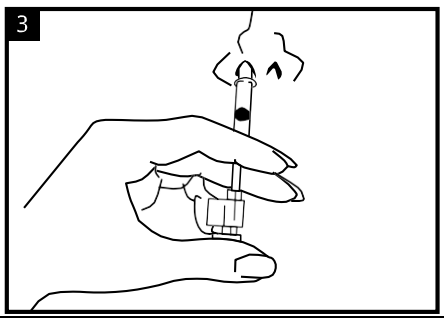
The expiry date is written on the side of the nasal applicator as a day, month and year and is the last date the vaccine can be administered.

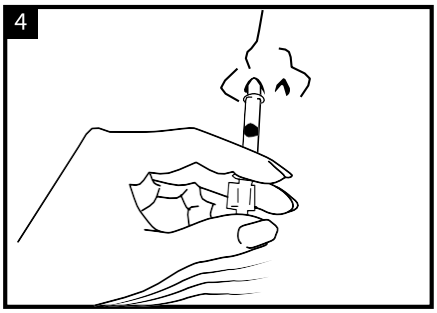
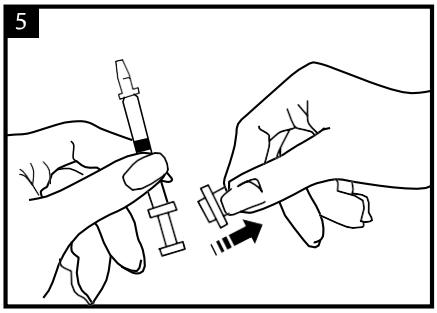
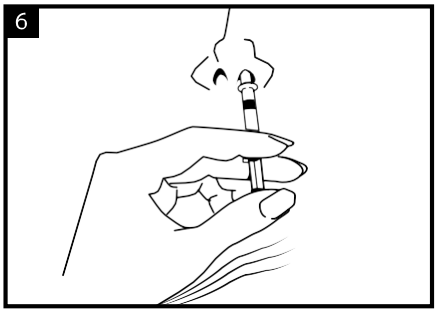
How is LAIV administered?

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.

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. 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.

What if a child aged 2-17 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.

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 (**https://ordervaccines.ie**).

How should LAIV be stored?

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

QUICK REFERENCE GUIDE TO INFLUENZA VACCINES

Protect yourself. Protect others.

Name of vaccine	Fluenz Tetra LAIV	Quadrivalent influenza vaccine virus (split viron, inactivated) QIV	Fluad Tetra aQIV
Type of vaccine	Reassortant influenza virus (live attenuated) Active immunisation against four influenza virus strains (two A subtypes and two B types)	Influenza vaccine – surface antigen inactivated Active immunisation against four influenza virus strains (two A subtypes and two B types)	Influenza vaccine – surface antigen inactivated and adjuvanted Adjuvant MF59C.1 Active immunisation against four influenza virus strains (two A subtypes and two B types)
Licenced for	Aged 2 to 17 years	Aged 6 month and over	Aged from 65 years and over only
Target groups	2 to 17 year olds	In recommended "at-risk" as per Department of Health	65 years and older
Dose	0.2 ml (administered as 0.1 ml per nostril).	0.5 mls intramuscularly	0.5 mls intramuscularly
Number of doses required	One Two for at risk groups specific age groups**	One Two for at risk groups or specific age groups*	One
Interval	For those requiring 2 doses: 4 week interval between doses	For those requiring 2 doses: 4 week interval between doses	Not applicable (one dose only per flu season)
Supplied by National Cold Chain Services (NCCS)	Box of 10 nasal applicators Store in a refrigerator (+2°C to + 8°C). Do not freeze Discard if the vaccine has been frozen Keep the nasal applicator in the outer carton in order to protect from light	Box of 10 prefilled syringes with needles Store in a refrigerator (+2°C to + 8°C). Do not freeze Discard if the vaccine has been frozen Keep the pre filled syringe in the outer carton in order to protect from light	Box of 10 prefilled syringes with needles Store in a refrigerator (+2 °C to +8 °C). Do not freeze Discard if the vaccine has been frozen Keep the pre filled syringe in the outer carton in order to protect from light
Preparation	Ready to administer, no dilution required	Ready to administer, no dilution required	Ready to administer, no dilution required
Appearance	Nasal spray, suspension colourless to pale yellow Small white particles may be visible	Reach room temperature before use Gently shake before use After shaking gently, is a colourless opalescent liquid Visually inspect -should not be used if foreign particles in the suspension	Gently shake before use After shaking, the normal appearance milky-white suspension Visually inspect the contents of each pre-filled Should not be used if foreign particles are in the suspension
Shelf Life	Until expiry date	Until expiry date	Until expiry date
Ovalbumin content	≤0.024 micrograms per dose**	≤0.06 micrograms per dose***	≤1.0 micrograms per dose***

PROTECT PREVENT IMMUNISE

QUICK REFERENCE GUIDE TO INFLUENZA VACCINES

Protect yourself. Protect others.

Packaging			
			

*QIV - 2 doses 4 week apart for children aged 6 months and less than 9 years receiving the flu vaccine for the first time.
2 dose 4 weeks apart if post haematopoietic stem cell transplant or post solid organ transplant and receiving the vaccine post-transplant. Cancer patient who receive the vaccine while on chemotherapy and who complete their chemotherapy in the same season require two doses with the second dose at least 4 weeks after the completion of chemotherapy and at least four weeks after the first dose(regardless of influenza vaccine in the last season).

**LAIV - 2 dose 4 weeks apart for children aged 2 to 8 years who are clinically “at risk” and first time receiving any influenza vaccine. See the following for more information:

- https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/chapter11.pdf
- https://www.hse.ie/eng/health/immunisation/pubinfo/flu-vaccination/algorithmflu.pdf

***Those with confirmed egg anaphylaxis or egg allergy can be given all of the above influenza vaccines in a primary care or school setting with the exception of those who have required admission to ICU for a previous severe anaphylaxis to egg.
Those requiring inactivated influenza vaccine who have had a previous ICU admission for a severe anaphylaxis to egg should be referred for specialist assessment with regard to vaccine administration in hospital.

PROTECT PREVENT IMMUNISE

Useful Links

- WHO Recommended composition of influenza virus vaccines for use in the 2021-2022 northern hemisphere influenza season https://www.who.int/publications/i/item/recommended-composition-of-influenza-virus-vaccines-for-use-in-the-2021-2022-northern-hemisphere-influenza-season

- CDC Vaccine Effectiveness: How Well Do Flu Vaccines Work? https://www.cdc.gov/flu/vaccines-work/vaccineeffect.htm

- HPRA Human Vaccines https://www.hpra.ie/homepage/medicines/medicines-information/vaccines

- HSE Pneumococcal Vaccine https://www.hse.ie/eng/health/immunisation/hcpinfo/othervaccines/pneumo/

- HSE Pertussis in Pregnancy https://www.hse.ie/eng/health/immunisation/hcpinfo/othervaccines/pertussis/

- HSE Pneumococcal Disease: The Disease and The Vaccine https://www.hse.ie/eng/health/immunisation/pubinfo/pcischedule/vpds/pneumococcal/

- Immunisation Guidelines for Ireland: Chapter 11 Influenza https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/chapter11.pdf

- WHO Europe Methods for assessing influenza vaccination coverage in target groups https://www.euro.who.int/__data/assets/pdf_file/0004/317344/Methods-assessing-influenza-vaccination-coverage-target-groups.pdf

- HPSC https://www.hpsc.ie/

- HPRA Human Medicines Adverse Reaction Report https://www.hpra.ie/homepage/about-us/report-an-issue/human-adverse-reaction-form

- National Cold Chain Service Vaccine Ordering https://ordervaccines.ie

Notes

hse.ie/flu
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Public Health Advice

FLU VACCINE

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