



**Toolkit to Support the Administration of Flu
Vaccination to Children and Young People in School
or Community Settings**

Seasonal Influenza Vaccination Programme 2022-2023

October 2022

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1 Introduction

The National Immunisation Advisory Committee (NIAC) have recommended influenza (flu) vaccination for all children aged 2-17 years for the 2022-2023 seasonal influenza programme. The aim of the influenza programme for children is to protect children from influenza related morbidity and mortality, particularly those aged under four years in whom influenza infection can be more severe. In addition, young children may shed and transmit influenza for longer than adults and are therefore important drivers of influenza infection in the community.¹ Reducing infection among children provides direct protection to vaccinated children and decreases transmission of flu within the wider community, providing indirect protection to those at higher risk of severe disease.²

This toolkit aims to support staff from GP practices and community pharmacies across Ireland as they undertake vaccination of children and young people aged 2-17 years in the 2022-23 seasonal influenza programme. The toolkit should be used in conjunction with existing guidance published by the [Irish College of General Practitioners](#) and the [Pharmaceutical Society of Ireland](#).

1.1 The Seasonal Influenza Programme 2022-2023

The goal for the seasonal influenza campaign for the 2022-2023 season is to increase the overall uptake of flu vaccinations with a focused target for key groups including children and young people aged 2-17 years.

The 2022/2023 HSE seasonal vaccination programme will offer:

- Quadrivalent live attenuated influenza vaccine (LAIV), nasal application for those aged 2-17 years.
Brand available:
 - ✓ Fluenz Tetra nasal spray suspension Influenza vaccine (live attenuated, nasal) manufactured by AstraZeneca AB
- Inactivated quadrivalent influenza vaccine (QIV) available for all other eligible populations including those aged 2-17 with contraindications to LAIV (QIV is licensed for those 6 months of age and older). Two brands of injectable vaccine will be distributed and are interchangeable where two doses are required:
 - ✓ Quadrivalent Influenza Vaccine (split virion, inactivated) manufactured by Sanofi Pasteur
 - ✓ Influvac Tetra marketed by Mylan

The groups recommended the free HSE flu vaccine include: ¹

1. Quadrivalent Influenza Vaccine (QIV) which is given by intramuscular (IM) injection and recommended for:
 - Children aged 6-23 months old and adults aged 18-64 years who are at risk of influenza related complications
 - Children and young people aged 2-17 years for whom LAIV is contraindicated

- Pregnant women
 - Healthcare workers (HCWs)
 - Carers
 - All those aged over 65 years
2. Live Attenuated Influenza Vaccine (LAIV) which is administered intranasally and is recommended for:
- Those aged 2-17 years (unless contraindicated)

A full list of eligible groups for the influenza vaccines is available at www.hse.ie/flu and in the NIAC guidelines Chapter 11 available at: ¹

<https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/chapter11.pdf>

Vaccination of all children in Ireland aged 2-17 years with LAIV was first added to the national influenza vaccine campaign in the 2020-2021 flu season. For the 2020-21 season, LAIV was initially offered to those aged 2-12 years. Younger children were prioritised for vaccination as they are more susceptible to the complications of flu and more likely to be drivers of infection in the community ². Later in the 2020-2021 flu season, the programme was extended to those aged 13-17 years. For the 2021-22 flu season, LAIV was offered to all children and young people aged 2-17 from the beginning of the season and a similar approach is being taken for the 2022-23 flu season.

The LAIV was primarily administered in the community by General Practitioners (GPs) and community Pharmacists during the 2021-2022 season, alongside a small pilot scheme involving vaccination in a school context in a number of areas nationally.

In the small scale pilots undertaken in Ireland last year local school teams offered the vaccine to 600 children in schools. Uptake of the LAIV in these pilot areas in a school setting was 63.9%. Uptake in the community among the study population was 12.4%. Therefore this pilot programme increased uptake within the participating schools populations from 12.4% to 76.3%. There is also strong international evidence that the administration of vaccines in school settings increases vaccination uptake and that a school setting is an appropriate and safe setting to enable the vaccination of large numbers of students.

Based on HPSC data, there has been a decrease in the uptake among 2-12 year olds from the 2020-21 season (29%) to the 2021-22 season (18.8%), but an increase among the older group of children and young people (from 2.5% to 11.6%). The target uptake for those aged 2-17 years for the 2022-2023 flu season is 50% with an ambition of 75%.

1.2 Opportunities for the provision of LAIV to children and young people

The most effective means of providing opportunities for children and young people to access Flu vaccination in the community will vary and will need to be tailored to specific local circumstances. In order to help GPs and Community Pharmacists meet the ambitions set out in the 2022-23 Flu Plan, for vaccination of children and young people aged 2-17 years, this toolkit will lay out some possible approaches to facilitating flu vaccine uptake. However, it is recognised that primary care and community services are under particular pressures at the present time, and the approach taken in a local context may need to reflect this reality.

A range of options exist for supporting the uptake of Flu vaccinations in this target population, including displaying information posters in GP practices and community pharmacies, opportunistic vaccine promotion and administration via parents or carers, running specific pre-booked or walk-in vaccination clinics in the practice or pharmacy or running special clinics in a community setting e.g. schools, outside of the practice or retail pharmacy environment. Each of these options will require a different level of resource investment but may also provide new opportunities to reach children and young people and offer them access to Flu vaccination.

Schools offer an opportunity to reach this target demographic in a focussed and efficient way. In the UK, intranasal live attenuated influenza vaccine (LAIV) has been offered to children aged 2-4 years old by GP's and to older children in primary school since 2013. It was extended to secondary school children in 2020-21. The extension of the influenza immunisation programme to children in a school setting was informed by a number of successful pilot projects that demonstrated that school-based delivery of flu vaccines to children improves uptake and that school-based vaccination is likely to achieve higher coverage than delivery via existing primary care pathways.^{2,3}

GP practices and community pharmacies could work in partnership with local schools, to offer opportunities for children and young people to access LAIV in the school setting with consent from parents, potentially reducing barriers to access that might be posed by parents' work commitments or transport constraints, for example. These clinics could happen on site, during the normal school day and could therefore bring flu vaccination opportunities to highly concentrated groups of the target population.

Depending on local circumstances, LAIV could also be administered in other community settings, outside of schools, for example in childcare facilities, sports clubs or youth centres. Involving community organisations in the planning and promotion of these vaccination clinics may allow a wider audience to be reached with important information about seasonal flu vaccination, and may also

facilitate volunteer participation in promoting and running the clinics.

Local GP practices and local community pharmacies could consider partnering with community organisations in the provision of LAIV in community settings. In 2020, relevant legislation was amended to allow appropriately trained pharmacists to supply and administer the flu vaccine at any suitable and appropriate place, having regard to public convenience and the need to protect the health and safety of the public.

Pharmacists providing Flu vaccine services offsite from the Pharmacy premises should consult relevant Pharmaceutical Society of Ireland guidance on the safe provision of this service offsite:

[https://www.thepsi.ie/Libraries/Folder Pharmacy Practice Guidance/2_9 Guidance to Support Pharmacies in Providing Safe Influenza Vaccination Services Offsite from the Pharmacy Premises.sflb.ashx](https://www.thepsi.ie/Libraries/Folder_Pharmacy_Practice_Guidance/2_9_Guidance_to_Support_Pharmacies_in_Providing_Safe_Influenza_Vaccination_Services_Offsite_from_the_Pharmacy_Premises.sflb.ashx)

The remainder of this toolkit will provide information and resources to support the provision of Flu vaccination opportunities, by GP and community pharmacy teams, with the information relevant to the provision of vaccinations both inside and outside of the normal practice or retail pharmacy setting. The Appendices contain supporting information, which could be tailored to local settings and which may assist GPs and local pharmacies in delivering this important aspect of the Flu Vaccination plan for 2022-23.

2 LAIV Administration in Children

2.1 Vaccine, Dose and Route of Administration

The vaccine recommended by NIAC for children aged 2-17 years is a Live Attenuated Influenza Vaccine (LAIV), it is called Fluenz Tetra and is manufactured by Astra Zeneca. This vaccine may be given to all children aged 2-17 years, unless contraindicated. Vaccinators should be aware that LAIV viruses cannot cause influenza as they are cold adapted and cannot replicate efficiently at body temperature.

The dose of this vaccine is 0.2ml. LAIV must only be given intranasally, one spray (0.1ml) should be given in each nostril. Children aged 2-17 years, who are not in a high-risk group, should receive a single dose of LAIV as effectiveness studies have shown that a second dose of LAIV is of little added benefit to healthy children¹.

Those children aged 2-8 years in a clinically at-risk group, who are at higher risk of complications from influenza, should receive two doses of LAIV, at least four weeks apart, where they are receiving **any** influenza vaccine for the first time or where they have an unknown vaccination history. This is

summarised in Table 1 and information on which groups of children are considered high risk is provided in Section 2.2, overleaf.

Please see Appendix A for list of training material available to support administration of the LAIV.

Table 1 Dose of LAIV

| Age Group | Dose |
|---|---|
| Children aged 2-17 years | One dose |
| Children aged 2-8 years in a clinically at-risk group | Two doses 4 weeks apart if they are receiving influenza vaccine for the first time or if the vaccination history is unknown |

Please note:

- If the child sneezes or their nose drips, the vaccine does not need to be repeated. LAIV is immediately absorbed after administration and there is a surplus of attenuated virus particles in the vaccine required for immunity.
- If LAIV is only tolerated / given in one nostril, the vaccine does not need to be repeated. A 0.1ml dose given into one nostril contains enough attenuated viral particles to induce an immune response.
- If all of the vaccine doses are given in the same nostril, the vaccine does not need to be repeated.

2.2 Children in Clinically At-Risk Groups

The following children are considered to be in clinically at-risk groups:

- Those with chronic illness, e.g., chronic heart disease, chronic liver disease, chronic neurological disease, chronic renal failure, chronic respiratory disease (including 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
 - LAIV is contraindicated in children with severe immunocompromise due to disease or treatment (Section 2.4)
- 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 with Down syndrome
- Children with moderate to severe neurodevelopmental disorders such as cerebral palsy

and intellectual disability

- Residents of long stay facilities where rapid spread is likely to follow introduction of infection
- Morbid obesity

Children aged 2-8 years who fall into any of the above categories and who have never had any influenza vaccine before should be offered two doses of LAIV four weeks apart unless it is contraindicated (Section 2.4). Where a school or community-based Flu vaccine clinic has been organised, children in high-risk groups who have never had any influenza vaccine before would need to be identified by the immunisation team, from the information provided on the consent form completed by parents (which includes a pre-vaccination screening questionnaire). Children in this category could be offered a dose of LAIV in the school or community setting and, following vaccination, their parents could be given a letter advising them to attend their GP or pharmacy for the second dose of LAIV four weeks after the first dose.

2.3 Precautions to LAIV Administration

- In the event of acute severe febrile illness, vaccination should be deferred until recovery
- LAIV can be given to children with confirmed egg anaphylaxis or egg allergy in a primary care or school setting. LAIV has an ovalbumin content ≤ 0.024 micrograms per dose. However, children who have required ICU/Critical care admission for a previous severe anaphylaxis to egg should be given LAIV in hospital

2.4 Contraindications to LAIV Administration

The following are contraindications to receiving the LAIV:

- Anaphylaxis following a previous dose of influenza vaccine or any of its constituents except ovalbumin (See precautions in Section 2.3 above)
- Asthma
 - If a child has had an acute exacerbation of symptoms, increased wheezing and/or additional bronchodilator treatment in the last 72 hours vaccination is contraindicated
 - If a child has severe asthma, is on regular oral steroids or has had previous ICU/Critical care for asthma, specialist advice should be sought
- Concomitant use of aspirin/salicylates
- Children who live with a severely immunosuppressed person
 - e.g. living in isolation post haematopoietic stem cell transplant
- Use of influenza antiviral medications 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 other immunosuppressing 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 neutropaenia
 - Absolute neutrophil count <0.5 x 10⁹/L, to avoid an acute vaccine related febrile episode. This does not apply to those with primary autoimmune neutropaenia, who can receive influenza vaccine unless contraindicated.
- Those on combination checkpoint inhibitors
 - e.g., ipilimumab plus nivolumab because of a potential association with immune related adverse reactions
 - Patients on combination checkpoint inhibitors should not receive any influenza vaccines

Children for whom the LAIV is contraindicated should be offered the QIV provided it is also not contraindicated. If they present to a school or community based clinic where LAIV is being offered, their parents should be advised to bring the child to their GP or pharmacy to receive the QIV.

There is an algorithm which outlines the procedure for the LAIV in children aged 2-17 years included as Appendix B to this toolkit.

LAIV is not contraindicated for use in those with asymptomatic HIV infection, those who are receiving topical/inhaled corticosteroids or low-dose systemic corticosteroids or those receiving corticosteroids as replacement therapy, e.g., for adrenal insufficiency.

2.5 Adverse Reactions to the Vaccination

Local Side Effects:

- Nasal congestion is very common ($\geq 1/10$)

General Side Effects:

- Malaise is very common ($\geq 1/10$)
- Decreased appetite, headache, myalgia and fever are common ($\geq 1/100$ to $< 1/10$)
- Fever is no more frequent than that following other recommended childhood vaccines, is generally mild and resolves in a few days

Very Rare Side Effects (< 1/10,000)

- Immediate allergic reactions

Very rare cases of Guillain-Barré syndrome (GBS) have been observed in post marketing surveillance

following the flu vaccine. However, the risk of GBS following influenza infection is significantly greater than that following influenza vaccination.

Read the Summary of Product Characteristics (SmPC) contains further information on adverse events associated with Fluenz Tetra. Available here: https://www.ema.europa.eu/en/documents/product-information/fluenz-tetra-epar-product-information_en.pdf

2.6 Co-administration of LAIV

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 vaccines.

3 Practical considerations for the administration of LAIV in School or Community settings.

3.1 Planning

A key initial step in considering the provision of vaccination clinics outside of the GP practice or community pharmacy is the identification of relevant groups and stakeholders that may facilitate such efforts. This could build on existing relationships established with schools or community groups, or it could be an opportunity to develop new links. This identification of potential opportunities should happen early in the flu vaccination season, so as to allow sufficient time for the practical aspects of establishing the vaccination clinic to be addressed.

Following identification of a location and time, key practical aspects to consider when planning an 'off-site' vaccination clinic might include:

- Vaccine supply
- Vaccine storage
- Vaccinators
- Medicines protocols
- Materials for circulation to parents of children attending the school or community group
- Administrative approach to recording vaccinations
- Procedures and equipment for managing adverse reactions to the vaccine

3.2 Preparation

As part of preparation for the vaccination session, vaccine information packs should be developed locally and sent to the school or community group for onward distribution to all parents.

Parents/legal guardian/young people should receive this pack through the schools or community groups in advance of the planned vaccination session.

This pack should contain:

- An information leaflet for parents in English and Irish (Appendix C)
- A consent form in English and Irish including a pre-vaccination screening questionnaire (Appendix D). Parents should be advised that if their child has already received an influenza vaccine since September this year or has an appointment already arranged, they should not consent for their child to receive a vaccine in the school or community clinic
- A letter for parents sent from the GP or Community Pharmacist (Suggested wording for two different scenarios are in Appendix E but should be tailored locally)
- An envelope to return the completed consent form

Prior to the vaccination date it should be ensured that:

- All consent forms are reviewed and children with contraindications to LAIV and children in high-risk groups who require two doses of LAIV are identified (Section 2.2)
- All queries should be dealt with so no child attends for vaccination with an outstanding query
- A system should be available locally to deal with immunisation queries or concerns from parents/legal guardians/students and schools
- The target cohort (denominator) should be identified
- The composition of immunisation teams should be agreed locally in advance and will depend on the number of students in the school
- Vaccinators are working within their scope of practice

Prior to vaccination, all clinical staff should be familiar with the following documents

- Immunisation Guidelines for Ireland available at <https://bit.ly/NIACGuide>
- Summary of Product Characteristics (SmPCs) for LAIV available at www.hpra.ie
- " Anaphylaxis: Immediate Management in the Community " protocol, in the Immunisation Guidelines for Ireland available at <https://bit.ly/NIACGuide>
- HSE Communicating Clearly with Patients and Service Users guidelines <http://bit.ly/CommClear>
- Each vaccinator must also be familiar with
 - Techniques for resuscitation of a patient with anaphylaxis and have completed a Basic Life Support training course within two years

3.3 Resources and Equipment

Each local context will have access to different amounts of staff resource to facilitate vaccinations in a school or community setting but it is important that the following aspects are considered when forming a vaccination team:

- There should be a sufficient number of appropriately trained vaccinators to meet the predicted or expected demand in the clinic, particularly in 'walk-in' clinics where care needs to be taken to avoid the congregation of a large number of people in confined indoor spaces.
- Having administrative staff on site may allow an increased efficiency in checking-in attendees and logging/recording vaccinations delivered.
- Support staff may be helpful, to assist with the transport of equipment and the practical set up of the space.
- Volunteers may be useful to assist in 'crowd management' activities. These volunteers may be recruited from members of staff, if a school setting is being used, or from adult volunteers in community or sports groups.

The following resources and equipment are required for administration of the LAIV

- A LAIV (This comes as a suspension in pre-filled nasal applicator. Ready to use. No reconstitution or dilution needed)
- Fridge/Cooler box with data logger with external temperature monitoring display to maintain cold chain temperature between +2° to +8°C
- Disposable kidney dishes/trays
- Sharps bins, and bins for the disposal of healthcare risk and non-riskwaste
- Alcohol hand sanitiser
- Surgical facemasks
- Access to telephone
- Resuscitation equipment and drugs in accordance with Anaphylaxis: Treatment in the Community (National Immunisation Advisory Committee, 2019) available at <https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/anaphylaxis.pdf>
- Safe storage areas for medicines and equipment
- Medicine protocols if being used by nurse vaccinators

3.4 Vaccine Ordering and Storage

Flu vaccines can be ordered by vaccination sites at the HSE National Cold Chain Service (NCCS) using the online ordering system ordervaccines.ie where your calendar is available, indicating order dates and delivery dates. There are no restrictions on LAIV orders- please order what you require.

The vaccine expiry date should be checked prior to administration. It is important to be

particularly aware of the short shelf-life of the LAIV compared to other vaccines when arranging and planning LAIV clinics.

LAIV should be stored in a fridge/cooler box with a data logger with external temperature monitoring display to maintain cold chain temperature between +2° to +8°. Vaccines which have been exposed to temperatures outside the permitted range should not be disposed of. These vaccines should be quarantined and maintained between +2° to +8° until advised by the National Immunisation Office.

3.5 Pre-Vaccination Procedures

3.5.1 Consent

Informed consent must be obtained prior to vaccination.

The Guide to Professional Conduct & Ethics for Registered Medical Practitioners, 8th Edition, 2019 (Medical Council) states in section 11.1 that:

- “(You must) give patients enough information, in a way that they can understand, to enable them to exercise their right to make informed decisions about their care.
- Consent is not valid if the patient has not been given enough information to make a decision” See <http://bit.ly/MC8thEd>

In order to support the provision of appropriate information to children and their parents/legal guardians, an information leaflet is available in Appendix C, and in a broad range of different languages online (<https://www.hse.ie/eng/health/immunisation/pubinfo/flu-vaccination/information/information-material.html>). A suggested consent form for LAIV administration in children and young people has been developed and can be found in Appendix D.

3.5.2 Assessment of the Child or Young Person for Vaccination

Before assessing the suitability of a child or young person for vaccination:

- Confirm their identity
 - Confirm name, address, date of birth and parent or legal guardian’s name by asking: “What is your full name? When is your Birthday? Where do you live? Who signed the consent form? What is their name?”
- Confirm that informed consent has been given by a parent/legal guardian
- Address any clinical issues raised on the consent form
 - This process should identify children for whom the LAIV is contraindicated and children who are in high-risk groups and require two doses of the LAIV 4 weeks apart (Template letters for parents in these circumstances are included in Appendix F)
- Vaccines should only be given to children and young people who are well on the day, and for whom no contraindication is identified as per the Immunisation Guidelines of

Ireland available at <https://bit.ly/NIACGuide>

- The child or young person's temperature should not be checked routinely in the school or community clinic at the time as this is not conclusive and is therefore unhelpful in the decision-making process
- Any child or young person feeling unwell on the day or considered by the clinical lead in charge of the vaccination clinic to require deferral of the vaccine should be advised to re-attend their GP or Pharmacist for vaccination at an appropriate time. In this case a letter can be sent home with the child, suggested wording in Appendix F)

3.5.3 Vaccination Record Forms

Once the parent/legal guardian completes their part of the consent form, and once vaccination staff introduce clinical content to the form, it should be considered as a clinical record and treated accordingly and stored in accordance with General Data Protection Regulations (GDPR). Vaccination data should be recorded onto your respective ICT systems.

GP patient management systems have been reconfigured, and the HSE GPVax system and PharmaVax updated, to enable:

- Flu vaccination records from GPs and pharmacists to transmit electronically from their software to COVAX.
- Flu payment claims from GPs and pharmacists to be sent to PCRS team

All clinical notes on events around vaccination should be stored as part of the vaccination record on the vaccination form. It is important to ensure that all written information recorded is in black ink, in block capitals and is clear and legible.

3.6 Post-Vaccination Advice

This post-vaccination information leaflet also called the tear sheet <https://www.hse.ie/eng/health/immunisation/pubinfo/flu-vaccination/postvacchildflu.pdf> (Appendix G) should be given to children/parents/legal guardians . If appropriate, depending on the age of the child, vaccinators may reiterate some of the information that is contained in the information leaflet.

This information leaflet advises parents/legal guardians that:

- Their child received Fluenz Tetra nasal fluvaccine.
- Most children have no problem after this vaccine.
- Some children may get:
 - a runny or blocked nose

- headache or muscle aches
- a fever (temperature) after the vaccine.
- These are usually mild and only last a day or two.
- If their child has a fever (temperature) or a headache they can give them paracetamol or ibuprofen.
- Their child should not be given aspirin or medicines called salicylates, unless they have been prescribed by a doctor.
 - This is especially important in the 4 weeks after getting the vaccine.
- Serious side effects such as a severe allergic reaction are very rare.
- If their child is very unwell after the vaccine, they should talk to their GP (doctor) or Pharmacist as it may be for some other reason.

There may be a number of circumstances where additional correspondence with parents/legal guardians is necessary. A number of suggested letter templates are included as Appendix F for these scenarios, for example:

- In relation to a child in a high-risk group who requires two doses of the LAIV vaccine (Section 3.7)
- In relation to a child who is eligible for the LAIV but could not receive it on the day e.g., due to a child feeling unwell or refusing vaccination
- In relation to a child for whom the LAIV is contraindicated (Section 2.4), advice should be given to parents/legal guardians that their child should get the QIV (unless also contraindicated).

3.7 Post-Vaccination Procedures

Following administration of the vaccine the child or young person should be advised to remain in the vaccination clinic for 15 minutes to allow monitoring for any immediate reaction including possible anaphylactic reaction. The vaccination should be recorded on a vaccination record form and given to the child/parents/legal guardians to be taken home.

3.7.1 Adverse Reactions

In the unlikely event of adverse reaction occurring following administration of the vaccine, parents/legal guardians should inform the GP or pharmacist who organised the vaccination clinic.

The vaccinator should report relevant suspected adverse reactions to the HPRA. Details of adverse events may be recorded on the adverse event clinical record (Appendix H). When reporting suspected adverse reactions to the HPRA, details of the brand name and batch number of the vaccine should be included in the report. An adverse reaction report form can be accessed

by:

- Following the links to the online reporting options accessible from the HPRA website at <http://bit.ly/HPRAar>
- Using a downloadable report form also accessible from HPRA website, which may be completed manually and submitted to the HPRA via “freepost” available from the HPRA website <http://bit.ly/HPRAIssue>
- By using the traditional “yellow card” report which can be requested in bulk from the HPRA. The “yellow card” also utilises the free post system.
- By telephoning the HPRA Pharmacovigilance Section 01-6764971.

3.7.2 Incident Reporting

In the event of an incident occurring during a vaccination session, an incident report must be completed by the professional primarily involved in the incident and forwarded to the relevant manager and/or to local or regional Risk Manager as per local policy. The vaccine recipient and/or significant others should be informed of the incident.

In the case of medication errors that directly involve the vaccine recipient, i.e., wrong medication/dose/route being administered or another medication error, the vaccinator must remain with the person and closely monitor them for any adverse reactions. The recipient should be reviewed by the relevant medical practitioner/clinical lead/ lead vaccinator and the vital signs should be recorded. The incident must be reported to the relevant line manager/person in charge as soon as possible and the vaccine recipient and/or significant others should be informed of the incident.

Any suspected adverse reactions associated with medication errors should be reported to the HPRA as outlined above.

3.8 Management of Children in High-Risk Groups

Children age 2-8 years who are in an at-risk group and who have never had **any** flu vaccine before should get two doses of the LAIV four weeks apart. It is expected that this will be a small number of children as the LAIV was available in previous flu seasons, and the QIV prior to that for medically at-risk children. Children with underlying conditions can be identified in advance via information on the consent form completed by parents/legal guardians (which includes a pre-vaccination screening questionnaire). Children in this category should be offered one dose of LAIV administered at the school or community clinic and the child should be given a letter advising the parent to attend their GP or Pharmacist four weeks later to receive their second dose (Suggested wording of letter to parent included as Appendix F).

3.9 Delayed Vaccination

Children or young people who have consented but have missed their vaccination should be directed to their GP or pharmacy to receive their vaccine.

Appendix A: Training Available to Community administration of LAIV

- 2 HSEland training modules on LAIV developed by NIO. These programmes can be found by following these steps:
 - Register or Log into hse.land
 - Select Course Catalogues along the top ribbon
 - Select Clinical skills on the page that opens
 - Select National Immunisation Office from the programme options
 - Select Influenza vaccination and begin the programmes by enrolling.
- Website www.hse.ie/flu has been updated to provide information for those who are recommended the influenza vaccine through the HSE programme.
- FAQs to support vaccinators available here: www.hse.ie/eng/health/immunisation/hcpinfo/fluinfo/flufaq/
- A video to demonstrate how to give a nasal flu vaccine produced by the NIO available here: <https://youtu.be/89N1Yf9svRk>
- Information for healthcare professionals on the flu vaccine including immunisation guidelines: www.immunisation.ie
- Clinical enquires please email: immunisation@hse.ie
- There are also limited training nasal applicators that could be made available if vaccinators wish to practice administration of nasal flu vaccine.

Appendix B: LAIV in Children Algorithm

Algorithm outlining the procedure for the LAIV in children aged 2-17 years available at:

<https://www.hse.ie/eng/health/immunisation/pubinfo/flu-vaccination/laivalgorithm.pdf>



[hse.ie/flu](https://www.hse.ie/flu)
 Order Code: H9801367



Appendix C: Pre-Vaccination Information Leaflet for Parents

Patient information leaflet is in different translations, is available here:


<https://www.hse.ie/eng/health/immunisation/pubinfo/flu-vaccination/information/information-material.html>



Appendix D: Consent Form and Pre-Screening Questionnaire for LAIV in Schools:

<https://www.hse.ie/eng/health/immunisation/hcpinfo/fluinfo/lai consentform.pdf>

<https://www.hse.ie/eng/health/immunisation/hcpinfo/fluinfo/irishlai consentform.pdf>

 **Vaccination Consent Form for children aged 2-17**
Fluenz Tetra (LAIV) nasal flu vaccine

If you wish to give consent, please fill in Parts 1, 2 and 4. If you do not wish to give consent, please fill in parts 1 & 3.

Please note only a parent or legal guardian can consent or refuse consent for for students.
Read more about consent on the HSE website <https://bit.ly/ConsentHSE>.
Please return this form to your vaccinator as soon as possible.

Privacy Statement: HSE staff are aware of their obligation under the Data Protection Acts, 1988-2018 (including GDPR). The information provided will be included in an Immunisation Database. The HSE will use this information to validate clients, monitor vaccination programmes and provide health care.

Part 1: Personal Details
Complete this part for all children (PLEASE USE BLOCK CAPITALS)

Child's Forename:

Child's Middle Name:

Child's Surname (Family Name):

Otherwise known as:

Child's Personal Public Service Number (PPSN):

Child's Date of Birth: DDMM/YYYY

Gender: (please circle) Male Female

Mother's Surname at birth:

Child's Address:

Enode: County:

Parent/Legal Guardian Forename and Surname:

Parent/Legal Guardian Daytime Phone Number:

Parent/Legal Guardian Mobile Phone Number:

Do you consent for getting texts about vaccine appointments? (please circle) Yes No

Parent/Legal Guardian Email Address:

Do you consent for getting emails about vaccine appointments? (please circle) Yes No

School: Class: Year:

1 Version 1.0 27th September 2022

Appendix E: Suggested Wording for Letters for Parents from Local GP/Community Pharmacy

Template Letter 1 – For a dedicated LAIV clinic, either on site or in the community

Dear Parent/Legal Guardian

This year, all children aged 2-17 years of age will be offered the Influenza (Flu) vaccine free of charge. Flu circulates in the community during flu season, normally from the beginning of October through to the end of April, and children are more likely than adults to get severe complications of flu. Children who are sick with flu may miss days in crèche, childcare or school and may miss out on their usual activities, such as hobbies and sports.

As well as helping to protect your child from serious complications if they get Flu, the Flu vaccine reduces the spread of Flu virus to other people, meaning that siblings, parents and grandparents of vaccinated children may also have increased protection from Flu.

The flu vaccine is recommended for all children aged 2-17 years. The vaccine that your child is being offered is called Fluenz Tetra. It is a safe and effective vaccine that is given as a nasal spray.

All children can get the nasal flu vaccine by visiting their GP or local Pharmacist however, this year we have partnered with your child's [school/sports club/crèche] *delete or insert alternative location as appropriate* to provide a convenient opportunity for your child to receive the vaccine.

Getting the flu vaccine will protect your child against infection with flu which can sometimes cause complications in children. Complications of flu in children include:

- Pneumonia
- Bronchitis
- Rarely inflammation of the brain (encephalitis)

Vaccinating your child benefits them and also benefits their community as children can spread flu to those around them including those who may be older or have underlying medical conditions.

Please find attached:

- An information leaflet about the nasal flu vaccine in children
- A consent form for vaccination

Please read the information leaflet, complete the consent form and bring it to the vaccine clinic.

You can find Irish translations of the information leaflet and consent form on our website at

<https://bit.ly/PilotLAIV2122>

You can find further information in the attached materials or at www.hse.ie/flu or you can speak to your GP or Pharmacist.

If your child has already received a flu vaccine since September this year or has an appointment already arranged, please do not consent for your child to receive a flu vaccine in this extra clinic.

There will be a small number of children not able to have the nasal spray flu vaccine because of pre-existing medical conditions or treatments. They will be identified by the information provided by you on the attached consent form. If your child falls into this category, they should still be vaccinated against flu with an injected vaccine, unless this vaccine is also not recommended for your child. They should attend their GP or Pharmacist to receive their flu vaccine, you will need to contact your GP or Pharmacist and make an appointment to arrange this.

Furthermore if there is any change in the medical conditions since the completion of the consent questionnaire please contact the team on Telephone: Email:

Additionally, if you have any questions or concerns, members of the vaccination team are happy to help.

Yours sincerely

Template Letter 2- Sporadic or Opportunistic Vaccine opportunities

Dear Parent/Legal Guardian

This year, all children aged 2-17 years of age will be offered the Influenza (Flu) vaccine free of charge. Flu circulates in the community during flu season, normally from the beginning of October through to the end of April, and children are more likely than adults to get severe complications of flu. Children who are sick with flu may miss days in crèche, childcare or school and may miss out on their usual activities, such as hobbies and sports.

As well as helping to protect your child from serious complications if they get Flu, the Flu vaccine reduces the spread of Flu virus to other people, meaning that siblings, parents and grandparents of vaccinated children may also have increased protection from Flu.

The flu vaccine is recommended for all children aged 2-17 years. The vaccine that your child is being offered is called Fluenz Tetra. It is a safe and effective vaccine that is given as a nasal spray.

Getting the flu vaccine will protect your child against infection with flu which can sometimes cause complications in children. Complications of flu in children include:

- Pneumonia
- Bronchitis
- Rarely inflammation of the brain (encephalitis)

Vaccinating your child benefits them and also benefits their community as children can spread flu to those around them including those who may be older or have underlying medical conditions.

Please find attached:

- An information leaflet about the nasal flu vaccine in children
- A consent form for vaccination

We would ask you to please read the information leaflet and complete the consent form; this form can then be brought with you to the vaccination appointment.

There will be a small number of children not able to have the nasal spray flu vaccine because of pre-existing medical conditions or treatments. They will be identified by the information provided by you on the attached consent form. If your child falls into this category, they should still be vaccinated

against flu with an injected vaccine, unless this vaccine is also not recommended for your child. Your GP or Pharmacist will be able to advise on this.

If your child has already received a flu vaccine since September this year or has an appointment already arranged, please make sure you inform the staff when making a vaccination appointment – most children only need one Flu vaccine per year.

If you have any questions about the Flu vaccine, please don't hesitate to ask. Both your GP and your local pharmacist should be able to answer your questions.

Yours sincerely,

Appendix F: Suggested Template Letters

Template letter 3: Child in high-risk group who requires second dose of LAIV in four weeks

Dear Parent/Legal Guardian,

Your child received their nasal spray flu vaccine today given in a community vaccination clinic. Along with this letter, you will also receive a post-vaccination information leaflet sent home from school with your child.

Based on the information you provided to the immunisation team in the pre-vaccination consent form, your child is in a group **at high-risk of complications from influenza infection and therefore requires a second dose of the vaccine for maximum protection.**

This second dose of the nasal spray flu vaccine should be given in **four weeks time**. This will be available free of charge from your child's GP or Pharmacist. Please make an appointment with your GP or Pharmacist for your child to receive this vaccine and bring this letter and the post-vaccination information leaflet with the details of your child's vaccination with you.

Yours sincerely,

Template letter 4: Child who is eligible for LAIV but did not receive on the day as, for example, the child felt unwell or refused vaccination

Dear Parent/Legal Guardian,

Unfortunately, due to an issue identified on the day by the immunisation team, **your child did not receive the nasal spray flu vaccine in the community vaccination clinic today.**

Your child can still receive the nasal spray flu vaccine at an alternative time from your GP or Pharmacist and your child should still be vaccinated against the flu to protect them against infection with flu which can sometimes cause complications in children. Vaccinating your child benefits them and also benefits their community as children can spread flu to those around them including those who may be older or have underlying medical conditions.

The flu vaccine is available to all children aged 2-17 years free of charge from your GP or pharmacy. Please make an appointment with your GP or Pharmacist for your child to receive this vaccine.

Yours sincerely,

Template letter 5: Child identified as having a contraindication to the LAIV advising them to get QIV

Dear Parent/Legal Guardian,

Many thanks for completing the consent form for your child to receive the nasal spray flu vaccine. Based on the information provided to the immunisation team in this form, your child **should not receive the nasal spray flu vaccine** due to their pre-existing medical condition or current medical treatment.

Your child should still be vaccinated against the flu to protect them against infection with flu which can sometimes cause complications in children. Vaccinating your child benefits them and also benefits their community as children can spread flu to those around them including those who may be older or have underlying medical conditions. **Therefore, your child should receive the injected flu vaccine.**

Please make an appointment with your GP or Pharmacist for your child to get the injected flu vaccine and bring this letter with you.

Yours sincerely,

Appendix G: Post-Vaccination Information Leaflet for Parents

Post-vaccination information leaflet for parents/tear sheet available at:

<https://www.hse.ie/eng/health/immunisation/pubinfo/flu-vaccination/postvacchildflu.pdf>

For Children



Name: _____

Vaccination Date:
D D M M Y Y Y Y

Vaccine Given: **Fluenz Tetra** (Live Attenuated Influenza Vaccine)

Batch No: Expiry Date:
D D M M Y Y Y Y

Today your child received Fluenz Tetra nasal flu vaccine. Most children have no problem after this vaccine. Some children may get:

- a runny or blocked nose,
- headache or muscle aches,
- a fever (temperature) after the vaccine.



These are usually mild and only last a day or two.

If your child has a fever (temperature) or a headache you can give them paracetamol or ibuprofen.

Do not give your child aspirin or medicines called salicylates, unless they have been prescribed by a doctor. This is especially important in the 4 weeks after getting the vaccine. Serious side effects such as a severe allergic reaction are very rare.

Talk to your GP (doctor) or pharmacist if your child is very unwell after the vaccine, as it may be for some other reason.

Please visit www.hse.ie/flu for more information.

hse.ie/flu
Public Health Advice



Appendix H: Adverse Clinical Record Form

Adverse event clinical record is available if you wish to use it:

<https://www.hse.ie/eng/health/immunisation/hcpinfo/schoolproghcp/aeci.pdf>

Appendix I: Suggested Wording for Letter for Principals from Local GP or Community Pharmacist

NB – This text could be amended to assist in writing to the organiser/manager of a community group, crèche or other similar setting.

Dear Principal,

Principals and staff of primary schools have been instrumental in the implementation of the HSE's Schools Immunisation Programme to protect children from serious infectious diseases.

In recent years, the new nasal flu vaccine was introduced in Ireland. This was delivered through GPs and pharmacies but only a fifth of younger children were vaccinated. Parents can once again choose to get the flu vaccine for their child at their GP or local pharmacy this season. However, in countries such as the United Kingdom where the flu vaccine is delivered through primary schools – there has been a significant increase in uptake and reduction in flu transmission in the community.

Therefore, this season we would like to invite your school to partner with us to deliver the flu vaccine directly to children to increase uptake. Parents/legal guardians will be asked to consent to the vaccine and will be sent an information pack. The vaccine will be administered free of charge.

The flu vaccine is really important particularly in younger children to reduce flu related complications such as bronchitis, pneumonia and encephalitis. Getting children protected will also reduce absenteeism from school. Vaccinating children also benefits their community as children can spread flu to those around them including those who may be older or have underlying medical conditions. This is particularly important this winter where there may be COVID-19 circulating.

Please find attached:

- An information leaflet about the flu vaccine in children

If you need more information about this initiative please do not hesitate to get in touch with us and please do let us know if you are interested in supporting this initiative before *(insert date)* by contacting us via *(insert details)*

Yours sincerely,

References

1. National Immunisation Advisory Committee. NIAC Guidelines Chapter 11 Influenza. Dublin: NIAC; 2022.
2. Pebody RG, Green HK, Andrews N, Boddington NL, Zhao H, Yonova I, et al. 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 : bulletin Europeen sur les maladies transmissibles = European communicable disease bulletin. 2015;20(39). 10.2807/1560-7917.es.2015.20.39.30029
3. Public Health England. Childhood Influenza Pilot Programme, England 2014/15. London: Public Health England; 2016.