

Toolkit to Support the Administration of the Live Attenuated Influenza Vaccine (LAIV) Fluenz nasal spray suspension to Children in School or Community Settings by Primary Care

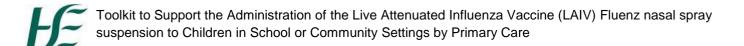
Winter Vaccination Programme 2025-2026

Intended Audience	Primary Care (General Practice and Pharmacy)
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1 Resource Tool: Top Tips for delivering the LAIV (Live Attenuated Influenza Vaccine) Programme





Delivering the LAIV programme in school and community settings



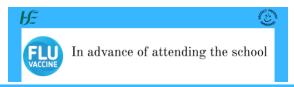
In all settings (GP practices Pharmacies, schools), to deliver a safe and high quality LAIV programme, GPs, GP Nurses, Pharmacists and HSE vaccinators are required to

 Ensure that all professionals vaccinating have undertaken all relevant training that is required for their profession

Administer vaccines aligned with the advice of the <u>National Immunisation Advisory</u>
 Committee (NIAC)

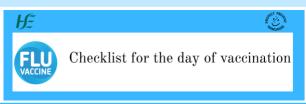
- Follow the advice provided in the HSE toolkits for the provision of vaccinations in Primary Schools or Community Settings and ensure that any local materials, policies and/or protocols that may be developed align with HSE advice
- Ensure that there is a robust process in place to obtain informed consent prior to vaccination and adhere to best practice aligned with the <u>HSE national consent policy</u>
- Ensure vaccines are stored correctly review the <u>HSE Guideline for maintaining the vaccine</u>
 cold-chain in vaccine cool boxes in advance
- Ensure vaccines are stored correctly and that the <u>HSE Guideline for maintaining the</u>
 vaccine cold-chain in vaccine cool boxes has been adhered to
- Correctly identify children and young people with contraindications to LAIV or children for whom two LAIV doses are required (refer to the <u>Immunisation Guidelines of Ireland</u> and email <u>immunisation@hse.ie</u> with any clinical questions)
- . Check the child or young person's vaccination status on the day of vaccination
- Enter vaccination records on to the IT system that sends the record to NIIS (formerly COVAX) on the day of vaccination
- Check vaccine expiry dates prior to administration
- Provide post vaccination advice





In school settings, to deliver a safe and high quality LAIV programme, GPs, GP Nurses,
Pharmacists and HSE vaccinators are required to

| Identify primary schools as early as possible in the planning stage to allow sufficient time for the practical aspects of establishing vaccination clinics to be addressed
| Send vaccine information packs to the school for onward distribution to all parents. Parents/legal guardians should receive this pack through the schools.
| Ensure all consent forms are reviewed in advance of the vaccination clinic, before attending the school Ensure that there are sufficient clinical and administrative staff attending the school vaccination clinics
| Ensure that children and young people are correctly identified in advance of vaccination
| Provide the HSE with details of the schools where LAIV vaccines are being provided
| Offer LAIV to all children in all class groups in each participating primary school



On the day of vaccination in all settings, for each child to be safely vaccinated, it is important to carry out the below checks in order to avoid vaccination errors

Ensure that vaccines have been stored correctly and transported correctly (if relevant) adhering to
HSE guidance
Ensure that all children and young people are correctly identified in advance of vaccination
Confirm that informed consent has been provided for each child to be vaccinated
Confirm there are no contraindications to LAIV before each child is vaccinated
Check the child or young person's vaccination status
Check the vaccine expiry date before administration
Enter vaccination records on to the IT system/NIIS(formerly COVAX)
Record the vaccination on a vaccine record form and give to the child/parent/legal guardian to be

Reporting side effects

If you think, you or your patient have had a side effect after receiving a vaccine, you can report it to the Health Products Regulatory Authority (HPRA) at www.hpra.ie. Your doctor, nurse, pharmacist or a family member can also report the side effect to the HPRA.

In the event that any vaccine errors occur, practice open disclosure and follow local reporting policies and procedures and contact <u>immunisation@hse.ie</u> for clinical advice

taken home

Provide the written post vaccination advice

2 Introduction

The Live Attenuated Influenza Vaccine (LAIV) nasal flu vaccine (Fluenz nasal spray suspension) is recommended for all children aged 2 to 17 years for the HSE Winter Vaccination Programme 2025-2026. The influenza vaccine provides the best available protection for children against 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. Therefore, 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 General Practice (GP) and community pharmacies across Ireland if they wish to undertake vaccination of children and young people aged 2-17 years in the 2025-2026 winter vaccination programme in a primary schools or community settings (e.g. community group, crèche or other similar settings working with children. HSE community vaccination teams may also offer the LAIV Fluenz vaccine in the primary school setting. In advance of the winter vaccination programme, vaccination teams have been advised to liaise with the school setting to arrange the administration of LAIV in the Primary school.

The toolkit should be used in conjunction with existing guidance published by the <u>Irish College of General Practitioners</u> and the <u>Pharmaceutical Society of Ireland (PSI)</u>.

PSI guidance on delivery of a vaccination service by pharmacists is available on the <u>PSI website</u>, including Guidance to support pharmacies in providing safe vaccination services offsite from the pharmacy premises and Guidance on the Provision of an Influenza Vaccination Service for Children Aged 6 Months and Older who are eligible for vaccination.

2.1 The Winter Vaccination Programme – Seasonal Influenza Vaccination Programme 2025-2026

Two types of influenza vaccine will be used in the HSE winter vaccination programme in the 2025/2026 season:

- Inactivated influenza vaccine (IIV) which is an injectable vaccine given by intramuscular (IM) injection and
- Live attenuated influenza vaccine (LAIV) which is a nasal spray vaccine.

LAIV is recommended for all children aged 2-17 years, including those at increased risk of influenza related complications. There will be one LAIV product available, Fluenz, manufactured by AstraZeneca. The vaccine is licensed for those aged 2-17 years. The vaccine is packed in boxes of 10 applicators and is available to order form the National Cold Chain.

IIV is the vaccine available for all other recommended groups. This includes those aged 2 years to 17 years for whom LAIV is 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.

2.2 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 2025-2026 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 vaccination promotion and administration in specific pre-booked or walk-in vaccination clinics in the practice or pharmacy, or by 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.

Primary schools offer an opportunity to reach this target demographic in a focused and efficient way. School-based vaccination it is likely to achieve higher coverage than delivery via existing primary care pathways.

GP practices and community pharmacies could also work in partnership with local primary schools, to offer opportunities for eligible children to access LAIV in the school setting with consent from parents. Administration in the school setting has the potential to reduce 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. Parents can provide consent through pre-filled consent forms in a primary school setting and the GP practice and community Pharmacy can order HSE LAIV School Packs in advance.

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 LAIV vaccination clinics may reach a wider audience, with important information about seasonal flu vaccination, and may facilitate volunteer participation in promoting and running the clinics.

Local GP practices and local community pharmacies could consider collaborating 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.

Where vaccines are administered in, other community settings it would be recommend that parents or legal guardians attend the vaccination session with their child.

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. Updated guidance for 2025/26 will be uploaded here: <u>Guidance -Vaccination Services-PSI</u>

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.



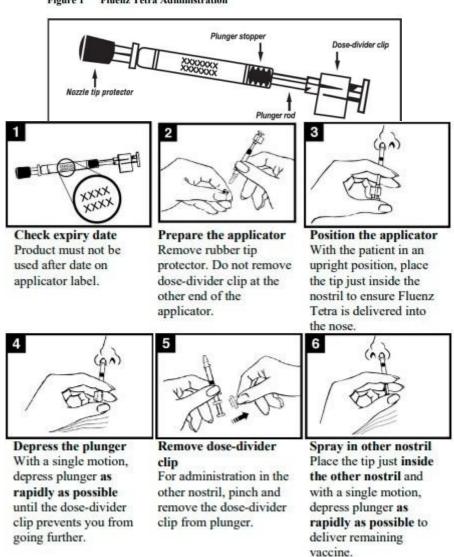
3 LAIV Administration in Children

3.1 Vaccine, Dose and Route of Administration

The vaccine recommended for all children aged 2-17 years is a Live Attenuated Influenza Vaccine (LAIV); it is called Fluenz nasal spray suspension and is manufactured by Astra Zeneca. This vaccine may be given to all eligible children, 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. Refer to the Fluenz administration diagram (Figure 1) for step-by-step administration instructions.

Figure 1 Fluenz Tetra Administration



Any unused medicinal product or waste material should be disposed of in accordance with local requirements for medical waste.



- If the child sneezes or 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.

All eligible children aged 2 years to 17 years, who are not in a high-risk group, should receive a single dose of LAIV

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

Table 1 Schedule for Live Attenuated Influenza Vaccine (LAIV)

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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					

3.2 Children in Clinically At-RiskGroups

In some circumstances, two doses of the vaccine may be required 4 weeks apart:

Children aged from 2 years to less than 9 years in a clinically at-risk group* should receive two doses of LAIV, at least four weeks apart, if receiving influenza vaccine for the first time or if their vaccination history is unknown. *See table 11.3 taken from the National Immunisation Guidelines Chapter 11

Immunisation Guidelines for Ireland: Chapter 11 Influenza (June 2025)

National Immunisation Advisory Committee (NIAC)

Table 11.3 Medical conditions* associated with an increased risk of influenzarelated complications

Medical conditions*
Cancer
Chronic heart disease
Chronic kidney disease
Chronic liver disease
Chronic neurological disease
Chronic respiratory disease
Diabetes and other metabolic disorders, including inherited metabolic disorders
Haemoglobinopathies
Immunocompromise due to disease or treatment
Body mass index ≥40kg/m ²
Serious mental health conditions
Children and adults with Down syndrome
Children with moderate to severe neurodevelopmental disorders
Children on long-term aspirin therapy

^{*} This list is not exhaustive, and the medical practitioner should apply clinical judgment to consider the risk of influenza exacerbating any medical condition that a patient may have, as well as the risk of serious illness from influenza.

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 the LAIV four weeks apart unless it is contraindicated.

For the purposes of the LAIV programme in schools, children in high-risk groups who have never had any influenza vaccine before will be identified by the immunisation teams from the information provided on the consent form completed by parents (which includes a pre-vaccination screening questionnaire). Children in this category will be offered a dose of the LAIV in school and, following vaccination, they should be advised to attend their GP or pharmacy, four weeks after the first dose for their second dose of LAIV.

3.3 Precautions to LAIV Administration

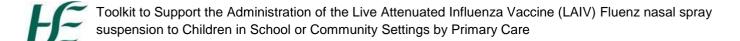
- Acute severe febrile illness: Defer until recovery
- Egg anaphylaxis or egg allergy:

NIAC (2025) advises that as LAIV Fluenz Nasal Spray has an ovalbumin content ≤ 0.024 micrograms per dose, it can be given to children with confirmed egg anaphylaxis or egg allergy in a primary care or school setting. The exception is children who have required intensive care unit (ICU)/critical care admission for a previous severe anaphylaxis to egg who should be given LAIV Fluenz Nasal Spray in hospital.

- Salicylates should not be used for 4 weeks after vaccination unless medically indicated, as Reye Syndrome has been reported following the use of salicylates during wild type influenza infection.
- Seek specialist advice for those who require regular oral steroids or who have previously required ICU care for asthma.
- Receiving combination checkpoint inhibitors (e.g. ipilumumab plus nivolumab), because of a potential association with immune related adverse reactions: Consult with the relevant specialist.
- Some children with decompensating inherited metabolic disorders may not be able to receive LAIV. LAIV is not contraindicated in those with stable, non-decompensating inherited metabolic disorders without associated immunocompromise e.g., phenylketonuria, homocystinuria, galactosaemia, and some lysosomal storage disorders. If there is uncertainty about whether a child's diagnosis is considered a decompensating metabolic disorder, advice should be sought from a treating specialist. If there is uncertainty about the suitability of any child with an inherited metabolic disorder to receive LAIV, this should be discussed with the child's specialist medical team.

3.4 Contraindications to LAIV Administration

- Anaphylaxis following a previous dose of influenza vaccine or any of its constituents (other than ovalbumin – see precautions above)
- Those with severe neutropoenia (absolute neutrophil count <0.5 x10⁹/L) should not receive any vaccines, to avoid an acute vaccine related febrile episode. This does not apply to those with primary autoimmune neutropenia who can receive influenza vaccine unless contraindicated.
- Asthma: Those experiencing an acute exacerbation of asthma, including those who have had increased wheezing and/or needed additional bronchodilator treatment in the previous 72 hours.
- Children who live with severely immunocompromised persons requiring isolation (e.g. post haematopoietic stem cell transplant)
- Concomitant use of aspirin/salicylates, because of the association of Reye Syndrome with salicylates and wild-type influenza infection



- Influenza antiviral medication within the previous 48 hours
- Severe immunocompromise due to disease or treatment
- Children post cochlear implant, until the risk of a Cerebrospinal Fluid (CSF) leak has resolved consult with the relevant specialist
- Children with a cranial CSF leak
- Pregnancy
- Vaccine recipients who have already received a full course of any recommended flu vaccine for their age in the 2025/2026 influenza season.

Children for whom the LAIV is contraindicated should be offered the inactivated influenza vaccine (IIV) provided it is not also contraindicated. For the purposes of this programme, children who fall into this category should be advised to attend their GP or pharmacy to receive the injectable inactivated influenza vaccine (IIV).

An algorithm for LAIV in children aged 2-17 years is available at www.hse.ie/eng/health/immunisation/pubinfo/flu-vaccination/laivalgorithm.pdf

3.5 The following are not contraindications to LAIV Fluenz Nasal Spray

- Children living with HIV who are receiving antiretroviral therapy and attaining viral suppression
- Children receiving topical or inhaled corticosteroids or Low dose systemic corticosteroids
- Children receiving corticosteroids as replacement therapy (e.g. for adrenal insufficiency)

3.6 Adverse Reactions

The following side effects may be experienced

(in addition see Summary of Product Characteristics (SmPC) contains further information on adverse events associated with Fluenz. Available here: https://www.medicines.ie/medicines/fluenz-nasal-spray-suspension-36276/spc):

Very common: Nasal congestion, malaise

Common: Decreased appetite, myalgia, fever and headache.

Fever is no more frequent than that following other recommended childhood vaccines, is generally mild and resolves in a few days

Uncommon: rash, nose bleed, allergic reactions

Very rare: Immediate allergic reactions

Very rare reports of Guillain-Barré syndrome (GBS) have been observed in the post-marketing setting following inactivated influenza vaccination. The incidence following live influenza vaccination is not known.

In the unlikely event of an adverse reaction occurring following administration of the vaccine, parents/legal guardians/students should inform the vaccinator.

The vaccine recipient's parent/legal guardian should be advised that they can also report any side effects to

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the Health Products Regulatory Authority (HPRA) at www.hpra.ie.

The vaccinator should report to the HPRA any suspected adverse reactions, in accordance with criteria outlined by the HPRA. This reporting may be carried out online at https://www.hpra.ie

The vaccine recipient's GP should be informed if there is a reported adverse reaction.

3.7 Vaccine co-administration in Primary School Age Children

- 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. It should ideally be provided to eligible children between October and December 2025.
- Parents should not be routinely invited to attend school vaccinations. There is no requirement to have a parent present at the time of vaccination.
- Where there is a valid consent form from parents, all children should be vaccinated regardless of
 whether a parent is present or not. Children should be treated in the same manner regardless of
 whether a parent is present or not.

4 Supporting teams for the Administration of LAIV in the Primary School Setting

4.1 Preparation for Administration of LAIV in the School Setting

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 primary 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, to allow sufficient time for the practical aspects of establishing the vaccination clinic to be addressed and avoid the potential for two providers to attend the same setting. 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 and transport
- Vaccinators
- Medicine protocols to facilitate vaccination without individual prescriptions where applicable
- · LAIV school packs
- Recording of vaccinations on the IT system, ability to check the child vaccine record in advance
 of the vaccination session and record the vaccine administered in a timely way ensure that
 duplicate vaccines are not administered.
- Procedures and equipment to manage and adverse reaction to the vaccine or anaphylaxis
- Vaccination teams should satisfy themselves that they have the necessary insurance in place to attend the setting
- Vaccination teams should ensure they link with the school or community setting to ensure they



have meet the relevant safeguarding requirements prior to the vaccination session

4.2 In advance of Administration of LAIV in the School Setting

In advance of the vaccination session, LAIV packs should be should be sent to the school for onward distribution to all parents/legal guardians. Parents/legal guardians should receive this pack through the schools in advance of the planned vaccination session, in order to provide informed consent.

In advance of delivering the packs, the vaccination team will need to identify a way for parents to contact them to notify them of any changes to the child's vaccination status prior to LAIV to be administered in the school setting.

This pack should contain:

- An <u>information leaflet for parents</u> in English and Irish
- A consent form in <u>English</u> and Irish including a pre-vaccination screening questionnaire
- A factsheet for parents in English and Irish
- An envelope to return the completed consent form

4.2.1 Prior to the vaccination date, providers should ensure:

- 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
- All queries should be dealt with by the relevant provider of the vaccination service 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 contact details for vaccination bases will be uploaded onto immunisation.ie for parents to access. Please ensure these details are correct and the communication channels are routinely monitored
- o As system is in place with the school to identify children with similar or identical names.
- The composition of immunisation teams should be agreed locally in advance and will depend on the number of students in the school. At least two trained vaccinators are required at each vaccination clinic
- o Review the top tips for delivering LAIV in the school setting at the start of this document

4.2.2 Education, Training and Resources

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

- o Immunisation Guidelines for Ireland available at NIAC
- o Summary of Product Characteristics (SmPCs) for LAIV available at www.medicines.ie
- Undertaken the HSeLanD Module developed on LAIV by the NIO available at www.hseland.ie
- "Anaphylactic Reactions: Treatment in the Community" protocol, in the Immunisation Guidelines for Ireland available at NIAC
- HSE Communicating Clearly with Patients and Service Users guidelines http://bit.ly/CommClear



- o Identify if they are using a medicine protocol for the administration of LAIV, develop this protocol and be familiar with this protocol
- 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
 - All education and training relevant to their profession

Details of training available to support the flu programme

- 1) Be a registered healthcare professional, on the active register maintained by the relevant professional regulatory body in Ireland
- 2) An approved *Basic Life Support for Health Care Providers Course* within the last two years (For e.g. Irish Heart Foundation (IHF), American Heart Association (AHA))
- 3) Initial National Anaphylaxis Education Programme for Health Care Professionals accessible on www.HSELanD.ie followed by a two-hour classroom based skills workshop. Recertification is required every two years by completing the on-line National Anaphylaxis Education Programme for Health Care Professionals accessible on www.HSELanD.ie or the relevant anaphylaxis management programme approved by their professional organisation.
- 4) Live Attenuated Influenza Vaccine (LAIV) education programme 2025/2026 accessible on www.HSELanD.ie
- 5) Storing and Managing Vaccines accessible on www.HSELanD.ie

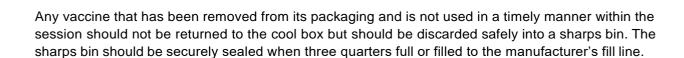
Note: In addition to the above, the vaccinator must complete the education, training, and self-assessment of competence requirements as recommended by their professional organisation /regulatory authority.

4.3 Vaccine Ordering, Storage and Handling

Vaccines for the programme should be ordered through the National Cold Chain Service using the I online ordering system (website: www.ordervaccines.ie). 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 (Fluenz nasal spray suspension) compared to other vaccines when arranging and planning LAIV clinics.

The SPC for Fluenz nasal spray suspension recommends:

- Store in a refrigerator (2°C 8°C).
- Do not freeze.
- Keep the nasal applicator in the outer carton in order to protect from light.
- Before use, the vaccine may be taken out of the refrigerator once for a maximum period of 12 hours at a temperature not above 25°C. Stability data indicate that the vaccine components are stable for 12 hours when stored at temperatures from 8°C to 25°C. At the end of this period, Fluenz should be used immediately or discarded



4.4 Maintenance of the Cold Chain

- The National Immunisation Office has published guidance on maintenance of the cold chain: <u>HSE</u>
 Guidelines for maintaining the vaccine cold chain including maintenance of vaccine fridges and management of vaccines
- HSE Guidelines for maintaining the vaccine cold chain in vaccine cool boxes

Standard operating procedures (SOPs) should be developed locally for transporting vaccines. It is important to test and validate the method of packing vaccines by simulating the process and recording the cold chain for a similar period required for a typical transportation and clinic duration.

When transporting vaccines in cool boxes:

- Record the current temperature of the probe in the coolbox:
 - when vaccines are packed
 - o upon arrival at the immunisation clinic
 - o throughout the immunisation clinic
 - o when returning vaccines to the fridge
- o Ensure that the cool box is placed in,
 - An appropriately ventilated room,
 - Away from any heat source,
 - o Away from direct sunlight.
- o Ensure that the cool box remains closed as much aspossible.
- o If there are any unused vaccines remaining at the end of a vaccination session, providing that the cold chain has been maintained, the vaccines can be returned to the vaccine fridge. They must be marked and should be used first at the next vaccination session. If these marked vaccines are taken to a second vaccination session and are not used -they can be returned to the vaccine fridge and administered at the next clinic provided the cold chain has been maintained.

If temperatures outside the permitted range are recorded the NIO should be contacted for further advice by e-mailing pharmacynio@hse.ie. Ensure that the vaccines are quarantined between +2 °C and +8 °C. Do not use or discard the vaccines until advised by the National Immunisation Office. The NIO will carry out a risk assessment and will advise on a case by case basis whether it is appropriate to use the vaccines or whether they should be discarded.

5 Pre-Vaccination Procedures

5.1 Consent

Informed consent must be obtained prior to vaccination. This is done by providing the parent/legal guardians with adequate information, in the form of an information leaflet along with the consent form in the LAIV pack distributed by the school in advance of the vaccination clinic.



The process for parental and legal guardian consent as per the HSE National Consent Policy

- Who are a child's legal guardians?
 - o Where a child's mother and father are married, both are the legal guardians.
 - o If a child's mother and father marry after the child's father automatically becomes the child's legal guardian.
 - Where a child has been jointly adopted, the adoptive parents are the child's legal guardians.
 - Following a separation or divorce, both parents remain the child's legal guardian even if the child is not living with them and they have not been awarded custody of the child.
 - O Where a child's mother and father are not married:
 - The child's mother is an automatic legal guardian;
 - The child's father is an automatic legal guardian if from 18 January 2016, he has lived with the child's mother for 12 consecutive months including at least 3 months with the mother and child following the child's birth;

or

If the child's father has not become a guardian by satisfying the cohabitation requirement, he may become a guardian if the mother and father of the child may make a statutory declaration to the effect that they agree to the appointment of the father as legal guardian,

or

- The father may apply to Court to be appointed legal guardian.
- Who are a child's legal guardians in respect to same-sex couples?
 - In respect of same-sex couples, the child's biological parent is a legal guardian.
 - The biological parent's partner or spouse may apply to the Court become a legal guardian in accordance with the requirements set out below.
 - Where a same-sex couple has a child through Donor Assisted Human Reproduction (not including surrogacy) after 4 May 2020 and has complied with the provisions of Part 2 of the Children and Family Relationships Act 2015 (i.e. they have used a recognised fertility clinic and have signed all the relevant consents and declarations), the spouse, civil partner or cohabitant of the mother will be the legal parent of the child. In this situation, the spouse or civil partner of the biological parent will automatically be a legal guardian. A cohabitant will be a legal guardian if they fulfil the residence requirement (i.e. have lived with the child's mother for 12 consecutive months including at least 3 months with the mother and child following the child's birth).



- A guardian may nominate another person to act as temporary guardian in the event of the guardian's incapacity. This is subject to Court approval.
- A guardian may, in their will, appoint a person to act as the child's guardian in the event of the guardian's death.
- For Children/young people in voluntary care of Tusla-The Child and Family Agency the legal rules of parental consent apply.
- For Children/young people under a care order refer to section 7.2 of the National Consent Policy:
- For Children/young people in foster care refer to section 7.3 of the National Consent Policy
- There is no maximum duration for consent. Consent remains valid for an indefinite period unless
 - > It is withdrawn
 - If a parent/legal guardian contacts the HSE team, to withdraw consent they should speak to the staff member, ideally a clinical staff member looking after the vaccine programme.
 - ➤ If the consent is withdrawn during an intervention, the healthcare worker should document this in the person's healthcare record
- Consent forms and screening questions should be reviewed in advance of attending the school

Read "Who can give consent for vaccination of a young person aged under 16 years?" From www.hse.ie/who-can-give-consent-for-young-people-aged-under-16.pdf

Watch this video from Dr. Siobhan Ni Bhriain, HSE National Lead Integrated Care covering Consent for vaccination. https://youtu.be/8uKqmkFe8hs

5.2 Assessment of the Student for Vaccination

Review the child's consent form in advance of the vaccination session

- Confirm that informed consent has been given by a parent/legal guardian
- Confirm that the child is eligible to receive LAIV
- Confirm the child has no contraindications to vaccination.
- Confirm that if the child has precautions to vaccination that the relevant specialist advice has been sought

5.3 During the vaccination session

Prior to administering the vaccine (please also see the top tips in section 1), the vaccinator should ensure:

They have correctly identified the child,

There is a valid consent form with no precautions or contraindications,

The child has not received the vaccine already this season.

They have the correct vaccine, and they have checked the expiry date to ensure the vaccine is in date.

A valid prescription or medicine protocol if necessary

Confirming student's identity

- In advance of the vaccination session ask the school to identify children with similar or the same names (Class lists will not be provided for LAIV administration in the school setting)
- 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?"
- For younger children it may be necessary to confirm identity with the child's teacher or an appropriate liaison person (as agreed with the School Principal) from the school
- If the child has an acute febrile illness on the day of the vaccination clinic, LAIV should not be administered as per the Immunisation Guidelines of Ireland. There is no need to routinely check children's temperatures at the vaccination session.
- Any child that reports feeling unwell at the vaccination session should be reviewed by the
 clinical lead in charge of the vaccination clinic to assess their suitability to receive LAIV on the
 day. If a decision is made to defer vaccination communication should be sent to the child's
 parent/legal guardians advising them to attend their GP or Pharmacist for LAIV when the child
 has recovered. (see Appendix A for suggested wording for written communication)
- Address any clinical issues raised on the consent form, ensuring children with contraindications
 to LAIV are not vaccinated and identify any children for whom two doses of LAIV are required
 (Template letters for parents in these circumstances are included in Appendix A)
- Once the parent/legal guardian completes their part of the consent form, and the HSE staff
 introduce clinical content to the form, it should be considered as a clinical record, treated
 accordingly, and stored in accordance with General Data Protection Regulations (GDPR) and
 HSE records retention policy. The immunisation record will be captured on the National
 Immunisation Information System-NIIS (formerly known as COVAX)

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

5.4 Clinical Staff Roles

- If the parent/legal guardian requests further clinical advice about the vaccine they can be referred to a clinical member of the vaccination team
- If a parent/legal guardian consents but the student refuses vaccination on the day of the session, the student should not be vaccinated. This must be recorded on the consent form and on the software system that links to NIIS and the parent/legal guardian informed if the child is aged under 16 years of age.
- Where a consent form is returned and a parent/legal guardian has left the consent signature blank, a clinical member of the team should phone the parent/legal guardian to seek clarification

about their consent.

The date and time of the phone call should be recorded on the consent form and the clinician's PIN, consent or refusal witnessed by two members of staff.

6 Post-Vaccination information

6.1 Post Vaccination Advice

This post-vaccination information leaflet also called the tear sheet https://www.hse.ie/eng/health/immunisation/pubinfo/flu-vaccination/postvaccchildflu.pdf should be given to children/their teachers to be sent home with the child following vaccination. If appropriate, depending on the age of the child, vaccinators may reiterate some of the information that is contained in the information leaflet.

6.2 Post-Vaccination Procedures

Following administration of the vaccine the child should be advised to remain in the vaccination clinic for at least 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/teacher to be taken home.

The vaccine recipient's parent/legal guardian should be advised that they can also report any side effects to the Health Products Regulatory Authority (HPRA) at www.hpra.ie

6.3 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 as per local policy. The vaccine recipient and/or significant others should be informed of the incident.

In the case of medicine errors that directly involves the child, i.e. wrong medicine/patient/dose/route being administered or another medicine error, the vaccinator must remain with the child and closely monitor them for any adverse reactions.

Vital signs should be recorded and the child should be reviewed by the vaccinator.

The incident must be reported to the relevant line manager as soon as possible.

The child's parent and/or legal guardian must be informed of the incident. Further information can be found in the HSE Open Disclosure Policy 2025

Any suspected adverse reactions associated with medication errors should be reported to the HPRA as outlined below and as per local policy.

6.4 Delayed Vaccination

In the context of the LAIV programme, it will not be possible to offer a mop-up clinic, as is the case with other schools immunisation programmes. Children who have consented but have missed their vaccination should be directed to their GP or pharmacy to receive their vaccine.

6.5 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, treated accordingly, and stored in accordance with General Data Protection Regulations (GDPR) principles and other relevant legislation on vaccine record storage. 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 NIIS
- Flu payment claims from GPs and pharmacists to be sent to PCRS team

As there are many providers of flu vaccinations, it is essential that all vaccines given are recorded promptly onto the above ICT systems sending data to NIIS, so that clinical records are kept up to date and two doses are not administered in error.

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.

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

Template Letter 1 - For a dedicated LAIV clinic, either on site 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. 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 collaborated 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 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 (Irish version available at the QR code below)



A consent form for vaccination (Irish version available at the QR code below)



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

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 clinic.

There will be a small number of children not able to have the nasal spray flu vaccine because of preexisting 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: 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 school 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.

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Yours sincerely.

Template letter 3: Child identified as having a precaution to the LAIV advising them to get specialist review prior to vaccination

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 schools immunisation team in this form, your child should not receive the nasal spray flu vaccine until they have a consultant review due to their pre-existing medical condition or current medical treatment.

Please make an appointment with your GP to request a consultant referral and bring this letter with you.

Yours sincerely,

Template letter 4: Child identified as having a contraindication to the LAIV advising them to get Inactivated Influenza Vaccine

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 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.

ours/	sincerely,	



7 References

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