Master Medicine Protocol for the Administration of Fluenz nasal spray suspension influenza vaccine (live, nasal) to children aged 2-17 years

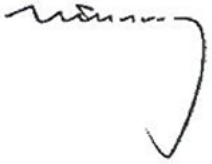
This medicine protocol is a specific written instruction for the administration of Fluenz nasal spray suspension influenza vaccine (live, nasal), a Live Attenuated Influenza Vaccine (LAIV), to children aged 2-17 years by healthcare professionals included in Statutory Instruments S.I. No. 245 of 2021 and S.I. No. 422 of 2023 who are registered with their respective regulatory body. This medicine protocol is valid for the 2025/2026 Health Service Executive (HSE) Winter Vaccination Programme This medicine protocol enables the healthcare professionals listed in S.I. No. 245 of 2021 who have undertaken the required education and training programmes for their profession to administer LAIV Fluenz Nasal Spray suspension influenza vaccine to vaccine recipients (children aged 2-17 years of age). This master medicine protocol is with reference to and guidance from the National Immunisation Advisory Committee (NIAC), National Immunisation Office (NIO), HSE and in accordance with the Summary of Product Characteristics (SmPC) for Fluenz nasal spray suspension influenza vaccine (live, nasal) available at www.medicines.ie See below:

- National Immunisation Advisory Committee (2023) Anaphylaxis: Immediate Management in the Community. Available at https://www.hiqa.ie/areas-we-work/national-immunisation-advisory-committee/immunisation-guidelines-ireland
- National Immunisation Advisory Committee Immunisation Guidelines for Ireland online update available at https://www.hiqa.ie/areas-we-work/national-immunisation-advisory-committee/immunisation-guidelines-ireland
- Summary of Product Characteristics for LAIV, Fluenz nasal spray suspension influenza vaccine (live, nasal) available at https://www.medicines.ie/medicines/fluenz-nasal-spray-suspension-36276/spc

A medicine protocol has been defined as “written directions that allow for the supply and administration of a named medicinal product by a nurse or midwife in identified clinical situations. A medicine protocol involves the authorisation of the nurse/midwife to supply and administer a medicine to groups of patients in a defined situation meeting specific criteria and who may not be individually identified before presentation for treatment. An individually named prescription is not required for the supply and administration of medication when a medication protocol is in effect” (An Bord Altranais, 2007, page 37).

A medicine protocol is a nationally approved prescription for the supply and administration of a medicine as per above definition. The HSE Chief Clinical Officer and Director of National Health Protection have approved the use of medicine protocols by healthcare professionals listed in S.I. No. 245 of 2021 and S.I. No. 422 of 2023. This medicine protocol is developed to facilitate the delivery of HSE seasonal influenza vaccination programme 2025/2026 in line with National Immunication Advisory Committee (NIAC) recommendations endorsed by the Department of Health (DoH).

Master Medicine Protocol for the Administration of Live Attenuated Influenza Vaccine (LAIV) - Fluenz nasal spray suspension influenza vaccine to children aged 2-17 years of age Note: (LAIV) Fluenz should be administered via nasal spray only

Document reference number	NIO September 2025 Version 2
1.0 Critical Elements	
Name of Organisation & Settings where protocol applies	Health Service Providers across the voluntary and statutory services of the HSE, schools/special schools/home schools, non-HSE healthcare facilities and vaccination clinic venues. This Medicine Protocol applies to: Healthcare professionals included in S.I. No. 245 of 2021 and S.I. No. 422 of 2023 employed by the HSE who have undertaken the required education and training programmes relevant to their profession.
Date the protocol comes into effect	September 2025 to April 2026
Date for review of protocol	May 2026
Document prepared by	The National Immunisation Office (NIO), HSE
Names and Signatures ofthe employing authority who is authorising the implementation of the protocol ***"On behalf of the authority employing professionals authorised to administer under this medicine protocol, I have read this medicine protocol and authorise its implementation"***	Name: **Dr Éamonn O' Moore**, Director of National Health Protection, HSE  Signature: Name: **Dr Colm Henry**, Chief Clinical Officer, HSE Signature: 

2.0 Clinical Criteria	
Clinical condition for use of this medicine protocol	The clinical condition for which this medicine protocol has been developed is for the immunisation of vaccine recipients (children aged 2 to 17 years of age), against influenza virus for the 2025/2026 Winter Vaccination Programme.
Circumstances in which the medicine protocol applies	Administration of Fluenz nasal spray suspension influenza vaccine (live, nasal) Live Attenuated Influenza vaccine (LAIV) to children aged 2 to 17 years of age. Targeted immunisation programme for vaccine recipients (children aged 2 to 17 years of age) during the 2025/2026 influenza season. Children aged 2 to 17 years are at risk of influenza infection and associated complications and they may transmit influenza virus in the community, including to those vulnerable to complications of influenza infection.
Inclusion criteria for children receiving LAIV Fluenz Nasal Spray under this medicine protocol	Active immunisation to prevent influenza infection caused by influenza virus, in all children aged 2 to 17 years of age where valid consent has been obtained. **Note:** LAIV Fluenz Nasal Spray can be given at the same time as other live (e.g. MMR or varicella) or inactivated vaccines. There are limited data on co-administration of COVID-19 vaccines with influenza vaccines in children. Theoretically, co-administration may lead to higher rates of adverse events including fever.
Precautions for children receiving LAIV Fluenz Nasal Spray under this medicine protocol	**Precautions:** • 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. 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)

Exclusion criteria for children receiving LAIV Fluenz Nasal Spray under this medicine protocol	**Contraindications** • 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 ×10^9/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.
Actions to be taken for children who are excluded from receiving the LAIV Fluenz nasal spray vaccine under medicine protocol	• All children with precautions should be assessed by the vaccinator for suitability and if required referred to a specialist medical team for advice. • All children meeting exclusion criteria must be referred to the relevant medical professional for an individual medical assessment. • Document assessment in clinical notes/on NIIS • Where LAIV Fluenz nasal spray suspension is indicated following specialist review, the vaccinator may administer LAIV Fluenz nasal spray suspension within their scope of practice. **Note:** In determining their scope of practice, vaccinators must make judgements about their competency to carry out a role or activity in accordance with the guidance from their regulator **Note**: Suitability for the injectable inactivated influenza vaccine (IIV) should be considered where LAIV Fluenz nasal spray suspension is contraindicated
Description of circumstances and referral arrangements when further advice or consultation is required	Discuss the child with the Medical Practitioner, Lead Nurse, or Lead Vaccinator in the event of: • Previous adverse reaction • Other clinical concerns
Documentation required for the implementation of this medicine protocol	• Check for and ensure consent has been obtained Consent form must be completed by the parent/legal guardian for children under 16 years of age who receive the LAIV Fluenz Nasal Spray vaccine. Children aged 16 years and over can consent on their own behalf to have a vaccine. • Vaccine information leaflets • NIIS record/ Patient held record cards It is the responsibility of each vaccinator to be familiar with the appropriate documentation to support the safe administration of influenza vaccine which includes the following: • This Medicine Protocol for the administration of LAIV Fluenz nasal spray to children aged 2-17 years • Please refer to Section B for registered nurses / midwives and *Self- Assessment of Competency Form* • National Immunisation Advisory Committee (2023) *Anaphylaxis: Immediate Management in the Community* • Chapter 11 Influenza from NIAC Immunisation Guidelines for Ireland
3.0 Name of Medicine and recommendations in line with the Immunisation Guidelines of Ireland	

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Name of Medicine	Fluenz nasal spray suspension Influenza vaccine (live, nasal)
Dose & route of administration	**Dose:** 0.2 ml - one spray (0.1 ml) in each nostril **Route:** Fluenz nasal spray suspension influenza vaccine (live, nasal) is administered by the intranasal route. It is supplied in an applicator that allows a divided dose to be administered in each nostril (total dose of 0.2ml, 0.1ml in each nostril). Only 1 dose of the vaccine is usually required each flu season. **Second Dose**: In some circumstances 2 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 Chapter 11 of the National Immunisation Guidelines of Ireland
	What to do: • If the child sneezes or blows their nose after administration: the vaccine does not need to be repeated. LAIV Fluenz Nasal Spray is immediately absorbed after administration and there is a surplus of attenuated virus particles in the vaccine required for immunity • If LAIV Fluenz Nasal Spray is only tolerated/given in one nostril: the vaccine does not need to be repeated. A single dose of 0.1ml 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
Details of product information and other data including instructions for supply and administration is available atwww.medicines.ie **Link to Medicine**	• LAIV Fluenz Nasal Spray is a trivalent reassortant influenza virus vaccine containing antigens from two type A and one type B virus strains, produced in Vero cells and cultured in hens' eggs. The vaccine complies with World Health Organisation (Northern hemisphere) recommendation for the 2025/2026 season. • Link to Summary of Product Characteristics (SmPC) for LAIV Fluenz Nasal Spray and link to Patient information Leaflet (PIL) available at https://www.medicines.ie/medicines/fluenz-nasal-spray-suspension-36276/spc
Potential adverse reactions and procedures for treatment of same	Following administration of the vaccine, the vaccine recipient should be advised to remain seated in the post vaccination observation area for at least 15 minutes to allow monitoring of any immediate reaction including suspected anaphylactic reaction. The vaccine recipient /Parent/Legal Guardian should be advised to contact the relevant medical personnel in the event of an adverse reaction occurring following administration of the vaccine (General Practitioner (GP) /out of hours/Emergency Department) after the above period of observation. Reporting side effects The vaccine recipient's parent/legal guardian should be advised that they can report any side effects to the Health Products Regulatory Authority (HPRA) at www.hpra.ie .
Procedure for the reporting and documentation of errors and near misses involving themedicine	In the case of medicine errors that directly involve 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 incident and all actions taken must be promptly recorded and the relevant National Incident Report Form (NIRF) completed as soon as is practicable after the event occurs and within one working day, available online

	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. Any errors and near misses not involving medications (i.e. needle stick injuries etc.) the incident and all actions taken must be promptly recorded on the relevant National Incident Management Report form and forwarded to the relevant line manager. Refer to 'EMI Tool Kit' available at https: //www.hpsc.ie/a-z/EMIToolkit/.
Procedure for reporting adverse drug reactions to the HPRA	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 recipients 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. The vaccine recipient's GP should be informed if there is a reported adverse reaction. In the event of anaphylactic reaction, the incident and all actions taken must be promptly recorded in accordance with the National Immunisation Advisory Committee (2023) *Anaphylaxis: Immediate Management in the Community* available online
Resources and equipmentrequired	• LAIV - Fluenz nasal spray suspension • Fridge/cool box with minimum/maximum temperature recording device to monitor the cold chain temperature (between +2°C and +8°C) • Ice/gel packs for cool box • Disposable kidney dishes/coloured trays and covering • Gauze swabs • Sharps bins and bags for disposal of healthcare risk and non-risk waste • Alcohol hand sanitiser • Access to telephone • National Immunisation Advisory Committee (February 2023) Anaphylaxis: Immediate Management in the Community online • Safe storage areas for medicines and equipment • Current medicine protocol for LAIV Fluenz Nasal Spray Vaccine. • Anaphylaxis kit (in line with NIAC guidance)
Audit process to identify appropriate use of the protocol or unexpected outcomes	All documentation will be held for review and audit purposes as per local policy.
4.0 Information for child/parent/legal guardian	
Advice to be given to the child/parent/legal guardian before treatment	**Vaccine information material must be supplied along with the consent form to the parent/legal guardian/child over 16 years of age on the LAIV Fluenz Nasal Spray vaccine prior to administration.** **Before Treatment** 1. Review consent in line with the HSE National Consent Policy and confirm that there are no contraindications or precautions to vaccination. 2. Discuss the influenza vaccine 3. Discuss potential side effects The following side effects may be experienced (in addition see Summary of Product Characteristics): **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 **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.
Advice to be given to the child//parent/legal guardian after treatment	**After Vaccination** The child must be advised to remain seated in the post vaccination observation area for at least 15 minutes to allow monitoring of any immediate reaction including possible anaphylactic reaction and must be advised to report any side effects to the staff who is present. Ensure the post vaccination advice is given (the following advice is on the leaflet): - Paracetamol or ibuprofen may be given for common side effects - **Avoid** Aspirin/salicylates for 4 weeks unless medically indicated (Reye's Syndrome reported after salicylate use during wild-type influenza infection) - **Avoid** Antiviral medication for 2 weeks post vaccination.
Details of any necessary follow-up, action and referral arrangements	In the event of an adverse reaction the vaccinator must ensure that all procedures are adhered to as outlined in Section 3.
5.0 Staff authorised to use this medicine protocol	
Professional qualifications, training and competence required prior to using this medicine protocol	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. Registered Nurses and Registered Midwives, Registered Physiotherapists, Radiographers, Radiation Therapists, Optometrists and Vaccinators registered with Pre-Hospital Emergency Care Council (PHECC) must read their Section B document specific to this medicine protocol and complete the Self-Assessment of Competency Form relevant to their profession.

Appendix I

Signature Sheet

Name of Medicine Protocol: Master Medicine Protocol for the Administration of Fluenz nasal spray suspension influenza vaccine (live, nasal) Live Attenuated Influenza Vaccine (LAIV) to children between 2-17 years of age by healthcare professionals included in Statutory Instruments S.I. No. 245 of 2021 and S.I. No. 422 of 2023 who are registered with their respective regulatory body and have undertaken the required education and training programmes for their profession to administer LAIV Fluenz Nasal Spray in the 2025/2026 Influenza season

I have read, understand & agree to adhere to this medicine protocol

Name	Signature	Occupation	NMBI/other Regulatory PIN	Date

The above signed healthcare professionals are authorised by the signatories on page 2 to administer Fluenz nasal spray suspension influenza vaccine (live, nasal) Live Attenuated Influenza Vaccine (LAIV) in accordance with this medicine protocol.

References

An Bord Altranais (2007) *Guidance to Nurses and Midwives on Medication Management* Dublin: An Bord Altranais

Nursing and Midwifery Board of Ireland (2020) *Guidance for Registered Nurses and Registered Midwives on Medication Administration*. Dublin: Nursing and Midwifery Board of Ireland available at: https://www.nmbi.ie/NMBI/media/NMBI/NMBI-Medication-Administration-2020

Health Service Executive (2022) Revised National Consent Policy 2022 V1www.hse.ie/nationalconsentpolicy

Health Service Executive (2025) Open Disclosure Policy https://www2.healthservice.hse.ie/files/220/

Live Attenuated Influenza Vaccine - Fluenz (LAIV Fluenz Nasal Spray), *Summary of Product Characteristics andPatient Information Leaflet,* available at www.ema.ie

National Immunisation Advisory Committee (2023) Anaphylaxis: Immediate Management in the Community. Available at https://www.hiqa.ie/areas-we-work/national-immunisation-advisory-committee/immunisation-guidelines-ireland

National Clinical Guideline No. 30 (2023) – Infection Prevention and Control (IPC) https://www.gov.ie/en/publication/a057e-infection-prevention-and-control-ipc/.

National Immunisation Advisory Committee *Immunisation Guidelines for Ireland*: *available at https://www.hiqa.ie/areas-we-work/national-immunisation-advisory-committee/immunisation-guidelines-ireland*

S.I. No. 245/2021 - Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 7) Regulations 2020. Available at https://www.irishstatutebook.ie/eli/2021/si/245/made/en/print

S.I. No. 422/2023 - Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 7) Regulations 2020. Available at https://www.irishstatutebook.ie/eli/2021/si/245/made/en/print