Master Medicine Protocol for the Administration of Live Attenuated Influenza Vaccine (LAIV) Fluenz Tetra to all children between 2-17 years of age

Note: (LAIV) Fluenz Tetra should be administered via nasal spray only

This medicine protocol is a specific written instruction for the administration of LAIV Fluenz Tetra to all 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 2023/2024 Health Service Executive (HSE) Seasonal Influenza Vaccination Programme. This medicine protocol enables the COVID-19 vaccinators listed in S.I. No. 245 of 2021 who have undertaken the required education and training programmes for their profession to administer LAIV Fluenz Tetra to vaccine recipients (listed above). This Master medicine protocol is with reference to and guidance from the National Immunisation Advisory Committee (NIAC), National Immunisation Office (NIO), HSE and inaccordance with the Summary of Product Characteristics (SmPC) for LAIV Fluenz Tetra as detailed by the European Medicines Agency (EMA) (available at www.ema.ie) See below:

- National Immunisation Advisory Committee (2023) Anaphylaxis: Immediate Management in the Community. Available at https://rcpi.access.preservica.com/uncategorized/IO_a36f9e4b-4c80-432d-8264-546089359925/

- National Immunisation Advisory Committee, *Immunisation Guidelines for Ireland*: Royal College of Physicians of Ireland National Immunisation Advisory Committee *Online Update available at* https://www.rcpi.ie/Healthcare-Leadership/NIAC/Immunisation-Guidelines-for-Ireland

- Summary of Product Characteristics of LAIV Fluenz Tetra available at https://www.ema.europa.eu/en/documents/product-information/fluenz-tetra-epar-product-information_en.pdf

- National Immunisation Office (2023) Seasonal Influenza Vaccination Programme (SIVP) Supportive Information Document for HSE Vaccinators. Dublin: Health Service Executive, available at www.immunisation.ie

- HSE COVID-19 Vaccination Programme (2023) Operational Guidance (Note: This guidance document covers 2023/2024 Seasonal Influenza Vaccination Programme), available at www.immunisation.ie

The NMBI defines medicine protocols 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 35).

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 Master medicine protocol is developed in line with NIAC (2022) recommendations endorsed by the Department of Health (DoH).

Master Medicine Protocol for the Administration of Live Attenuated Influenza Vaccine (LAIV) Fluenz Tetra to all children between 2-17 years of age

Document reference number	NIO December 2023 Version 2
1.0 Critical Elements	
Name of Organisation 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 mass 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 as COVID-19 vaccinators who have undertaken the required education and training programmes.
Date the protocol comes into effect	December 2023 to April 2024
Date for review of protocol	May 2024
Document prepared by	The National Immunisation Office (NIO), HSE
Names and Signatures of the 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 the protocol	The clinical condition for which this medicine protocol has been developed is for immunisation of : • all children aged 2 – 17 years
Circumstances in which the medicine protocol applies	To administer LAIV FluenzTetra vaccine for children during the influenza season as they are at risk of influenza and of transmitting the influenza virus. COVID-19 vaccines (for children aged 5 and over) and other vaccines e.g. MMR and 4 in 1 vaccines may be co-administered at the sametime or at any interval as the LAIV Fluenz Tetra vaccine is given.
Inclusion criteria for children receivingLAIV Fluenz Tetra under medicine protocol	• Children with valid consent. • All children aged 2 – 17 years The following are **not** contraindications to LAIV Fluenz Tetra: • Asymptomatic HIV infection • Children receiving: - topical or inhaled corticosteroids - low dose systemic corticosteroids - receiving corticosteroids as replacement therapy (e.g. for adrenal insufficiency) LAIV Fluenz Tetra can be given at the same time as other live (e.g. MMR or varicella) or inactivated vaccines. **Precautions:** • Acute severe febrile illness, defer vaccination until recovery • Egg allergy: NIAC (2023) advises that as LAIV Fluenz Tetra 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 ICU/critical care admission for a previous severe anaphylaxis to egg who should be given LAIV Fluenz Tetra 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.
Exclusion criteria for children receiving LAIV Fluenz Tetra under medicine protocol	**Contraindications** 1. Anaphylaxis following a previous dose of influenza vaccine or any of its constituents (other than ovalbumin – see precautions). 2. 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 neutropoenia who can receive influenza vaccine unless contraindicated. 3. Receiving combination checkpoint inhibitors (e.g. ipilumumab plus nivolumab), because of a potential association with immune related adverse reactions.

	4. 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. 5. Children who live with severely immunocompromised persons requiring isolation (e.g. post haematopoietic stem cell transplant) 6. Concomitant use of aspirin/salicylates, because of the association of Reye Syndrome with salicylates and wild-type influenza infection 7. Influenza antiviral medication within the previous 48 hours 8. Significant immunocompromise due to disease or treatment 9. Those post cochlear implant until the risk of a Cerebrospinal Fluid (CSF) leak has resolved - consult with the relevant specialist 10. Those with a cranial CSF leak 11. Pregnancy Injectable Quadrivalent influenza vaccine should be given if LAIV Fluenz Tetra is contraindicated(provided it is not also contraindicated)

Actions to be taken for children who are excluded from receiving the vaccine under medicine protocol	• All children meeting exclusion criteria must be referred to the medicalpractitioner for an individual medical assessment. • Document action in clinical notes. • Where LAIV Fluenz Tetra vaccine is prescribed following medical assessment, the vaccinator may administer LAIV Fluenz Tetra vaccine within their scope of practice.
Description of circumstances and referral arrangements when further advice or consultation is required	Discuss the child with the Medical Practitioner or Lead Nurse in the event of: • Previous adverse reaction • Other clinical concerns
Documentation required for the implementation of this medicine protocol	Consent form must be completed by the parent/legal guardian for all children who receive the LAIV Fluenz Tetra vaccine. Relevant details including the batch number must be recorded on the consent form. Children aged 16 years and over can consent on their own behalf to have a vaccine. The following documents will be required at each school vaccination session: • Vaccination session form • Blank vaccine consent forms/COVAX system • Vaccine Information Leaflets • Patient held record cards/vaccine passport • HPRA Adverse Reaction Reporting forms • HSE incident/Near Miss report forms It is the responsibility of each vaccinator to be familiar with the appropriate documentation to support the safe administration of LAIV Fluenz Tetra vaccine which includes the following: • Master Medicine Protocol for the Administration of Live Attenuated Influenza Vaccine (LAIV) Fluenz Tetra to all children between 2-17years of age • National Immunisation Advisory Committee (2023) Anaphylaxis: Immediate Management in the Community. Available at https://rcpi.access.preservica.com/uncategorized/IO_a36f9e4b-4c80-432d-8264-546089359925/ • HSE COVID-19 Vaccination Programme (2023) Operational Guidance (Note: This guidance document covers 2023/2024 Seasonal Influenza Vaccination Programme)

<table>
<tr><td>3.0 Name of Medicine</td><td>Live Attenuated Influenza Vaccine - Fluenz Tetra</td></tr>
<tr><td>Dose & route of administration</td><td>
The dose is 0.2ml - one spray (0.1ml) in each nostril
<table>
<tr><td>Route of administration: Intranasal Group</td><td>Age</td><td>Previous Vaccination</td><td>Dose</td></tr>
<tr><td>Medically at-risk</td><td>2-8 years</td><td>No previous influenza vaccine received</td><td>Two doses (4 weeks apart)</td></tr>
<tr><td>Medically at-risk</td><td>2-8 years</td><td>Previously received influenza vaccine</td><td>One dose</td></tr>
<tr><td>Medically at-risk</td><td>9-17 years</td><td>Not relevant</td><td>One dose</td></tr>
<tr><td>Healthy</td><td>2-17 years</td><td>Not relevant</td><td>One dose</td></tr>
</table>
</td></tr>
<tr><td>Details of product information and other data including instructions for supply and administration is available at www.ema.ie

Link to Medicine</td><td>

LAIV Fluenz Tetra is a reassortant influenza virus vaccine containing antigens from two type A and two 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 2023/2024 season. https://www.who.int/publications/m/item/recommended-composition-of-influenza-virus-vaccines-for-use-in-the-2023-2024-northern-hemisphere-influenza-season
Link to Summary of Product Characteristics (SmPC) for LAIV Fluenz Tetra & link to Patient information Leaflet (PIL) available at https://www.ema.europa.eu/en/documents/product-information/fluenz-tetra-epar-product-information_en.pdf

</td></tr>
<tr><td>Potential adverse reactions and procedures for treatment of same</td><td>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 should be advised to contact the vaccinator in the event of adverse reaction occurring following administration of the vaccine (General Practitioner (GP) /out of hours/Emergency Department) after the above period of observation.</td></tr>
<tr><td>Procedure for the reporting and documentation of errors and near misses involving the medicine</td><td>In the case of medication errors that directly involve the child, i.e. wrong medication/patient/dose/route being administered or another medication 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 at:</td></tr>
</table>

	https://www.hse.ie/eng/about/who/nqpsd/qps-incident-management/nims/nirf-01-v12-person-interactive.pdf The child's parent and/or legal guardian must be informed of the incident. 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 or through the use of the yellow card system which is available in the downloadable format from the HPRA website, or on the request from the HPRA. 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 at https://rcpi.access.preservica.com/uncategorized/IO_a36f9e4b-4c80-432d-8264-546089359925/
Resources and equipment required	• LAIV - Fluenz Tetra nasal spray suspension • Fridge/cool box with minimum/maximum temperature recording device to monitor the cold chain temperature (between +2°C and +8°C) • Disposable kidney dishes/coloured trays and covering • Gauze swabs • Bags for disposal of healthcare risk and non-risk waste • Alcohol hand sanitizer • Face masks • Access to telephone • National Immunisation Advisory Committee (February 2023) Anaphylaxis: Immediate Management in the Community. Available at https://rcpi.access.preservica.com/uncategorized/IO_a36f9e4b-4c80-432d-8264-546089359925/ • Access to medical support • Safe storage areas for medicines and equipment • Current medicine protocol for LAIV Fluenz Tetra 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	**The HSE to provide the information material and consent form to the parent/legal guardian on the LAIV Fluenz Tetra vaccine prior to administration.**

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. What to do: • If the child sneezes or nose drips: the vaccine does not need to be repeated. LAIV Fluenz Tetra is immediately absorbed after administration and there is a surplus of attenuated virus particles in the vaccine required for immunity • If LAIV Fluenz Tetra 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 notneed to be repeated • Paracetamol or ibuprofen may be given for common side effects **Avoid:** - Aspirin/salicylates for 4 weeks unless medically indicated (Reye's Syndromereported after salicylate use during wild-type influenza infection) - Antiviral medication for 2 weeks post The following side effects may be experienced (see Summary of Product Characteristics): **Very common:** - Nasal congestion/rhinorrhoea and malaise. **Common:** - Decreased appetite, pyrexia, myalgia and headache. **Very rare:** - Immediate allergic reactions Very rare reports of Guillain-Barré syndrome (GBS) have been observed in the post-marketing setting following influenza vaccination. The incidence cannot be estimated from known data. The risk of GBS following influenza infection is several times greater than that following influenza 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.

Appendix I

Signature Sheet

Name of Medicine Protocol: Master Medicine Protocol for the Administration of Live Attenuated Influenza Vaccine (LAIV) Fluenz Tetra to all 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 Tetra

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 Live Attenuated Influenza Vaccine (LAIV) Fluenz Tetra 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 V1 www.hse.ie/nationalconsentpolicy

HSE COVID-19 Vaccination Programme (2023) Operational Guidance (Note: This guidance document covers 2023/2024 Seasonal Influenza Vaccination Programme), available at www.immunisation.ie

National Immunisation Office (2023) Seasonal Influenza Vaccination Programme (SIVP) Supportive Information Document for HSE Vaccinators. Dublin: Health Service Executive, available at www.immunisation.ie

Live Attenuated Influenza Vaccine - Fluenz Tetra (LAIV Fluenz Tetra), *Summary of Product Characteristics and Patient Information Leaflet,* available at www.ema.ie

National Immunisation Advisory Committee (2023) Anaphylaxis: Immediate Management in the Community. Available at https://rcpi.access.preservica.com/uncategorized/IO_a36f9e4b-4c80-432d-8264-546089359925/

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* Dublin: Royal College of Physicians Ireland *(Online Update available at* https://www.rcpi.ie/Healthcare-Leadership/NIAC/Immunisation-Guidelines-for-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