Medicine Protocol for the administration of the
Live Attenuated Influenza Vaccine (LAIV)
Fluenz Tetra (Astra Zeneca)
by
General Practice Nurse(s) employed at

Medigroup Medical Centre

- This medicine protocol is a specific written instruction for the administration of Live Attenuated Influenza Vaccine (LAIV) Fluenz Tetra by the General Practice Nurse(s) to persons attending Medigroup Medical Centre who are included in the target population to receive seasonal influenza vaccine.

- This 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-eparproduct-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

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 medication 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 medicine protocol is in effect" (An Bord Altranais, 2007, p35).

It is important to be familiar with the professional guidance on Medication Management and Medication Administration from NMBI www.nmbi.ie and HSE National Immunisation Office (NIO) https://www.hse.ie/eng/health/immunisation/hcpinfo/fluinfo/ for information specific to the vaccine respectively.

The following is a minimum recommended list of professional guidance documents relating to the use of Medicine protocols:

- An Bord Altranais (2007) *Guidance to Nurses and Midwives on Medication Management* Dublin: An Bord Altranais https://www.nmbi.ie/nmbi/media/NMBI/Publications/Guidance-Medicines-Management.pdf?ext=.pdf
- National Immunisation Advisory Committee *Immunisation Guidelines for Ireland*. Royal College of Physicians Ireland (RCSI) online update available at http://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/
- National Immunisation Office (2018) *Guidelines for Vaccinations in General Practice* www.hse.ie/eng/health/immunisation/infomaterials/pubs/guidelinesgp.pdf
- Nursing and Midwifery Board of Ireland (2020) *Guidance for Registered Nurses and Midwives on Medication Administration*: Dublin. NMBI https://www.nmbi.ie/NMBI/media/NMBI/NMBI-Medication-Administration-2020.pdf?ext=.pdf
- Nursing and Midwifery Board of Ireland (2015) *Recording Clinical Practice*. *Professional Guidance* Dublin: NMBI https://www.nmbi.ie/nmbi/media/NMBI/Publications/recording-clinical-practice-professional-guidance.pdf?ext=.pdf
- Nursing and Midwifery Board of Ireland (2015) *Scope of Nursing and Midwifery Practice Framework*. Dublin: NMBI https://www.nmbi.ie/nmbi/media/NMBI/Publications/Scope-of-Nursing-Midwifery-Practice-Framework.pdf?ext=.pdf
- Nursing and Midwifery Board of Ireland (2014) *The Code of Professional Conduct and Ethics for Registered Nurses and Registered Midwives*. Dublin: NMBI https://www.nmbi.ie/NMBI/media/NMBI/Code-of-Professional-Conduct-and-Ethics.pdf?ext=.pdf

Learning resources:

- The National Immunisation Office eLearning Programmes available on HSeLanD for all HSeLanD learners including :

    - **Live Attenuated Influenza Vaccine (LAIV) 2023/2034 season**
    - **Quadrivalent Influenza Vaccine (QIV)**
    - **Immunisation Foundation Programme**
    - **Storing and Managing Vaccines**
    - **Talking about Immunisation Live Attenuated Influenza Vaccine (LAIV)**
    - **Quadrivalent Influenza Vaccine (QIV)**
    - **The Flu Vaccine - Protect yourself, Protect others"**
    - **Pneumococcal Polysaccharide Vaccine**

- National Immunisation Office website www.immunisation.ie

    - **Frequently asked questions for Healthcare workers on LAIV**
    - **Algorithms for administration of influenza vaccine**
    - **Information leaflets, Posters, Tear pad for LAIV**

Medicine Protocol for the Administration of Live Attenuated Influenza Vaccine (LAIV) Fluenz Tetra 2023/2024 to vaccine recipients

1.0 Critical Elements	
1.1 Name of Organisation where protocol applies	Medigroup, Cathedral Road, Cork.
1.2 Date the protocol comes into effect	From October 2023
1.3 Date for review of protocol	To April 2024
1.4 Document adapted from the HSE 2023/2024 Medicine Protocol	Master Medicine Protocol for the Administration of Live Attenuated Influenza Vaccine (LAIV) Fluenz Tetra to all children between 2-12 years of age and children those aged 13-17 years who are in the "at-risk group"
1.5 Name and signature of the employing authority who is authorising the implementation of the protocol **Document prepared in collaboration with**	"On behalf of the authority employing professionals authorised to administer under this medicine protocol, I have read this medication protocol and authorise its implementation" Name: _____(Employer/Principal GP) Title: _____ Signature: _____ MCRN: _____ Name: _____(GP Nurse) Title: _____ Signature: _____ NMBI: _____

1.6.1 Names and signatures of general practice nurses agreeing to work within the protocol	"I have read the medicine protocol and I am competent under my Scope of Nursing and Midwifery Practice Framework (NMBI, 2015) to administer vaccines using this protocol" Name:_____ Title:_____ Signature:_____ Address:_____ NMBI PIN:_____
	Name:_____ Title:_____ Signature:_____ Address:_____ NMBI PIN:_____
	Name:_____ Title:_____ Signature:_____ Address:_____ NMBI PIN:_____
	Name:_____ Title:_____ Signature:_____ Address:_____ NMBI PIN:_____
	Name:_____ Title:_____ Signature:_____ Address:_____ NMBI PIN:_____

2.0 Clinical Criteria	
2.1 Clinical Condition for use of the medicine protocol	The clinical condition for which this medicine protocol has been developed is for immunisation of : • all children aged 2 – 12 years • children aged 13-17 years who are in the "at-risk group" against influenza illness (Note: "At-risk group" clinical conditions are listed in the NIAC Chapter 11 Influenza).
2.2 Circumstances in which the medicine protocol applies	The Department of Health & HSE seasonal influenza programme offers the LAIV to children aged 2 – 12 years. And children aged 13-17 who are in the 'at risk' group. Other children (aged 6 months – 23 months and > 17 years) should receive Quadrivalent Inactivated Influenza Vaccine (QIV) if they are in an at-risk group). COVID-19 vaccines and other vaccines e.g. MMR and 4 in 1 vaccines may be coadministered at the sametime or at any interval as the LAIV Fluenz Tetra vaccine is given. *Considering these recommendations, you should specify below what groups of clients are suitable for inclusion in this medicine protocol within your practice to receive the Live Attenuated Influenza Vaccine (LAIV) Fluenz Tetra under medicine protocol.*
2.3 Inclusion criteria for patient treatment using the medicine protocol*	• Children with valid consent • All children aged 2 – 12 years and • children aged 13-17 years who are in the "at-risk group" (Note: "At-risk group" clinical conditions are listed in the NIAC chapter 11 Influenza). 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.
2.3a Precautions	• Egg anaphylaxis or egg allergy: NIAC advises that as LAIV Fluenz Tetra has an ovalbumin content of ≤0.024 micrograms per dose, it can be given to children with confirmed egg anaphylaxis or egg allergy in a primary care 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. • Acute severe febrile illness:

	Defer until recovery. The presence of a minor infection such as a mild upper respiratory infection or low grade fever is not a contraindication to immunisation. • 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.
2.4 Exclusion criteria for patient treatment using the medicine protocol	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 × 109 /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)
2.5 Actions to be taken for those who are excluded from the medicine protocol	1. Refer to the GP for medical assessment 2. Document all actions in clinical notes 3. Where LAIV is prescribed following medical assessment, the nurse/midwife may administer LAIV within their scope of practice. Note: In determining their scope of practice, nurses/midwives must make judgements about their competency to carry out a role or activity (NMBI 2015)
2.6 Actions to be followed for eligible persons who do <u>not</u> wish to receive vaccine	1. Advise on the risks of not having the vaccine, including risk of transmission of virus to vulnerable patients 2. Advice regarding the minimisation of risk 3. Document in clinical notes
2.7 Documentation	1. Vaccine Consent Forms

<table>
<tr><td>required to support implementation of the medicine protocol</td><td>
<ol start="2">
Vaccine Information Leaflets
Patient-held record cards
Practice clinical record- electronic or paper patient file
Health Products Regulatory Authority Adverse Reaction Reporting Forms https://www.hpra.ie/homepage/about-us/report-an-issue

It is the responsibility of each nurse or midwife to be familiar with the appropriate documentation to support the safe administration of Influenza vaccine which includes a valid Medicine Protocol.
</td></tr>
<tr><td>3.0 Details of Medication to be supplied</td><td></td></tr>
<tr><td>3.1 Name of Medication</td><td>Live Attenuated Influenza Vaccine - Fluenz Tetra</td></tr>
<tr><td>3.2 Dose and Route of administration</td><td>

The dose is 0.2ml- One spray (0.1ml) in each nostril
Route of administration: Intranasal

<table>
<tr><td>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>Have never had any influenza vaccine

Have had any influenza vaccine before</td><td>Two doses
(4 weeks apart)

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>2-17years</td><td>Not relevant</td><td>One dose</td></tr>
</table>
</td></tr>
<tr><td>3.3 Link to Medicine

Details of product information and other data including instructions for supply and administration is available on the Health Product Regulatory Authority at www.hpra.ie</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-ofinfluenza-virus-vaccines-for-use-in-the-2023-2024-northern-hemisphereinfluenza-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/fluenztetra-epar-product-information_en.pdf</td></tr>
</table>

3.4 Possible Side Effects	**Very common** (≥1/10)**:** - Decreased appetite, Nasal congestion/rhinorrhoea, and Malaise. **Common** (≥1/100 to <1/10) **:** - Decreased appetite, pyrexia, myalgia and headache. **Uncommon** (≥1/1,000 to <1/100)**:** - Hypersensitivity reactions (including facial oedema, urticaria) - Epistaxis and rash **Very rare** (<1/10,000) - Immediate allergic reactions *Very rare reports of Guillain-Barré syndrome (GBS) have been observed in the postmarketing 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* See SPC and information provided in Patient Information leaflet (PIL) for this specific vaccine in respect of possible side effects. *(Note: The patient / parent / guardian should be reassured there may be no side effects following the vaccination)*
3.5 Potential adverse reactions and procedures for treatment of same	1. 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 2. 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 dose given into one nostril contains enough attenuated viral particles to induce an immune response 3. If all of the vaccine doses are given in the same nostril: the vaccine does not need to be repeated 4. Post vaccination, reiterate information contained in the patient information leaflet. 5. Following administration of the vaccine the patient should be advised to remain in the clinic for 15 minutes to allow monitoring for any immediate reaction including possible anaphylactic reaction. This applies after any child or adult vaccination because of the very rare possibility of anaphylaxis. In addition, syncope may occur with most cases occurring less than 5 minutes after vaccine administration. In most instances, following vaccination there is a period of at least 5 minutes when the record card is being completed before the vaccinated person leaves the room. https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/niacpostvaccobs.pdf 6. In the unlikely event of adverse reaction occurring after the period of observation, the patient should be advised to contact the general practitioner / out of hours

	service Emergency Department

3.6 Procedure for reporting Adverse Drug Reactions to the Health Products Regulatory Authority (HPRA)	All adverse drug reactions or suspected adverse drug reactions following administration of the vaccine must be reported as soon as possible in accordance with criteria outlined by the HPRA. Adverse Reaction Reporting Forms can be accessed at the following link: https://www.hpra.ie/homepage/about-us/report-an-issue 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/
3.7 Procedure for the reporting and documentation of errors and near misses involving the vaccine	In the case of medication errors that directly involve the patient, i.e. wrong medication/patient/dose/route being administered or another medication error, the general practice nurse/general practitioner must remain with the patient and closely monitor the patient for any adverse reactions (if the reaction has occurred while the patient is still on the premises). Vital signs should be recorded and the patient should be reviewed by the general practice nurse and general practitioner. 1. The incident must be reported to the general practitioner as soon as possible. 2. The incident and all actions taken must be promptly recorded 3. The patient, parent or guardian should be informed of the nature of the incident 4. Incident Report Form must be completed by the practice and held by the authorising general practitioner (may use NIRF form https://www.hse.ie/eng/about/who/nqpsd/qps-incident-management/nims/nirf-01- v12-person-interactive.pdf) 5. Any suspected adverse reactions associated with medication errors should be reported to the HPRA as outlined above.
3.8 Mechanisms for storage of vaccines and for obtaining supply	Storage and ordering of vaccines in accordance with guidance included in the document Supporting Infromation for Vaccinations in General Practice: https://www.hse.ie/eng/health/immunisation/infomaterials/gpsupportingdocpci.pdf
3.9 Resources and equipment required	1. Vaccine Fridge with minimum/maximum temperature recording device to monitor the cold chain temperature (between +2°C and +8°C) 2. Vaccine (LAIV prefilled nasal spray) 3. Sharps bins, and bins for disposal of other hazardous materials 4. Disposable kidney dishes/trays 5. Cotton wool balls/tape/plasters 6. Alcohol hand sanitiser 7. Surgical face masks 8. Access to telephone 9. Resuscitation equipment and drugs in accordance with National Immunisation Advisory Committee (2022) Anaphylaxis: Immediate Management in the Community available online: https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/anaphylaxis.pdf 10. Safe storage areas for medicines and equipment

	11. Current medicine protocol LAIV
3.10 Audit process to identify appropriate use of the protocol or unexpected outcomes	1. All documentation to be held for review and audit purposes 2. Regular team meetings are advisable to review the use of the medication protocol
4.0 Information for Vaccine Recipients/Carers	
4.1 Advice to be given to the patient/parent/guardian before and/or after treatment* ** literature for patients whose first language is not English is available on the National Immunisations Office website and should be made available to patients if required*	**Before vaccination:** • The patient information leaflet (PIL) should be supplied in advance of obtaining informed consent. • Discuss the influenza vaccine and the importance of protecting not only their own health but also the health of people who run a high risk of associated complications if they contract influenza. • Discuss potential side-effects • Inquire if they have any questions before proceeding. • Obtain informed consent and a signed consent form **After vaccination:** • The child must be advised to remain seated in the post vaccination observation area for 15 minutes to allow monitoring of any immediate reaction including possible anaphylactic reaction and must be advised to report any side effects to the registered nurse or registered midwife who is present. • 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) ○ - Antiviral medication for 2 weeks post vaccination.
4.2 Details of any necessary follow-up, action and referral arrangements	1. Inform patient/parent/guardian if and when a subsequent vaccine is due. 2. Document all advice/details in patients records 3. In the event of an adverse reaction, the general practice nurse must ensure that all procedures are adhered to as outlined in section 3.0 of this protocol.

5.0 Staff authorised to use medicine protocol	**** all nurses working under medicine protocol should do so guided by their scope of practice and should be supported and encouraged to achieve and maintain competence in all areas noted by the authorising general practitioner.***
5.1 **Professional qualifications, training, experience and competence required prior to using this medicine protocol**	Registered nurse or registered midwife, maintained on the active register of the Nursing and Midwifery Board of Ireland. **Required Training** • Basic Life Support for Health Care Workers within the last two years • Initial anaphylaxis programme *("National Anaphylaxis Education Programme for Health Care Professionals")* via HSELanD followed by a one and a half hour classroom based skills workshop (replacing the previous four hour classroom based programme). • Subsequent updates every two years via HSELanD Anaphylaxis e-learning programme available at www.hseland.ie **Recommended Training** Having successfully completed the following programmes: • Immunisation Foundation Programme (available on www.hseland.ie) • eLearning Medication Management Programme (available from www.nmbi.ie) • The Flu Vaccine – It's a Lifesaver (www.hseland.ie) • Vaccinations and pregnancy (www.hseland.ie) **Required Experience** Currently employed as a general practice nurse and have had an opportunity to shadow experienced vaccinator in gaining experience. **Required Competence** Competence in vaccination technique Self-assessment of competency assessed as per GP supporting document https://www.hse.ie/eng/health/immunisation/infomaterials/gpsupportingdocpci.pdf

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) Supporting Information for Vaccinations in General Practice. Dublin: Health Service Executive, available at https://www.hse.ie/eng/health/immunisation/infomaterials/gpsupportingdocpci.pdf

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. No. 245/202 - Available at https://www.irishstatutebook.ie/eli/2021/si/245/made/en/print