Fluenz Tetra LAIV

Medicine Protocol for the Administration of Live Attenuated Influenza Vaccine (LAIV) Fluenz Tetra to Vaccine Recipients

**2021/2022**

**by**

**General Practice Nurses (GPN’s) employed**

**at**

**(Insert Name and location of Practice)**

This medicine protocol (MP) is a specific written instruction for the administration of LAIV Fluenz Tetra vaccine by NMBI registered General Practice Nurses (GPN’s) employed in {Insert Name of Practice here}

This MP has been informed and adapted from the NIO *“Master Medicine Protocol for the Administration of Live Attenuated Influenza Vaccine (LAIV) Fluenz Tetra to Vaccine Recipients”*

The protocol enables the named GPN’s employed in this practice, who have undertaken the required education and training programmes to administer LAIV Fluenz Tetra to vaccine recipients, with reference to guidelines and guidance from National Immunisation Advisory Committee (NIAC), National Immunisation Office (NIO), HSE and in accordance with the Summary of Product Characteristics for LAIV Fluenz Tetra as detailed by the European Medicines Agency (EMA).

* National Immunisation Advisory Committee *Immunisation Guidelines for Ireland* Dublin: Royal College of Physicians Ireland *(Online Update available at* [http://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/*)*](about:blank)
* Summary of Product Characteristics available at

https://www.ema.europa.eu/en/documents/product-information/fluenz-tetra-epar-product-information\_en.pdf

The professional groups using this protocol must ensure that the protocol is organisationally authorised by an appropriate authorising person, relating to the professional cohort of vaccinators by whom the vaccine is to be administered, including requirements of registration, training and assessment of competency.

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| **Medicine Protocol for the Administration of Live Attenuated Influenza Vaccine (LAIV) Fluenz Tetra to vaccine recipients** | |
| **1.0 Critical Elements** | |
| **Name of Organisation where medicine protocol applies** | Insert Name and Location of Practice here |
| **Date the medicine protocol comes into effect** | XXX September 2021 |
| **Date for review of medicine protocol** | August 2022 |
| **Names and signatures of protocol adopters and reviewers** | Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Title:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  NMBI:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_    Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Title:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Signature:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  MCRN:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \*Add more if required - All GPNs and GPs working in the practice who have contributed to the adaptation of this protocol should be included here. |
| **Names and signature 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 medication protocol and authorise its implementation”  Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_(Employer/Principal GP)  Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Address:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  MCRN: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **Names and signatures of GPN’s 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 LAIV using this protocol”  Name:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Title:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Signature:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Address:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  NMBI PIN:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Name:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Title:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Signature:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Address:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  NMBI PIN:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

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| **2.0 Clinical Criteria** | |
| **Clinical Condition for use of the medicine protocol** | The clinical condition for which this medicine protocol has been developed is for vaccination of children aged 2 – 17 years against influenza virus for the 2021/2022 seasonal influenza vaccination programme. |
| **Circumstances in which the medicine protocol applies** | The NIAC guidelines recommend LAIV for all children aged 2 – 17 years. The Department of Health & HSE seasonal influenza programme offers the LAIV to children aged 2 – 17 years. 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 may be co-administered at the same time or at any interval as this vaccine. |
| **Inclusion criteria for vaccine recipient using the medicine protocol** | **Inclusion Criteria:**   * All children aged 2 – 17 years   The following are not contraindications to LAIV  • Asymptomatic HIV infection  • Children receiving  - Topical or inhaled corticosteroids  - Low dose systemic corticosteroids  - Replacement therapy corticosteroids (e.g. for adrenal insufficiency)  Live attenuated influenza vaccine (LAIV) 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 advises that as LAIV has an ovalbumin content <0.1 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 in hospital. LAIV has an ovalbumin content of ≤0.024 micrograms per dose. |

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| **Exclusion criteria for vaccine recipient using the medicine protocol** | **Contraindications**  1. Anaphylactic or hypersensitivity reaction to a preceding dose of an influenza vaccine or any of the constituents (except ovalbumin - NIAC advises that as LAIV has an ovalbumin content <0.1 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 in hospital)  2. Asthma  - If an acute exacerbation of symptoms, increased wheezing and/or additional bronchodilator treatment in the last 72 hours.  - Severe asthma if on regular oral steroids or have had previous ICU/Critical care for asthma, seek advice  3. Concomitant use of aspirin/salicylates  4. Children who live with a severely immunosuppressed persons ( post haematopoietic stem cell transplant)  5. Influenza antiviral medications within the previous 48 hours  7. Pregnancy  8. Significant immunosuppression due to disease or treatment  9. Those post cochlear implant until the risk of a CSF leak has resolved - consult with the relevant specialist  10. Those with a cranial CSF leak.  11. Those with neutropoenia (absolute neutrophil count <0.5 x 109/L) to avoid an acute vaccine related febrile episode  12. Those on combination checkpoint inhibitors (e.g. ipilumumab plus nivolumab) because of a potential association with immune related adverse reactions  *\*QIV should be given if LAIV is contraindicated (provided not contraindicated).*  *Prior to administration of QIV an individual prescription by GP or RNP is required or may be included in a separate Medicine Protocol for QIV* |
| **Actions to be taken for those who are excluded from the medicine protocol** | * Refer to/discuss with the relevant Medical Practitioner/clinical lead/lead vaccinator for an individual medical assessment. * Document action in clinical record electronic or paper based * Where LAIV Fluenz Tetra is prescribed following medical assessment, the vaccinator may administer the vaccine within his/her 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 |
| **Action to be followed for vaccine recipients who do not wish to receive the vaccine** | * Advise on the risks of not having the vaccine, including risk of transmission of virus to vulnerable persons * Advise regarding the minimisation of risk * Document in clinical notes |
| **Description of circumstances and referral arrangements when further advice or**  **consultation is required** | Refer and discuss with the GP if the vaccine recipient had previous adverse reaction or other clinical concerns as outlined in Exclusion Criteria. |
| **Documentation required to support implementation of the medicine protocol** | * Check for and ensure consent has been obtained and documented * LAIV Information Leaflets * Patient held record cards if available * Health Products Regulatory Authority Adverse Reaction Reporting forms https://www.hpra.ie/homepage/about-us/report-an-issue * National Incident Management System Form NIRF‐01‐v11 available at: https://[www.hse.ie/eng/about/qavd/incident](about:blank)‐management/nirf‐01‐v11‐ person.pdf   It is the responsibility of each vaccinator to be familiar with the appropriate documentation to support the safe administration of which includes the following:   * Medicine Protocol for the Administration of Live Attenuated Influenza Vaccine (LAIV) Fluenz Tetra Astra Zeneca to vaccine recipients * Treatment of anaphylaxis in the community. National Immunisation Advisory Committee, Immunisation Guidelines for Ireland. https://[www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/anaphylaxis.](about:blank) pdf * Influenza chapter 11 from NIAC immunisation Guidelines for Ireland (2020) available at https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/chapter11.pdf |

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| **3.0 Name of Medicine** | **Live Attenuated Influenza Vaccine - Fluenz Tetra Astra Zeneca** |
| **Dose & Route of administration** | * The dose is 0.2ml- One spray (0.1ml) in each nostril * Route of administration: Intranasal  |  |  |  |  | | --- | --- | --- | --- | | Group | Age | Previous Vaccination | Dose | | Medically at risk | 2-8 years | Have never had any influenza vaccine  Have had any influenza vaccine before | Two doses  (4 weeks apart)  One dose | |  | 9-17 years | Not relevant | One dose | | Healthy | 2-17years | Not relevant | One dose | |
| **Link to Medicine**  **Details of product information and other data including instructions for supply and administration is available from the Health Products Regulatory Authority** | Link to Summary of Product Characteristics (SPC) & Link to Patient information Leaflet (PIL) available at   * https://www.ema.europa.eu/en/documents/product-information/fluenz-tetra-epar-product-information\_en.pdf |
| **Potential adverse reactions and procedures for treatment of same** | 1. Post vaccination, reiterate information contained in the patient information leaflet.  2. 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. The recipient can wait in the vicinity accompanied by an adult who has been given post-vaccination advice. [https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/niacpostvaccobs.pdf](about:blank)  3. In the unlikely event of adverse reaction occurring following administration of the vaccine, the patient should be advised to contact the practice nurse / general practitioner, and if outside of practice opening hours contact the out of hours service.  4. What to do:  - If the child sneezes or nose drips – The vaccine does not need to be repeated. LAIV 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. |
| **Procedure for reporting Adverse Drug Reactions to the Health Products Regulatory Authority (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 on line at [http://www.hpra.ie](about:blank) or through use of the yellow card system which is available in a downloadable format from the HPRA website, or on request from the HPRA.  The incident and all actions taken must be promptly recorded in accordance with the *Management of a Patient with Anaphylaxis*: *Treatment in the Community* (National Immunisation Advisory Committee 2019), available online at  [https://www.hse.ie/eng/](about:blank)healt[h/immunisatio](about:blank)n[/hcpinfo/guidelines/anaphylaxis.p](about:blank)df  Record actions in patient file |
| **Procedure for the reporting and documentation of errors and near misses involving the medicine** | 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 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 GPN and the GP.   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\*) 5. Any suspected adverse reactions associated with medication errors should be reported to the HPRA as outlined above.   \*[https://www.hse.ie/eng/about/qavd/incident-management/nirf-01-v11-person.pdf](about:blank) |

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| **Resources and equipment required** | * Vaccine Fridge with minimum/maximum temperature recording monitoring display to maintain cold chain temperature between +2° to +8°C * A LAIV nasal spray * Disposable kidney dishes/trays * Sharps bins, and bins for the disposal of healthcare risk and non‐risk waste * Alcohol hand sanitiser * Surgical facemasks * Resuscitation equipment and drugs in accordance with Anaphylaxis: Treatment in the Community (National Immunisation Advisory Committee, 2019) available at: [https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/niacpostvaccobs.pdf](about:blank) * Safe storage areas for medicines and equipment * LAIV medicine protocol |
| **Audit process to identify appropriate use of the medicine protocol or unexpected outcomes** | * All documentation will be held for review and audit purposes as per local/national agreement. * Regular team meetings are advisable to review the use of the medicine protocol |
| **4.0 Information for vaccine recipient** | |
| **Advice to be given to the vaccine recipient before and after vaccination.**  **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 also easy-read materials for those with literacy issues** | **Before vaccination:**   * The patient information leaflet (PIL) should be supplied in advance of obtaining informed consent from the parent/legal guardian for children aged 2-15 or from individuals themselves aged 16 -17. * Discuss the influenza vaccine and the importance of protecting not only their child’s own health but also the health of people who run a high risk of associated complications if they contact flu. * Inquire if they have any questions before proceeding.   **After vaccination:**   * Discuss potential common side effects and advise on management of the same. Individuals remain on the premises for a minimum 15 minutes following vaccine administration. The recipient can wait in the vicinity accompanied by an adult who has been given post-vaccination advice. [https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/niacpostvaccobs.pdf](about:blank) * 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   * If more serious adverse or persistent effects occur, advise them to call the practice and if out of hours, they should contact the local out of hours service. |
| **Details of any necessary follow‐up, action and referral arrangements** | 1. Inform parent/legal guardian and individual where appropriate when a subsequent vaccine is due. 2. Document all advice/details in patients’ records 3. In the event of an adverse reaction, the vaccinator must ensure that all procedures are adhered to as outlined in section 3.0 of this protocol |

**References**

National Immunisation Advisory Committee (2019) Anaphylaxis: Treatment in the Community. Available at https://[www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/anaphylaxis.pdf](about:blank)

National Immunisation Advisory Committee *Immunisation Guidelines for Ireland (2020)* Dublin: Royal College of Physicians Ireland. Online update available at [http://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/](about:blank)