**Fluad Tetra aQIV**

**Medicine Protocol for the administration of Fluad Tetra aQIV to all 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 Fluad Tetra aQIV vaccine 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 Fluenz Tetra aQIV to Vaccine Recipients”*

The protocol enables the named healthcare professionals employed in this practice, who have undertaken the required education and training programmes to administer Quadrivalent Influenza Vaccine (split virion, inactivated) 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 Fluad 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)
* Fluad Tetra Summary of Product Characteristics Form available at: [https://www.ema.europa.eu/en/documents/product-information/fluad-tetra-epar-product-information\_en.pdf](about:blank)

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 Fluad Tetra aQIV Influenza Vaccine to all 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:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **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 the immunisation of vaccine recipients against influenza virus for the 2021/2022 seasonal influenza vaccination programme. | |
| **Inclusion criteria for vaccine recipients using the medicine protocol** | Active immunisation to prevent influenza infection caused by influenza virus, in individuals **65 years of age and older** | |
| **Exclusion criteria for vaccine recipients using the medicine protocol** | Anaphylactic or hypersensitivity reaction to a previous dose of an influenza vaccine or any of its constituents.  Egg anaphylaxis or egg allergy:  The ovalbumin content in Fluad Tetra is equal to or less than 1 micrograms per 0.5 ml dose.  NIAC advises that those with confirmed egg anaphylaxis or egg allergy can be given influenza vaccine with an ovalbumin content <0.1 micrograms per dose. Those who have required admission to ICU for a previous severe anaphylaxis to egg should be referred for specialist assessment with regard to vaccine administration in hospital. Therefore those with a confirmed egg allergy or anaphylaxis should not receive Fluad Tetra and be referred for an alternative flu vaccine.  NIAC continues to advise that patients on combination checkpoint inhibitors (e.g. ipilumumab plus nivolumab) should not receive any influenza vaccines, because of a potential association with immune-related adverse reactions.  People with severe neutropoenia (absolute neutrophil count <0.5 × 109/L) should not receive any vaccines, to avoid an acute febrile episode.  Vaccine recipients who already received a dose of the Fluad Tetra or another flu vaccine in the 2021/2022 influenza season.  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. | |
| **Actions to be taken for those who are excluded from the medicine protocol** | * Refer and discuss with GP for an individual medical assessment * Document action in clinical notes * Where Fluad Tetra is prescribed following medical assessment, the vaccinator may administer Fluad Tetra within their scope of practice. | |
| **Action to be followed for those who do not wish to receive the vaccine:** | Advise of the risks of not having the vaccine, including risk of transmission of virus to others. | |
| **Description of circumstances and referral arrangements when further advice or consultation is required** | Refer and discuss with 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** | * Vaccine consent forms * Vaccine Information Leaflets * Patient held record cards * Health Products Regulatory Authority Adverse Reaction Reporting forms * National Incident Management System Form NIRF-01-v11 available at:   [https://www.hse.ie/eng/about/qavd/incident-management/nirf-01-v11-person.pdf](about:blank) | |
| **3.0 Name of Medicine** | Fluad Tetra | |
| **Dose & Route of administration** | 0.5ml of vaccine, Intramuscular only  Only 1 dose of the vaccine is required each flu season. | |
| **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**](about:blank) | Fluad Tetra containing influenza virus of the following strains for 2021/2022 flu season:   * an A/Victoria/2570/2019 (H1N1)pdm09-like virus * an A/Cambodia/e0826360/2020 (H3N2)-like virus * a B/Washington/02/2019-like virus (B/Victoria/2/87 lineage) * an B/Phuket/3073/2013-like virus (B/Yamagata/16/88 lineage) * **Link to Summary of Product Characteristics here** [**www.hpra.ie**](about:blank) * **Link to Patient Information Leaflet here:** [**www.hpra.ie**](about:blank) | |
| **Potential adverse reactions and procedures for treatment of same** | In the event of adverse reaction occurring following administration of the vaccine, the recipient is advised to contact the practice and if it occurs out of hours they should contact the local out of hours services.  Following administration of the vaccine, the vaccine recipient should be advised to remain seated in the post vaccination observation area for 15 minutes to allow monitoring of any immediate reaction including suspected anaphylactic reaction. | |
| **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 GP should be informed of any reported adverse reaction.  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/health/immunisation/hcpinfo/guidelines/anaphylaxis.pdf | |
| **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) | |
| **Resources and equipment required** | * Vaccine (pre-filled syringe 0.5 mls volume) * Vaccine Fridge with temperature monitoring device to maintain cold chain temperature between +2° to +8°C * Disposable kidney dishes/trays * Gauze swabs, tape/plasters * Sharps bins, and bins for disposal of other hazardous material * Alcohol hand sanitizer * Surgical face masks * 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/anaphylaxis.pdf](about:blank)   * Safe storage areas for medicines and equipment * Current medicine protocol for Fluad Tetra | |
| **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 policy. | |
| 1. **Information for vaccine recipients** | | |
| **Advice to be given to the vaccine recipient before treatment**  **Advice to be given to the recipient healthcare worker after treatment** | **Vaccine Information material must be supplied to the vaccine recipient prior to administration of the vaccine.**  **Before Treatment**  Discuss about the Influenza vaccine and the importance of protecting not only their own health but also protecting others.  Provide vaccine recipient with patient vaccine information material  Discuss potential side effects.  Obtain informed consent  **After Treatment**  Discuss potential side effects.  The vaccine recipient should be advised to remain in the healthcare facility for fifteen minutes.  The vaccine recipient should not leave the healthcare facility if they are feeling unwell and must report any unwanted side effects to the nurse or midwife who has administered the vaccine.  **The vaccine recipient may be advised:**  The following symptoms are reported as very common (affecting 1 in 10 people):  Injection site pain  Headache  Fatigue  Common side effects (affecting more than 1 in 100 people) include: bruising,  redness or inflammation at the injection site, loss of appetite, nausea, diarrhoea,  flu-like symptoms including chills, muscle aches and joint pain.  Some people may get a fever and vomiting after the vaccine  Paracetamol/Ibuprofen may be taken to relieve symptoms of fever or pain.  If more serious adverse or persistent effects occur, vaccine recipient should be advised to call the practice or out of hours service.  Details of any serious adverse reaction to the vaccine should be reported to HPRA at outlined in section 3 above | |
| **Details of any necessary follow-up, action and referral arrangements** | In the event of an adverse reaction the vaccination team must ensure that all procedures are adhered to as outlined in Section 3. | |

**References**

Health Service Executive (2010) *Healthcare Risk Waste Management Segregation Packaging and Storage Guidelines for healthcare Risk Waste.* Dublin: Health Service Executive.

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* Dublin: Royal College of Physicians Ireland. Online update available at

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National Immunisation Office (2019) *Seasonal Influenza Peer Vaccination Programme 2016: Guidelines for Staff* Dublin: Health Service Executive