Medicine Protocol for the administration of the INFLUVAC TETRA INFLUENZA VACCINE 2023/2024 by General Practice Nurse(s) employed at Medigroup Medical Centre

- This medicine protocol is a specific written instruction for the administration of Influvac Tetra Influenza Vaccine 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 valid for the 2023/2024 HSE Seasonal Influenza Vaccination Programme and is guided by the NIAC Immmunisation Guidelines at https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/chapter11.pdf
- 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, Guidance to Nurses and Midwives on Medication Management, JULY 2007, p35).

This sample medicine protocol is based on the HSE template for this medication in the current season https://www.hse.ie/eng/health/immunisation/hcpinfo/fluinfo/master-protocol-influvac-tetra.pdf

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:

- Nursing and Midwifery Board of Ireland (2021) *Code of Professional Conduct and Ethics for Registered Nurses and Registered Midwives*. Dublin: Nursing and Midwifery Board of Ireland.
- Nursing and Midwifery Board of Ireland (2020) *Guidance for Registered Nurses and Midwives on Medication Administration*. Dublin: Nursing and Midwifery Board of Ireland

- Nursing and Midwifery Board of Ireland (2022) *Practice Standards for Midwives.* Dublin: Nursing and Midwifery Board of Ireland
- An Bord Altranais (2007) *Guidance to Nurses and Midwives on Medication Management.* Dublin: An Bord Altranais
- 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* Dublin: Royal College of Physicians Ireland, online update available at http://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/
- National Immunisation Office (2023) *Seasonal Influenza Vaccination Programme (SIVP) Supportive Information Document for HSE Vaccinators.* Dublin: Health Service Executive, available at www.immunisation.ie
- Nursing and Midwifery Board of Ireland (2015) *Recording Clinical Practice. Guidance to Nurses and Midwives.* Dublin: Nursing and Midwifery Board of Ireland
- Nursing and Midwifery Board of Ireland (2015) *Scope of Nursing and Midwifery Practice Framework.* Dublin: Nursing and Midwifery Board of Ireland

Learning resources:

- The National Immunisation Office eLearning Programmes available on HSeLanD for all HSeLanD learners including :
    - **Flu vaccine administration programme**
    - **Storing and Managing Vaccines**
    - **Live Attenuated Influenza Vaccine (LAIV) 2023/2024 season**
    - **Quadrivalent Influenza Vaccine (QIV)**
    - **The Flu and Covid vaccine for healthcare workers- Protect yourself, Protect others**
    - **Pneumococcal Polysaccharide Vaccine (PPV23)**

- National Immunisation Office website www.immunisation.ie
    - **Frequently asked questions for Healthcare workers on QIV**
    - **Algorithms for administration of influenza vaccine**
    - **Information leaflets, Posters, Tear pad for QIV**

Medicine Protocol for the Administration of Quadrivalent Influenza Vaccine (QIV) 2023/2024 to vaccine recipients

1.0 Critical Elements	
1.1 Name of Organisation where protocol applies	Medigroup Medical Centre, Cathedral Road, Cork.
1.2 Date the protocol comes into effect	September 2023
1.3 Date for review of protocol	May 2024
1.4 Document adapted from the HSE 2023/2024 Medicine Protocol	Master Medicine Protocol for the administration of Influvac Tetra to adult vaccine by registered nurses and registered midwives https://www.hse.ie/eng/health/immunisation/hcpinfo/fluinfo/master-protocol-influvac-tetra.pdf
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: _____(Author) Title: _____ Signature: _____ Name: _____(GP Principal) Title: _____ Signature: _____ MCRN: _____

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 the immunisation of vaccine recipients against influenza virus for the 2023/2024 seasonal influenza vaccination programme
2.2 Circumstances in which the medicine protocol applies	The NIAC guidelines recommend annual influenza immunisation for specific cohorts that are at risk of influenza and of transmitting the influenza virus to vulnerable groups. *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 Influvac Tetra under medicine protocol.*
2.3 Inclusion criteria for patient treatment using the medicine protocol*	Under the HSE influenza vacacination programme the following groups are eligible to receive the flu vaccaine free of charge: 1. Those aged 65 years and over 2. All pregnant women 3. Aged 6-23 months and 18-64 years at increased risk of influenza-related complications 4. Residents of long-term care facilities 5. Health care workers 6. In regular contact with pigs, poultry or waterfowl 7. Living with someone who has a health condition that puts them at higher risk of flu 8. Out of home caregivers for people who have an underlying chronic health condition or Down Syndrome COVID-19 vaccines may be co-administered at the same time or at any interval as the Influvac Tetra. As it is not known if reactogenicity is increased with co-administration, the vaccines should preferably be administered in different limbs. ** However Influvac Tetra is recommended for other categories and may be administered according to the NIAc guidelines at* [*https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/chapter11.pdf*](https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/chapter11.pdf)
2.3a Precautions	• Egg anaphylaxis or egg allergy: Influvac Tetra contains Ovalbumin (≤ 0.1 micrograms per dose). NIAC advises that those with confirmed egg anaphylaxis or egg allergy can be given influenza vaccine in a primary care or school setting with the exception of those who have required admission to ICU for a previous severe anaphylaxis to egg. This group should be referred for specialist assessment with regard to vaccine administration in hospital. • Acute severe febrile illness: Defer until recovery.

2.4 Exclusion criteria for patient treatment using the medicine protocol	• Anaphylaxis to a previous dose of an influenza vaccine or any of its constituents. • 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. • Those receiving combination checkpoint inhibitors (e.g. ipilumumab plus nivolumab), because of a potential association with immune related adverse reactions. • People with severe neutropoenia (absolute neutrophil count <0.5 × 10^9/L) should not receive any vaccines, to avoid an acute febrile episode. This does not apply to those with primary autoimmune neutropoenia who can receive influenza vaccine unless contraindicated. • Vaccine recipients who already received a full course of any recommended flu vaccine for their age in the 2023/2024 influenza season.
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 Influvac Tetra is prescribed following medical assessment, the nurse/midwife may administer Influrvac Tetra 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 vaccination	1. Advise on the risks of not having the vaccine, including risk of transmission of Influenza virus to vulnerable patients 2. Advice regarding the minimisation of risk 3. Document in clinical notes
2.7 Documentation required to support implementation of the medicine protocol	✓ Vaccine Consent Forms ✓ 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 the following: • This medicine protocol • 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/

3.0 Details of Medication to be supplied	
3.1 Name of Medication	Influvac Tetra
3.2 Dose and Route of administration	0.5ml of vaccine, Intramuscular only Only 1 dose of the vaccine is usually required each flu season. In rare circumstances 2 doses of the vaccine will be required 4 weeks apart: 1. For cancer patients vaccinated while on chemotherapy and who complete treatment in the same season (regardless of previous influenza vaccination) 2nd dose at least 4 weeks after completion of chemotherapy and at least 4 weeks after 1st dose. 2. If post haematopoeitic stem cell transplant or post solid organ transplant they should receive 2 doses of the vaccine 4 weeks apart, if receiving influenza vaccine for the first time post-transplant ***N.B. A general practitioner must be on the premises during the administration of vaccines and during the 15 minutes post vaccination period to assist with any adverse events which may result from vaccine administration and should remain on the premises for 30 minutes after the last vaccination.***
3.3 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 **Links to Medicine**	Influvac Tetra, containing influenza virus of the following strains for 2023/2024 flu season: ● an A/Victoria/4897/2022 (H1N1)pdm09-like virus; ● an A/Darwin/9/2021 (H3N2)-like virus; ● a B/Austria/1359417/2021 (B/Victoria lineage)-like virus; ● B/Phuket/3073/2013 - like strain (B/Phuket/3073/2013, Yamagata lineage type) **Link to Summary of Product Characteristics here;** **https://www.hpra.ie/homepage/medicines/medicines-information/vaccines** **Link to Patient Information Leaflet here:** **https://www.hpra.ie/homepage/medicines/medicines-information/vaccines**

3.4 Possible Side Effects	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. 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 observation area for 15 minutes to allow monitoring for any immediate reaction including suspected 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. 3. In the unlikely event of adverse reaction occurring after the period of observation, the patient should be advised to attend for appropriate medical care ie Emergency Department/GP for immediate assessment and treatment, if required. 4. The vaccine recipient should be advised to report their reaction to the vaccine clinic.
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 The incident and all actions taken must be promptly recorded in accordance with Anaphylaxis: Treatment in the Community (NIAC, 2016) available on line at http://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/Anaphylaxis.pdf Record actions in patient file
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 Guidelines for Vaccinations in General Practice (see section 8, pages 22-27) https://www.hse.ie/eng/health/immunisation/infomaterials/gpguidelines.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 (pre-filled syringe 0.5mls volume 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 Influvac Tetra Influenza Vaccine
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 record on patient electronic record **After vaccination:** • Advise on management of potential common side effects. • Individual advised to remain on the premises for min 15 minutes following vaccine administration. • The vaccine recipient should not leave the healthcare facility if they are feeling unwell and must report any unwanted side effects to the vaccinator who has administered the vaccine. • If more serious adverse or persistent effects occur after the waiting period, advise

	them to call the practice and if out of hours, they should contact the local OOH's This includes the very rare risk of Guillain- Barré syndrome (GBS) in the weeks after vaccination. • Paracetamol/Ibuprofen may be taken to relieve symptoms of fever or pain. • Details of any serious adverse reaction to the vaccine should be forwarded to the medical practitioner.
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 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**	The registered nurse or registered midwife must have completed all of the following: 1. Be a Registered Nurse or Registered Midwife, on the active register maintained by the NMBI 2. Education programme for registered nurses and registered midwives on the Seasonal Influenza Vaccination Programme: Education Programme for Nurses and Midwives and any updates for nurses and midwives accessible on www.HSELanD.ie 3. An approved Basic Life Support for Health Care Providers Course within the last two years (i.e. Irish Heart Foundation (IHF)) 4. 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 5. Self-Assessment of Competency Form available at www.immunisation.ie 6. COVAX online programme available at: https://www.hse.ie/eng/health/immunisation/hcpinfo/hsecovid19vms.html Youtube video on COVAX:https://www.youtube.com/watch?v=wzDXzRCgA_0 7. Quadrivalent Influenza Vaccine (QIV) – Influvac Tetra , available at www.hseland.ie **Recommended:** 1. The flu vaccine – protect yourself, protect others, available at www.hseland.ie
References	• An Bord Altranais (2007) Guidance to Nurses and Midwives on Medication Management Dublin: An Bord Altranais • 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 (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 Dublin: Royal College of Physicians Ireland. Online update available at http://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/ • National Immunisation Office (2023) Seasonal Influenza Vaccination Programme (SIVP) Supportive Information Document for HSE Vaccinators Dublin: Health Service Executive • Nursing and Midwifery Board of Ireland (2021) Code of Professional Conduct and Ethics for Registered Nurses and Registered Midwives. Dublin: Nursing and Midwifery Board of Ireland available at: http://www.nmbi.ie/Standards-Guidance/Code • Nursing and Midwifery Board of Ireland (2020) Guidance for Registered Nurses and Midwives on Medication Administration. Dublin: Nursing and Midwifery Board of Ireland • Nursing and Midwifery Board of Ireland (2022) Practice Standards for Midwives. Dublin: Nursing and Midwifery Board of Ireland available at: http://www.nmbi.ie/Standards-Guidance/Midwives-Standards • Nursing and Midwifery Board of Ireland (2015) Recording Clinical Practice. Guidance to Nurses and Midwives. Dublin: Nursing and Midwifery Board of Ireland available at: http://www.nmbi.ie/Standards-Guidance/More-Standards-Guidance/Recording-Clinical-Practice • Nursing and Midwifery Board of Ireland (2015) Scope of Nursing and Midwifery Practice Framework. Dublin: Nursing and Midwifery Board of Ireland available at: http://www.nmbi.ie/Standards-Guidance/Scope-of-Practice/Nursing-Practise-Scope-Definition

Appendix 1.

Signature Sheet

Name of Medicine Protocol: Medicine Protocol for the Administration of Influvac Tera to patients who meet the criteria contained in Clinical Criteria 2.3 of this protocol.

I have read and understand and agree to adhere to this medication protocol

Name	Signature	Occupation	NMBI Pin	Date

The above signed registered nurses/registered midwives are authorised by the signatories on page 3 to administer seasonal influenza vaccine in accordance with this medicine protocol.

Appendix II: Self Assessment of Competency Assessment Form

NAME: _____

(print clearly in capitals)

		onal Influenza Vaccine under Medicine		
Domain of Practice	**Critical Element**	**Competent** Date/Initials	**Needs Practice** Date/Initials	**Needs Theory** Date/Initials
1	I understand the role and function of medicine protocols in the context of NMBI guidelines in relation to: • The Code of Professional & Ethical Conduct • Scope of Nursing and Midwifery Practice • Guidance to Nurses and Midwives on Medication Management • Guidance for Registered Nurses and Midwives on Medication Administration (Guiding Principle 2, page 12, section 2.8).			
2	I practice within my scope of practice to undertake administration of Seasonal Influenza Vaccine, under medicine protocol.			
3	I am familiar with and adhere to the practices as set out in: • Seasonal Influenza Vaccination Programme (SIVP) Supportive Information Document for HSE Vaccinators • Immunisation Guidelines for Ireland (NIAC).			
4	I have successfully completed the HSELanD education programme for registered nurses and registered midwives: Seasonal Influenza Vaccination Programme 2023/2024. Education Programme for Nurses and Midwives. Quadrivalent Influenza Vaccine (QIV) –			

	Influvac Tetra available at www.hseland.ie			
5	I have attended Basic Life Support for Health Care Providers within the last two years.			
6	I am competent in safe intramuscular injection technique.			
7	I have successfully completed an approved Anaphylaxis education programme as outlined in section 5.0 of the medicine protocol and am familiar with NIAC (2023) Anaphylaxis: Immediate Management in the Community.			
8	I undertake to review the most current vaccination information from the NIO - www.immunisation.ie.			
9	I can outline the inclusion/exclusion criteria for administering influenza vaccine under the named medicine protocol			
10	In assessing suitability for vaccination I can undertake a clinical assessment of vaccine recipients within the scope of the medicine protocol.			
11	I can refer those who meet the exclusion criteria to the relevant medical practitioner for an individual medical assessment as per medicine protocol.			
12	I am familiar with the documentation required to support implementation of the medicine protocol to ensure safe administration of influenza vaccine.			
13	I can provide information regarding seasonal influenza vaccine, benefits and side effects to vaccine recipients.			
14	I am aware of the procedure for treatment and reporting of adverse reactions.			
15	I understand the procedure for reporting and documentation of medication errors/near misses.			
16	I dispose of all equipment and sharps in accordance with guidance for Healthcare Risk Waste HSE (2010).			
17	I am aware of and comply with the guidance on vaccine storage and handling including the maintenance of the cold chain in accordance with national and local policies.			
18	I have undertaken the following HSELanD/online programmes:			

	• AMRIC Aseptic Technique • AMRIC Hand Hygiene • GDPR Guidelines • National Consent Policy: https://www.hse.ie/eng/about/who/qid/other-quality-improvement-programmes/consent/national-consent-policy.html			

I have sufficient theoretical knowledge and practice to undertake vaccination under this medicine protocol independently, and I acknowledge my responsibility to maintain my own competence in line with the Scope of Nursing and Midwifery Practice and current best evidence.

Registered Nurse/Registered Midwife Signature:

_____ Date: _____

If any deficits in theory and/or clinical practice are identified, the registered nurse/registered midwife must discuss with relevant line manager and implement appropriate action plan to achieve competency within an agreed time frame.

Action Plan (for use if needed to reach competencies outlined)

Action necessary to achieve competency:

_____

_____

_____

Date to be achieved: _____

Supporting evidence of measures taken to achieve competency:

_____

_____

_____

Registered Nurse/Registered Midwife Signature: Date:

_____ _____

Line Manager Signature Date:

_____ _____