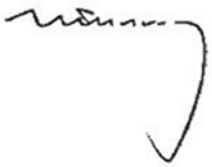
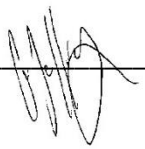
Medicine Protocol for the Administration of Influvac Tetra to adult vaccine recipients including nurses, midwives, healthcare workers, agency staff, contract workers and volunteers by registered nurses and registered midwives

This medicine protocol is a specific written instruction for the administration of Influvac Tetra to adult vaccine recipients including nurses, midwives, healthcare workers, agency staff, contract workers and volunteers (hereafter referred to as vaccine recipients) by registered nurses and registered midwives. This medicine protocol is valid for the 2023/2024 Health Service Executive (HSE) Seasonal Influenza Vaccination Programme (SIVP). This medicine protocol enables registered nurses and registered midwives employed in the voluntary and statutory services of the HSE who have undertaken the required education and training programmes to administer Influvac Tetra. This is with reference to and guidance from the Nursing & Midwifery Board of Ireland (NMBI), National Immunisation Advisory Committee (NIAC), National Immunisation Office (NIO) and in accordance with the Summary of Product Characteristics (SmPC) for Influvac Tetra available at www.hpra.ie.

- 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

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).

Medicine Protocol for the administration of Influvac Tetra to adult vaccine recipients

Document reference number:	ONMSD 2023- 001
1.0 Critical Elements	
Name of health service provider where medicine protocol applies	Health service providers across the voluntary and statutory services of the HSE. This medicine protocol applies to: • Registered nurses and registered midwives involved in the administration of the seasonal influenza vaccine to adult vaccine recipients.
Date the medicine protocol comes into effect	September 2023
Date for review of medicine protocol	May 2024
Document prepared by	ONMSD, HSE in collaboration with the NIO
Names and signatures of the employing authority who is authorising the implementation of the medicine 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 Eamonn Moore**, Director of National Health Protection Health Protection, HSE  Signature:_____ Name: **Dr Colm Henry**, Chief Clinical Officer, HSE  Signature: _____ Name: **Dr Grant Jeffrey** Director Workplace Health and Wellbeing Unit, HSE Signature:_____  Name: **Dr Geraldine Shaw**, Nursing and Midwifery Services Director, HSE Signature: _____ 

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 adult vaccine recipients against influenza virus for the 2023/2024 seasonal influenza vaccination programme.
Circumstances in which the medicine protocol applies	Targeted immunisation programme for adult vaccine recipients during the influenza season as they are at risk of influenza and of transmitting the influenza virus to vulnerable patients/people.
Inclusion criteria for adult vaccine recipients receiving seasonal influenza vaccine under medicine protocol	Active immunisation to prevent influenza infection caused by influenza virus, in adult vaccine recipients, especially those who have clinical contact with patients. This vaccine is licensed for use in those aged 6 months and over. 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. **Precautions:** <u>Egg anaphylaxis or egg allergy</u> 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.
Exclusion criteria for adult vaccine recipients receiving seasonal influenza vaccine under 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 $<0.5 \times 10^9$/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.
Actions to be taken for those who are excluded from receiving the vaccine under medicine protocol	• Refer to the Occupational Health Physician / Medical Practitioner as per local escalation process pathway for an individual medical assessment. Record action taken in the Covax system • Where Influvac Tetra is prescribed following medical assessment, the

	registered nurse or registered midwife may administer the vaccine within their scope of practice. **Note:** In determining their scope of practice, the registered nurse or registered midwife must make judgements about their competency to carry out a role or activity (NMBI, 2015).
Action to be followed for adult vaccine recipients who do not wish to receive the vaccine	Advise of the risks of not having the vaccine, including risk of transmission of influenza virus to vulnerable patients/people. Advise regarding minimisation of risk.
Description of circumstances and referral arrangements when further advice or consultation is required	Refer to/discuss with Occupational Health Physician/ Medical Practitioner if the adult 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 that consent has been obtained • Vaccine information leaflets • Patient held record cards • HPRA Adverse Reaction Reporting Forms • National Incident Management System Form NIRF-01-v12 available at: https://www.hse.ie/eng/about/who/nqpsd/qps-incident-management/nims/nirf-01-v12-person-interactive.pdf It is the responsibility of each registered nurse or registered midwife to be familiar with the appropriate documentation to support the safe administration of influenza vaccine which includes 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/ • NIO (2023) *Seasonal Influenza Vaccination Programme (SIVP) Supportive Information Document for HSE Vaccinators*
3.0 Name of medicine	Influvac Tetra
Dose & route of administration	0.5ml of vaccine, Intramuscular injection **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: • 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. • 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
Details of product information and other data including instructions for supply and administration is available at www.hpra.ie	Influvac Tetra, containing influenza virus of the following strains for 2023/2024 flu season: • an A/Victoria/4897/2022 (H1N1)pdm09-like virus;

Links to medicine	• an A/Darwin/9/2021 (H3N2)-like virus; • a B/Austria/1359417/2021 (B/Victoria lineage)-like virus; and • a B/Phuket/3073/2013 (B/Yamagata lineage)-like virus **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
Potential adverse reactions and procedures for treatment of same	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. The vaccine recipient should be advised to attend for appropriate medical care ie Emergency Department/GP for immediate assessment and treatment, if required. The vaccine recipient should be advised to report their reaction to the vaccine clinic.
Procedure for reporting adverse drug reactions to the HPRA	The registered nurse or registered midwife 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 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 vaccine recipient's GP should be informed of any reported adverse reaction. In the event of an 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 at: https://rcpi.access.preservica.com/uncategorized/IO_a36f9e4b-4c80-432d-8264-546089359925/
Procedure for the reporting and documentation of errors and near misses involving the medicine	In the case of medication errors that directly involve the adult vaccine recipient, i.e. wrong medication/dose/route being administered or another medication error, the registered nurse or registered midwife must remain with the vaccine recipient and closely monitor him/her for any adverse reactions. Vital signs should be recorded and the vaccine recipient should be monitored in the vaccine clinic or moved to an appropriate treatment location if necessary. The incident must be reported to the relevant line manager as soon as possible. The incident and all actions taken must be recorded and the relevant National Incident Management Report Form (NIRF) completed as soon as is practicable after the event https://www.hse.ie/eng/about/who/nqpsd/qps-incident management/nims/nirf-01-v12-person-interactive.pdf The vaccine recipient and/or significant others should be informed of the incident An incident report form must be completed by the registered nurse or registered midwife and forwarded to local or regional Risk Manager as per local policy. Any suspected adverse reactions associated with medication errors must be reported

	to the HPRA as outlined above.
Resources and equipment required	• Vaccine (pre-filled syringe) 0.5mls volume • Fridge/cool box with minimum/maximum temperature recording device to monitor the cold chain temperature between +2°C and +8°C • Disposable kidney dishes/trays • Gauze swabs, plasters, tape • Sharps bins, and bins for disposal of healthcare risk and non-risk waste (HSE, 2010) • Alcohol hand sanitizer • Access to telephone • Resuscitation equipment and drugs in accordance with 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/ • Safe storage areas for medicines and equipment
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.
4.0 Information for vaccine recipients	
Advice to be given to the vaccine recipient before treatment	**Vaccine information material must be supplied to the adult vaccine recipient prior to administration of the vaccine.** **Before vaccination** Discuss the influenza vaccine and the importance of protecting not only their own health but also the health of vulnerable patients/people Provide adult vaccine recipient with patient vaccine information material Discuss potential side effects Check for and ensure consent has been obtained **After vaccination** Discuss potential side effects.
Advice to be given to the adult vaccine recipient after treatment	The adult vaccine recipient should be advised to remain in the healthcare facility for fifteen minutes. The adult vaccine recipient should not leave the healthcare facility if they are feeling unwell and must report any unwanted side effects to the registered nurse or registered midwife who has administered the vaccine. **The adult vaccine recipient should be advised:** The following side effects may be experienced (see Summary of Product Characteristics): *Local:* Injection site pain and swelling are very common. *General:* Fever, fatigue, myalgia, and irritability in young children are very common. Drowsiness, sweating and arthralgia are common. *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. Paracetamol/Ibuprofen may be taken to relieve symptoms of fever or pain. If more serious adverse or persistent effects occur, adult vaccine recipient should be advised to contact their GP/out of hours service. This includes the very rare risk of GBS in the weeks after vaccination. Details of any serious adverse reaction to the vaccine should be forwarded to the medical practitioner or Occupational Health Physician (for recipient healthcare worker).
Details of any necessary follow-up, action and referral arrangements	In the event of an adverse reaction the registered nurse or registered midwife must ensure that all procedures are adhered to as outlined in Section 3.0.
4.0 Staff authorised to use this medicine protocol	
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 athttps://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 I

Signature Sheet

Name of Medicine Protocol: Medicine Protocol for the Administration of Influvac Tetra to adult vaccine recipients

I have read, understand & agree to adhere to this medicine protocol

Name	Signature	Occupation	NMBI PIN	Date

The above signed registered nurses/registered midwives are authorised by the signatories on page 2 to administer seasonal influenza vaccine in accordance with this medicine protocol.

Appendix II: Self-Assessment of Competency Form

NAME:_____

(PRINT CLEARLY in CAPITALS)

NMBI PIN

Self-Assessment of Competency to Administer Seasonal Influenza Vaccine under Medicine Protocol

	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 www.hseland.ie • AMRIC Hand Hygiene www.hseland.ie • GDPR Guidelines www.hseland.ie • 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 Framework 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:

_____ _____