Medicine Protocol for the administration of Influvac Tetra to vaccine recipients

This medicine protocol is a specific written instruction for the administration of Influvac Tetra by healthcare professionals included in Statutory Instruments S.I. No. 245 of 2021 and S.I. No. 511 of 2021 who are registered with their respective regulatory body and students in healthcare professionals included in S.I. No. 245 of 2021. This medicine protocol is valid for the 2022/2023 Health Service Executive (HSE) Seasonal Influenza Vaccination Programme. This medicine protocol enables the COVID-19 vaccinators listed in S.I. No. 245 of 2021 who have undertaken the required education and training programmes for their profession to administer Influvac Tetra to vaccine recipients. This is with reference to guidelines and guidance from the National Immunisation Advisory Committee (NIAC), National Immunisation Office (NIO), HSE and in accordance with the Summary of Product Characteristics for Influvac Tetra as detailed by the Health Products Regulatory Authority (HPRA).

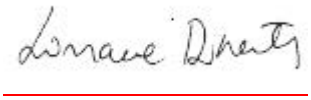
- National Immunisation Advisory Committee *Immunisation Guidelines for Ireland* Dublin: Royal College of Physicians Ireland *(Online Update available at* http://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/*)*

- Summary of Product Characteristics available at https://www.hpra.ie/img/uploaded/swedocuments/Licence_PA2010-053-002_03082022111533.pdf

A medicine protocol has been defined 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).

A medicine protocol is a nationally approved prescription for the supply and administration of a medicine as per above definition. The HSE Chief Clinical Officer and National Clinical Director Health Protection have approved the use of medicine protocols by healthcare professionals listed in S.I. No. 245 and 511 of 2021. The HSE NIO has developed this medicine protocol to facilitate the delivery of HSE seasonal influenza vaccination programme 2022/2023 by this group in line with NIAC recommendations, Department of Health (DoH) and HSE policy.

Medicine Protocol for the Administration of Influvac Tetra to vaccine recipients

Document reference number:	NIO 2022
1.0 Critical Elements	
Name of Organisation where medicine protocol applies	Health Service Providers across the voluntary and statutory services of the Health Service Executive (HSE), non-HSE healthcare facilities and mass vaccination clinic venues. This Medicine Protocol applies to: Healthcare professionals and students in healthcare professionals included in S.I. No 245 of 2021 employed as Covid vaccinators who have undertaken the required education and training programmes.
Date the medicine protocol comes into effect	October 2022 (from October 2022 to April 2023)
Document prepared by:	The National Immunisation Office (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. Lorraine Doherty**, National Clinical Director Health Protection, HSE Signature:  Name: **Dr Colm Henry**, Chief Clinical Officer, 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 vaccine recipients against influenza virus for the 2022/2023 seasonal influenza vaccination programme.
Circumstances in which the medicine protocol applies	Targeted immunisation programme for vaccine recipients during the influenza season as they are at risk of influenza and of transmitting the influenza virus to vulnerable people in the community.
Inclusion criteria for vaccine recipients receiving Influvac Tetra under this medicine protocol	Active immunisation to prevent influenza infection caused by influenza virus, in adults, including pregnant women, and children from 6 months of age and older. 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 given in different limbs. **Precautions:** <u>Egg anaphylaxis or egg allergy:</u> Influvac Tetra contains Ovalbumin equal to or less than 0.1 micrograms per dose NIAC advises that those with confirmed egg anaphylaxis or egg allergy can be given influenza vaccine in a community setting with the exception of 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. 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.
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. 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 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 $<0.5 \times 10^9$/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 2022/2023 influenza season. If Influvac Tetra is used for children aged 12-23 months of age, it should be separated from Pneumococcal Conjugate Vaccine (PCV) by at least 1 week

Actions to be taken for those who are excluded from the medicine protocol	● Refer to / discuss with Medical Practitioner for an individual medical assessment ● Record action taken in the Covax system ● Where Influvac Tetra, is prescribed following medical assessment, the vaccinator may administer Influvac 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 influenza virus to others.
Description of circumstances and referral arrangements when further advice or consultation is required	Refer to/discuss with relevant Medical Practitioner /clinical lead/ lead vaccinator 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 • Vaccine Information Leaflets • Patient held record cards • Health Products Regulatory Authority 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 • Seasonal Influenza Vaccination Programme Operational Guidelines • Practice protocol for students It is the responsibility of each vaccinator to be familiar with the appropriate documentation to support the safe administration of influenza vaccine which includes the following: • Medicine Protocol for the administration of Influvac Tetra to vaccine recipients • National Immunisation Advisory Committee (2022) *Anaphylaxis: Immediate Management in the Community*
3.0 Name of Medicine	Influvac Tetra
Dose & 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) Children aged 6-23 months in clinical risk groups who are receiving the vaccine for the first time or vaccination history is unknown 2) Children aged 2-8 years old in whom the nasal flu vaccine is contraindicated and are receiving any influenza vaccine for the first time or vaccination history is unknown 3) Those aged 9 years and over if receiving vaccine for the first time post haematopoeitic stem cell or solid organ transplant 4) 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.

Link to Medicine **Details of product information and other data including instructions for supply and administration is available on the HPRA website at www.hpra.ie**	Influvac Tetra, containing influenza virus of the following strains for 2022/2023 flu season: • A/Victoria/2570/2019 (H1N1)pdm09 - like strain (A/Victoria/2570/2019, IVR-215) • A/Darwin/9/2021 (H3N2) - like strain (A/Darwin/9/2021, IVR-228) • B/Austria/1359417/2021 - like strain (B/Michigan/01/2021, wild type) • B/Phuket/3073/2013 - like strain (B/Phuket/3073/2013, wild type) **Link to Summary of Product Characteristics here** **https://www.hpra.ie/img/uploaded/swedocuments/Licence_PA2010-053-002_03082022111533.pdf** **Link to Patient Information Leaflet here:** **https://www.hpra.ie/img/uploaded/swedocuments/be1e51bc-5bc5-43e2-8749-22618b549f9d.pdf**
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 contact relevant medical personnel in the event of adverse reaction occurring following administration of the vaccine (GP/out of hours/Emergency Department/Occupational Health Department) after the above period of observation.
Procedure for reporting Adverse Drug Reactions to the 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 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 General Practitioner should be informed of any reported adverse reaction. • The incident and all actions taken must be promptly recorded in accordance with the National Immunisation Advisory Committee (2022) *Anaphylaxis: Immediate Management in the Community* 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 vaccine recipient, i.e. wrong medication/patient/dose/route being administered or another medication error, the vaccinator must remain with the vaccine recipient and closely monitor them for any adverse reactions. Vital signs should be recorded and the vaccine recipient should be reviewed by the

	vaccinator/relevant medical practitioner/clinical lead/ lead vaccinator The incident must be reported to the relevant line manager as soon as possible. The incident and all actions taken must be promptly recorded and the relevant National Incident Management Report Form completed: https://www.hse.ie/eng/about/who/nqpsd/qps-incident-management/nims/nirf-01-v12-person-interactive.pdf Any suspected adverse reactions associated with medicine errors should be reported to the HPRA as outlined above.
Resources and equipment required	● Vaccine (pre-filled syringe 0.5 mls volume) ● Fridge/Cooler box 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 ● Access to telephone ● Resuscitation equipment and drugs in accordance with National Immunisation Advisory Committee (2022) *Anaphylaxis: Immediate Management in the Community* available online at https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/anaphylaxis.pdf ● Safe storage areas for medicines and equipment ● Current medicine protocol for Influvac 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.
4.0 **Information for vaccine recipients**	
Advice to be given to the vaccine recipient before 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

Advice to be given to the recipient after treatment	**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 vaccinator who has administered the vaccine. **The vaccine recipient may be advised:** The following side effects may be experienced (see Summary of Product Characteristics): **Very common (may affect more than 1 in 10 people):** Local: Injection site pain and swelling. General: Fever, fatigue, myalgia, and irritability in young children. **Common (may affect up to 1 in 10 people):** Drowsiness, sweating and arthralgia. **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, vaccine recipient should be advised to contact their GP/out of hours service. This includes the very rare risk of Guillain-Barré syndrome (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 vaccination team ensure that all procedures are adhered to as outlined in Section 3.

References

An Bord Altranais (2007) *Guidance to Nurses and Midwives on Medication Management* Dublin: An Bord Altranais

Government of Ireland (2021) *Statutory Instruments Number 245 of 2021*. Dublin: Stationery Office

Government of Ireland (2021) *Statutory Instruments Number 511 of 2021*. Dublin: Stationery Office

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 (2022) *Anaphylaxis: Immediate Management in the Community* available online at https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/anaphylaxis.pdf

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/