Medicine Protocol for the administration of Tetravac (Diphtheria, Tetanus, Pertussis and Poliomyelitis) vaccine (adsorbed), by registered nurses and registered midwives to children/students in primary/ school through a School Immunisation Programme

This medicine protocol is a specific written instruction for the administration of Tetravac DTaP/IPV (diphtheria, tetanus, pertussis and poliomyelitis) vaccine (adsorbed), to children in primary school by registered nurses and registered midwives. This medicine protocol is valid for the 2024/2025 Health Service Executive (HSE) Schools Immunisation Programme (SIP).

This medicine protocol enables registered nurses and midwives employed in the voluntary and statutory services of the HSE who have undertaken the required education and training programmes to administer Tetravac vaccine, with reference to and guidance from Nursing & Midwifery Board of Ireland (NMBI), National Nursing and Midwifery Immunisation Group, National Immunisation Advisory Committee (NIAC), National Immunisation Office (NIO), HSE and in accordance with the Summary of Product Characteristics (SmPC) for Tetravac vaccine as detailed by the Health Products Regulatory Authority (HPRA) at www.hpra.ie

- 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 (2023): Royal College of Physicians of Ireland National Immunisation Advisory Committee available at: https://www.rcpi.ie/Healthcare-Leadership/NIAC/Immunisation-Guidelines-for-Ireland

- National Immunisation Office (2024/2025) *Supporting Information for Staff*: Schools Immunisation Programme**:** https://www.hse.ie/eng/health/immunisation/hcpinfo/schoolproghcp/supportingdoc.pdf

- 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: https://www.nmbi.ie/NMBI/media/NMBI/Code-of-Professional-Conduct-and-Ethics.pdf

- Nursing and Midwifery Board of Ireland (2020) *Guidance for Registered Nurses and Midwives on Medication Administration* available at: https://www.nmbi.ie/NMBI/media/NMBI/NMBI-Medication-Administration-2020.pdf?ext=.pdf

- Nursing and Midwifery Board of Ireland (2022) *Practice Standards for Midwives.* Dublin: Nursing and Midwifery Board of Ireland available at:
- https://www.nmbi.ie/Standards/Guidance/MidwivesStandards

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- Nursing and Midwifery Board of Ireland (2015) *Recording Clinical Practice. Guidance to Nurses and Midwives.* Dublin: Nursing and Midwifery Board of Ireland available at: https://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: https://www.nmbi.ie/nmbi/media/NMBI/Publications/Scope-of-Nursing-Midwifery-Practice-Framework.pdf?ext=.pdf.

The Nursing and Midwifery Board of Ireland 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, pg35, 2007)

Medicine Protocol for the administration of Tetravac (Diphtheria, Tetanus, Pertussis and Poliomyelitis) vaccine (adsorbed), by registered nurses and registered midwives to children/students in primary school through a School Immunisation Programme

Document reference number	**ONMSD 2024-003**
1.0 Critical Elements	
Name of Organisation where protocol applies	Health Service Providers across the voluntary and statutory services of the HSE. This Medicine Protocol applies to: Registered nurses and midwives involved in the supply and administration of the Tetravac vaccine to children/students in primary school through a SIP.
Date the protocol comes into effect	September 2024 (For the school year September 2024 - September2025)
Date for review of protocol	May 2025
Document prepared by	Office of the Nursing and Midwifery Services Director (ONMSD) HSE, in collaboration with the NIO at the request of Dr Éamonn O'Moore, Director of National Health Protection, HSE
Names and Signatures 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 medicine protocol and authorise its implementation"**	Name: **Dr Éamonn O' Moore**, Director of National Health Protection, HSE Signature: Dr Éamonn O'Moore (Jul 19, 2024 10:03 GMT+1) Name: **Dr Colm Henry**, Chief Clinical Officer, HSE Signature: _____ Name: **Dr Geraldine Shaw**, Nursing and Midwifery Services Director, HSE Signature: _____

2.0 Clinical Criteria	
Clinical condition for use of the protocol	The clinical condition for which this medicine protocol has been developed is for the active immunisation against and prevention of diphtheria, tetanus, pertussis (whooping cough) and poliomyelitis (polio) disease. Tetravac is administered as a booster vaccination to children who have previously received DTaP/IPV containing vaccines in the primary childhood immunisation schedule.
Circumstances in which the medicine protocol applies	The SIP will be delivered annually by the HSE. The aim of the immunisation programme is to provide a booster dose of diphtheria, tetanus, pertussis (acellular, component) and poliomyelitis (inactivated) vaccine (adsorbed), vaccine to children who previously completed primary vaccination against these diseases as recommended in the Immunisation Guidelines for Ireland https://www.rcpi.ie/Healthcare-Leadership/NIAC/Immunisation-Guidelines-for-Ireland
Inclusion criteria for children/students treatment using the medicine protocol	All children in primary school usually delivered in junior infants and age equivalent in e.g. special schools and home schooled students. https://www.hse.ie/eng/health/immunisation/hcpinfo/schoolproghcp/ • Children with valid consent. • Students with valid consent given and missed the opportunity to attend the vaccination clinic due to illness or other personal circumstances.
Exclusion criteria children/students using the medicine protocol	• Children who have not commenced primary immunisation course. • Note: Children who have commenced their primary 6 in1 vaccines but not completed the schedule can receive Tetravac in school at the correct interval to primary doses. So they can catch up on the schedule after the Tetravac vaccine. • Anaphylaxis to any of the vaccine constituents. **Precautions** • Acute severe febrile illness, defer until recovery. • Type III (Arthus) hypersensitivity reaction to a previous dose (see adverse reactions in NIAC chapter 6 and 21). Persons experiencing these reactions usually have very high serum diphtheria or tetanus antitoxin levels; they should not be given further routine or emergency booster doses of tetanus or diphtheria containing vaccines more frequently than every 10 years. **Note:** COVID-19 vaccines (except for COVID-19 vaccine given to children aged 6 months-4 years when a 14 day interval is recommended
Actions to be taken for those who are excluded from the Protocol	• All children meeting exclusion criteria must be referred to the medical practitioner for an individual medical assessment. • Document action in clinical notes • Where Tetravac vaccine is prescribed following medical assessment, the nurse or midwife may administer Tetravac vaccine within their scope of practice. • **Note:** In determining their scope of practice, nurses and midwives must make judgements about their competency to carry out a role or activity (NMBI, 2015).

Description of circumstances and referral arrangements when further advice or consultation is required	Discuss the student with the Medical Practitioner or lead nurse in the event of: • Confirmed or suspected anaphylactic reaction to the vaccine itself or to a constituent of that vaccine and/or other clinical concerns.
Documentation required for the implementation of this medicine protocol	A consent form must be completed by the parent /legal guardian for all children who receive the Tetravac vaccine. Relevant details including the batch number must be recorded on the consent form. The following documents will be required at each school vaccination session: • Vaccination session form • Blank Vaccine consent forms • Vaccine information leaflets • Patient held record cards/vaccine passports • HPRA adverse reaction reporting forms • HSE Incident/Near Miss report forms • Tear pads for after vaccination and advise It is the responsibility of each nurse or midwife to be familiar with the appropriate documentation to support the safe administration of Tetravac vaccine which includes the following: • Supporting information for Staff: School Immunisation Programme 2024/2025 • Medicine Protocol for the administration of Tetravac • NIAC (2023) Anaphylaxis: *Immediate Management in the Community* https://rcpi.access.preservica.com/uncategorized/IO_a36f9e4b-4c80-432d-8264-546089359925/

3.0 Name of Medicine	Tetravac **Dose:** 0.5ml **Route:** Intramuscular injection **Site:** Deltoid (left arm recommended)
Link to Medicine **Details of product information and other data including instructions for supply and administration is available from the HPRA at www.hpra.ie**	**Link to Summary of Product Characteristics** http://www.hpra.ie/img/uploaded/vaccines/SPC_PA2131009001.pdf **Link to Patient Information Leaflet:** http://www.hpra.ie/img/uploaded/vaccines/PIL_PA2131009001.pdf
Procedure for the reporting and documentation of errors and near misses involving the medication	In the case of medicine errors that directly involve the child/student, i.e. wrong medicine/patient/dose/route being administered or another medicine error, the registered nurse or registered midwife must remain with the child and closely monitor them for any adverse reactions. Vital signs should be recorded and the student should be reviewed by the registered nurse/midwife and/ or medical practitioner. The incident must be reported to the relevant line manager as soon as possible. The incident and all actions taken must be promptly recorded in the child's/student's documentation/notes and the relevant incident report form completed. https://www.hse.ie/eng/about/who/nqpsd/qps-incident-management/nims/nirf-01-v12-person-interactive.pdf The child/student parent and/or legal guardian must be informed of the incident. Any suspected adverse reactions associated with medication errors should be reported to the HPRA as outlined below Any errors and near misses not involving medications (Needle stick injuries etc.), the incident and all actions taken must be promptly recorded on the relevant national incident management report form and forwarded to the relevant line manager as per local policy Refer 'EMI Tool Kit' (https: //www.hpsc.ie/a-z/EMIToolkit/).
Procedure for reporting Adverse Drug Reactions to the Health Products Regulatory Authority (HPRA)	The relevant nursing or midwifery staff should report to the HPRA any suspected adverse reactions, in accordance with criteria outlined by the HPRA. This reporting may be carried out online at https://www.hpra.ie or through the use of the yellow card system which is available in the downloadable format from the HPRA website, or on the request from the HPRA.

Resources and equipment required	• Tetravac Vaccine (pre-filled syringe) • Fridge/Cool box with minimum/maximum temperature recording device to monitor the cold chain temperature (between +2°C and +8°C) • Vaccination cool packs • Disposable kidney dishes/coloured trays • Gauze swabs/Plasters • Sharps bins, and bags for disposal of healthcare risk and non-risk waste • HSE Policy on the Management of Sharps and Prevention of Sharp Injuries (2022). https://healthservice.hse.ie/filelibrary/staff/policy-on-the-management-of-sharps-and-prevention-of-sharp-injuries.pdf • Alcohol hand sanitizer • Face masks(if required) • Access to telephone • Resuscitation equipment and drugs in accordance with the NIAC (2023) Anaphylaxis: *Immediate Management in the Community* https://rcpi.access.preservica.com/uncategorized/IO_a36f9e4b-4c80-432d-8264-546089359925/ Access to medical support • Safe storage areas for medicines and equipment • Current medicine protocol for Tetravac Vaccine.
Audit process to identify appropriate use of the protocol or unexpected outcomes	All documentation will be held for review and audit purposes as per local policy.

4.0 Information for child/student/parent/legal guardian	
Advice to be given to the child/student/parent / legal guardian before treatment	The HSE 4 in 1 and MMR vaccine Information for parents of children in Junior infant's booklet must have been supplied with the consent form to each parent/legal guardian prior to administration of the Tetravac (DTaP/IPV) vaccine.
Advice to be given to the child/student/parent / legal guardian after treatment	**After Treatment** An Information Tear Pad, stating date and time of vaccination must be given to all students for parental/legal guardian's attention. The Tear Pad includes advice about contacting relevant medical personnel in the event of adverse reaction occurring following administration of the vaccination. The child/student must be advised to remain seated in the post vaccination observation area for 15 minutes to allow monitoring of any immediate reaction including possible anaphylactic reaction and must be advised to report any side effects to the registered nurse or registered midwife who is present.
Details of any necessary follow-up, action and referral arrangements	In the event of an adverse reaction the nurse/midwife must ensure that all procedures are adhered to as outlined in Section 3.

5.0 Staff authorised to use this medicine protocol	
Professional qualifications, training, and competence required prior to using this medicine protocol	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 nurses and midwives on *Schools Immunisation Programme* 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 www.HSELanD.ie. 5. Immunisation Foundation Programme, available on www.HSELanD.ie. Note: The Immunisation Foundation Programme will be replaced with Primary Childhood Immunisation Programme (PCIP) accessible on www.HSELanD.ie 6. *Critically examining the evidence and practice of holding children for clinical procedures* (masterclass recording-6th Dec 2022) available at www.HSELanD.ie. The registered nurse/midwife must complete the Competency Self-Assessment Form available at www.immunisation.ie

References

GlaxoSmithKline, Ireland Limited Boostrix *Summary of Product Characteristics and Patient Information Leaflet,* available at: www.hpra.ie

Health Products Regulatory Authority available at: www.hpra.ie

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