Medicine Protocol for the Administration of Boostrix (Diphtheria, tetanus and pertussis (acellular, component) vaccine (adsorbed, reduced antigen(s) content) by registered nurses and registered midwives to Refugees and Applicants Seeking Protection in Ireland and in the event of an outbreak

This medicine protocol is a specific written instruction for the administration of Boostrix to Refugees and Applicants Seeking Protection in Ireland (hereafter referred to as vaccine recipients) and in the event of an outbreak as advised by public health by registered nurses and registered midwives. This medicine protocol is valid for the 2023/2024 Health Service Executive (HSE), Schools Immunisation Programme (SIP) and National Immunisation Advisory Committee (NIAC) catch up Immunisation Programme and in the event of an outbreak as advised by public health.
This medicine protocol enables registered nurses and registered midwives employed in the voluntary and statutory services of the HSE including Mass vaccination clinics who have undertaken the required education and training programmes to administer Boostrix with reference to and guidance from Nursing & Midwifery Board of Ireland (NMBI) , National Immunisation Advisory Committee (NIAC), National Immunisation Office (NIO), HSE and in accordance with the Summary of Product Characteristics (SmPC) for Boostrix as detailed by the Health Products Regulatory Authority (HPRA) at www.hpra.ie

- 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*: 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 (2023/2024) *Supporting Information for Staff: Schools Immunisation Programme* available at: https://www.hse.ie/eng/health/immunisation/hcpinfo/schoolproghcp/supportingdoc.pdf
- National Immunisation Office (2023) Clinical information to support healthcare staff to deliver catch-up vaccination for Refugees and Applicants Seeking Protection in Ireland and in the event of an outbreak available at: https://www.hse.ie/eng/health/immunisation/hcpinfo/botpipa/clinicalinfobotpipa.pdf
- National Immunisation Office (2022) *Supporting Information for Vaccinations in General Practice* available at: https://www.hse.ie/eng/health/immunisation/infomaterials/gpsupportingdocpci.pdf
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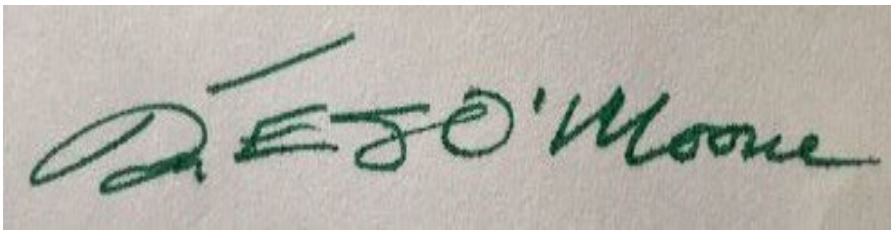
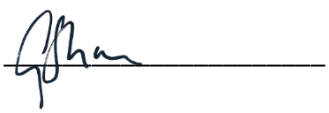
- Nursing and Midwifery Board of Ireland (2015) *Scope of Nursing and Midwifery Practice Framework.* Dublin: Nursing and Midwifery Board of Ireland available at: https://www.nmbi.ie/StandardsGuidance/Scope-of-Practice/Nursing-Practise-Scope-Definition

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, 2007).

Medicine Protocol for the Administration of Boostrix (Diphtheria, tetanus and pertussis (acellular, component) vaccine (adsorbed, reduced antigen(s) content) by registered nurses and registered midwives to Refugees and Applicants Seeking Protection in Ireland and in the event of an outbreak

Document reference number	NIO 2023
1.0 Critical Elements	
Name of Organisation where medicine protocol applies	Health Service Providers/Mass vaccination clinics across the voluntary and statutory services of the HSE. This Medicine Protocol applies to: • registered nurses and registered midwives employed in the voluntary and statutory services of the HSE including Mass vaccination clinics, congregated settings, temporary clinics and mobile units
Date the medicine protocol comes into effect	December 2023
Date for review of medicine protocol	December 2024
Document prepared by	National Immunisation Office (NIO) in collaboration with the Office of the Nursing and Midwifery Services Director (ONMSD) 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. Eamonn O 'Moore** Director of National Health Protection Signature:  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 medicine protocol	The clinical condition for which this medicine protocol has been developed is for the active immunisation against and prevention of tetanus, diphtheria, and pertussis disease.
Circumstances in which the medicine protocol applies	To provide a Boostrix (Tdap vaccine) to Refugees and Applicants Seeking Protection in Ireland (hereafter referred to as vaccine recipients), or in the event of an outbreak as advised by public health.
Inclusion criteria for vaccine recipient of Boostrix (Diphtheria, tetanus and pertussis (acellular, component) under this medicine protocol	A booster dose of Boostrix (Tdap vaccine) should be given to children aged 11-14 years (usually given to students in 1st year of second level school and age equivalent in special schools and home schooled students). **<u>Catch up vaccination</u>** **Tdap/IPV (IPV Boostrix) vaccine is no longer available in Ireland.** Therefore NIAC have issued new guidelines for catch-up vaccination. For people aged 14 years and older the following vaccines are now recommended: a) First give a **Boostrix** (**Tdap vaccine) x1** b) followed by Revaxis (Td/IPV) x 3 at ≥28 days intervals (Leave ≥28 days interval after Boostrix (Tdap vaccine)) **<u>Outbreak vaccination</u>**

	Vaccination as advised by public health **Precautions** • Acute febrile illness, defer until recovery • Type III (Arthus) hypersensitivity reaction to a previous dose (see adverse reactions in NIAC chapter 6). 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 where a 14-day interval is recommended) and other vaccines may be administered at the same time or at any interval.
Exclusion criteria for vaccine recipient of Boostrix (Diphtheria, tetanus and pertussis (acellular, component) under this medicine protocol	A known history of anaphylactic or hypersensitivity reaction to Boostrix (Tdap Vaccine) or to any of the Boostrix (Tdap vaccine) constituents.
Actions to be taken for those who are excluded from this medicine protocol	All recipients meeting exclusion criteria must be referred to the medical practitioner for an individual medical assessment. • Document action in clinical notes. • Where Boostrix (Tdap vaccine) is prescribed following medical assessment, the nurse or midwife may administer Boostrix (Tdap vaccine) within their scope of practice. **Note**: In determining their scope of practice, nurses and midwives must make judgements about their competence to carry out a role or activity (NMBI, 2015).
Description of circumstances and referral arrangements when further advice or consultation is required	Discuss the vaccine recipient with the Medical Practitioner in the event of: • Previous adverse reaction • Other clinical concerns
Documentation required for the implementation of this medicine protocol	A consent form must be completed by the parent /legal guardian for children who receive the Boostrix (Tdap vaccine) vaccine, once understood and translation of consent is undertaken with support of translator if required. Relevant details including the batch number must be recorded on the consent form. The following documents will be required at each vaccination session: • Vaccination session form • Blank vaccine consent forms • Vaccine Information Leaflets • Patient held record cards /Vaccine passport • HPRA Adverse Reaction Reporting forms • HSE Incident/Near Miss report forms • Post vaccination advice It is the responsibility of each registered nurse or midwife to be familiar with the appropriate documentation to support the safe administration of Boostrix (Tdap vaccine) vaccine which includes the following: • Medicine Protocol for the Administration of Boostrix (Diphtheria, tetanus and pertussis (acellular, component) vaccine (adsorbed, reduced antigen(s) content)

	by registered nurses and registered midwives to Refugees and Applicants Seeking Protection in Ireland and in the event of an outbreak. NIAC (2023) *Anaphylaxis: Immediate Management in the Community* available at: https://rcpi.access.preservica.com/uncategorized/IO_a36f9e4b-4c80-432d-8264-546089359925/
3.0 Name of Medicine	Boostrix (Tdap vaccine) **Dose:** 0.5ml **Route:** Intramuscular injection **Site:** Deltoid muscle (right 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_PA1077020001.pdf **Link to Patient Information Leaflet:** https://www.hpra.ie/img/uploaded/vaccines/PIL_PA1077020001.pdf
Procedure for the reporting and documentation of errors and near misses involving the medicine	In the case of medicine errors that directly involve the vaccine recipient, i.e. wrong medicine/patient/dose/route being administered or another medicine error, the registered nurse or registered midwife 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 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 recipient's documentation/notes 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 For children, the child's parent and/or legal guardian must be informed of the incident. Any suspected adverse reactions associated with medicine 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 to 'EMI Tool Kit' (https: //www.hpsc.ie/a-z/EMIToolkit/).

Procedure for reporting Adverse Drug Reactions to the 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 use of the yellow card system which is available in the downloadable format from the HPRA website or on request from the HPRA.
Resources and equipment required for the administration of Boostrix Diphtheria, tetanus and pertussis (acellular, component) vaccine	• Boostrix vaccine • Fridge/cool box with minimum/maximum temperature recording device to monitor the cold chain temperature (between +2°C and +8°C) • Disposable kidney dishes/coloured trays and covering • Gauze swabs/Plasters • Sharps bins and bags for disposal of healthcare risk and non-risk waste material • Face mask (as per local guideline) • Alcohol hand sanitizer • Access to telephone • Resuscitation equipment and drugs in accordance with the NIAC (2023) *Anaphylaxis: Immediate Management in the Community* available at: 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 Boostrix 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 the vaccine recipient/parent/guardian	
Advice to be given to vaccine recipient/parent/ guardian before treatment	Reiterate the information provided in the HSE patient information leaflet for the vaccine in the appropriate language and translator support if required. For children, Patient Information Leaflet/Fact Sheet **must** be supplied with the consent form to each parent/legal guardian prior to administration of the vaccine as above.
Advice to be given to vaccine recipient/parent/ guardian after treatment	**After Treatment** The vaccine recipient 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) Immunisation Foundation Programme* accessible on www.HSELanD.ie 3) Education programme for nurses and midwives on *Primary Childhood Immunisation Programme* and any updates for nurses and midwives accessible on www.HSELanD.ie 4) Education programme for nurses and midwives on *Schools Immunisation Programme* and any updates for nurses and midwives accessible on www.HSELanD.ie 5) NIO education programme on *Catch up vaccination for Refugees and Applicants Seeking Protection in Ireland* accessible on www.HSELanD.ie 6) An approved *Basic Life Support for Health Care Providers Course* within the last two years (i.e. Irish Heart Foundation (IHF)) 7) 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 8) The registered nurse/midwife must complete the Competency Self-Assessment Form to vaccinate* Refugees and Applicants Seeking Protection in Ireland *Health Service Executive (HSE) Primary Childhood Immunisation Programme (PCIP), Schools Immunisation Programmes (SIP) and the National Immunisation Advisory Committee (NIAC) Catch Up Immunisation Programme available at www.immunisation.ie

References

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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

National Clinical Guideline No. 30 (2023) – Infection Prevention and Control (IPC) https://www.gov.ie/en/publication/a057e-infection-prevention-and-control-ipc/.

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