Medicine Protocol for the Administration of IPV Boostrix (Diphtheria, Tetanus, Pertussis and Poliomyelitis) vaccine (adsorbed, reduced antigen(s) content) by registered nurses and registered midwives to people seeking international protection in Ireland from the war in Ukraine

This medicine protocol is a specific written instruction for the administration of IPV Boostrix, to people seeking international protection in Ireland from the war in Ukraine (hereafter referred to as vaccine recipients) by registered nurses and registered midwives. This medicine protocol is valid for the 2022/2023 Health Service Executive (HSE) Primary Childhood Immunisation Programme (PCIP), Schools Immunisation Programme (SIP) and National Immunisation Advisory Committee (NIAC) catch up Immunisation Programme.

This medicine protocol enables registered nurses and registered midwives employed in the voluntary and statutory services of the HSE and registered nurse and midwife COVID-19 vaccinators enabled under Statutory Instruments (S.I. No. XXXX of 2022) who have undertaken the required education and training programmes to administer IPV Boostrix, with reference to and guidance from Nursing & Midwifery Board of Ireland (NMBI), National Immunisation Working Group, National Immunisation Advisory Committee (NIAC), National Immunisation Office (NIO), HSE and in accordance with the Summary of Product Characteristics (SmPC) for IPV Boostrix vaccine 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 (2022) *Anaphylaxis: Immediate Management in the Community* available at: https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/anaphylaxis.pdf
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- National Immunisation Office (2022/2023) *Supporting Information for Staff: Schools Immunisation Programme* available at: https://www.hse.ie/eng/health/immunisation/pubinfo/schoolprog/suppinfo4staff.docx
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- 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 (2015) *Practice Standards for Midwives.* Dublin: Nursing and Midwifery Board of Ireland available at: https://www.nmbi.ie/Standards-Guidance/MidwivesStandards
- 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/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 medicine protocol is in effect" (An Bord Altranais, 2007).

Medicine Protocol for the Administration of IPV Boostrix (Diphtheria, Tetanus, Pertussis and Poliomyelitis) vaccine (adsorbed, reduced antigen(s) content) by registered nurses and registered midwives to people seeking international protection in Ireland from the war in Ukraine

Document reference number	NIO 2022.8
1.0 Critical Elements	
Name of Organisation where protocol applies	Health Service Providers/COVID-19 Central Vaccination Centres (CVCs) 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 and registered nurse and midwife COVID-19 vaccinators enabled under Statutory Instruments (S.I. No. XXXX of 2022)
Date the protocol comes into effect	April 2022
Date for review of protocol	April 2023
Document prepared by	HSE National Immunisation Office in collaboration with the Office of the Nursing and Midwifery Services Director 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. Lorraine Doherty**, National Clinical Director Health Protection, HSE 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 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.
Circumstances in which the medicine protocol applies	To provide an IPV Boostrix to people seeking international protection in Ireland from the war in Ukraine (hereafter referred to as vaccine recipients).
Inclusion criteria for vaccine recipients using the medicine protocol	For catch-up vaccine in those aged 10 years and above with no history or receipt of these antigens previously. For those aged 10 years and older IPV Boostrix can be given at any interval following a Td (Tetanus and diphtheria) containing vaccine.
Exclusion criteria for vaccine recipients using the medicine protocol	• A known history of anaphylactic or hypersensitivity reaction to IPV Boostrix or any of the vaccine's 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). 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.
Actions to be taken for those who are excluded from the Protocol	All vaccine recipients meeting exclusion criteria must be referred to the medical practitioner for an individual medical assessment. • Document action in clinical notes • Where IPV Boostrix is prescribed following medical assessment, the nurse or midwife may administer IPV Boostrix 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 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 all children who receive the IPV Boostrix vaccine. Children aged 16 years and over consent on their own behalf, once understood and translation of consent is undertaken with support of translator if required. Appropriate details including the batch number must be recorded on the consent form. The following documents will be required at each vaccination session: • Vaccination session report 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 IPV Boostrix which includes the following: • Medicine Protocol for the administration of IPV Boostrix (Diphtheria, Tetanus, Pertussis and Poliomyelitis) vaccine (adsorbed, reduced antigen(s) content) by registered nurses and midwives to people seeking international protection in Ireland from the war in Ukraine • NIAC (2022) *Anaphylaxis: Immediate Management in the Community* available at: https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/anaphylaxis.pdf
3.0 Name of Medicine	IPV Boostrix **Dose:** 0.5ml **Route:** Intramuscular injection **Site:** Deltoid muscle (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:** **https://www.hpra.ie/img/uploaded/swedocuments/Licence_PA1077-101-001_16112020162047.pdf** **Link to Patient Information Leaflet:** **https://www.hpra.ie/img/uploaded/vaccines/pil_pa1077101001.pdf**
Procedure for the reporting and documentation of errors and near misses involving the medication	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 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 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 medication e.g. needle stick injuries, 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 the 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	• IPV 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 • Gauze swabs/Plasters • Sharps bins, and bags for disposal of healthcare risk and non-risk waste material • Alcohol hand sanitiser • Face masks • Access to telephone • Resuscitation equipment and drugs in accordance with the NIAC (2022) *Anaphylaxis: Immediate Management in the Community* available at: https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/Anaphylaxis.pdf • Access to medical support • Safe storage areas for medicines and equipment • Current medicine protocol for IPV 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 vaccine recipient/parent/legal guardian	
Advice to be given to the vaccine recipient 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 the vaccine recipient 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 people who have come to Ireland from Ukraine* 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 people seeking international protection in Ireland from the war in Ukraine available at www.immunisation.ie

References

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