Medicine Protocol for the Administration of Infanrix Hexa (Diphtheria (D), tetanus (T), pertussis (acellular, component) (Pa), hepatitis B (rDNA) (HBV), poliomyelitis (inactivated) (IPV) and Haemophilus influenzae type b (Hib) conjugate vaccine (adsorbed).) 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 Infanrix Hexa (6 in 1 vaccine), to Refugees and Applicants Seeking Protection in Ireland (hereafter referred to as vaccine recipients) and in the event of an outbreak by registered nurses and registered midwives. This medicine protocol is valid for the 2024/2025 Health Service Executive (HSE) Primary Childhood Immunisation Programme (PCIP), for National Immunisation Advisory Committee (NIAC) recommended catch up immunisation 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 HSE community vaccination clinics who have undertaken the required education and training programmes to administer Infanrix Hexa (6 in 1 vaccine), 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 Infanrix Hexa (6 in 1 vaccine) as detailed by the European Medicines Agency (EMA) at www.ema.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*: 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* available at: https://www.hse.ie/eng/health/immunisation/hcpinfo/schoolproghcp/supportingdoc.pdf
- National Immunisation Office (2024) 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 (2024) *Supporting Information for Vaccinations in General Practice* available at: https://www.hse.ie/eng/health/immunisation/infomaterials/gpsupportingdocpci.pdf
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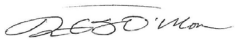
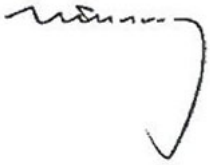
- Nursing and Midwifery Board of Ireland (2020) *Guidance for Registered Nurses and Midwives on Medication Administration* available at: https://www.nmbi.ie/NMBI/media/NMBI/NMBI-Medication-Administration-2020.pdf?ext=.pdf
- Nursing and Midwifery Board of Ireland (2022) *Practice Standards for Midwives.* Dublin: Nursing and Midwifery Board of Ireland available at:https://www.nmbi.ie/NMBI/media/NMBI/NMBI-Practice-Standards-for-Midwives.pdf?ext=.pdf
- 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/nmbi/media/NMBI/Publications/recording-clinical-practice-professional-guidance.pdf?ext=.pdf
- 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 registered nurse or midwife in identified clinical situations. A medication protocol involves the authorisation of the nurse or midwife to supply and administer a medication to groups of patients in a defined situation meeting specific criteria and who may not be individually identified before presentation for treatment (An Bord Altranais, 2007, page 37).

Document reference number	Version3-NIO-6in1-December 2024
1.0 Critical elements	
Name of organisation/setting where medicine protocol applies	Health Service Providers across the voluntary and statutory services of the HSE including HSE community vaccination clinics. This Medicine Protocol applies to:This Medicine Protocol applies to: • registered nurses and registered midwives employed in the voluntary and statutory services of the HSE including vaccination clinics, congregated settings, temporary clinics and mobile units
Date the medicine protocol comes into effect	December 2024
Date for review of medicine protocol	December 2025
Document prepared by	HSE 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 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 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 Diphtheria, Tetanus, Pertussis, Hepatitis B, Poliomyelitis and Haemophilus type b disease.
Circumstances in which the medicine protocol applies	To provide an Infanrix Hexa (6 in 1 vaccine) to Refugees and Applicants Seeking Protection in Ireland and in the event of an outbreak (hereafter referred to as vaccine recipients).
Inclusion criteria for vaccine recipients receiving Infanrix Hexa (6 in 1 vaccine) under this medicine protocol	**For primary immunisation**: **Children born on or before 30th September 2024:** The primary course consists of 3 doses given at 2, 4 and 6 months only. **Children born on or after the 1st of October 2024**: The primary course consists of 4 doses given at 2, 4, 6 and 13 months. Please refer to the NIAC chapter 2. **For catch-up programme:** Children under the age of 10 years of age with no history of receipt of these antigens previously as per the NIAC catch up schedule in the NIAC Chapter 2. **For outbreak response:** As advised by public health **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. **Note:** COVID-19 vaccines (except for COVID-19 vaccine given to children aged 6 months to aged 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 recipients receiving Infanrix Hexa (6 in 1 vaccine) under this medicine protocol	• A known history of anaphylactic or hypersensitivity reaction to Infanrix Hexa (6 in 1 vaccine) or any of the vaccine's constituents.
Actions to be taken for those who are excluded from the medicine protocol	All recipients meeting exclusion criteria must be referred to the clinical lead for an individual clinical assessment. • Document action in clinical notes • Where Infanrix Hexa (6 in 1 vaccine) is prescribed following clinical assessment, the nurse or midwife may administer Infanrix Hexa (6 in1 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 vaccine recipient with the clinical lead 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 Infanrix Hexa (6 in 1 vaccine), once understood and translation of consent undertaken with support of translator if required. Appropriate details including the batch

<table>
<tr><td></td><td>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 information
It is the responsibility of each registered nurse or midwife to be familiar with the appropriate documentation to support the safe administration of Infanrix Hexa (6 in 1 vaccine) vaccine which includes the following:
Medicine Protocol for the administration of Infanrix Hexa (6 in 1 vaccine) by registered nurses and 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/</td></tr>
<tr><td>3.0 Name of Medicine</td><td>Infanrix hexa, Powder and suspension for suspension for injection.

Diphtheria (D), tetanus (T), pertussis (acellular, component) (Pa), hepatitis B (rDNA) (HBV), poliomyelitis (inactivated) (IPV) and Haemophilus influenzae type b (Hib) conjugate vaccine (adsorbed).

Dose: 0.5 ml

Route: Intramuscular injection

<table>
<tr><th>Patients Age</th><th>Site</th><th>Needle length & Size</th></tr>
<tr><td>Birth to <12 months</td><td>Vastus lateralis muscle</td><td>25 mm (Use a 16 mm needle in infants under 2.5 - 3 kg)

23-25 gauge</td></tr>
<tr><td>12 to <36 months</td><td>Vastus lateralis or deltoid muscle (depending on muscle mass)</td><td>25 mm

23-25 gauge</td></tr>
<tr><td>3 years and older</td><td>Deltoid muscle</td><td>25 mm

23-25 gauge</td></tr>
</table>
Note: Vaccine must be reconstituted</td></tr>
<tr><td>Link to Medicine

Details of product information and other data including instructions for supply and administration is available from the Health Products Regulatory Authority at www.ema.ie</td><td>Link to Summary of Product Characteristics:https://www.ema.europa.eu/en/documents/product-information/infanrix-hexa-epar-product-information_en.pdf

Link to Patient Information Leaflet:https://www.ema.europa.eu/en/documents/product-information/infanrix-hexa-epar-product-information_en.pdf</td></tr>
</table>

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/not directly involving the vaccine recipient (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 https://www.hpsc.ie/a-z/emi/algorithms/EMISharpsAlgo.pdf
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 for the administration of Infanrix Hexa (6in1) Vaccine	• Infanrix Hexa (6 in 1 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 material • Alcohol hand sanitiser • Handwashing facilities • 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/ • Safe storage areas for medicines and equipment • Current medicine protocol for Infanrix Hexa (6 in 1 vaccine).
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 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 registered nurse or 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) *Primary Childhood Immunisation Programme* accessible on www.HSELanD.ie 3) Education programme for nurses and midwives on *Schools Immunisation Programme* and any updates for nurses and midwives accessible on www.HSELanD.ie 4) An approved *Basic Life Support for Health Care Providers Course* within the last two years (i.e. Irish Heart Foundation (IHF)) 5) 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 6) Children having vaccinations and healthcare procedures: Clinical Holding (Professor Lucy Bray/ONMSD, 2023) available at www.HSELanD.ie 7) 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

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

Health Products Regulatory Authority available at www.hpra.ie

Infanrix Hexa *Summary of Product Characteristics and Patient Information Leaflet,* available at: https://www.ema.europa.eu/en/medicines/human/EPAR/infanrix-hexa#product-information-section

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 at: https://rcpi.access.preservica.com/uncategorized/IO_a36f9e4b-4c80-432d-8264-546089359925/

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National Immunisation Office (2024) 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

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

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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/Standards-Guidance/Scope-ofPractice/Nursing-Practice-Scope-Definition

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