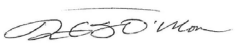
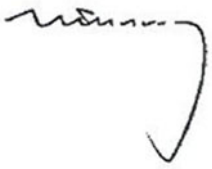
Medicine Protocol for the Administration of Rotarix oral suspension (Rotavirus vaccine, live) by registered and registered midwives to Refugees and Applicants Seeking Protection in Ireland

This medicine protocol is a specific written instruction for the administration of Rotarix oral suspension (Rotavirus vaccine, live) to Refugees and Applicants Seeking Protection in Ireland (hereafter referred to as vaccine recipients) by registered nurses and registered midwives. This medicine protocol is valid for the 2024/2025 Health Service Executive (HSE) Primary Childhood Immunisation Programme (PCIP) and for National Immunisation Advisory Committee (NIAC) recommended catch up immunisation.

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 Rotarix oral suspension (Rotavirus vaccine, live) 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 Rotarix oral suspension (Rotavirus vaccine, live) as detailed by the European Medicines Agency (EMA) at www.ema.eu

- 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 (2025) 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 (2025) *Supporting Information for Vaccinations in General Practice* available at: https://www.hse.ie/eng/health/immunisation/infomaterials/gpsupportingdocpci.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
- 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 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 (AnBord Altranais, 2007, page 37).

Document reference number	Version3-NIO- Rotavirus vaccine-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: • registered nurses and registered midwives employed in the voluntary and statutory services of the HSE including HSE Community 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	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: 

<table>
<tr><td colspan="2">2.0 Clinical Criteria</td></tr>
<tr><td>Clinical condition for use of the medicine protocol</td><td>The clinical condition for which this medicine protocol has been developed is for the prevention of gastroenteritis due to rotavirus infection.</td></tr>
<tr><td>Circumstances in which the medicine protocol applies</td><td>To provide a Rotarix oral suspension (Rotavirus vaccine, live) to Refugees and Applicants Seeking Protection in Ireland and in the event of an outbreak.</td></tr>
<tr><td>Inclusion criteria for vaccine recipient receiving Rotarix oral suspension (Rotavirus vaccine, live) under this medicine protocol</td><td>
Primary immunisation

The primary schedule consists of 2 doses at 2 and 4 months of age.

For catch up programme

Unvaccinated children up to 8 months of age should be vaccinated as per the NIAC catch up schedule as below.
<table>
<tr><td>Vaccine</td><td>4 months to <8 months (catch-up schedule)</td></tr>
<tr><td>Rotavirus</td><td>2 doses 8 weeks apart (No dose after 8 months 0 days)</td></tr>
</table>
Children who are aged older than 8 months and 0 days should NOT receive this vaccine as per the NIAC guidelines.

If an infant is late presenting for vaccination, they can receive their first dose before the age of 7 months and 0 days. The final dose can then be given before 8 months and 0 days (the minimum interval between doses is 4 weeks) – NIAC chapter 19.

Precaution

Acute severe febrile illness – defer until recovery.
Moderate or severe vomiting or diarrhoea – defer until recovery. However, infants with mild acute gastroenteritis can be vaccinated, particularly if the delay in vaccination might make the infant ineligible to receive the vaccine, even though the immunogenicity and efficacy of the vaccine could be reduced.
Immunodeficiency (other than SCID). Little safety or efficacy data are available following administration of rotavirus vaccine to other infants who are immunocompromised or potentially immunocompromised. Thus, although vaccine strains of rotavirus are considerably attenuated their administration to infants with known or suspected immunodeficiency other than SCID should be based on careful consideration of potential benefits and risks. HIV positive infants and those of unknown HIV status should receive rotavirus vaccine.
Contacts of immunocompromised persons. The vaccine virus could be transmitted from the infant to severely immunocompromised contacts through faecal material for at least 14 days. However, vaccination of the infant will offer protection to household contacts from wild-type rotavirus disease and outweigh any risk from transmission of vaccine virus to any immunocompromised close contacts. All members of the household should employ measures such as good handwashing and correct disposal of nappies after changing a nappy or otherwise coming in to contact with the faeces of a vaccinated child.

Note: A 14-day interval is recommended between COVID-19 vaccine given to children and rotavirus vaccine
</td></tr>
<tr><td>Exclusion criteria for vaccine recipients receiving Rotarix oral suspension (Rotavirus vaccine, live) under this</td><td>1. Anaphylaxis to the vaccine or syringe constituents.
2. Uncorrected congenital GIT malformation (e.g., Meckel’s diverticulum) which would predispose an infant to intussusception.
3. Previous intussusception
4. Severe combined immunodeficiency (SCID).</td></tr>
</table>

medicine protocol	5. Hereditary fructose intolerance, sucrose-isomaltase deficiency or glucose-galactose malabsorption. 6. Infants of mothers receiving infliximab throughout the pregnancy and/or during breastfeeding, should not receive rotavirus vaccine.
Actions to be taken for those who are excluded from the medicine protocol	All vaccine recipients meeting exclusion criteria must be referred to the clinical lead for an individual assessment. • Document action in clinical notes • Where Rotarix oral suspension (Rotavirus vaccine, live) is prescribed following clinical assessment, the nurse or midwife may administer Rotarix oral suspension (Rotavirus vaccine, live) 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: • Adverse reaction • Other clinical concerns
Documentation required to support implementation of the medicine protocol	A consent form must be completed by the parent /legal guardian for all children who receive Rotarix oral suspension (Rotavirus vaccine, live) 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 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 Rotarix oral suspension (Rotavirus vaccine, live) which includes the following: • Medicine Protocol for the administration of Rotarix oral suspension (Rotavirus vaccine, live) 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	Rotarix oral suspension (Rotavirus vaccine, live) **Dose:** 1.5 ml **Route:** Oral
Link to Medicine **Details of product information and other data including instructions for supply and administration is available from the EMA at www.ema.eu**	**Link to Summary of Product Characteristics:** **https://www.ema.europa.eu/en/documents/product-information/rotarix-epar-product-information_en.pdf** **Link to Patient Information Leaflet:** **https://www.ema.europa.eu/en/documents/product-information/rotarix-epar-product-information_en.pdf**
Procedure for reporting and documentation of errors and near misses	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

involving the medicine	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 notes and the relevant National Incident Management Report Form completed: https://www.hse.ie/eng/about/who/nqpsd/qps-incident-management/nims/nirf-01-12-person-interactive.pdf For infants/children, their 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 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 administration Rotarix oral suspension (Rotavirus vaccine, live)	• Rotarix oral suspension (Rotavirus vaccine, live) • Fridge/cool box with minimum/maximum temperature recording device to monitor the cold chain temperature (between +2° to +8˚C) • Disposable kidney dishes/coloured trays • Gauze swabs/Plasters • Sharps bins and bags for disposal of healthcare risk and non-risk waste materials • 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 Rotarix oral suspension (Rotavirus vaccine, live) .
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/guardian	
Advice to be given to the vaccine recipient/parent/ legal 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 the vaccine recipient/parent/ legal 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 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, experience and competence required prior to working under 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

GlaxoSmithKline Rotarix oral suspension (Rotavirus vaccine, live) *Summary of Product Characteristics and Patient Information Leaflet,* available at www.ema.eu

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/.

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 (2025) 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 (2025) *Supporting Information for Vaccinations in General Practice* available at: https://www.hse.ie/eng/health/immunisation/infomaterials/gpsupportingdocpci.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/Standards-Guidance/Code

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

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/Midwives-Standards

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-Practise-Scope-Definition

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