

This medicine protocol is a specific written instruction for the administration of Varicella (live) vaccine (VARIVAX) 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 2025/2026 Health Service Executive (HSE) immunisation programme against Varicella infection 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 Varicella (live) vaccine (VARIVAX) with reference to and guidance from the National Immunisation Advisory Committee (NIAC), National Immunisation Office (NIO), HSE and in accordance with the Summary of Product Characteristics (SmPC) for Varicella (live) vaccine (VARIVAX) as approved by the Health Products Regulatory Authority (HPRA) available at www.medicines.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://www.hiqa.ie/areas-we-work/national-immunisation-advisory-committee/immunisation-guidelines-ireland
- National Immunisation Advisory Committee Immunisation Guidelines for Ireland: National Immunisation
   Advisory Committee available at: <a href="https://www.hiqa.ie/areas-we-work/national-immunisation-advisory-committee/immunisation-guidelines-ireland">https://www.hiqa.ie/areas-we-work/national-immunisation-advisory-committee/immunisation-guidelines-ireland</a>
- National Immunisation Office (2025)Children Who Have Come To Ireland From Another Country: Information
  For Healthcare Professionals On Catch-Up Vaccination available at
  <a href="https://www.hse.ie/eng/health/immunisation/hcpinfo/botpipa/hcwcatchupothercountries.pdf">https://www.hse.ie/eng/health/immunisation/hcpinfo/botpipa/hcwcatchupothercountries.pdf</a>
- National Immunisation Office Supporting Information for Staff: Schools Immunisation Programme 2025/2026 available at: https://www.hse.ie/eng/health/immunisation/hcpinfo/schoolproghcp/supportingdoc.pdf
- National Immunisation Office (2025) *Supporting Information for Vaccinations in General Practice* available at: <a href="https://www.hse.ie/eng/health/immunisation/infomaterials/gpsupportingdocpci.pdf">https://www.hse.ie/eng/health/immunisation/infomaterials/gpsupportingdocpci.pdf</a>
- Nursing and Midwifery Board of Ireland (2025) Code of Professional Conduct and Ethics for Registered Nurses and Registered Midwives incorporating the Scope of Practice and Professional Guidance. Dublin: Nursing and Midwifery Board of Ireland available at: https://www.nmbi.ie/NMBI/media/NMBI/NMBI-Code-of-Professional-Conduct-and-Ethics.pdf?ext=.pdf
- 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: <a href="https://www.nmbi.ie/NMBI/media/NMBI/NMBI-Medication-Administration-2020.pdf?ext=.pdf">https://www.nmbi.ie/NMBI/media/NMBI/NMBI-Medication-Administration-2020.pdf?ext=.pdf</a>
- Nursing and Midwifery Board of Ireland (2022) Practice Standards for Midwives. Dublin: Nursing and
  Midwifery Board of Ireland available at: <a href="https://www.nmbi.ie/NMBI/media/NMBI/NMBI-Practice-Standards-for-Midwives.pdf">https://www.nmbi.ie/NMBI/media/NMBI/NMBI-Practice-Standards-for-Midwives.pdf</a>?

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, page 35).



| Document reference number   | Version 1-NIO-Varivax- September 2025   |  |  |  |  |  |
|---|---|--|--|--|--|--|
| 1.0 Critical elements   |   |  |  |  |  |  |
| Name of Organisation where protocol applies   | Health Service Providers across the voluntary and statutory services of the HSE including HSE community vaccination clinics. This Medicine Protocol applies to:   |  |  |  |  |  |
|   | <ul> <li>registered nurses and registered midwives employed in the voluntary and<br/>statutory services of the HSE including vaccination clinics, congregated settings,<br/>temporary clinics and mobile units</li> </ul> |  |  |  |  |  |
| Date the protocol comes into effect   | September 2025  |  |  |  |  |  |
| Date for review of protocol   | September 2026  |  |  |  |  |  |
| 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<br>the employing authority<br>who is authorising the<br>implementation of the<br>protocol   | Name: <b>Dr Éamonn O'Moore</b> , Director of National Health Protection, HSE  |  |  |  |  |  |
| "On behalf of the authority employing professionals authorised to administer under this medicine protocol, I have read this medicine protocol and authorise its implementation" | Signature:  |  |  |  |  |  |
|   | Name: <b>Dr Colm Henry</b> , Chief Clinical Officer, HSE  Signature:  Name: <b>Dr Geraldine Shaw</b> , 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 Varicella Zoster (Chickenpox) infection.   |  |  |  |  |
| Circumstances in which the medicine protocol applies                  | The primary childhood immunisation schedule for children born on or after 1 <sup>st</sup> October 2024, and for any subsequent presentation for first and second varicella vaccine doses e.g. varicella outbreak, late entrants (born on or after 1 <sup>st</sup> October 2024) or in the prevention and control of varicella cases.   |  |  |  |  |
| Inclusion criteria for vaccine recipients using the medicine protocol | <ol> <li>All children born on or after 1<sup>st</sup> October 2024, at 12 months of age should receive a first dose of Varicella (live) vaccine (VARIVAX) under the primary childhood immunisation schedule, with a second dose at 4-5 years of age usually given in junior infants as a combined MMRV vaccine.</li> <li>For catch-up programme: Varicella catch-up vaccination is recommended for eligible children (i.e. born on or after 1<sup>st</sup> October 2024) as per the NIAC catch-up schedule in the NIAC chapter 2.</li> </ol>   |  |  |  |  |
|   | <b>Note: Children born before 1st October 2024</b> , are <b>not eligible</b> to receive varicella vaccine as part of the PCI schedule and are therefore not eligible for varicella catch-up vaccination.   |  |  |  |  |
|   | 3. Varicella outbreak –In the event of an outbreak, follow public health advice.   |  |  |  |  |
| Exclusion criteria for vaccine recipients using the medicine protocol | <ul> <li>Previous anaphylaxis to any of the vaccine constituents.</li> <li>Immunocompromise from disease or treatment (Chapter 3).</li> <li>Active untreated tuberculosis.</li> <li>Pregnancy (there is no requirement to carry out a pregnancy test prior to vaccination)</li> <li>Individuals with a family history of congenital or hereditary immunodeficiency, unless the immune competence of the potential recipient is demonstrated.</li> </ul>  |  |  |  |  |
|   | Precautions  |  |  |  |  |
|   | <ul> <li>Acute severe febrile illness, defer until recovery.</li> <li>Recent (3-11 months) receipt of an antibody-containing product (NIAC Chapter 2, Table 2.6).</li> <li>Receipt of some antivirals (e.g. acyclovir, famciclovir, or valacyclovir) 24 hours before vaccination.</li> <li>Pregnancy should be avoided for four weeks following vaccination.</li> <li>If not given at the same time as MMR vaccine, the vaccines should be separated by at least four weeks. The risk of breakthrough varicella is increased if varicella vaccine is administered less than four weeks following MMR vaccine.</li> <li>Infants of breastfeeding mothers receiving monoclonal antibody treatment (including infliximab) post-partum should be immunised with varicella vaccines according to routine schedule. If there is any doubt as to whether an infant due</li> </ul> |  |  |  |  |
|   | to receive a live attenuated vaccine such as varicella vaccine may be immunosuppressed due to the mother's therapy, specialist advice should be sought.  Note: if given at the same time as Varicella (live) vaccine (VARIVAX), MenB vaccine should be administered in a separate limb.  |  |  |  |  |
| Actions to be taken for those who are excluded from the Protocol      | All recipients meeting exclusion criteria must be referred to the clinical lead for an individual clinical assessment.  • Document assessment & action in clinical notes  • Where Varicella (live) vaccine (VARIVAX) is prescribed following medical assessment, the registered nurse or midwife may administer Varicella (live) vaccine (VARIVAX) within their scope of practice.   |  |  |  |  |



|   | ives  |   |                      |  |  |
|---|---|---|----------------------|--|--|
|   | <b>Note:</b> In determining their scope of practice, registered nurses and midwives must make judgements about their competency to carry out a role or activity (NMBI, 2025).   |   |                      |  |  |
| Description of circumstances and referral arrangements when further advice or consultation is required                            | Discuss with the clinical lead in the event of:  Confirmed or suspected anaphylactic reaction to the vaccine itself or to a constituent of that vaccine  Other clinical concerns  |   |                      |  |  |
| Documentation required for the implementation of this medicine protocol   | A consent form must be understood and completed by the parent/legal guardian for all children who receive the Varicella (live) Vaccine (VARIVAX. Translation of consent undertaken with support of translator if required. Appropriate details should 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  Post vaccination advice should be provided  It is the responsibility of each registered nurse or midwife to be familiar with the appropriate documentation to support the safe administration of VARIVAX Varicella vaccine which includes the following:  This medicine protocol  NIAC (2023) Anaphylaxis: Immediate Management in the Community available at:  https://www.hiqa.ie/sites/default/files/NIAC/Immunisation Guidelines/Anaphylax is.pdf |   |                      |  |  |
| 3.0 Name of medicine  | VARIVAX powder and solvent for suspension for injection in a pre-filled syringe Varicella Vaccine (live)  Dose: 0.5 ml  |   |                      |  |  |
|   | Routine schedule: All children born on or after 1st October 2024, at 12 months of agroutinely receive a first dose of Varicella (live) vaccine (VARIVAX) under the primary childhood immunisation schedule, with a second dose at 4-5 years of age usually given junior infants as a combined MMRV vaccine.  In the event of varicella outbreak: Follow public health advice and in line with the NIAC recommendations in the NIAC chapter 23.  Presentation: VARIVAX powder and solvent for suspension for injection in a pre-filler syringe   |   |                      |  |  |
|   | Vaccine recipients age  | Site  | Needle length & Size |  |  |
|   | 12 to <36 months  | Vastus lateralis or deltoid muscle (depending on muscle mass) | 25 mm<br>23-25 gauge |  |  |
|   | 3 years and older   | Deltoid muscle  | 25 mm<br>23-25 gauge |  |  |
| Link to Medicine  Details of product information and other data including instructions for supply and administration is available | https://www.medicines.ie/medicines/varivax-34140/spc Link to Patient Information Leaflet: https://www.medicines.ie/medicines/varivax-34140/patient-info   |   |                      |  |  |



#### Procedure for the reporting and documentation of errors and near misses involving the vaccine

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 vaccine recipients documentation/notes and the relevant National Incident Management Report Form completed, available at:

 $\frac{https://www.hse.ie/eng/about/who/nqpsd/qps-incident-management/nims/nirf-01-v12-person-interactive.pdf}{}$ 

Any suspected adverse reactions associated with medicine errors should be reported to the HPRA as outlined below.

The child's parent and/or legal guardian must be informed of the incident.

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 <a href="https://www.hpra.ie">https://www.hpra.ie</a>

### Resources and equipment required

- Varicella (live) vaccine (VARIVAX)
- 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 sanitizer
- Face masks (if required)
- Access to telephone
- Resuscitation equipment and drugs in accordance with the NIAC (2023)
   Anaphylaxis: Immediate Management in the Community available at: <a href="https://www.hiqa.ie/sites/default/files/NIAC/Immunisation\_Guidelines/Anaphylaxis.pdf">https://www.hiqa.ie/sites/default/files/NIAC/Immunisation\_Guidelines/Anaphylaxis.pdf</a>
- Safe storage areas for medicines and equipment
- Current medicine protocol for Varicella (live) vaccine (VARIVAX)

## 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



# Advice to be given to the vaccine recipient/parent/legal guardian before treatment

Patient Information Leaflet/Fact Sheet **must** be supplied with the consent form to vaccine recipient/parent/legal guardian prior to administration of the vaccine. Reiterate the information provided in the HSE patient information leaflet for the vaccine and translator support if required.

#### Advice to be given to the vaccine recipient/parent/legal guardian after treatment

#### **After Treatment**

The vaccine recipient must be advised to remain in the post vaccination observation area for 15 minutes to allow monitoring of any immediate reaction including possible anaphylactic reaction and they/their parent/guardian must be advised to report any side effects to the registered nurse or midwife who is present.

The vaccine recipient or their parent/legal guardian should be advised if they developed vaccine-related rash 7-25 days after vaccination, they should avoid direct contact with immunocompromised persons, non-immune pregnant women and their new born in the first week of life, and non-immune infants in neonatal units, for the duration of the rash.

## 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:

- 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
- Education programme for nurses and midwives on National Vaccination Education Programme for Registered Nurses/Midwives/Public Health Nurses: 2025/2026 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 <a href="www.HSeLanD.ie">www.HSeLanD.ie</a> 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 <a href="www.HSeLanD.ie">www.HSeLanD.ie</a>
- 6) Children having vaccinations and healthcare procedures: Clinical Holding (Professor Lucy Bray/ONMSD, 2023) available at www.HSeLanD.ie

The registered nurse/midwife must complete the Competency Self-Assessment Form to vaccinate Refugees and Applicants Seeking Protection in Ireland available at <a href="https://www.immunisation.ie">www.immunisation.ie</a>



#### References

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

MSD Ireland (Human Health) Limited. Varicella (live) vaccine (VARIVAX) Summary of Product Characteristics and Patient Information Leaflet available at: <a href="https://www.medicines.ie">www.medicines.ie</a>

HSE Policy on the Management of Sharps and Prevention of Sharp Injuries (2022) available at: https://healthservice.hse.ie/filelibrary/staff/policy-on-the-management- of-sharps-and-prevention-of-sharp-injuries.pdf

National Clinical Guideline No. 30 (2023) – Infection Prevention and Control (IPC) available at: 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://www.hiqa.ie/areas-we-work/national-immunisation-advisory-committee/immunisation-guidelines-ireland

National Immunisation Advisory Committee *Immunisation Guidelines for Ireland*: Royal College of Physicians of Ireland National Immunisation Advisory Committee available at: <a href="https://www.hiqa.ie/areas-we-work/national-immunisation-advisory-committee/immunisation-quidelines-ireland">https://www.hiqa.ie/areas-we-work/national-immunisation-advisory-committee/immunisation-quidelines-ireland</a>

National Immunisation Office *Supporting Information for Staff: Schools Immunisation Programme 2025/2026* available at: https://www.hse.ie/eng/health/immunisation/hcpinfo/schoolproghcp/supportingdoc.pdf

National Immunisation Office (2025) Children Who Have Come To Ireland From Another Country: Information For Healthcare Professionals On Catch-Up Vaccination available at <a href="https://www.hse.ie/eng/health/immunisation/hcpinfo/botpipa/hcwcatchupothercountries.pdf">https://www.hse.ie/eng/health/immunisation/hcpinfo/botpipa/hcwcatchupothercountries.pdf</a>

National Immunisation Office (2025) *Supporting Information for Vaccinations in General Practice* available at: <a href="https://www.hse.ie/eng/health/immunisation/infomaterials/gpsupportingdocpci.pdf">https://www.hse.ie/eng/health/immunisation/infomaterials/gpsupportingdocpci.pdf</a>

Nursing and Midwifery Board of Ireland (2025) Code of Professional Conduct and Ethics for Register Nurses and Registered Midwives incorporating the Scope of Practice and Professional Guidance. Dublin: Nursing and Midwifery Board of Ireland available at: https://www.nmbi.ie/NMBI/media/NMBI/NMBI-Code-of-Professional-Conduct-and-Ethics.pdf?ext=.pdf

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: <a href="https://www.nmbi.ie/NMBI/media/NMBI/NMBI-Medication-Administration-2020">https://www.nmbi.ie/NMBI/media/NMBI/NMBI-Medication-Administration-2020</a>

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