Medicine Protocol for the Administration of Havrix Monodose Vaccine (Hepatitis A Vaccine (inactivated, 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 Havrix Monodose Vaccine (Hepatitis A Vaccine (inactivated, adsorbed)) to refugees and applicants seeking protection in Ireland (hereafter referred to as vaccine recipients aged 16 years and above) 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) vaccination programme 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 Havrix Monodose Vaccine, (Hepatitis A Vaccine (inactivated, adsorbed)) with reference to and guidance from the 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 Havrix Monodose Vaccine (Hepatitis A Vaccine (inactivated, adsorbed)) as detailed by the Health Products Regulatory Authority (HPRA) at www.hpra.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
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- 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 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) *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 (NMBI, 2020, p. 6).

Medicine Protocol for the Administration of Havrix Monodose Vaccine (Hepatitis A Vaccine (inactivated, adsorbed)) by registered nurses and registered midwives to Refugees and Applicants seeking protection in Ireland and in the event of an outbreak

Document reference number	Version3-NIO-HepA-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, 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 medicine protocol	The clinical condition for which this medicine protocol has been developed is for the active immunisation against and prevention of Hepatitis A virus infection.
Circumstances in which the medicine protocol applies	Active immunisation with Havrix Monodose Vaccine (Hepatitis A Vaccine (inactivated, adsorbed)) for refugees and applicants seeking protection in Ireland aged 16 years and above and in the event of an outbreak as advised by public health (hereafter referred to as vaccine recipients). It applies to those **aged 16 years and older** at-risk of Hepatitis A infection (See Section 8.5 of NIAC Immunisation Guidelines for Ireland), close contacts of cases of Hepatitis A virus infection, or in the case of an outbreak identified by public health as part of outbreak management.
Inclusion criteria for vaccine recipients receiving Havrix Monodose Vaccine (Hepatitis A Vaccine) under this medicine protocol	For those aged 16 years and above **Precautions** • Acute severe febrile illness, defer until recovery • All monocomponent Hepatitis A vaccines contain phenylalanine, which may be harmful to patients that have phenylketonuria (PKU) <u>Pregnancy</u> Hepatitis A Virus (HAV) containing vaccines may be given to pregnant women if clinically indicated. Safety data in pregnant women are not available, but the risk is considered to be low or non-existent because the vaccines contain inactivated purified viral proteins. **Note:** The presence of a minor infection such as a mild upper respiratory infection or low-grade fever is not a contraindication to immunisation
Exclusion criteria for vaccine recipients receiving Havrix Monodose Vaccine (Hepatitis A Vaccine) under this medicine protocol	• A known history of anaphylaxis to Havrix Monodose Vaccine (Hepatitis A Vaccine (inactivated, adsorbed)) or to any of its 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 Havrix Monodose Vaccine, (Hepatitis A Vaccine (inactivated, adsorbed)) is prescribed following clinical assessment, the registered nurse or registered midwife may administer Havrix Monodose Vaccine (Hepatitis A Vaccine (inactivated, adsorbed)) within their scope of practice. **Note:** In determining their scope of practice, registered 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 Clinical lead in the event of: • Previous severe adverse reaction • Other clinical concerns
Documentation required for the implementation of this medicine protocol	Children aged 16 years and over consent on their own behalf as per the HSE National Consent Policy (2022). Informed consent should be obtained prior to vaccination once understood and translation of consent is undertaken with support of translator if required. Relevant details including the batch number of the vaccine 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 Havrix Monodose Vaccine (Hepatitis A Vaccine (inactivated, adsorbed)) which includes the following: • Medicine Protocol for the Administration of Havrix Monodose Vaccine (Hepatitis A Vaccine (inactivated, adsorbed) by registered nurses and registered midwives to Refugees and Applicants Seeking Protection in Ireland and in the event of an outbreak as advised by Public Health 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	Havrix Monodose Vaccine Hepatitis A Vaccine (inactivated, adsorbed) 1440 ELISA units/1 ml Suspension for Injection in a pre-filled syringe **Dose:** 1 ml The recommended schedule is two doses, 6 -12 months apart **Route:** Intramuscular Injection **Site:** Deltoid muscle
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_PA1077026002.pdf Link to Patient Information Leaflet: https://www.hpra.ie/img/uploaded/vaccines/PIL_PA1077026002.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 clinical lead. 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: 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. 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.
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 Havrix Monodose Vaccine (Hepatitis A Vaccine)	• Havrix Monodose Vaccine (Hepatitis A Vaccine (inactivated, adsorbed)) • 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 • 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 Havrix Monodose Vaccine (Hepatitis A Vaccine (inactivated, adsorbed)).
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 before treatment **Advice to be given to the vaccine recipient after treatment**	Reiterate the information provided in the HSE patient information leaflet for the vaccine in the appropriate language and translator support if required. Patient Information Leaflet/Fact Sheet **must** be supplied with the consent form to vaccine recipient prior to administration of the vaccine as above. **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

GlaxoSmithKline Havrix Monodose Vaccine (Hepatitis A Vaccine (inactivated, adsorbed)) *Summary of Product Characteristics and Patient Information Leaflet,* available at www.hpra.ie

Health Products Regulatory Authority available at: www.hpra.ie

Health Service Executive (2022) National Consent Policy available at: https://www.hse.ie/eng/about/who/national-office-human-rights-equality-policy/consent/hse-national-consent-policy.pdf

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) *Supporting Information for Vaccinations in General Practice* available at: https://www.hse.ie/eng/health/immunisation/infomaterials/gpsupportingdocpci.pdf

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