Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

**Medicine Protocol for the Administration of Quadrivalent Influenza Vaccine (split virion, inactivated) to nurses, midwives, healthcare workers, agency staff, contract workers and volunteers by registered nurses and registered midwives**

This medicine protocol is a specific written instruction for the administration of Quadrivalent Influenza Vaccine (split virion, inactivated) to nurses, midwives, healthcare workers (HCWs), agency staff, contract workers and volunteers (hereafter referred to as recipient HCWs) by registered nurses and registered midwives. This medicine protocol is valid for the 2021/2022 Health Service Executive (HSE) Seasonal Influenza Peer Vaccination Programme. This medicine protocol enables registered nurses and registered midwives employed in the voluntary and statutory services of the HSE who have undertaken the required education and training programmes to administer Quadrivalent Influenza Vaccine (split virion, inactivated), with reference to and guidance from the Nursing & Midwifery Board of Ireland (NMBI), National Immunisation Advisory Committee (NIAC), National Immunisation Office (NIO) and in accordance with the Summary of Product Characteristics (available at www.hpra.ie). See below:

- Nursing and Midwifery Board of Ireland (2020) *Guidance for Registered Nurses and Midwives on Medication Administration*. Dublin: Nursing and Midwifery Board of Ireland
- An Bord Altranais (2007) *Guidance to Nurses and Midwives on Medication Management.* Dublin: An Bord Altranais
- National Immunisation Advisory Committee (2021) *Management of a Patient with Anaphylaxis.* Available at https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/anaphylaxis.pdf
- National Immunisation Advisory Committee *Immunisation Guidelines for Ireland* Dublin: Royal College of Physicians Ireland, available at http://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/
- National Immunisation Office (2021) *Seasonal Influenza Peer Vaccination Programme: Guidelines for Staff.* Dublin: Health Service Executive, available at https://www.hse.ie/eng/health/immunisation/hcpinfo/fluinfo/peerguidelines.pdf
- Nursing and Midwifery Board of Ireland (2015) *Practice Standards for Midwives.* Dublin: Nursing and Midwifery Board of Ireland
- Nursing and Midwifery Board of Ireland (2015) *Recording Clinical Practice. Guidance to Nurses and Midwives.* Dublin: Nursing and Midwifery Board of Ireland
- Nursing and Midwifery Board of Ireland (2015) *Scope of Nursing and Midwifery Practice Framework.* Dublin: Nursing and Midwifery Board of Ireland
- 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.

The NMBI 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).

**Medicine Protocol for the administration of Quadrivalent Influenza Vaccine (split virion, inactivated) to recipient healthcare workers**

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| **Document reference number:** | ONMSD 2021-012 |
| **1.0 Critical Elements** | |
| **Name of organisation where medicine protocol applies** | Health service providers across the voluntary and statutory services of the HSE. This medicine protocol applies to:<br>• Registered nurses and registered midwives involved in the supply and administration of the seasonal influenza vaccine to recipient HCWs. |
| **Date the medicine protocol comes into effect** | September 2021 |
| **Date for review of medicine protocol** | September 2022 |
| **Document prepared by** | ONMSD, HSE in collaboration with the NIO. |
| **Names and signatures of the employing authority who is authorising the implementation of the medicine protocol**<br>***"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 John Cuddihy** , Interim National Clinical Director Health Protection, HSE<br>Signature: John Cuddihy.<br><br>Name: **Dr Colm Henry**, Chief Clinical Officer, HSE<br>Signature: _____<br><br>Name: **Dr Lynda Sisson**, National Clinical Lead, Workplace Health and Wellbeing, HSE<br>Signature: Lynda Sisson<br><br>Name: **Dr Geraldine Shaw**, Nursing and Midwifery Services Director, HSE<br>Signature: _____ |

| **2.0 Clinical Criteria** | |
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| **Clinical condition for use of the medicine protocol** | The clinical condition for which this medicine protocol has been developed is for the immunisation of recipient HCWs against influenza virus for the 2021/2022 seasonal influenza peer vaccination programme. |
| **Circumstances in which the medicine protocol applies** | Targeted immunisation programme for recipient HCWs during the influenza season as they are at risk of influenza and of transmitting the influenza virus to vulnerable patients in the course of their duties. |
| **Inclusion criteria for recipient healthcare workers receiving seasonal influenza vaccine under medicine protocol** | Active immunisation to prevent influenza infection caused by influenza virus, in recipient HCWs in the HSE, especially those who have clinical contact with patients. This vaccine is licensed for use in those aged 6 months and over.<br><br>COVID-19 vaccines may be co-administered at the same time or at any interval as the Quadrivalent Influenza Vaccine (split virion, inactivated). As it is not known if reactogenicity is increased with co-administration, the vaccines should preferably be administered in different limbs.<br><br>**Precautions:**<br><u>Egg anaphylaxis or egg allergy</u><br>Quadrivalent Influenza Vaccine (split virion, inactivated) is a low ovalbumin vaccine (≤0.06 micrograms per dose).<br><br>NIAC advises that those with confirmed egg anaphylaxis or egg allergy can be given influenza vaccine in a primary care or school setting with the exception of those who have required admission to ICU for a previous severe anaphylaxis to egg.<br><br>Acute severe febrile illness: defer until recovery.<br><br>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 recipient healthcare workers receiving seasonal influenza vaccine under medicine protocol** | Those who have required admission to ICU for a previous severe anaphylaxis to egg should be referred for specialist assessment with regard to vaccine administration in hospital.<br><br>NIAC continues to advise that patients on combination checkpoint inhibitors (e.g. ipilumumab plus nivolumab) should not receive any influenza vaccines, because of a potential association with immune-related adverse reactions.<br><br>People with severe neutropoenia (absolute neutrophil count $<0.5 \times 10^9$/L) should not receive any vaccines, to avoid an acute febrile episode.<br><br>Vaccine recipients who already received a full course of any recommended flu vaccine for their age in the 2021/2022 influenza season. |
| **Actions to be taken for recipient healthcare workers who are excluded from receiving the vaccine** | • Refer to the Occupational Health Physician or other Medical Practitioner for an individual medical assessment<br>• Document action in clinical notes<br>• Where Quadrivalent Influenza Vaccine (split virion, inactivated) is prescribed |

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| **under medicine protocol** | following medical assessment, the registered nurse or midwife may administer the vaccine within their scope of practice.<br><br>**Note:** In determining their scope of practice, the registered nurse or midwife must make judgements about their competency to carry out a role or activity (NMBI, 2015). |
| **Action to be followed for healthcare workers who do not wish to receive the vaccine** | Advise of the risks of not having the vaccine, including risk of transmission of virus to vulnerable patients.<br><br>Advise regarding minimisation of risk. |
| **Description of circumstances and referral arrangements when further advice or consultation is required** | Refer to/discuss with Occupational Health Physician or other Medical Practitioner if the recipient HCW had previous adverse reaction or other clinical concerns. |
| **Documentation required to support implementation of the medicine protocol** | • Vaccine consent forms<br>• Vaccine information leaflets<br>• Patient held record cards<br>• Health Products Regulatory Authority (HPRA) Adverse Reaction Reporting forms<br>• National Incident Management System Form NIRF-01-v11 available at: https://www.hse.ie/eng/about/qavd/incident-management/nirf-01-v11-person.pdf<br><br>It is the responsibility of each registered nurse or midwife to be familiar with the appropriate documentation to support the safe administration of influenza vaccine which includes the following:<br>• This medicine protocol<br>• National Immunisation Advisory Committee (2021) *Management of a Patient with Anaphylaxis*<br>• HSE (2021) *Seasonal Influenza Peer Vaccination Programme 2021: Guidelines for Staff*. |
| **3.0 Name of medicine** | Quadrivalent Influenza Vaccine (split virion, inactivated) |
| **Dose & route of administration** | 0.5ml of vaccine, Intramuscular injection **only**<br>Only 1 dose of the vaccine is usually required each flu season. |
| **Details of product information and other data including instructions for supply and administration is available at www.hpra.ie**<br><br>**Links to medicine** | Quadrivalent Influenza Vaccine (split virion, inactivated), containing influenza virus of the following strains for 2021/2022 flu season:<br><br>• A/Victoria/2570/2019 (H1N1)pdm09-likevirus<br>• A/Cambodia/e0826360/2020 (H3N2)-likevirus<br>• B/Washington/02/2019-like virus (B/Victoria/2/87 lineage)<br>• B/Phuket/3073/2013-like virus (B/Yamagata/16/88 lineage)<br><br>**Link to Summary of Product Characteristics here:**<br>http://www.hpra.ie/img/uploaded/vaccines/SPC_PA2131013001.pdf<br><br>**Link to Patient Information Leaflet here:**<br>http://www.hpra.ie/img/uploaded/swedocuments/2e9ec029-a3ba-44ca-8f1e-8f3b76e94055.pdf |

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| **Potential adverse reactions and procedures for treatment of same** | The recipient HCW should be advised to contact relevant medical personnel in the event of adverse reaction occurring following administration of the vaccine (Occupational Health Department/General Practitioner (GP)/out of hours/Emergency Department).<br><br>Following administration of the vaccine, the recipient healthcare worker should be advised to remain seated in the post vaccination observation area for 15 minutes to allow monitoring of any immediate reaction including suspected anaphylactic reaction. |
| **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 on line at http://www.hpra.ie or through use of the yellow card system which is available in a downloadable format from the HPRA website, or on request from the HPRA.<br><br>The recipient HCW's GP should be informed of any reported adverse reaction.<br><br>In the event of an anaphylactic reaction, the incident and all actions taken must be promptly recorded in accordance with the *Management of a Patient with Anaphylaxis* (NIAC, 2021), available at https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/anaphylaxis.pdf |
| **Procedure for the reporting and documentation of errors and near misses involving the medicine** | In the case of medication errors that directly involve the recipient HCW, i.e. wrong medication/dose/route being administered or another medication error, the registered nurse or midwife must remain with the person and closely monitor them for any adverse reactions.<br><br>Vital signs should be recorded and the recipient HCW should be reviewed by the Occupational Health Physician or other appropriate physician.<br><br>The incident must be reported to the relevant line manager as soon as possible.<br><br>The incident and all actions taken must be recorded and the relevant National Incident Management Report Form (NIRF) completed as soon as is practicable after the event occurs and within one working day available at: https://www.hse.ie/eng/about/qavd/incident-management/nirf-01-v11-person.pdf<br><br>The recipient HCW and/or significant others should be informed of the incident.<br><br>An incident report form must be completed by the registered nurse or midwife and forwarded to local or regional Risk Manager as per local policy.<br><br>Any suspected adverse reactions associated with medication errors must be reported to the HPRA as outlined above. |
| **Resources and equipment required** | • Vaccine (pre-filled syringe) 0.5ml volume<br>• Fridge/cool box with minimum/maximum temperature recording device to monitor the cold chain temperature (between +2°C and +8°C)<br>• Disposable kidney dishes/coloured trays and covering<br>• Gauze swabs/plasters<br>• Sharps bins, and bags for disposal of healthcare risk and non-risk waste (HSE, 2010) |

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| | • Alcohol hand sanitizer<br>• Surgical face masks<br>• Access to telephone<br>• Resuscitation equipment and drugs in accordance with the *Management of a Patient with Anaphylaxis* (NIAC, 2021) available at: https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/anaph ylaxis.pdf<br>• Safe storage areas for medicines and equipment |
| **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 recipient healthcare workers** | |
| **Advice to be given to the recipient healthcare worker before treatment** | **Vaccine information material must be supplied to the recipient healthcare worker prior to administration of the vaccine.**<br><br>**Before vaccination**<br>Discuss the influenza vaccine and the importance of protecting not only their own health but also the health of vulnerable patients in their care.<br><br>Provide recipient HCW with patient vaccine information material.<br><br>Discuss potential side effects.<br><br>Obtain informed consent. |
| **Advice to be given to the recipient healthcare worker after treatment** | **After vaccination**<br>Discuss potential side effects.<br><br>The recipient HCW should be advised to remain in the healthcare facility for fifteen minutes.<br><br>The recipient HCW should not leave the healthcare facility if they are feeling unwell and must report any unwanted side effects to the registered nurse or midwife who has administered the vaccine.<br><br>**The recipient HCW should be advised:**<br>The following side effects may be experienced (see Summary of Product Characteristics):<br><br>**Very common (may affect more than 1 in 10 people):**<br>- Headache, myalgia, malaise, pain at the injection site.<br><br>**Common (may affect up to 1 in 10 people):**<br>- Fever, shivering, reactions at the injection site: erythema, induration.<br><br>**Uncommon (may affect up to 1 in 100 people):**<br>- Dizziness, diarrhoea, nausea, fatigue, reactions at the injection site: ecchymosis, pruritus, and warmth.<br>- Swelling of the glands in the neck, armpit or groin (lymphadenopathy). |

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| | **Rare (may affect up to 1 in 1000 people):**<br>- Anomalies in the perception of touch, pain, heat and cold (paraesthesia), sleepiness, increased sweating (hyperhidrosis), unusual tiredness and weakness (asthenia), flu-like illness.<br>- Joint pain (arthralgia), discomfort at the injection site.<br><br>If more serious adverse or persistent effects occur, the recipient healthcare worker should be advised to contact their GP/out of hour's service.<br>Details of any serious adverse reaction to the vaccine should be forwarded to the Occupational Health Physician or other medical practitioner for inclusion in the recipient HCW's personnel/occupational health file (as per health service provider local policy). |
| **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 3.0. |
| **5.0 Staff authorised to use this medicine protocol** | |
| **Professional qualifications, training, experience and competence required prior to using this medicine protocol** | **Mandatory:**<br>Registered nurse or registered midwife, maintained on the active register maintained by the NMBI.<br><br>HSELanD education programme for registered nurses and midwives: *Seasonal Influenza Peer Vaccination Programme 2021/2022. Education Programme for Nurses and Midwives*<br><br>Basic Life Support for Health Care Providers within the last two years.<br><br>Initial anaphylaxis programme *(National Anaphylaxis Education Programme for Health Care Professionals)* via HSELanD followed by a one and a half hour classroom based skills workshop (replacing the previous four hour classroom based programme). Subsequent updates every two years via HSELanD Anaphylaxis e-learning programme available at www.hse.ie<br><br>The registered nurse/midwife must complete the *Competency Assessment Form* (Appendix II) to administer the seasonal influenza vaccine.<br><br>**Recommended:**<br>*Immunisation Foundation Programme*, available at www.hseland.ie<br><br>*The Flu Vaccine – It's a Lifesaver*, available at www.hseland.ie |

**References**


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

Health Service Executive (2010) *Healthcare Risk Waste Management Segregation Packaging and Storage Guidelines for healthcare Risk Waste.* Dublin: Health Service Executive

National Immunisation Advisory Committee (2021) *Management of a Patient with Anaphylaxis.* Available at https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/anaphylaxis.pdf

National Immunisation Advisory Committee *Immunisation Guidelines for Ireland* Dublin: Royal College of Physicians Ireland. Online update available at http://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/

National Immunisation Office (2021) *Seasonal Influenza Peer Vaccination Programme: Guidelines for Staff* Dublin: Health Service Executive

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: http://www.nmbi.ie/Standards-Guidance/Code

Nursing and Midwifery Board of Ireland (2020) Guidance for Registered Nurses and Midwives on Medication Administration. Dublin: Nursing and Midwifery Board of Ireland

Nursing and Midwifery Board of Ireland (2015) *Practice Standards for Midwives.* Dublin: Nursing and Midwifery Board of Ireland available at: http://www.nmbi.ie/Standards-Guidance/Midwives-Standards

Nursing and Midwifery Board of Ireland (2015) *Recording Clinical Practice. Guidance to Nurses and Midwives.* Dublin: Nursing and Midwifery Board of Ireland available at: http://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: http://www.nmbi.ie/Standards-Guidance/Scope-of-Practice/Nursing-Practise-Scope-Definition.

**Appendix I**

**Signature Sheet**

**Name of Medicine Protocol: Medicine Protocol for the Administration of Quadrivalent Influenza Vaccine (split virion, inactivated) to recipient healthcare workers**

I have read, understand & agree to adhere to this medicine protocol

| Name | Signature | Occupation | NMBI PIN | Date |
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The above signed registered nurses/midwives are authorised by the signatories on page 2 to administer influenza vaccine in accordance with this medicine protocol.

## Appendix II: Competency Assessment Form

Seirbhís Sláinte Nios Fearr á Forbairt | Building a Better Health Service

Office of the Nursing & Midwifery Services Director

NAME:_____

(PRINT CLEARLY in CAPITALS)

NMBI PIN:_____

**Self-Assessment of Competency to Administer Seasonal Influenza Vaccine under Medicine Protocol**

| | **Critical Element** | **Competent** Date/Initials | **Needs Practice** Date/Initials | **Needs Theory** Date/Initials |
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| 1 | I understand the role and function of medicine protocols in the context of NMBI guidelines in relation to:<br>• The Code of Professional & Ethical Conduct<br>• Scope of Nursing and Midwifery Practice<br>• Guidance to Nurses and Midwives on Medication Management<br>• Guidance for Registered Nurses and Midwives on Medication Administration (Guiding Principle 2, page 12, 2.8). | | | |
| 2 | I practice within my scope of practice to undertake administration of seasonal influenza vaccine, under medicine protocol. | | | |
| 3 | I am familiar with and adhere to the practices as set out in:<br>• *Seasonal Influenza Peer Vaccination Programme: Guidelines for Staff* (HSE, 2021)<br>• *Immunisation Guidelines for Ireland* (NIAC). | | | |
| 4 | I have successfully completed the HSELanD education programme for registered nurses and midwives: *Seasonal Influenza Peer Vaccination Programme 2021/2022. Education Programme for Nurses and Midwives*. | | | |
| 5 | I have attended Basic Life Support for Health Care Providers within the last two years. | | | |
| 6 | I am competent in safe intramuscular injection technique. | | | |
| 7 | I have successfully completed an approved Anaphylaxis education programme as outlined in section 5.0 of the medicine protocol and am familiar with NIAC protocol *Management of a Patient with Anaphylaxis* (2021). | | | |
| 8 | I undertake to review the most current vaccination information from the NIO - www.immunisation.ie. | | | |
| 9 | I can outline the inclusion/exclusion criteria for administering influenza vaccine under the named medicine protocol. | | | |
| 10 | In assessing suitability for vaccination I can undertake a clinical assessment of recipient healthcare workers within the scope of the medicine protocol. | | | |
| 11 | I can refer those who meet the exclusion criteria to the relevant medical practitioner for an individual medical assessment as per medicine protocol. | | | |
| 12 | I am familiar with the documentation required to support implementation of the medicine protocol to ensure safe administration of influenza vaccine. | | | |
| 13 | I can provide information regarding seasonal influenza vaccine, benefits and side effects to recipient healthcare workers. | | | |
| 14 | I am aware of the procedure for treatment and reporting of adverse reactions. | | | |
| 15 | I understand the procedure for reporting and documentation of | | | |

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| | medication errors/near misses. | | | |
| 16 | I dispose of all equipment and sharps in accordance with guidance for Healthcare Risk Waste HSE (2010). | | | |
| 17 | I am aware of and comply with the guidance on vaccine storage and handling including the maintenance of the cold chain in accordance with national and local policies. | | | |
| 18 | I have undertaken the following HSELanD/online programmes:<br>• AMRIC Aseptic Technique www.hseland.ie<br>• AMRIC Hand Hygiene www.hseland.ie<br>• GDPR Guidelines www.hseland.ie<br>• National Consent Form www.hse.ie | | | |

*I have sufficient theoretical knowledge and practice to undertake vaccination under this medicine protocol independently, and I acknowledge my responsibility to maintain my own competence in line with the Scope of Nursing and Midwifery Practice Framework and current best evidence.*

Registered Nurse/Midwife **Signature:**_____ **Date:** _____

*If any deficits in theory and/or clinical practice are identified, the registered nurse/midwife must discuss with relevant Line Manager and implement appropriate action plan to achieve competency within an agreed time frame.*

**Action Plan** (for use if needed to reach competencies outlined)

Action necessary to achieve competency:

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Date to be achieved:……

Supporting evidence of measures taken to achieve competency:

……

……

Registered Nurse/Midwife signature: Date:

_____ _____

Line Manager signature Date:

_____ _____