Medicine Protocol for the Administration of Vaxzevria® Vaccine (AstraZeneca) to Vaccine Recipients

This medicine protocol is a specific written instruction for the administration of Vaxzevria® Vaccine (AstraZeneca) to vaccine recipients by healthcare professionals included in Statutory Instruments S.I. No. 698 of 2020, S.I. No. 81 of 2021 and S.I. No. 245 of 2021 who are registered with their respective regulatory body and students in healthcare professions included in S.I. No. 245 of 2021. This medicine protocol is valid for the 2021/2022 HSE COVID-19 Vaccination Programme. This medicine protocol enables the healthcare professionals and students described above employed in the voluntary and statutory services of the Health Service Executive (HSE) who have undertaken the required education and training programmes to administer Vaxzevria® Vaccine (AstraZeneca) to vaccine recipients, with reference to guidelines and guidance from the National Immunisation Advisory Committee (NIAC), National Immunisation Office (NIO), HSE and in accordance with the Summary of Product Characteristics for Vaxzevria® Vaccine (AstraZeneca) as detailed by the European Medicines Agency (EMA).

- 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 (2020) *Clinical Guidance for COVID-19 Vaccinations* https://www.hse.ie/eng/health/immunisation/hcpinfo/covid19vaccineinfo4hps/clinicalguidance.pdf
- Summary of Product Characteristics https://www.ema.europa.eu/en/documents/product-information/Vaxzevria® Vaccine (AstraZeneca) -previously-covid-19-vaccine-astrazeneca-epar-product-information_en.pdf

A medicine protocol has been defined as follows: written directions that allow for the supply and administration of a named medicinal product by specified healthcare professionals or students in identified clinical situations. A medicine protocol involves the authorisation of the healthcare professional or student 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.

The HSE has developed this medicines protocol to facilitate the delivery of COVID-19 immunisation in line with NIAC recommendations, Department of health (DoH) and HSE policy.

The professional groups and students using this protocol must ensure that the protocol is organisationally authorised by an appropriate authorising person, related to the professional or student cohort of vaccinators by whom the vaccine is to be administered, including requirements of registration, training and assessment of competency.

Medicine Protocol for the Administration of Vaxzevria® Vaccine (AstraZeneca) to vaccine recipients

Document reference number:	NIO 001.3
1.0 Critical Elements	
Name of Organisation where medicine protocol applies	Health Service Providers across the voluntary and statutory services of the Health Service Executive (HSE), non-HSE healthcare facilities and mass vaccination clinic venues. This Medicine Protocol applies to: Registered healthcare professionals included in S.I. 698, S.I. 81 and S.I. 245, employed in the voluntary and statutory services of the Health Service Executive (HSE) and students in healthcare professions included in S.I. No. 245 of 2021 who have undertaken the required education and training programmes.
Date the medicine protocol comes into effect	February 2021
Date for review of medicine protocol	February 2022
Document prepared by:	The National Immunisation Office (NIO)
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 Kevin Kelleher,** Assistant National Director, National Office for Public Health/Child Health Strategic Planning and Transformation, HSE Signature:  Name: **Dr Colm Henry**, Chief Clinical Officer, 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 immunisation of vaccine recipients (see Inclusion Criteria) against COVID-19.
Circumstances in which the medicine protocol applies	Targeted immunisation programme for vaccine recipients against COVID-19 as identified in the DoH policy based on the NIAC recommendations. The World Health Organisation declared COVID-19 outbreak as a pandemic on 11th March 2020 which is still ongoing.
Inclusion criteria for vaccine recipient using the medicine protocol	**Note: Vaccine Recipients who have received Vaxzevria® Vaccine (AstraZeneca) as a first dose MUST be advised that the second dose is ALSO Vaxzevria® Vaccine (AstraZeneca) ONLY.** **Inclusion Criteria:** ● Active immunisation to prevent COVID-19 caused by SARS-CoV-2 virus ● Generally recommended for People aged 50 years and older. ● Vaxzevria® may be administered for those aged 18-34 years to provide early protection. The vaccine is provided as they have made an informed decision based on their understanding of the risk of developing thrombosis with thrombocytopenia syndrome (TTS) compared with the consequences of COVID-19 infection, the options of other effective public health measures and the benefits of a sooner vaccine. (People aged 70 years and older should be offered an mRNA vaccine as this is Department of Health policy) **2nd dose of Vaxzevria (for those that have already received a 1st dose):** People aged 18 years and older **Precautions:** ● Acute severe febrile illness defer until recovery <u>Advice from a relevant specialist should be sought for:</u> • a person with a history of immediate severe allergic reaction to multiple , drug classes, with no identified allergen •anaphylaxis to a vaccine, injected antibody preparation or a medicine likely to contain polysorbate 80 • idiopathic anaphylaxis If vaccination is advised, in a patient with prior anaphylaxis to an unrelated allergen, the patient should be observed for 30 minutes after vaccination. ● Vaccination should be deferred until clinical recovery from COVID-19 at least four weeks after diagnosis or onset of symptoms, or four weeks from the first PCR positive specimen in those who are asymptomatic ● Vaccination is not contraindicated for those with persisting symptoms post COVID-19 unless there is evidence of recent clinical deterioration ● Individuals with a bleeding disorder or receiving anticoagulant therapy may develop haematomas in IM (intramuscular) injection sites. Prior to vaccination, inform the recipient about this risk. For those with thrombocytopenia (platelet count <50 x 10^3/ml) consult the supervising consultant ● Those with inherited coagulopathies who require factor replacement therapy

	should receive it on the day of vaccination, prior to the IM vaccination. If there is uncertainty about the need for cover, contact the patient's Comprehensive Care Centre ● COVID-19 vaccines and other vaccines may be administered at the same time or at any interval. As it is not known if COVID-19 vaccine reactogenicity is increased with coadministration, vaccines should preferably be given in different limbs. ● Patients with planned immunosuppressive therapy should ideally complete vaccination two weeks before treatment. An interval of 4-12 weeks may be used **Pregnancy:** mRNA COVID-19 vaccines (Comirnaty® or COVID-19 Vaccine Moderna®) should be offered as per the NIAC recommendation **Pregnant women who have already received a 1st dose** The 2nd dose should be given with an interval of between 4 - 12* weeks between 14 and 36 completed weeks of gestation or else post-partum. **a 4 week interval is now recommended by the National Immunisation Advisory Committee and is being operationalised by the HSE over the coming weeks* **Breastfeeding:** ● There is no known reason for vaccine recipients to avoid breastfeeding
Exclusion criteria for vaccine recipient using the medicine protocol	Vaxzevria® Vaccine (AstraZeneca) should not be given under this medicine protocol if the vaccine recipient has: ● Anaphylaxis (serious systemic allergic reaction requiring medical intervention) following a previous dose of the vaccine or any of its constituents (including polysorbate 80). ● A history of capillary leak syndrome ● A second dose of Vaxzevria® should not be given to anyone who developed Thrombosis with Thrombocytopenia Syndrome (TTS) after the first dose ● Those with a contraindication to one viral vector COVID-19 vaccine should not receive another authorised viral vector vaccine.
Actions to be taken for those who are excluded from the medicine protocol	● Refer to/discuss with the relevant Medical Practitioner/Clinical lead/Lead vaccinator for an individual medical assessment. ● Those with a contraindication to one viral vector COVID-19 vaccine should not receive another authorised viral vector vaccine. Consideration may be given to mRNA vaccination which should be given after an interval of at least 28 days. ● The Medical Practitioner/clinical lead/lead vaccinator can consider referring the individual to an allergist/Immunologist for a further discussion. ● Document action in clinical record or IT System ● Where Vaxzevria® Vaccine (AstraZeneca) is prescribed following medical assessment, the vaccinator may administer the vaccine within his/her scope of practice. **Note:** In determining their scope of practice, vaccinators must make judgements about their competency to carry out a role or activity in accordance with the guidance from their regulator.
Action to be followed for vaccine recipients who do not wish to receive the vaccine	Advise of the risks of not having the vaccine, including risk of possible severe COVID-19 disease. Advise regarding minimisation of risk
Description of circumstances and referral arrangements when further advice or consultation is required	Refer to/discuss with relevant Medical Practitioner/Clinical lead/lead vaccinator if the vaccine recipient had previous adverse reaction or other clinical concerns as outlined in Exclusion Criteria.

Documentation required to support implementation of the medicine protocol	• Check for and ensure consent has been obtained • Vaccine Information Leaflets • Patient held record cards • Health Products Regulatory Authority Adverse Reaction Reporting forms • National Incident Management System Form NIRF-01-v11 available at: https://www.hse.ie/eng/about/qavd/incident-management/nirf-01-v11-person.pdf It is the responsibility of each vaccinator to be familiar with the appropriate documentation to support the safe administration of Vaxzevria® Vaccine (AstraZeneca) which includes the following: • Medicine Protocol for the Administration of Vaxzevria® Vaccine (AstraZeneca) to vaccine recipients • Treatment of anaphylaxis in the community. National Immunisation Advisory Committee, Immunisation Guidelines for Ireland. https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/anaphylaxis • Clinical Guidance for Covid-19 Vaccination, available at https://www.hse.ie/eng/health/immunisation/hcpinfo/covid19vaccineinfo4hps/clinicalguidance.pdf • COVID-19 chapter from NIAC immunisation Guidelines for Ireland (2020) available at https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/covid19.pdf

3.0 Name of Medicine	Vaxzevria® Vaccine (AstraZeneca)
Dose & Route of administration	• The dose is 0.5ml • Route of administration: Intramuscular (IM) • Site: The preferred site is the deltoid muscle • Two doses of Vaxzevria® Vaccine (AstraZeneca) • Do not inject the vaccine intravascularly, subcutaneously or intradermally **Recommended intervals between doses of Vaxzevria® vaccine (AstraZeneca): 4-12 weeks (The reduction to an 4 week interval is now recommended by the National Immunisation Advisory Committee and is being operationalised by the HSE over the coming weeks)** The National Immunisation Advisory Committee recommends an interval of 4-12 weeks apart, therefore the following applies; • If the interval between doses is longer than 12 weeks, the second dose should still be given as soon as possible. The course does not need to be restarted. • If the second dose was given between 24 and 27 days after the first dose, it is a valid dose. • If the second dose is given before 24 days, this is not considered a valid vaccine. A third dose should be given 28 days after the second (invalid) vaccine.
Link to Medicine **Details of product information and other data including instructions for supply and administration is available from the European Medicines Agency (EMA)**	**Link to Summary of Product Characteristics and Patient Information Leaflet** Available at: https://www.ema.europa.eu/en/documents/product-information/Vaxzevria® Vaccine (AstraZeneca) -previously-covid-19-vaccine-astrazeneca-epar-product- information_en.pdf

Potential adverse reactions and procedures for treatment of same	Following administration of the vaccine, the vaccine recipient should be advised to remain seated in the post vaccination observation area to enable monitoring of any immediate reaction including suspected anaphylactic reaction ● Those with no history of anaphylaxis from any cause: 15 minutes ● Those with a history of anaphylaxis from any cause: 30 minutes ● Those with immediate itching, swelling or urticarial reaction at the vaccination site: 30 minutes or longer as clinically indicated The vaccine recipient should be advised to contact relevant medical personnel in the event of adverse reaction occurring following administration of the Vaxzevria® Vaccine (AstraZeneca) after the above period of observation.
Procedure for reporting Adverse Drug Reactions to the Health Products Regulatory Authority (HPRA)	The vaccinator 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. The vaccine recipient's General Practitioner should be informed of any clinically significant reported adverse reaction. In the event of anaphylaxis, the incident and all actions taken must be promptly recorded in accordance with the Management of a Patient with Anaphylaxis: Treatment in the Community (National Immunisation Advisory Committee 2019), available online 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 vaccine recipient, i.e. wrong medication/dose/route being administered or another medication error, the vaccinator must remain with the person and closely monitor them for any adverse reactions. The vaccine recipient should be reviewed by the relevant medical practitioner/clinical lead/lead vaccinator and vital signs should be recorded. The incident must be reported to the relevant line manager/person in charge as soon as possible. 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. (National Incident Report Form (NIRF 01 – V11)) (2020) available at: https://www.hse.ie/eng/about/qavd/incident-management/nirf-01-v11-person.pdf The vaccine recipient and/or significant others should be informed of the incident. An incident report form must be completed by the vaccinator and forwarded to local or regional Risk Manager as per local policy. Any suspected adverse reactions associated with medication errors should be reported to the HPRA as outlined above.
Resources and equipment required	● A multidose vial of Vaxzevria® Vaccine (AstraZeneca) ● 1 ml/2ml/2.5ml syringe, 23/25 gauge needle for IM administration ● Fridge/Cooler box with data logger with external temperature monitoring

	display to maintain cold chain temperature between +2° to +8°C ● Disposable kidney dishes/trays ● 70% alcohol swabs (for sterilizing vials) ● Gauze swabs, tape/plasters ● Sharps bins, and bins for disposal of healthcare risk and non-risk waste ● Alcohol hand sanitiser ● Access to telephone ● Resuscitation equipment and drugs in accordance with *Anaphylaxis*: *Treatment in the Community* (National Immunisation Advisory Committee, 2019) available at https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/anaphylaxis.pdf ● Safe storage areas for medicines and equipment ● Current Vaxzevria® Vaccine (AstraZeneca) medicine protocol
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/national agreement.
4.0 Information for vaccine recipient	
Advice to be given to the vaccine recipient before treatment	**Vaccine Information material must be supplied with the consent form to the vaccine recipient prior to administration of the vaccine.** **Before Treatment** Check and confirm that consent has been obtained Discuss the Vaxzevria® Vaccine (AstraZeneca) and the importance of protecting their health. Inform vaccine recipient that patient information leaflet is available online at https://www.ema.europa.eu/en/documents/product-information/Vaxzevria® Vaccine (AstraZeneca) -previously-covid-19-vaccine-astrazeneca-epar-product-information_en.pdf The most up to date patient information leaflet should be provided. Discuss potential side effects as below. Side effects may occur with following frequencies: Local: Very common: injection site bruising, pain, pruritus, tenderness, warmth Common: injection site erythema, swelling Uncommon: injection site haematoma General: Very common: arthralgia, chills, fatigue, feverishness, headache, malaise, myalgia, nausea Common: diarrhoea, fever >38°C, vomiting, thrombocytopenia Uncommon: decreased appetite, dizziness, hyperhidrosis, lymphadenopathy, pruritus, somnolence, rash Very rare: Thrombosis in combination with thrombocytopenia, capillary leak syndrome A combination of thrombosis and thrombocytopenia, in some cases accompanied by bleeding, has been observed very rarely following vaccination with Vaxzevria® Vaccine

Advice to be given to the recipient after treatment	(AstraZeneca). This includes severe cases presenting as venous thrombosis, including unusual sites such as cerebral venous sinus thrombosis, splanchnic vein thrombosis, as well as arterial thrombosis, concomitant with thrombocytopenia. The majority of these cases occurred within the first fourteen days following vaccination. Recipients of Vaxzevria® Vaccine (AstraZeneca) should be instructed to seek prompt medical assistance and mention recent vaccination if they have any of the following in the weeks after receiving the Vaxzevria® Vaccine (AstraZeneca): ● breathlessness, ● pain in the chest or stomach, ● swelling or coldness in a leg, ● severe or worsening headache or blurred vision after vaccination, ● persistent bleeding, ● multiple small bruises, reddish or purplish spots, or blood blisters under the skin Additionally, anyone with neurological symptoms including severe or persistent headaches (particularly 3 or more days after vaccination), blurred vision, confusion or seizures or who develops petechiae or ecchymoses beyond the site of vaccination, should seek prompt medical attention Capillary leak syndrome is now listed as a rare side effect of Vaxzevria vaccine. Recipients should be advised so seek medical attention if they have the following symptoms in the days after vaccination, which may be associated with feeling faint (due to low blood pressure): ● oedema in the extremities ● sudden weight gain. Guillain-Barré syndrome (GBS) has been reported very rarely following vaccination with Vaxzevria. A causal link has not been established. Healthcare professionals should be alert of GBS signs and symptoms to ensure correct diagnosis, in order to initiate adequate supportive care and treatment, and to rule out other causes. A full list of adverse reactions may be found in the Summary of Product Characteristics (SmPC), available at https://www.ema.europa.eu/en/documents/product-information/Vaxzevria® Vaccine (AstraZeneca) -previously-covid-19-vaccine-astrazeneca-epar-product- information_en.pdf **After Treatment** Discuss potential side effects Following administration of the vaccine, the vaccine recipient should be advised to remain seated in the post vaccination observation area to enable monitoring of any immediate reaction including suspected anaphylactic reaction. Events of anaphylaxis have been reported therefore NIAC recommends the following monitoring for the post-vaccination period: ● Post vaccination observation period ● Those with no history of anaphylaxis from any cause: 15 minutes ● Those with a history of anaphylaxis from any cause: 30 minutes ● Those with immediate itching, swelling or urticarial reaction at the vaccination site: 30 minutes or longer as clinically indicated ● The second dose of the vaccine should not be given to those who have experienced anaphylaxis to the first dose of Vaxzevria® Vaccine (AstraZeneca) or any of its constituents including Polysorbate 80 The vaccine recipient should not leave the healthcare facility if they are feeling unwell and must report any side effects to a member of the vaccination team. The vaccine recipient should be advised to report any side effects to the relevant medical practitioner.

	If required, symptomatic treatment with analgesic and/or anti-pyretic medicinal products (e.g. paracetamol or ibuprofen-containing products) may be used. Ibuprofen is not recommended in pregnancy. If more serious adverse or persistent effects occur, vaccine recipient should be advised to contact their GP/out of hours service.
Details of any necessary follow-up, action and referral arrangements	In the event of an adverse reaction the vaccination team must ensure that all procedures are adhered to as outlined in Section 3.

References

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 (2019) Anaphylaxis: Treatment in the Community. Available at https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/anaphylaxis.pdf

National Immunisation Advisory Committee *Immunisation Guidelines for Ireland (2020)* Dublin: Royal College of Physicians Ireland. Online update available at http://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/

National Immunisation Office (2020) *Clinical Guidance for COVID-19 Vaccinations* (available at https://www.hse.ie/eng/health/immunisation/hcpinfo/covid19vaccineinfo4hps/)

S.I. No. 81/2021 - Medicinal Products (Prescription and Control of Supply) (Amendment) (No.4) Regulations 2021. Available at http://www.irishstatutebook.ie/eli/2021/si/81/made/en/pdf

S.I. No. 698/2020 - Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 7) Regulations 2020. Available at http://www.irishstatutebook.ie/eli/2020/si/698/made/en/pdf

S.I. No. 245 of 2021 - Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 7) Regulations 2021. Available at http://www.irishstatutebook.ie/eli/ResultsSITitle.html?&years=2021

Section B Information Specific to Registered Nurses and Registered Midwives for the administration of the COVID-19 vaccines

Statement of Support from Dr Geraldine Shaw, Nursing and Midwifery Services Director, Office of the Nursing and Midwifery Services, HSE

I am delighted to support Registered Nurses and Registered Midwives to administer COVID-19 vaccines under medicine protocol.

Nurses and midwives have a long tradition of supporting vaccination programmes, for example Schools Immunisation Programme, Seasonal Influenza Peer Vaccination Programme and Primary Childhood Immunisation Programme.

The national COVID-19 vaccination programme commenced in December 2020. Statutory Instruments No. 698 of 2020, No. 8 of 2021 and No. 43 of 2021 identify nurses and midwives as professions that can administer named COVID-19 vaccines, subject to approval of an education programme by the regulatory body concerned.

In order to administer the vaccines, registered nurses and registered midwives must be familiar with the most up to date version of the medicine protocols including the content of this section and have completed the *COVID-19 Vaccination Programme for Nurses and Midwives* on HSELanD. Nurses and midwives must also have completed the Competency Assessment Form, also included in this section.

I would like to acknowledge the contribution of the nursing and midwifery professions to this very important national initiative.

Signature

30th March 2021

Date

Professional Qualifications, Training, Experience and Competence Required

Professional qualifications, training, experience and competence required prior to using this medicine protocol / Professional Qualifications :	Registered nurse or registered midwife, maintained on the active register maintained by The Nursing and Midwifery Board of Ireland. HSELanD education programme titled *COVID-19 Vaccination Programme for Nurses and Midwives* Basic Life Support for Health Care Providers within the last two years.
Training, Experience, Competence:	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. The nurse/midwife must complete the *Competency Assessment Form* to administer the COVID-19 Vaccines. COVAX IBM/Salesforce online programme https://www.hse.ie/eng/health/immunisation/hcpinfo/hsecovid19vms.html **Recommended:** *Storing and Managing Vaccines* www.hseland.ie

Supporting Documents for Registered Nurses and Registered Midwives

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

Health Service Executive (2019) *Directions for Nurses and Midwives for the Management of a Patient who Develops Anaphylaxis or Suspected Anaphylaxis incorporating Medicine Protocol for the Administration of Epinephrine (Adrenaline) Injection BP 1:1,000 by intramuscular injection by nurses and midwives for the management of a patient with anaphylaxis or suspected anaphylaxis.* Dublin: Health Service Executive

Government of Ireland (2020) *Statutory Instruments Number 698 of 2020*. Dublin: Stationery Office

Government of Ireland (2021) *Statutory Instruments Number 8 of 2021*. Dublin: Stationery Office

Government of Ireland (2021) *Statutory Instruments Number 43 of 2021*. Dublin: Stationery Office

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

Nursing and Midwifery Board of Ireland (2014) *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 (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

Nursing and Midwifery Board of Ireland (2020) Guidance for Registered Nurses and Midwives on Medication Administration. Dublin: Nursing and Midwifery Board of Ireland, available at: http://www.nmbi.ie

Competency Assessment Form

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

Office of the Nursing & Midwifery Services Director

NAME:

Self-Assessment of Competency to Administer COVID-19 Vaccine under Medicine Protocol

Domain of Practice	**Critical Element**	**Competent** Date/ Initials	**Needs Practice** Date/ Initials	**Needs Theory** Date/ Initials
1	I understand the role and function of medicine protocols in the context of NMBI guidelines in relation to: ● The Code of Professional & Ethical Conduct ● Scope of Nursing and Midwifery Practice ● Guidance to Nurses and Midwives on Medication Management ● NIAC Immunisation Guidelines for Ireland.			
2	I practice within my scope of practice to undertake administration of COVID-19 Vaccines under medicine protocol.			
3	I have undertaken the *COVID-19 Vaccination Programme for Nurses and Midwives* on HSELanD.			
4	I have attended Basic Life Support for Health Care Providers within the last two years.			
5	I am competent in safe injection technique.			
6	I have attended an approved Anaphylaxis education programme and I am familiar with the current medicine protocol on the administration of Epinephrine by RNs/RMs.			
7	I can outline the inclusion/ exclusion criteria for administering COVID-19 Vaccine under the named medicine protocol.			
8	I can refer to/discuss those that are meeting the exclusion criteria to the relevant medical practitioner for an individual medical assessment as per medicine protocol.			
9	I am familiar with the documentation required to support implementation of the medicine protocol to ensure safe administration of COVID-19 Vaccine.			
10	In assessing suitability for vaccination I can undertake a clinical assessment of individuals within the scope of the medicine protocol.			
11	I can provide information regarding COVID-19 Vaccine, benefits and side effects to vaccine recipients.			
12	I am aware of the procedure for treatment and reporting of potential adverse reactions.			
13	I understand the procedure for reporting and documentation of medicine errors/ near misses.			
14	I dispose of all equipment and sharps in accordance with guidance for Healthcare Risk Waste (HSE, 2010).			
15	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.			

16	I have undertaken the following HSELanD/online programmes: ● AMRIC Aseptic Technique www.hseland.ie ● AMRIC Hand Hygiene www.hseland.ie ● GDPR guidelines www.hseland.ie ● COVAX IBM/Salesforce online programme https://www.hse.ie/eng/health/immunisation/hcpinfo/hsecovid19vms.html			

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 and current best evidence.

Registered Nurse/Midwife Signature:_____ Date:_____

If any deficits in theory and/or clinical practice are identified, the 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:

……

……

……

.. Date to be achieved:……

Supporting evidence of measures taken to achieve competency:

……

……

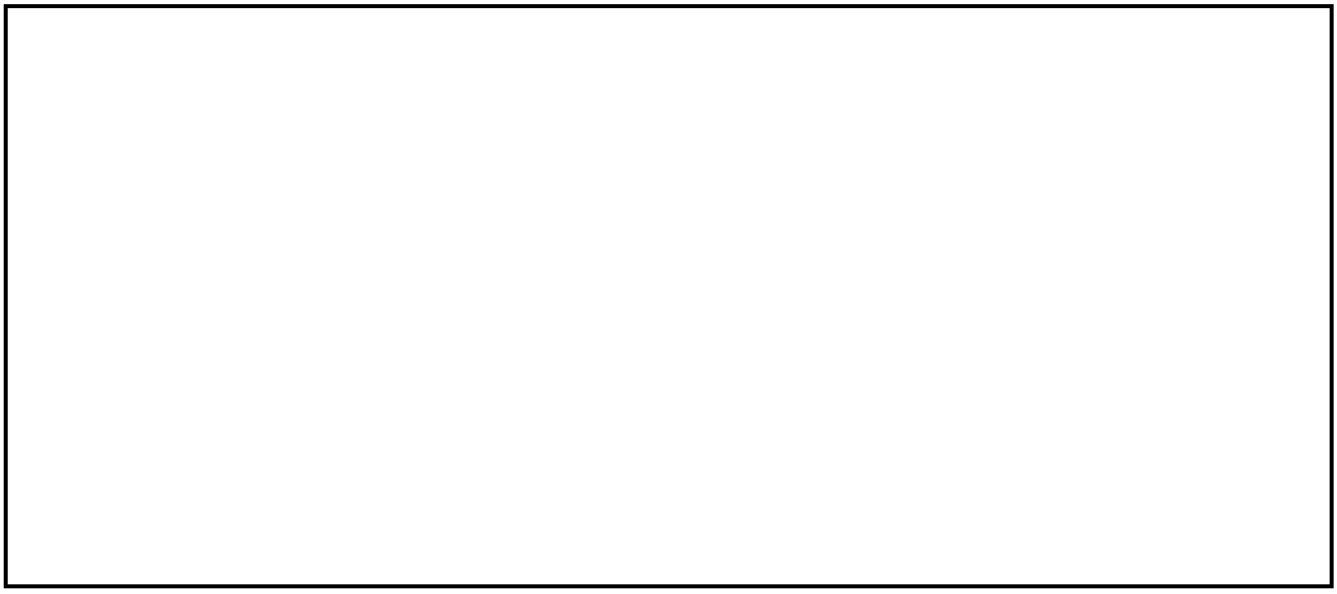
Nurse/Midwife signature:

ate:_____

Line Manager signature

ate:_____

Nursing and Midwifery Board of Ireland Statement of Support 2021



Updated on 13th July 2021