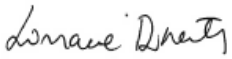
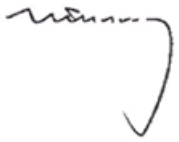
Medicine Protocol for the Administration of COVID-19 Vaccine AstraZeneca to Vaccine Recipients

This medicine protocol is a specific written instruction for the administration of COVID-19 Vaccine AstraZeneca to vaccine recipients by registered nurses and registered midwives. This medicine protocol is valid for the 2021/2022 HSE COVID-19 Vaccination Programme. This medicine protocol enables registered nurses and registered midwives employed in the voluntary and statutory services of the Health Service Executive (HSE) who have undertaken the required education and training programmes to administer COVID-19 Vaccine AstraZeneca to vaccine recipients, 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 for COVID-19 Vaccine AstraZeneca as detailed by the European Medicines Agency (EMA).

- 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
- 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* (available at https://www.hse.ie/eng/health/immunisation/hcpinfo/covid19vaccineinfo4hps/clinicalguidance.pdf)
- 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
- 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 (2020) *Guidance for Registered Nurses and Midwives on Medication Administration*. Dublin: Nursing and Midwifery Board of Ireland

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) (See Appendix III NMBI Statement of Support 2020).

Medicine Protocol for the Administration of COVID-19 Vaccine AstraZeneca to vaccine recipients

Document reference number:	ONMSD 2021-003
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 nurses and registered midwives involved in the administration of COVID-19 Vaccine AstraZeneca to vaccine recipients under this medicine protocol.
Date the medicine protocol comes into effect	February 2021
Date for review of medicine protocol	February 2022
Document prepared by:	Office of the Nursing and Midwifery Services Director (ONMSD) HSE in collaboration with 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. Lorraine Doherty**, National Clinical Director 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 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: The dosing interval for COVID-19 Vaccine AstraZeneca is 12 weeks for all age groups. Vaccine Recipients who have received COVID-19 Vaccine AstraZeneca as a first dose MUST be advised that the second dose is ALSO COVID-19 Vaccine AstraZeneca ONLY.** **Inclusion Criteria:** • Active immunisation to prevent COVID-19 caused by SARS-CoV-2 virus, in individuals aged ≥ 18 years. People aged 70 years and older should be offered an mRNA vaccine as this is Department of Health policy. **Precautions:** • Acute severe febrile illness defer until recovery • Advice from a relevant specialist should be sought for a person with a history of an immediate severe allergic reaction to any other vaccine or injectable therapy and the risks should be weighed against the benefits of vaccination. 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 • Co-administration with other vaccines has not been studied. It is prudent to leave 14 days between administering COVID-19 vaccine and administering another vaccine • Patients with planned immunosuppressive therapy should ideally complete vaccination two weeks before treatment. The recommended minimum interval

	may be used. **Pregnancy:** • Women who are at less than 14 weeks or more than 33 weeks of gestation should not receive the vaccine • Pregnant women who are between 14 weeks and 33 weeks of gestation and wish to receive the vaccine should confirm they have consulted with their obstetric care giver (Obstetrician or GP) and decided to receive the vaccine. When COVID-19 Vaccine AstraZeneca is being administered in pregnancy, the two dose schedule should be given 12 weeks apart if possible. However, as the two dose schedule should be given between 14 and 33 completed weeks of gestation, a shorter interval can be used, 4-12 weeks apart. **Breastfeeding:** • There is no known reason for vaccine recipients to avoid breastfeeding. Breastfeeding mothers should be vaccinated according to their risk grouping.
Exclusion criteria for vaccine recipient using the medicine protocol	COVID-19 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).
Actions to be taken for those who are excluded from the medicine protocol	• Refer to/discuss with the relevant Medical Practitioner for an individual medical assessment • Document action in clinical notes • Where COVID-19 Vaccine AstraZeneca is prescribed following medical assessment, the nurse or midwife may administer the vaccine within his/her scope of practice. **Note:** In determining their scope of practice, nurses and midwives must make judgements about their competency to carry out a role or activity (NMBI, 2015).
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. Advice regarding minimisation of risk
Description of circumstances and referral arrangements when further advice or consultation is required	Refer to/discuss with relevant Medical Practitioner 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	• Vaccine consent forms or check for and ensure online consent • 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 nurse or midwife to be familiar with the appropriate documentation to support the safe administration of COVID-19 Vaccine AstraZeneca which includes the following:

	• Medicine Protocol for the Administration of COVID-19 Vaccine AstraZeneca to vaccine recipients • Directions for nurses and midwives for the management of a patient who develops anaphylaxis or suspected anaphylaxis incorporating *Medication Protocol for the Administration of Epinephrine (Adrenaline) Injection BP 1:1000 by intramuscular injection by nurses and midwives for the management of a patient with anaphylaxis or suspected anaphylaxis (HSE,* 2019), available at http://www.hse.ie/eng/health/immunisation/hcpinfo/fluinfo/adrenalineprotocol.pdf • 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	COVID-19 Vaccine AstraZeneca
Dose & Route of administration	• The dose is 0.5ml • Route of administration: IM Site • The preferred site is the deltoid muscle • Two doses of COVID-19 Vaccine AstraZeneca are required with an interval of 12 weeks between doses. 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 interval between doses is less than 24 days, a further dose is not required. • Do not inject the vaccine intravascularly, subcutaneously or intradermally
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/covid-19-vaccine-astrazeneca-product-information-approved-chmp-29-january-2021-pending-endorsement_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 COVID-19 Vaccine AstraZeneca after the above period of observation.

Procedure for reporting Adverse Drug Reactions to the Health Products Regulatory Authority (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. The vaccine recipient's General Practitioner should be informed of any reported adverse reaction. 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 registered nurse or midwife must remain with the person and closely monitor them for any adverse reactions. Vital signs should be recorded and the vaccine recipient should be reviewed by the relevant medical practitioner or other appropriate physician. 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 nurse or midwife 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 COVID-19 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 other hazardous material • Alcohol hand rinse • 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 COVID-19 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 the online consent has been provided or obtain signed consent. Discuss the COVID-19 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/covid-19-vaccine-astrazeneca-product-information-approved-chmp-29-january-2021-pending-endorsement_en.pdf Discuss potential side effects. Evidence shows that protection starts from approximately 3 weeks after first dose of vaccine and persists up to 12 weeks. Modelling showed no evidence of waning of protection in the first three months after vaccination. Higher efficacy after the second dose was found if the booster dose was given at 12 weeks.
Advice to be given to the recipient healthcare worker after treatment	**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 COVID-19 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 may be advised:** 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 **Uncommon:** decreased appetite, dizziness, hyperhidrosis, lymphadenopathy, pruritus, somnolence, rash 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/covid-19-vaccine-astrazeneca-product-information-approved-chmp-29-january-2021-pending-endorsement_en.pdf 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.
5.0 Staff authorised to use this medicine protocol	
Professional qualifications, training, experience and competence required prior to using this medicine protocol / Professional Qualifications: **Training, Experience, Competence:**	Registered nurse or registered midwife, maintained on the active register maintained by The Nursing and Midwifery Board of Ireland. Education programme for nurses and midwives on the use of *COVID-19 Medicine Protocol for the Administration of COVID-19 Vaccine AstraZeneca* to vaccine recipients by registered nurses and registered midwives and any updates. Basic Life Support for Health Care Providers within the last two years. 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* (Appendix II) to administer the *COVID-19 Vaccine AstraZeneca.* **Recommended:** *Storing and Managing Vaccines* www.hseland.ie

References

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

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/)

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

Appendix I

Signature Sheet:

Name of Protocol: *Medicine Protocol for the Administration of COVID-19 Vaccine AstraZeneca* to vaccine recipients by registered nurses and registered midwives.
I have read, understood & agreed to adhere to the attached medicine protocol.

Name:	**Signature:**	**Occupation:**	**Pin No:**	**Date:**

The above signed nurses and midwives are authorised by the signatories on page 2 to administer *COVID-19 Vaccine AstraZeneca* in accordance with this medicine protocol.

Appendix II: Competency Assessment Form

NAME:_____

(PRINT CLEARLY in CAPITALS)

Self-Assessment of Competency to Administer COVID-19 Vaccine AstraZeneca 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 Vaccine AstraZeneca under medicine protocol.			
3	I have undertaken the education programme for nurses and midwives on the use of medicine protocol for the administration of COVID-19 Vaccine AstraZeneca			
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 AstraZeneca 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 AstraZeneca.			
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 AstraZeneca, 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 programmes: • AMRIC Aseptic Technique www.hse.ie • AMRIC Hand Hygiene www.hse.ie • GDPR guidelines www.hseland.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 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:

_____ Date:_____

Line Manager signature

_____ Date:_____

Appendix III: Nursing and Midwifery Board of Ireland Statement of Support 2021