Master Medicine Protocol for the Administration of Spikevax® (COVID-19 Vaccine Moderna) to Vaccine Recipients

This medicine protocol is a specific written instruction for the administration of Spikevax® (COVID-19 Vaccine Moderna) to vaccine recipients by healthcare professionals included in Statutory Instruments S.I. No. 698 of 2020, S.I. No. 81 of 2021, S.I. No. 245 of 2021 and S.I. No. 441 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 2020/2021 HSE COVID-19 Vaccination Programme. This medicine protocol enables the healthcare professionals and students described above who are employed in the voluntary and statutory services of the Health Service Executive (HSE) who have undertaken the required education and training programmes to administer Spikevax® (COVID-19 Vaccine Moderna) to vaccine recipients, with reference to guidelines and guidance from National Immunisation Advisory Committee (NIAC), National Immunisation Office (NIO), HSE and in accordance with the Summary of Product Characteristics for Spikevax® (COVID-19 Vaccine Moderna) 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* (available at https://www.hse.ie/eng/health/immunisation/hcpinfo/covid19vaccineinfo4hps/clinicalguidance.pdf)
- Summary of Product Characteristics https://www.ema.europa.eu/en/medicines/human/EPAR/covid-19-vaccine-moderna#product- information-section

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 and 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, relating 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 Spikevax® (COVID-19 Vaccine Moderna) to vaccine recipients

Document reference number:	NIO 001.2
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 of 2020, S.I. 81 of the 2021, S. I. No. 245 and 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	January 2021
Date for review of medicine protocol	January 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 Organization declared COVID-19 outbreak as a pandemic on 11th March 2020 which is still ongoing.
Inclusion criteria for vaccine recipient using the medicine protocol	**Inclusion Criteria:** ● Active immunisation to prevent COVID-19 caused by SARS-CoV-2 virus, in individuals 12 years of age and older. **Precautions:** ● Acute severe febrile illness defer until recovery ● Those with the following history should receive a viral vector vaccine: ● Anaphylaxis after multiple, different drug classes, with no identified allergen (may indicate PEG allergy) ● Anaphylaxis after a vaccine, or a medicine which contained PEG ● Idiopathic anaphylaxis (may indicate PEG allergy) ● Specialist advice should be sought before vaccination for those with a prior history of pericarditis after a previous dose of an mRNA vaccine If vaccination is advised for a person with prior anaphylaxis to an unrelated allergen observe 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 • For those receiving a booster dose of vaccine, who have had laboratory-confirmed breakthrough COVID-19 disease since completion of primary vaccination, the booster dose should be deferred until at least 6 months following diagnosis. • For those who are immunocompromised and receiving as additional dose of vaccine: if they have had laboratory-confirmed breakthrough COVID-19 disease since completion of primary vaccination, the booster dose should be deferred until at least 6 months following diagnosis. ● 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 intramuscular (IM) injection sites. Prior to vaccination, inform the recipient about this risk. For those with

	thrombocytopoenia (platelet count <50 x 103/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. The recommended minimum interval may be used. **Pregnancy:** • The vaccine can be given at any stage of pregnancy. • Pregnant women should confirm they have consulted with their obstetric care giver (Obstetrician or GP) and decided to receive the vaccine. **Breastfeeding:** ● There is no known reason for vaccine recipients to avoid breastfeeding. Breastfeeding mothers should be vaccinated according to their risk grouping. **Individuals who are immunocompromised due to disease or treatment (see the NIAC chapter 5aTable 2)** • An additional mRNA vaccine dose should be given to those aged 12 and older with immunocompromise due to disease or treatment who have completed their primary course, regardless of whether the primary course was of an mRNA or an adenoviral vector vaccine. This is an extended primary vaccination course. The additional vaccine should be given after a minimum interval of two months following the last dose of an authorised COVID-19 vaccine.
Exclusion criteria for vaccine recipient using the medicine protocol	Spikevax® (COVID-19 Vaccine Moderna) 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 polyethylene glycol (PEG)). ● Anaphylaxis following another mRNA vaccine. ● A history of myocarditis after a previous dose of an mRNA vaccine ● Those with a contraindication to one mRNA COVID-19 vaccine should not receive another authorised mRNA 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 mRNA COVID-19 vaccine should not receive another authorised mRNA vaccine. Consideration may be given to viral vector 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 assessment. • Document action in clinical record or IT system • Where Spikevax® (COVID-19 Vaccine Moderna) 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 minimization 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 if available • 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 Spikevax® (COVID-19 Vaccine Moderna) which includes the following: • Medicine Protocol for the Administration of Spikevax® (COVID-19 Vaccine Moderna) 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.pdf https://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	Spikevax® (COVID-19 Vaccine Moderna)
Dose & Route of administration	• The dose is 0.5ml, 2 doses 28 days apart • Route of administration: Intramuscular (IM) • Site: The preferred site is the deltoid muscle • If the interval between doses is longer than 28 days, the second dose should be given as soon as possible. The course does not need to be restarted • If the second dose was given between 21 and 27 days after the first dose, it is a valid dose • If the second dose is given before 21 days, this is not considered a valid vaccine. A third dose should be given 28 days after the second (invalid) vaccine. • Do not inject the vaccine intravascularly, subcutaneously or Intradermally • For those who have received Vaxzevria® as a first dose and are receiving Spikevax ®as a second dose, there should be at least a 28 day interval between doses.
Individuals who are immunocompromised due to disease or treatment: (see the NIAC chapter 5a, Table 2)- extended primary course	• An additional mRNA vaccine dose should be given to those aged 12 and older with immunocompromise condition due to disease or treatment who have completed their primary course, regardless of whether the primary course was of an mRNA or an adenoviral vector vaccine. This is an extended primary vaccination course. • The additional vaccine should be given after a minimum interval of two months following the last dose of an authorised COVID-19 vaccine.
Booster dose of COVID-19 Vaccine	The following groups who have completed their primary course with any COVID-19 vaccine type are recommended a single dose of an mRNA vaccine as a booster dose • People aged 65 years and older living in residential care facilities • Those aged 80 years and older living in the community The booster dose should be given after an interval of six months following the last dose of an authorised COVID-19 vaccine and can be given at the same time or at any interval before or after seasonal influenza 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/covid-19-vaccine- moderna-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 COVID-19 Vaccine Moderna 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. 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 recipient should be reviewed by the relevant medical practitioner/clinical lead/ lead vaccinator and the Vital signs to 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 Spikevax® (COVID-19 Vaccine Moderna) ● 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 the 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 COVID-19 Vaccine Moderna 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 to the vaccine recipient prior to administration of the vaccine.** **Before Treatment** Check and confirm that consent has been obtained Discuss the Spikevax® (COVID-19 Vaccine Moderna) 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- moderna-product-information_en.pdf Discuss potential side effects as below Side effects may occur with following frequencies: Local: Very common: injection site pain and swelling Common: injection site erythema, rash and urticaria Uncommon: injection site pruritus. General: Very common: arthralgia, axillary lymphadenopathy (on the side of injection), chills, fatigue, fever, headache, myalgia, nausea, vomiting

	Rare: acute peripheral facial paralysis, facial swelling (in those with dermatological fillers) Frequency unknown: Erythema Multiforme While there are no immediate serious safety concerns, accumulating data indicates that the rates of side effects may be higher in those receiving an mRNA vaccine as a 2nd dose, following a 1st dose of Vaxzevria®. As per the European Medicines Agency latest advice, cases of myocarditis and pericarditis have been reported very rarely following vaccination with the COVID-19 mRNA Vaccine including Spikevax®. Healthcare professionals should advise vaccinated individuals to seek immediate medical attention should they experience chest pain, shortness of breath, or palpitations. The cases primarily occurred within 14 days after vaccination, more often after the second dose and in younger men. 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- moderna-product-information_en.pdf Individuals may not be protected until at least 14 days after their second dose of the vaccine.
Advice to be given to the recipient 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: ● Close observation for at least 15 minutes is recommended following vaccination ● The second dose of the vaccine should not be given to those who have experienced anaphylaxis to the first dose of COVID-19 Vaccine Moderna. 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. 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

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