Master Medicine Protocol for the Administration of Nuvaxovid XBB.1.5 COVID-19 Vaccine to Vaccine Recipients 12 years and older

This medicine protocol is a specific written instruction for the administration of Nuvaxovid XBB.1.5 COVID-19 Vaccine to vaccine recipients, 12 years and older, included in the Statutory Instruments S.I. No. 584 of 2023 by healthcare professionals who are registered with their respective regulatory body in healthcare professions included in S.I. No. 698 of 2020, S.I. No. 81 of 2021, S.I. No. 245 of 2021 and S.I. No. 284 of 2023. This medicine protocol is valid for the 2024 HSE COVID-19 Vaccination Programme. This medicine protocol enables the healthcare professionals 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 Nuvaxovid XBB.1.5 COVID-19 Vaccine to vaccine recipients, 12 years and older, with reference to guidelines and guidance from National Immunisation Advisory Committee (NIAC), HSE National Immunisation Office (NIO), HSE and in accordance with the Summary of Product Characteristics (SmPC) for Nuvaxovid XBB.1.5 COVID-19 Vaccine 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 https://www.rcpi.ie/Healthcare-Leadership/NIAC/Immunisation-Guidelines-for-Ireland

- HSE National Immunisation Office (2024) 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/documents/product-information/nuvaxovid-epar-product-information_en.pdf

The Nursing and Midwifery Board of Ireland (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).

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

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 cohort of vaccinators by whom the vaccine is to be administered, including requirements of registration, education, training and assessment of competency

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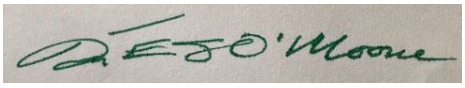
Document reference number	NIO April 2024
1.0 Critical Elements	
Name of organisation where medicine protocol applies	Health Service Providers across the voluntary and statutory services of the HSE, non-HSE healthcare facilities and central vaccination centres. This Medicine Protocol applies to: Healthcare professionals who are registered with their respective regulatory body in healthcare professions included in S.I. No. 698 of 2020, S.I. No.81 of 2021 and S.I. No. 245 of 2021 employed in the voluntary and statutory services of the HSE.
Date the medicine protocol comes into effect	April 2024
Date for review of medicine protocol	April 2025 (Regularly updated as per the NIAC recommendations & DoH policy)
Document prepared by	HSE National Immunisation Office
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. Éamonn O' Moore**, Director of National Health Protection, 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 this protocol applies	Targeted immunisation programme for vaccine recipients against COVID-19 based on the NIAC recommendations endorsed by the DoH.
Inclusion criteria for vaccine recipient using this medicine protocol for administration of Nuvaxovid XBB.1.5 Vaccine	**Inclusion Criteria:** ● Active immunisation to prevent COVID-19 caused by SARS-CoV-2 virus in individuals 12 years of age and older in line with NIAC Chapter 5a, Table 5a.1. ● Nuvaxovid XBB.1.5 may be used for homologous and heterologous booster doses **Note:** May be used as a **primary course** and **booster dose.** **Precautions** ● Acute severe illness; defer until recovery. ● Previous history of myocarditis or pericarditis after any COVID-19 vaccine; seek specialist advice ● Allow a four-week interval between mpox vaccine and subsequent Nuvaxovid XBB.1.5. No interval is required between Nuvaxovid XBB.1.5 and subsequent mpox vaccines. ● Advice from a relevant specialist should be sought for a person with a history of an immediate severe allergic reaction to multiple drug classes with no identified allergen, any other vaccine injected antibody preparation or medicine likely to contain polysorbate 80 or idiopathic anaphylaxis, and the risks should be weighed against the benefits of vaccination. ● 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 thrombocytopoenia (platelet count <50 x 10^9/L) 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. ● This vaccine may be administered at the same time as inactivated influenza vaccines or at any interval. ● **Pregnancy:** There is limited experience with use of Nuvaxovid in pregnancy. Administration of Nuvaxovid XBB.1.5 in pregnancy should only be considered when the potential benefits outweigh any potential risks for the mother and fetus. **Breastfeeding:** COVID-19 vaccines can be used during breastfeeding. There is no evidence that breastfeeding after COVID-19 vaccination causes harm to the breastfed infants or interferes with ability to breastfeed.

Exclusion criteria for vaccine recipient using the medicine protocol	Nuvaxovid XBB.1.5 COVID-19 Vaccine 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/clinical lead/lead vaccinator for an individual medical assessment. • 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 Nuvaxovid XBB.1.5 COVID-19 Vaccine 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. Advice 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 • Health Products Regulatory Authority Adverse Reaction Reporting forms or availability on-line • National Incident Management System Form NIRF-01-v12 available at: https://www.hse.ie/eng/about/who/nqpsd/qps-incident management/nims/nirf-01-v12-person-interactive.pdf It is the responsibility of each vaccinator to be familiar with the appropriate documentation to support the safe administration of Nuvaxovid XBB.1.5 COVID-19 Vaccine which includes the following: • Medicine Protocol for the Administration of Nuvaxovid XBB.1.5 COVID-19 Vaccine to vaccine recipients • *Anaphylaxis: Immediate Management in the community*. NIAC, *Immunisation Guidelines for Ireland (2023)*. https://rcpi.access.preservica.com/uncategorized/IO_a36f9e4b-4c80-432d-8264-546089359925/ • HSE National Immunisation Office (2024) *Clinical Guidance for Covid-19 Vaccination* https://www.hse.ie/eng/health/immunisation/hcpinfo/covid19vaccineinfo4hps/clinicalguidance.pdf • COVID-19 chapter from NIAC *Immunisation Guidelines for Ireland* (2024) https://www.rcpi.ie/Healthcare-Leadership/NIAC/Immunisation-Guidelines-for-Ireland

Master Medicine Protocol for the Administration of Nuvaxovid XBB.1.5 COVID-19 Vaccine to Vaccine Recipients 12 years and older

<table>
<tr><td>3.0 Name of Medicine</td><td>Nuvaxovid XBB.1.5 COVID-19 Vaccine</td></tr>
<tr><td>Dose & Route of administration</td><td>

The dose is 0.5ml
Note: The vaccine does not require dilution.
Route of administration: Intramuscular (IM)
Site: The preferred site is the deltoid muscle

</td></tr>
<tr><td>Primary Course</td><td>A single dose of Nuvaxovid XBB.1.5 COVID-19 Vaccine

Nuvaxovid XBB.1.5. can be offered for primary vaccination in adults and children aged 12 years and older with a contraindication to a mRNA vaccine, or in those who choose not to receive a mRNA vaccine.</td></tr>
<tr><td>Primary Course for those with Immunocompromising conditions</td><td>Two doses of Nuvaxovid XBB.1.5 COVID-19 Vaccine should be administered, with a four week interval between dose one and dose two.

If a third dose is recommended following instruction from the relevant specialist physician, there should be an interval of eight weeks between dose two and three.

Patients with planned immunosuppressive therapy should ideally complete vaccination two weeks before treatment.

<u>Note:</u>
If there is a contraindication or precaution to a booster dose of an mRNA vaccine, or a person has chosen not to receive an mRNA COVID-19 booster, Nuvaxovid XBB.1.5 vaccine may be used as homologous and heterologous boosters.

Eligibility for COVID-19 booster dose and recommended interval for booster doses refer to the NIAC Table 5a.1 Recommendations for COVID-19 vaccines by age and immune status available at https://rcpi.access.preservica.com/uncategorized/IO_43750ce7-2657-44a3-9e2b-48d245f0fc4d/</td></tr>
<tr><td>Booster vaccination in Spring 2024</td><td>
<table>
<tr><td>Age</td><td colspan="2">Spring 2024 Recommendations</td></tr>
<tr><td></td><td>Interdose Interval</td><td>Further booster doses</td></tr>
<tr><td>80 years and older</td><td>Six months</td><td>Irrespective of number of prior booster doses: A spring booster vaccine is recommended.</td></tr>
<tr><td>70-79 years</td><td>Six months</td><td>Access to a spring vaccine should be available for those aged 70 to 79 years who, following discussion with a health care provider (e.g., GP, pharmacist or vaccination centre), request vaccination.</td></tr>
<tr><td>12-69 years</td><td>Six months</td><td>A spring booster vaccine is recommended for:
• those with immunocompromise associated with a suboptimal response to vaccination.</td></tr>
<tr><td colspan="2">Those living in Long term care facilities for older adults</td><td>A spring booster vaccine is recommended</td></tr>
<tr><td colspan="2">Healthcare workers</td><td>A spring booster is NOT recommended unless immunocompromised</td></tr>
</table>
</td></tr>
</table>

	• COVID-19 booster vaccines may be given to the above-mentioned risk groups irrespective of the number of previous doses or types of COVID-19 vaccines, with an interval of **six months** recommended following any previous COVID-19 vaccine dose or infection. • A **minimum interval of three months** is permissible in exceptional circumstances e.g.,planned immunosuppressive therapy or operational reasons.
Link to Medicine Details of product information and other data including instructions for supply and administration is available from the EMA	Link to Summary of Product Characteristics and Patient Information Leaflet available at: https://www.ema.europa.eu/en/documents/product-information/nuvaxovid-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 • Vaccine recipients: 15 minutes • Those with a history of mastocytosis: 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 Nuvaxovid XBB.1.5 COVID-19 Vaccine 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 reactions. 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*: *Immediate Management in the Community* (NIAC, 2023), available online at https://rcpi.access.preservica.com/uncategorized/IO_a36f9e4b-4c80-432d-8264-546089359925/
Procedure for the reporting and documentation of errors and near misses involving the medicine	In the case of medicine errors that directly involve the vaccine recipient, i.e. wrong 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 – V12) available at: https://www.hse.ie/eng/about/who/nqpsd/qps-incident management/nims/nirf-01-v12-person-interactive.pdf The vaccine recipient and/or carer 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	• Vaccine vial (Ready to use, multidose vial) • 23 gauge / 25g 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) • Face masks, Gauze swabs, tape/plasters • Sharps bins, and bins for the disposal of healthcare risk and non-risk waste • Alcohol based hand rub • Access to telephone • Resuscitation equipment and drugs in accordance with *Anaphylaxis*: *Immediate Management in the Community* (NIAC, 2023) available at https://rcpi.access.preservica.com/uncategorized/IO_a36f9e4b-4c80-432d-8264-546089359925/ • Safe storage areas for medicines and equipment • Current 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 Nuvaxovid XBB.1.5 COVID-19 Vaccine and the importance of protecting their health. Discuss that an mRNA vaccine is the recommended vaccine, unless the person has a contraindication or special precaution to mRNA vaccines. Inform vaccine recipient that patient information leaflet is available online at https://www.ema.europa.eu/en/documents/product-information/nuvaxovid-epar-product-information_en.pdf Common adverse events are listed below, a full list of adverse reactions may be found in the Summary of Product Characteristics (SmPC). ***Local:*** Very common: injection site pain, tenderness Common: injection site erythema, swelling ***General:*** Very common: arthralgia, fatigue, headache, malaise, myalgia, nausea, vomiting Common*:* , pain in extremity, pyrexia Myocarditis and pericarditis are very rare adverse reactions. Myocarditis and pericarditis are very rare side effects of mRNA vaccines and Nuvaxovid, occurring predominantly after the second dose and in males under 30 years of age.These conditions can develop within a few days after vaccination and have primarily occurred within 14 days. Available data suggest that the course of myocarditis or pericarditis following vaccination is not different from myocarditis or pericarditis in general 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/nuvaxovid-epar-product-information_en.pdf
Advice to be given to the recipient after treatment	**After Treatment** Discuss potential side effects and give advice how to manage common adverse reactions. 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: ● Vaccine recipients: 15 minutes ● Those with a history of mastocytosis: 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 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

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

National Clinical Guideline No. 30 (2023) – Infection Prevention and Control (IPC) https://www.gov.ie/en/publication/a057e-infection-prevention-and-control-ipc/.

National Immunisation Advisory Committee (2023) Anaphylaxis: Immediate Management in the Community. Available at https://rcpi.access.preservica.com/uncategorized/IO_a36f9e4b-4c80-432d-8264-546089359925/

National Immunisation Advisory Committee *Immunisation Guidelines for Ireland (2024)* Dublin: Royal College of Physicians Ireland. Online update available at https://www.rcpi.ie/Healthcare-Leadership/NIAC/Immunisation-Guidelines-for-Ireland

HSE National Immunisation Office (2024) *Clinical Guidance for COVID-19 Vaccinations.* Available at https://www.hse.ie/eng/health/immunisation/hcpinfo/covid19vaccineinfo4hps/clinicalguidance.pdf

Irish Statutory Instruments, Available at https://www.irishstatutebook.ie/eli/statutory.html

Master Medicine Protocol for the Administration of Nuvaxovid XBB.1.5 COVID-19 Vaccine to Vaccine Recipients 12 years and older