COVID-19 Vaccine Moderna

National Protocol

Reference no:	COVID-19 Vaccine Moderna Protocol
Version no:	v3.3
Valid from:	29 March 2022
Review date:	01 March 2023
Expiry date:	31 March 2023

1. About the National Protocol

This protocol is for the supply and administration of COVID-19 Vaccine Moderna to individuals in accordance with the national COVID-19 vaccination programme. This protocol only allows administration during or in anticipation of COVID-19 pandemic where the disease represents a serious risk or potentially serious risk to human health.

This protocol is for the supply and administration of COVID-19 Vaccine Moderna by appropriately trained persons in accordance with regulation 247A of the Human Medicines Regulation 2012, as inserted by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020

The Scottish Government has developed this protocol which has been approved by the Scottish Ministers to facilitate the delivery of the national COVID-19 vaccination programme by Health Boards in Scotland and any organisation a Health Board makes arrangements with to deliver such services on its behalf, referred to as "the provider". Please note that in the context of this protocol, "the provider" means:

(a) a Health Board,
(b) a Health Board working with Armed Forces staff where Armed Forces staff are working in Health Board settings, or
(c) an organisation delivering services on behalf of a Health Board.

This protocol may be followed wholly from patient assessment through to post-vaccination by a single person. Alternatively, obtaining consent and patient assessment may be undertaken by a registered healthcare professional with the process of administration undertaken by a non-registered professional or a non-registered Armed Forces staff member under clinical supervision.

Where multiple person models are used the provider must ensure that all elements of the protocol are complied with in the provision of vaccination to each patient.

The provider is responsible for ensuring that persons are trained and competent to safely deliver the activity they are authorised to provide under this protocol. As a minimum, competence requirements stipulated in the protocol under 'Characteristics of staff' must be adhered to.

The provider must identify a clinical supervisor who has overall responsibility for provision of vaccinations under the protocol at all times. This includes overall responsibility for the activities of any Armed Forces staff working under the protocol.

The clinical supervisor must be a registered healthcare professional trained and competent in all aspects of the protocol and provide clinical supervision for the overall provision of clinical care provided under the protocol.

The clinical supervisor must be identifiable to service users. Whenever the protocol is used, the name of the clinical supervisor taking responsibility and all of the people working under different activity stages of the protocol must be recorded for the session using the schedule in Annex C or maintaining an equivalent electronic record. The clinical supervisor has ultimate responsibility for safe care being provided under the terms of the protocol. Persons working under the protocol may be supported by additional registered healthcare professionals, but the clinical supervisor retains responsibility.

Persons working to the protocol must understand who the clinical supervisor for their practice is at any time and can only work under their authority. The clinical supervisor may withdraw this authority for all persons or individual persons at any time and has authority to stop and start service provision under the protocol as necessary. All members of staff have a responsibility to, and should, report immediately to the clinical supervisor any concerns they have about working under the protocol in general or about a specific individual, process, issue or event.

Individual practitioners must be designated by name to work to this protocol. Individuals working in accordance with this protocol must ensure they meet the staff characteristics for the activity they are undertaking, make a declaration of competence and be authorised in writing by the provider. This can be done by completing Annex B of this protocol or maintaining an equivalent electronic record.

It is a Health Board's responsibility to adhere to this protocol. Where the Health Board is not the provider, it is the Health Board's responsibility to ensure that the provider adheres to this protocol. The final authorised copy of this protocol should be kept, by Health Boards for 8 years after the protocol expires. Providers adopting authorised versions of this protocol should also retain copies, along with the details of those authorised to work under it, for 8 years after the protocol expires.

Providers must check that they are using the current version of this protocol. Amendments may become necessary prior to the published expiry date. Current versions of protocols authorised by the Scottish Ministers in accordance with

regulation 247A of the Human Medicines Regulations 2012 can be found on the Scottish Government website: (tbc)

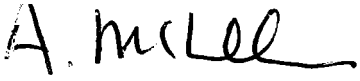
Any concerns regarding the content of this protocol should be addressed to: vaccineoperationaloversight@gov.scot

2. Approval and Clinical Authorisation

This protocol is not legally valid, in accordance with regulation 247A of Human Medicines Regulation 2012, as inserted by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020, until approved by the Scottish Ministers.

On 1 April 2021 the Scottish Ministers, approved this protocol in accordance with regulation 247A of Human Medicines Regulation 2012. Approval of clinical information in Annex A is via the Scottish Government Chief Medical Officer, Chief Pharmaceutical Officer and Chief Nursing Officer for the delivery of the national COVID-19 vaccination programme, with defined limitations to authorisation that may be updated from time to time as may be required.

Authorised for use by the following organisations and/or services
All Health Boards in Scotland, and organisations Health Boards make arrangements with to deliver services on their behalf.
Limitations to authorisation
This authorisation applies to the supply and administration of the vaccine(s) only under the conditions set out in the authorisation for supply or license set out by the Medicines and Healthcare products Regulatory Agency

Clinical authorisation			
Role	**Name**	**Sign**	**Date**
CMO	**Gregor Smith**		**28 March 2022**
CNO	**Alex McMahon**		**28 March 2022**
CPO	**Alison Strath**		**28 March 2022**

It is Health Boards' responsibility to ensure they and any organisations they make arrangements with to deliver services on their behalf operate the specified vaccination services in accordance with the protocol. Any provider administering COVID-19 Vaccine Moderna under protocol must work strictly within the terms of this protocol.

The national COVID-19 vaccination programme may also be provided under patient group direction, under written instruction for supply and administration in the course of an occupational health scheme, or on a patient specific basis, by or on the directions of an appropriate prescriber. Supply and administration in these instances are not related to this protocol.

3. Change history

Version number	Change details	Date
V01.00	New protocol for COVID-19 Vaccine Moderna	31.03.2021
V01.10	Clinical annex updated	20.04.2021
V01.20	Clinical annex updated	10.05.21
V01.30	Clinical annex updated	24.05.21
V02.0	Updated protocol to add Military General Duties Vaccinators	02.06.21
V02.1	Clinical annex updated	05.07.21
V02.2	Clinical annex updated	22.07.21
V02.3	Clinical annex updated	05.08.21
V02.4	Clinical annex updated	18.09.21
V02.5	Clinical annex updated	30.09.21
V02.6	Clinical annex updated	05 November 2021
V02.7	Clinical annex updated	16.11.2021
V02.8	Clinical annex updated	01.12.2021
V02.9	Clinical annex updated	14.12.2021
V03.0	Clinical annex updated	24.12.2021
V03.1	Clinical annex updated	14.01.2022
V03.2	Clinical annex updated	01.03.2022
V03.3	Expiry date extended to 31 March 2023 and clinical annex updated	25.03.2022

4. Characteristics of staff

The Provider is responsible for the designation and authorisation of persons within the classes set out below permitted to administer medicinal products under this protocol. In doing so the provider must establish that those persons

a) demonstrate appropriate knowledge and skills to work under the National Protocol for the supply/administration of COVID-19 vaccine.
b) have met the requirements of the NES Proficiency document -COVID-19 vaccine administration for registered staff or the NES Proficiency document – COVID-19 vaccine administration - Healthcare support workers as appropriate https://learn.nes.nhs.scot/37676/immunisation/covid-19-vaccines

Classes of persons permitted to administer medicinal products under this protocol

This protocol may be adhered to wholly from assessment through to post-vaccination by a single appropriately specified registered healthcare professional. Alternatively, multiple persons may undertake specific activity stages in the vaccination pathway in accordance with this protocol.

Activity stages of the vaccination pathway under this protocol

Stage 1	a. Assessment of the individual presenting for vaccination b. Provide information and obtain informed consent c. Provide advice to the individual	Registered Healthcare Professionals Only
Stage 2	• Vaccine Preparation	Registered Healthcare Professionals, non-registered professionals or non-registered Armed Forces staff
Stage 3	• Vaccine Administration	Registered Healthcare Professionals, non-registered professionals or non-registered Armed Forces staff
Stage 4	• Record Keeping	Registered Healthcare Professionals, non-registered professionals or non-registered Armed Forces staff

Providers are responsible for assessing the competency of, designating and recording the names of all those persons permitted to supply and administer under this protocol.

The following specified registered healthcare professionals are permitted to administer under the protocol subject to the requirements set out below:

- Nurses and midwives currently registered with the Nursing and Midwifery Council (NMC).
- Pharmacists currently registered with the General Pharmaceutical Council (GPhC).
- Chiropodists/podiatrists, dieticians, occupational therapists, operating department practitioners, orthoptists, orthotists/prosthetists, paramedics, physiotherapists, radiographers and speech and language therapists currently registered with the Health and Care Professions Council (HCPC).
- Dental hygienists and dental therapists registered with the General Dental Council.
- Optometrists registered with the General Optical Council.
- Doctors currently registered with General Medical Council.
- Dentists currently registered with General Dental Council.

The following professionals (who are in the main non-registered) are permitted to administer under the protocol with appropriate supervision as set out below, subject to the requirements set out below:

- Healthcare support workers.
- Pharmacy technicians, provisionally registered pharmacists, pre-registration pharmacists and other pharmacy support practitioners.
- Retired clinical practitioners such as doctors, dentists, pharmacists, nurses, optometrists, chiropodists/podiatrists, dieticians, occupational therapists, orthoptists, orthotists/prosthetists, paramedics, pharmacy technicians, physiotherapists, radiographers, speech and language therapists, dental hygienists and dental therapists not currently registered.
- Student doctors, dentists, pharmacists, nurses, midwives, optometrists, chiropodists/podiatrists, dieticians, occupational therapists, orthoptists, orthotists/prosthetists, paramedics, physiotherapists, radiographers, speech and language therapists, dental hygienists and dental therapists not currently registered.
- Healthcare Scientists.
- Dental nurses.
- Physician's assistants.

The following non-registered Armed Forces staff are permitted to administer under the protocol with appropriate supervision as set out below, subject to the requirements set out below:

- Combat Medical Technician – Class 1,2 &3 (CMT)
- Royal Navy Medical Assistant (RN MA)
- Royal Air Forces Medic
- Defence Medic
- Healthcare Assistant (HCA)
- Military General Duties Vaccinators

Requirements

All those working under this protocol must have undertaken training, be assessed as competent and receive supervision appropriate to the stage of activity they are undertaking.

Where multiple person models are used, the provider must ensure that all elements of the protocol are complied with in the provision of vaccination to each individual. The provider is responsible for ensuring that persons are trained and competent to safely deliver the activity they are employed to provide under this protocol. As a minimum, competence requirements stipulated in the protocol must be adhered to.

All persons must be designated by name by the provider as an approved person under the current terms of this protocol before working to it, and listed on the practitioner authorisation sheet in Annex B. All staff listed on the sheet will be covered by NHS indemnity extended by the Health Board who is responsible for the COVID 19 vaccination programme in that locality. Protocols do not remove inherent obligations or accountability. All practitioners operating under this protocol must work within their terms of employment at all times; registered healthcare professionals should also abide by their professional code of conduct.

There are three underpinning principles to which every person undertaking activities under the remit of this protocol must adhere.

1. Training
   - They must have undertaken training appropriate to this protocol and relevant to their role, as required by local policy and health board standard operating procedures and in line with the training recommendations for COVID-19 vaccinators.
   - They must have met the requirements set out in the NES Proficiency document - COVID-19 vaccine administration for registered staff or the NES Proficiency document –COVID-19 vaccine administration- Healthcare support workers

2. Competency
   - Those providing clinical supervision to those administering the vaccine must be competent to assess individuals for suitability for vaccination, identify any contraindications or precautions, discuss issues related to vaccination and obtain informed consent from the individuals being vaccinated.
   - All persons must either be an appropriate prescriber or one of above noted registered professionals. Those that are not registered professionals, and those returning to immunisation after a prolonged interval (more than 12 months), should be assessed and signed off as meeting the requirements of the relevant NES Proficiency document -COVID-19 vaccine administration. They should be observed administering the vaccine until both they, and their supervisor or trainer, feel confident that they have the necessary knowledge and skills to administer vaccines safely and competently.
   - Experienced vaccinators should use the relevant NES Proficiency document to self-assess that they are able to meet all the competencies listed and confirm that they have the knowledge and skills necessary to administer COVID-19 vaccine.
   - They must have completed local IPC training and comply with the vaccination guidance with the National COVID-19 IPC guidelines available: National Infection Prevention and Control Manual: Scottish COVID-19 Infection Prevention and Control Addendum for Acute Settings

In addition, and where indicated as relevant to the role -

- They must be familiar with the vaccine product and alert to any changes in the manufacturers summary of product characteristics (SPC), should it become licensed, or the Regulation 174 Information for UK Healthcare Professionals and familiar with the national recommendations for the use of this vaccine.
- They must be familiar with, and alert to changes in relevant chapters of Immunisation Against Infectious Disease: the Green Book COVID-19: the green book, chapter 14a - GOV.UK (www.gov.uk).
- They must be familiar with, and alert to changes in the relevant provider's standard operating procedures (SOPs) and provider's arrangements for the national COVID-19 vaccination programme.
- They must be competent in the correct handling and storage of vaccines and management of the cold chain if receiving, responsible for, or handling the vaccine.
- They must be competent in the recognition and management of anaphylaxis, have completed basic life support training and be able to respond appropriately to immediate adverse reactions.
- They must have access to the provider's protocols and relevant COVID-19 vaccination programme online resources.
- They must be competent in intramuscular injection technique if they are administering the vaccine, this should include a practical element.
- For those preparing the vaccine, they must be competent in the handling of the vaccine product, procedure for dilution of the vaccine and use of the correct technique for drawing up the correct dose.
- For those in record keeping roles, they must understand the importance of making sure vaccine information is recorded on the vaccination management app.
- They should fulfil any additional requirements defined by local policies developed in accordance with any national guidance.

3. Supervision
- A period of supervised practice to allow observation of, and development of skills in vaccine administration and application of knowledge to practice is essential. Supervision for new immunisers and support for all immunisers is critical to the safe and successful delivery of the COVID-19 immunisation programme.
- Non-registered professionals and non-registered Armed Forces staff must be supervised and supported by a registered healthcare professional at all times.
- The clinical supervisor must be a registered healthcare professional trained and competent in all aspects of the protocol and provide clinical supervision for the overall provision of clinical care provided under the protocol.

5. Clinical condition or situation to which this Protocol applies

COVID-19 Vaccine Moderna is indicated for active immunisation against COVID-19 disease caused by SARS-CoV-2 virus in accordance with Scottish Government COVID-19 immunisation programme and recommendations given in Chapter 14a of the Immunisation Against Infectious Disease: the 'Green Book' COVID-19: the green book, chapter 14a - GOV.UK (www.gov.uk) and Scottish Government CMO letters relating to COVID-19 vaccination.

ANNEX A: Clinical Information

This Annex provides information about the clinical situation or condition and treatment in relation to the National Protocol.

Most Recent Changes

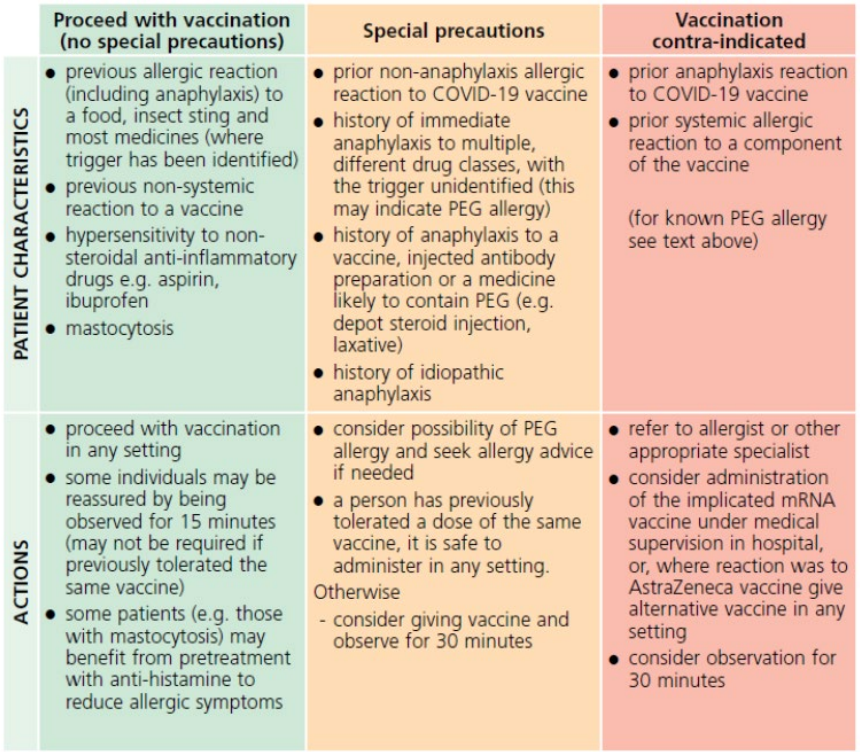
Version	Date	Summary of changes
3.32	25/03/22	The following sections have been updated: Frequency section updated to clarify eligibility for spring booster 2022 programme. Advice to patient or carer section updated with advice on fever following vaccination.

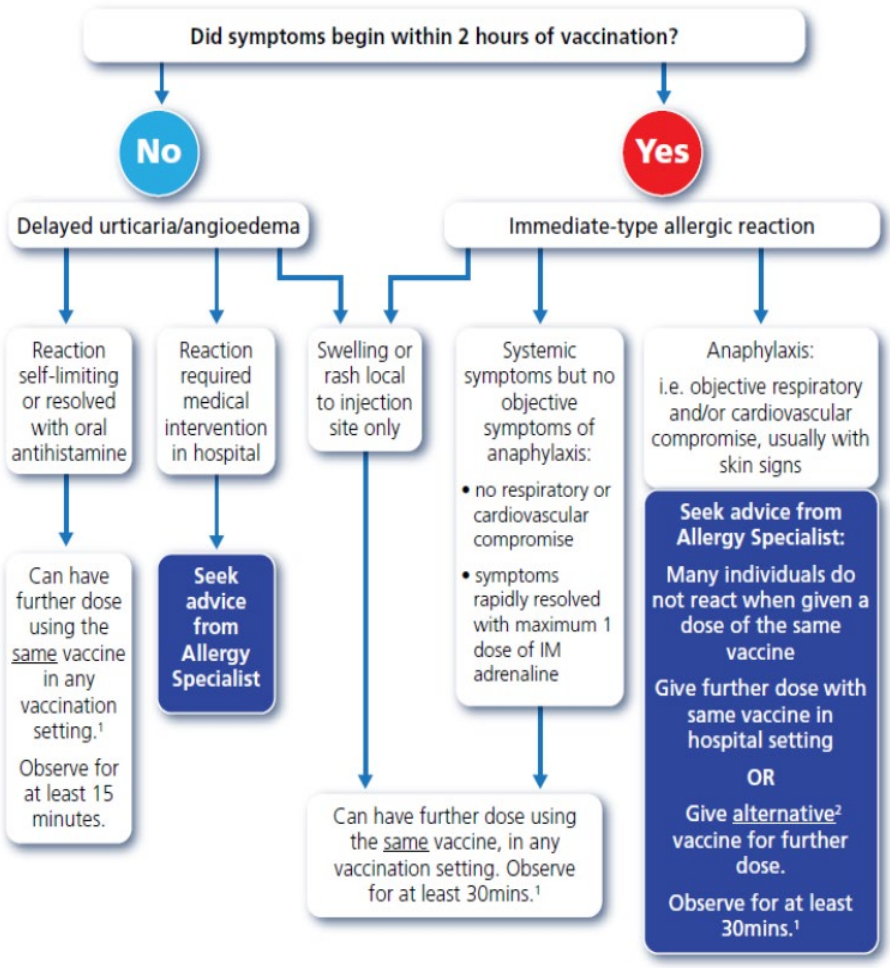
1. Clinical condition or situation to which this Protocol applies

Category	Description
Indication	Spikevax® (COVID-19 Vaccine Moderna dispersion for injection) is indicated for active immunisation against COVID-19 disease caused by SARS-CoV-2 virus in accordance with Scottish Government COVID-19 immunisation programme and recommendations given in: Chapter 14a of the Immunisation Against Infectious Disease: the 'Green Book'; statements from Joint Committee on Vaccination and Immunisation (JCVI); and subsequent correspondence/publications from Scottish Government.
Inclusion criteria	Spikevax® (COVID-19 Vaccine Moderna dispersion for injection) should be offered to all individuals aged 18 years and over in accordance with the recommendations in Chapter 14a of the Green Book and JCVI advice. National policy must be followed in relation to the priority groups eligible for vaccination at a particular point in time. Individuals are eligible for different dose schedules based on their age and recognised risk group (see the frequency section).

Category	Description
Exclusion criteria	The vaccine should not be given to: • Those who have had a previous systemic anaphylaxis reaction to any COVID-19 vaccine. • Those who have had a prior systemic allergic reaction to any component (excipient) of Spikevax® (COVID-19 Vaccine Moderna dispersion for injection) e.g. polyethylene glycol • Those with a history of immediate anaphylaxis to multiple, different drug classes, with the trigger unidentified (this may indicate PEG allergy) unless the advice from relevant specialist, local immunisation or health protection team is that vaccination should proceed. • Those with a history of anaphylaxis to a vaccine, injected antibody preparation or a medicine likely to contain PEG (e.g. depot steroid injection, laxative) unless the advice from relevant specialist, local immunisation or health protection team is that vaccination should proceed. • Those with a history of idiopathic (unexplained) anaphylaxis unless the advice from relevant specialist, local immunisation or health protection team is that vaccination should proceed. • Those in whom no valid consent has been received • Those who are under 18 years of age • Those with evidence of current deterioration of COVID-19 symptoms, deferral of vaccination may be considered to avoid incorrect attribution of any change in the person's underlying condition to the vaccine. • Those with acute febrile illness – consider postponing immunisation until individual has fully recovered. • Those bone marrow and peripheral blood stem cell donors who have commenced GCSF, the vaccination (first or second dose) must be delayed at least until 72 hours after stem cell collection (both peripheral blood stem cell and bone marrow donation). This is a precautionary advice to

Category	Description
	avoid vaccination when receiving Granulocyte-colony stimulating factor (GCSF) and allow for post donation recovery period. • Those who developed myocarditis or pericarditis following a previous dose of COVID-19 vaccination
Cautions/need for further advice/ circumstances when further advice should be sought from a doctor	The COVID-19 chapter of the Green Book advises that there are very few individuals who cannot receive COVID vaccine. Where there is doubt, rather than withholding vaccination, appropriate advice should be sought from the relevant specialist, or from the local immunisation or health protection team. Individuals with a history of allergy The Pfizer BioNTech and Moderna mRNA vaccines contain polyethylene glycol (PEG). PEGs (also known as macrogols) are a group of known allergens commonly found in medicines, many household products and cosmetics. Medicines containing PEG include some tablets, laxatives, depot steroid injections, and some bowel preparations used for colonoscopy. Known allergy to PEG is rare but would contraindicate receipt of mRNA vaccines. Published data now show that some individuals with prior allergic reaction to PEG containing medicines (e.g. PEG-asparaginase) can tolerate the Pfizer BioNTech vaccine (although the historical reaction may have been due a non-PEG component). Expert advice should be obtained and if a decision is made to administer an mRNA vaccine, then this should only be done in hospital under medical supervision under a patient specific direction. There is now evidence that many individuals with initial apparent allergic reaction to an mRNA vaccine can tolerate a second dose of the same vaccine. Where there were no objective signs of anaphylaxis and symptoms rapidly resolved (with no more than 1 dose of IM adrenaline), a further dose of the same vaccine can be given in any vaccination setting. Observe for 30 minutes. If the reaction might have been anaphylaxis, obtain expert advice; if a decision is made to administer the same vaccine, then this should be done under medical supervision in the hospital setting under a patient specific direction.

Category	Description
	The COVID-19 chapter of the Green Book states individuals with non-allergic reactions (vasovagal episodes, non-urticarial skin reaction or non-specific symptoms) to the first dose of a COVID-19 vaccine can receive the second dose of vaccine in any vaccination setting. Observation for 15 minutes is recommended. No specific management is required for individuals with a family history of allergies Figure 1 summarises the management of patients with a history of allergy. **Figure 1: Management of patients with a history of allergy**  Figure 2 shows the Green Chapter flowchart for managing patients who have allergic reactions to the first dose of COVID-19 vaccine. **Figure 2: Flowchart for managing patients who have allergic reactions to the first dose of COVID-19 vaccine**

Category	Description
	 [1] Consider pre-treatment with non-sedating antihistamine, at least 30mins prior to vaccination [2] If reaction was to AstraZeneca vaccination, complete or boost with an mRNA vaccine. If reaction was to an mRNA vaccine, give the same or alternative mRNA vaccine in hospital setting. Those with an anaphylaxis immediate-type allergic reaction are excluded from receiving vaccination under this protocol – a patient specific direction is required if further doses are offered. Individuals with a bleeding history Individuals with a bleeding disorder may develop a haematoma at the injection site (see Route of Administration).

Category	Description
	Co-administration with other vaccines As all of the early COVID-19 vaccines are considered inactivated, where individuals in an eligible cohort present having recently received another inactivated or live vaccine, COVID-19 vaccination should still be given. The same applies for most other live and inactivated vaccines where COVID-19 vaccination has been received first or where a patient presents requiring two or more vaccines. It is generally better for vaccination to proceed to avoid any further delay in protection and to avoid the risk of the patient not returning for a later appointment. An exception to this is shingles vaccination, where a seven-day interval should ideally be observed given the potential for an inflammatory response to COVID-19 vaccine to interfere with response to the live virus in the older population and because of the potential difficulty of attributing systemic side effects to the newer adjuvanted shingles vaccine. A UK study of co-administration of AstraZeneca and Pfizer BioNTech COVID-19 vaccines with inactivated influenza vaccines confirmed acceptable immunogenicity and reactogenicity. Where co-administration does occur, patients should be informed about the likely timing of potential adverse events relating to each vaccine. If the vaccines are not given together, they can be administered at any interval, although separating the vaccines by a day or two will avoid confusion over systemic side effects. Syncope Syncope (fainting) can occur following, or even before, any vaccination especially in adolescents as a psychogenic response to the needle injection. This can be accompanied by several neurological signs such as transient visual disturbance, paraesthesia and tonic-clonic limb movements during recovery. It is important that procedures are in place to avoid injury from faints. Pregnancy and breastfeeding JCVI advise there is no known risk associated with giving these types of vaccines during pregnancy. These vaccines cannot

Category	Description
	replicate, so they cannot cause infection in either the woman or the unborn child. Although clinical trials on the use of COVID-19 vaccines during pregnancy are not advanced, the available data do not indicate any harm to pregnancy. JCVI has therefore advised that women who are pregnant should be considered as falling into a clinical risk group (JCVI Priority Cohort 6 for COVID-19 vaccination) . There is now extensive post-marketing experience of the use of the Pfizer BioNTech and Moderna vaccines in the USA with no safety signals so far. These vaccines are therefore the preferred vaccines to offer to pregnant women (for those under 18 years Comirnaty® (COVID-19 mRNA vaccine, Pfizer/BioNTech) is preferred). Clinicians (such as obstetricians, mid-wives, GPs or other healthcare professionals authorised to offer COVID-19 vaccination) should discuss the risks and benefits of vaccination with the woman, who should be told about the limited evidence of safety for the vaccine in pregnancy. There is no known risk associated with giving non-live vaccines whilst breastfeeding. JCVI advises that breastfeeding women may be offered vaccination with any suitable COVID-19 vaccine. Emerging safety data is reassuring: mRNA was not detected in the breast milk of recently vaccinated and protective antibodies have been detected in breast milk. The developmental and health benefits of breastfeeding should be considered along with the woman's clinical need for immunisation against COVID-19. Clinical trial participants Individuals who have participated in a clinical trial of either primary or booster COVID-19 vaccines should be provided with written advice on whether and when they should be safely vaccinated in the routine programme. Advice should also be provided from the trial investigators on whether any individual should receive additional doses for the purposes of vaccine certification. Trial participants who are eligible for boosters could be offered vaccination in line with the general population, at least three months after the dose considered as the final primary dose or the final revaccination (if the latter is required for certification purposes).

Category	Description
	Individuals with a past history of COVID-19 infection There is no convincing evidence of any safety concerns from vaccinating individuals with a past history of COVID-19 infection, or with detectable COVID-19 antibody. Vaccination of individuals who may be infected or asymptomatic or incubating COVID-19 infection is unlikely to have a detrimental effect on the illness. As clinical deterioration can occur up to two weeks after infection, vaccination of adults and high risk children should ideally be deferred until clinical recovery to around four weeks after onset of symptoms or four weeks from the first confirmed positive specimen to avoid confusing the differential diagnosis. There is no need to defer immunisation in individuals after recovery from a recent episode with compatible symptoms who were not tested unless there are strong clinical or epidemiological features to suggest the episode was COVID-19 infection. The four week interval may be reduced to ensure operational flexibility when rapid protection is required, for example high incidence or circulation of a new variant in a vulnerable population. Currently, the JCVI consider that, in care home residents and the housebound, there may be an advantage in offering vaccination to some individuals with recent confirmed COVID-19, without a four-week deferral, where individuals are clinically stable and when infection control procedures can be maintained. These populations are likely to be highly vulnerable and will facilitate vaccination without the need for multiple visits.
Action if excluded	Specialist advice should be sought on the vaccine and circumstances under which it could be given as vaccination using a patient specific direction may be indicated. In case of postponement due to acute illness advise when the individual can be vaccinated and ensure another appointment is arranged. In case of deferral due to COVID-19 symptoms or recent positive COVID test advise when the individual can be vaccinated and how future vaccination may be accessed.

Category	Description
	Document the reason for exclusion and any action taken in accordance with local procedures.
Action if patient declines	Advise the individual/carer about the protective effects of the vaccine, the risks of infection and potential complications if not immunised. Advise how future immunisation may be accessed if they subsequently decide to receive the COVID-19 vaccine Document patient's declined consent and advice given.

2. Description of treatment

Category	Description
Name of medicine	Spikevax® (COVID-19 Vaccine Moderna dispersion for injection)
Form/strength	Spikevax® (COVID-19 Vaccine Moderna dispersion for injection) is a multidose vial. 1 vial contains 10 doses
Route of administration	Each vial contains at least the number of doses stated. It is normal for liquid to remain in the vial after withdrawing the final dose. When low dead volume syringes and/or needles are used, the amount remaining in the vial may be sufficient for an additional dose. Care should be taken to ensure a full 0.5 ml dose is administered. Where a full 0.5 ml dose cannot be extracted, the remaining volume should be discarded. Spikevax® (COVID-19 Vaccine Moderna dispersion for injection) must be administered by intramuscular (IM) injection preferably into the deltoid area of the upper arm. Where administration into the deltoid is not possible the anterolateral thigh can be considered. Inspect visually prior to administration and ensure appearance is consistent with the description in the manufacturer's product literature or summary of product characteristics.

Category	Description
	Individuals with bleeding disorders may be vaccinated intramuscularly if, in the opinion of a doctor familiar with individual's bleeding risk, vaccines or similar small volume intramuscular injections can be administered with reasonable safety by this route. If the individual receives medication/ treatment to reduce bleeding, for example treatment for haemophilia, intramuscular vaccination can be scheduled shortly after such medication/treatment is administered. Individuals on stable anticoagulation therapy, including individuals on warfarin who are up-to-date with their scheduled INR testing and whose latest INR is below the upper level of the therapeutic range, can receive intramuscular vaccination. A fine needle (23 or 25 gauge) should be used for the vaccination, followed by firm pressure applied to the site without rubbing for at least 2 minutes. The individual/parent/carer should be informed about the risk of haematoma from the injection. The site at which each vaccine was given should be noted in the individual's records.
Dosage	The dose of Spikevax® (COVID-19 Vaccine Moderna dispersion for injection) is 0.5ml which contains 100 micrograms (0.1mg) mRNA. For those offered a third primary dose for severe immunosuppression the dose is 0.5mL which contains 100 micrograms (0.1mg) mRNA. For those offered a COVID-19 booster vaccine dose the dose is a half dose (0.25ml which contains 50 micrograms mRNA).
Frequency	**Primary Vaccination** Spikevax® (COVID-19 Vaccine Moderna dispersion for injection) course consists of two separate doses of 0.5ml each, a minimum of 28 days apart. For both AstraZeneca COVID-19 Vaccine (ChAdOx1-S [Recombinant]) and mRNA vaccines, there is evidence of better immune response and/or protection where longer intervals between doses in the primary schedule are used.

Category	Description
	Based on this evidence, longer intervals are likely to provide more durable protection. JCVI is currently recommending a minimum interval of eight weeks between doses of all the available COVID-19 vaccines where a two-dose primary schedule is used. Operationally, using the same minimum interval for all products will simplify booking, and will help to ensure a good balance between achieving rapid and long-lasting protection. If an interval longer than the recommended interval is left between doses in the two dose primary schedule, the second dose should still be given (preferably using the same vaccine as was given for the first dose if possible). The course does not need to be restarted. The main exception to the eight-week lower interval would be those about to commence immunosuppressive treatment. In these individuals, the minimal intervals outlined above may be followed to enable the vaccine to be given whilst their immune system is better able to respond. Individuals who are about to receive planned immunosuppressive therapy should be considered for vaccination prior to commencing therapy (ideally at least two weeks before), when their immune system is better able to make a response. Where possible, it would also be preferable for the 2-dose schedule to be completed prior to commencing immunosuppression. This would entail offering the second dose at the recommended minimum for that vaccine (three or four weeks from the first dose) to provide maximum benefit that may not be received if the second dose was given during the period of immunosuppression. Evidence suggests that those who receive mixed schedules, including mRNA and AstraZeneca COVID-19 Vaccine (ChAdOx1-S [Recombinant]) make a good immune response, although rates of side effects with a heterologous second dose are higher. Accumulating evidence now supports the use of heterologous schedules for primary immunisation, and these are now recognised by the European Medicines Agency. For individuals who started the schedule and who attend for vaccination where the same

Category	Description
	vaccine is not available or suitable, or if the first product received is unknown or not available, one dose of the locally available product should be given to complete the primary course. Individuals who experienced severe expected reactions after a first dose of AstraZeneca or Pfizer BioNTech vaccines should be informed about the higher rate of such reactions when they receive a second dose of an alternate vaccine. **Severely Immunosuppressed – Third Primary Dose** For those aged from 18 years identified as meeting the definition for severe immunosuppression in proximity of their first and second vaccine doses in the primary schedule, in line with specialist advice, for a third primary dose (as defined in COVID-19 chapter of Green Book) The third primary dose should be given at least 8 weeks after the second dose, with special attention paid to current or planned immunosuppressive therapies guided by the following principles: a) where possible the third primary dose should be delayed until two weeks after the period of immunosuppression, in addition to the time period for clearance of the therapeutic agent, b) if not possible, consideration should be given to vaccination during a treatment 'holiday' or at a nadir of immunosuppression between doses of treatment. For those aged over 18 years, JCVI advises a preference for mRNA vaccines - Pfizer BioNTech (Comirnaty®) or Moderna (Spikevax®) - for the third primary dose for those with severe immunosuppression. Pfizer BioNTech (Comirnaty®) is preferred for 12-17 year olds. AstraZeneca COVID-19 vaccine (Vaxzevria®) is an option for individuals who have received this vaccine previously where mRNA vaccines are clinically contraindicated. In exceptional circumstances, persons aged 40 years or over who received a mRNA COVID-19 vaccine previously may be offered a third dose of AstraZeneca Vaxzevria vaccine following a decision by a health professional on a case-by-case basis. **Booster vaccination**

Category	Description
	Booster vaccination should not be given within three months (12 weeks) of completion of the primary course. The JCVI have advised that a full dose (30µg) of Pfizer-BioNTech vaccine or a half dose (50µg) of the Moderna COVID-19 vaccine should be offered for boosting irrespective of the vaccine used for the primary course. Both vaccines are suitable for boosting adults aged 18 years or over, with Pfizer BioNTech preferred for those aged 16-17 and those aged 12-15 years in clinical risk groups. Both vaccines have been shown to give good immune responses in those already primed. The half dose of Moderna and is expected to have a lower rate of side effects (including myocarditis) than a full dose. Where mRNA vaccines are clinically contra-indicated, vaccination with AstraZeneca vaccine may be considered in those who had received at least one dose of this vaccine previously. Severely immunosuppressed individuals (aged 12 years and over) who have completed their primary course (three doses) should be offered a booster dose with a minimum of three months (12 weeks) between the third primary and booster dose. Those who have not yet received their third dose may be given the third dose now (provided there has been an interval of at least 8 weeks since the second primary dose) to avoid further delay. A fourth dose can be given in three months (12 weeks), in line with the clinical advice on optimal timing. Spring booster 2022 JCVI have advised a further booster dose should be given around six months after the last dose to adults aged 75 years and over*; residents of any age in a care home for older adults, and; individuals aged 12 years and over who are immunosuppressed (as defined in COVID-19 chapter of Green Book). *or who will turn 75 years by 30 June 2022 The vast majority of people aged over 75 will reach an interval of around six months from their previous dose

Category	Description
	between March and June 2022. Although vaccination should ideally be offered around six months from any previous dose, operational flexibility may be used. For example, individuals in care homes or housebound patients may be offered the booster alongside other residents providing there is at least three months (12 weeks) from the previous dose. Immunosuppressed individuals who have received an additional primary dose may have received the booster (fourth) dose more recently. These latter individuals and other eligible people who received their last vaccine more recently should also be offered the booster during the spring campaign providing there is at least three months (12 weeks) from the previous dose. This will ensure they have additional protection against a potential summer wave and will align with their peers to facilitate an autumn programme. Someone in an eligible group who has received a full course of primary vaccination (two or three doses) but has not received their first booster by March 2022, may be given the spring booster in the campaign provided there is at least three months from the previous dose. An additional dose is not then recommended before the autumn. The vaccines offered should follow the age-appropriate advice as for other reinforcing doses (see below).The JCVI have advised that a full dose (30µg) of Pfizer-BioNTech vaccine or a half dose (50µg) of the Moderna COVID-19 vaccine should be offered for the additional booster irrespective of the vaccine used previously. Both vaccines are suitable for boosting adults aged 18 years or over, with Pfizer BioNTech preferred for those aged 12-17 years in clinical risk groups.
Duration of treatment	See Dose and frequency of administration above.
Maximum or minimum treatment period	See Frequency of administration above.
Quantity to supply/administer	Administer 0.5ml (100 micrograms (0.1mg) mRNA) per administration.

Category	Description
▼ black triangle medicines	All adverse reactions occurring in individuals of any age after vaccination should be reported to the MHRA using the Coronavirus Yellow Card Scheme. Anyone can report a suspected adverse reaction to the MHRA using the Coronavirus Yellow Card reporting scheme. **https://coronavirus-yellowcard.mhra.gov.uk/**
Legal category	Prescription only medicine (POM).
Is the use out with the SPC?	Spikevax® (COVID-19 Vaccine Moderna dispersion for injection) has been granted a Conditional Marketing Authorisation (CMA) by the MHRA. The vaccine manufacturer's summary of product characteristics states that the vaccine is a two-dose regimen. Each dose is 0.5 ml. It is recommended to administer the second dose 28 days after the first dose. This is superseded by the JCVI recommendation, as detailed in Chapter 14a of the green book, of a minimum interval of eight weeks between doses of all the available COVID-19 vaccines where a two-dose primary schedule is used. And by JCVI advice, as detailed in Chapter 14a of the green book, for third primary dose vaccination in those with severe immunosuppression in proximity of their first and second vaccine doses in the primary schedule. And by JCVI advice, as detailed in Chapter 14a of the green book, for COVID-19 booster vaccine which recommends a dose of 50 microgram mRNA (half dose) can be offered at an interval of three months (12 weeks) of completion of the primary course see frequency section). And by JCVI advice as detailed in Chapter 14a of the green book in the fourth/fifth doses in eligible groups - see frequency section. The vaccine marketing authorisation holder's summary of product characteristics states that close observation for at least 15 minutes is recommended following vaccination. In recognition of the need to accelerate delivery of the programme in response to the emergence of the Omicron

Category	Description
	variant, the UK Chief Medical Officers have recommended temporary suspension of this requirement. This temporary suspension in individuals without a history of allergy has also been agreed by the Commission on Human Medicines. The Scottish Government has made further recommendations that all doses of COVID-19 vaccines be followed by a 5 minute observation period. Vaccine should be stored according to the conditions detailed below. However, in the event of a deviation of these conditions where vaccine is assessed as appropriate for continued use, administration under this PGD is allowed.
Storage requirements	Spikevax® (COVID-19 Vaccine Moderna dispersion for injection) must be stored frozen at minus 25ºC to minus 15ºC in accordance with manufacturer's advice. **Thawed vial** Once thawed, the vaccine should not be re-frozen and may be stored refrigerated at +2°C to +8°C protected from light for up to 30 days if not used (needle-punctured). **Precautions for storage** During storage it is recommended that the vials are stored in the original packaging/cartons, away from direct sunlight to protect from light and kept upright. NHS Board guidance on Storage and Handling of vaccines should be observed. In the event of an inadvertent or unavoidable deviation of these conditions, vaccine that has been stored outside the conditions stated above should be quarantined and risk assessed for suitability of continued use or appropriate disposal. After first use – use as soon as practically possible and within six hours. The vaccine may be stored between +2 and +25°C during the in-use period in accordance with manufacturer's advice. The vaccine vial has space to write the date and time that the vial was first punctured; write this on the vial label.

Category	Description
	The manufacturer may advise of updated storage requirements and product stability as new data becomes available, vaccine may be stored in accordance with updated recommendations from the manufacturer.
Additional information	Minor illnesses without fever or systemic upset are not valid reasons to postpone immunisation. If an individual is acutely unwell, immunisation should be postponed until they have fully recovered. Having prolonged COVID-19 symptoms is not a contraindication to receiving COVID-19 vaccine but if the patient is seriously debilitated, still under active investigation, or has evidence of recent deterioration, deferral of vaccination may be considered to avoid incorrect attribution of any change in the person's underlying condition to the vaccine.

3. Adverse reactions

Category	Description
Warnings including possible adverse reactions and management of these	A high proportion (more than 75%) of vaccine recipients had localised pain at the injection site after both dose 1 and dose 2 of COVID-19 Vaccine Moderna dispersion for injection. Redness and swelling were also seen after the second dose and local pain tended to last longer (around 3 days). Mild systemic effects were also common, including headache, fatigue, joint and muscle aches and chills. Systemic events were more severe after dose 2 and fever was only seen after dose 2, and both local and systemic reactions were less common in older participants. Adverse events were less common in those with pre-existing SARS-CoV-2 antibody. Axillary lymphadenopathy on the same side as the injection site was detected in more than one in ten recipients. Bell's palsy was reported by three participants in the vaccine group and one participant in the placebo group. As for the Pfizer vaccine, this will be monitored closely post-implementation. There were no cases of severe COVID-19

Category	Description
	disease in the vaccine group, and thus no signal for enhanced disease. Recently a number of cases of myocarditis and pericarditis have been reported after Pfizer BioNTech vaccine from Israel and the USA. The reported rate appears to be highest in those under 25 years of age and in males, and after the second dose. Onset is within a few days of vaccination and most cases are mild and have recovered without any sequalae. The MHRA has advised the benefits of vaccination still outweigh any risk in most individuals. Individuals who have had myocarditis or pericarditis should be investigated, and a second or booster dose can be given once they are fully recovered in line with advice in the COVID-19 chapter of the Green Book, under a PSD. A protocol for the management of anaphylaxis and an anaphylaxis pack must always be available whenever vaccines are given. Immediate treatment should include early treatment with intramuscular adrenaline, with an early call for help and further IM adrenaline every 5 minutes. The health professionals overseeing the immunisation service must be trained to recognise an anaphylactic reaction and be familiar with techniques for resuscitation of a patient with anaphylaxis. . In the event of a severe adverse reaction individual should be advised to seek medical advice. For full details/information on possible adverse reaction, refer to manufacturer's product literature or summary of product characteristics.
Reporting procedure for adverse reactions	Healthcare professionals and individuals/carers should report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Coronavirus Yellow Card reporting scheme on: https://coronavirus-yellowcard.mhra.gov.uk/ As this vaccine is labelled with a black triangle, all adverse reactions occurring in individuals of any age after vaccination should be reported to the MHRA using the Coronavirus Yellow

Category	Description
	Card Scheme. Anyone can report a suspected adverse reaction to the MHRA using the Coronavirus Yellow Card reporting scheme https://coronavirus-yellowcard.mhra.gov.uk/ Any adverse reaction to a vaccine should be documented in accordance with locally agreed procedures in the individual's record and the individual's GP should be informed. Anaphylaxis is a very rare, recognised side effect of most vaccines and suspected cases should be reported via the Coronavirus Yellow Card Scheme. Chapter 8 of the Green Book gives detailed guidance on distinguishing between faints, panic attacks and the signs and symptoms of anaphylaxis. If a case of suspected anaphylaxis meets the clinical features described in Chapter 8, this should be reported via the Yellow Card Scheme as a case of 'anaphylaxis' (or if appropriate 'anaphylactoid reaction'). Cases of less severe allergic reactions (i.e. not including the clinical features of anaphylaxis) should not be reported as anaphylaxis but as 'allergic reaction'. Programmatic Adverse Events should be recorded in line with local procedures and where appropriate escalated in accordance with the national framework.
Advice to patient or carer including written information	Written information to be given to individual • Provide manufacturer's consumer information leaflet/patient information leaflet (PIL) provided with the vaccine. • Provide copy of Public Health Scotland post-vaccination leaflet • Provide copy of Pregnant, planning a pregnancy or breastfeeding, a guide to COVID-19 vaccine to women of child bearing years Individual advice / follow up treatment • Inform the individual/carer of possible side effects and their management. • Vaccinated individuals should be advised that it is common to develop a fever after vaccination and that this normally happens within 48 hours after the

Category	Description
	vaccination and usually goes away within 48 hours. This is a common, expected reaction, and self-isolation and testing for COVID-19 are not required. • Vaccinated individuals should be advised that if the fever started 48 hours after the vaccination or lasts longer than 48 hours, they should seek medical advice as they may have COVID-19 or another infection. They may be advised to take a COVID-19 test. • Vaccinated individuals should be advised that feeling generally unwell, shivery, achy and tired were also symptoms commonly reported by vaccine recipients in the clinical trials. Generally, these symptoms were found to resolve within one to two days without treatment but paracetamol can be taken if necessary to relieve any of these symptoms. • Inform the individual/carer that anyone who has any of the following symptoms after vaccination should seek medical advice urgently: ➢ chest pain ➢ shortness of breath ➢ feelings of having a fast-beating, fluttering, or pounding heart • As has always been recommended, any fever after vaccination should be monitored and if individuals are concerned about their health at any time, they should seek advice from their GP or NHS24 • The individual should be advised to seek medical advice in the event of a severe adverse reaction. • Inform the individual that they can report suspected adverse reactions to the MHRA using the Yellow Card reporting scheme on: http://yellowcard.mhra.gov.uk. • Immunosuppressed individuals should be advised that they may not make a full immune response to the vaccine and they should continue to take appropriate measures to protect themselves against this infection.

Category	Description
	• When administration is postponed advise the individual how future vaccination may be accessed • When applicable, advise the individual/carer when to return for vaccination or when a subsequent vaccine dose is due.
Observation following vaccination	Following COVID-19 vaccine administration, individuals should be observed for any immediate reactions whilst they are receiving any verbal post vaccination information and exiting the centre. According to the Summaries of Product Characteristics, it is recommended that all recipients of the Pfizer BioNTech and Moderna vaccines are kept for observation and monitored for a minimum of 15 minutes. In recognition of the need to accelerate delivery of the programme in response to the emergence of the Omicron variant, the UK Chief Medical Officers have recommended suspension of this requirement. This temporary suspension in individuals without a history of allergy has also been agreed by the Commission on Human Medicines. There is no routine requirement for observation following COVID-19 Vaccine AstraZeneca. The Scottish Government has made further recommendations that all doses of mRNA COVID-19 vaccines be followed by a 5 minute observation period. A longer observation period when indicated after clinical assessment as set out in Figure 1 and Figure 2 (above). Vaccinated individuals should be informed about how to access immediate healthcare advice in the event of displaying any symptoms. In some settings, for example domiciliary vaccination, this may require a responsible adult to be present for at least 15 minutes after vaccination. As syncope (fainting) can occur following vaccination, all vaccinees should either be driven by someone else or should not drive for 15 minutes after vaccination.

Category	Description
Follow up	Not applicable
Additional facilities	A protocol for the management of anaphylaxis and an anaphylaxis pack must always be available whenever vaccines are given. Immediate treatment should include early treatment with intramuscular adrenaline, with an early call for help and further IM adrenaline every 5 minutes. The health professionals overseeing the immunisation service must be trained to recognise an anaphylactic reaction and be familiar with techniques for resuscitation of a patient with anaphylaxis.

4. Audit Trail/Records

Name	Description
Record/ audit trail	Record: • that valid informed consent was given • name of individual, address, date of birth and GP with whom the individual is registered • name of person that undertook assessment of individual's clinical suitability for vaccine • name of person that administered the vaccine • name and brand of vaccine • date of administration • dose, form and route of administration of vaccine • batch number • where possible expiry date • anatomical site of vaccination • advice given, including advice given if excluded or declines immunisation • details of any adverse drug reactions and actions taken

Name	Description
	• administered under protocol Records should be kept line with local procedures. Ideally records should be kept within the NHS Scotland COVID-19 vaccine administration app. Local policy should be followed to encourage information sharing with the individual's General Practice. All records should be clear, legible and contemporaneous.

5. References

Name	Description
Additional references	Immunisation against Infectious Disease [Green Book] https://www.gov.uk/government/organisations/public-health-england/series/immunisation-against-infectious-disease-the-green-book Immunisation against Infectious Disease [Green Book] COVID-19 https://www.gov.uk/government/publications/covid-19-the-green-book-chapter-14a Manufacturer's product information/ Summary of Product Characteristics https://www.gov.uk/government/publications/regulatory-approval-of-covid-19-vaccine-moderna Educational resources for registered professionals produced by National Education for Scotland https://learn.nes.nhs.scot/37676/immunisation/covid-19-vaccines All relevant JCVI statements

Name	Description
	All relevant Scottish Government advice including the relevant CMO letter(s)

ANNEX B: Practitioner authorisation sheet

COVID-19 Vaccine Moderna Protocol
Valid from: Expiry:

Before signing this Protocol, check that the document has had the necessary authorisations in section 1 and 2. Without these, this Protocol is not lawfully valid.

Practitioner

By signing this Protocol, you are indicating that you agree to its contents and that you will work within it.

Protocols do not remove inherent professional obligations or accountability.

It is the responsibility of each practitioner to practise only within the bounds of their own competence and any appropriate professional code of conduct.

I confirm that I have read and understood the content of this Protocol and that I am willing and competent to work to it within my professional code of conduct.			
Name	Designation	Signature	Date

Person authorising on behalf of Provider

I confirm that the practitioners named above have declared themselves suitably trained and competent to work under this Protocol. I give authorisation on behalf of **insert name of organisation** for the above named health care professionals who have signed the Protocol to work under it.			
Name	Designation	Signature	Date

Note to person authorising on behalf of Provider

Score through unused rows in the list of practitioners to prevent practitioner additions post managerial authorisation.

ANNEX B: Continued

This authorisation sheet should be retained to serve as a record of those practitioners authorised to work under this Protocol.

ANNEX C: Clinical Supervision sheet

COVID-19 Vaccine Moderna Protocol
Valid from: Expiry:

This sheet must record the name of the clinical supervisor taking responsibility and all of the people working under different activity stages of the protocol.

Activity stages of the vaccination pathway under this protocol:

Stage 1	a. Assessment of the individual presenting for vaccination b. Provide information and obtain informed consent c. Provide advice to the individual	Registered Healthcare Professionals Only
Stage 2	• Vaccine Preparation	Registered Healthcare Professionals, non-registered professionals or non-registered Armed Forces staff
Stage 3	• Vaccine Administration	Registered Healthcare Professionals, non-registered professionals or non-registered Armed Forces staff
Stage 4	• Record Keeping	Registered Healthcare Professionals, non-registered professionals or non-registered Armed Forces staff

The clinical supervisor has ultimate responsibility for safe care being provided under the terms of the protocol. Persons working under the protocol may be supported by additional registered healthcare professionals, but the clinical supervisor retains responsibility.

Before signing this Protocol, check that the document has had the necessary authorisations. Without these, this Protocol is not lawfully valid.

Clinical Supervisor

Name	Designation	Signature	Date

ANNEX C: Continued

Practitioner(s) and Activity Stages

Name	Activity Stage(s)	Signature	Date

Note to Clinical Supervisor

Score through unused rows in the list of practitioners to prevent practitioner additions post managerial authorisation.

This authorisation sheet should be retained to serve as a record of clinical supervision arrangements for those working under this Protocol.

Annex Version history

Version	Date	Summary of changes
1.0	31/03/21	Version 1.0 new national protocol
1.1	20/04/21	The following sections have been updated: • Inclusion section updated to highlight that the inclusion criteria refer to COVID-19 Vaccine Moderna. • Inclusion section updated to align with JCVI advice on the use of vaccination in pregnancy. • Cautions section updated to align with JCVI advice on the use of vaccination in pregnancy. • Warnings section updated to align with Green Book Chapter. • Route of administration updated with advice on obtaining additional dose from vial. • Reference section updated to include JCVI advice on phase 2 priority groups.
1.2	10/05/21	The following sections have been updated: • Inclusion section updated to include those requiring a different type of COVID-19 vaccine for the second dose than that given as the first dose when clinically indicated • Inclusion section updated to remove wording on pregnancy from CEV section. • Exclusion section updated to include those bone marrow and peripheral blood stem cell donors who have commenced GCSF, the vaccination (first or second dose) must be delayed at least until 72 hours after stem cell collection (both peripheral blood stem cell and bone marrow donation). • Caution section updated to remove reference to AstraZeneca vaccine. Frequency section updated to remove advice that the second vaccine dose should be with the same vaccine as for the first dose.
1.3	24/05/21	The following sections have been updated: • Frequency section updated to include JCVI advice that second doses of all vaccines should be brought forward from 12 to 8 weeks for all priority groups, with priority given to those areas where the B.1.617.2 variant is of the highest threat.

2.1	05/07/21	The following sections have been updated: • Cautions section updated to align with Green Book chapter on co-administration with other vaccines. • Frequency section updated to align with Green Book chapter advice on scheduling. • Frequency section updated to align with Green Book chapter on interchangeability between COVID-19 vaccines. • Duration of treatment section updated to align with Green Book chapter on reinforcing immunisation. • Black triangle section updated to remove wording on regulation 174 approval • Legal category section updated to remove wording on regulation 174 approval • Use out with the SPC section updated to refer to Conditional Marketing authorisation. • Use out with the SPC section updated with Green Book chapter advice on scheduling.
2.2	22/07/21	The following sections have been updated: • Inclusion section updated regarding pregnancy and authorised vaccines for different age groups. • Frequency section updated to include advice on exceptions to the recommended 8-week dosage interval. • Warnings and ADR section updated to include Green Book Chapter information on myocarditis and pericarditis • Advice to patient or carer section updated to include advice to seek urgent medical advice if experiencing chest pain, shortness of breath, feelings of having a fast-beating, fluttering or pounding heart
2.3	05.08.21	The following sections have been updated:

		• Frequency section updated to align with wording in the Green Book recommending a minimum interval of eight weeks between doses of all the available COVID-19 vaccines where a two-dose primary schedule is used. • Use out with SPC section updated to reflect JCVI advice on interval between doses.
2.4	18.09.21	The following sections have been updated: • Name of vaccine updated to include brand name. • Indication section updated to include JCVI advice on third primary dose vaccination. • Indication section updated to include JCVI statement on COVID-19 booster vaccination from 14th September 2021 • Inclusion section updated to include JCVI advice on third primary dose vaccination. • Inclusion section updated to include information about use of vaccine in different age groups in pregnancy. • Dose section updated to align with JCVI advice for a half dose for COVID-19 booster vaccine. • Frequency section updated to include JCVI advice on third primary dose vaccination. • Frequency section updated to align with JCVI advice on COVID-19 booster vaccination • Use out with SPC section updated to include JCVI advice on third primary dose vaccination • Use out with the SPC section update to include JCVI advice for a COVID-19 booster vaccine of 50 microgram mRNA (half dose).
2.5	30/09/21	The following sections have been updated: • Exclusion criteria section updated to align with COVID-19 chapter of Green Book advice on contraindications and precautions in individuals with a history of allergy.

		• Exclusion criteria section updated to include those who developed myocarditis or pericarditis following a previous COVID-19 vaccination. • Cautions section updated to align with COVID-19 chapter of Green Book advice on contraindications and precautions in individuals with a history of allergy, including updated figure and flowchart. • Cautions section updated to align with COVID-19 chapter of Green Book advice on co-administration with shingles vaccine and inactivated influenza vaccine • Duration of treatment section updated to remove wording about booster doses. • Frequency section updated with new flow and advice from Green Book chapter on vaccine choice for third primary dose for those with severe immunosuppression • Frequency section updated to advise in those identified as requiring a booster vaccine dose the booster dose should be administered no earlier than six months (24 weeks) after completion of the primary vaccine course.
2.6	05 November 2021	The following sections have been updated: • Minor changes to change history section for PGD version 1.7 • Exclusion section updated to remove participation in a COVID-19 vaccine clinical trial as an exclusion. • Cautions section updated to align with wording on co-administration with other vaccines in COVID-19 chapter of Green Book. • Cautions section updated to align with wording on safety in breastfeeding in updated COVID-19 chapter of Green Book. • Cautions section updated to align with wording on use of COVID-19 vaccine in those who participated in a COVID-19 vaccine clinical trial.

		• Action if excluded section updated to reflect that participation in a clinical trial for COVID -19 vaccine is no longer an exclusion. • Frequency section updated to align with wording on interval for booster doses in updated COVID-19 chapter of Green Book. • Frequency section updated to align with wording on choice of vaccine for booster doses in updated COVID-19 chapter of Green Book. • Use out with SPC section updated to align with wording on interval for booster doses in updated COVID-19 chapter of Green Book
2.7	16/11/21	The following sections have been updated: • Inclusion section updated to align with wording on JCVI advice on groups who should be offered a booster dose as set out in COVID-19 chapter of Green Book. • Cautions section updated to align with wording on use of COVID-19 vaccine in those who participated in a COVID-19 vaccine clinical trial. • Frequency section updated to align with wording on interval for booster doses in updated COVID-19 chapter of Green Book (removal of 22 weeks as interval but retaining 5 months). • Frequency section updated to align with wording that third doses given to those who were severely immunosuppressed at/around the time of their first or second primary dose do not count as booster doses in updated COVID-19 chapter of Green Book. • Warnings section updated to align with Green Book advice on vaccination in those with myocarditis or pericarditis.
2.8	30/12/21	The following sections have been updated: • Indication section updated to include JCVI advice on the UK vaccine response to the Omicron variant from 29 November 2021

		• Inclusion section updated include a generic statement of inclusion in with Green Book chapter and JCVI advice rather than listing all groups. • Caution section updated to reflect updated advice on interval for booster vaccination in those have participated in a clinical trial of COVID-19 vaccines. • Frequency section updated to align with wording on interval between booster vaccine and completion of primary course as set out in JCVI advice on the UK vaccine response to the Omicron variant from 29 November 2021 • Use out with SPC section updated to highlight JCVI advice on the UK vaccine response to the Omicron variant from 29 November 2021
2.9	13/12/21	Frequency section updated to indicate that booster vaccination should not be given within three months (12 weeks) of completion of the primary course. Use out with the SPC section updated to reflect updated advice for observation following vaccination. Observation following vaccination section updated to reflect updated advice for observation following vaccination.
3.0	16/12/21	• The following sections have been updated: • Cautions section updated to align with updated Green Book chapter advice on managing individuals with a history of allergy (including changes to figures 1 and 2). • Cautions section updated to align with JCVI advice that women who are pregnant should be considered as falling into a clinical risk group (JCVI Priority Cohort 6 for COVID-19). • Frequency section updated to align with updated Green Book chapter advice for individuals who started the schedule and who attend for vaccination where the same vaccine is not available or suitable, or if the first product received is unknown or not available. • Frequency section updated to align with updated Green Book chapter advice on booster vaccination where mRNA vaccines are clinically contra-indicated.

		• Observation following vaccination section updated to align with updated Green Book chapter and Scottish Government advice on post vaccination observation including more detail on the circumstances in which a longer observation period when indicated after clinical assessment as set out in Figure 1 and Figure 2.
3.1	14/01/22	The following sections have been updated: There have been minor typographical changes to align with current COVID-19 Green Book chapter. Indication section updated to remove listing of all JCVI statements. Exclusion section updated with removal of JCVI advice on individuals with a past history of COVID-19 infection (added to cautions section). Cautions section updated to include advice on individuals with a past history of COVID-19 infection added to cautions section. Cautions section updated to align with updated Green Book chapter advice on managing individuals with a history of allergy (including changes to figure 1). Action if excluded section updated with advice on deferral of vaccination in individuals with a past history of COVID-19 infection Frequency section updated to align with updated Green Book chapter advice on third primary dose for those with severe immunosuppression with AstraZeneca COVID-19 vaccine (Vaxzevria®) where mRNA vaccines are clinically contraindicated. Use outwith SPC section updated to include information on use of vaccine in the event of a deviation of these recommended storage conditions. Warnings section advice on management of anaphylaxis modified. Additional facilities section updated with advice on management of anaphylaxis modified.

3.2	28/02/22	The following sections have been updated: Caution section updated to include updated figure on managing patients with a history of allergy from Green Book chapter. Caution section updated with minor changes to align with Green Book chapter advice on vaccination of clinical trial participants. Caution section updated with to align with Green Book chapter advice on vaccination of individuals with a past history of COVID-19 infection. Frequency section updated with recommendations in Green Book chapter for a further booster dose for adults aged 75 years and over; residents of any age in a care home for older adults, and; individuals aged 12 years and over who are immunosuppressed. Is the use out with the SPC section updated to highlight that further booster dose for adults aged 75 years and over; residents of any age in a care home for older adults, and; individuals aged 12 years and over who are immunosuppressed if out with SPC but aligned with JCVI advice as set out in Green Book chapter Reference section has been updated.
3.3	25/03/22	The following sections have been updated: Advice to patient or carer section updated with advice on fever following vaccination.