UK Health Security Agency

NHS

Publications gateway number: GOV-11808

National protocol for Spikevax (formerly COVID-19 Vaccine Moderna)

Reference no:	Spikevax COVID-19 Vaccine (Moderna) protocol
Version no:	v06.00
Valid from:	31 March 2022
Expiry date:	1 April 2023

This protocol is for the administration of Spikevax (formerly COVID-19 Vaccine Moderna) to individuals 18 years and over in accordance with the national COVID-19 vaccination programme.

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

The UK Health Security Agency (UKHSA) has developed this protocol for authorisation by or on behalf of the Secretary of State for Health and Social Care to facilitate the delivery of the national COVID-19 vaccination programme commissioned by NHS England and NHS Improvement (NHSEI).

This protocol may be followed wholly from assessment through to post-vaccination by an appropriately registered healthcare professional (see Characteristics of staff). Alternatively, multiple persons may undertake stages in the vaccination pathway in accordance with this protocol. Where multiple person models are used, the service provider/contractor must ensure that all elements of the protocol are complied with in the provision of vaccination to each individual. The provider/contractor 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 under Characteristics of staff must be adhered to.

The provider/contractor and registered healthcare professionals are responsible for ensuring that they have adequate and appropriate indemnity cover.

Persons must be authorised by name to work under this protocol. They must ensure they meet the staff characteristics for the activity they are undertaking, make a declaration of competence and be authorised in writing. This can be done by completing Section 4 of this protocol or maintaining an equivalent electronic record.

A clinical supervisor[1], who must be a registered doctor, nurse or pharmacist trained and competent in all aspects of the protocol, must be present and take overall responsibility for provision of vaccination under the protocol at all times and be identifiable to service users. The drawing up of the vaccine has its own supervision requirements in accordance with Part 1 of the HMR 2012 and will need to be done by, or under the supervision of, a registered doctor, nurse or pharmacist. If a vaccination service is being provided at scale, the clinical supervisor should only take on specific supervision requirements in relation to the drawing up of the vaccine if this can be

[1] This role is different to the Band 6 'COVID-19 Vaccination Programme - RHCP Clinical Supervisor (Vaccinations)' (see Accountability and delegation under the national protocols for COVID-19 vaccines: visual diagram at Coronavirus » Summary of the legal mechanisms for administering the COVID-19 vaccine(s) (england.nhs.uk))

done safely alongside their overarching role. Any time the protocol is used, the name of the clinical supervisor taking responsibility and all the people working under different stages of the protocol must be recorded for the session. The clinical supervisor has ultimate responsibility for safe care being provided under the terms of the protocol. Staff working under the protocol may be supported by additional registered healthcare professionals, but the clinical supervisor retains overall responsibility. Staff working to the protocol must understand who the clinical supervisor for their practice at any time is and can only proceed with their authority. The clinical supervisor may withdraw this authority for all members of staff or individual members of staff at any time and has authority to stop and start service provision under the protocol as necessary. Every member of staff has 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.

Operation under this protocol is the responsibility of service providers/contractors. Provider organisations/contractors using this protocol should retain copies, along with the details of those authorised to work under it, for 8 years after the protocol expires.

Persons must check that they are using the current version of this protocol and current versions of any documents this protocol refers to. Amendments may become necessary prior to the published expiry date. Current versions of national protocols for COVID-19 vaccines, authorised by or on behalf of the Secretary of State for Health and Social Care in accordance with regulation 247A of the HMR 2012, can be found via: COVID-19 vaccination programme

Any concerns regarding the content of this protocol should be addressed to: immunisation@phe.gov.uk

Change History

Version	Change details	Date
V01.00	New protocol for COVID-19 Vaccine Moderna.	01/04/2021
V02.00	National protocol for COVID-19 Vaccine Moderna amended to: • update organisation from PHE to UKHSA • update name of vaccine • remove specific reference to clinically extremely vulnerable (CEV) individuals as they are covered by the inclusion of those in at risk groups • include individuals referred for a third primary dose of COVID-19 vaccine in accordance with patient specific recommendations from their specialist, GP or prescriber • update the additional information on immunosuppressed individuals • include individuals eligible for a booster dose as part of the national COVID-19 vaccination programme • exclude individuals who have experienced myocarditis or pericarditis determined as likely to be related to previous COVID-19 vaccination • move cautions relating to pregnancy and those involved in clinical trials to the additional information section • update to cautions • update the additional information on immunosuppressed individuals, co-administration and incomplete vaccination • remove key references to JCVI statements which are now incorporated into the guidance in Chapter 14a of the Green Book • minor wording changes and additions to text for consistency; updated references	06/10/2021
V03.00	National protocol for COVID-19 Vaccine Moderna V02.00 amended to: • reword criteria for inclusion • reword criteria for exclusion pertaining to allergic reactions • update cautions in line with revisions to Chapter 14a of the Green Book • reword actions if excluded pertaining to age • update the myocarditis and pericarditis section in actions to be taken if excluded section in line with updates in the Chapter 14a of the Green Book • update off-label section in line with updated SPC and revised recommendations from JCVI and in Chapter 14a of the Green Book • update storage section • update dose and frequency of administration section, to include a paragraph on minimum intervals post COVID-19 infection, recommend that immunosuppressed individuals who have not yet received a third dose may be given their third dose now (8 weeks after their second dose) to avoid further delay and that a booster dose can be given to immunosuppressed individuals 3 months after their third primary dose and all individuals from 18 years of age • provide a minimum interval of 3 months between completion of primary vaccination and a booster dose • update adverse reactions section in line with updated SPC • update drug interactions and special considerations and additional information sections in line with the revisions to Chapter 14a of the Green Book • update special considerations and additional information section in line with revisions to Chapter 14a of the Green Book • remove line stating that pregnant women should be vaccinated at the same time as non-pregnant women • minor wording changes and additions to text for consistency; updated references	08/12/2021
V04.00	National Protocol for Spikevax COVID-19 Vaccine (Moderna) V03.00 amended to:	16/12/2021

	• update the cautions section in line with updated Chapter 14a of the Green Book 14 December 2021 and UK Chief Medical Officers (CMO) report 14 December 2021 • update the off-label use section regarding temporary removal of 15 minutes observation and monitoring requirement in in line with updated Chapter14a of the Green Book 14 December 2021 and CMO report 14 December 2021 • update the special considerations and additional information section regarding use of heterologous schedules in primary immunisation in line with updated Chapter 14a of the Green Book 14 December 2021 and add subtitles • update patient advice and follow up treatment section in line with updated Chapter 14a of the Green Book 14 December 2021 and CMO report 14 December 2021 • update the key references	
V04.00a	National Protocol for Spikevax COVID-19 Vaccine (Moderna) V04.00 amended to: • update Stage 3 post vaccination advice section to remove requirement for 15 minutes observation • minor formatting and typographical amendments	17/12/2021
V05.00	National Protocol for Spikevax COVID-19 Vaccine (Moderna) V04.00a amended to: • provide clarity in cautions, off-label and patient advice sections for individuals without history of allergy • update cautions section to include immune thrombocytopenia (ITP) in line with the updated Chapter 14a of the Green Book 12 January 2022 • update off-label and dose and frequency sections with reference to boosting in line with the updated Chapter 14a of the Green Book 12 January 2022 • update shelf life in storage section • update the special considerations section regarding the completion of the course in pregnancy at the recommended interval in line with the updated Chapter 14a of the Green Book 12 January 2022 • update references section	14/01/2022
V06.00	National Protocol for Spikevax COVID-19 Vaccine (Moderna) amended to: • move exclusions pertaining to allergy to cautions section, as special precautions, to allow for administration on the expert advice of an allergy specialist or where at least one dose of the same vaccine has been tolerated previously and similarly update the actions if excluded section • reflect the revised recommendations for deferring those with a past history of COVID-19 infection • add a paragraph to off-label section pertaining to expiry extended vaccines • update dose and frequency of administration section • update pregnancy paragraph to reflect inclusion as a risk group • update to other sections of the protocol to address the above points and for minor typographical amendment	24/03/2022

1. Ministerial authorisation

This protocol is not legally valid, in accordance with regulation 247A of the HMR 2012, inserted by the Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020, until it is approved by or on behalf of the Secretary of State for Health and Social Care.

On 28 March 2022 Department of Health and Social Care Ministers approved this protocol in accordance with regulation 247A of HMR 2012.

Any provider/contractor administering Spikevax (formerly COVID-19 Vaccine Moderna) under this protocol must work strictly within the terms of this protocol and contractual arrangements with the commissioner, for the delivery of the national COVID-19 vaccination programme.

Assembly, final preparation and administration of vaccines supplied and administered under this protocol must be subject to NHS governance arrangements and standard operating procedures that ensure that the safety, quality or efficacy of the product is not compromised. The assembly, final preparation and administration of the vaccines should also be in accordance with the manufacturer's instructions in the product's UK Summary of Product Characteristics (SPC) and/or in accordance with official national recommendations.

Note: The national COVID-19 vaccination programme may also be provided under patient group direction or on a patient specific basis (that is, by or on the directions of an appropriate independent prescriber, such as under a patient specific direction (PSD)). Supply and administration in these instances should be in accordance with contractual arrangements with the commissioner for the delivery of the national COVID-19 vaccination programme and are not related to this protocol.

1. Characteristics of staff

Classes of persons permitted to administer medicinal products under this protocol

This protocol may be followed wholly from assessment through to post-vaccination by an appropriately registered healthcare professional (see Table 2). Alternatively, multiple persons may undertake stages in the vaccination pathway in accordance with this protocol. Where multiple person models are used, the service provider/contractor must ensure that all elements of the protocol are complied with, in the provision of vaccination to each individual. The service provider/contractor is responsible for ensuring that there is a clinical supervisor present at all times and 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.

The provider/contractor and registered healthcare professionals are responsible for ensuring that they have adequate and appropriate indemnity cover.

This protocol is separated into operational stages of activity as outlined in Table 1.

The clinical supervisor[1] must be a registered doctor, nurse or pharmacist trained and competent in all aspects of the protocol and provide clinical supervision, see page 1, for the overall provision of clinical care provided under the legal authority of the protocol.

Table 1: Operational stages of activity under this protocol

Stage 1	a. Assessment of the individual presenting for vaccination b. Provide information and obtain informed consent[2] c. Provide advice to the individual	Specified Registered Healthcare Professionals Only (see Table 2)
Stage 2	• Vaccine Preparation	Registered or non-registered persons
Stage 3	• Vaccine Administration	Registered or non-registered persons
Stage 4	• Record Keeping	Registered or non-registered persons

Persons must only work under this protocol where they are competent to do so.

Non-professionally qualified persons operating under this protocol must be adequately supervised by experienced registered healthcare professionals.

Protocols do not remove inherent professional obligations or accountability. All persons operating under this protocol must work within their terms of employment at all times; registered healthcare professionals must also abide by their professional code of conduct.

To undertake the assigned stage(s) of activity under this protocol, persons working to this protocol must meet the criteria specified in Table 2 (see below).

Table 2: Protocol stages and required characteristics of persons working under it

Persons working to this protocol must meet the following criteria, as applicable to undertake their assigned stage(s) of activity under this protocol:	**Stage 1**	**Stage 2**	**Stage 3**	**Stage 4**
must be authorised by name as an approved person under the current terms of this protocol before working to it, see Section 4	Y	Y	Y	Y
must be competent to assess individuals for suitability for vaccination, identify any contraindications or precautions, discuss issues related to vaccination and obtain informed consent[2] and must be an appropriately qualified prescriber or one of the following registered professionals who can operate under a PGD or as an occupational health vaccinator in accordance with HMR 2012:	Y	N	N	N

[2] For those lacking mental capacity, a decision may be made in the individual's best interests in accordance with the Mental Capacity Act 2005, (for further information on consent see Chapter 2 of 'The Green Book').

• nurses, nursing associates 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.				
must be a doctor, nurse or pharmacist or a person who is under the supervision of, a doctor, nurse or pharmacist (see Page 1)	N	Y	N	N
must be competent in the handling of the vaccine product and use of the correct technique for drawing up the correct dose	N	Y	N	N
must be familiar with the vaccine product and alert to any changes in the manufacturer's summary of product characteristics (SPC) and familiar with the national recommendations for the use of this vaccine	Y	Y	Y	N
must be familiar with, and alert to changes in relevant chapters of Immunisation Against Infectious Disease: the Green Book	Y	Y	Y	N
must be familiar with, and alert to changes in the relevant standard operating procedures (SOPs) and commissioning arrangements for the national COVID-19 vaccination programme	Y	Y	Y	N
must have undertaken training appropriate to this protocol and relevant to their role, as required by local policy and national SOPs and in line with the Training recommendations for COVID-19 vaccinators	Y	Y	Y	N
must have completed the national covid-19 vaccination e-learning programme, including the relevant vaccine specific session, and/or locally-provided COVID-19 vaccine training	Y	Y	Y	N
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	N	Y	Y	N
must be competent in intramuscular injection technique if they are administering the vaccine	N	N	Y	N
must be competent in the recognition and management of anaphylaxis, have completed basic life support training and able to respond appropriately to immediate adverse reactions	Y	N	Y	N
must have access to the protocol and relevant COVID-19 vaccination programme online resources such as the Green Book, particularly Chapter 14a of the Green Book, and the COVID-19 vaccination programme: Information for healthcare practitioners document	Y	Y	Y	N
must understand the importance of making sure vaccine information is recorded on the relevant data system, meeting relevant competencies of the COVID-19 vaccinator competency assessment tool	Y	Y	Y	Y
must have been signed off as competent using the COVID-19 vaccinator competency assessment tool if new to or returning to immunisation after a prolonged period (more than 12 months), or have used the tool for self-assessment if an experienced vaccinator (vaccinating within past 12 months)	Y	Y	Y	Y
should fulfil any additional requirements defined by local or national policy	Y	Y	Y	Y

Stage 1: Assessment of the individual presenting for vaccination

Activity stage 1a:	**Assess the individual presenting for vaccination. If they are not eligible for vaccination or need to return at a later date, advise them accordingly.**
Clinical condition or situation to which this protocol applies	Spikevax (formerly COVID-19 Vaccine Moderna and hereafter referred to as Spikevax) is indicated for the active immunisation of individuals for the prevention of coronavirus disease (COVID-19) caused by the SARS-CoV-2 virus, in accordance with the national COVID-19 vaccination programme (see COVID-19 vaccination programme page) and recommendations given in Chapter 14a of Immunisation Against Infectious Disease: the 'Green Book' (hereafter referred to as Chapter 14a), and subsequent correspondence/publications from the UKHSA and/or NHS England and NHS Improvement.
Criteria for inclusion	Spikevax should be offered to individuals, aged 18 years and over, in accordance with the recommendations in Chapter 14a. Individuals are eligible for different dose schedules based on their recognised risk group (see the Dose and frequency of administration section).
Criteria for exclusion[3]	Individuals for whom valid consent, or 'best-interests' decision in accordance with the Mental Capacity Act 2005, has not been obtained (for further information on consent see Chapter 2 of 'The Green Book'). The Patient information leaflet for Spikevax should be available to inform consent. Individuals who: • are less than 18 years of age • have had a previous systemic allergic reaction (including immediate onset anaphylaxis) to a previous dose of a COVID-19 mRNA vaccine or to any component or residue from the manufacturing process[4] in Spikevax • have experienced myocarditis or pericarditis determined as likely to be related to previous COVID-19 vaccination • are suffering from acute severe febrile illness (the presence of a minor infection is not a contraindication for vaccination) • have received a full dose of COVID-19 vaccine in the preceding 28 days
Cautions including any relevant action to be taken Continued over page	Facilities for management of anaphylaxis should be available at all vaccination sites. (see Chapter 8 of the Green Book) and advice issued by the Resuscitation Council. There is a temporary suspension of the recommended observation and monitoring for 15 minutes in individuals without a history of allergy (see off-label use section below). Following COVID-19 vaccine administration, individuals without a history of allergy should be: • observed for any immediate reactions whilst they are receiving any verbal post vaccination information and exiting the centre • informed about the signs and symptoms of anaphylaxis and how to access immediate healthcare advice in the event of displaying any symptoms. In some settings, for example domiciliary vaccination, this

[3] Exclusion under this protocol does not necessarily mean the medication is contraindicated, but it would be outside its remit and another form of authorisation will be required

[4] Contains polyethylene glycol (PEG), refer to the product's SPC for a full list of excipients.

Cautions including any relevant action to be taken (continued)	may require a responsible adult to be present for at least 15 minutes after vaccination. Individuals with a personal history of allergy should be managed in line with Chapter 14a Table 5. Special precautions are advised for individuals with a personal history of allergy including a: • prior non-anaphylaxis allergic reaction to COVID-19 vaccine • history of immediate anaphylaxis to multiple, different drug classes, with the trigger unidentified (this may indicate polyethylene glycol (PEG) allergy) • history of anaphylaxis to a vaccine, injected antibody preparation or a medicine likely to contain PEG (such as depot steroid injection, laxative) • history of idiopathic anaphylaxis Individuals with undiagnosed polyethylene glycol (PEG) allergy often have a history of immediate onset-unexplained anaphylaxis or anaphylaxis to multiple classes of drugs. Such individuals should not be vaccinated with the Comirnaty® 30 micrograms/dose COVID-19 mRNA vaccine, except on the expert advice of an allergy specialist or where at least one dose of the same vaccine has been tolerated previously. Where individuals experienced a possible allergic reaction to a dose of COVID-19 vaccine, follow the guidance in Chapter 14a in relation to the administration of subsequent doses. Individuals with non-allergic reactions (vasovagal episodes, non-urticarial skin reaction or non-specific symptoms) to a COVID-19 vaccine can receive subsequent doses of vaccine in any vaccination setting. Observation for 15 minutes is recommended for these individuals. No specific management is required for individuals with a family history of allergies. 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. As fainting can occur following vaccination, all those vaccinated with any of the COVID-19 vaccines should be advised not to drive for 15 minutes after vaccination. Individuals with a bleeding disorder may develop a haematoma at the injection site. Individuals with bleeding disorders may be vaccinated intramuscularly if, in the opinion of a doctor familiar with the 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 was below the upper threshold of their therapeutic range, can receive intramuscular vaccination. A fine needle (equal to 23 gauge or finer calibre such as 25 gauge) should be used for the vaccination, followed by firm pressure applied to the site (without rubbing) for at least 2 minutes. If in any doubt, consult with the clinician responsible for prescribing or monitoring the individual's anticoagulant therapy. If the registered professional clinically assessing the individual is not the vaccinator, they must ensure the

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Cautions including any relevant action to be taken (continued)	vaccinator is aware of the individuals increased risk of haematoma and the need to apply firm pressure to the injection site for at least 2 minutes. The individual/carer should be informed about the risk of haematoma from the injection. Very rare reports have been received of Guillain-Barre Syndrome (GBS) following COVID-19 vaccination (further information is available in Chapter 14a). Healthcare professionals should be alert to the signs and symptoms of GBS to ensure correct diagnosis and to rule out other causes, in order to initiate adequate supportive care and treatment. Individuals who have a history of GBS should be vaccinated as recommended for their age and underlying risk status. In those who are diagnosed with GBS after the first dose of vaccine, the balance of risk benefit is in favour of completing a full COVID-19 vaccination schedule. On a precautionary basis, however, where GBS occurs within six weeks of an Astra Zeneca vaccine, for any future doses Pfizer or Moderna COVID-19 vaccines are preferred. Where GBS occurs following either of the mRNA vaccines, further vaccination can proceed as normal, once recovered. Guidance produced by the UK Immune Thrombocytopenia (ITP) Forum Working Party advises discussing the potential for a fall in platelet count in individuals with a history of ITP receiving any COVID-19 vaccine and recommends a platelet count check 2-5 days after the vaccine (British Society for Haematology-COVID-19). **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. For adults, vaccination after COVID-19 infection should ideally be deferred until clinical recovery to around 4 weeks after onset of symptoms or 4 weeks from the first confirmed positive specimen. This is to avoid confusing the differential diagnosis as clinical deterioration can occur up to 2 weeks after infection. This recommended interval after COVID-19 infection may be reduced to ensure operational flexibility when rapid protection is required, for example in periods of high incidence or circulation of a new variant in a vulnerable population. When rapid protection is required, any reduction in the recommended interval after COVID-19 infection will be advised by the JCVI or UKHSA and published in NHSEI operational guidance. Having prolonged COVID-19 symptoms is not a contraindication to receiving COVID-19 vaccine but if the individual 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.
Dose and frequency of administration Continued over page	**Interval post SARS-CoV-2 infection** For adults, vaccination after COVID-19 infection should ideally be deferred until clinical recovery to around 4 weeks after onset of symptoms or 4 weeks from the first confirmed positive specimen, to avoid confusing the differential diagnosis. The recommended interval after COVID-19 infection 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. When rapid protection is required, any reduction in the recommended

Dose and frequency of administration (continued)	interval after COVID-19 infection will be advised by JCVI or UKHSA and published in NHSEI operational guidance. **Primary vaccination** A primary dose of Spikevax is 0.5ml and contains 100micrograms of COVID-19 mRNA vaccine in 0.5ml. The 2-dose primary course consists of a first dose of 100micrograms in 0.5ml followed, after an interval of at least 28 days, by a second dose of 100micrograms in 0.5ml. However, the programme schedule, including both the number of doses and the intervals between them, should be administered in accordance with official national guidance which, at the time or writing, recommends a minimum interval of 8 weeks between primary doses for adults, as set out in Chapter 14a. For both adenovirus vector and mRNA vaccines, there is evidence of better immune response and/or protection where longer intervals between doses in the primary schedule are used. Based on this evidence, longer intervals are likely to provide more durable protection. JCVI is currently recommending a minimum interval of 8 weeks between doses of all the available COVID-19 vaccines where a 2-dose primary schedule is used for adults. Operationally, using the same minimum interval for all products will simplify supply and booking, and will help to ensure a good balance between achieving rapid and long-lasting protection. The main exception to the 8-week lower interval would be those about to commence immunosuppressive treatment. In these individuals, the licensed minimal interval of at least 28 days may be followed to enable the vaccine to be given whilst their immune system is better able to respond. If the primary course is interrupted or delayed, it should be resumed (using the same vaccine as was given for the first dose if possible, see Additional Information) but doses should not be repeated. **Third primary dose** Individuals 18 years and over who had severe immunosuppression in proximity to their first or second COVID-19 doses in the primary schedule should receive a 3-dose primary course (see 'Box 1: Criteria for a third primary dose of COVID-19 vaccine in those aged 12 year and above' in Chapter 14a). The third primary dose (0.5ml) should be given ideally at least 8 weeks after the second dose, with special attention paid to current or planned immunosuppressive therapies. Where possible the third dose should be delayed until 2 weeks after the period of immunosuppression, in addition to the time period for clearance of the therapeutic agent. If not possible, consideration should be given to vaccination during a treatment 'holiday' or when the degree of immunosuppression is at a minimum (see Additional information section). **Booster vaccination** A booster dose of Spikevax is 0.25ml and contains 50micrograms of COVID-19 mRNA vaccine in 0.25ml Boosters should be offered to individuals eligible as part of the national COVID-19 vaccination programme in accordance with the recommendations from the JCVI and in Chapter 14a. Individuals should complete a primary course of COVID-19 vaccination before receiving any boosters. Boosters should be given at a minimum interval of 3 months from the previous dose.

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Dose and frequency of administration (continued)	JCVI have advised that the Moderna (50microgram), for those aged 18 years and over, and Pfizer-BioNTech (30microgram) vaccines should be used with equal preference in the COVID-19 booster programme. Both vaccines have been shown to substantially increase antibody levels when offered as a booster dose.
Action to be taken if the individual is excluded	This Protocol is for individuals aged 18 years and over in accordance with recommendations in Chapter 14a for the use of Spikevax. For individuals under 18 years of age, Comirnaty® vaccine is recommended (see National protocol for Comirnaty®). The risk to the individual of not being immunised must be considered. The indications for risk groups are not exhaustive, and the healthcare practitioner should consider the risk of COVID-19 exacerbating any underlying disease that an individual may have, as well as the risk of serious illness from COVID-19 itself. Where appropriate, such individuals should be referred for assessment of clinical risk. Where risk is identified as equivalent to those currently eligible for immunisation, vaccination may only be provided by an appropriate prescriber or on a patient specific basis, under a PSD. For individuals who have had previous systemic allergic reaction (including immediate onset anaphylaxis) to a previous dose of COVID-19 mRNA vaccine, or any component of the vaccine, advice should be sought from an allergy specialist. Individuals who have experienced myocarditis or pericarditis following COVID-19 vaccination should be assessed by an appropriate clinician to determine whether it is likely to be vaccine related. As the mechanism of action and risk of recurrence of myocarditis and pericarditis are being investigated, the current advice is that an individual's second or subsequent doses should be deferred pending further investigation. Following investigation, any subsequent dose should be provided by an appropriate prescriber or on a patient specific basis, under a PSD. In case of postponement due to acute illness, advise when the individual can be vaccinated and, if possible, ensure another appointment is arranged. Document the reason for exclusion and any action taken.
Action to be taken if the individual or carer declines treatment	Informed consent, from the individual or a person legally able to act on the person's behalf, must be obtained for each administration and recorded appropriately. Where a person lacks the capacity, in accordance with the Mental Capacity Act 2005, a decision to vaccinate may be made in the individual's best interests. Advise the individual/carer about the protective effects of the vaccine, the risks of infection and potential complications if not immunised. Document advice given and the decision reached.
Arrangements for referral	As per local policy.

Stage 1b: Description of treatment

Activity stage 1b:	**Consider any relevant cautions, interactions or adverse drug reactions.** **Provide advice to the individual and obtain informed consent[2].** **Record individual's consent[2] and ensure vaccinator, if another person, is informed of the vaccine product and dose to be administered.**
Name, strength and formulation of drug	Spikevax dispersion for injection. COVID-19 mRNA vaccine (nucleoside modified). This is a multidose vial and one vial contains 10 primary doses. One multidose vial should contain 20 booster doses (see Off-label use). One primary dose (0.5ml) contains 100micrograms of mRNA (embedded in SM-102 lipid nanoparticles). One booster dose (0.25ml) contains 50micrograms of mRNA (embedded in SM-102 lipid nanoparticles).
Legal category	Prescription only medicine (POM).
Black triangle▼	Yes. As a new vaccine product, the Medicines and Healthcare products Regulatory Agency (MHRA) has a specific interest in the reporting of adverse drug reactions for this product.
Off-label use	**Primary immunisation** The Spikevax SPC recommends an interval of 28 days between primary doses. There is evidence of better immune response and/or protection from COVID-19 vaccines where longer intervals between doses are used. Therefore, Spikevax should be administered under this national protocol in accordance with recommendations from the JCVI and Chapter 14a for the delivery of the COVID-19 vaccination programme in England (see Dose and frequency of administration section). **Booster immunisation** The Spikevax SPC recommends a booster dose may be administered 6 months after the second dose. Booster vaccination may be offered under this protocol to individuals aged 18 years and over, at a minimum interval of 3 months from the previous dose, in accordance with the recommendations from the JCVI and Chapter 14a. **Allergy** According to the respective SPCs, 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 (CMO) 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. However, vaccinated individuals should be informed about the signs and symptoms of anaphylaxis and 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. Individuals with a personal history of allergy, should be managed in line with Chapter 14a Table 5. No specific management is required for individuals with a family history of allergies.

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Off-label use (continued)	As fainting can occur following vaccination, all those vaccinated with any of the COVID-19 vaccines should be advised not to drive for 15 minutes after vaccination. The MHRA will continue to closely monitor anaphylaxis post-COVID-19 vaccination; reporting of adverse events via the Yellow Card Scheme is strongly encouraged. **Storage** Vaccine should be stored according to the conditions detailed in the Storage section below. However, in the event of an inadvertent or unavoidable deviation of these conditions refer to Vaccine Incident Guidance. Where vaccine is assessed in accordance with these guidelines as appropriate for continued use this would constitute off-label administration under this protocol. In the event that available data supports extension to the vaccine shelf life any resulting off-label use of expiry extended vaccine under this protocol should be supported by NHS operational guidance or standard operating procedure. Where a vaccine is recommended off-label consider, as part of the consent process, informing the individual/carer that the vaccine is being offered in accordance with national guidance but that this is outside the product licence.
Drug interactions	Immunological response may be diminished in those receiving immunosuppressive treatment, but it is important to still immunise this group. Although no data for co-administration of COVID-19 vaccine with other vaccines exists, in the absence of such data, first principles would suggest that interference between inactivated vaccines with different antigenic content is likely to be limited. Based on experience with other vaccines, any potential interference is most likely to result in a slightly attenuated immune response to one of the vaccines. There is no evidence of any safety concerns, although it may make the attribution of any adverse events more difficult. Similar considerations apply to co-administration of inactivated (or non-replicating) COVID-19 vaccines with live vaccines such as MMR. In particular, live vaccines which replicate in the mucosa, such as live attenuated influenza vaccine (LAIV) are unlikely to be seriously affected by concomitant COVID-19 vaccination. A seven-day interval should ideally be observed between COVID-19 vaccination and shingles vaccination. This is based on the potential for an inflammatory response to COVID-19 vaccine to interfere with the 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. For further information about co-administration with other vaccines see Additional Information section.
Identification and management of adverse reactions Continued over page	Spikevax adverse reactions most commonly reported are pain at the injection site, fatigue, headache, myalgia, arthralgia, chills, nausea, vomiting, axillary swelling/tenderness, fever, injection site swelling, redness, injection site erythema, injection site urticaria, injection site rash, delayed injection site reaction. Lymphadenopathy was captured as axillary lymphadenopathy on the same side as the injection site. Other lymph nodes (such as cervical, supraclavicular) were affected in some cases. Acute peripheral facial paralysis, facial swelling, hypoaesthesia (numbness) dizziness and injection site pruritis have been rarely reported.

Identification and management of adverse reactions (continued)	Anaphylaxis and hypersensitivity have also been reported. Adverse reactions are usually mild or moderate in intensity and resolve within a few days after vaccination. A slightly lower frequency of reactogenicity events is associated with greater age. Local and systemic adverse reactions are more frequently reported after dose 2 than after dose one. Very rare cases of myocarditis and pericarditis have been observed following vaccination with Spikevax. These cases have primarily occurred within 14 days following vaccination, more often after the second vaccination, and more often in younger males. Available data suggest that the course of myocarditis and pericarditis following vaccination is not different from myocarditis or pericarditis in general. Healthcare professionals should be alert to the signs and symptoms of myocarditis and pericarditis. Vaccinated individuals should be instructed to seek immediate medical attention if they develop symptoms indicative of myocarditis or pericarditis such as (acute and persisting) chest pain, shortness of breath, or palpitations following vaccination. Healthcare professionals should consult guidance and/or specialists to diagnose and treat this condition. Individuals should be provided with the advice within the leaflet What to expect after your COVID-19 vaccination, which covers the reporting of adverse reactions and their management, such as with analgesic and/or antipyretic medication. A detailed list of adverse reactions is available in the product's SPC.
Reporting procedure of adverse reactions	Healthcare professionals and individuals/carers should report suspected adverse reactions to the MHRA using the Coronavirus Yellow Card reporting scheme or search for MHRA Yellow Card in the Google Play or Apple App Store. As a new vaccine product, MHRA has a specific interest in the reporting of all adverse drug reactions for this product. Any adverse reaction to a vaccine should also be documented in the individual's record and the individual's GP should be informed. The Green Book Chapter 14a and Chapter 8 provide further details regarding the clinical features of reactions to be reported as 'anaphylaxis'. Allergic reactions that do not include the clinical features of anaphylaxis should be reported as 'allergic reaction'.
Written information to be given to individual or carer	Ensure the individual has been provided appropriate written information such as the: • Patient Information Leaflet (PIL) for Spikevax • COVID-19 Vaccination Record Card • What to expect after your COVID-19 vaccination • COVID-19 vaccination: women of childbearing age, currently pregnant, or breastfeeding • COVID-19 vaccination: a guide to booster vaccination • Waiting after COVID-19 vaccination
Advice / follow up treatment Continued over page	There is a temporary suspension of the recommended observation and monitoring for 15 minutes in individuals without a history of allergy (see off-label use section). Following COVID-19 vaccine administration, individuals without a history of allergy should be: • observed for any immediate reactions whilst they are receiving any verbal post vaccination information and exiting the centre • informed about the signs and symptoms of anaphylaxis and how to

Advice / follow up treatment (continued)	access immediate healthcare advice in the event of displaying any symptoms (see leaflets What to expect after your COVID-19 vaccination and Waiting after COVID-19 vaccination) Individuals with a personal history of allergy should be managed in line with Chapter 14a Table 5. Inform the individual/carer of possible side effects and their management. As fainting can occur following vaccination, all those vaccinated with any of the COVID-19 vaccines should be advised not to drive for 15 minutes after vaccination. The individual/carer should be advised to seek appropriate advice from a healthcare professional in the event of an adverse reaction. In some settings, for example domiciliary vaccination, this may require a responsible adult to be present for at least 15 minutes after vaccination. Vaccinated individuals should be advised to seek immediate medical attention should they experience new onset of chest pain, shortness of breath, palpitations or arrhythmias. Advise the individual/carer that they can report side effects directly via the national reporting system run by the MHRA known as the Coronavirus Yellow Card reporting scheme or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, they can help provide more information on the safety of medicines. As with all vaccines, immunisation may not result in protection in all individuals. Immunosuppressed individuals should be advised that they may not make a full immune response to the vaccine. When applicable, advise the individual/carer when to return for vaccination or when a subsequent vaccine dose is due.
Special considerations / additional information Continued over page	Ensure there is immediate access to an anaphylaxis pack including adrenaline (epinephrine) 1 in 1,000 injection and easy access to a telephone at the time of vaccination. Minor illnesses without fever or systemic upset are not valid reasons to postpone vaccination. If an individual is acutely unwell, vaccination should be postponed until they have fully recovered. This is to avoid confusing the differential diagnosis of any acute illness (including COVID-19) by wrongly attributing any signs or symptoms to the adverse effects of the vaccine. **Pregnancy** Vaccination in pregnancy should be offered in accordance with recommendations in Chapter 14a, following a discussion of the risks and benefits of vaccination with the woman. In December 2021, following the recognition of pregnancy as a risk factor for severe COVID-19 infection and poor pregnancy outcomes during the Delta wave, pregnancy was added to the clinical risk groups recommended COVID-19 vaccination. Because of wider experience with mRNA vaccines, these are currently the preferred vaccines to offer to pregnant women. If a woman finds out she is pregnant after she has started a course of vaccine, she should complete vaccination at the recommended interval. **Breastfeeding** There is no known risk associated with being given a non-live vaccine whilst breastfeeding. JCVI advises that breastfeeding women may be offered any suitable COVID-19 vaccine. Emerging safety data is reassuring: mRNA was

Special considerations / additional information (continued)	not detected in the breast milk of recently vaccinated women and protective antibodies have been detected in breast milk. The developmental and health benefits of breastfeeding are clear and should be discussed with the woman, along with her clinical need for immunisation against COVID-19. **Previous incomplete vaccination** If the course is interrupted or delayed, it should be resumed using the same vaccine if possible but the earlier doses should not be repeated. Evidence suggests that those who receive mixed schedules, including mRNA and adenovirus vectored vaccines make a good immune response, although rates of side effects with heterologous doses are higher. Accumulating evidence now supports the use of heterologous schedules for primary immunisation, and these are now recognised by the European Medicines Agency (EMA). 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, 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.. In these circumstances, this protocol may be used. For individuals with a history of thrombosis combined with thrombocytopenia following vaccination with the AstraZeneca COVID-19 vaccine, current evidence would support completion of the course with an mRNA vaccine, provided a period of at least 12 weeks has elapsed since the dose of AstraZeneca vaccine. Individuals with a history of capillary leak syndrome should be carefully counselled about the risks and benefits of vaccination. An alternative vaccine to the AstraZeneca COVID-19 vaccine, such as Spikevax, may be offered. Individuals who have participated in a clinical trial of either primary or booster COVID-19 vaccination 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 could receive additional doses for the purposes of vaccine certification. Trial participants who are eligible for boosters should be offered vaccination in line with the general population, at least 3 months after the dose considered as the final primary dose or the final revaccination (if the latter is required for certification purposes). Individuals who have been vaccinated abroad are likely to have received an mRNA or vector vaccine based on the spike protein, or an inactivated whole viral vaccine. Specific advice on Vaccination of those who received COVID-19 vaccine overseas is available from the UKHSA. **Co-administration with other vaccines** Where individuals in an eligible cohort present having recently received one or more inactivated or live vaccines, 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 an individual presents requiring 2 or more vaccines. It is generally better for vaccination to proceed and may be provided under this protocol, to avoid any further delay in protection and to avoid the risk of the individual not returning for a later appointment. This includes but is not limited to vaccines commonly administered around the same time or in the same settings (including influenza and pneumococcal polysaccharide vaccine in those aged over 65 years, pertussis-containing vaccines and influenza vaccines in pregnancy,

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Special considerations / additional information (continued)	and HPV, MenACWY and Td-IPV vaccines. The only exceptions to this are the shingles vaccines, where a seven-day interval should ideally be observed. This is based on the potential for an inflammatory response to COVID-19 vaccine to interfere with the 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 Pfizer BioNTech mRNA and AstraZeneca COVID-19 vaccines with inactivated influenza vaccines confirmed acceptable immunogenicity and reactogenicity. Where co-administration of COVID-19 vaccine with influenza vaccine does occur, individuals 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 2 will avoid confusion over systemic side effects. **Non-responders / immunosuppressed** Immunological response may be lower in immunocompromised individuals, but they should still be vaccinated. JCVI advises that a third primary vaccine dose be offered to individuals aged 12 years and over who had severe immunosuppression in proximity to their first or second COVID-19 doses in the primary schedule (see 'Box 1: Criteria for a third primary dose of COVID-19 vaccine in those aged 12 years and above' in Chapter 14a). Most individuals whose immunosuppression commenced at least 2 weeks after the second dose of vaccination do not require an additional primary vaccination at this stage. Individuals who had received brief immunosuppression (≤40mg prednisolone per day) for an acute episode (for example, asthma / COPD / COVID-19) and individuals on replacement corticosteroids for adrenal insufficiency are not considered severely immunosuppressed sufficient to have prevented response to the primary vaccination. Third primary doses should be given ideally at least 8 weeks after the second dose, with special attention paid to current or planned immunosuppressive therapies. Where possible the third dose should be delayed until 2 weeks after the period of immunosuppression, in addition to the time period for clearance of the therapeutic agent. If not possible, consideration should be given to vaccination during a treatment 'holiday' or when the degree of immunosuppression is at a minimum. Individuals who have received a bone marrow transplant after vaccination should be considered for a re-immunisation programme for all routine vaccinations and for COVID-19 (see Chapter 7 of the Green Book). This is not covered by this protocol and should be provided on a patient specific basis.

Stage 2: Vaccine preparation

Activity stage 2:	Vaccine preparation
Vaccine presentation	Spikevax dispersion for injection. COVID-19 mRNA Vaccine (nucleoside modified). This is a multidose vial and one vial contains 10 primary doses. One multidose vial should contain 20 booster doses (see Off-label use). One primary dose (0.5ml) contains 100micrograms of mRNA (embedded in SM-102 lipid nanoparticles). One booster dose (0.25ml) contains 50micrograms of mRNA (embedded in SM-102 lipid nanoparticles).
Supplies	Providers should order/receive COVID-19 vaccines via the national appointed supply route for the provider. NHS standard operating procedures should be followed for appropriate ordering, storage, handling, preparation, administration and waste minimisation of Spikevax, which ensure use is in accordance with the product's SPC and official national recommendations.
Storage	Spikevax multiple-dose vials are stored frozen at -25ºC to -15ºC. Shelf life of an unopened vial is 9 months at -25ºC to -15ºC. Do not store on dry ice. Store in the original carton to protect from light. Once thawed (see below) the vaccine should not be refrozen. **Transportation** Do not store or transport below -50ºC. If transport at -50°C to -15°C is not feasible, available data support transportation of one or more thawed vials in liquid state for up to 12 hours at 2°C to 8°C (within the 30 days shelf life at 2°C to 8°C). **Thaw each vial before use** Remove the required number of vials from freezer storage and thaw each vial before use: • thaw in refrigerated conditions between 2°C to 8°C for 2½ hours. Then let each vial stand at room temperature for 15 minutes before administering • alternatively, thaw at room temperature between 15°C to 25°C for 1 hour Thawed vials and syringes can be handled in room light conditions. **After thawing** Once thawed, do not re-freeze. The unopened vaccine may be stored at 2°C to 8°C, protected from light, for up to 30 days if not used (needle-punctured), 12 hours of this period may be used for transportation (see above). The unopened vaccine may be stored at 8°C to 25°C for up to 24 hours after removal from refrigerated conditions.

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Storage (continued)	**Punctured Vial** Chemical and physical in-use stability has been demonstrated for 6 hours at 2ºC to 25ºC after first puncture (within the allowed use period of 30 days at 2ºC to 8ºC and 24 hours at 8ºC to 25ºC). Spikevax is preservative-free. Once the vial has been used (needle-punctured) to withdraw the initial dose, the vaccine should be used immediately. Any unused vaccine should be discarded after 6 hours. The above details relate to storage requirements and available stability data at the time of product authorisation. This may be subject to amendment as more data becomes available. Refer to NHS standard operating procedures for the service and the most up to date manufacturer's recommendations in the product's SPC. 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 off-label use or appropriate disposal. Refer to Vaccine Incident Guidance.
Vaccine preparation	Vaccine should be prepared in accordance with the manufacturer's recommendations and NHS standard operating procedures for the service. The vaccine should not be mixed in the same syringe with any other vaccines or medicinal products. Inspect visually prior to administration and ensure appearance is a white to off-white dispersion. It may contain white or translucent product-related particulates. If foreign particulate matter or discolouration are present, the vaccine should not be administered. Check product name, batch number and expiry date. Swirl the vial gently after thawing and between each withdrawal. Do not shake. Aseptic technique should be used to withdraw each dose of vaccine from the vial, using a new sterile needle and syringe for each injection to prevent transmission of infectious agents from one person to another. The dose in the syringe should be used promptly. The stopper of each vial should ideally be pierced at a different site for each dose that can be withdrawn from the vial. Spikevax vials are multidose and, if low dead-volume syringes and/or needles are used, one vial contains at least 10 primary or 20 booster doses. Care should be taken to ensure a full 0.5ml primary or 0.25ml booster dose is administered. Where a full dose cannot be extracted, the remaining volume should be discarded. Do not pool excess vaccine from multiple vials. This product is preservative-free. Once the vial has been used (needle-punctured) to withdraw the initial dose, the vaccine should be used immediately. Any unused vaccine should be discarded after 6 hours. The vaccine may be drawn up and administered by the same person or separate persons with the required competence and supervision. If the vaccine is to be administered by a person other than the person preparing it, ensure that there are clear procedures for transferring the vaccine to the vaccinator in a safe way, allowing for appropriate checks of vaccine particulars, batch number and expiry by both parties.
Disposal Continued over page	Follow local clinical waste policy and NHS standard operating procedures and ensure safe and secure waste disposal.

Disposal (continued)	Equipment used for vaccine preparation, including used vials, ampoules, or discharged vaccines in a syringe or applicator, should be disposed of safely and securely, according to local authority arrangements and guidance in the technical memorandum 07-01: Safe management of healthcare waste (Department of Health, 2013).

Stage 3: Vaccine administration

Activity stage 3:	**Before administering the vaccine, ensure:** **1. The individual has been assessed in accordance with stage one of this protocol.** **2. The vaccine to be administered has been identified, by the registered practitioner consenting the individual, as Spikevax** **3. The vaccine dose to be administered (primary 0.5ml or booster 0.25ml) has been identified, by the registered practitioner consenting the individual, and communicated to the vaccinator** **4. Consent for vaccination has been provided and documented.[2]** **Administer Spikevax and provide any post-vaccination advice.**
Vaccine to be administered	Spikevax dispersion for injection (formerly COVID-19 Vaccine Moderna)
Quantity to be supplied / administered	Administer 0.5ml (100micorgrams) per primary dose. Administer 0.25ml (50micrograms) per booster dose.
Route / method of administration	Spikevax is for administration by intramuscular injection only, preferably into deltoid region of the upper arm. Vaccinators should administer a 0.5ml primary dose or 0.25ml booster dose prepared in accordance with Stage 2 above and as advised by the registered practitioner consenting the individual. If vaccine is not drawn up by the vaccinator, safe procedures must be in place for the vaccinator to safely receive, check, and use the vaccine immediately after preparation. Inspect visually prior to administration and ensure appearance is a white to off-white dispersion. It may contain white or translucent product-related particulates. If foreign particulate matter or discolouration are present, the vaccine should not be administered. Check product name, batch number and expiry date prior to administration. Swirl the vial gently after thawing and between each withdrawal. Do not shake. Aseptic technique should be used to withdraw each dose of vaccine from the vial, using a new sterile needle and syringe for each injection to prevent transmission of infectious agents from one person to another. The dose in the syringe should be used promptly. The stopper of each vial should ideally be pierced at a different site for each dose that can be withdrawn from the vial. Care should be taken to ensure a full 0.5ml primary or 0.25ml booster dose is administered. Where a full dose cannot be extracted, the remaining volume should be discarded. Do not pool excess vaccine from multiple vials. This product is preservative-free. Once the vial has been used (needle-punctured) to withdraw the initial dose, the vaccine should be used immediately. Any unused vaccine should be discarded after 6 hours. Where the individual has been identified by the assessing registered professional as being at increased risk of bleeding, a fine needle (equal to 23 gauge or finer calibre such as 25 gauge) should be used for the vaccination, followed by firm pressure applied to the site (without rubbing)

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Route / method of administration (continued)	for at least 2 minutes. The individual/carer should be informed about the risk of haematoma from the injection.
Disposal	Follow local clinical waste policy and NHS standard operating procedures and ensure safe and secure waste disposal. Equipment used for immunisation, including used vials, ampoules, or discharged vaccines in a syringe or applicator, should be disposed of safely and securely according to local authority arrangements and guidance in the technical memorandum 07-01: Safe management of healthcare waste (Department of Health, 2013).
Post-vaccination advice	Ensure the individual has been provided appropriate written information such as the: • Patient information leaflet for Spikevax • COVID-19 Vaccination Record Card • What to expect after your COVID-19 vaccination • COVID-19 vaccination: women of childbearing age, currently pregnant, or breastfeeding • COVID-19 vaccination: a guide to booster vaccination • Waiting after COVID-19 vaccination

Stage 4: Recording vaccine adminstration

Activity stage 4:	**Complete a record of vaccination for the individual and in accordance with local policy.** **The required records should be completed by the person who is undertaking the recorded activity or a designated record keeper who is a witness to the activity undertaken.**
Records	Record: • that valid informed consent was given or a decision to vaccinate made in the individual's best interests in accordance with the Mental Capacity Act 2005 • name of individual, address, date of birth and GP with whom the individual is registered (or record where an individual is not registered with a GP) • name of supervisor, immuniser and, where different from the immuniser, ensure the professional assessing the individual, person preparing the vaccine, and person completing the vaccine record are identified • name and brand of vaccine • date of administration • dose, form and route of administration of vaccine • quantity administered • batch number and 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 • supplied via national protocol All records should be clear, legible and contemporaneous. As a variety of COVID-19 vaccines are available, it is especially important that the exact brand of vaccine, batch number and site at which each vaccine is given is accurately recorded in the individual's records. It is important that vaccinations are recorded in a timely manner on appropriate health care records for the individual. Systems should be in place to ensure this information is returned to the individual's general practice record in a timely manner to allow clinical follow up and to avoid duplicate vaccination. A record of all individuals receiving treatment under this protocol should also be kept for audit purposes in accordance with local and national policy.

2. Key references

Key references	**Spikevax** • Immunisation Against Infectious Disease: The Green Book, Chapter 14a. Updated 28 February 2022. https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book • UK Chief Medical Officers Report; suspension of the 15minutes wait for vaccination with mRNA vaccine for COVID-19. 13 December 2021. • COVID-19 vaccination programme. Updated 3 March 2022. https://www.gov.uk/government/collections/covid-19-vaccination-programme • Training recommendations for COVID-19 vaccinators. Updated 4 October 2021. https://www.gov.uk/government/publications/covid-19-vaccinator-training-recommendations/training-recommendations-for-covid-19-vaccinators • National COVID-19 vaccination e-learning programme https://www.e-lfh.org.uk/programmes/covid-19-vaccination/ • COVID-19 vaccinator competency assessment tool. Updated 16 March 2021. https://www.gov.uk/government/publications/covid-19-vaccinator-competency-assessment-tool • COVID-19: vaccination programme guidance for healthcare practitioners. Updated 10 March 2022. https://www.gov.uk/government/publications/covid-19-vaccination-programme-guidance-for-healthcare-practitioners • Summary of product characteristics and patient information leaflet for Spikevax. Published 24 December 2021. https://www.gov.uk/government/publications/regulatory-approval-of-covid-19-vaccine-moderna **General** • Health Technical Memorandum 07-01: Safe Management of Healthcare Waste. Department of Health 20 March 2013 https://www.england.nhs.uk/publication/management-and-disposal-of-healthcare-waste-htm-07-01/ • Regulation 247A, UK Statutory Instrument 2012 No. 1916, The Human Medicines Regulations 2012 https://www.legislation.gov.uk/uksi/2012/1916/regulation/247A • UK Statutory Instrument 2020 No. 1125, The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 https://www.legislation.gov.uk/uksi/2020/1125/contents/made • UK Statutory Instrument 2020 No. 1594, The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 https://www.legislation.gov.uk/uksi/2020/1594/regulation/4/made

4. Practitioner/staff authorisation sheet

Spikevax COVID-19 Vaccine (Moderna) protocol v06.00
Valid from: 31 March 2022 Expiry: 1 April 2023

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

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. All persons operating under this protocol must work within their terms of employment at all times; registered healthcare professionals must abide by their professional code of conduct.

It is the responsibility of each person operating under this protocol to do so within the bounds of their own competence.

I confirm that I have read and understood the content of this protocol and that I am willing and competent to work to it.							
Name	Designation	Activity Stage:				Signature	Date
		1	2	3	4		

Authorising registered healthcare professional

I confirm that I, as a registered healthcare professional who is familiar with the competence required in all aspects of this protocol, provide authority on behalf of the below named provider organisation, that the persons named above are competent to work under this protocol and may provide vaccination in accordance with this protocol in the course of working for **insert name of organisation / service**			
Name	Designation	Signature	Date

Note to authorising registered healthcare professional

Score through unused rows in the list of persons to prevent additions post authorisation.

If the clinical supervisor is also the authorising registered healthcare professional, they may make a self-declaration of competency above.