**Publications gateway number: GOV-13080**

## National protocol for Spikevax® bivalent Original/Omicron

## COVID-19 Vaccine

Reference no: Spikevax® bivalent Original/Omicron COVID-19 vaccine Protocol

Version no: v1.01

Valid from: 24 August 2022

Expiry date: 25 August 2023

This protocol is for the administration of Spikevax® bivalent Original/Omicron COVID-19 vaccine to individuals 18 years and over as a booster dose in accordance with the national COVID-19 vaccination programme.

This protocol is for the administration of Spikevax® bivalent Original/Omicron COVID-19 vaccine by appropriately trained persons in accordance with [regulation 247A](https://www.legislation.gov.uk/uksi/2020/1125/regulation/14/made) of the [Human Medicines Regulations 2012](https://www.legislation.gov.uk/uksi/2012/1916/contents) (HMR 2012), inserted by [The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020](https://www.legislation.gov.uk/uksi/2020/1125/contents/made)

**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 (NHSE).**

This protocol may be followed wholly from assessment through to post-vaccination by an appropriately registered healthcare professional (see [Characteristics of staff](#_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](#_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](#PractitionerAuthorisationSheet) of this protocol or maintaining an equivalent electronic record.

A clinical supervisor[[1]](#footnote-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](https://www.legislation.gov.uk/uksi/2012/1916/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 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](https://www.gov.uk/government/collections/covid-19-vaccination-programme)

Any concerns regarding the content of this protocol should be addressed to: [immunisation@ukhsa.gov.uk](mailto:immunisation@phe.gov.uk)

**Change History**

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| **Version** | **Change details** | **Date** |
| V01.00 | New Protocol for Spikevax® bivalent Original/Omicron COVID-19 vaccine is to support the booster programme for individuals aged 18 years old and over.  The Direct Healthcare Professional Communication (DHPC) informs that the initial supply of Spikevax® bivalent Original / Omicron COVID-19 vaccine will have a different tradename (in particular the word “Bivalent” is not included), and different carton and vial labels to the licensed product. The product will consist of:   * 16 batches of vials containing 2.5 ml (5 doses) entering the supply chain from mid/end August * 1 batch of vial containing 5 ml (10 doses) entering the supply chain from end of August * both 2.5 ml and 5 ml vials may be circulating in the supply chain at the same time, but these batches will only differ in fill volume/number of doses per vial   To ensure continuity in supply, the MHRA has agreed for these batches to be supplied to market via a Batch Specific Variation and therefore they are approved to be used as a licensed product. The leaflet supplied with the batches is approved, therefore this Spikevax® bivalent Patient Information Leaflet (PIL) should be provided to vaccine recipients.  • under characteristics of staff additional requirements the condition to be familiar with the Direct Health Professional Communication from manufacturer for Spikevax bivalent ® Original/Omicron COVID-19 vaccine, Moderna | 20 August 2022 |
| V1.01 | New PGD template for Spikevax® bivalent Original/Omicron COVID-19 has been updated to change ‘adults’ to’ individuals’ in allergy section under off-label use and cautions section following Minister’s requirement for the change | 24 August 2022 |

**1. Ministerial authorisation**

This protocol is not legally valid, in accordance with [regulation 247A](https://www.legislation.gov.uk/uksi/2020/1125/regulation/14/made) of the [HMR 2012](https://www.legislation.gov.uk/uksi/2012/1916/contents), inserted by the [Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020](https://www.legislation.gov.uk/uksi/2020/1125/contents/made), until it is approved by or on behalf of the Secretary of State for Health and Social Care.

On 24 August 2022 Department of Health and Social Care Ministers approved this protocol in accordance with [regulation 247A](https://www.legislation.gov.uk/uksi/2020/1125/regulation/14/made) of HMR 2012.

Any provider/contractor administering Spikevax® bivalent Original/Omicron COVID-19 vaccine 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](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1097996/Spikexax_bivalent_Original_Omicron_SmPC.pdf)) 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.

#### Characteristics of staff

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| 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](#Table2)). 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](#Table1).  The [clinical supervisor1](#clinicalsupervisor) must be a registered doctor, nurse or pharmacist trained and competent in all aspects of the protocol and provide clinical supervision, see [page 1](#Page1ClinicalSupervisor), 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 | 1. Assessment of the individual presenting for vaccination 2. Provide information and obtain informed consent[[2]](#footnote-2) 3. Provide advice to the individual | Specified Registered Healthcare Professionals Only (see [Table 2](#Table2)) | | 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](#Table2) (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](#PractitionerAuthorisationSheet) | 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 consent2 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](https://www.legislation.gov.uk/uksi/2012/1916/contents):   * 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 | Y | N | N | N | | must be a doctor, nurse or pharmacist or a person who is under the supervision of, a doctor, nurse or pharmacist (see [Page 1](#Page1ClinicalSupervisor)) | 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](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1097996/Spikexax_bivalent_Original_Omicron_SmPC.pdf)) 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](https://www.gov.uk/government/collections/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](https://www.gov.uk/government/publications/covid-19-vaccinator-training-recommendations/training-recommendations-for-covid-19-vaccinators) | Y | Y | Y | N | | must have completed the [national covid-19 vaccination e-learning programme](https://www.e-lfh.org.uk/programmes/covid-19-vaccination/), 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](https://www.gov.uk/government/collections/covid-19-vaccination-programme) online resources such as the [Green Book](https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book), particularly [Chapter 14a](https://www.gov.uk/government/publications/covid-19-the-green-book-chapter-14a) of the Green Book, and the [COVID-19 vaccination programme: Information for healthcare practitioners](https://www.gov.uk/government/publications/covid-19-vaccination-programme-guidance-for-healthcare-practitioners) document and the DHPC letter from Moderna providing the information with regard to the batches which will have a different tradename (in particular the word “Bivalent” is not included), and different carton and vial labels to the licensed | 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](https://www.gov.uk/government/publications/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](https://www.gov.uk/government/publications/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 | | must have read and be familiar with the contents of the DHPC letter from Moderna providing the information with regard to the batches which will have a different tradename (in particular the word “Bivalent” is not included), and different carton and vial labels to the licensed | 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**

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| **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® bivalent Original/Omicron COVID-19 vaccine is indicated as a booster for 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](https://www.gov.uk/government/collections/covid-19-vaccination-programme)) and recommendations given in [Chapter 14a](https://www.gov.uk/government/publications/covid-19-the-green-book-chapter-14a) of Immunisation Against Infectious Disease: the ‘Green Book’ (hereafter referred to as [Chapter 14a](https://www.gov.uk/government/publications/covid-19-the-green-book-chapter-14a)), and subsequent correspondence/publications from the UKHSA and/or NHSE |
| **Criteria for inclusion** | A booster dose of Spikevax® bivalent Original/Omicron COVID-19 vaccine should be offered to individuals, aged 18 years and over, in accordance with the recommendations in [Chapter 14a](https://www.gov.uk/government/publications/covid-19-the-green-book-chapter-14a). |
| **Criteria for exclusion[[3]](#footnote-3)** | Individuals for whom valid consent, or ‘best-interests’ decision in accordance with the [Mental Capacity Act 2005](https://www.legislation.gov.uk/ukpga/2005/9/contents), has not been obtained (for further information on consent see [Chapter 2](https://www.gov.uk/government/publications/consent-the-green-book-chapter-2) of ‘The Green Book’). The [Patient information leaflet](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1097997/Spikexax_bivalent_Original_Omicron_PIL.pdf) for Spikevax® bivalent Original/Omicron COVID-19 vaccine 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]](#footnote-4)   in Spikevax® bivalent Original/Omicron COVID-19 vaccine   * have experienced myocarditis or pericarditis determined as likely to be related to previous COVID-19 vaccination * have previously experienced episodes of capillary leak syndrome (CLS) * are suffering from acute severe febrile illness (the presence of a minor infection is not a contraindication for vaccination) * have not had the full primary COVID-19 vaccine course * have had a full dose of COVID-19 vaccine in the preceding 3 months (see ‘Action to be taken if the patient is excluded’ section [below](#ActionIfExcluded)) |
| **Cautions including any relevant action to be taken**  Continued over page  **Cautions including any relevant action to be taken** (continued)  Continued over page  **Cautions including any relevant action to be taken**  (continued) | Facilities for management of anaphylaxis should be available at all vaccination sites. (see [Chapter 8](https://www.gov.uk/government/publications/vaccine-safety-and-adverse-events-following-immunisation-the-green-book-chapter-8) of the Green Book) and advice issued by the [Resuscitation Council](https://www.resus.org.uk/about-us/news-and-events/rcuk-publishes-anaphylaxis-guidance-vaccination-settings).  There is suspension of the recommended observation and monitoring for 15 minutes in individuals without a history of allergy (see [off-label](#Allergy) 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 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](https://www.gov.uk/government/publications/covid-19-the-green-book-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 Spikevax® bivalent Original/Omicron COVID-19 vaccine, except on the expert advice of an allergy specialist or where at least one dose of the same vaccine has been tolerated previously (for further information see [Chapter 14a](https://www.gov.uk/government/publications/covid-19-the-green-book-chapter-14a)).  Where individuals experienced a possible allergic reaction to a dose of COVID-19 vaccine, follow the guidance in [Chapter 14a](https://www.gov.uk/government/publications/covid-19-the-green-book-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 (23 gauge or 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 vaccinator is aware of the individual’s 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](https://www.gov.uk/government/publications/covid-19-the-green-book-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 Pfizer or Moderna COVID-19 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](https://b-s-h.org.uk/about-us/news/covid-19-updates/)).  **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 NHSE operational guidance.  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.  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 and epidemiological features to suggest the episode was COVID-19 infection.  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** | **Booster vaccination**  A booster dose of Spikevax® bivalent Original / Omicron COVID-19 vaccine is 0.5 ml containing 25 micrograms Original and 25 micrograms Omicron COVID-19 mRNA.  Booster doses should be given at a minimum interval of 3 months from the previous dose.  Boosters should be offered to individuals eligible as part of the national COVID-19 vaccination programme in accordance with the recommendations from the [JCVI](https://www.gov.uk/government/collections/covid-19-vaccination-programme#programme-documents) and in [Chapter 14a](https://www.gov.uk/government/publications/covid-19-the-green-book-chapter-14a).  Individuals should complete a primary course of COVID-19 vaccination before receiving any boosters.  **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 interval after COVID-19 infection will be advised by JCVI or UKHSA and published in NHSE operational guidance. |
| **Action to be taken if the individual is excluded**  Continued over page  **Action to be taken if the individual is excluded**  continued | This Protocol is for individuals aged 18 years and over in accordance with recommendations in [Chapter 14a](https://www.gov.uk/government/publications/covid-19-the-green-book-chapter-14a) for the use of Spikevax® bivalent Original/Omicron COVID-19 vaccine. For individuals under 18 years of age, Comirnaty® vaccine is recommended (see [Comirnaty® 30 micrograms/dose concentrate Protocol](https://www.gov.uk/government/publications/national-protocol-for-comirnaty-covid-19-mrna-vaccine)  and [Comirnaty® 10microgram/dose concentrate Protocol](https://www.gov.uk/government/publications/national-protocol-for-comirnaty-10-microgramdose-covid-19-mrna-vaccine)).  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 be provided by an appropriate prescriber or on a patient specific basis, under a PSD.  For individuals who have had a 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 and any subsequent doses should be provided by an appropriate prescriber or on a patient specific basis, under a PSD .  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.  For individuals with capillary leak syndrome, after specialist advice any doses should be provided by an appropriate prescriber or on a patient specific basis, under a PSD.  Individuals who have not completed their primary course should complete the recommended schedule before receiving the booster.  Where the individuals have had a dose of COVID-19 vaccine in the preceding 3 months, advise the individual should return at or after 3 month period has passed since their last vaccine dose.  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](https://www.legislation.gov.uk/ukpga/2005/9/contents), 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**

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| **Activity stage 1b:** | **Consider any relevant cautions, interactions or adverse drug reactions.**  **Provide advice to the individual and obtain** [**informed consent2**](#informedconsent)**.**  **Record individual’s consent2 and ensure vaccinator, if another person, is informed of the vaccine product and dose to be administered.** |
| **Name, strength and formulation of drug** | Spikevax® bivalent Original / Omicron 0.1 mg/ml dispersion for injection  One dose (0.5 ml) contains:  25 micrograms of elasomeran (Original), a COVID-19 mRNA Vaccine (embedded in SM-102 lipid nanoparticles) and  25 micrograms of imelasomeran (Omicron), a COVID-19 mRNA Vaccine (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**  Continued over page  **Off-label use**  (continued) | **Allergy**  According to the respective SPCs, it is recommended that all recipients of the 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](https://www.gov.uk/government/publications/suspension-of-the-15-minute-wait-for-vaccination-with-mrna-vaccine-for-covid-19-uk-cmos-opinion/suspension-of-the-15-minute-wait-for-vaccination-with-mrna-vaccine-for-covid-19-uk-cmos-opinion)) recommended suspension of this requirement in December 2021. The 15-minute observation period following vaccination with the mRNA COVID-19 vaccines has since been removed for individuals who have no history of a severe allergic reaction. This follows careful review of the safety data by the MHRA and advice from 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(see [Chapter 14a](https://www.gov.uk/government/publications/covid-19-the-green-book-chapter-14a)).  Individuals with a personal history of allergy, should be managed in line with [Chapter 14a](https://www.gov.uk/government/publications/covid-19-the-green-book-chapter-14a) Table 5. No specific management is required for individuals with a family history of allergies.  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](#Storage) below. However, in the event of an inadvertent or unavoidable deviation of these conditions refer to [Vaccine Incident Guidance](https://www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors). 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](#AdditionalInformation) section. |
| **Identification and management of adverse reactions**  Continued over page  **Identification and management of adverse reactions**  (continued) | Spikevax® bivalent Original/Omicron COVID-19 vaccine adverse reactions most commonly reported are pain at the injection site, fatigue, headache, myalgia, arthralgia, chills, nausea, vomiting, diarrhoea, axillary swelling/tenderness, fever, injection site swelling, redness, injection site erythema, injection site urticaria, injection site rash, delayed injection site reaction. Lymphadenopathy was observed 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.  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.  Very rare cases of myocarditis and pericarditis have been observed following vaccination with Spikevax® bivalent Original/Omicron COVID-19 vaccine. 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](https://www.gov.uk/government/publications/covid-19-vaccination-myocarditis-and-pericarditis-information-for-healthcare-professionals) 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](https://www.gov.uk/government/publications/covid-19-vaccination-what-to-expect-after-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](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1097996/Spikexax_bivalent_Original_Omicron_SmPC.pdf). |
| **Reporting procedure of adverse reactions** | Healthcare professionals and individuals/carers should report suspected adverse reactions to the MHRA using the [Yellow Card reporting scheme](https://yellowcard.mhra.gov.uk/) 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](https://www.gov.uk/government/publications/covid-19-the-green-book-chapter-14a) and [Chapter 8](https://www.gov.uk/government/publications/vaccine-safety-and-adverse-events-following-immunisation-the-green-book-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® bivalent Original/Omicron COVID-19 vaccine](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1097997/Spikexax_bivalent_Original_Omicron_PIL.pdf) * [COVID-19 Vaccination Record Card](https://www.healthpublications.gov.uk/ViewArticle.html?sp=Scovidvaccinerecordcard2doses) * [What to expect after your COVID-19 vaccination](https://www.gov.uk/government/publications/covid-19-vaccination-what-to-expect-after-vaccination) * [COVID-19 vaccination: women of childbearing age, currently pregnant, or breastfeeding](https://www.gov.uk/government/publications/covid-19-vaccination-women-of-childbearing-age-currently-pregnant-planning-a-pregnancy-or-breastfeeding) * [COVID-19 vaccination: a guide to booster vaccination](https://www.gov.uk/government/publications/covid-19-vaccination-booster-dose-resources) * [Waiting after COVID-19 vaccination](https://www.gov.uk/government/publications/covid-19-vaccination-observation-period) |
| **Advice and follow up treatment**  Continued over page  **Advice and follow up treatment**  (continued) | There is a suspension of the recommended observation and monitoring for 15 minutes in adult individuals without a history of allergy (see [off-label use](#OffLabelUse) 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 access immediate healthcare advice in the event of displaying any symptoms (see leaflets [What to expect after your COVID-19 vaccination](https://www.gov.uk/government/publications/covid-19-vaccination-what-to-expect-after-vaccination) and [Waiting after COVID-19 vaccination](https://www.gov.uk/government/publications/covid-19-vaccination-observation-period))   Individuals with a personal history of allergy should be managed in line with [Chapter 14a](https://www.gov.uk/government/publications/covid-19-the-green-book-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 [Yellow Card reporting scheme](https://yellowcard.mhra.gov.uk/) 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 and additional information**  Continued over page  **Special considerations / additional information**  (continued) | 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**  Spikevax® bivalent Original / Omicron can be used during pregnancy.  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 the primary course at the recommended interval before being vaccinated with a booster.  **Breastfeeding**  Spikevax® bivalent Original / Omicron can be used during breastfeeding.  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.  **Participants in clinical trials** 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). **Vaccinated abroad**  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](https://www.gov.uk/government/publications/covid-19-vaccinations-received-overseas?utm_medium=email&utm_campaign=govuk-notifications&utm_source=3c463247-a307-4b90-8176-b464d02c8066&utm_content=immediately) 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 it 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, 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.  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.  Individuals in the eligible group who have received a full course of primary vaccination (two or three doses) but have not received a booster before September 2022, may be given the autumn booster in the campaign provided it is given at a minimum interval of 3 months from the previous dose.  JCVI has advised that the timeliness of vaccination is more important than the type of booster vaccine used.  **Immunosuppressed**  Immunological response may be lower in immunosuppressed individuals, but they should still be vaccinated. |

**Stage 2: Vaccine preparation**

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| **Activity stage 2:** | **Vaccine preparation** |
| **Vaccine presentation** | Spikevax® bivalent Original / Omicron 0.1 mg/ml dispersion for injection  One dose (0.5 ml) contains:  25 micrograms of elasomeran (Original), a COVID-19 mRNA Vaccine (embedded in SM-102 lipid nanoparticles) and  25 micrograms of imelasomeran (Omicron), a COVID-19 mRNA Vaccine (embedded in SM-102 lipid nanoparticles) |
| **Supplies** | The DHPC informs that the initial supply of Spikevax® bivalent Original / Omicron COVID-19 vaccine will have a different tradename (in particular the word “Bivalent” is not included), and different carton and vial labels to the licenced product. The product will consist of:   * 16 batches of vials containing 2.5 ml (5 doses) entering the supply chain from mid/end August * 1 batch of vial containing 5 ml (10 doses) entering the supply chain from end of August * Both 2.5 ml and 5 ml vials may be circulating in the supply chain at the same time, but these batches will only differ in fill volume/number of doses per vial   To ensure continuity in supply, the MHRA has agreed for these batches to be supplied to market via a Batch Specific Variation and therefore they are approved to be used as licensed product.  The leaflet supplied with the batches is approved, therefore please ensure that this Spikevax® bivalent Original / Omicron COVID-19 vaccine Patient Information Leaflet (PIL) is provided to vaccine recipients. Copies of the PIL and SPC are also available by scanning the QR code on the carton or [Gov.UK](https://www.gov.uk/government/publications/regulatory-approval-of-spikevax-bivalent-originalomicron-booster-vaccine) website.  Where necessary, reassure vaccine recipients that they are receiving the correct vaccine and that it is the same vaccine approved by the MHRA.  NHSE informs that the DHPC letter will be provided by the Specialist Pharmaceutical Logistics Partners and NHSE will highlight it within the NHS internal working spaces.  COVID-19 vaccines for those authorised by the NHS to deliver the programme will be made available for ordering on the ImmForm website https://portal.immform.phe.gov.uk/ telephone 0207 183 8580 or through the Foundry ordering platform in England..  NHS standard operating procedures should be followed for appropriate ordering, storage, handling, preparation, administration and waste minimisation of Spikevax® bivalent Original/Omicron COVID-19 vaccine, which ensure use is in accordance with the product’s [SPC](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1097996/Spikexax_bivalent_Original_Omicron_SmPC.pdf) and official national recommendations. |
| **Storage**  Continued over page  **Storage**  (continued) | Spikevax® bivalent Original / Omicron COVID-19 vaccine multiple-dose vials are stored frozen between -50ºC to -15ºC.  Store in the original carton to protect from light.  Do not store below -50ºC.  Unopened multidose vial shelf life is 9 months at -50ºC to -15ºC.  **Transportation of thawed multidose vials in liquid state at 2°C to 8°C**  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).  Once thawed and transported in liquid state at 2°C to 8°C, vials should not be refrozen and should be stored at 2°C to 8°C until use.  **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.  The unopened vaccine may be stored at 8°C to 25°C for up to 24 hours after removal from refrigerated conditions. 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).  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](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1097996/Spikexax_bivalent_Original_Omicron_SmPC.pdf).  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](https://www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors). |
| **Vaccine preparation**  Continued over page  **Vaccine preparation**  continued | Vaccine should be prepared in accordance with manufacturer’s recommendations (see the product’s [SPC](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1097996/Spikexax_bivalent_Original_Omicron_SmPC.pdf)) 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. The vaccine 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 (see DHPC information for product name and batches in ‘Supplies’ section [above](#Supplies)) and expiry date prior to administration.  Thaw each vial to room temperature before use.  The vaccine comes ready to use once thawed.  Do not shake or dilute. Swirl the vial gently after thawing and before each withdrawal.  Spikevax® bivalent Original / Omicron vials are multidose. Each vial contains 2.5ml and five (5) doses can be withdrawn from each vial.  The DHPC letter informs that both 2.5 ml and 5 ml vials will initially be circulating in the supply chain at the same time. Note the 5.0 ml vial will provide 10 doses (see DHPC information for doses in ‘Supplies’ section [above](#Supplies)).  Pierce the stopper preferably at a different site each time. Do not puncture the vial more than 5 or 10 times. An additional overfill is included in each vial to ensure that 5 doses or 10 doses of 0.5 ml can be delivered.  Record the date and time after the first puncture on the vial label  Thawed vials and filled syringes can be handled in room light conditions.  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.  Care should be taken to ensure a full amount 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.  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. |
| **Disposal** | Follow local clinical waste policy and NHS standard operating procedures and ensure safe and secure waste disposal.  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](https://www.england.nhs.uk/publication/management-and-disposal-of-healthcare-waste-htm-07-01/): Safe management of healthcare waste (Department of Health, 2013). |

**Stage 3: Vaccine administration**

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| **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® bivalent Original/Omicron COVID-19 vaccine** 3. **The vaccine dose to be administered (booster 0.5ml) 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® bivalent Original/Omicron COVID-19 vaccine and provide any post-vaccination advice.** |
| **Vaccine to be administered** | Spikevax® bivalent Original / Omicron COVID-19 vaccine 0.5 ml containing 25 micrograms Original and 25 micrograms Omicron COVID-19 mRNA.  Dispersion for injection |
| **Quantity to be supplied and administered** | Administer 0.5ml (25 micrograms plus 25 micrograms) per booster dose. |
| **Route and method of administration**  Continued over page  **Route and method of administration**  (continued) | Spikevax® bivalent Original / Omicron COVID 19 vaccine is for administration by intramuscular injection only, preferably into the deltoid region of the upper arm.  Vaccine should be prepared in accordance with manufacturer’s recommendations (see the product’s [SPC](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1097996/Spikexax_bivalent_Original_Omicron_SmPC.pdf)) 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. The vaccine 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 (see DHPC information for product name and batches in ‘Supplies’ section [below](#Supplies)) and expiry date prior to administration.  Thaw each vial to room temperature before use.  The vaccine comes ready to use once thawed.  Do not shake or dilute. Swirl the vial gently after thawing and before each withdrawal.  Spikevax® bivalent Original / Omicron vials are multidose. Each vial contains 2.5ml and five (5) doses can be withdrawn from each vial.  The DHPC letter informs that both 2.5 ml and 5 ml vials will initially be circulating in the supply chain at the same time. Note the 5.0 ml vial will provide 10 doses (see DHPC information for doses in ‘Supplies’ section [below](#Supplies)).  Pierce the stopper preferably at a different site each time. Do not puncture the vial more than 5 or 10 times. An additional overfill is included in each vial to ensure that 5 doses or 10 doses of 0.5 ml can be delivered  Record the date and time after the first puncture on the vial label.  Thawed vials and filled syringes can be handled in room light conditions.  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.  Care should be taken to ensure a full amount 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.  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. |
| **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](https://www.england.nhs.uk/publication/management-and-disposal-of-healthcare-waste-htm-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](https://www.gov.uk/government/publications/regulatory-approval-of-covid-19-vaccine-moderna) for Spikevax® * [COVID-19 Vaccination Record Card](https://www.healthpublications.gov.uk/ViewArticle.html?sp=Scovidvaccinerecordcard2doses) * [What to expect after your COVID-19 vaccination](https://www.gov.uk/government/publications/covid-19-vaccination-what-to-expect-after-vaccination)  * [COVID-19 vaccination: women of childbearing age, currently pregnant, or breastfeeding](https://www.gov.uk/government/publications/covid-19-vaccination-women-of-childbearing-age-currently-pregnant-planning-a-pregnancy-or-breastfeeding) * [COVID-19 vaccination: a guide to booster vaccination](https://www.gov.uk/government/publications/covid-19-vaccination-booster-dose-resources) * [Waiting after COVID-19 vaccination](https://www.gov.uk/government/publications/covid-19-vaccination-observation-period) |

**Stage 4: Recording vaccine adminstration**

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| **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](https://www.legislation.gov.uk/ukpga/2005/9/contents) * 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. |

1. **Key references**

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| **Key references**  Continued over page  **Key references**  (continued) | Spikevax® bivalent Original / Omicron COVID-19 vaccine   * Immunisation Against Infectious Disease: The Green Book, [Chapter 14a](https://www.gov.uk/government/publications/covid-19-the-green-book-chapter-14a). Updated 18 August 2022   [www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book](http://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book)   * UK Chief Medical Officers [Report](https://www.gov.uk/government/publications/suspension-of-the-15-minute-wait-for-vaccination-with-mrna-vaccine-for-covid-19-uk-cmos-opinion/suspension-of-the-15-minute-wait-for-vaccination-with-mrna-vaccine-for-covid-19-uk-cmos-opinion); suspension of the 15minutes wait for vaccination with mRNA vaccine for COVID-19. 13 December 2021 * COVID-19 vaccination programme   [www.gov.uk/government/collections/covid-19-vaccination-programme](http://www.gov.uk/government/collections/covid-19-vaccination-programme)   * Training recommendations for COVID-19 vaccinators.   [www.gov.uk/government/publications/covid-19-vaccinator-training-recommendations/training-recommendations-for-covid-19-vaccinators](http://www.gov.uk/government/publications/covid-19-vaccinator-training-recommendations/training-recommendations-for-covid-19-vaccinators)   * National COVID-19 vaccination e-learning programme   [www.e-lfh.org.uk/programmes/covid-19-vaccination/](http://www.e-lfh.org.uk/programmes/covid-19-vaccination/)   * COVID-19 vaccinator competency assessment tool   [www.gov.uk/government/publications/covid-19-vaccinator-competency-assessment-tool](http://www.gov.uk/government/publications/covid-19-vaccinator-competency-assessment-tool)   * COVID-19: vaccination programme guidance for healthcare practitioners.   [www.gov.uk/government/publications/covid-19-vaccination-programme-guidance-for-healthcare-practitioners](http://www.gov.uk/government/publications/covid-19-vaccination-programme-guidance-for-healthcare-practitioners)   * Summary of product characteristics Spikevax® bivalent Original / Omicron COVID-19 vaccine   [[\*4 (publishing.service.gov.uk)](https://www.gov.uk/government/publications/regulatory-approval-of-covid-19-vaccine-moderna)](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1097996/Spikexax_bivalent_Original_Omicron_SmPC.pdf)   * Patient Information Leaflet (PIL)   [Spikevax® bivalent Original Omicron PIL.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1097997/Spikexax_bivalent_Original_Omicron_PIL.pdf)   * Joint Committee on Vaccination and Immunisation (JCVI) statement   on the COVID-19 booster vaccination programme for autumn 2022 –  update 12 August 2022   * Direct Healthcare Professional Communication   Spikevax®▼ bivalent Original / Omicron (elasomeran / imelasomeran): Temporary supply of product with different carton and multidose vial labels - GB Marketing Authorisation number PLGB 53720/0004  **General**   * Health Technical Memorandum 07-01: Safe Management of Healthcare Waste. Department of Health 20 March 2013 [www.england.nhs.uk/publication/management-and-disposal-of-healthcare-waste-htm-07-01/](http://www.england.nhs.uk/publication/management-and-disposal-of-healthcare-waste-htm-07-01/) * NICE Medicines Practice Guideline 2 (MPG2): Patient Group Directions. Published March 2017.   [www.nice.org.uk/guidance/mpg2](http://www.nice.org.uk/guidance/mpg2)   * NICE MPG2 Patient group directions: competency framework for health professionals using patient group directions. Updated March 2017.   [www.nice.org.uk/guidance/mpg2/resources](http://www.nice.org.uk/guidance/mpg2/resources)   * Patient Group Directions: who can use them. Medicines and Healthcare products Regulatory Agency. 4 December 2017.   [www.gov.uk/government/publications/patient-group-directions-pgds/patient-group-directions-who-can-use-them](http://www.gov.uk/government/publications/patient-group-directions-pgds/patient-group-directions-who-can-use-them)   * UK Statutory Instrument 2012 No. 1916, The Human Medicines Regulations 2012   [www.legislation.gov.uk/uksi/2012/1916/contents](http://www.legislation.gov.uk/uksi/2012/1916/contents)   * UK Statutory Instrument 2020 No. 1125, The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020   [www.legislation.gov.uk/uksi/2020/1125/contents/made](http://www.legislation.gov.uk/uksi/2020/1125/contents/made)   * UK Statutory Instrument 2020 No. 1594, The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020   [www.legislation.gov.uk/uksi/2020/1594/regulation/4/made](http://www.legislation.gov.uk/uksi/2020/1594/regulation/4/made) |

**4. Practitioner/staff authorisation sheet**

**Spikevax® bivalent Original/Omicron COVID-19 vaccine Protocol v1.01**

**Valid from: 24 August 2022 Expiry: 25 August 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.

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| 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 |
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**Authorising registered healthcare professional**

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| 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.

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)](https://www.england.nhs.uk/coronavirus/publication/summary-of-the-legal-mechanisms-for-administering-the-covid-19-vaccines/)) [↑](#footnote-ref-1)
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](https://www.legislation.gov.uk/ukpga/2005/9/contents), (for further information on consent see [Chapter 2](https://www.gov.uk/government/publications/consent-the-green-book-chapter-2) of ‘The Green Book’). [↑](#footnote-ref-2)
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 [↑](#footnote-ref-3)
4. Contains polyethylene glycol 2000 (PEG2000-DMG), refer to the product’s [SPC](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1097996/Spikexax_bivalent_Original_Omicron_SmPC.pdf) for a full list of excipients. [↑](#footnote-ref-4)