UK Health Security Agency

NHS England

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National protocol for COVID-19 vaccine (adults)

Reference no:	COVID-19 vaccine (adults) protocol
Version no:	v4.00
Valid from:	4 October 2023
Expiry date:	1 April 2024

This protocol is for the administration of COVID-19 vaccine to individuals 18 years and over in accordance with the national COVID-19 vaccination programme.

This protocol is for the administration of COVID-19 vaccines 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 (NHSE)

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 or contractor must ensure that all elements of the protocol are complied with in the provision of vaccination to each individual. The provider or 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 or 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, 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 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 or contractors. Provider organisations or 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.

Individual users 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@ukhsa.gov.uk

Change history

Version	Change details	Date
V1.00	New UKHSA combined (adults) COVID-19 vaccine protocol to support delivery of the COVID-19 vaccination programme to eligible individuals aged 18 years and over.	27 March 2023
V2.00	UKHSA combined (adults) COVID-19 vaccine protocol updated to: • include eligible cohorts for the Autumn 2023 campaign • include the recommended COVID-19 vaccines for the Autumn 2023 campaign • include a recommended interval of 3 months between doses • recommend a minimum 3 week interval between doses for all vaccines, in individuals receiving planned immunosuppressive treatment (changed from minimum interval recommended in the product SPC) • include updated storage conditions for Spikevax® bivalent Original/Omicron BA.4-5 (50 micrograms/50 micrograms)/ml dispersion for injection • remove designation of dosing schedule as primary and booster doses, in line with Chapter 14a • remove recommendation of 3 primary doses for severely immunosuppressed individuals • recommend VidPrevtyn Beta® for previously unvaccinated individuals aged 75 years and over and as an alternative for those aged 18 years and over where an mRNA COVID-19 vaccine is not considered clinically suitable, including in severely immunosuppressed individuals	7 September 2023
V3.00	UKHSA combined (adults) COVID-19 vaccine protocol updated to: • include dose, handling, administration and storage details for Comirnaty® Omicron XBB.1.5 (30 micrograms/dose) dispersion for injection • reflect change in manufacturer shelf life from 18 months to 24 months and change in licensing for Comirnaty® Original/Omicron BA.4-5 (15/15 micrograms)/dose dispersion for injection • clarify that individuals about to commence or undergo new or intensified immunosuppressive treatment should receive a dose under PSD (added to Criteria for exclusion)	19 September 2023
V4.00	UKHSA combined (adults) COVID-19 vaccine protocol updated to: • include dose, handling, administration and storage details for Spikevax® XBB.1.5 (0.1mg/ml) dispersion for injection	4 October 2023

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 4 October 2023, Department of Health and Social Care Ministers approved this protocol in accordance with regulation 247A of HMR 2012.

Any provider or contractor administering COVID-19 vaccines 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 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.

2. 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 or contractor must ensure that all elements of the protocol are complied with, in the provision of vaccination to each individual. The service provider or 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 or 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 must be a registered doctor, nurse or pharmacist trained and competent in all aspects of the protocol and provide clinical supervision (see page 1 and 2), 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[1] 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[1] 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

[1] 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 (vaccinated 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	COVID-19 vaccination is indicated for the active immunisation of individuals for the prevention of coronavirus disease (COVID-19) caused by the SARS-CoV-2 virus. Immunisation is indicated in accordance with the national COVID-19 vaccination programme (see COVID-19 vaccination programme page), recommendations given in Chapter 14a of the Immunisation Against Infectious Disease: the Green Book (hereafter referred to as Chapter 14a), and subsequent correspondence and publications from the UKHSA and NHSE.
Criteria for inclusion	COVID-19 vaccination should be offered to individuals aged 18 years and over, in accordance with the recommendations in Chapter 14a. Individuals are eligible for different vaccines (see Table 4) based on their age and risk group (see the Dose and frequency of administration section). **The following criteria apply to all individuals irrespective of prior COVID-19 immunisation status.** **Individuals who have not already received a dose during the current seasonal campaign,** who are**:** • aged 65 years and over, including those due to turn 65 years of age on or before 31 March 2024 • residents and staff in a care home for older adults • frontline health and social care workers • aged 18 to 64 years in a clinical risk group as defined in Table 3 of Chapter 14a • carers aged 18 to 64 years: those who are eligible for a carer's allowance or who are the sole or primary carer of an elderly or disabled individual who are themselves defined as clinically vulnerable to COVID-19 infection in Chapter 14a • aged 18 to 64 years and are household contacts of immunosuppressed individuals (as defined in Tables 3 and 4 of Chapter 14a) of any age • included in the recommended cohort(s) for vaccination, if and when JCVI, DHSC or other appropriate authority recommend an emergency surge vaccine response is required
Criteria for exclusion[2] (continued over page)	Individuals for whom valid consent, or a '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). Several UKHSA resources are available to inform consent (see Written information to be given to individual or carer section). **As of 30 June 2023, the evergreen offer of two primary doses of COVID-19 ended. Therefore, individuals who do not fall into a clinical risk or other eligible group are not eligible for vaccination.**

[2] 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

Criteria for exclusion (continued)	Individuals who: • are under 18 years of age • do not meet any of the criteria for inclusion, irrespective of prior vaccination status or previous vaccine eligibility • have received a dose of COVID-19 vaccine in the last 3 months • have had a previous systemic allergic reaction (including immediate-onset anaphylaxis to a previous dose of a COVID-19 vaccine or to any component or residue from the manufacturing process[3] in the vaccine • 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)
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 UK). The 15 minute observation period following vaccination with COVID-19 vaccines has been suspended for individuals who have no history of an allergic reaction (see off-label use section and Chapter 14a). 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 premises • 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. Special precautions, such as those outlined in Chapter 14a (flowchart for managing patients who have allergic reactions to a previous dose of COVID-19 vaccine) 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 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 Comirnaty® or Spikevax® mRNA vaccines, 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). VidPrevtyn Beta® contains compounds related to PEG, polysorbate 20 and polysorbate 80. Despite limited experience with this vaccine, it is unlikely that individuals with a PEG allergy would have an allergic reaction, particularly if they have tolerated vaccines containing polysorbate compounds (including inactivated or adjuvanted influenza vaccine, the AstraZeneca (CDAdOx1-S recombinant) COVID-19 vaccine, Vaxzevria® or Nuvaxovid®). It may therefore be considered as an alternative for individuals aged 18 years and over where an mRNA COVID-19 is not considered to be clinically suitable, including in severely immunosuppressed individuals.

[3] Refer to the product's SPC for a full list of excipients.

Cautions including any relevant action to be taken (continued)	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 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 or other treatment to reduce bleeding, for example treatment for haemophilia, intramuscular vaccination can be scheduled shortly after such medication or 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 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 or carer should be informed about the risk of haematoma from the injection. Very rare reports have been received of Guillain-Barré 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, 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, where GBS occurred within 6 weeks of an Astra Zeneca© vaccine, mRNA COVID-19 vaccines are preferred for subsequent doses. 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 to 5 days after the vaccine is given (British Society for Haematology-COVID-19). **Past history of COVID-19 infection** There are no safety concerns from vaccinating individuals with a 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, though those with suspected COVID-19 infection should not attend vaccination sessions to avoid infecting

(continued over page)

Cautions including any relevant action to be taken (continued)

others. As clinical deterioration can occur up to 2 weeks after infection, vaccination should be deferred until clinical recovery.

During care home outbreaks, vaccination of residents with confirmed COVID-19 can proceed, provided that individuals are clinically stable and infection control procedures can be maintained. These populations are likely to be highly vulnerable and this approach facilitates vaccination without the need for multiple visits.

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

Table 3: Summary of dosing regimes

Vaccine	Recommended dose
Comirnaty® Omicron XBB.1.5 (30 micrograms/ dose)	0.3ml
Spikevax® XBB.1.5 (0.1mg/ml)	0.5ml
Comirnaty® Original/Omicron BA.4-5 (15/15 micrograms)/dose	0.3ml
VidPrevtyn Beta®	0.5ml
Spikevax® bivalent Original/Omicron BA.4-5 (50 micrograms/50 micrograms)/ml	0.5ml

Vaccination should be offered to individuals eligible for the current campaign as part of the national COVID-19 vaccination programme in accordance with the recommendations from the JCVI and in Chapter 14a, at a minimum interval of 3 months from the previous dose of COVID-19 vaccine. As the primary course has reduced from 2 doses to a single dose, there is no requirement to complete this regime before receiving further doses.

VidPrevtyn Beta® may be given where an mRNA vaccine is contraindicated or otherwise not clinically suitable to individuals aged 18 years and over, including individuals with severe immunosuppression.

In line with Chapter 14a, there is no requirement to administer the same vaccine brand as previously administered.

Vaccination in incompletely vaccinated or previously unvaccinated individuals

If the primary course was interrupted or delayed before Autumn 2023, doses should neither be repeated or the course resumed, in line with JCVI recommendations to change to a single dose regime. Previously unvaccinated individuals should be offered a single dose of COVID-19 vaccine as recommended in Table 4.

The main exception would be for those about to commence immunosuppressive treatment (see Special considerations and additional information).

Interval post COVID-19 infection

Refer to Cautions section (Past history of COVID-19) for information.

Action to be taken if the individual is excluded	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 an immediate-onset anaphylaxis to a previous dose of COVID-19 vaccine, or any component of the vaccine (as per full list of excipients in the relevant SPC), advice should be sought from an allergy specialist. Any subsequent dose should be provided by an appropriate prescriber, 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. Individuals who commenced but did not complete their primary course prior to the current seasonal vaccination campaign no longer require a second dose. If the individual continues to meet inclusion criteria, a dose can be given a minimum of 3 months from the date of the last administered dose, if this is possible within the campaign period. Otherwise, individuals who have never received a dose of COVID-19 and do not meet inclusion criteria, or who were previously eligible for a booster during previous campaigns but not the present one, should be reassured that the evidence does not currently support a need to vaccinate them. If new evidence means that they are considered to be at high risk during a future campaign, they will then be invited for vaccination. When the seasonal vaccination campaign has ended, individuals with severe immunosuppression (as defined in Box 1 of Chapter 14a) can be considered for vaccination outside of campaign periods, as described in the Green Book. A decision to proceed would be subject to individual clinical decision and therefore a PSD should be used to administer the vaccine. If COVID-19 vaccine has been given in the preceding 3 months, advise the individual to return when they are next invited forward for vaccination, which may coincide with the next seasonal COVID-19 campaign. 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. For further information on consent, see Chapter 2 of the Green Book. Advise the individual or 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. Inform or refer to the GP or a prescriber as appropriate.

Arrangements for referral	As per local policy.

Stage 1b: Description of treatment

<table>
<tr><td>Activity stage 1b:</td><td>Consider any relevant cautions, interactions or adverse drug reactions. Provide advice to the individual and obtain informed consent[1]
Record individual's consent[1] and ensure vaccinator, if another person, is informed of the vaccine product and dose to be administered.</td></tr>
<tr><td>Name, strength and formulation of drug

(continued over page)</td><td>
Comirnaty® Omicron XBB.1.5 (30 micrograms/dose) dispersion for injection COVID-19 mRNA vaccine (nucleoside modified)
One dose (0.3ml) contains:
30 micrograms of raxtozinameran (embedded in lipid nanoparticles)

Spikevax® XBB.1.5 (0.1mg/ml) dispersion for injection
One dose (0.5ml) contains:
50 micrograms of andusomeran (embedded in SM-102 lipid nanoparticles).

Comirnaty® Original/Omicron BA.4-5 (15/15 micrograms)/dose dispersion for injection COVID-19 mRNA vaccine (nucleoside modified)
One dose (0.3ml) contains:
15 micrograms of tozinameran (Original) (embedded in lipid nanoparticles) and
15 micrograms of famtozinameran (Omicron BA.4-5) (embedded in lipid nanoparticles)

VidPrevtyn Beta® solution and emulsion for emulsion for injection COVID-19 vaccine (recombinant, adjuvanted)
Following reconstitution of antigen and adjuvant vials, one dose (0.5ml) contains:
5 micrograms of SARS-CoV-2 spike protein (B.1.351 strain)

Spikevax® bivalent Original/Omicron BA.4-5 (50 micrograms/50 micrograms)/ml dispersion for injection
One dose (0.5ml) contains:
25 micrograms of elasomeran and
25 micrograms of davesomeran, a COVID-19 mRNA vaccine (embedded in SM-102 lipid nanoparticles).

More stringent age limits than outlined in the vaccine SPCs are being applied to COVID-19 vaccines in scope for the current seasonal vaccination campaign and in line with JCVI recommendations (summarised below).

Table 4: Age specific recommendations on vaccine type
<table>
<tr><th>Age</th><th>Recommended COVID-19 vaccine(s)[4]</th></tr>
<tr><td>18 to 74 years of age (including pregnant women)</td><td>Comirnaty® Omicron XBB.1.5 (30 micrograms/dose)
Spikevax® XBB.1.5 (0.1mg/ml)
Comirnaty® Original/Omicron BA.4-5 (15/15 micrograms/dose)</td></tr>
</table>
</td></tr>
</table>

[4] As outlined in the Green Book, vaccines that target the latest variant are preferable. However, an available, authorised and age-appropriate vaccine should be offered without delay, particularly to individuals at highest risk.

<table>
<tr><td>Name, strength and formulation of drug
(continued)</td><td>
<table>
<tr><td></td><td>Spikevax® bivalent Original/Omicron BA.4-5 (50 micrograms/50 micrograms)/ml
Note: If an mRNA vaccine is not considered clinically suitable, VidPrevtyn Beta® may be given under this protocol.</td></tr>
<tr><td>75 years and above[5]

Residents in an older person’s care home aged 65 years and over</td><td>Comirnaty® Omicron XBB.1.5 (30 micrograms/dose)
Spikevax® XBB.1.5 (0.1mg/ml)
Comirnaty® Original/Omicron BA.4-5 (15/15 micrograms/dose)
VidPrevtyn Beta®
Spikevax® bivalent Original/Omicron BA.4-5 (50 micrograms/50 micrograms)/ml</td></tr>
</table>
Note: Where mRNA vaccines are not considered clinically suitable, VidPrevtyn Beta® is a suitable alternative for those aged 18 years and over, including those with severe immunosuppression.
</td></tr>
<tr><td>Legal category</td><td>Prescription only medicine (POM).</td></tr>
<tr><td>Black triangle</td><td>All recommended COVID-19 vaccines are black triangle products. As new vaccine products, the Medicines and Healthcare products Regulatory Agency (MHRA) has a specific interest in the reporting of adverse drug reactions for these products.</td></tr>
<tr><td>Off-label use

(continued over page)</td><td>
Previously unvaccinated individuals
VidPrevtyn Beta® is not licensed for previously unvaccinated individuals, whereas JCVI advice recommends all currently approved COVID-19 vaccines should be offered as a single dose, regardless of prior immunisation history. COVID-19 vaccines are administered under this protocol in accordance with recommendations from both the JCVI and Chapter 14a for the delivery of the COVID-19 vaccination programme in England (see Dose and frequency of administration section).
Reinforcing immunisation
The VidPrevtyn Beta® COVID-19 SPC recommends a booster dose may be administered 4 months after the last dose of any COVID-19 vaccine.
Reinforcing 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 COVID-19 vaccines are kept for observation and monitored for a minimum of 15 minutes. Following careful review of the safety data by the MHRA and advice from the Commission on Human Medicines, the 15 minute observation period following vaccination with all COVID-19 vaccines has since been suspended for individuals who have no history of an allergic reaction. 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.
</td></tr>
</table>

[5] Includes those individuals due to turn 75 years of age by 31 March 2024.

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 Coronavirus Yellow Card reporting 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 vaccines are 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 procedures. Where a vaccine is recommended off-label consider, as part of the consent process, informing the individual or carer that the vaccine is being offered in accordance with national guidance but outside of 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. For further information about co-administration with other vaccines see Additional Information section.
Identification and management of adverse reactions (continued over page)	The most frequently reported adverse reactions are injection-site pain, swelling or redness, fatigue, headache, myalgia, arthralgia, chills, pyrexia, nausea, diarrhoea and vomiting. These reactions are usually mild or moderate in intensity and resolve within a few days after vaccination. Uncommon side effects include enlarged lymph nodes, feeling unwell, arm pain, insomnia, injection site itching, allergic reactions such as rash or itching, feeling weak, decreased appetite, excessive sweating and night sweats. Very rare cases of myocarditis and pericarditis have been observed following vaccination with both Comirnaty® and Spikevax®. These cases have primarily occurred within 14 days following vaccination, more often after the second vaccination and more often in younger men. 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.

Identification and management of adverse reactions (continued)	Heavy menstrual bleeding has been reported after COVID-19 vaccination. In most cases, this is self-limiting. 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	MHRA has a specific interest in the reporting of all adverse drug reactions for all COVID-19 vaccines. Healthcare professionals, individuals and carers should report suspected adverse reactions to the MHRA using the Coronavirus Yellow Card reporting scheme or by searching for MHRA Yellow Card in the Google Play or Apple App Store. As new vaccines, MHRA has a specific interest in the reporting of all adverse drug reactions for these products. 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 8 and Chapter 14a 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 an '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 Comirnaty® Omicron XBB.1.5 (30 micrograms/dose), Spikevax® XBB.1.5 (0.1mg/ml), Comirnaty®Original/Omicron BA.4-5, VidPrevtyn Beta® or Spikevax® bivalent Original/Omicron BA.4-5 COVID-19 vaccine as applicable • COVID-19 vaccination record card • what to expect after your COVID-19 vaccination • COVID-19 vaccination: women who are pregnant or breastfeeding For resources in accessible formats and alternative languages, please visit Home-Health Publications. Where applicable, inform the individual, parent or carer that large print, Braille or audio CD PILs may be available from emc accessibility (freephone 0800 198 5000) by providing the medicine name and product code number, as listed on the electronic Medicines Compendium.
Advice and follow up treatment (continued over page)	The 15 minute observation period following vaccination with COVID-19 vaccines has been suspended for individuals who have no history of an allergic reaction (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 premises • informed about the signs and symptoms of anaphylaxis and how to access immediate healthcare advice in the event of displaying any symptoms (see leaflet What to expect after your COVID-19 vaccination) Individuals with a personal history of allergy should be managed in line with Chapter 14a Table 5. Inform the individual or 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.

Advice and follow up treatment (continued)	Vaccinated individuals should be advised to seek immediate medical attention should they experience new onset of chest pain, shortness of breath, palpitations or arrhythmias. The individual or 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. Advise the individual or 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 by searching 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 or carer when to return for vaccination or when a subsequent vaccine dose is due.
Special considerations and 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** There is no known risk associated with being given a non-live vaccine during pregnancy (see Chapter 14a). 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 for COVID-19 vaccination. Because of wider experience with mRNA vaccines, these are the preferred vaccines to offer to pregnant women. Evidence for use of VidPrevtyn Beta® in pregnancy is presently limited and therefore should only be considered where the potential benefit is thought to outweigh the potential risk to the mother and fetus. **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 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** Vaccination can be resumed provided a minimum interval of 3 months has been observed and the individual continues to be eligible for the current seasonal campaign. There is no need to administer extra doses to compensate for previously missed primary or booster doses, even if the individual was previously eligible.

Special considerations and additional information (continued)	**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. 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 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 may be found in COVID-19 vaccination programme: information for healthcare practitioners. **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 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 to avoid any further delay in protection and 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, shingles and pneumococcal polysaccharide vaccine in those aged over 65 years and pertussis-containing vaccines and influenza vaccines in pregnancy. A 7 day gap between administration of the inactivated shingles and COVID-19 vaccine is no longer required and both may be given together. Where co-administration does occur, individuals should be informed about the likely timing of potential adverse events relating to each vaccine. **Immunosuppressed** Immunological response may be lower in immunocompromised individuals, but they should still be vaccinated. Individuals who had received brief immunosuppression (≤40mg prednisolone per day) for an acute episode (such as asthma or COPD) and individuals on replacement corticosteroids for adrenal insufficiency are not considered severely immunosuppressed sufficient to have prevented response to the primary vaccination. **Individuals with severe immunosuppression** The need for additional doses for individuals who have severe immunosuppression (as defined by Box 1: Criteria for additional doses of COVID-19 vaccine in those aged 12 years and above, Chapter 14a) should be at the discretion of the individual's specialist. A minimum 3 month interval between doses is recommended. However, for individuals about to receive planned treatment, a minimum interval of 3 weeks between COVID-19 doses may be followed, to enable the vaccine to be given whilst the individual's immune system is better able to respond. Ideally vaccination should take place 2 weeks before immunosuppressive treatment commences, or until 2 weeks after the period of immunosuppression, in addition to time needed for clearance of the therapeutic agent. If not possible, consideration could be given to vaccination during a treatment holiday or when the degree of immunosuppression is at a minimum. Due consideration must be given to the risk of delaying COVID-19 vaccination against that of delaying treatment.

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Special considerations and additional information (continued)	More information on optimal timing of doses may be found in Chapter 14a**.** Such individual should receive a dose under a PSD. 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, such as a PSD.

Stage 2: Vaccine preparation

Activity stage 2:	Vaccine preparation
Vaccine presentation	**Comirnaty® Omicron XBB.1.5 (30 micrograms/dose) dispersion for injection COVID-19 mRNA vaccine (nucleoside modified)** 2.25 ml ready to use dispersion is contained in a 2 ml clear multidose vial (type I glass) with a stopper (synthetic bromobutyl rubber) and a grey flip-off plastic cap with aluminium seal. Each vial contains 6 doses
	Spikevax® XBB.1.5 (0.1mg/ml) dispersion for injection 2.5ml dispersion in a multidose vial (type 1 or type 1 equivalent glass) with a stopper (chlorobutyl rubber) and a blue flip-off plastic cap with aluminum seal. Each vial contains 5 doses of 0.5ml.
	Comirnaty® Original/Omicron BA.4-5 (15/15 micrograms)/dose dispersion for injection COVID-19 mRNA vaccine (nucleoside modified) 2.25ml ready to use dispersion is contained in a 2ml clear multidose vial (type I glass) with a stopper (synthetic bromobutyl rubber) and a grey flip-off plastic cap with aluminium seal. Each vial contains 6 doses.
	VidPrevtyn Beta® solution and emulsion for emulsion for injection COVID-19 vaccine (recombinant, adjuvanted) 2.5ml antigen solution in a multidose vial (type 1 glass) with a stopper (chlorobutyl) and an aluminum seal with a green plastic flip-off cap. 2.5ml adjuvant emulsion in a multidose vial (type 1 glass) with a stopper (chlorobutyl) and an aluminum seal with a yellow plastic flip-off cap. Each vial contains 10 doses.
	Spikevax® bivalent Original/Omicron BA.4-5 (50 micrograms/50 micrograms)/ml dispersion for injection 2.5ml dispersion in a multidose vial (type 1 or type 1 equivalent glass) with a stopper (chlorobutyl rubber) and a blue flip-off plastic cap with aluminium seal. Each vial contains 5 doses of 0.5ml.
Supplies	Providers will receive COVID-19 vaccines via the nationally appointed supply route. NHS standard operating procedures should be followed for appropriate supply, storage, handling, preparation, administration and waste minimisation of COVID-19 vaccines and ensure use is in accordance with the product's SPC and official national recommendations. Further information is also available in the Green Book Chapter 3.
Storage (continued over page)	**General advice** Store at 2°C to 8°C. Do not freeze. Store in original packaging to protect from light if not in use. Manufacturer storage details relate to storage requirements and available stability data at the time of product authorisation. Refer to NHS standard operating procedures for the service and the most up to date manufacturer's recommendations in the product's SPC. The SPC also contains further information on stability to guidehealthcare professionals only in case of temporary temperature excursion. 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.

Storage (continued)

Table 5: Summary of vaccine handling and storage (thawed product)

Vaccine product	Transportation time	Product shelf life		
		Thawed vial (unopened)	Punctured vial	Temperature deviations
Comirnaty® Omicron XBB.1.5 (30 micrograms/dose)	Up to 10 weeks at 2°C to 8°C (within the 18 month shelf life) Punctured vial: up to 6 hours at 2°C to 30°C	10 weeks at 2°C to 8°C	Up to 12 hours at 2°C to 30°C	Up to 24 hours at 8°C to 30°C (includes up to 12 hours following first puncture)
Spikevax® XBB.1.5 (0.1mg/ml)	Up to 12 hours at 2°C to 8°C (within the 30 day* post-thaw expiry)	30 days* at 2°C to 8°C	Up to 6 hours at 2°C to 25ºC	Up to 24 hours at 8°C to 25°C
Comirnaty® Original/Omicron BA.4-5 (15/15 micrograms) bivalent	Up to 10 weeks at 2°C to 8°C (within the 24 month shelf life) Punctured vial: up to 6 hours at 2°C to 30°C	10 weeks at 2°C to 8°C	Up to 12 hours at 2°C to 30°C	Up to 24 hours at 8°C to 30°C (includes up to 12 hours following first puncture)
Spikevax® bivalent Original/ Omicron BA.4-5	Up to 12 hours at 2°C to 8°C (within the 30 day* post-thaw expiry)	30 days* at 2°C to 8°C	Up to 6 hours at 2°C to 25ºC	Up to 24 hours at 8°C to 25°C
VidPrevtyn Beta®	No data	No data	Up to 6 hours at 2°C to 8°C	No data (contact manufacturer)

*****where Spikevax® XBB.1.5 (0.1mg/ml) and Spikevax® bivalent Original/Omicron BA.4-5 have been stored at -50°C to -15°C for between 9 to 12 months, the unopened vial must be used within a maximum of 14 days and not exceeding a total storage time of 12 months, provided once thawed, the vial is protected from light and stored at 2°C to 8°C throughout.

Specific directions pertinent to each vaccine are outlined below.

a) Comirnaty® XBB.1.5 (30 micrograms/dose) dispersion for injection COVID-19 mRNA vaccine

Thawed vial

Thawed unopened vials have a 10 week shelf-life at 2°C to 8°C, including for transportation.

If the vaccine is received at 2°C to 8°C it should be stored at 2°C to 8°C. Except where a shelf-life extension applies, the 10 week shelf life should not exceed the printed manufacturer's expiry date (EXP) on the outer carton.

Prior to use, the unopened vials can be stored for up to 12 hours at temperatures between 2°C to 30°C.

Thawed vials can be handled in room light conditions.

Once thawed, the vaccine cannot be re-frozen.

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Storage (continued)	**Punctured vial** Shelf life of the opened vial is 12 hours at 2°C to 30°C. From a microbiological point of view, the product should be used as soon as practicably possible once opened. **Special precautions for storage** Store in original packaging to protect from light. During storage, minimise exposure to room light and avoid exposure to direct sunlight and ultraviolet light.
	b) Spikevax® XBB.1.5 (0.1mg/ml) dispersion for injection **Thawed vial** Thawed unopened vials must be stored at 2°C to 8°C for no longer than 30 days. Vials kept in a frozen state for between 9 and 12 months will be given a 14 day thaw expiry, which will be indicated on the outer packaging. Within this period, up to 12 hours may be used for transportation. The 30 (or 14) day shelf life should not exceed the manufacturer printed expiry date (EXP) on the outer carton. Prior to use, the unopened vial can be stored for up to 24 hours at 8°C to 25°C Once thawed at 2°C to 8°C, vials must not be refrozen. **Punctured vial** After initial puncture, the shelf life of the punctured vial is 6 hours at 8°C to 25°C, within a 24 hour expiry if stored unopened between 8°C to 25°C and not exceeding the 30 day or 14 day (thawed) shelf life. From a microbiological point of view, the product should be used as soon as practicably possible. In-use storage times and conditions are the responsibility of the user.
	c) Comirnaty® Original/Omicron BA.4-5 (15/15 micrograms)/dose dispersion for injection COVID-19 mRNA vaccine **Thawed vial** Thawed unopened vials have a 10 week shelf-life at 2°C to 8°C, including for transportation. If the vaccine is received at 2°C to 8°C it should be stored at 2°C to 8°C. Prior to use, the unopened vials can be stored for up to 12 hours at temperatures between 8°C to 30°C. Thawed vials can be handled in room light conditions. Once thawed the vaccine cannot be re-frozen. **Punctured vial** Shelf life of the punctured vial is 12 hours at 2°C to 30°C, which includes up to 6 hours transportation time. From a microbiological point of view, the product should be used as soon as practicably possible once opened. **Special precautions for storage** Store in original packaging in order to protect from light. During storage, minimise exposure to room light and avoid exposure to direct sunlight and ultraviolet light.

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Storage (continued)	**d) VidPrevtyn Beta® solution and emulsion for emulsion for injection COVID-19 vaccine** **Punctured vial** Upon mixing the separate vial components, the reconstituted vaccine has a shelf life of up to 6 hours, if stored at 2°C to 8°C and protected from light. From a microbiological point of view, the product should be used as soon as practicably possible. **Special precautions for storage** The antigen and adjuvant vial should be placed at room temperature (up to 25°C) for a minimum of 15 minutes before mixing. Protect from light throughout. When not in use, the reconstituted vial contents should be stored at between 2°C to 8°C and protected from light. An MHRA review of quality data has shown that the mixed antigen/adjuvant for VidPrevtyn Beta® is stable at 23°C to 27°C for several hours. During the in-use period, when doses are being withdrawn from the vial and administered, the vial may remain at room temperature (up to 25°C). This may include the time it takes to move short distances between individuals, for example, in a care home, or the time between individuals in a clinic. If there is no immediate need to withdraw further doses, the vial should be returned to storage between 2°C to 8°C in a container which protects the vial from light and maintains segregation from the un-mixed vials. The vial must be discarded 6 hours after mixing.
	e) Spikevax® bivalent Original/Omicron BA.4-5 (50 micrograms/50micrograms/ml) dispersion for injection COVID-19 mRNA vaccine **Thawed vial** The unopened vials must be stored at 2°C to 8°C for no longer than 30 days. Vials kept in a frozen state for between 9 and 12 months will be given a 14 day thaw expiry, which will be indicated on the outer packaging. Within this period, up to 12 hours may be used for transportation. The 30 (or 14) day shelf life should not exceed the manufacturer printed expiry date (EXP) on the outer carton. Prior to use, the unopened vial can be stored for up to 24 hours at 8°C to 25°C Once thawed at 2°C to 8°C, vials must not be refrozen. **Punctured vial** After initial puncture, the shelf life of the punctured vial is 6 hours at 8°C to 25°C, within a 24 hour expiry if stored unopened between 8°C to 25°C and not exceeding the 30 day or 14 day (thawed) shelf life. From a microbiological point of view, the product should be used as soon as practicably possible. In-use storage times and conditions are the responsibility of the user.
Vaccine preparation (continued over page)	Vaccine should be prepared in accordance with the manufacturer's recommendations as per the product SPC 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. 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.

V**accine preparation** (continued)	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 Specific handling requirements of each vaccine are outlined below.
	a) Comirnaty® XBB.1.5 (30 micrograms/dose) dispersion for injection COVID-19 mRNA vaccine Verify that the vial has a grey plastic cap and the product name reads as Comirnaty® Omicron XBB.1.5 (30 micrograms/dose) dispersion for injection. The vaccine should be used or discarded by the post-thaw expiry date. Thawed vials can be handled in room light conditions. Gently mix by inverting vials 10 times prior to use. Do not shake. **Do not dilute the vial contents.** Prior to mixing, the vaccine may contain white to off-white opaque amorphous particles. After mixing, the vaccine should present as a white to off-white dispersion with no particulates available. Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab. Withdraw 0.3 ml of Comirnaty® Omicron XBB.1.5. The vaccine dose should be drawn up from the vial immediately prior to administration. Each dose must contain 0.3 ml of vaccine. Low dead-volume syringes and/or needles should be used to extract 6 doses from a single vial. The low dead-volume syringe and needle combination should have a dead volume of no more than 35 microlitres. If standard syringes and needles are used, there may not be sufficient volume to extract a sixth dose from a single vial. If the amount of vaccine remaining in the vial cannot provide a full dose of 0.3 ml, discard the vial and any excess volume. Do not pool excess vaccine from multiple vials. Record the date and time of first puncture on the vial and discard unused vaccine within 12 hours of puncture (if stored between 2°C and 30°C).
	b) Spikevax® XBB.1.5 (0.1mg/ml) dispersion for injection Verify the vial has a blue flip-off cap and bears the correct name. Each vial contains 5 doses of 0.5ml. Thawed vials and filled syringes may be handled in room light conditions. After removing the flip-off cap, using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab. **Do not shake or dilute** – the vial should be gently swirled after thawing and before each administration. Prior to injection, inspect each dose to confirm the vaccine is white to off-white in colour in both vial and syringe. The vaccine may contain white or translucent product-related particulates. Withdraw 0.5ml of Spikevax® XBB.1.5. The dose should be used immediately. Once the vial is punctured, the vial should be discarded after 6 hours. Record the date and time the vial is to be discarded onto the vial label. An additional overfill is included in each vial to ensure 5 doses of 0.5ml can be delivered. Any remaining should be discarded in line with local procedures. Where possible, the stopper should be pierced at a different site each time, to minimise the chances of dislodging a fragment of the bung.
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Vaccine preparation (continued)	**c) Comirnaty Original/Omicron BA.4-5 (15/15 micrograms/dose) dispersion for injection COVID-19mRNA vaccine** Verify that the vial has a grey plastic cap and the product name is Comirnaty® injection Original/Omicron BA.4-5 (15/15 micrograms)/dose dispersion for injection. The vaccine should be used or discarded by the post-thaw expiry date. Thawed vials can be handled in room light conditions. Gently mix by inverting vials 10 times prior to use. Do not shake. **Do not dilute the vial contents.** Prior to mixing, the thawed dispersion may contain white to off-white opaque amorphous particles. After mixing, the vaccine should present as a white to off-white dispersion with no particulates visible. Discard the vaccine if particulates or discolouration are present. Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab. Withdraw 0.3 ml of Comirnaty® Original/Omicron BA.4-5 (15/15 micrograms)/dose. The vaccine dose should be drawn up from the vial immediately prior to administration. Each dose must contain 0.3 ml of vaccine. Low dead-volume syringes and/or needles should be used in order to extract 6 doses from a single vial. The low dead-volume syringe and needle combinationshould have a dead volume of no more than 35 microlitres. If standard syringes and needles are used, there may not be sufficient volume to extract a sixth dose from a single vial. If the amount of vaccine remaining in the vial cannot provide a full dose of 0.3ml, discard the vial and any excess volume. Do not pool excess vaccine from multiple vials. Record the date and time of first puncture on the vial and discard unused vaccine within 12 hours of puncture.
(continued over page)	**d) VidPrevtyn Beta® solution and emulsion for emulsion for injection** Prior to administration, the antigen and adjuvant vials must be left at room temperature (up to 25°C) and protected from light for at least 15 minutes, before being mixed together. Each vial should be inverted and inspected visually for particles or discolouration; in presence of either of these, dispose of the vial. Remove the flip-off caps and using aseptic technique, cleanse both vial stoppers with a single-use antiseptic swab. Using a sterile 21-gauge or narrower needle and a sterile syringe, invert the adjuvant vial (yellow cap) to facilitate full withdraw of the entire contents into the syringe, before transferring the full contents into the antigen vial (green cap). Removing the syringe from the antigen vial, mix the contents of both vials together, by inverting 5 times. Do not shake. The resultant vaccine is an off-white to yellow homogenous milky liquid emulsion. The expiry date and time of the reconstituted vaccine should be marked on the vial. Use within 6 hours after mixing if protected from light and stored between 2°C to 8°C (also refer to Storage section). Before each administration of VidPrevtyn Beta®, visually inspect the vial for any particulate matter or discolouration. In the presence of either, discard the vial, following local procedures. Using an appropriately sized sterile needle and syringe, withdraw 0.5ml from the vial immediately prior to administration.

Vaccine preparation (continued)	**e) Spikevax® bivalent Original/Omicron BA.4-5 (50 micrograms/50 micrograms)/ml dispersion for injection** Verify the vial has a blue flip-off cap and bears the correct name. Each vial contains 5 doses of 0.5ml. Thawed vials can be handled in room light conditions. After removing the flip-off cap, using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab. **Do not shake or dilute** – the vial should be gently swirled after thawing and before each administration. Prior to injection, inspect each dose to confirm the vaccine is white to off-white in colour in both vial and syringe. The vaccine may contain white or translucent product-related particulates. Withdraw 0.5ml of Spikevax® bivalent Original/Omicron BA.4-5. The dose should be used immediately. Once the vial is punctured, the vial should be discarded after 6 hours. Record the date and time the vial is to be discarded onto the vial label. An additional overfill is included in each vial to ensure 5 doses of 0.5ml can be delivered. Any remaining should be discarded in line with local procedures. Where possible, the stopper should be pierced at a different site each time, to minimise the chances of dislodging a fragment of the bung.
Disposal	Follow local clinical waste policy and NHS standard operating procedures to 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 NHSE guidance (HTM 07-01): Management and disposal of healthcare waste.

Stage 3: Vaccine administration

<table>
<tr><td>Activity stage 3:</td><td>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.
3. Consent for vaccination has been provided and documented.[1]

Administer the COVID-19 vaccination recommended by the assessing practitioner in accordance with the summary tables below. Provide any post-vaccination advice.</td></tr>
<tr><td>Vaccine to be administered</td><td>Table 4: Age specific recommendations on vaccine type
<table>
<tr><th>Age</th><th>Recommended COVID-19 vaccine(s)*</th></tr>
<tr><td>18 to 74 years of age (including pregnant women)</td><td>Comirnaty® Omicron XBB.1.5 (30 micrograms/dose)
Spikevax® XBB.1.5 (0.1mg/ml)
Comirnaty® Original/Omicron BA.4-5 (15/15 micrograms)/dose
Spikevax® bivalent Original/Omicron BA.4-5 (50 micrograms/50 micrograms)/ml
Note: If an mRNA vaccine is not considered clinically suitable, VidPrevtyn Beta® may be given under this protocol.</td></tr>
<tr><td>75 years and above[6]

Residents in an older person’s care home aged 65 years and over</td><td>Comirnaty® Omicron XBB.1.5 (30 micrograms/dose)
Spikevax® XBB.1.5 (0.1mg/ml)
Comirnaty® Original/Omicron BA.4-5 (15/15 micrograms)/dose
VidPrevtyn Beta®
Spikevax® bivalent Original/Omicron BA.4-5 (50 micrograms/50 micrograms)/ml</td></tr>
</table>
Note: Where mRNA vaccines are not considered clinically suitable, VidPrevtyn Beta® is a suitable alternative for those aged 18 years and over, including those with severe immunosuppression.</td></tr>
<tr><td>Quantity to be supplied and administered</td><td>As per Table 3</td></tr>
</table>

[6] Includes those individuals due to turn 75 years of age by 31 March 2024

Route and method of administration	**General principles** Administer the required dose of COVID-19 vaccine (as indicated in Table 3 above) by intramuscular injection only, preferably into the deltoid muscle of the upper arm. Vaccinators should prepare the dose in accordance with Stage 2 and as advised by the registered practitioner consenting the individual. Where it is within their competence, experienced vaccinators may draw the required dose from a vial diluted by another person, under the supervision of a doctor, nurse or pharmacist. 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. The name of the vaccine must be checked to ensure the intended vaccine is being used (as summarised in Table 4). Care should be taken to ensure a full 0.3ml or 0.5ml is administered. Where a full dose cannot be extracted, the remaining vial volume must be discarded. Do not pool excess vaccine from multiple vials. Recheck the product name, batch number and expiry date prior to administration. 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) for at least 2 minutes. The individual or carer should be informed about the risk of haematoma from the injection. Specific handling requirements of each vaccine is outlined in the Storage and Vaccine preparation sections above.
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 NHSE guidance (HTM 07-01): Management and disposal of healthcare waste
Post-vaccination advice	Ensure the individual has been provided with appropriate written information such as the: • patient information leaflet for Comirnaty® Omicron XBB.1.5 (30 micrograms/dose), Spikevax® XBB.1.5 (0.1mg/ml) , Comirnaty® Original/Omicron BA.4-5, VidPrevtyn Beta® or Spikevax® bivalent Original/Omicron BA.4-5 • COVID-19 vaccination record card • what to expect after your COVID-19 vaccination • COVID-19 vaccination: women who are pregnant or breastfeeding For resources in accessible formats and alternative languages, please visit Home-Health Publications. Where applicable, inform the individual, parent or carer that large print, Braille or audio CD PILs may be available from emc accessibility (freephone 0800 198 5000) by providing the medicine name and product code number, as listed on the electronic Medicines Compendium.

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	The practitioner must ensure the following is recorded: • that valid informed consent was given or a decision to vaccinate was 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 (including variant) 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 * Note: For VidPrevtyn Beta®, the batch number is indicated on the outer packaging, not on the antigen and adjuvant vials. Please take care to ensure the correct batch number is recorded. 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.

3. Key references

Key references	• Summary of Product Characteristics, Comirnaty® Omicron XBB.1.5 (30 micrograms/dose) dispersion for injection COVID-19 mRNA vaccine, last updated 5 September 2023 • Summary of Product Characteristics, Spikevax® XBB.1.5 (0.1mg/ml) dispersion for injection, last updated 18 September 2023 • Summary of Product Characteristics. Comirnaty® Original/Omicron BA.4-5 (15/15micrograms)/dose COVID-19 mRNA vaccine, last updated 14 September 2023 • Summary of Product Characteristics. VidPrevtyn Beta®, last updated 9 March 2023 • Summary of Product Characteristics. Spikevax® bivalent Original/Omicron BA.4-5 (50/50 micrograms)/dose dispersion for injection, last updated 1 August 2023 • Immunisation Against Infectious Disease: The Green Book, Chapter 14a. Updated 4 September 2023. 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. 14 December 2021. • COVID-19 vaccination programme. Updated 7 September 2023. https://www.gov.uk/government/collections/covid-19-vaccination-programme • Training recommendations for COVID-19 vaccinators. Updated 20 October 2022. 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 20 October 2022. https://www.gov.uk/government/publications/covid-19-vaccinator-competency-assessment-tool • COVID-19 vaccination programme: information for healthcare practitioners. Updated 9 May 2023. https://www.gov.uk/government/publications/covid-19-vaccination-programme-guidance-for-healthcare-practitioners **General** • NHSE Health Technical Memorandum 07-01: Safe Management of Healthcare Waste. Updated 7 March 2023 https://www.england.nhs.uk/publication/management-and-disposal-of-healthcare-waste-htm-07-01/ • 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 • Vaccine Incident Guidance: responding to errors in vaccine storage, handling and administration. Updated 7 July 2022. https://www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors

4. Practitioner/ staff authorisation sheet

COVID-19 Vaccine protocol (adults) v4.00.
Valid from: 4 October 2023 Expiry: 1 April 2024

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.