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## National protocol for COVID-19 mRNA vaccine (5 years and over)

Reference no: COVID-19 mRNA vaccine protocol (5 years and over)  
Version no: v1.00  
Valid from: 3 October 2024  
Expiry date: 31 March 2025

This protocol is for the administration of COVID-19 mRNA vaccine to eligible individuals from the age of 5 years, in accordance with the national COVID-19 vaccination programme.

This protocol is for the administration of COVID-19 mRNA vaccine 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 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 final preparation 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 dilution and 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 25 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](mailto:immunisation@ukhsa.gov.uk)

## Change history

Version	Change details	Date
v1.00	New UKHSA combined national protocol to support delivery of the COVID-19 vaccination programme to eligible individuals aged 5 years and over. This protocol reflects the change in antigenic content of the COVID-19 vaccine, from XBB (as utilised in Autumn 2023 and Spring 2024 campaigns) to JN.1. The protocol also amalgamates the 2 previously separate protocols for adults and children aged 5 to 17 years, into a single legal framework.	6 September 2024

## 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 13 September 2024, 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 mRNA vaccine under this protocol must work strictly within contractual arrangements with the commissioner as well as the terms of this protocol for the delivery of the national COVID-19 vaccination programme.

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/contractor must ensure that all elements of the protocol are complied with, in the provision of vaccination to each individual. The service provider/contractor is responsible for ensuring that there is a clinical supervisor present at all times and that persons are trained and competent to safely deliver the activity they are employed to provide under this protocol. As a minimum, competence requirements stipulated in the protocol must be adhered to.

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

This protocol is separated into operational stages of activity as outlined in [Table 1](#).

The clinical supervisor 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 <sup>1</sup> c. Provide advice to the individual/parent/carer	Specified registered healthcare professionals only (see <a href="#">Table 2</a> )
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 <a href="#">Section 4</a>	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 <sup>1</sup> 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 <a href="#">HMR 2012</a> :	Y	N	N	N

<sup>1</sup> For further information on consent see [Chapter 2](#) of the Green Book.

<ul style="list-style-type: none"> <li>nurses, nursing associates and midwives currently registered with the Nursing and Midwifery Council (NMC)</li> <li>pharmacists and pharmacy technicians currently registered with the General Pharmaceutical Council (GPhC)</li> <li>chiropractors/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)</li> <li>dental hygienists and dental therapists registered with the General Dental Council</li> <li>optometrists registered with the General Optical Council</li> </ul>				
must be a doctor, nurse or pharmacist or a person who is under the supervision of, a doctor, nurse or pharmacist (see <a href="#">Page 1</a> )	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 ( <a href="#">SPC</a> ) 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 <a href="#">Green Book</a>	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 <a href="#">training recommendations for COVID-19 vaccinators</a>	Y	Y	Y	N
must have completed the <a href="#">national COVID-19 vaccination e-learning programme</a> , 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 <a href="#">COVID-19 vaccination programme</a> online resources such as the <a href="#">Green Book</a> , particularly <a href="#">Chapter 14a</a> , and the <a href="#">COVID-19 vaccination programme: Information for healthcare practitioners</a> 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 <a href="#">COVID-19 vaccinator competency assessment tool</a>	Y	Y	Y	Y
must have been signed off as competent using the <a href="#">COVID-19 vaccinator competency assessment tool</a> 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 1a: Assessment of the individual presenting for vaccination

<b>Activity stage 1a:</b>	<b>Assess the individual presenting for vaccination. If they are not eligible for vaccination or need to return at a later date, advise the individual, parent or carer accordingly.</b>
<b>Clinical condition or situation to which this protocol applies</b>	COVID-19 vaccination is indicated for the active immunisation of eligible individuals from the age of 5 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 <a href="#">COVID-19 vaccination programme page</a> ), recommendations given in <a href="#">Chapter 14a</a> of the Green Book (hereafter referred to as <a href="#">Chapter 14a</a> ), <a href="#">JCVI</a> and subsequent correspondence and publications from the UKHSA and NHSE.
<b>Criteria for inclusion</b>	<p><b>Individuals who have not already received a dose during the current seasonal campaign</b> who are:</p> <ul style="list-style-type: none"> <li>(i) aged 5 years to 64 years in a clinical risk group, as defined in either table 3 or 4 of <a href="#">Chapter 14a</a></li> <li>(ii) residents and staff in a care home for older adults</li> <li>(iii) aged 65 years and over, including those due to turn 65 of years on or before 31 March 2025</li> <li>(iv) frontline health and social care workers</li> <li>(v) included in the recommended cohort(s) for vaccination if and when JCVI, DHSC or other appropriate authority announce an emergency surge vaccine response is required</li> </ul>
<b>Criteria for exclusion<sup>2</sup></b>	<p>Individuals who have not given valid consent (or for whom a best-interests decision in accordance with the <a href="#">Mental Capacity Act 2005</a>, has not been obtained). For further information on consent, see Green Book <a href="#">Chapter 2</a>. Several resources are available to inform consent (see <a href="#">written information to be given to individual, parent or carer</a> section).</p> <p>Individuals who:</p> <ul style="list-style-type: none"> <li>• are aged under 5 years</li> <li>• do not meet any of the <a href="#">criteria for inclusion</a>, irrespective of prior vaccination status or previous vaccine eligibility</li> <li>• have already received a dose of COVID-19 vaccine in the last 3 months</li> <li>• 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<sup>3</sup> in the COVID-19 mRNA vaccines</li> <li>• have experienced myocarditis or pericarditis determined as likely to be related to previous COVID-19 vaccination</li> <li>• are suffering from acute severe illness (the presence of a minor infection is not a contraindication for vaccination)</li> </ul>
<p><b>Cautions including any relevant action to be taken</b></p> <p>(continued over page)</p>	<p>Facilities for management of anaphylaxis should be available at all vaccination sites (see <a href="#">Chapter 8</a> of the Green Book and advice issued by the <a href="#">Resuscitation Council UK</a>).</p> <p>The 15 minute observation period following vaccination with the COVID-19 vaccines has been suspended for individuals who have no history of allergy (see <a href="#">off-label use</a> section below and <a href="#">Chapter 14a</a>).</p>

<sup>2</sup> 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.

<sup>3</sup> The Comirnaty® vaccines contain polyethylene glycol (PEG); refer to the respective [SPC](#) for a full list of excipients.

**Cautions including any relevant action to be taken**

(continued)

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 injections, laxatives)
- 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. Unless at least one dose of the same vaccine has been previously tolerated, it is advisable to seek advice from an allergy specialist (for further information, see [Chapter 14a](#)).

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.

Syncope (fainting) can occur following, or even before, any vaccination as a psychogenic response to the needle injection, particularly in adolescents. 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.

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 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 vaccination.

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 ([British Society for Haematology- COVID-19](#)).

**Past history of COVID-19 infection**

There are no 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, 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 others. There is no need to defer immunisation in individuals after recovery from a recent episode of compatible symptoms, whether or not they are tested for COVID-19.

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

(continued over page)



<p><b>Cautions including any relevant action to be taken</b> (continued)</p>	<p>underlying condition to the vaccine.</p>
<p><b>Action to be taken if the individual is excluded</b></p>	<p>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 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.</p> <p>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. In case of postponement due to acute illness, advise when the individual can be vaccinated and if possible, ensure another appointment is arranged.</p> <p>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. Vaccination may be provided by an appropriate prescriber or on a patient-specific basis, under a PSD.</p> <p>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 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 (see <a href="#">Chapter 14a</a> for further details).</p> <p>Individuals who have never received a dose of COVID-19 and do not meet <a href="#">inclusion criteria</a>, or who were previously eligible for a dose during previous campaigns but not the present one, should be reassured (or their parent or carer) that the evidence doesn't currently support a need to vaccinate them. If new evidence means they are considered to be at high risk of COVID-19 during a future campaign, they will then be invited for vaccination.</p> <p>When the seasonal vaccination campaign has ended, individuals with severe immunosuppression (as defined in Boxes 1 and 2 of <a href="#">Chapter 14a</a>) can be considered for vaccination outside of campaign periods, in accordance with 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.</p> <p>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 vaccine campaign.</p> <p>Document the reason for exclusion and any action taken.</p>
<p><b>Action to be taken if the individual or carer declines treatment</b> (continued over page)</p>	<p>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. In the case of individuals under 16 years, consent of someone with parental responsibility should be sought, unless the individual is assessed as being Gillick competent.</p>

<p><b>Action to be taken if the individual or carer declines treatment</b> (continued)</p>	<p>For further information on consent, see <a href="#">Chapter 2</a> of the Green Book.</p> <p>Advise the individual, parent or carer about the protective effects of the vaccine, the risks of infection and potential complications if not immunised.</p> <p>Document advice given and the decision reached.</p> <p>Inform or refer to the GP or a prescriber as appropriate.</p>
<p><b>Arrangements for referral</b></p>	<p>As per local policy.</p>

## Stage 1b and 1c: Description of treatment and advice to the individual

<b>Activity stages 1b and 1c:</b>	<p><b>Consider any relevant cautions, interactions or adverse drug reactions. Provide advice to the individual and obtain informed consent<sup>1</sup> Record individual's consent<sup>1</sup> and ensure the vaccinator (if another person) is informed of the vaccine product to be administered.</b></p>
<b>Name, strength and formulation of drug</b>	<p><b>Comirnaty® JN.1 (10 micrograms/dose) dispersion for injection COVID-19 mRNA vaccine (nucleoside modified)</b></p> <p>Each vial contains a single dose of 0.3ml.</p> <p>One dose (0.3ml) contains 10 micrograms of bretovameran, embedded in lipid nanoparticles.</p> <p><b>Comirnaty® JN.1 30 micrograms/dose) dispersion for injection COVID-19 mRNA vaccine (nucleoside modified)</b></p> <p>One vial (2.25ml) contains 6 doses of 0.3ml.</p> <p>One dose (0.3ml) contains 30 micrograms of bretovameran, embedded in lipid nanoparticles.</p> <p><b>Spikevax® JN.1 (0.1mg/ml) dispersion for injection.</b></p> <p>One vial (2.5ml) contains 5 doses of 0.5ml.</p> <p>One dose contains 50 micrograms of mRNA-1273.167.</p>
<b>Legal category</b>	<p>Prescription only medicine (POM).</p>
<b>Black triangle▼</b>	<p>Yes - 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.</p>
<b>Off-label use</b>	<p><b>Allergy</b></p> <p>The <a href="#">SPCs</a> for all strengths of Comirnaty® COVID-19 mRNA recommend close observation for at least 15 minutes following vaccination. Following careful review of the safety data by the MHRA and advice from the Commission on Human Medicines, the 15 minute observation has since been suspended for individuals who have no history of allergy following vaccination with all COVID-19 vaccines. Individuals (or their parent or carer) should be counselled in line with the relevant points from the <a href="#">advice and follow-up treatment</a> section. The MHRA will continue to closely monitor anaphylaxis post-COVID-19 vaccination; reporting of adverse events via the <a href="#">Yellow Card reporting scheme</a> is strongly encouraged.</p> <p><b>Storage</b></p> <p>Vaccines should be stored according to the conditions detailed in the <a href="#">storage</a> section below.</p> <p>However, in the event of an inadvertent or unavoidable deviation of these conditions, refer to <a href="#">Vaccine Incident Guidance</a>. Where vaccines are assessed in accordance with these guidelines as appropriate for continued use, this constitutes off-label administration under this protocol.</p> <p>Where a vaccine is recommended off-label, as part of the consent process consider informing the individual, parent or carer the vaccine is being offered in accordance with national guidance but outside of product licence.</p>

<p><b>Drug interactions</b></p>	<p>Immunological response may be diminished in those receiving immunosuppressive treatment, but it is important to still immunise this group.</p> <p>Although no data for co-administration of COVID-19 vaccine with other vaccines exist, 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.</p> <p>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.</p> <p>For further information about co-administration with other vaccines, see the <a href="#">additional information</a> section.</p>
<p><b>Identification and management of adverse reactions</b></p>	<p>The most frequent adverse reactions are injection-site pain, fatigue, headache, injection-site redness and swelling, fever, myalgia and chills. Nausea and lymphadenopathy are additional very commonly reported side-effects following immunisation with Spikevax®. Diarrhoea is a very common side effect specific to Comirnaty.®</p> <p>Very rare cases of myocarditis and pericarditis have been observed following COVID-19 mRNA vaccination. The reported rate is highest in individuals under 25 years and in males, usually within a few days following vaccination, after a second dose. Most cases are mild and self-limiting. The MHRA has advised the benefits from vaccination outweigh any risk in most individuals.</p> <p>Healthcare professionals should be alert to the signs and symptoms of myocarditis and pericarditis. Individuals, parents and carers 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 <a href="#">guidance</a> and/or specialists to diagnose and treat this condition.</p> <p>Heavy menstrual bleeding has been reported after vaccination with mRNA vaccines. In most cases, this is self-limiting.</p> <p>Individuals, parents and carers should be provided with the advice within the leaflet <a href="#">what to expect after your child's COVID-19 vaccination</a> or <a href="#">what to expect after your COVID-19 vaccination</a> as applicable, which covers the reporting of adverse reactions and their management, such as with analgesics.</p> <p>A detailed list of adverse reactions across all age groups is available in the product's <a href="#">SPC</a>.</p>
<p><b>Reporting procedure of adverse reactions</b></p>	<p>The MHRA has a specific interest in the reporting of all adverse drug reactions for new COVID-19 vaccines. Healthcare professionals and individuals, parents and carers should report suspected adverse reactions to the MHRA using the <a href="#">Yellow Card reporting scheme</a> or search for MHRA Yellow Card in the Google Play or Apple App Store.</p> <p>Any adverse reaction to a vaccine should also be documented in the individual's record and the individual's GP should be informed.</p> <p><a href="#">Chapter 8</a> and <a href="#">Chapter 14a</a> 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.</p>

<p><b>Written information to be given to the individual, parent or carer</b></p>	<p>Ensure the individual, parent or carer has been provided appropriate written information such as the:</p> <ul style="list-style-type: none"> <li>• patient information leaflet (PIL) for <a href="#">Comirnaty® JN.1 (30 micrograms/dose)</a>, <a href="#">Comirnaty® JN.1 (10 micrograms/dose)</a> or <a href="#">Spikevax® JN.1 (0.1mg/ml)</a> COVID-19 mRNA vaccine as appropriate</li> <li>• <a href="#">what to expect after your child's COVID-19 vaccination</a></li> <li>• <a href="#">what to expect after your COVID-19 vaccination</a></li> </ul> <p>For resources in accessible formats and alternative languages, please visit <a href="#">Home - Health Publications</a>. 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.</p>
<p><b>Advice and follow up treatment</b></p>	<p>Inform the individual, parent or carer of possible side effects and their management.</p> <p>The 15 minute observation following vaccination with COVID-19 vaccines has been suspended for individuals without a history of allergy (see <a href="#">off-label use</a> section).</p> <p>Following COVID-19 vaccine administration, individuals without a history of allergy should be:</p> <ul style="list-style-type: none"> <li>• observed for any immediate reactions whilst they are receiving any verbal post vaccination information and exiting the premises</li> <li>• informed about the signs and symptoms of anaphylaxis and how to access immediate healthcare advice in the event of displaying any symptoms (see the leaflet <a href="#">what to expect after your child's COVID-19 vaccination</a> or <a href="#">what to expect after your COVID-19 vaccination</a> as applicable)</li> <li>• where applicable, advised not to drive for 15 minutes after vaccination, as fainting can occur</li> </ul> <p>In some settings, for example domiciliary vaccination, this may require a responsible adult to be present for at least 15 minutes after vaccination.</p> <p>Individuals with a personal history of allergy should be managed in line with <a href="#">Chapter 14a</a>, Table 5. No specific management is required for individuals with a family history of allergies.</p> <p>The individual, parent or carer should be advised to seek appropriate advice from a healthcare professional in the event of an adverse reaction. Seek immediate medical attention should the vaccinated individual experience new onset of chest pain, shortness of breath, palpitations or arrhythmias.</p> <p>Advise the individual, parent or carer they can report side effects directly via the national reporting system run by the MHRA known as the <a href="#">Yellow Card reporting scheme</a> 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.</p> <p>As with all vaccines, immunisation may not result in protection in all individuals. The individual, parent or carer should be advised that immunosuppressed individuals may not make a full immune response to the vaccine.</p> <p>When applicable, advise the individual, parent or carer when to return for vaccination or when a subsequent dose is due.</p>

**Special considerations and additional information**

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.

**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 to prevent 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 LAIV, HPV, influenza, MenACWY and Td-IPV vaccines in the school age programmes and pertussis in pregnancy).

When administering at the same time as other vaccines, care should be taken to ensure that the appropriate route of injection is used for all the vaccinations. The vaccines should be given at separate sites, preferably into different limbs. If given into the same limb, they should be given at least 2.5cm apart. The site at which each vaccine was given should be noted in the individual's records.

Co-administration of the COVID-19 vaccine with the respiratory syncytial virus (RSV) vaccine is not routinely recommended in older adults. Refer to the [RSV PGD](#) and [Chapter 27a](#) of the Green Book for further details.

Where co-administration does occur, the individual, parent or carer 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 ( $\geq 40$ mg prednisolone per day or [equivalent for children](#)) for an acute episode of asthma 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**

Regardless of the time of year or previous vaccination history, additional doses of COVID-19 vaccine may be considered for individuals with severe immunosuppression (as defined by either Box 1 or Box 2: Criteria for additional doses of COVID-19 vaccine, [Chapter 14a](#), as applicable to the individual's age).

The need for additional doses and the optimal dose intervals should be at the discretion of the individual's specialist. In such circumstances, the dose should be given under a PSD. Due consideration must be given to the risk of delaying COVID-19 vaccination against that of delaying treatment.

More information on optimal timing of doses for this group may be found in [Chapter 14a](#).

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). Revaccination with COVID-19 vaccine is not covered by this protocol and should be provided on a patient-specific basis, such as a PSD.

(continued over page)

<p><b>Special considerations and additional information</b> (continued)</p>	<p><b>Pregnancy</b></p> <p>There is no known risk associated with being given a non-live vaccine during pregnancy (see <a href="#">Chapter 14a</a>).</p> <p>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.</p> <p><b>Breastfeeding</b></p> <p>There is no known risk associated with being given a non-live vaccine whilst breastfeeding. JCVI advises that eligible breastfeeding females may be offered any suitable COVID-19 vaccine. Emerging safety data is reassuring: mRNA was not detected in the breast milk of recently vaccinated females and protective antibodies have been detected in breast milk.</p> <p>The developmental and health benefits of breastfeeding are clear and should be discussed with the female, along with her clinical need for immunisation against COVID-19.</p>
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## Stage 2: Vaccine preparation

<b>Activity stage 2:</b>	<b>Vaccine preparation</b>																				
<b>Vaccine presentation</b>	<p><b>Comirnaty® JN.1 (10 micrograms/dose) dispersion for injection COVID-19 mRNA vaccine (nucleoside modified)</b></p> <p>Each vial contains a single dose of 0.3ml.</p> <p>One dose (0.3ml) contains 10 micrograms of bretovameran, embedded in lipid nanoparticles.</p>																				
	<p><b>Comirnaty® JN.1 (30 micrograms/dose) dispersion for injection COVID-19 mRNA vaccine (nucleoside modified)</b></p> <p>One vial (2.25ml) contains 6 doses of 0.3ml.</p> <p>One dose (0.3ml) contains 30 micrograms of bretovameran, embedded in lipid nanoparticles.</p>																				
	<p><b>Spikevax® JN.1 (0.1mg/ml) dispersion for injection</b></p> <p>One vial (2.5ml) contains 5 doses of 0.5ml.</p> <p>One dose (0.5ml) contains 50 micrograms of mRNA-1273.167</p>																				
<b>Supplies</b>	<p>Providers will receive COVID-19 vaccines via the national appointed supply route for delivery of NHS-commissioned services.</p> <p>Standard operating procedures should be followed for appropriate supply, storage, handling, preparation, administration and waste minimisation of COVID-19 mRNA vaccines, which ensure use is in accordance with product's <a href="#">SPC</a> and official national recommendations. Further information is also available in the Green Book <a href="#">Chapter 3</a>.</p>																				
<b>Storage</b>	<p><b>Table 3: Summary of vaccine handling and storage (thawed product)</b></p> <table border="1"> <thead> <tr> <th rowspan="2">Vaccine product</th> <th rowspan="2">Transportation time</th> <th colspan="3">Product shelf life</th> </tr> <tr> <th>Thawed vial (unopened)</th> <th>Punctured vial</th> <th>Temperature deviations</th> </tr> </thead> <tbody> <tr> <td><b>Comirnaty® JN.1 (10 micrograms/dose)</b></td> <td>Up to 10 weeks at 2°C to 8°C (within the 18 month shelf life)</td> <td rowspan="2">10 weeks at 2°C to 8°C</td> <td rowspan="2">Up to 12 hours at 2°C to 30°C</td> <td rowspan="2">Up to 24 hours at 8°C to 30°C (includes up to 12 hours following first puncture)</td> </tr> <tr> <td><b>Comirnaty® JN.1 (30 micrograms/dose)</b></td> <td>Punctured vial: up to 6 hours at 2°C to 30°C</td> </tr> <tr> <td><b>Spikevax® JN.1 0.1mg/ml dispersion for injection</b></td> <td>Up to 36 hours at 2°C to 8°C (within the 30 day* post-thaw expiry) of which 30 hours is by road</td> <td>30 days* at 2°C to 8°C</td> <td>Up to 6 hours at 2°C to 25°C</td> <td>Up to 24 hours at 8°C to 25°C</td> </tr> </tbody> </table>	Vaccine product	Transportation time	Product shelf life			Thawed vial (unopened)	Punctured vial	Temperature deviations	<b>Comirnaty® JN.1 (10 micrograms/dose)</b>	Up to 10 weeks at 2°C to 8°C (within the 18 month shelf life)	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)	<b>Comirnaty® JN.1 (30 micrograms/dose)</b>	Punctured vial: up to 6 hours at 2°C to 30°C	<b>Spikevax® JN.1 0.1mg/ml dispersion for injection</b>	Up to 36 hours at 2°C to 8°C (within the 30 day* post-thaw expiry) of which 30 hours is by road	30 days* at 2°C to 8°C	Up to 6 hours at 2°C to 25°C	Up to 24 hours at 8°C to 25°C
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(continued over page)	<p>*where Spikevax® JN.1 (0.1mg/ml) has 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.</p>																				



<b>Storage</b> (continued)	<p><b>General advice</b></p> <p>Store at 2°C to 8°C. Do not freeze. Thawed vaccines should not be re-frozen. Store in original packaging to protect from light if not in use.</p> <p>Manufacturer storage details relate to storage requirements and available stability data at the time of product authorisation. Refer to standard operating procedures for the service and the most up to date manufacturer’s recommendations in the product’s <a href="#">SPC</a>. The product’s <a href="#">SPC</a> also contains further information on stability to guide healthcare professionals only in case of temporary temperature excursion.</p> <p>In the event of an inadvertent or unavoidable deviation of these conditions, vaccines that have been stored outside the conditions stated above should be quarantined and risk assessed on a case-by-case basis for suitability of continued off-label use or appropriate disposal. Refer to <a href="#">Vaccine Incident Guidance</a>.</p>
	<p><b>a) Comirnaty® JN.1 (10 micrograms/ dose and 30 micrograms/dose) dispersion for injection COVID-19 mRNA vaccine</b></p> <p><b>Thawed vial</b></p> <p>Up to 10 weeks storage and transportation at 2°C to 8°C within the overall product shelf life.</p> <p>Except where a shelf-life extension applies, the 10 week post thaw shelf life should not exceed the printed manufacturer’s expiry date (EXP) on the outer carton.</p> <p>Prior to use, the unopened vials can be stored for up to 12 hours at temperatures up to 30°C.</p> <p>Thawed vials can be handled in room light conditions.</p> <p><b>Punctured vial</b></p> <p>Chemical and physical in-use stability has been demonstrated for 12 hours at 2°C to 30°C, which includes up to 6 hours transportation time for all Comirnaty® products in scope of this protocol. From a microbiological point of view, unless the method of opening precludes the risk of microbial contamination, the product should be used as soon as practicably possible. Otherwise, in-use storage times and conditions are the responsibility of the user.</p> <p><b>Special precautions for storage</b></p> <p>During storage, minimise exposure to room light and avoid exposure to direct sunlight and ultraviolet light.</p>
	<p><b>b) Spikevax® JN.1 (0.1mg/ml) dispersion for injection</b></p> <p><b>Thawed vial</b></p> <p>Thawed unopened vials must be stored at 2°C to 8°C and used within the 30 day post-thaw expiry date, indicated on the outer packaging.</p> <p>Note: vials kept in a frozen state for between 9 and 12 months will be given a reduced 14 day thaw expiry, provided a total storage time of 12 months has not been exceeded.</p> <p>Within this period, up to 36 hours may be used for transportation: a maximum of 30 hours by road and 6 hours by airfreight. The 30 day post thaw expiry should not exceed the manufacturer printed expiry date (EXP) on the outer carton, except where a shelf-life extension is advised.</p> <p>Prior to use, the unopened vial can be stored at 8°C to 25°C up to 24 hours after removal from refrigerated conditions.</p> <p><b>Punctured vial</b></p> <p>After initial puncture, the shelf life of the punctured vial is 6 hours at 2°C to 25°C, within</p>

(continued over page)



<b>Vaccine preparation</b> (continued)	<p>35 microlitres. If standard syringes and needles are used, there may not be sufficient volume to extract a sixth dose from a single vial.</p> <p><b>Spikevax® JN.1 (0.1mg/ml) dispersion for injection</b></p> <p>Verify the vial bears the correct name.</p> <p><b>Do not shake or dilute</b> – the vial should be gently swirled after thawing and before each administration.</p> <p>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.</p>
<b>Disposal</b>	<p>Follow local clinical waste policy and NHS standard operating procedures to ensure safe and secure waste disposal.</p> <p>Equipment used for vaccination, 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): <a href="#">safe and sustainable management of healthcare waste</a>.</p>

### Stage 3: Vaccine administration

<b>Activity stage 3:</b>	<p><b>Before administering the vaccine, ensure:</b></p> <ol style="list-style-type: none"> <li>1. The individual has been assessed in accordance with stage one of this protocol.</li> <li>2. The vaccine to be administered has been identified as appropriate for the individual's age (as per <a href="#">Table 4</a>) by the registered practitioner consenting the individual.</li> <li>3. <a href="#">Consent</a> for vaccination has been provided and documented<sup>1</sup>.</li> </ol> <p><b>Administer the vaccine recommended by the assessing practitioner and provide any post-vaccination advice.</b></p>														
<b>Vaccine to be administered</b>	<p><b>Table 4: Age-specific recommendations on vaccine type and dose regimes</b></p> <table border="1" data-bbox="395 562 1426 994"> <thead> <tr> <th>Age</th> <th>Recommended COVID-19 vaccine(s)<sup>4</sup></th> <th>Dose</th> </tr> </thead> <tbody> <tr> <td>5 to 11 years of age</td> <td>Comirnaty® JN.1 (10 micrograms/dose)</td> <td>0.3ml</td> </tr> <tr> <td>12 to 17 years of age</td> <td>Comirnaty® JN.1 (30 micrograms/dose)</td> <td>0.3ml</td> </tr> <tr> <td rowspan="2">18 years and over</td> <td>Comirnaty® JN.1 (30 micrograms/dose)</td> <td>0.3ml</td> </tr> <tr> <td>Spikevax® JN.1 (0.1mg/ml)</td> <td>0.5ml</td> </tr> </tbody> </table> <p>Note: use of alternative variant vaccines such as XBB are not covered by this protocol.</p>	Age	Recommended COVID-19 vaccine(s) <sup>4</sup>	Dose	5 to 11 years of age	Comirnaty® JN.1 (10 micrograms/dose)	0.3ml	12 to 17 years of age	Comirnaty® JN.1 (30 micrograms/dose)	0.3ml	18 years and over	Comirnaty® JN.1 (30 micrograms/dose)	0.3ml	Spikevax® JN.1 (0.1mg/ml)	0.5ml
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	Spikevax® JN.1 (0.1mg/ml)	0.5ml													
<b>Dose and frequency of administration</b>	<p>Vaccination should be offered to individuals eligible for the current campaign, in accordance with the recommendations from the <a href="#">JCVI</a> and in <a href="#">Chapter 14a</a>, at a minimum interval of 3 months from the previous dose of COVID-19 vaccine.</p> <p><a href="#">Table 4</a> above summarises the recommended vaccines by age.</p> <p>In line with <a href="#">Chapter 14a</a>, there is no requirement to administer the same vaccine brand as previously administered.</p>														
<b>Duration of treatment</b>	<p>As outlined above in <a href="#">dose and frequency of administration</a>.</p>														
<b>Quantity to be supplied and administered</b>	<p>A single dose, as outlined for the individual's age in <a href="#">Table 4</a>.</p>														
<b>Route and method of administration</b>  (continued over page)	<p>Administer the required dose of COVID-19 vaccine (as indicated in <a href="#">Table 4</a> above) by intramuscular injection only, preferably into the deltoid muscle of the upper arm.</p> <p>Vaccinators should prepare the dose in accordance with <a href="#">Stage 2</a> above 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 prepared by another person, under the supervision of a doctor, nurse, or pharmacist, in accordance with <a href="#">Stage 2</a>.</p>														

<sup>4</sup> 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, in preference to a substantial delay to vaccination with a slightly better matched vaccine.

<p><b>Route and method of administration</b> (continued)</p>	<p>If the vaccine is not prepared 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 <a href="#">Table 4</a>).</p> <p>Individuals with bleeding disorders may be vaccinated intramuscularly if, in the opinion of a clinician 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 be vaccinated via the intramuscular route. If in any doubt, consult with the clinician responsible for prescribing or monitoring the individual's anticoagulant therapy. 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. The individual, parent or carer should be informed about the risk of haematoma from the injection.</p> <p>Immediately prior to administration, recheck the product name, batch number, dose volume and post-thaw expiry date, including the expiry date and time of the thawed, punctured vial.</p> <p>Specific handling requirements for each of the vaccines are outlined in the <a href="#">storage</a> and <a href="#">vaccine preparation</a> sections above.</p>
<p><b>Disposal</b></p>	<p>Follow local clinical waste policy and NHS standard operating procedures to ensure safe and secure waste disposal.</p> <p>Equipment used for vaccination, 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): <a href="#">safe and sustainable management of healthcare waste</a></p>
<p><b>Post-vaccination advice</b></p>	<p>Ensure the individual, parent or carer has been provided appropriate written information such as the:</p> <ul style="list-style-type: none"> <li>• patient information leaflet (PIL) for the <a href="#">Comirnaty® JN.1 (30 micrograms/dose)</a>, <a href="#">Comirnaty® JN.1 (10 micrograms/dose)</a> or <a href="#">Spikevax® JN.1</a> COVID-19 mRNA vaccine as appropriate</li> <li>• <a href="#">what to expect after your child's COVID-19 vaccination</a></li> <li>• <a href="#">what to expect after your COVID-19 vaccination</a></li> </ul> <p>For resources in accessible formats and alternative languages, please visit <a href="#">Health Publications - Home</a>. 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.</p>

## Stage 4: Recording vaccine administration

<b>Activity stage 4:</b>	<p><b>Complete a record of vaccination for the individual in accordance with local policy.</b></p> <p><b>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.</b></p>
<b>Records</b>	<p>The practitioner must ensure the following is recorded:</p> <ul style="list-style-type: none"> <li>• that valid informed consent was given or a decision to vaccinate was made in the individual's best interests in accordance with the <a href="#">Mental Capacity Act 2005</a></li> <li>• 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)</li> <li>• 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</li> <li>• name and brand of vaccine</li> <li>• date of administration</li> <li>• dose, form and route of administration of vaccine</li> <li>• quantity administered</li> <li>• batch number and expiry date</li> <li>• anatomical site of vaccination</li> <li>• advice given, including advice given if the individual is excluded or the individual (or their parent or carer) declines immunisation</li> <li>• details of any adverse drug reactions and actions taken</li> <li>• supplied via national protocol</li> </ul> <p>Records should be signed and dated (or password-controlled on e-records).</p> <p>All records should be clear, legible and contemporaneous.</p> <p>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.</p> <p>A record of all individuals receiving treatment under this protocol should also be kept for audit purposes in accordance with local and national policy.</p>



<p><b>Key references</b> (continued)</p>	<ul style="list-style-type: none"> <li>• UK Statutory Instrument 2020 No. 1125, The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 <a href="https://www.legislation.gov.uk/uksi/2020/1125/contents/made">https://www.legislation.gov.uk/uksi/2020/1125/contents/made</a></li> <li>• UK Statutory Instrument 2020 No. 1594, The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 <a href="https://www.legislation.gov.uk/uksi/2020/1594/regulation/4/made">https://www.legislation.gov.uk/uksi/2020/1594/regulation/4/made</a></li> <li>• UK Statutory Instruments 2024, Number 729. The Human Medicines (Amendments relating to Registered Dental Hygienists, Registered Dental Therapists and Registered Pharmacy Technicians) Regulations 2024, published 29 May 2024 <a href="https://www.legislation.gov.uk/uksi/2024/729/introduction/made">https://www.legislation.gov.uk/uksi/2024/729/introduction/made</a></li> <li>• Vaccine Incident Guidance: responding to errors in vaccine storage, handling and administration. Updated 7 July 2022 <a href="https://www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors">https://www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors</a></li> </ul>
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#### 4. Practitioner/staff authorisation sheet

### COVID-19 mRNA vaccine protocol (5 years and over) v1.00

Valid from: 3 October 2024      Expiry: 31 March 2025

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 <b>insert name of organisation / service</b>			
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.

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