## Vaccination protocol for COVID-19 mRNA vaccines (adults)

Reference no: COVID-19 mRNA vaccines protocol (adults)

Version no: v4.0

Valid from: 1 October 2025

Expiry date: 31 January 2026

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

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

The Strategic Planning and Performance Group (SPPG) and the Public Health Agency (PHA) have adapted the UK Health Security Agency’s (UKHSA) COVID-19 mRNA vaccine (5 years and over) national protocol v03.00 (Publications gateway number GOV-**1913**). SPPG and PHA have developed this protocol for authorisation by the Northern Ireland Minister for Health to facilitate the delivery of the national COVID-19 vaccination programme in Northern Ireland.

This protocol may be followed wholly from assessment through to post-vaccination by an appropriately registered healthcare professional (see [Characteristics of staff](#CharacteristicsOfStaff)). Alternatively, multiple persons may undertake stages in the vaccination pathway in accordance with this protocol. Where multiple person models are used, the service provider/contractor must ensure that all elements of the protocol are complied with, in the provision of vaccination to each individual. The provider/contractor is responsible for ensuring that persons are trained and competent to safely deliver the activity they are employed to provide under this protocol and that adequate supervision arrangements are in place. As a minimum, competence requirements stipulated in the protocol under [Characteristics of staff](#CharacteristicsOfStaff) must be adhered to.

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

Persons must be authorised by name to work under this protocol. They must ensure they meet the staff characteristics for the activity they are undertaking, make a declaration of competence and be authorised in writing. This can be done by completing [Section 4](#Section4) 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](https://www.legislation.gov.uk/uksi/2012/1916/part/1) of the HMR 2012 and will need to be done by, or under the supervision of a registered doctor, nurse or pharmacist. If a vaccination service is being provided at scale, the clinical supervisor should only take on specific supervision requirements in relation to the 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/contractors. Provider organisations/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, authorised by or on behalf of the Minister for Health for Northern Ireland, in accordance with regulation 247A of the HMR 2012 can be found via:

* Trust Intranet or
* [Primary Care Intranet](http://primarycare.hscni.net/pharmacy-and-medicines-management/resources/pgds/)

Any concerns regarding the content of this protocol should be addressed to:

pha.immunisation@hscni.net

# **Change history**

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| **Version number** | **Change details** | **Date** |
| V1.0 | * New national protocol for COVID-19 vaccines (adults) | 5 April 2024 |
| V2.0 | * Updated to reflect the change in antigenic content of the COVID-19 mRNA vaccine, from XBB (as utilised in Autumn 2023 and Spring 2024 campaigns) to JN.1. | 16 September 2024 |
| V3.0 | * Updated to include eligibility criteria for Spring 2025 * Updated references and hyperlinks | 6 March 2025 |
| V4.0 | SPPG/PHA COVID-19 National Protocol updated to include:   * eligibility criteria for Autumn 2025 * recommended vaccines for the Autumn 2025 campaign, including the introduction of KP.2 30 micrograms * advice that COVID-19 and RSV vaccines may be co-administered in line with updates to [Chapter 27a](https://www.gov.uk/government/publications/respiratory-syncytial-virus-the-green-book-chapter-27a) * replacement of the training recommendations for COVID-19 vaccinators and the COVID-19 vaccinator competency assessment tool, with the national minimum standards and core curriculum for vaccination training * removal of reference to the British Society of Haematology guidance on platelet monitoring in those with a history of idiopathic thrombocytic purpura (ITP), as this has been withdrawn | 18 September 2025 |

1. **Ministerial and clinical authorisation**

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

On 9.10.25 the Minister for Health, Mike Nesbitt MLA, approved this protocol in accordance with [regulation 247A](https://www.legislation.gov.uk/uksi/2020/1125/regulation/14/made) of HMR 2012.

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| **Ministerial Authorisation** | | | |
| **Role** | **Name** | **Sign** | **Date** |
| Minister for Health | Mike Nesbitt MLA | A screenshot of a computer  Description automatically generated | 09.10.25 |

Unless explicitly revoked, the Minister for Health’s approval of this protocol remains valid in the event of any subsequent variation to the COVID-19 vaccination specifications or key reference material set out in this protocol.

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| **Clinical Authorisation** | | | |
| **Role** | **Name** | **Sign** | **Date** |
| Consultant in Public Health, PHA | Dr Louise Herron |  | 1/10/25 |
| Interim Assistant Director for Public Health Nursing for Children and Young People, PHA | Mrs Deirdre Ward |  | 30/9/25 |
| Interim Head of Pharmacy and Medicines Management, Directorate of Primary Care, SPPG | Mrs Kathryn Turner | C:\Users\ceast004.hscb\Desktop\kt.jpg | 2/10/25 |

Any provider/contractor administering COVID-19 mRNA vaccines under this protocol must work strictly within the terms of this protocol and any relevant contractual arrangements with the commissioner for the delivery of the national COVID-19 vaccination programme.

Assembly, preparation and administration of vaccines supplied and administered under this protocol must be subject to all HSC governance arrangements and standard operating procedures that ensure that the safety, quality or efficacy of the product is not compromised. The assembly, preparation and administration of the vaccines should also be in accordance with the general requirements of the Human Medicines Regulations 2012 and Medicines Act 1968, and with the [Summary of Product Characteristics](#refs) (SPC).

Note: The national COVID-19 vaccination programme may also be provided under a patient group direction (PGD) 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 are not related to this protocol.

#### Characteristics of staff

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| Classes of persons permitted to administer medicinal products under this protocol |
| This protocol may be followed wholly from assessment through to post-vaccination by an appropriately registered healthcare professional (see [Table 2](#Table2)). Alternatively, multiple persons may undertake stages in the vaccination pathway in accordance with this protocol. Where multiple person models are used, the service provider 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/contractor and registered healthcare professionals are responsible for ensuring that they have adequate and appropriate indemnity cover.  This protocol is separated into operational stages of activity as outlined in [Table 1](#Table1).  The clinical 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 | 1. Assessment of the individual presenting for vaccination 2. Provide information and obtain informed consent[[1]](#footnote-1) 3. Provide advice to the individual/carer | Specified registered healthcare professionals only (see [Table 2](#Table2)) | | Stage 2 | * Vaccine preparation | Specified registered healthcare professionals or specified non-registered persons | | Stage 3 | * Vaccine administration | Specified registered healthcare professionals or specified non-registered persons | | Stage 4 | * Record keeping | Specified registered healthcare professionals or specified non-registered persons |   Persons must only work under this protocol where they are competent to do so.  Non-professionally qualified persons operating under this protocol must be adequately supervised by experienced registered healthcare professionals.  Protocols do not remove inherent professional obligations or accountability. All persons operating under this protocol must work within their terms of employment at all times; registered healthcare professionals must also abide by their professional code of conduct.  To undertake the assigned stage(s) of activity under this protocol, persons working to this protocol must meet the criteria specified in [Table 2](#Table2) (see below).  **Table 2: Protocol stages and required characteristics of persons working under it**   |  |  |  |  |  | | --- | --- | --- | --- | --- | | **Persons working to this protocol must meet the following criteria, as applicable to undertake their assigned stage(s) of activity under this protocol:** | **Stage 1** | **Stage 2** | **Stage 3** | **Stage 4** | | must be authorised by name as an approved person under the current terms of this protocol before working to it, see [Section 4](#Section4) | 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 consent1 and must be an appropriately qualified prescriber or one of the following registered professionals who can operate under a PGD or as an occupational health vaccinator in accordance with [HMR 2012](https://www.legislation.gov.uk/uksi/2012/1916/contents):   * Nurses and midwives currently registered with the Nursing and Midwifery Council (NMC). * Pharmacists currently registered with the Pharmaceutical Society of Northern Ireland (PSNI). * Chiropodists/podiatrists, dieticians, occupational therapists, operating department practitioners, orthoptists, orthotists/prosthetists, paramedics, physiotherapists, radiographers and speech and language therapists currently registered with the Health and Care Professions Council (HCPC). * Dental hygienists and dental therapists registered with the General Dental Council. * Optometrists registered with the General Optical Council. * Doctors currently registered with a licence to practice with the General Medical Council. * Dentists currently registered with the General Dental Council. * an **occupational health vaccinator** for the administration of influenza and coronavirus vaccines in accordance with [HMR 2012](https://www.legislation.gov.uk/uksi/2020/1125/regulation/3/made) * operating department practitioners currently registered with the HCPC | Y | N | N | N | | must be a doctor, nurse or pharmacist or a person who is under the supervision of, a doctor, nurse or pharmacist (see [Page 1](#Page1ClinicalSupervisor)) | N | Y | N | N | | must be competent in the handling of the vaccine product and use of the correct technique for drawing up the correct dose | N | Y | N | N | | must be familiar with the vaccine product and alert to any changes in the manufacturer’s Summary of Product Characteristics ([SPC](#refs)) and familiar with the national recommendations for the use of this vaccine | Y | Y | Y | N | | must be familiar with and alert to changes in relevant chapters of Immunisation Against Infectious Disease: the [Green Book](https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book) | Y | Y | Y | N | | must 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 [national minimum standards and core curriculum for vaccination training](https://www.gov.uk/government/publications/national-minimum-standards-and-core-curriculum-for-immunisation-training-for-registered-healthcare-practitioners) | Y | Y | Y | N | | must have completed the [national COVID-19 vaccination e-learning programme](https://www.e-lfh.org.uk/programmes/covid-19-vaccination/), including the relevant vaccine specific session and/or locally-provided COVID-19 vaccine training | Y | Y | Y | N | | must be competent in the correct handling and storage of vaccines and management of the cold chain if receiving, responsible for, or handling the vaccine | N | Y | Y | N | | must be competent in intramuscular injection technique if they are administering the vaccine | N | N | Y | N | | must be competent in the recognition and management of anaphylaxis, have completed basic life support training and able to respond appropriately to immediate adverse reactions; must be familiar with [Resuscitation Council UK (RCUK) Anaphylaxis guidance for vaccination setting](https://www.resus.org.uk/about-us/news-and-events/rcuk-publishes-anaphylaxis-guidance-vaccination-settings)s | Y | N | Y | N | | must have access to the protocol and relevant [COVID-19 vaccination programme](https://www.gov.uk/government/collections/covid-19-vaccination-programme) online resources such as the [Green Book](https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book), particularly the [COVID-19 chapter](https://www.gov.uk/government/publications/covid-19-the-green-book-chapter-14a)and the [COVID-19 vaccination programme: Information for healthcare practitioners](https://www.gov.uk/government/publications/covid-19-vaccination-programme-guidance-for-healthcare-practitioners) document | 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 [vaccinator competency assessment tool](https://assets.publishing.service.gov.uk/media/688a481f1affbf4bedb7b0f1/UKHSA_Appendix_A_Vaccinator_competency_assessment_tool_workbook.pdf) | Y | Y | Y | Y | | must have been signed off as competent using the [vaccinator competency assessment tool](https://assets.publishing.service.gov.uk/media/688a481f1affbf4bedb7b0f1/UKHSA_Appendix_A_Vaccinator_competency_assessment_tool_workbook.pdf) 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 |   **Table 3: Specified non-registered person (this includes registered healthcare professionals (not listed in** [**Table 2**](#Table2professionals) **above)**  The following persons are permitted to practice under the protocol with appropriate supervision and subject to the requirements set out in [Table 2](#Table2).   * Veterinary surgeons currently registered with the Royal College of Veterinary Surgeons * Pharmacy technicians and Pharmacy Foundation Year trainees * Retired clinical practitioners who have left the register in good standing such as doctors, dentists, pharmacists, nurses, optometrists, chiropodists/podiatrists, dieticians, occupational therapists, orthoptists, orthotists/prosthetists, paramedics, physiotherapists, radiographers, speech and language therapists, dental hygienists and dental therapists not currently registered * Student doctors, dentists, pharmacists, nurses, midwives, optometrists, chiropodists/podiatrists, dieticians, occupational therapists, orthoptists, orthotists/prosthetists, paramedics, physiotherapists, radiographers, speech and language therapists, dental hygienists and dental therapists not currently registered * Healthcare scientists * Dental nurses * Physician’s associates * Optometry staff * Emergency Medical Technicians who work for NI Ambulance Service * Healthcare Support Workers who have an NVQ in healthcare or 2 years’ experience in the health sector. |

**Stage 1a: Assessment of the individual presenting for vaccination**

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| **Activity stage 1a:** | **Assess the individual presenting for vaccination. If they are not eligible for vaccination or need to return at a later date, advise them accordingly.** |
| **Clinical condition or situation to which this protocol applies** | COVID-19 vaccination is indicated for the active immunisation of eligible individuals aged 18 years and over 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](https://www.gov.uk/government/collections/covid-19-vaccination-programme)), recommendations given in the [COVID-19 chapter](https://www.gov.uk/government/publications/covid-19-the-green-book-chapter-14a) of the Green Book, [JCVI](https://www.gov.uk/government/publications/covid-19-vaccination-in-2025-and-spring-2026-jcvi-advice/jcvi-statement-on-covid-19-vaccination-in-2025-and-spring-2026), and subsequent correspondence / publications from the [Department of Health for Northern Ireland (DH(NI))](https://www.health-ni.gov.uk/topics/professional-medical-and-environmental-health-advice/hssmd-letters-and-urgent-communications) and Public Health Agency (PHA). |
| **Criteria for inclusion** | **Individuals who have not already received a dose during the current seasonal campaign** who are**:**   1. aged 18 years to 74 years who are immunosuppressed, as defined in the immunosuppression section of either table 3 or 4 of the [COVID-19 chapter](https://www.gov.uk/government/publications/covid-19-the-green-book-chapter-14a) 2. all residents of a registered care home 3. aged 75 years and over, including those due to turn 75 of years on or before 31 March 2026 4. people in prisons aged 65 years and over, including those due to turn 65 of years on or before 31 March 2026 5. included in the recommended cohort(s) for vaccination, if and when JCVI, DH(NI), PHA or other appropriate authority announce an emergency surge vaccine response is required |
| **Criteria for exclusion[[2]](#footnote-2)** | Individuals for whom valid consent or a ‘best-interests’ decision in  accordance with the common law in Northern Ireland in relation to the best interests of the incapacitous individual has not been received (for further information on consent see [Reference guide to consent for examination or treatment](https://www.gov.uk/government/publications/reference-guide-to-consent-for-examination-or-treatment-second-edition)).  A number of PHA resources are available to inform consent (see [Written information to be given to individual or carer](#Written_information_to_be_given_to_indiv) section).  Individuals who:   * are under 18 years of age * do not meet any of the [criteria for inclusion](#CriteriaForInclusion), irrespective of prior vaccination status or previous vaccine eligibility * have already 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 componentor residue[[3]](#footnote-3) from the manufacturing process in the COVID-19 mRNA vaccines * 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 immunisation) |
| **Cautions including any relevant action to be taken**  (continued over page)  **Cautions including any relevant action to be taken**  (continued) | Facilities for management of anaphylaxis should be available at all vaccination sites (see [Chapter 8](https://www.gov.uk/government/publications/vaccine-safety-and-adverse-events-following-immunisation-the-green-book-chapter-8) of the Green Book) and advice issued by the [Resuscitation Council UK](https://www.resus.org.uk/about-us/news-and-events/rcuk-publishes-anaphylaxis-guidance-vaccination-settings).  The 15 minute observation period following vaccination with the COVID-19 vaccines has been removed for individuals who have no history of allergy (see [off-label](#off_label) use below, [CMO letter HSS(MD) 21/2022](https://www.health-ni.gov.uk/sites/default/files/publications/health/doh-hss-md-21-2022.pdf), and the [COVID-19 chapter](https://www.gov.uk/government/publications/covid-19-the-green-book-chapter-14a)).  Individuals with a personal history of allergy should be managed in line with [COVID-19 chapter](https://www.gov.uk/government/publications/covid-19-the-green-book-chapter-14a), Table 5.  Special precautions, such as those outlined in the [COVID-19 chapter](https://www.gov.uk/government/publications/covid-19-the-green-book-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 have a PEG component (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 the [COVID-19 chapter](https://www.gov.uk/government/publications/covid-19-the-green-book-chapter-14a)).  Where individuals experienced a possible allergic reaction to a dose of COVID-19 vaccine, follow the guidance in the [COVID-19 chapter](https://www.gov.uk/government/publications/covid-19-the-green-book-chapter-14a) in relation to the administration of subsequent doses.  Individuals with non-allergic reactions (vasovagal episodes, non-urticarial skin reaction or non-specific symptoms) to a COVID-19 vaccine can receive subsequent doses of vaccine in any vaccination setting. Observation for 15 minutes is recommended for these individuals.  No specific management is required for individuals with a family history of allergies.  Syncope (fainting) can occur following, or even before, any vaccination 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.  Very rare reports have been received of Guillain-Barré Syndrome (GBS) following COVID-19 vaccination (further information is available in [the](https://www.gov.uk/government/publications/covid-19-the-green-book-chapter-14a) [COVID-19 chapter](https://www.gov.uk/government/publications/covid-19-the-green-book-chapter-14a)). Healthcare professionals should be alert to the signs and symptoms of GBS to ensure correct diagnosis and 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.  For individuals with a history of ITP receiving any COVID-19 vaccine, checking their platelet count check should be considered 2 to 5 days post vaccination.  **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 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 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.  PHA have issued Guidance for vaccination in care homes during COVID / Flu like illness outbreaks. 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 maximises vaccination coverage 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. |
| **Action to be taken if the individual is excluded**  (continued over page)  **Action to be taken if the patient is excluded**  (continued) | In a GP practice setting, inform or refer to the GP or a prescriber as appropriate.  The risk to the individual of not being immunised must be considered. The indications for risk groups are not exhaustive, and the healthcare practitioner should consider the risk of COVID-19 exacerbating any underlying disease that an individual may have, as well as the risk of serious illness from COVID-19 itself. Where appropriate, such individuals should be referred for assessment of clinical risk. Where risk is identified as equivalent to those currently eligible for immunisation, vaccination may be provided by an appropriate prescriber or on a patient specific basis, under a PSD.  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.  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.  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 the [COVID-19 chapter](https://www.gov.uk/government/publications/covid-19-the-green-book-chapter-14a) for further details).  Individuals who have never received a dose of COVID-19 vaccine and do not meet [inclusion criteria](#CriteriaForInclusion), or who were previously eligible for a dose 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 the [COVID-19 chapter](https://www.gov.uk/government/publications/covid-19-the-green-book-chapter-14a)) 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.  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.  A PSD may be indicated and appropriate advice should be sought from the individual’s clinician in the first instance. Further advice also may be provided from the PHA Immunisation Team: [pha.immunisation@hscni.net](mailto:pha.immunisation@hscni.net) or telephone 0300 555 0119.  Document the reason for exclusion and any action taken in the individual’s clinical records. |
| **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 common law in Northern Ireland in relation to the best interests of the incapacitous individual, a decision to vaccinate may be made in the individual’s best interests. For further information on consent see [Reference guide to consent for examination or treatment](https://www.gov.uk/government/publications/reference-guide-to-consent-for-examination-or-treatment-second-edition).  Advise 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 for medical advice** | Seek appropriate advice from the individual’s clinician as required. |

**STAGE 1b and 1c: Description of treatment and advice to the individual**

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| **Activity stage 1b and 1c:** | **Consider any relevant cautions, interactions or adverse drug reactions.**  **Provide advice to the individual and obtain** [**informed consent1**](#informedConsent)**.**  **Record individual’s consent1 and ensure vaccinator, if another person, is informed of the vaccine product to be administered.** |
| **Name, strength and formulation of drug** | **Comirnaty® KP.2 (30 micrograms/dose) dispersion for injection COVID-19 mRNA vaccine (nucleoside modified)**  One vial (2.25ml) contains 6 doses of 0.3ml.  One dose (0.3ml) contains 30 micrograms of cemivameran. |
| **Legal category** | Prescription only medicine (POM) |
| **Black triangle▼** | Yes, Comirnaty® COVID-19 vaccines are black triangle products, the Medicines and Healthcare products Regulatory Agency (MHRA) has a specific interest in the reporting of adverse drug reactions for these products. |
| **Off-label use**  (continued over page) | **Allergy**  The [SPCs](http://www.medicines.org.uk) for all strengths of Comirnaty® COVID-19 mRNA recommends 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 carer) should be counselled in line with the relevant points from the [advice and follow-up treatment](#adviceandfollowup) section. Refer to [CMO letter HSS(MD) 21/2022](https://www.health-ni.gov.uk/sites/default/files/publications/health/doh-hss-md-21-2022.pdf) for further information.  The MHRA will continue to closely monitor anaphylaxis post-COVID-19 vaccination; reporting of adverse events via the [Yellow Card reporting scheme](https://yellowcard.mhra.gov.uk/) is strongly encouraged.  **Storage**  Vaccine should be stored according to the conditions detailed in the [Storage](#storage) section below. However, in the event of an inadvertent or unavoidable deviation of these conditions refer to [Guidance on vaccine handling & storage in GP practices](http://primarycare.hscni.net/pharmacy-and-medicines-management/resources/vaccines/) for advice. Where vaccine is assessed following advice by the Medicine Information Service 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 NI operational guidance or standard operating procedure.  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 that this is outside the product licence. |
| **Drug interactions** | Immunological response may be diminished in those receiving immunosuppressive treatment, but it is important to still immunise this group.  Although no data for co-administration of COVID-19 vaccine with other vaccines exists, in the absence of such data, first principles would suggest that interference between inactivated vaccines with different antigenic content is likely to be limited. Based on experience with other vaccines, any potential interference is most likely to result in a slightly attenuated immune response to one of the vaccines. There is no evidence of any safety concerns, although it may make the attribution of any adverse events more difficult.  Similar considerations apply to co-administration of inactivated (or non-replicating) COVID-19 vaccines with live vaccines such as MMR. In particular, live vaccines which replicate in the mucosa, such as live attenuated influenza vaccine (LAIV) are unlikely to be seriously affected by concomitant COVID-19 vaccination.  For further information about co-administration with other vaccines see [Special considerations and additional Information](#SpecialConsiderations). |
| **Identification and management of adverse reactions** | The most frequent adverse reactions are injection-site pain, fatigue, headache, injection-site redness and swelling, fever, myalgia and chills and diarrhoea  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.  Healthcare professionals should be alert to the signs and symptoms of myocarditis and pericarditis. Vaccinated individuals should be instructed to seek immediate medical attention if they develop symptoms indicative of myocarditis or pericarditis such as acute and persisting chest pain, shortness of breath, or palpitations following vaccination. Healthcare professionals should consult [guidance](https://www.gov.uk/government/publications/covid-19-vaccination-myocarditis-and-pericarditis-information-for-healthcare-professionals) and/or specialists to diagnose and treat this condition.  Heavy menstrual bleeding has been reported after vaccination with mRNA vaccines. 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](https://www.publichealth.hscni.net/publications/covid-19-vaccination-what-expect-and-translations), 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 [SPC](http://www.medicines.org.uk). |
| **Reporting procedure of adverse reactions** | The MHRA has a specific interest in the reporting of all adverse drug reactions for new COVID-19 vaccines. Healthcare professionals and individuals and carers should report suspected adverse reactions to the MHRA using the [Yellow Card reporting scheme](https://yellowcard.mhra.gov.uk/) or search for MHRA Yellow Card in the Google Play or Apple App Store.  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](https://www.gov.uk/government/publications/vaccine-safety-and-adverse-events-following-immunisation-the-green-book-chapter-8) and the [COVID-19 chapter](https://www.gov.uk/government/publications/covid-19-the-green-book-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 leaflets for relevant vaccine, [Comirnaty®KP.2 (30 micrograms/dose)](https://www.medicines.org.uk/emc/product/100163/pil) * PHA leaflets, [What to expect after your COVID-19 vaccination](https://www.publichealth.hscni.net/publications/covid-19-vaccination-what-expect)   PHA leaflets are available in English and alternative languages.  For resources in accessible formats and alternative languages, please visit [Home - Health Publications](https://www.healthpublications.gov.uk/). 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 [eMC](https://www.medicines.org.uk/emc/xpil#gref). |
| **Advice and follow up treatment** | Inform the individual or carer of possible side effects and their management.  The 15-minute observation following vaccination with COVID-19 vaccines has been removed for individuals who have no history of an allergic reaction (see [off-label](#off_label) 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 leaflets [What to expect after your COVID-19 vaccination](https://www.publichealth.hscni.net/publications/covid-19-vaccination-what-expect-and-translations)) * where applicable, advised not to drive for 15 minutes after vaccination, as fainting can occur.   Individuals with a personal history of allergy should be managed in line with the [COVID-19 chapter](https://www.gov.uk/government/publications/covid-19-the-green-book-chapter-14a) Table 5. No specific management is required for individuals with a family history of allergies.  In some settings, for example domiciliary vaccination, this may require a responsible adult to be present for at least 15 minutes after vaccination.  The individual 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 they experience new onset of chest pain, shortness of breath, palpitations or arrhythmias.  Advise the individual or carer that they can report side effects directly via the national reporting system run by the MHRA known as the [Yellow Card reporting scheme](https://yellowcard.mhra.gov.uk/) or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, they can help provide more information on the safety of medicines.  As with all vaccines, immunisation may not result in protection in all individuals. Immunosuppressed individuals should be advised that they may not make a full immune response to the vaccine.  When applicable, advise the individual or carer when to return for vaccination or when a subsequent vaccine dose is due. |
| **Special considerations and additional information**  (continued over page)  **Special considerations and additional information**  (continued) | Ensure there is immediate access to an anaphylaxis pack including adrenaline (epinephrine) 1 in 1,000 injection and easy access to a telephone at the time of vaccination.  **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, and pertussis in pregnancy).  Studies have shown that RSV and COVID-19 vaccines may be co-administered safely, with non-inferior immunogenicity and acceptable reactogenicity in both vaccines.  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.  Where co-administration does occur, the individual 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 (≤40mg prednisolone per day) 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 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 Box 1: Criteria for additional doses of COVID-19 vaccine in those aged 12 years and above, [COVID-19 chapter](https://www.gov.uk/government/publications/covid-19-the-green-book-chapter-14a)).  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 timing of additional doses may be found in the [COVID-19 chapter](https://www.gov.uk/government/publications/covid-19-the-green-book-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](https://www.gov.uk/government/publications/immunisation-of-individuals-with-underlying-medical-conditions-the-green-book-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.  **Pregnancy**  There is no known risk associated with being given a non-live vaccine during pregnancy (see [Criteria for inclusion](#CriteriaForInclusion) and the [COVID-19 chapter](https://www.gov.uk/government/publications/covid-19-the-green-book-chapter-14a)).  **Breastfeeding**  There is no known risk associated with being given a non-live vaccine whilst breastfeeding. JCVI advises that breastfeeding women may be offered vaccination with any suitable COVID-19 vaccine. Emerging safety data is reassuring: mRNA was not detected in the breast milk of recently vaccinated 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. |

**Stage 2: Vaccine Preparation**

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| **ACTIVITY STAGE 2:** | **Vaccine preparation** |
| **Vaccine presentation** | **Comirnaty® KP.2 (30 micrograms/dose) dispersion for injection COVID-19 mRNA vaccine (nucleoside modified)**  One vial (2.25ml) contains 6 doses of 0.3ml.  One dose (0.3ml) contains 30 micrograms of cemivameran. |
| **Supplies** | A central supply of COVID-19 vaccines has been procured.  Standard operating procedures should be followed for appropriate ordering, storage, handling, preparation, administration and waste minimisation of COVID-19 mRNA vaccines, in accordance with product’s [SPC](http://www.medicines.org.uk) and official national recommendations. Further information is also available in the Green Book [Chapter 3](https://www.gov.uk/government/publications/storage-distribution-and-disposal-of-vaccines-the-green-book-chapter-3). |
| **Storage**  (continued over page) | **Table 3: Summary of vaccine handling and storage (thawed product)**   |  |  |  |  |  | | --- | --- | --- | --- | --- | | **Vaccine product** | **Transportation time** | **Product shelf life** | | | | **Thawed vial (unopened)** | **Punctured vial** | **Temperature deviations** | | **Comirnaty® KP.2 (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) |     **Comirnaty® KP.2 (30 micrograms/dose) dispersion for injection COVID-19 mRNA vaccine**  **When received thawed from Movianto (thawed vial)**  The vaccine has a 10-week expiry at 2°C to 8°C once thawed by Movianto; the expiry date on the outer carton should be updated by Movianto to reflect the refrigerated expiry. Thawed vaccines must not be re-frozen. Store in original packaging to protect from light if not in use. During storage, minimise exposure to room light and avoid exposure to direct sunlight and ultraviolet light.  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.  Prior to use, the unopened vials can be stored for up to 12 hours at temperatures between 8 °C and 30 °C.  Vials can be handled in room light conditions.  **Punctured vial**  Chemical and physical in-use stability has been demonstrated for 12 hours at 2°C to 30°C after first puncture, which includes up to 6 hours transportation time. 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. |
| **Storage**  (continued) | **General advice**  Manufacturer storage details relate to storage requirements and available stability data at the time of product authorisation. Refer to standard operating procedures and the most up to date manufacturer’s recommendations in the product’s [SPC](http://www.medicines.org.uk). The [SPC](http://www.medicines.org.uk)also contains further information on stability to guide healthcare professionals only in case of temporary temperature excursion.  Breaches in the cold-chain should be reported in line with local arrangements. Vaccines that have been stored outside of the cold-chain should be quarantined and further advice re use should be sought from the NI Medicines Information Service, see [Guidance on vaccine handling and storage in GP practices](https://www.publichealth.hscni.net/publications/guidance-vaccine-handling-and-storage-gp-practices) for contact details.  Vaccine losses outside of secondary care should be reported to the PHA Duty Room (telephone 0300 555 0119) for further risk assessment, including whether individuals need revaccination following a cold chain breach. |
| **Vaccine preparation** | **General principles**  Vaccine should be prepared in accordance with the manufacturer’s recommendations as per the product [SPC](http://www.medicines.org.uk) and standard operating procedures.  Unopened vials should be used or discarded by the post-thaw expiry date indicated on the outer packaging.  Prior to administration, the thawed dispersion may contain white to off-white opaque amorphous particles. After mixing, the vaccine should appear as a white to off-white dispersion with no particulates visible.  Vials should be inspected for foreign particulate matter and other variation of expected appearance not in line with the product [SPC](http://www.medicines.org.uk), before preparation and administration. Should either occur, discard the vial in accordance with local procedures.  Verify that the vial has the correct coloured plastic cap and the label matches the intended vaccine to be administered.   |  |  | | --- | --- | | **Vaccine** | **Vial cap colour** | | **Comirnaty®KP.2 (30 micrograms/dose)** | Grey |   **Do not shake or dilute the vial contents**. Gently invert the vial 10 times prior to administration. The vaccine should not be mixed in the same syringe with any other vaccines or medicinal products. Thawed vials may be handled in room light conditions.  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.  Record the date and time of first puncture and ensure the vial is discarded within the time limits as outlined in [Storage](#storage) section. From a microbiological point of view, the product should be used as soon as practicably possible once opened.  To extract the anticipated number of doses from a multidose vial, low dead-volume syringes and/or needles should be used, with a combined 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.  Care should be taken to ensure a full dose of 0.3ml is given as outlined in [Vaccine to be administered](#VaccineToBeAdministered) section. Each dose must contain the correct volume of vaccine. If a full dose cannot be extracted from the remaining amount in the vial, discard the vial and any excess volume. Do not pool excess vaccine from multiple vials.  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 punctured vial. |
| **Disposal** | Follow local clinical waste policy and 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): [safe and sustainable management of healthcare waste](https://www.england.nhs.uk/publication/management-and-disposal-of-healthcare-waste-htm-07-01/). |

**Stage 3: Vaccine Administration**

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| **ACTIVITY STAGE 3:** | **Before administering the vaccine, ensure:**   1. **The individual has been assessed in accordance with stage one of this protocol.** 2. **The vaccine to be administered has been identified as appropriate, by the registered practitioner consenting the individual.** 3. **Consent for vaccination has been provided and documented.1**   **Administer the vaccine recommended by the assessing practitioner. Provide any post-vaccination advice.** |
| **Vaccine to be administered** | |  |  |  | | --- | --- | --- | | **Age** | **Recommended COVID-19 vaccine(s) [[4]](#footnote-4)** | **Dose** | | 18 years and over | Comirnaty® KP.2  (30 micrograms/dose) | 0.3ml |   Note: use of alternative variant vaccines such as XBB or JN.1 are not covered by this protocol. |
| **Dose and frequency of administration** | As per [Vaccine to be administered](#VaccineToBeAdministered).  Vaccination should be offered to individuals eligible for the current campaign, in accordance with the recommendations from the [JCVI](https://www.gov.uk/government/publications/covid-19-spring-2024-and-future-vaccination-programmes-jcvi-advice-4-december-2023/jcvi-statement-on-covid-19-vaccination-in-spring-2024-and-considerations-on-future-covid-19-vaccination-4-december-2023#considerations-on-future-covid-19-vaccination-programmes-beyond-spring-2024) and in the [COVID-19 chapter](https://www.gov.uk/government/publications/covid-19-the-green-book-chapter-14a), at a minimum interval of 3 months from the previous dose of COVID-19 vaccine.  In line with the [COVID-19 chapter](https://www.gov.uk/government/publications/covid-19-the-green-book-chapter-14a), there is no requirement to administer the same vaccine brand as previously administered. |
| **Duration of treatment** | As outlined above in [dose and frequency of administration](#DoseAndFrequencyOfAdministration). |
| **Quantity to be supplied and administered** | A single dose as per [Vaccine to be administered](#VaccineToBeAdministered) section |
| **Route and method of administration**  (continued over page)  **Route and method of administration**  (continued) | Administer the required dose of COVID-19 vaccine (as indicated in [Vaccine to be administered](#VaccineToBeAdministered) section above) by intramuscular injection only, preferably into the deltoid muscle of the upper arm.  Vaccinators should prepare the dose in accordance with [Stage 2](#Stage2) 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 [Stage 2](#Stage2).  If 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.  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.  Immediately prior to administration, recheck the product name, batch number, dose volume and expiry date prior to administration.  Specific handling requirements of each vaccine is outlined in the [Storage](#storage) and [Vaccine preparation](#VaccinePrepSection) sections above. |
| **Disposal** | Follow local clinical waste policy and 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): safe and sustainable management of healthcare waste](https://www.england.nhs.uk/publication/management-and-disposal-of-healthcare-waste-htm-07-01/) |
| **Post-vaccination advice** | Ensure the individual has been provided appropriate written information such as the:   * Patient information leaflets for relevant vaccine, [Comirnaty®KP.2 (30 micrograms/dose)](https://www.medicines.org.uk/emc/product/100163/pil) * PHA leaflet, [What to expect after your COVID-19 vaccination](https://www.publichealth.hscni.net/publications/covid-19-vaccination-what-expect)   For resources in accessible formats and alternative languages, please visit [Health Publications - Home](https://www.healthpublications.gov.uk/). 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 [eMC](http://www.medicines.org.uk). |

**Stage 4: Recording vaccine adminstration**

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| **ACTIVITY STAGE 4:** | **Complete a record of vaccination for the individual and in accordance with local policy.**  **The required records should be completed by the person who is undertaking the recorded activity or a designated record keeper who is a witness to the activity undertaken.** |
| **Records** | Verbally confirm individual’s name, address, date of birth, HSC number (for healthcare professionals) and  Record data required by the data capture form (including):   * that valid informed consent was given or a decision to vaccinate made in the individual’s best interests in accordance with the common law in Northern Ireland in relation to the best interests of the incapacitous individual * name, 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 vaccination protocol   Records should be signed and dated by the practitioner (or password-controlled on e-records).  All records should be clear, legible and contemporaneous.  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.  For pregnant women, also record immunisation in the hand-held and electronic maternity record if available.  The local Child Health Information Systems team (Child Health Records Department) must be notified using the appropriate documentation/pathway when vaccine is administered to individuals under 19 years of age.  A record of all individuals receiving treatment under this vaccination protocol should also be kept for audit purposes in accordance with local policy. |

1. **Key references**

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| **COVID-19 mRNA vaccines (Adults)**   * UKHSA. National Protocol for COVID-19 mRNA vaccine (5 years and over) v3.00 (with thanks)   <https://www.gov.uk/government/collections/covid-19-vaccination-programme#protocols-and-patient-group-directions-(pgds)>   * Summary of Product Characteristics for Comirnaty® KP.2 (30 micrograms/dose) COVID-19 mRNA vaccine, last updated 7 July 2025     [https://www.medicines.org.uk/emc/product/100163/smpc](https://www.medicines.org.uk/emc/product/100163/smpc )   * UKHSA. The Green Book Immunisation against Infectious Disease COVID-19 Chapter. <https://www.gov.uk/government/publications/covid-19-the-green-book-chapter-14a> * [JCVI statement on COVID-19 vaccination in 2025 and spring 2026,](https://www.gov.uk/government/publications/covid-19-vaccination-in-2025-and-spring-2026-jcvi-advice/jcvi-statement-on-covid-19-vaccination-in-2025-and-spring-2026#introduction) updated 14 November 2024 * DH(NI). Autumn 2025 COVID-19 VACCINATION CAMPAIGN   <https://www.health-ni.gov.uk/publications/letters-and-urgent-communications-2025>   * National COVID-19 Vaccination e-learning programme   <https://www.e-lfh.org.uk/covid-19-vaccination-e-learning-programme-now-live/>   * Resuscitation Council UK. Anaphylaxis guidance for vaccination settings.   <https://www.resus.org.uk/about-us/news-and-events/rcuk-publishes-anaphylaxis-guidance-vaccination-settings>   * COVID-19 vaccination: information for healthcare practitioners.   <https://www.gov.uk/government/publications/covid-19-vaccination-programme-guidance-for-healthcare-practitioners>   * Department of Health, NI. HSS(MD)21/2022: Permanent Suspension of the 15 minute wait (13 May 22)   <https://www.health-ni.gov.uk/sites/default/files/publications/health/doh-hss-md-21-2022.pdf>  **General**   * Health Technical Memorandum 07-01: safe and sustainable management of healthcarewaste.   <https://www.england.nhs.uk/publication/management-and-disposal-of-healthcare-waste-htm-07-01/>   * NICE Medicines Practice Guideline 2 (MPG2): Patient Group Directions. Updated March 2017 <https://www.nice.org.uk/guidance/mpg2> * NICE MPG2 Patient group directions: competency framework for health professionals using patient group directions. Updated March 2017 <https://www.nice.org.uk/guidance/mpg2/resources> * Reference guide to consent for examination or treatment, Department of Health. Published 4 August 2009. <https://www.gov.uk/government/publications/reference-guide-to-consent-for-examination-or-treatment-second-edition> * Guidance on vaccine handling and storage in GP practices. PHA, HSC and DH(NI). Updated August 2024.   <https://www.publichealth.hscni.net/publications/guidance-vaccine-handling-and-storage-gp-practices> |

**4. Practitioner / staff authorisation sheet**

**COVID-19 mRNA vaccines (adults) protocol v4.0**

**Valid from: 1 October 2025 Expiry: 31 January 2026**

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

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

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

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

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| I confirm that I have read and understood the content of this protocol and that I am willing and competent to work to it. | | | | | | | |
| Name | Designation | Activity Stage: | | | | Signature | Date |
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**Authorising registered healthcare professional**

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

1. For those lacking mental capacity, a decision may be made in the individual’s best interests in accordance with the common law in Northern Ireland in relation to the best interests of the incapacitous individual [↑](#footnote-ref-1)
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 [↑](#footnote-ref-2)
3. The Comirnaty® vaccines contain polyethylene glycol (PEG); refer to the product [SPC](http://www.medicines.org.uk) for a full list of excipients. [↑](#footnote-ref-3)
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, in preference to a substantial delay to vaccination with a slightly better matched vaccine. [↑](#footnote-ref-4)