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## National protocol for COVID-19 mRNA vaccine BNT162b2 (Pfizer/BioNTech)

Reference no: COVID-19 mRNA vaccine BNT162b2 protocol

Version no: v02.00

Valid from: 10 January 2021

Review date: 10 July 2021

Expiry date: 9 January 2022

This protocol is for the administration of COVID-19 mRNA vaccine BNT162b2 30micrograms in 0.3ml to individuals in accordance with the national COVID-19 vaccination programme.

This protocol is for the administration of COVID-19 mRNA Vaccine BNT162b2 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)

**Public Health England (PHE) has developed this protocol for authorisation by the Secretary of State for Health and Social Care to facilitate the delivery of the national COVID-19 vaccination programme commissioned by NHS England and NHS Improvement.**

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

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

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

A clinical supervisor, 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 dilution and drawing up of the vaccine has its own supervision requirements in accordance with [Part 1](https://www.legislation.gov.uk/uksi/2012/1916/part/1) of the HMR 2012 and will need to be done by, or under the supervision of, a 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 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.

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

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 10 years after the protocol expires.

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

[https://www.gov.uk/government/collections/covid-19-vaccination-programme](https://eur01.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.gov.uk%2Fgovernment%2Fcollections%2Fcovid-19-vaccination-programme&data=04%7C01%7Cbeth.graham%40phe.gov.uk%7C8a53f9787c3a47e478c008d892d99d6e%7Cee4e14994a354b2ead475f3cf9de8666%7C0%7C0%7C637420810633032773%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C1000&sdata=2LUZ14PEOdm7T093K6UJ3bSiHh%2Bhsg0DYXLSvnmrjYE%3D&reserved=0)

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

# **Change history**

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| **Version number** | **Change details** | **Date** |
| V01.00 | New protocol for COVID-19 mRNA Vaccine BNT162b2. | 17 December 2020 |
| V01.01 | Correction of 30mg to 30micrograms in ‘Dose and frequency of administration’ section. | 22 December 2020 |
| V02.00 | National protocol for COVID-19 mRNA vaccine BNT162b2 V01.01 amended to:   * allow Stage 2 to be undertaken by registered or non-registered persons under the supervision of a doctor, nurse or pharmacist * clarify that vaccine may be diluted, drawn up and administered by the same person or separate persons with the required competence and supervision * mention consent or ‘best-interests’ decision in accordance with the Mental Capacity Act 2005 * footnote that carers are included in priority group 6 * update criteria for exclusion and cautions pertaining to anaphylaxis * remove criteria for exclusion and update caution relating to past history of COVID-19 infection * define minimum dose interval and vaccination in accordance with national recommendations * update advice for women of childbearing age and remove requirement to avoid pregnancy until 2 months after the second dose of vaccine * allow for vaccination of breastfeeding women * allow for administration of a sixth dose if obtainable from the multidose vial * update supplies section to order via the national appointed supply route for the provider | 5 January 2021 |

1. **Ministerial authorisation**

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

On 10/01/2021 the Secretary of State for Health and Social Care, Matt Hancock, approved this protocol in accordance with [regulation 247A](https://www.legislation.gov.uk/uksi/2020/1125/regulation/14/made) of HMR 2012.

Any provider/contractor administering COVID-19 mRNA Vaccine BNT162b2 under this protocol must work strictly within the terms of this protocol and contractual arrangements with the commissioner for the delivery of the national COVID-19 vaccination programme.

Assembly, final preparation and administration of vaccines supplied and administered under this protocol must be subject to NHS governance arrangements and standard operating procedures that ensure that the safety, quality or efficacy of the product is not compromised. The assembly, final preparation and administration of the vaccines must also be in accordance with the instructions for usage that are conditions of the authorisation to supply the product. These conditions for usage are in the Information for UK Healthcare Professionals, published alongside the conditions of authorisation and available at:

<https://www.gov.uk/government/publications/regulatory-approval-of-pfizer-biontech-vaccine-for-covid-19>

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

#### Characteristics of staff

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| Classes of persons permitted to administer medicinal products under this protocol |
| This protocol may be followed wholly from assessment through to post-vaccination by an appropriately registered healthcare professional (see [Table 2](#Table2)). Alternatively, multiple persons may undertake stages in the vaccination pathway in accordance with this protocol. Where multiple person models are used, the service provider/contractor must ensure that all elements of the protocol are complied with in the provision of vaccination to each individual. The service provider/contractor is responsible for ensuring that 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 doctor, nurse or pharmacist trained and competent in all aspects of the protocol and provide clinical supervision, see [page 1](#Page1ClinicalSupervisor), for the overall provision of clinical care provided under the legal authority of the protocol.  **Table 1: Operational stages of activity under this protocol**   |  |  |  | | --- | --- | --- | | Stage 1 | 1. Assessment of the individual presenting for vaccination 2. Provide information and obtain informed consent[[1]](#footnote-2) 3. Provide advice to the individual | Registered Healthcare Professionals Only | | Stage 2 | * Vaccine Preparation | Registered or non-registered persons | | Stage 3 | * Vaccine Administration | Registered or non-registered persons | | Stage 4 | * Record Keeping | Registered or non-registered persons |   Persons must only work under this protocol where they are competent to do so.  Non-professionally qualified persons operating under this protocol must be adequately supervised by experienced registered healthcare professionals.  Protocols do not remove inherent professional obligations or accountability. All persons operating under this protocol must work within their terms of employment at all times; registered healthcare professionals must also abide by their professional code of conduct.  To undertake the assigned stage(s) of activity under this protocol, persons working to this protocol must meet the criteria specified in [Table 2](#Table2) (see below).  **Table 2: Protocol stages and required characteristics of persons working under it**   |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | **Persons working to this protocol must meet the following criteria, as applicable to undertake their assigned stage(s) of activity under this protocol:** | **Clinical supervisor** | **Stage 1** | **Stage 2** | **Stage 3** | **Stage 4** | | must be authorised by name as an approved person under the current terms of this protocol before working to it, see [Section 4](#PractitionerAuthorisationSheet) | Y | Y | Y | Y | 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:   * nurses, nursing associates and midwives currently registered with the Nursing and Midwifery Council (NMC) * pharmacists currently registered with the General Pharmaceutical Council (GPhC) * chiropodists/podiatrists, dieticians, occupational therapists, operating department practitioners, orthoptists, orthotists/prosthetists, paramedics, physiotherapists, radiographers and speech and language therapists currently registered with the Health and Care Professions Council (HCPC) * dental hygienists and dental therapists registered with the General Dental Council * optometrists registered with the General Optical Council. | Y | 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 | N | Y | N | N | | must be competent in the handling of the vaccine product, procedure for dilution of the vaccine and use of the correct technique for drawing up the correct dose | Y | N | Y | N | N | | must be familiar with the vaccine product and alert to any changes in the manufacturers summary of product characteristics (SPC), should it become licensed, or the [Regulation 174 Information for UK Healthcare Professionals](https://www.gov.uk/government/publications/regulatory-approval-of-pfizer-biontech-vaccine-for-covid-19) and familiar with the national recommendations for the use of this vaccine | Y | 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 | Y | N | | must be familiar with, and alert to changes in the relevant standard operating procedures (SOPs) and commissioning arrangements for the national COVID-19 vaccination programme | Y | Y | Y | Y | N | | must have undertaken training appropriate to this protocol and relevant to their role, as required by local policy and national standard operating procedures and in line with the [Training recommendations for COVID-19 vaccinators](https://www.gov.uk/government/publications/covid-19-vaccinator-training-recommendations/training-recommendations-for-covid-19-vaccinators) | Y | Y | Y | 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 | 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 | Y | N | Y | Y | N | | must be competent in intramuscular injection technique if they are administering the vaccine | Y | 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 | Y | N | Y | N | | must have access to the protocol and relevant [COVID-19 vaccination programme](https://www.gov.uk/government/collections/covid-19-vaccination-programme) online resources such as the [Green Book](https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book), particularly [Chapter 14a](https://www.gov.uk/government/publications/covid-19-the-green-book-chapter-14a), and the PHE [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 | Y | N | | must understand the importance of making sure vaccine information is recorded on the relevant data system, meeting competencies 3k and 3l of the [COVID-19 vaccinator competency assessment tool](https://www.gov.uk/government/publications/covid-19-vaccinator-competency-assessment-tool) | Y | Y | Y | Y | Y | | must have been signed off as competent using the [COVID-19 vaccinator competency assessment tool](https://www.gov.uk/government/publications/covid-19-vaccinator-competency-assessment-tool) if new to or returning to immunisation after a prolonged period (more than 12 months), or have used the tool for self-assessment if an experienced vaccinator (vaccinating within past 12 month) | Y | Y | Y | Y | Y | | should fulfil any additional requirements defined by local policy | Y | Y | Y | Y | Y | |

**STAGE 1: Assessment of the individual presenting for vaccination**

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| **ACTIVITY STAGE 1a:** | **Assess the individual presenting for vaccination against the inclusion and exclusion criteria below. 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 mRNA Vaccine BNT162b2 is indicated for the active immunisation of individuals for the prevention of coronavirus (SARS-CoV-2) infection and subsequent COVID-19, in accordance with the national COVID-19 vaccination programme (see [COVID-19 vaccination programme page](https://www.gov.uk/government/collections/covid-19-vaccination-programme)) and recommendations given in [Chapter 14a](https://www.gov.uk/government/publications/covid-19-the-green-book-chapter-14a) of Immunisation Against Infectious Disease: the ‘Green Book’ and subsequent correspondence/publications from PHE and/or NHS England and NHS Improvement. |
| **Criteria for inclusion** | COVID-19 mRNA Vaccine BNT162b2 should be offered to individuals in accordance with Joint Committee on Vaccination and Immunisation (JCVI) guidance on [‘Priority groups for coronavirus (COVID-19) vaccination’](https://www.gov.uk/government/publications/priority-groups-for-coronavirus-covid-19-vaccination-advice-from-the-jcvi-30-december-2020) in the following order of priority, starting with those to be vaccinated first:   |  |  | | --- | --- | | **Priority** | **Risk group** | | 1 | Residents in a care home for older adults and their carers | | 2 | All those 80 years of age and over  Frontline health and social care workers (see [Chapter 14a](https://www.gov.uk/government/publications/covid-19-the-green-book-chapter-14a)) | | 3 | All those 75 years of age and over | | 4 | All those 70 years of age and over  Clinically extremely vulnerable[[2]](#footnote-3) individuals (see [Definition of clinically extremely vulnerable groups](https://www.gov.uk/government/publications/guidance-on-shielding-and-protecting-extremely-vulnerable-persons-from-covid-19/guidance-on-shielding-and-protecting-extremely-vulnerable-persons-from-covid-19#cev)) | | 5 | All those 65 years of age and over | | 6 | All individuals aged 16 to 64 years with underlying health conditions which put them at higher risk of serious disease and mortality (see [Appendix A](#AppendixA) or [Chapter 14a](https://www.gov.uk/government/publications/covid-19-the-green-book-chapter-14a))[[3]](#footnote-4) | | 7 | All those 60 years of age and over | | 8 | All those 55 years of age and over | | 9 | All those 50 years of age and over |   Only individuals included in one or more of the priority groups tabled above may be vaccinated in accordance with this protocol.  Implementation of the COVID-19 vaccination programme should aim to achieve high vaccine uptake whilst prioritising those most at risk. Implementation should also involve flexibility in vaccine deployment at a local level. Operational considerations, such as minimising wastage, may require a flexible approach to prioritisation, where decisions are taken in consultation with national or local public health experts. However, the priority order in the table above should be followed if it is reasonably practicable to do so. |
| **Criteria for exclusion[[4]](#footnote-5)** | Individuals for whom valid consent, or ‘best-interests’ decision in accordance with the Mental Capacity Act 2005, has not been obtained. The [Regulation 174 Information for UK recipients](https://www.gov.uk/government/publications/regulatory-approval-of-pfizer-biontech-vaccine-for-covid-19) for COVID-19 mRNA vaccine BNT162b2 should be available to inform consent.  Individuals who:   * are less than 16 years of age * have had a previous systemic allergic reactions (including immediate onset anaphylaxis) to a previous dose of COVID-19 mRNA Vaccine BNT162b2 or to any component of the vaccine or residues from the manufacturing process[[5]](#footnote-6) [[6]](#footnote-7) * have a history of immediate-onset anaphylaxis to multiple classes of drugs or unexplained anaphylaxis * are pregnant (see [Additional Information](#AdditionInformationPregnancy)) * are suffering from acute severe febrile illness (the presence of a minor infection is not a contraindication for vaccination) * are participating in a clinical trial of COVID-19 vaccines * have received a dose of COVID-19 vaccine in the preceding 21 days * have completed a course of COVID-19 vaccination |
| **Cautions including any relevant action to be taken**  Continued over page  **Cautions including any relevant action to be taken**  (continued) | A very small number of individuals have experienced anaphylaxis when vaccinated with the COVID-19 mRNA vaccine BNT162b2. Following close surveillance of the initial roll-out, the MHRA has advised that individuals with a history of anaphylaxis to food, an identified drug or vaccine, or an insect sting can receive any COVID-19 vaccine, as long as they are not known to be allergic to any component (excipient) of the vaccine. All recipients of the COVID-19 mRNA vaccine BNT162b2 should be kept for observation and monitored for a minimum of 15 minutes. 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)).  The British Society for Allergy and Clinical Immunology (BSACI) has advised that:   * individuals with a history of immediate onset-anaphylaxis to multiple classes of drugs or an unexplained anaphylaxis should not be vaccinated with the Pfizer BioNTech vaccine. The AstraZeneca vaccine can be used as an alternative (if not otherwise contraindicated) * individuals with a localised urticarial (itchy) skin reaction (without systemic symptoms) to the first dose of a COVID-19 vaccine should receive the second dose of vaccine with prolonged observation (30 minutes) in a setting with full resuscitation facilities (such as a hospital) * individuals with non-allergic reactions (vasovagal episodes, non-urticarial skin reaction or non-specific symptoms) to the first dose of a COVID-19 vaccine can receive the second dose of vaccine in any vaccination setting   Syncope (fainting) can occur following, or even before, any vaccination especially in adolescents as a psychogenic response to the needle injection. This can be accompanied by several neurological signs such as transient visual disturbance, paraesthesia and tonic-clonic limb movements during recovery. It is important that procedures are in place to avoid injury from faints.  Individuals with a bleeding disorder may develop a haematoma at the injection site.  Individuals with bleeding disorders may be vaccinated intramuscularly if, in the opinion of a doctor familiar with the individual's bleeding risk, vaccines or similar small volume intramuscular injections can be administered with reasonable safety by this route. If the individual receives medication/treatment to reduce bleeding, for example treatment for haemophilia, intramuscular vaccination can be scheduled shortly after such medication/treatment is administered. Individuals on stable anticoagulation therapy, including individuals on warfarin who are up to date with their scheduled INR testing and whose latest INR was below the upper threshold of their therapeutic range, can receive intramuscular vaccination. A fine needle (equal to 23 gauge or finer calibre such as 25 gauge) should be used for the vaccination, followed by firm pressure applied to the site (without rubbing) for at least 2 minutes. If in any doubt, consult with the clinician responsible for prescribing or monitoring the individual’s anticoagulant therapy. If the registered professional clinically assessing the individual is not the vaccinator, they must ensure the vaccinator is aware of the individuals increased risk of haematoma and the need to apply firm pressure to the injection site for at least 2 minutes. The individual/carer should be informed about the risk of haematoma from the injection.  On 30 December 2020 [JCVI recommendations](https://www.gov.uk/government/publications/priority-groups-for-coronavirus-covid-19-vaccination-advice-from-the-jcvi-30-december-2020) pertaining to women of childbearing age, pregnant, planning a pregnancy or breastfeeding were updated (see [Additional Information](#AdditionInformationPregnancy)).  **Past history of COVID-19 infection**  There is no evidence of any safety concerns from vaccinating individuals with a past history of COVID-19 infection, or with detectable COVID-19 antibody.  Vaccination of individuals who may be infected but asymptomatic or incubating COVID-19 infection is unlikely to have a detrimental effect on the illness. Vaccination should be deferred in those with confirmed infection to avoid onward transmission and confusing the differential diagnosis. As clinical deterioration can occur up to two weeks after infection, ideally vaccination should be deferred until clinical recovery to around four weeks after onset of symptoms or four weeks from the first confirmed positive specimen in those who are asymptomatic.  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.  **Vaccine Surveillance**  The UK regulator will maintain real-time surveillance post deployment of COVID-19 vaccines in the UK. In response to any safety signals, MHRA may provide temporary advice or make substantive amendments to the authorised conditions of the vaccine product’s supply in the UK. Supply under this protocol must be in accordance with the most up-to-date advice or amendments (see Green Book [Chapter 14a](https://www.gov.uk/government/publications/covid-19-the-green-book-chapter-14a) and [Regulatory approval of Pfizer/BioNTech vaccine for COVID-19](https://www.gov.uk/government/publications/regulatory-approval-of-pfizer-biontech-vaccine-for-covid-19)). |
| **Action to be taken if the patient is excluded** | The risk to the individual of not being immunised must be considered. The indications for risk groups are not exhaustive, and the healthcare practitioner should consider the risk of COVID-19 exacerbating any underlying disease that an individual may have, as well as the risk of serious illness from coronavirus (SARS-CoV-2) itself. Where appropriate, such individuals should be referred for assessment of clinical risk. Where risk is identified as equivalent to those currently eligible for immunisation, vaccination may only be provided by an appropriate prescriber or on a patient specific basis, under a patient specific direction (PSD).  Children at very high risk of exposure and serious outcomes such as older children with severe neuro-disabilities that require residential care should be referred to specialists for consideration for vaccination, under a PSD, following assessment of the individual’s risk.  Individuals who have had previous systemic allergic reaction (including immediate onset anaphylaxis) to a previous dose of COVID-19 mRNA vaccine BNT162b2 or any component of the vaccine should not receive further COVID-19 mRNA vaccine BNT162b2. Individuals who suffer from milder reactions following the first dose of COVID-19 mRNA vaccine BNT162b2 may proceed to a second dose in an appropriate setting (see [Cautions](#Cautions)).  Individuals who have a history of immediate-onset anaphylaxis to multiple classes of drugs or unexplained anaphylaxis, should not be vaccinated with COVID-19 mRNA vaccine BNT162b2. The AstraZeneca COVID-19 vaccine (ChAdOx1-S [recombinant]) can be used as an alternative (if not otherwise contraindicated).  Women who are pregnant should not routinely be offered COVID-19 mRNA vaccine BNT162b2 during pregnancy and should postpone vaccination until completion of pregnancy. Vaccination may be considered for those at high risk of exposure or very high risk of serious complications of COVID-19 (see [Additional Information](#AdditionInformationPregnancy)). A PSD would be required.  In case of postponement due to acute illness, advise when the individual can be vaccinated and, if possible, ensure another appointment is arranged.  Individuals who are participating in a clinical trial of COVID-19 vaccines who present for vaccination should be referred back to the investigators.  Document the reason for exclusion and any action taken. |
| **Action to be taken if the patient or carer declines treatment** | Informed consent, from the individual or a person legally able to act on the person’s behalf, must be obtained for each administration and recorded appropriately. Where a person lacks the capacity, in accordance with the Mental Capacity Act 2005, a decision to vaccinate may be made in the individual’s best interests.  Advise the individual/carer about the protective effects of the vaccine, the risks of infection and potential complications if not immunised.  Document advice given and the decision reached. |
| **Arrangements for referral for medical advice** | As per local policy. |

**STAGE 1b: Description of treatment**

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| **ACTIVITY STAGE 1b:** | **Consider any relevant cautions, interactions or adverse drug reactions.**  **Provide advice to the individual and obtain informed consent1.**  **Record patient consent1 and ensure vaccinator, if another person, is informed of the vaccine product to be administered.** |
| **Name, strength & formulation of drug** | COVID-19 mRNA vaccine BNT162b2 concentrate for solution for injection, presented as a multidose vial.  1 vial (0.45ml) contains at least 5 doses of 30micrograms of BNT162b2 RNA (embedded in lipid nanoparticles).  Vials may alternatively be labelled:   * BNT162b2 (SARS-COV-2-mRNA vaccine), or * Pfizer-BioNTech COVID-19 vaccine |
| **Legal category** | COVID-19 mRNA Vaccine BNT162b2 did not have a UK marketing authorisation at the time of writing this protocol.  COVID-19 mRNA Vaccine BNT162b2 has been provided temporary authorisation by the MHRA for supply in the UK under regulation 174 and 174A of HMR 2012, see <https://www.gov.uk/government/publications/regulatory-approval-of-pfizer-biontech-vaccine-for-covid-19>  The regulation 174 authorised product is categorised as a prescription only medicine (POM). |
| **Black triangle▼** | COVID-19 mRNA Vaccine BNT162b2 is authorised for temporary supply in the UK in accordance with a Regulation 174 authorisation.  As a new vaccine product, MHRA has a specific interest in the reporting of adverse drug reactions for this product, see <https://yellowcard.mhra.gov.uk/the-yellow-card-scheme/> |
| **Off-label use** | COVID-19 mRNA Vaccine BNT162b2 is supplied in the UK in accordance with regulation 174 and did not have a UK marketing authorisation at the time of writing this protocol.  As part of the consent process, healthcare professionals must inform the individual/carer that this vaccine has been authorised for temporary supply in the UK by the regulator, MHRA, and that it is being offered in accordance with national guidance. |
| **Drug interactions**  Continued over page  **Drug interactions**  (continued) | 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.  It should not be routine to offer appointments to give this vaccine at the same time as other vaccines. Scheduling should ideally be separated by an interval of at least 7 days to avoid incorrect attribution of potential adverse events.  Where individuals in an eligible cohort present having received another inactivated or live vaccine, COVID-19 vaccination should still be considered. The same applies for other live and inactivated vaccines where COVID-19 vaccination has been received first or where an individual presents requiring two vaccines. In most cases, vaccination should proceed, and may be provided under the protocol, to avoid any further delay in protection and to avoid the risk of the individual not returning for a later appointment. In such circumstances, individuals should be informed about the likely timing of potential adverse events relating to each vaccine. |
| **Identification & management of adverse reactions** | The most frequent adverse reactions in participants 16 years of age and older were pain at the injection site (> 80%), fatigue (> 60%), headache (> 50%), myalgia (> 30%), chills (> 30%), arthralgia (> 20%) and pyrexia (> 10%) and were usually mild or moderate in intensity and resolved within a few days after vaccination. Redness at the injection site, injection site swelling, and nausea are reported as common. Lymphadenopathy was reported in less than 1%.  Individuals should be provided with the advice within the leaflet [What to expect after your COVID-19 vaccination](https://www.healthpublications.gov.uk/ViewArticle.html?sp=Swhattoexpectaftermycovidvaccinationleaflet8pdla5), which covers the reporting of adverse reactions and their management, such as with analgesic and/or antipyretic medication.  Vaccinated individuals should be advised that the COVID-19 vaccine may cause a mild fever, which usually resolves within 48 hours. This is a common, expected reaction and isolation is not required unless COVID-19 is suspected.  A detailed list of adverse reactions is available in the [Regulation 174 Information for UK Healthcare Professionals](https://www.gov.uk/government/publications/regulatory-approval-of-pfizer-biontech-vaccine-for-covid-19). |
| **Reporting procedure of adverse reactions** | Healthcare professionals and individuals/carers should report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Coronavirus Yellow Card reporting scheme on:  <https://coronavirus-yellowcard.mhra.gov.uk/> Or search for MHRA Yellow Card in the Google Play or Apple App Store.  As a new vaccine product, MHRA has a specific interest in the reporting of all adverse drug reactions for this product, see <https://yellowcard.mhra.gov.uk/the-yellow-card-scheme/>  Any adverse reaction to a vaccine should also be documented in the individual’s record and the individual’s GP should be informed.  The Green Book [Chapter 14a](https://www.gov.uk/government/publications/covid-19-the-green-book-chapter-14a) and [Chapter 8](https://www.gov.uk/government/publications/vaccine-safety-and-adverse-events-following-immunisation-the-green-book-chapter-8) provide further details regarding the clinical features of reactions to be reported as ‘anaphylaxis’. Allergic reactions that do not include the clinical features of anaphylaxis should be reported as ‘allergic reaction’. |
| **Written information to be given to patient or carer** | Ensure the individual has been provided appropriate written information such as the:   * [Regulation 174 Information for UK recipients](https://www.gov.uk/government/publications/regulatory-approval-of-pfizer-biontech-vaccine-for-covid-19) for COVID-19 mRNA vaccine BNT162b2 * [COVID-19 Vaccination Record Card](https://www.healthpublications.gov.uk/ViewArticle.html?sp=Scovidvaccinerecordcard2doses) * [What to expect after your COVID-19 vaccination](https://www.healthpublications.gov.uk/ViewArticle.html?sp=Swhattoexpectaftermycovidvaccinationleaflet8pdla5)  * [COVID-19 vaccination: women of childbearing age, currently pregnant, or breastfeeding](https://www.gov.uk/government/publications/covid-19-vaccination-women-of-childbearing-age-currently-pregnant-planning-a-pregnancy-or-breastfeeding) |
| **Patient advice / follow up treatment** | 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. Nationally recommended protective measures should still be followed.  Inform the individual/carer of possible side effects and their management.  The individual/carer should be advised to seek appropriate advice from a healthcare professional in the event of an adverse reaction.  Advise the individual/carer that they can report side effects directly via the national reporting system run by the MHRA known as the Coronavirus Yellow Card reporting scheme on:  <https://coronavirus-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.  Vaccine recipients should be monitored for 15 mins after vaccination, with a longer observation period when indicated after clinical assessment (see [Cautions](#Cautions)).  When applicable, advise the individual/carer when to return for vaccination or when a subsequent vaccine dose is due. |
| **Special considerations / additional information**  Continued over page  **Special considerations / additional information**  (continued) | Ensure there is immediate access to adrenaline (epinephrine) 1 in 1,000 injection and access to a telephone at the time of vaccination.  A protocol for the management of anaphylaxis and an anaphylaxis pack must be readily available in case of an anaphylactic event. Immediate treatment should include early treatment with 500micrograms of intramuscular adrenaline (0.5ml of 1:1000 or 1mg/ml adrenaline), with an early call for help and further IM adrenaline every 5 minutes. The health professionals overseeing the immunisation service must be trained to recognise an anaphylactic reaction and be familiar with techniques for resuscitation of an individual with anaphylaxis.  Minor illnesses without fever or systemic upset are not valid reasons to postpone vaccination. If an individual is acutely unwell, vaccination should be postponed until they have fully recovered. This is to avoid confusing the differential diagnosis of any acute illness (including COVID-19) by wrongly attributing any signs or symptoms to the adverse effects of the vaccine.  **Pregnancy**  There is no known risk associated with giving inactivated, recombinant viral or bacterial vaccines or toxoids during pregnancy or whilst breast-feeding. Since inactivated vaccines cannot replicate, they cannot cause infection in either the mother or the fetus. As with most pharmaceutical products, specific clinical trials of COVID-19 vaccine in pregnancy have not been carried out.  Developmental and reproductivity testing of the Pfizer BioNTech and AstraZeneca COVID-19 vaccines in animals have not raised any concerns. Although the available data do not indicate any harm to pregnancy, there is insufficient evidence to recommend routine use of COVID-19 vaccines during pregnancy.  Routine questioning about last menstrual period and/or pregnancy testing is not required before offering the vaccine. If a woman finds out she is pregnant after she has started a course of vaccine, routine advice is to complete her pregnancy before finishing the recommended schedule. Women should be offered vaccine as soon as possible after pregnancy.  JCVI has advised that vaccination in pregnancy should be considered where the risk of exposure to SARS-CoV2 infection is high and cannot be avoided, or where the woman has underlying conditions that put them at very high risk of serious complications of COVID-19. Vaccination of pregnant women is not covered by this protocol so a prescriber or PSD would be required.  Termination of pregnancy following inadvertent immunisation should not be recommended.  Surveillance of administration in pregnancy is being conducted for the UK by the PHE Immunisation Department, to whom such cases should be reported <https://www.gov.uk/guidance/vaccination-in-pregnancy-vip>.  **Breastfeeding**  There is no known risk associated with giving non-live vaccines whilst breastfeeding. JCVI advises that breastfeeding women may be offered vaccination with the Pfizer BioNTech COVID-19 mRNA vaccine BNT162b2.  The developmental and health benefits of breastfeeding should be considered along with the mother’s clinical need for immunisation against COVID-19, and the woman should be informed about the absence of safety data for the vaccine in breastfeeding women. Breastfeeding women may be vaccinated under this protocol.  **Previous incomplete vaccination**  Other COVID-19 vaccines may become available after this protocol has been written. There is no evidence on the interchangeability of the COVID-19 vaccines although studies are underway. Therefore, every effort should be made to determine which vaccine the individual received and to complete the course with the same vaccine. For individuals who started the schedule and who attend for vaccination at a site where the same vaccine is not available, or if the first product received is unknown, it is reasonable to offer one dose of the locally available product to complete the schedule. This option is preferred if the individual is likely to be at immediate high risk or is considered unlikely to attend again. In these circumstances, as COVID-19 vaccines are based on the spike protein, it is likely the second dose will help to boost the response to the first dose. |

**STAGE 2: Vaccine Preparation**

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| **ACTIVITY STAGE 2:** | **Vaccine preparation** |
| **Vaccine presentation** | COVID-19 mRNA vaccine BNT162b2 30micrograms in 0.3ml dose concentrate for suspension for injection multidose vial (Pfizer-BioNTech).  Vials may alternatively be labelled:   * BNT162b2 (SARS-COV-2-mRNA vaccine), or * Pfizer-BioNTech COVID-19 vaccine |
| **Supplies** | Providers should order COVID-19 vaccines via the national appointed supply route for the provider.  COVID-19 vaccines for the national COVID-19 vaccination programme will be made available for ordering on the ImmForm website: <https://portal.immform.phe.gov.uk/>  NHS standard operating procedures should be followed for appropriate ordering, storage, handling, preparation, administration and waste minimisation of COVID-19 mRNA Vaccine BNT162b2, which ensure use is in accordance with [Regulation 174 Information for UK Healthcare Professionals](https://www.gov.uk/government/publications/regulatory-approval-of-pfizer-biontech-vaccine-for-covid-19) and [Conditions of Authorisation for Pfizer/BioNTech COVID-19 vaccine BNT162b2](https://www.gov.uk/government/publications/regulatory-approval-of-pfizer-biontech-vaccine-for-covid-19). |
| **Storage** | COVID-19 mRNA Vaccine BNT162b2 is supplied from the manufacturer as a multiple-dose (5-dose) vial of frozen, preservative-free concentrate, which requires storage in an ultra-low temperature freezer at -80°C to -60°C or a thermal container at -90°C to -60°C.  Shelf life is 6 months at -80°C to -60°C  Store in original packaging in order to protect from light.  The undiluted vaccine can be stored for up to 5 days (120 hours) at 2-8°C, or up to 2 hours at temperatures up to 25°C, prior to use.  During storage, minimise exposure to room light, and avoid exposure to direct sunlight and ultraviolet light. Thawed vials can be handled in room light conditions.  Once thawed the vaccine cannot be re-frozen.  After aseptic dilution, vials should be marked with the dilution date and time, stored at 2°C to 25°C and used as soon as practically possible and within 6 hours from the time of dilution. The vaccine does not contain preservative.  Once the dose is drawn up from the vial it should be administered immediately.  The above details relate to storage requirements and available stability data at the time of product authorisation. This may be subject to amendment as more data becomes available. Refer to NHS standard operating procedures for the service and the most up to date manufacturer’s recommendations in the [Conditions of Authorisation for Pfizer/BioNTech COVID-19 vaccine BNT162b2](https://www.gov.uk/government/publications/regulatory-approval-of-pfizer-biontech-vaccine-for-covid-19) and [Regulation 174 Information for UK Healthcare Professionals](https://www.gov.uk/government/publications/regulatory-approval-of-pfizer-biontech-vaccine-for-covid-19). |
| **Vaccine preparation**  Continued over page  **Vaccine preparation**  (continued) | Using aseptic technique, thawed COVID-19 mRNA Vaccine BNT162b2 requires dilution in its original vial with 1.8ml of unpreserved sodium chloride 0.9% solution for injection, prior to withdrawing a 0.3ml dose for administration.  Vaccine should be prepared in accordance with manufacturers recommendations (see [Regulation 174 Information for UK Healthcare Professionals](https://www.gov.uk/government/publications/regulatory-approval-of-pfizer-biontech-vaccine-for-covid-19)) and NHS standard operating procedures for the service.  Gently invert the diluted solution 10 times. Do not shake the vaccine.  The vaccine dose should be drawn up from the diluted vial immediately prior to administration.  Inspect visually prior to administration and ensure appearance is consistent with the description in the [Regulation 174 Information for UK Healthcare Professionals](https://www.gov.uk/government/publications/regulatory-approval-of-pfizer-biontech-vaccine-for-covid-19), that is an off-white solution with no particulates visible. Discard the vaccine if particulates or discolouration are present.  Each vial contains at least 5 doses. It is normal for a small amount of liquid to remain in the vial after withdrawing the final dose. When low dead volume syringes and/or needles are used, the amount remaining in the vial after 5 doses have been extracted may be sufficient for an additional (sixth) dose. Care should be taken to ensure a full 0.3ml will be administered. Where a full 0.3ml dose cannot be extracted the contents should be discarded. Any unused vaccine should be discarded 6 hours after dilution.  The vaccine may be diluted, drawn up and administered by the same person or separate persons with the required competence and supervision. If the vaccine is to be administered by a person other than the person preparing it, ensure that there are clear procedures for transferring the vaccine to the vaccinator in a safe way, allowing for appropriate checks of vaccine particulars, batch number and expiry by both parties. |
| **Disposal** | Follow local clinical waste policy and NHS standard operating procedures and ensure safe and secure waste disposal.  Equipment used for vaccine preparation, including used vials, ampoules, or discharged vaccines in a syringe or applicator, should be disposed of safely and securely, according to local authority regulations and guidance in the [technical memorandum 07-01](https://www.gov.uk/government/publications/guidance-on-the-safe-management-of-healthcare-waste): Safe management of healthcare waste (Department of Health, 2013). |

**STAGE 3: Vaccine Administration**

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| **ACTIVITY STAGE 3:** | **Before administering the vaccine, ensure:**   1. **the individual has been assessed in accordance with stage one of this protocol** 2. **the vaccine to be administered has been identified, by the registered practitioner consenting the individual, as COVID-19 mRNA Vaccine BNT162b2** 3. **consent for vaccination has been provided and documented1**   **Administer COVID-19 mRNA Vaccine BNT162b2 and provide any post-vaccination advice.** |
| **Vaccine to be administered** | COVID-19 mRNA Vaccine BNT162b2, COVID-19 mRNA vaccine BNT162b2 30micrograms in 0.3ml dose |
| **Dose and frequency of administration** | A two-dose course should be administered consisting of 30micrograms in 0.3ml followed by a second dose of 30micrograms in 0.3ml after an interval of at least 21 days. For operational purposes the second dose may be given between 3 to 12 weeks following the first dose or in accordance with official guidance at the time.  If an interval longer than the recommended interval is left between doses, the second dose should still be given (using the same vaccine as was given for the first dose if possible, see [Additional Information](#AdditionalInformationIncompleteVacc)). The course does not need to be restarted. |
| **Duration of treatment** | See [Dose and frequency of administration](#DoseAndFrequencyOfAdministration) above.  Booster doses of COVID-19 vaccines are not yet recommended because the need for, and timing of, boosters has not yet been determined. |
| **Quantity to be supplied / administered** | Administer 30micrograms in 0.3ml  A two-dose course should be completed. |
| **Route / method of administration**  Continued over page  **Route / method of administration**  (continued) | COVID-19 mRNA Vaccine BNT162b2 30micrograms in 0.3ml, is for administration by intramuscular injection only, preferably into deltoid region of the upper arm.  Vaccinators should administer a 0.3ml dose prepared in accordance with [Stage 2](#Stage2) above. Where it is within their competence, experienced vaccinators may draw the required 0.3ml dose from a vial diluted 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 receive, check, and use the vaccine immediately after preparation.  Do not shake the vaccine.  Check product name, batch number and expiry prior to administration.  Inspect visually prior to administration and ensure appearance is consistent with the description in the [Regulation 174 Information for UK Healthcare Professionals](https://www.gov.uk/government/publications/regulatory-approval-of-pfizer-biontech-vaccine-for-covid-19), that is an off-white solution with no particulates visible. Discard the vaccine if particulates or discolouration are present.  Where the individual has been identified by the assessing registered professional as being at increased risk of bleeding, a fine needle (equal to 23 gauge or finer calibre such as 25 gauge) should be used for the vaccination, followed by firm pressure applied to the site (without rubbing) for at least 2 minutes. The individual/carer should be informed about the risk of haematoma from the injection. |
| **Disposal** | Follow local clinical waste policy and NHS standard operating procedures and ensure safe and secure waste disposal.  Equipment used for immunisation, including used vials, ampoules, or discharged vaccines in a syringe or applicator, should be disposed of safely and securely according to local authority regulations and guidance in the [technical memorandum 07-01](https://www.gov.uk/government/publications/guidance-on-the-safe-management-of-healthcare-waste): Safe management of healthcare waste (Department of Health, 2013). |
| **Post-vaccination advice** | Vaccine recipients should be monitored for 15 mins after vaccination, with a longer observation period when indicated after clinical assessment (see [Cautions](#Cautions)).  Ensure the individual has been provided appropriate written information such as the:   * [Regulation 174 Information for UK recipients](https://www.gov.uk/government/publications/regulatory-approval-of-pfizer-biontech-vaccine-for-covid-19) for COVID-19 mRNA vaccine BNT162b2 * [COVID-19 Vaccination Record Card](https://www.healthpublications.gov.uk/ViewArticle.html?sp=Scovidvaccinerecordcard2doses) * [What to expect after your COVID-19 vaccination](https://www.healthpublications.gov.uk/ViewArticle.html?sp=Swhattoexpectaftermycovidvaccinationleaflet8pdla5) |

**STAGE 4: Recording vaccine adminstration**

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| **ACTIVITY STAGE 4:** | **Complete a record of vaccination for the individual and in accordance with local policy.**  **The required records should be completed by the person who is undertaking the recorded activity or a designated record keeper who is a witness to the activity undertaken.** |
| **Records** | Record:   * that valid informed consent was given or a decision to vaccinate made in the individual’s best interests in accordance with the Mental Capacity Act 2005 * 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 and that appropriate advice has been given) * name of immuniser and, where different from the immuniser, ensure the professional assessing the individual, person preparing the vaccine, and person completing the vaccine record are identified * name and brand of vaccine * date of administration * dose, form and route of administration of vaccine * quantity administered * batch number and expiry date * anatomical site of vaccination * advice given, including advice given if excluded or declines immunisation * details of any adverse drug reactions and actions taken * supplied via national protocol   Records should be signed and dated (or password-controlled immuniser’s record on e-records).  All records should be clear, legible and contemporaneous.  A variety of COVID-19 vaccines are in development and may become available in the future, it is especially important that the exact brand of vaccine, batch number and site at which each vaccine is given is accurately recorded in the individual’s records.  It is important that vaccinations are recorded in a timely manner on appropriate health care records for the individual. Systems should be in place to ensure this information is returned to the individual’s general practice record to allow clinical follow up and to avoid duplicate vaccination.  A record of all individuals receiving treatment under this protocol should also be kept for audit purposes in accordance with local and national policy. |

1. **Key references**

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| **Key references**  Continued over page  **Key references**  (continued) | **COVID-19 mRNA vaccine BNT162b2 vaccination**   * Immunisation Against Infectious Disease: The Green Book, [Chapter 14a](https://www.gov.uk/government/publications/covid-19-the-green-book-chapter-14a). Published 31 December 2020.   <https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book>   * COVID-19 vaccination programme. Updated 8 December 2020.   <https://www.gov.uk/government/collections/covid-19-vaccination-programme> Priority groups for coronavirus (COVID-19) vaccination: advice from the JCVI. Published 30 December 2020https://www.gov.uk/government/publications/priority-groups-for-coronavirus-covid-19-vaccination-advice-from-the-jcvi-30-december-2020  * Definition of clinically extremely vulnerable groups <https://www.gov.uk/government/publications/guidance-on-shielding-and-protecting-extremely-vulnerable-persons-from-covid-19/guidance-on-shielding-and-protecting-extremely-vulnerable-persons-from-covid-19#cev> * Training recommendations for COVID-19 vaccinators. Published 8 December 2020. <https://www.gov.uk/government/publications/covid-19-vaccinator-training-recommendations/training-recommendations-for-covid-19-vaccinators> * National COVID-19 vaccination e-learning programme   <https://www.e-lfh.org.uk/programmes/covid-19-vaccination/>   * COVID-19 vaccinator competency assessment tool. Published 8 December 2020.   <https://www.gov.uk/government/publications/covid-19-vaccinator-competency-assessment-tool>   * COVID-19: vaccination programme guidance for healthcare practitioners. Published 11 December 2020.   <https://www.gov.uk/government/publications/covid-19-vaccination-programme-guidance-for-healthcare-practitioners>   * Regulatory approval of Pfizer / BioNTech vaccine for COVID-19, including [Regulation 174 Information for UK Healthcare Professionals](https://www.gov.uk/government/publications/regulatory-approval-of-pfizer-biontech-vaccine-for-covid-19) and [Regulation 174 Information for UK recipients](https://www.gov.uk/government/publications/regulatory-approval-of-pfizer-biontech-vaccine-for-covid-19) for COVID-19 mRNA vaccine BNT162b2 and [Conditions of Authorisation for Pfizer/BioNTech COVID-19 vaccine BNT162b2](https://www.gov.uk/government/publications/regulatory-approval-of-pfizer-biontech-vaccine-for-covid-19)   <https://www.gov.uk/government/publications/regulatory-approval-of-pfizer-biontech-vaccine-for-covid-19>  **General**   * Health Technical Memorandum 07-01: Safe Management of Healthcare Waste. Department of Health 20 March 2013 <https://www.gov.uk/government/publications/guidance-on-the-safe-management-of-healthcare-waste> * PHE Vaccine Incident Guidance   <https://www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors>   * Regulation 247A, UK Statutory Instrument 2012 No. 1916, The Human Medicines Regulations 2012   <https://www.legislation.gov.uk/uksi/2012/1916/regulation/247A>   * UK Statutory Instrument 2020 No. 1125, The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020   <https://www.legislation.gov.uk/uksi/2020/1125/contents/made> |

**4. Practitioner/staff authorisation sheet**

**COVID-19 mRNA Vaccine BNT162b2** **protocol v02.00**

**Valid from: 10/01/2021 Expiry: 09/01/2022**

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.

**APPENDIX A**

**Clinical risk groups 16 years of age and over who should receive COVID-19 immunisation**

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| Chronic respiratory disease | Individuals with a severe lung condition, including those with asthma that requires continuous or repeated use of systemic steroids or with previous exacerbations requiring hospital admission, and chronic obstructive pulmonary disease (COPD) including chronic bronchitis and emphysema; bronchiectasis, cystic fibrosis, interstitial lung fibrosis, pneumoconiosis and bronchopulmonary dysplasia (BPD). |
| Chronic heart disease and vascular disease | Congenital heart disease, hypertension with cardiac complications, chronic heart failure, individuals requiring regular medication and/or follow-up for ischaemic heart disease. This includes individuals with atrial fibrillation, peripheral vascular disease or a history of venous thromboembolism. |
| Chronic kidney disease | Chronic kidney disease at stage 3, 4 or 5, chronic kidney failure, nephrotic syndrome, kidney transplantation. |
| Chronic liver disease | Cirrhosis, biliary atresia, chronic hepatitis. |
| Chronic neurological disease | Stroke, transient ischaemic attack (TIA). Conditions in which respiratory function may be compromised due to neurological disease (e.g. polio syndrome sufferers). This includes individuals with cerebral palsy, severe or profound learning disabilities, Down’s Syndrome, multiple sclerosis, epilepsy, dementia, Parkinson’s disease, motor neurone disease and related or similar conditions; or hereditary and degenerative disease of the nervous system or muscles; or severe neurological disability. |
| Diabetes mellitus | Any diabetes, including diet-controlled diabetes. |
| Immunosuppression | Immunosuppression due to disease or treatment, including patients undergoing chemotherapy leading to immunosuppression, patients undergoing radical radiotherapy, solid organ transplant recipients, bone marrow or stem cell transplant recipients, HIV infection at all stages, multiple myeloma or genetic disorders affecting the immune system (e.g. IRAK-4, NEMO, complement disorder, SCID).  Individuals who are receiving immunosuppressive or immunomodulating biological therapy including, but not limited to, anti-TNF, alemtuzumab, ofatumumab, rituximab, patients receiving protein kinase inhibitors or PARP inhibitors, and individuals treated with steroid sparing agents such as cyclophosphamide and mycophenolate mofetil.  Individuals treated with or likely to be treated with systemic steroids for more than a month at a dose equivalent to prednisolone at 20mg or more per day.  Anyone with a history of haematological malignancy, including leukaemia, lymphoma, and myeloma and those with systemic lupus erythematosus and rheumatoid arthritis, and psoriasis who may require long term immunosuppressive treatments.  Some immunosuppressed patients may have a suboptimal immunological response to the vaccine. |
| Asplenia or dysfunction of the spleen | This also includes conditions that may lead to splenic dysfunction, such as homozygous sickle cell disease, thalassemia major and coeliac syndrome. |
| Morbid obesity | Adults with a Body Mass Index ≥40 kg/m². |
| Severe mental illness | Individuals with schizophrenia or bipolar disorder, or any mental illness that causes severe functional impairment |
| Adult carers | Those who are in receipt of a carer’s allowance, or those who are the main carer of an elderly or disabled person whose welfare may be at risk if the carer falls ill. |
| Younger adults in long-stay nursing and residential care settings | Many younger adults in residential care settings will be eligible for vaccination because they fall into one of the clinical risk groups above.  Given the likely high risk of exposure in these settings, where a high proportion of the population would be considered eligible, vaccination of the whole resident population is recommended.  Younger residents in care homes for the elderly will be at high risk of exposure, and although they may be at lower risk of mortality than older residents should not be excluded from vaccination programmes (see [priority 1](#Priority) above).  For consideration of children under 16 see [Action to be taken if the patient is excluded](#ActionIfExcluded). |

1. For those lacking mental capacity, a decision may be made in the individual’s best interests in accordance with the Mental Capacity Act 2005 [↑](#footnote-ref-2)
2. Individuals who have been identified as clinically extremely vulnerable should have this status flagged in their GP record. [↑](#footnote-ref-3)
3. This also includes those who are in receipt of a carer’s allowance, or those who are the main carer of an elderly or disabled person whose welfare may be at risk if the carer falls ill. [↑](#footnote-ref-4)
4. 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-5)
5. Contains polyethylene glycol (PEG), refer to [Regulation 174 Information for UK Healthcare Professionals](https://www.gov.uk/government/publications/regulatory-approval-of-pfizer-biontech-vaccine-for-covid-19) for a full list of excipients. [↑](#footnote-ref-6)
6. Although not yet available yet in the UK, PEG is also an excipient in the Moderna mRNA COVID-19 vaccine; individuals who have a systemic allergic reaction to the COVID-19 mRNA vaccine BNT162b2 should not be given a dose of the Moderna vaccine, and vice versa. [↑](#footnote-ref-7)