Public Health England

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

Reference no:	COVID-19 mRNA vaccine BNT162b2 protocol
Version no:	v03.00
Valid from:	26 March 2021
Review date:	1 October 2021
Expiry date:	31 March 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 of the Human Medicines Regulations 2012 (HMR 2012), inserted by The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020

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). 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 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 of this protocol or maintaining an equivalent electronic record.

A clinical supervisor[1], who must be a registered doctor, nurse or pharmacist trained and competent in all aspects of the protocol, must be present and take overall responsibility for provision of vaccination under the protocol at all times and be identifiable to service users. The final dilution and drawing up of the vaccine has its own supervision requirements in accordance with Part 1 of the HMR 2012 and will need to be done by, or under the supervision of, a registered doctor, nurse or pharmacist. If a vaccination service is being provided at scale, the clinical supervisor should only take on specific supervision requirements in relation to the dilution and drawing up of the vaccine if this can be done safely alongside their overarching role. Any time the

[1] This role is different to the Band 6 'COVID-19 Vaccination Programme - RHCP Clinical Supervisor (Vaccinations)' (see Accountability and delegation under the national protocols for COVID-19 vaccines: visual diagram at https://www.england.nhs.uk/coronavirus/publication/summary-of-the-legal-mechanisms-for-administering-the-covid-19-vaccines/).

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 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

Any concerns regarding the content of this protocol should be addressed to: immunisation@phe.gov.uk

Change History

Version	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
V03.00	National protocol for COVID-19 mRNA vaccine BNT162b2 V02.00 amended to: • add footnote to front page pertaining to the clinical supervisor role • delete clinical supervisor column from Table 2 • cover JCVI recommendations for phase 2 • include vaccination in pregnancy in accordance with the Green Book Chapter 14a, remove additional information on pregnancy and in cautions refer to Chapter 14a and the Royal College of Obstetricians and Gynaecologists (RCOG) decision aid • include JCVI advice for homelessness and detained settings • update of criteria for exclusion, cautions and actions if excluded which pertain to anaphylaxis, allergy and reactions to 1st dose • move participation in a clinical trial from the criteria for exclusion section to the caution section • include a paragraph in the legal category section to allow for protocol use to continue should the vaccine be provided a marketing authorisation in the future, so long as the protocol remains clinically appropriate • reword advice pertaining to the extraction of full doses from a vial and not pooling excess vaccine • remove specific reference to supply via ImmForm • remove detail on management of anaphylaxis which is outside the required scope of this protocol • update key references • remove Appendix A and refer directly to the Green Book Chapter 14a	17 March 2021

1. Ministerial authorisation

This protocol is not legally valid, in accordance with regulation 247A of the HMR 2012, inserted by the Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020, until it is approved by the Secretary of State for Health and Social Care.

On 26 March 2021 the Secretary of State for Health and Social Care, Matt Hancock, approved this protocol in accordance with regulation 247A 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.

1. Characteristics of staff

Classes of persons permitted to administer medicinal products under this protocol

This protocol may be followed wholly from assessment through to post-vaccination by an appropriately registered healthcare professional (see Table 2). Alternatively, multiple persons may undertake stages in the vaccination pathway in accordance with this protocol. Where multiple person models are used, the service provider/contractor must ensure that all elements of the protocol are complied with, in the provision of vaccination to each individual. The service provider/contractor is responsible for ensuring that there is a clinical supervisor present at all times and that persons are trained and competent to safely deliver the activity they are employed to provide under this protocol. As a minimum, competence requirements stipulated in the protocol must be adhered to.

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

This protocol is separated into operational stages of activity as outlined in Table 1.

The clinical supervisor[1] must be a registered doctor, nurse or pharmacist trained and competent in all aspects of the protocol and provide clinical supervision, see page 1, for the overall provision of clinical care provided under the legal authority of the protocol.

Table 1: Operational stages of activity under this protocol

Stage 1	a. Assessment of the individual presenting for vaccination b. Provide information and obtain informed consent[2] c. 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 (see below).

Table 2: Protocol stages and required characteristics of persons working under it

Persons working to this protocol must meet the following criteria, as applicable to undertake their assigned stage(s) of activity under this protocol:	**Stage 1**	**Stage 2**	**Stage 3**	**Stage 4**
must be authorised by name as an approved person under the current terms of this protocol before working to it, see Section 4	Y	Y	Y	Y
must be competent to assess individuals for suitability for vaccination, identify any contraindications or precautions, discuss issues related to vaccination and obtain informed consent[2] and must be an appropriately qualified prescriber or one of the following registered professionals who can	Y	N	N	N

[2] For those lacking mental capacity, a decision may be made in the individual's best interests in accordance with the Mental Capacity Act 2005

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.				
must be a doctor, nurse or pharmacist or a person who is under the supervision of, a doctor, nurse or pharmacist (see Page 1)	N	Y	N	N
must be competent in the handling of the vaccine product, procedure for dilution of the vaccine 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 manufacturers summary of product characteristics (SPC), should it become licensed, or the Regulation 174 Information for UK Healthcare Professionals and familiar with the national recommendations for the use of this vaccine	Y	Y	Y	N
must be familiar with, and alert to changes in relevant chapters of Immunisation Against Infectious Disease: the Green Book	Y	Y	Y	N
must be familiar with, and alert to changes in the relevant standard operating procedures (SOPs) and commissioning arrangements for the national COVID-19 vaccination programme	Y	Y	Y	N
must have undertaken training appropriate to this protocol and relevant to their role, as required by local policy and national standard operating procedures and in line with the Training recommendations for COVID-19 vaccinators	Y	Y	Y	N
must have completed the national covid-19 vaccination e-learning programme, including the relevant vaccine specific session, and/or locally-provided COVID-19 vaccine training	Y	Y	Y	N
must be competent in the correct handling and storage of vaccines and management of the cold chain if receiving, responsible for, or handling the vaccine	N	Y	Y	N
must be competent in intramuscular injection technique if they are administering the vaccine	N	N	Y	N
must be competent in the recognition and management of anaphylaxis, have completed basic life support training and able to respond appropriately to immediate adverse reactions	Y	N	Y	N
must have access to the protocol and relevant COVID-19 vaccination programme online resources such as the Green Book, particularly Chapter 14a, and the PHE COVID-19 vaccination programme: Information for healthcare practitioners document	Y	Y	Y	N
must understand the importance of making sure vaccine information is recorded on the relevant data system, meeting relevant competencies of the COVID-19 vaccinator competency assessment tool	Y	Y	Y	Y
must have been signed off as competent using the COVID-19 vaccinator competency assessment tool if new to or returning to immunisation after a prolonged period (more than 12 months), or have used the tool for self-assessment if an experienced vaccinator (vaccinating within past 12 months)	Y	Y	Y	Y
should fulfil any additional requirements defined by local or national policy	Y	Y	Y	Y

STAGE 1: Assessment of the individual presenting for vaccination

<table>
<tr><td>ACTIVITY STAGE 1a:</td><td>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.</td></tr>
<tr><td>Clinical condition or situation to which this Protocol applies</td><td>COVID-19 mRNA Vaccine BNT162b2 is indicated for the active immunisation of individuals for the prevention of coronavirus disease (COVID-19) caused by the SARS-CoV-2 virus, in accordance with the national COVID-19 vaccination programme (see COVID-19 vaccination programme page) and recommendations given in Chapter 14a of Immunisation Against Infectious Disease: the ‘Green Book’ and subsequent correspondence/publications from PHE and/or NHS England and NHS Improvement.</td></tr>
<tr><td>Criteria for inclusion

Continued over page</td><td>COVID-19 mRNA Vaccine BNT162b2 should be offered to individuals, aged 16 years and over, in accordance with Joint Committee on Vaccination and Immunisation (JCVI) guidance in the following order of priority, starting with those to be vaccinated first:
<table>
<tr><th>Priority</th><th>Risk group</th></tr>
<tr><td>1</td><td>Residents in a care home for older adults and their carers</td></tr>
<tr><td>2</td><td>All those 80 years of age and over
Frontline health and social care workers (see Chapter 14a)</td></tr>
<tr><td>3</td><td>All those 75 years of age and over</td></tr>
<tr><td>4</td><td>All those 70 years of age and over
Clinically extremely vulnerable[3] individuals (see Definition of clinically extremely vulnerable groups)</td></tr>
<tr><td>5</td><td>All those 65 years of age and over</td></tr>
<tr><td>6</td><td>All individuals aged 16 to 65 years in an at-risk group (see the table ‘Clinical risk groups 16 years of age and over who should receive COVID-19 immunisation’ in Chapter 14a)[4]</td></tr>
<tr><td>7</td><td>All those 60 years of age and over</td></tr>
<tr><td>8</td><td>All those 55 years of age and over</td></tr>
<tr><td>9</td><td>All those 50 years of age and over</td></tr>
</table>
Vaccination in pregnancy should be offered, in accordance with Chapter 14a, following a discussion of the risks and benefits of vaccination with the woman, who should be told about the absence of safety data for the vaccine in pregnancy (see Cautions).

Phase 2 of the COVID 19 vaccination programme should be offered in accordance with national recommendations and JCVI guidance on the ‘Priority groups for phase 2 of the coronavirus (COVID-19) vaccination programme’ in the following age-based order of priority, starting with the oldest adults first and proceeding in the following order:
• all those aged 40 to 49 years
• all those aged 30 to 39 years
• all those aged 18 to 29 years

Implementation of the COVID-19 vaccination programme should aim to achieve high vaccine uptake whilst prioritising those most at risk. The</td></tr>
</table>

[3] Individuals identified as clinically extremely vulnerable should have this status flagged in their GP record.
[4] This also includes adult carers.

Criteria for inclusion (continued)	priority order should be followed if it is reasonably practicable to do so. 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, such as advised for detained settings[5], where decisions are taken in consultation with national or local public health experts. JCVI advises that local teams exercise operational judgment and consider a universal offer to people experiencing homelessness and rough sleeping, alongside delivery of the programme to priority group 6, where appropriate.[5]
Criteria for exclusion[6]	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 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 reaction (including immediate onset anaphylaxis) to a previous dose of a COVID-19 mRNA Vaccine or to any component of the vaccine or residues from the manufacturing process[7] [8] • have a history of immediate anaphylaxis to multiple, different drug classes, with the trigger unidentified (this may indicate polyethylene glycol (PEG) allergy) • have a history of anaphylaxis to a vaccine, injected antibody preparation or a medicine likely to contain PEG (such as depot steroid injection, laxative) • have history of idiopathic anaphylaxis • are suffering from acute severe febrile illness (the presence of a minor infection is not a contraindication for vaccination) • have received a full 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	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. Where individuals experienced a possible allergic reaction to a first dose of COVID-19 vaccine follow the guidance in Chapter 14a of the Green Book in relation to the administration of subsequent doses. 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

[5] https://www.gov.uk/government/publications/letter-from-the-health-and-social-care-secretary-on-covid-19-vaccination-phase-1-advice

[6] 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

[7] Contains polyethylene glycol (PEG), refer to Regulation 174 Information for UK Healthcare Professionals for a full list of excipients.

[8] 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.

Cautions including any relevant action to be taken (continued)	movements during recovery. It is important that procedures are in place to avoid injury from faints. Vaccination in pregnancy should be offered in accordance with recommendations in Chapter 14a, following a discussion of the risks and benefits of vaccination with the woman. The Royal College of Obstetricians and Gynaecologists has produced a decision aid to support women to make a personal informed choice, in discussion with a healthcare professional, about whether to accept a COVID-19 vaccination in pregnancy (see https://www.rcog.org.uk/covid-vaccine). 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. Individuals who are participating in a clinical trial of COVID-19 vaccines who present for vaccination should be referred back to the trial investigators. Eligible individuals who are enrolled in vaccine trials should then be provided with written advice on whether and when they can be safely vaccinated in the routine programme. **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.
Continued over page	

Cautions including any relevant action to be taken (continued)	**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. Administration under this protocol must be in accordance with the most up-to-date advice or amendments (see Green Book Chapter 14a and Regulatory approval of Pfizer/BioNTech vaccine for COVID-19).
Action to be taken if the individual is excluded	The risk to the individual of not being immunised must be considered. The indications for risk groups are not exhaustive, and the healthcare practitioner should consider the risk of COVID-19 exacerbating any underlying disease that an individual may have, as well as the risk of serious illness from COVID-19 itself. Where appropriate, such individuals should be referred for assessment of clinical risk. Where risk is identified as equivalent to those currently eligible for immunisation, vaccination may only be provided by an appropriate prescriber or on a patient specific basis, under a PSD. 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. For individuals who have had 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. Special precautions as described in Chapter 14a, and consideration of the possibility of undiagnosed PEG-allergy, is required for individuals with: • history of immediate anaphylaxis to multiple, different drug classes, with the trigger unidentified (this may indicate PEG allergy) • history of anaphylaxis to a vaccine, injected antibody preparation or a medicine likely to contain PEG (such as depot steroid injection, laxative) • history of idiopathic anaphylaxis Such individuals should not be vaccinated with COVID-19 mRNA vaccine BNT162b2, except on the expert advice of an allergy specialist and under a PSD. The AstraZeneca COVID-19 vaccine can be used as an alternative (unless otherwise contraindicated), particularly if they previously tolerated an injected influenza vaccine. In these circumstances, the AstraZeneca COVID-19 vaccine should be administered in a setting with full resuscitation facilities (such as a hospital) and a 30 minute observation period is recommended. In case of postponement due to acute illness, advise when the individual can be vaccinated and, if possible, ensure another appointment is arranged. Document the reason for exclusion and any action taken.
Action to be taken if the individual or carer declines treatment Continued over page	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.

Action to be taken if the individual or carer declines treatment (continued)	Document advice given and the decision reached.
Arrangements for referral	As per local policy.

STAGE 1b: Description of treatment

ACTIVITY STAGE 1b:	**Consider any relevant cautions, interactions or adverse drug reactions.** **Provide advice to the individual and obtain informed consent[2].** **Record individual's consent[2] 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 6 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 Should COVID-19 mRNA vaccine BNT162b2 be issued a marketing authorisation in the future, this protocol may be used to administer licensed product so long as it remains clinically appropriate to do so and in accordance with the manufacturer's product information. COVID-19 mRNA vaccine BNT162b2 is categorised as a prescription only medicine (POM).
Black triangle▼	As a new vaccine product, MHRA has a specific interest in the reporting of adverse drug reactions for this product.
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. The Regulation 174 Information for UK recipients for COVID-19 mRNA Vaccine BNT162b2 should be available to inform consent.
Drug interactions Continued over page	Immunological response may be diminished in those receiving immunosuppressive treatment, but it is important to still immunise this group.

Drug interactions (continued)	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, fatigue, headache, myalgia, chills, arthralgia and pyrexia, 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, 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.
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 and Chapter 8 provide further details regarding the clinical features of reactions to be reported as 'anaphylaxis'. Allergic reactions that do not include the clinical features of anaphylaxis should be reported as 'allergic reaction'.

Written information to be given to individual or carer	Ensure the individual has been provided appropriate written information such as the: • Regulation 174 Information for UK recipients for COVID-19 mRNA vaccine BNT162b2 • COVID-19 Vaccination Record Card • What to expect after your COVID-19 vaccination • COVID-19 vaccination: women of childbearing age, currently pregnant, or breastfeeding
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 Chapter 14a). 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	Ensure there is immediate access to an anaphylaxis pack including adrenaline (epinephrine) 1 in 1,000 injection and easy access to a telephone at the time of vaccination. Minor illnesses without fever or systemic upset are not valid reasons to postpone vaccination. If an individual is acutely unwell, vaccination should be postponed until they have fully recovered. This is to avoid confusing the differential diagnosis of any acute illness (including COVID-19) by wrongly attributing any signs or symptoms to the adverse effects of the vaccine. **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** 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

Special considerations / additional information (continued)	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, this protocol may be used and, 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. For this reason, until additional information becomes available, further doses would not then be required.

STAGE 2: Vaccine Preparation

ACTIVITY STAGE 2:	Vaccine preparation
Vaccine presentation	COVID-19 mRNA vaccine BNT162b2 30micrograms in 0.3ml dose concentrate for solution 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/receive COVID-19 vaccines via the national appointed supply route for the provider. 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 and Conditions of Authorisation for Pfizer/BioNTech COVID-19 vaccine BNT162b2.
Storage	COVID-19 mRNA Vaccine BNT162b2 is supplied from the manufacturer as a multiple-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 and Regulation 174 Information for UK Healthcare Professionals.
Vaccine preparation Continued over page	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) and NHS standard operating procedures for the service.

Vaccine preparation (continued)	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, that is an off-white solution with no particulates visible. Discard the vaccine if particulates or discolouration are present. In order to extract at least 6 doses from a single vial, low dead-volume syringes and/or needles should be used. Each dose must contain 0.3ml of vaccine. If the amount of vaccine remaining in the vial cannot provide a full dose of 0.3 ml, discard the vial and any excess volume. Do not pool excess vaccine from multiple vials. 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: Safe management of healthcare waste (Department of Health, 2013).

STAGE 3: Vaccine Administration

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 documented[2].** **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 national 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). The course does not need to be restarted.
Duration of treatment	See Dose and frequency of administration 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	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 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. 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. 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, 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)

Continued over page

Route / method of administration (continued)	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: 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 Chapter 14a). Ensure the individual has been provided appropriate written information such as the: • Regulation 174 Information for UK recipients for COVID-19 mRNA vaccine BNT162b2 • COVID-19 Vaccination Record Card • What to expect after your COVID-19 vaccination

STAGE 4: Recording vaccine adminstration

ACTIVITY STAGE 4:	**Complete a record of vaccination for the individual and in accordance with local policy.** **The required records should be completed by the person who is undertaking the recorded activity or a designated record keeper who is a witness to the activity undertaken.**
Records	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) • 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 All records should be clear, legible and contemporaneous. As a variety of COVID-19 vaccines are available, it is especially important that the exact brand of vaccine, batch number and site at which each vaccine is given is accurately recorded in the individual's records. It is important that vaccinations are recorded in a timely manner on appropriate health care records for the individual. Systems should be in place to ensure this information is returned to the individual's general practice record in a timely manner to allow clinical follow up and to avoid duplicate vaccination. A record of all individuals receiving treatment under this protocol should also be kept for audit purposes in accordance with local and national policy.

2. Key references

Key references	**COVID-19 mRNA vaccine BNT162b2 vaccination** • Immunisation Against Infectious Disease: The Green Book, Chapter 14a. Published 12 February 2021. https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book • COVID-19 vaccination programme. Updated 20 February 2021. https://www.gov.uk/government/collections/covid-19-vaccination-programme • Priority groups for phase 2 of the coronavirus (COVID-19) vaccination programme: advice from the JCVI. Published 26 February 2021. https://www.gov.uk/government/publications/priority-groups-for-phase-2-of-the-coronavirus-covid-19-vaccination-programme-advice-from-the-jcvi • 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 16 March 2021. https://www.gov.uk/government/publications/covid-19-vaccinator-competency-assessment-tool • COVID-19: vaccination programme guidance for healthcare practitioners. Published 12 February 2021. 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 and Regulation 174 Information for UK recipients for COVID-19 mRNA vaccine BNT162b2 and Conditions of Authorisation for Pfizer/BioNTech COVID-19 vaccine BNT162b2. Published 28 January 2021. 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 • 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 v03.00
Valid from: 26/03/2021 Expiry: 31/03/2022

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.

I confirm that I have read and understood the content of this protocol and that I am willing and competent to work to it.							
Name	Designation	Activity Stage:				Signature	Date
		1	2	3	4		

Authorising registered healthcare professional

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

Note to authorising registered healthcare professional

Score through unused rows in the list of persons to prevent additions post authorisation.

If the clinical supervisor is also the authorising registered healthcare professional, they may make a self-declaration of competency above.