Public Health England

Publications approval reference: 001559

Patient Group Direction for COVID-19 mRNA vaccine BNT162b2 (Pfizer/BioNTech)

This Patient Group Direction (PGD) 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 PGD is for the administration of COVID-19 mRNA vaccine BNT162b2 by registered healthcare practitioners identified in Section 3.

Reference no:	COVID-19 mRNA vaccine BNT162b2 PGD
Version no:	v01.00
Valid from:	11 December 2020
Review date:	1 June 2021
Expiry date:	30 November 2021

Public Health England (PHE) has developed this PGD for authorisation by NHS England and NHS Improvement to facilitate the delivery of the national COVID-19 vaccination programme.

NHS England and NHS Improvement and those providing services in accordance with this PGD must not alter, amend or add to the clinical content of this document (sections 3, 4, 5 and 6); such action will invalidate the clinical sign-off with which it is provided. Section 2 may be amended only by the person(s) authorising the PGD, in accordance with Human Medicines Regulations 2012 (HMR2012)[1] Schedule 16 Part 2, on behalf of NHS England and NHS Improvement. Section 7 is to be completed by registered practitioners providing the service and their authorising/line manager.

Operation of this PGD is the responsibility of NHS England and NHS Improvement and service providers. The final authorised copy of this PGD should be kept by NHS England and NHS Improvement for 10 years after the PGD expires. Provider organisations adopting authorised versions of this PGD should also retain copies for the period specified above.

Individual registered practitioners must be authorised by name to work according to the current version of this PGD by signing section 7. A manager with the relevant level of authority should also provide a counter signature, unless there are contractual arrangements for self-declaration.

Providers must check that they are using the current version of the PGD. Amendments may become necessary prior to the published expiry date. Current versions of PHE developed COVID-19 vaccine PGDs can be found via:
https://www.gov.uk/government/collections/covid-19-vaccination-programme

The most current national recommendations should be followed. This may mean that a Patient Specific Direction (PSD) is required to administer the vaccine in line with updated recommendations that are outside the criteria specified in this PGD.

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

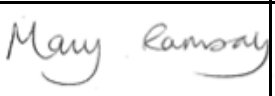
[1] This includes any relevant amendments to legislation (such as 2013 No.235, 2015 No.178, 2015 No.323 and 2020 No.1125).

Change history

Version number	Change details	Date
V01.00	New PHE PGD template for COVID-19 mRNA vaccine BNT162b2.	10 December 2020

1. PGD development

This PGD has been developed by the following health professionals on behalf of Public Health England:

Developed by:	Name	Signature	Date
Pharmacist (Lead Author)	Elizabeth Graham Lead Pharmacist Immunisation Services, Immunisation and Countermeasures, PHE		10/12/2020
Doctor	Mary Ramsay Consultant Epidemiologist and Head of Immunisation and Countermeasures, PHE		10/12/2020
Registered Nurse (Chair of Expert Panel)	David Green Nurse Consultant, Immunisation and Countermeasures, PHE		10/12/2020

In addition to the signatories above the working group included:

Name	Designation
Jane Horsfall	Senior Policy Manager, Primary Care Group, NHS England and NHS Improvement
Jo Jenkins	Specialist Pharmacist (Patient Group Directions), NHS Specialist Pharmacy Service
Jill Loader	Deputy Director, Primary Care Group, NHS England and NHS Improvement
Bhavana Reddy	Lead Pharmacy Adviser - Clinical Workstream, Flu and COVID-19 Vaccination Programme, NHS England and NHS Improvement
Gul Root	Principal Pharmaceutical Officer, Department of Health & Social Care and National lead pharmacy public health, Public Health England

This PGD has been peer reviewed by the PHE Immunisations PGD Expert Panel in accordance with PHE PGD Policy. It has been ratified by the PHE Medicines Governance Group and the PHE Quality and Clinical Governance Delivery Board.

Expert Panel

Name	Designation
Nicholas Aigbogun	Consultant in Communicable Disease Control, Yorkshire and Humber Health Protection Team, Public Health England
Sarah Dermont	Clinical Project Coordinator and Registered Midwife, NHS Infectious Diseases in Pregnancy Screening Programme, Public Health England
Ed Gardner	Advanced Paramedic Practitioner/Emergency Care Practitioner, Medicines Manager, Proactive Care Lead
Michelle Jones	Senior Medicines Optimisation Pharmacist, NHS Bristol North Somerset & South Gloucestershire CCG
Jacqueline Lamberty	Lead Pharmacist Medicines Management Services, Public Health England

Vanessa MacGregor	Consultant in Communicable Disease Control, Public Health England, East Midlands Health Protection Team
Alison Mackenzie	Consultant in Public Health Medicine, Screening and Immunisation Lead, Public Health England (South West) / NHS England and NHS Improvement South (South West)
Gill Marsh	Senior Screening and Immunisation Manager, Public Health England / NHS England and NHS Improvement (North West)
Lesley McFarlane	Screening and Immunisation Co-ordinator, Public Health England / NHS England and NHS Improvement Midlands (Central Midlands)
Tushar Shah	Lead Pharmacy Advisor, NHS England and NHS Improvement (London Region)

2. Organisational authorisation

The PGD is not legally valid until it has had the relevant organisational authorisation from NHS England and NHS Improvement completed below.

NHS England and NHS Improvement accepts governance responsibility for this PGD. Any provider delivering the national COVID-19 vaccination programme under PGD must work strictly within the terms of this PGD, relevant NHS standard operating procedures (SOPs) and contractual arrangements with the commissioner for the delivery of the national COVID-19 vaccination programme.

NHS England and NHS Improvement authorises this PGD for use by the services or providers delivering the national COVID-19 vaccination programme

Organisational approval (legal requirement)			
Role	**Name**	**Sign**	**Date**
Medical Director, COVID-19 Vaccination Programme, NHS England and NHS Improvement	Dr Jonathan Leach OBE		11 Dec 20

Section 7 provides a practitioner authorisation sheet. Individual practitioners must be authorised by name to work to this PGD. Alternative practitioner authorisation records, specifying the PGD and version number, may be used where appropriate in accordance with local policy. This may include the use of electronic records.

Assembly, final preparation and administration of vaccines supplied and administered under this PGD 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 national protocol for supply and administration during a pandemic or on a patient specific basis (that is by or on the directions of an appropriate independent prescriber). 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 PGD.

3. Characteristics of staff

Qualifications and professional registration	Practitioners must only work under this PGD where they are competent to do so. Practitioners working to this PGD must also be one of the following registered professionals who can legally supply and administer under a PGD (see Patient Group Directions: who can administer them): • nurses 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, 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. Practitioners must also fulfil all the Additional requirements.
Additional requirements	Additionally, practitioners: • must be authorised by name as an approved practitioner under the current terms of this PGD before working to it • must have undertaken appropriate training for working under PGDs for supply/administration of medicines • must be competent in the use of PGDs (see NICE Competency framework for health professionals using PGDs) • must be familiar with the vaccine product and alert to changes in the Summary of Product Characteristics (SPC), should it become licensed or the Regulation 174 Information for UK Healthcare Professionals for the vaccine and familiar with the national recommendations for the use of this vaccine • must be familiar with, and alert to changes in relevant chapters of Immunisation Against Infectious Disease: the Green Book • must be familiar with, and alert to changes in the relevant NHS standard operating procedures (SOPs) and commissioning arrangements for the national COVID-19 vaccination programme • must have undertaken training appropriate to this PGD as required by local policy and national NHS standard operating procedures and in line with the Training recommendations for COVID-19 vaccinators. • 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 • must be competent to assess individuals for suitability for vaccination, identify any contraindications or precautions, obtain informed consent and to discuss issues related to vaccination • must be competent in the correct handling and storage of vaccines, and management of the cold chain • 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 • must be competent in the intramuscular injection technique

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Additional requirements (continued)	• must be competent in the recognition and management of anaphylaxis, have completed basic life support training and be able to respond appropriately to immediate adverse reactions • must have access to the PGD and relevant COVID-19 vaccination programme online resources such as the Green Book and PHE COVID-19 vaccination programme: Information for healthcare practitioners • 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 experienced vaccinator (vaccinated within past 12 month) • should fulfil any additional requirements defined by local policy **The individual practitioner must be authorised by name, under the current version of this PGD before working according to it.**
Continued training requirements	Practitioners must ensure they are up to date with relevant issues and clinical skills relating to vaccination and management of anaphylaxis. Practitioners should be constantly alert to any subsequent recommendations from Public Health England and/or NHS England and NHS Improvement and other sources of medicines information.

4. Clinical condition or situation to which this PGD applies

<table>
<tr><td>Clinical condition or situation to which this PGD applies</td><td>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) and recommendations given in Chapter 14a of the 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</td><td>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’ 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[2] 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 years to 64 years with underlying health conditions which put them at higher risk of serious disease and mortality (see Appendix A or Chapter 14a)</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>
Only individuals included in one or more of the priority groups tabled above may be vaccinated in accordance with this PGD.

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.</td></tr>
</table>

[2] Individuals identified as clinically extremely vulnerable should have this status flagged in their GP record.

Criteria for exclusion[3]	Individuals for whom no valid consent has been obtained (for further information on consent see Reference guide to consent for examination or treatment). 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 confirmed anaphylactic reaction to a previous dose of a COVID-19 vaccine • have had a confirmed anaphylactic reaction to any component of the vaccine or residues from the manufacturing process[4] • are pregnant, think they may be pregnant, are planning to get pregnant or are breastfeeding (see Additional Information) • are suffering from acute severe febrile illness (the presence of a minor infection is not a contraindication for vaccination) • have had confirmed COVID-19 infection in the preceding 4 weeks • 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 • are advised by the UK regulator, the Medicines & Healthcare products Regulatory Agency (MHRA), not to receive COVID-19 mRNA vaccine BNT162b2 (see below and Cautions) On 9 December 2020, the MHRA issued the following guidance, announced at https://www.gov.uk/government/news/confirmation-of-guidance-to-vaccination-centres-on-managing-allergic-reactions-following-covid-19-vaccination-with-the-pfizer-biontech-vaccine: 1. Any person with a history of immediate-onset anaphylaxis to a vaccine, medicine or food should not receive the Pfizer BioNtech vaccine. A second dose of the Pfizer BioNtech vaccine should not be given to those who have experienced anaphylaxis to the first dose of Pfizer BioNtech vaccination. 2. Vaccine recipients should be monitored for 15 mins after vaccination, with a longer observation period when indicated after clinical assessment. 3. A protocol for the management of anaphylaxis and an anaphylaxis pack must always be available whenever the Pfizer BioNtech vaccine is given. Immediate treatment should include early treatment with 0.5mg 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 a patient with anaphylaxis.

[3] Exclusion under this PGD does not necessarily mean the medication is contraindicated, but it would be outside its remit and another form of authorisation will be required

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

Cautions, including any relevant action to be taken	Appropriate medical treatment, such as an anaphylaxis kit including adrenaline 1 in 1000, should be readily available in case of an anaphylactic event. 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 (see Route of Administration). All women of childbearing age should be provided the advice in the leaflet 'COVID-19 vaccination: a guide for women of childbearing age, pregnant, planning a pregnancy or breastfeeding' and their understanding checked as part of the consent process. They should be advised that pregnancy should be avoided until 2 months after the second dose of vaccine (see Additional Information below). **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 and at least four weeks after onset of symptoms or four weeks from the first positive specimen in those who are asymptomatic. Having prolonged COVID-19 symptoms is not a contraindication to receiving COVID-19 vaccine but if the patient 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 PGD must be in accordance with any such advice or amendments (see Regulatory approval of Pfizer/BioNTech vaccine for COVID-19 and for an example of such advice see Criteria for exclusion.
Action to be taken if the patient is excluded Continued over page	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 be provided

Action to be taken if the patient is excluded (continued)	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 PSD, following assessment of the individual's risk. Women who are pregnant, planning to get pregnant or breastfeeding must postpone COVID-19 vaccination until completion of pregnancy and breastfeeding. Individuals who think they may be pregnant should delay vaccination until they are sure they are not. Pregnancy should be avoided until 2 months after the second dose of vaccine. Individuals should be provided the advice in the leaflet 'COVID-19 vaccination: a guide for women of childbearing age, pregnant, planning a pregnancy or breastfeeding'. In case of postponement due to acute illness, advise when the individual can be vaccinated and if possible ensure another appointment is arranged. Individuals with confirmed COVID-19 infection in the preceding 4 weeks should postpone vaccination until clinical recovery and at least four weeks after onset of symptoms or four weeks from the first positive specimen in those who are asymptomatic. 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. 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.

5. Description of treatment

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 5 doses of 30 micrograms 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 PGD. COVID-19 mRNA vaccine BNT162b2 has been provided temporary authorisation by the Medicines & Healthcare products Regulatory Agency (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 In accordance with the UK Statutory Instrument 2020 No. 1125, The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020, a PGD may now be used to supply and/or administer a medicine authorised under regulation 174. 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 have 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 PGD. 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.
Route / method of administration Continued over page	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. COVID-19 mRNA vaccine BNT162b2 is for administration by intramuscular injection only, preferably into deltoid region of the upper arm. Vaccine should be prepared in accordance with the manufacturer's recommendations (see Regulation 174 Information for UK Healthcare Professionals) and NHS standard operating procedures for the service. Gently invert the diluted solution 10 times. Do not shake the vaccine.

Route / method of administration (continued)	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. Check product name, batch number and expiry date prior to administration. 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. The individual/carer should be informed about the risk of haematoma from the injection. Each vial contains 5 doses. It is normal for a small amount of liquid to remain in the vial after withdrawing the final 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 21 days. For operational purposes the second dose may be routinely scheduled at 28 days. If the course is interrupted or delayed, it should be resumed using the same vaccine (see Additional Information) but the first dose should not be repeated.
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.
Supplies	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 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 (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 within 6 hours from the time of dilution. The vaccine does not contain preservative. Once the dose is drawn 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.
Disposal	Follow local clinical waste policy and NHS standard operating procedures and ensure safe and secure waste disposal. Equipment used for vaccination, including used vials, ampoules, or discharged vaccines in a syringe or applicator, should be disposed of safely and securely according to local authority regulations and guidance in the technical memorandum 07-01: Safe management of healthcare waste (Department of Health, 2013).
Drug interactions	Immunological response may be diminished in those receiving immunosuppressive treatment, but it is important to still immunise this group. Although no data for co-administration of COVID-19 vaccine with other vaccines exists, in the absence of such data, first principles would suggest that interference between inactivated vaccines with different antigenic content is likely to be limited. Based on experience with other vaccines, any potential interference is most likely to result in a slightly attenuated immune response to one of the vaccines. There is no evidence of any safety concerns, although it may make the attribution of any adverse events more difficult. 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

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Drug interactions (continued)	vaccines where COVID-19 vaccination has been received first. In many cases vaccination should proceed, and may be provided under the PGD, 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, 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 have 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 patient 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 (Product code: COV2020311) • What to expect after your COVID-19 vaccination (Product code: COV2020307) • COVID-19 vaccination: a guide for women of childbearing age, pregnant, planning a pregnancy or breastfeeding (Product code COV2020374)

Patient advice / follow up treatment	As with all vaccines, immunisation may not result in protection in all individuals. Individuals may not be protected until at least 7 days after their second dose of the vaccine. 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. All women of childbearing age should be provided the advice in the leaflet 'COVID-19 vaccination: a guide for women of childbearing age, pregnant, planning a pregnancy or breastfeeding' and their understanding checked as part of the consent process. They should be advised that pregnancy should be avoided until 2 months after the second dose of vaccine (see Additional Information below). Vaccine recipients should be monitored for 15 mins after vaccination, with a longer observation period when indicated after clinical assessment. 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 adrenaline (epinephrine) 1 in 1,000 injection and 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. **Women of child-bearing age, currently pregnant, planning a pregnancy or breastfeeding** As with most pharmaceutical products, specific clinical trials in pregnant women have not been carried out for this vaccine. Because of the new formulation of this particular vaccine, the MHRA wants to see more non-clinical data before finalising the advice in pregnancy. It is standard practice when waiting for such data on any medicine, to avoid its use in those who may become pregnant or who are breastfeeding. Women should be advised that they should not receive a COVID-19 vaccine if they are breastfeeding, pregnant, may be pregnant or are planning a pregnancy. Vaccination should be postponed until completion of pregnancy and, if relevant, until finished breastfeeding.

Special considerations / additional information (continued)	Pregnancy should be avoided until 2 months after the second dose of vaccine. This advice is precautionary until additional evidence is available to support the use of this vaccine in pregnancy and breastfeeding. JCVI have advised that routine questioning about last menstrual period and/or pregnancy testing is not required before offering the vaccine. Those being invited for vaccination should be able to access the advice in the leaflet 'COVID-19 vaccination: a guide for women of childbearing age, pregnant, planning a pregnancy or breastfeeding' and their understanding checked as part of the consent process. Additional measures may need to be considered for potential recipients who are unable to access the information in written or online form. If a woman finds out she is pregnant after she has started a course of vaccine, she should complete her pregnancy and breastfeeding, if relevant, before finishing the recommended schedule. Termination of pregnancy following inadvertent vaccination should not be recommended. Surveillance of inadvertent administration in pregnancy is being conducted by the PHE Immunisation Department, to whom such cases should be reported (Tel: 020 8200 4400). **Previous incomplete vaccination** Other COVID-19 vaccines may become available after this PGD 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.
Records Continued over page	Record: • that valid informed consent was given; • 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 • 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 vaccination • details of any adverse drug reactions and actions taken • supplied via PGD

Records (continued)	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 PGD should also be kept for audit purposes.

6. Key references

Key references	COVID-19 mRNA vaccine BNT162b2 vaccination • Immunisation Against Infectious Disease: The Green Book, Chapter 14a. Published 5 December 2020. https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book • COVID-19 vaccination programme. Updated 7 December 2020. https://www.gov.uk/government/collections/covid-19-vaccination-programme • Priority groups for coronavirus (COVID-19) vaccination: advice from the JCVI. Published 2 December 2020 https://www.gov.uk/government/publications/priority-groups-for-coronavirus-covid-19-vaccination-advice-from-the-jcvi-2-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 27 November 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 27 November 2020. https://www.gov.uk/government/publications/covid-19-vaccinator-competency-assessment-tool • COVID-19: vaccination programme guidance for healthcare practitioners. Published 27 November 2020. https://www.gov.uk/government/publications/covid-19-vaccination-programme-guidance-for-healthcare-practitioners • Coronavirus (COVID-19): Shielded patients list. NHS Digital. Updated 18 August 2020. https://digital.nhs.uk/coronavirus/shielded-patient-list • 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. 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 • NICE Medicines Practice Guideline 2 (MPG2): Patient Group Directions. Published March 2017. https://www.nice.org.uk/guidance/mpg2

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Key references (continued)	• NICE MPG2 Patient group directions: competency framework for health professionals using patient group directions. Updated March 2017. https://www.nice.org.uk/guidance/mpg2/resources • Patient Group Directions: who can use them. Medicines and Healthcare products Regulatory Agency. 4 December 2017. https://www.gov.uk/government/publications/patient-group-directions-pgds/patient-group-directions-who-can-use-them • PHE Immunisation Collection https://www.gov.uk/government/collections/immunisation • PHE Vaccine Incident Guidance https://www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors • Reference guide to consent for examination or treatment, Department of Health and Social Care, published 4 August 2009. https://www.gov.uk/government/publications/reference-guide-to-consent-for-examination-or-treatment-second-edition • UK Statutory Instrument 2012 No. 1916, The Human Medicines Regulations 2012 https://www.legislation.gov.uk/uksi/2012/1916/contents • 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

7. Practitioner authorisation sheet

COVID-19 mRNA vaccine BNT162b2 PGD v01.00 Valid from: 11/12/2020 Expiry: 30/11/2021

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

PGDs do not remove inherent professional obligations or accountability.

It is the responsibility of each professional to practise only within the bounds of their own competence and professional code of conduct.

I confirm that I have read and understood the content of this PGD and that I am willing and competent to work to it within my professional code of conduct.			
Name	Designation	Signature	Date

Authorising manager

I confirm that the registered healthcare professionals named above have declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of **insert name of organisation** for the above named healthcare professionals who have signed the PGD to work under it.			
Name	Designation	Signature	Date

Note to authorising manager

Score through unused rows in the list of practitioners to prevent practitioner additions post managerial authorisation.

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

APPENDIX A

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

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	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	Many younger adults in residential care settings will be eligible for vaccination because they fall into one of the clinical risk groups above.

residential care settings	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 above). For consideration of children under 16 see Action to be taken if the patient is excluded