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

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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

The UK Health Security Agency (UKHSA) has developed this protocol for authorisation by or on behalf of the Secretary of State for Health and Social Care to facilitate the delivery of the national COVID-19 vaccination programme commissioned by NHS England and NHS Improvement (NHSEI).

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

[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 Coronavirus » Summary of the legal mechanisms for administering the COVID-19 vaccine(s) (england.nhs.uk))

2. Characteristics of staff

Classes of persons permitted to administer medicinal products under this protocol

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

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

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

The clinical supervisor[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	Specified Registered Healthcare Professionals Only (see Table 2)
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 operate under a PGD or as an occupational health vaccinator in accordance with HMR 2012:	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 (for further information on consent see Chapter 2 of 'The Green Book').

• 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 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 SOPs and in line with the Training recommendations for COVID-19 vaccinators	Y	Y	Y	N
must have undertaken training to meet the minimum standards in relation to vaccinating those under 18 as required by national and local policy.	Y	N	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 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

ACTIVITY STAGE 1a:	**Assess the individual presenting for vaccination. If they are not eligible for vaccination or need to return at a later date, advise them accordingly.**
Clinical condition or situation to which this Protocol applies	COVID-19 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 the UKHSA and/or NHSEI.
Criteria for inclusion	COVID-19 mRNA vaccine BNT162b2 should be offered to all individuals aged 12 years and over in accordance with the recommendations in Chapter 14a of the Green Book. Individuals are eligible for different dose schedules based on their age and recognised risk group (see the Dose and frequency of administration section).
Criteria for exclusion[3]	Individuals for whom valid consent, or 'best-interests' decision in accordance with the Mental Capacity Act 2005, has not been obtained (for further information on consent see Chapter 2 of 'The Green Book'). The Regulation 174 Information for UK recipients for COVID-19 mRNA vaccine BNT162b2 should be available to inform consent. Individuals who: • are less than 12 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 or residue from the manufacturing process[4] in the COVID-19 mRNA vaccine BNT162b2 • have a history of prior allergic reaction to COVID-19 vaccine that required medical intervention in hospital • 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 • have experienced myocarditis or pericarditis determined as likely to be related to previous COVID-19 vaccination • are suffering from acute severe febrile illness (the presence of a minor infection is not a contraindication for vaccination) • have received a full dose of COVID-19 vaccine in the preceding 21 days
Cautions including any relevant action to be taken Continued over page	Facilities for management of anaphylaxis should be available at all vaccination sites. Recipients of the COVID-19 mRNA vaccine BNT162b2 should be kept for observation and monitored for a minimum of 15 minutes.

[3] 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

[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 (continued)	Where individuals experienced a possible allergic reaction to a 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 a COVID-19 vaccine can receive subsequent doses of vaccine in any vaccination setting. Syncope (fainting) can occur following, or even before, any vaccination especially in adolescents as a psychogenic response to the needle injection. This can be accompanied by several neurological signs such as transient visual disturbance, paraesthesia and tonic-clonic limb movements during recovery. It is important that procedures are in place to avoid injury from faints. Individuals with a bleeding disorder may develop a haematoma at the injection site. Individuals with bleeding disorders may be vaccinated intramuscularly if, in the opinion of a doctor familiar with the individual's bleeding risk, vaccines or similar small volume intramuscular injections can be administered with reasonable safety by this route. If the individual receives medication/treatment to reduce bleeding, for example treatment for haemophilia, intramuscular vaccination can be scheduled shortly after such medication/treatment is administered. Individuals on stable anticoagulation therapy, including individuals on warfarin who are up to date with their scheduled INR testing and whose latest INR was below the upper threshold of their therapeutic range, can receive intramuscular vaccination. A fine needle (equal to 23 gauge or finer calibre such as 25 gauge) should be used for the vaccination, followed by firm pressure applied to the site (without rubbing) for at least 2 minutes. If in any doubt, consult with the clinician responsible for prescribing or monitoring the individual's anticoagulant therapy. If the registered professional clinically assessing the individual is not the vaccinator, they must ensure the vaccinator is aware of the individuals increased risk of haematoma and the need to apply firm pressure to the injection site for at least 2 minutes. The individual/parent/carer should be informed about the risk of haematoma from the injection. Very rare reports have been received of Guillain-Barre Syndrome (GBS) following COVID-19 vaccination (further information is available in Chapter 14a). Healthcare professionals should be alert to the signs and symptoms of GBS to ensure correct diagnosis and to rule out other causes, in order to initiate adequate supportive care and treatment. Individuals who have a history of GBS should be vaccinated as recommended for their age and underlying risk status. In those who are diagnosed with GBS after the first dose of vaccine, the balance of risk benefit is in favour of completing a full COVID-19 vaccination schedule. On a precautionary basis, however, where GBS occurs within six weeks of an Astra Zeneca vaccine, for any future doses Pfizer or Moderna COVID-19 vaccines are preferred. Where GBS occurs following either of the mRNA vaccines, further vaccination can proceed as normal, once recovered. **Past history of COVID-19 infection** There is no convincing 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 confusing the differential diagnosis. As clinical deterioration can occur up to two weeks after infection, vaccination of

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Cautions including any relevant action to be taken (continued)	adults and high risk children 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. In younger people, protection from natural infection is likely to be high for a period of months, and vaccination in those recently infected may increase the chance of side effects. Therefore, vaccination should ideally be deferred till at least twelve weeks from onset (or sample date) in children and young people under 18 years who are not in high risk groups (see Dose and frequency of administration section). This includes children and young people who developed Paediatric multisystem inflammatory syndrome temporally associated with SARS-CoV-2 infection (PIMS-TS) and then become eligible for vaccination. Current advice in PIMS-TS cases suggests that an interval of 12 weeks should be observed, although earlier administration can be considered in those at risk of infection and/or who are fully recovered. Such earlier vaccination should be on a patient specific basis and is not covered by this national protocol. Having prolonged COVID-19 symptoms is not a contraindication to receiving COVID-19 vaccine but if the individual is seriously debilitated, still under active investigation, or has evidence of recent deterioration, deferral of vaccination may be considered to avoid incorrect attribution of any change in the person's underlying condition to the vaccine. **Vaccine Surveillance** The UK regulator will maintain real-time surveillance post deployment of COVID-19 vaccines in the UK. In response to any safety signals, the Medicines and Healthcare products Regulatory Agency (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). These documents take precedence for the purposes of compliance with this protocol, if there is a delay in updating other provisions of this protocol that cut across them.
Dose and frequency of administration Continued over page	A dose of COVID-19 mRNA vaccine BNT162b2 is 0.3ml and contains 30micrograms of COVID-19 mRNA vaccine in 0.3ml. The two-dose primary course consists of 30micrograms in 0.3ml followed, after an interval of at least 21 days, by a second dose of 30micrograms in 0.3ml. However, the programme schedule, including both the number of doses and the intervals between them, should be administered in accordance with official national guidance which is set out in Chapter 14a of the Green Book and summarised below and in a table at Appendix A. For both adenovirus vector and mRNA vaccines, there is evidence of better immune response and/or protection where longer intervals between doses in the primary schedule are used. Based on this evidence, longer intervals are likely to provide more durable protection. JCVI is currently recommending a minimum interval of eight weeks between doses of all the available COVID-19 vaccines where a two-dose primary schedule is used for adults and for children at high risk. Operationally, this consistent interval should be used for all vaccines with a two-dose primary schedule to avoid confusion and simplify booking and will help to ensure a good balance between achieving rapid and long-lasting protection.

Dose and frequency of administration (continued)	For those under 18 years who are not in a high risk group a 12-week interval is preferred (see below and Appendix A). This is based on precautionary advice from the JCVI based on emerging evidence of a lower rate of myocarditis in countries that use a longer schedule. The main exception to the eight-week lower interval would be those about to commence immunosuppressive treatment. In these individuals, the licensed minimal interval of at least 21 days may be followed to enable the vaccine to be given whilst their immune system is better able to respond. 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. **Interval post SARS-CoV-2 infection** For individuals who have had proven SARS-CoV-2 infection (see Cautions), any subsequent COVID-19 vaccination should ideally be deferred until: • at least twelve weeks from onset (or sample date) for those under 18 years of age who are not in a risk group • at least four weeks from onset (or sample date) for individuals in a risk group and all those over 18 years of age Administration at intervals less than this is not covered by this national protocol. **Primary course for individuals at higher risk** The primary course for individuals at higher risk is recommended to be scheduled as follows: • individuals 12 years and over sharing living accommodation with an immunosuppressed individual of any age should receive a two-dose primary course at a recommended 8-week minimum interval • individuals 12 years and over in an at-risk group[5] and those from 16 years of age working in health and social care should receive a two-dose primary course at a recommended 8-week minimum interval. A third primary dose is recommended for those who have severe immunosuppression in proximity to their first or second COVID-19 doses. • individuals 12 years and over who had severe immunosuppression in proximity to their first or second COVID-19 doses in the primary schedule should receive a three-dose primary course at a recommended 8-week minimum interval (see 'Box: Criteria for a third primary dose of COVID-19 vaccine' in Chapter 14a). The decision on the timing of the third dose should be undertaken by the specialist involved in the care of the individual. The third dose should be given ideally at least 8 weeks after the second dose, with special attention paid to current or planned immunosuppressive therapies (see Additional information section). This group of individuals will also require a booster dose to extend protection from their primary course. Boosters are expected to be required from six months after the third dose, although JCVI will advise on optimal timing after evidence from trials in these populations become available. **Individuals who are not at higher risk** The primary course for individuals who are not at higher risk is recommended to be scheduled as follows:
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[5] At risk groups are listed in the Green Book Chapter 14a (Table 3 for individuals 16 years of age and over and Table 4 for children aged 12-15 years).

Dose and frequency of administration (continued)	• individuals 12 to 15 years of age and not in a recognised risk group can receive their first dose, as recommended by the Chief Medical Officers. A decision on when to offer the second dose to healthy children is pending further evidence on the safety of a second dose in this age group. • individuals 16 and 17 years of age and not in a recognised risk group nor working in health and social care should receive a two-dose primary course at a recommended 12-week minimum interval[6] • individuals 18 years of age and over and not in a recognised risk group should receive a two-dose primary course at a recommended 8-week minimum interval **Booster vaccination** A booster dose should be offered to individuals eligible for a booster dose as part of the national COVID-19 vaccination programme in accordance with the recommendations from the JCVI and Chapter 14a of the Green Book. The JCVI is recommending that booster vaccines are scheduled at a six-month interval from completing the primary course. This interval will automatically help to prioritise older and more vulnerable patients. For operational reasons, administration may be brought forward to a minimum of five months in certain circumstances including: • in a care home setting to enable all residents to be vaccinated in the same session • where an otherwise eligible individual attends for another reason (for example to receive influenza vaccine) For those about to receive immunosuppressive treatment the booster may be brought forward to a minimum of four months (~120 days) to avoid giving the booster when the immune system is less able to respond.
Action to be taken if the individual 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 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. 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 prior allergic reaction to COVID-19 vaccine that required medical intervention in hospital • 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)

[6] There will be a transitional period where this protocol can be used to administer second doses for those from 17 years and 9 months of age (not in a risk group) who have an existing second dose appointment booked at 8 weeks.

Action to be taken if the individual is excluded (continued)	• 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. Individuals who have experienced myocarditis or pericarditis following COVID-19 vaccination should be assessed by an appropriate clinician to determine whether it is likely to be vaccine related. As the mechanism of action and risk of recurrence of myocarditis and pericarditis are being investigated, the current advice is that an individual's second or subsequent doses should be deferred pending further investigation. Following investigation any subsequent dose should be provided by an appropriate prescriber or on a patient specific basis, under a PSD. 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	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. For further information on consent see Chapter 2 of 'The Green Book'. Advise the individual/parent/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	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 and 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 tozinameran, a 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 Continued over page	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 Regulatory approval of Pfizer/BioNTech vaccine for COVID-19 - GOV.UK (www.gov.uk) COVID-19 mRNA vaccine BNT162b2 is categorised as a prescription only medicine (POM).

Legal category (continued)	Note: For administration of Comirnaty COVID-19 mRNA vaccine, which has been granted a conditional marketing authorisation, see the National Protocol for Comirnaty COVID-19 mRNA vaccine.
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. As part of the consent process, healthcare professionals must inform the individual/parent/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	Immunological response may be diminished in those receiving immunosuppressive treatment, but it is important to still immunise this group. Although no data for co-administration of COVID-19 vaccine with other vaccines exists, in the absence of such data, first principles would suggest that interference between inactivated vaccines with different antigenic content is likely to be limited. Based on experience with other vaccines, any potential interference is most likely to result in a slightly attenuated immune response to one of the vaccines. There is no evidence of any safety concerns, although it may make the attribution of any adverse events more difficult. Similar considerations apply to co-administration of inactivated (or non-replicating) COVID-19 vaccines with live vaccines such as MMR. In particular, live vaccines which replicate in the mucosa, such as live attenuated influenza vaccine (LAIV) are unlikely to be seriously affected by concomitant COVID-19 vaccination. A seven-day interval should ideally be observed between COVID-19 vaccination and shingles vaccination. This is based on the potential for an inflammatory response to COVID-19 vaccine to interfere with the response to the live virus in the older population and because of the potential difficulty of attributing systemic side effects to the newer adjuvanted shingles vaccine. For further information about co-administration with other vaccines see Additional Information section.
Identification and management of adverse reactions Continued over page	The most frequent adverse reactions in individuals 16 years of age and older are injection site pain, fatigue, headache, myalgia, chills, arthralgia, pyrexia and injection site swelling. These reactions are usually mild or moderate in intensity and resolve within a few days after vaccination. Redness at the injection site, nausea and vomiting are reported as common. Lymphadenopathy is reported with a frequency of less than 1%. The most frequent adverse reactions in individuals 12 to 15 years of age are injection site pain, fatigue, headache, myalgia, chills, arthralgia and pyrexia. There have been very rare reports of myocarditis and pericarditis occurring after vaccination with COVID-19 mRNA Vaccine BNT162b2 often in younger men and shortly after the second dose of the vaccine. These are typically mild cases and individuals tend to recover within a short time following standard treatment and rest. Healthcare professionals should be alert to the signs and symptoms of myocarditis and pericarditis.

Identification and management of adverse reactions (continued)	Vaccinated individuals should also seek immediate medical attention should they experience new onset of chest pain, shortness of breath, palpitations or arrhythmias. 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 MHRA using the Coronavirus Yellow Card reporting scheme 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. 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 • COVID-19 vaccination: a guide to booster vaccination
Advice / follow up treatment Continued over page	Vaccine recipients should be monitored for 15 mins after vaccination, with a longer observation period when indicated after clinical assessment (see Chapter 14a). Inform the individual/parent/carer of possible side effects and their management. The individual/parent/carer should be advised to seek appropriate advice from a healthcare professional in the event of an adverse reaction. Vaccinated individuals should be advised to seek immediate medical attention should they experience new onset of chest pain, shortness of breath, palpitations or arrhythmias. Advise the individual/parent/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 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.

Advice / follow up treatment (continued)	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. When applicable, advise the individual/parent/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. **Pregnancy** 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. Although clinical trials on the use of COVID-19 vaccines during pregnancy are not advanced, the available data do not indicate any harm to pregnancy. JCVI has therefore advised that women who are pregnant should be offered vaccination at the same time as non-pregnant women, based on their age and clinical risk group. extensive post-marketing experience of the use of the Pfizer BioNTech and Moderna vaccines in the USA with no safety signals so far. Over 80,000 women now report having been vaccinated whilst pregnant or when they might be pregnant in England. Because of wider experience with mRNA vaccines, these are currently the preferred vaccines to offer to pregnant women. Routine questioning about last menstrual period and/or pregnancy testing is not required before offering the vaccine. Women who are planning pregnancy or in the immediate postpartum should be vaccinated with a suitable product for their age and clinical risk group. If a woman finds out she is pregnant after she has started a course of vaccine, she should complete vaccination during pregnancy using the same vaccine product (unless contra-indicated). **Breastfeeding** There is no known risk associated with being given a non-live vaccine whilst breastfeeding. JCVI advises that breastfeeding women may be offered any suitable COVID-19 vaccine. Emerging safety data is reassuring: mRNA was not detected in the breast milk of recently vaccinated women and protective antibodies have been detected in breast milk. The developmental and health benefits of breastfeeding are clear and should be discussed with the woman, along with her clinical need for immunisation against COVID-19. **Previous incomplete vaccination** If the course is interrupted or delayed, it should be resumed using the same vaccine but the earlier doses should not be repeated. Evidence suggests that those who receive mixed schedules, including mRNA and adenovirus vectored vaccines make a good immune response, although rates of side effects at the second dose are higher. Therefore, every effort should be made to determine which vaccine the individual received and to

Special considerations / additional information (continued)	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 considered suitable, or if the first product received is unknown, it is reasonable to offer one dose of the locally available product to complete the primary 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. Individuals who experience severe expected reactions after a first dose of AstraZeneca or Pfizer COVID-19 vaccines appear to have a higher rate of such reactions when they receive a second dose of the alternate vaccine. Therefore, individuals who have received a first dose of the AstraZeneca vaccine should complete the primary course with the same vaccine, with the exception of those who experienced an episode of anaphylaxis, thrombosis and thrombocytopaenia syndrome or GBS. For individuals with a history of thrombosis combined with thrombocytopaenia following vaccination with the AstraZeneca COVID-19 vaccine, current evidence would support completion of the course with an mRNA vaccine, provided a period of at least 12 weeks has elapsed since the dose of AstraZeneca vaccine. Individuals with a history of capillary leak syndrome should be carefully counselled about the risks and benefits of vaccination. An alternative vaccine to the AstraZeneca COVID-19 vaccine, such as COVID-19 mRNA vaccine BNT162b2, may be offered to complete a vaccination course. Individuals who are participating in a clinical trial of COVID-19 vaccines who present for vaccination should be referred back to the investigators. Eligible persons who are enrolled in vaccine trials should then be provided with written advice on whether and when they should be safely vaccinated in the routine programme. Advice should also be provided from the trial investigators on whether any individual could receive additional doses for the purposes of vaccine certification. Trial participants who are eligible for boosters should be offered vaccination in line with the general population, six months after the dose considered as the final primary dose or the final revaccination (if the latter is required for certification purposes). Individuals who have been vaccinated abroad are likely to have received an mRNA or vector vaccine based on the spike protein, or an inactivated whole viral vaccine. Specific advice on Vaccination of those who received COVID-19 vaccine overseas is available from the UKHSA. **Co-administration with other vaccines** Where individuals in an eligible cohort present having recently received one or more inactivated or live vaccines, COVID-19 vaccination should still be given. The same applies for most other live and inactivated vaccines where COVID-19 vaccination has been received first or where an individual presents requiring two or more vaccines. It is generally better for vaccination to proceed and it may be provided under this protocol, to avoid any further delay in protection and to avoid the risk of the individual not returning for a later appointment. This includes but is not limited to vaccines commonly administered around the same time or in the same settings (including influenza and pneumococcal polysaccharide vaccine in those aged over 65 years, pertussis-containing vaccines and influenza vaccines in pregnancy, and LAIV, HPV, MenACWY and Td-IPV vaccines in the schools programmes). The only exceptions to this are the shingles vaccines, where a seven-day interval should ideally be observed. This is based on the potential for an inflammatory response to COVID-19 vaccine to interfere with the response to the live virus in the older population and

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Special considerations / additional information (continued)	because of the potential difficulty of attributing systemic side effects to the newer adjuvanted shingles vaccine. A UK study of co-administration of AstraZeneca and Pfizer BioNTech COVID-19 vaccines with inactivated influenza vaccines confirmed acceptable immunogenicity and reactogenicity. Where co-administration does occur, individuals should be informed about the likely timing of potential adverse events relating to each vaccine. If the vaccines are not given together, they can be administered at any interval, although separating the vaccines by a day or two will avoid confusion over systemic side effects. **Non-responders / immunosuppressed** Immunological response may be lower in immunocompromised individuals, but they should still be vaccinated. JCVI advises that a third primary vaccine dose be offered to individuals aged 12 years and over who had severe immunosuppression in proximity to their first or second COVID-19 doses in the primary schedule (see 'Box: Criteria for a third primary dose of COVID-19 vaccine' in Chapter 14a). Most individuals whose immunosuppression commenced at least two weeks after the second dose of vaccination do not require an additional primary vaccination at this stage. The decision on the timing of the third primary dose should be undertaken by the specialist involved in the care of the individual. In general, vaccines administered during periods of minimum immunosuppression (where possible) are more likely to generate better immune responses. Individuals who have received a bone marrow transplant after vaccination should be considered for a re-immunisation programme for all routine vaccinations and for COVID-19 (see Chapter 7 of the Green Book). This is not covered by this protocol and should be provided on a patient specific basis.