Department of Health
An Roinn Sláinte
Männystrie O Poustie
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Vaccination protocol for COVID-19 mRNA Vaccine BNT162b2 (Pfizer/BioNTech Vaccine)

Reference no:	COVID-19 mRNA Vaccine BNT162b2 (Pfizer/BioNTech) Vaccine
Version no:	v02.00
Valid from:	20 August 2021
Review date:	1 October 2021
Expiry date:	31 March 2022

This protocol is for the administration of COVID-19 mRNA Vaccine BNT162b2 Pfizer/BioNTech to individuals in accordance with the national COVID-19 vaccination programme.

This protocol is for the administration of COVID-19 mRNA Vaccine BNT162b2 Pfizer/BioNTech 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 Department of Health has developed this protocol for authorisation by the Minister for Health to facilitate the delivery of the national COVID-19 vaccination programme in Northern Ireland.

This protocol may be followed wholly from assessment through to post-vaccination by an appropriately registered healthcare professional (see Characteristics of staff). Alternatively, multiple persons may undertake stages in the vaccination pathway in accordance with this protocol and the general requirements of the Human Medicines Regulations 2012 and Medicines Act 1968, as appropriate. 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 patient. The provider/contractor is responsible for ensuring that persons are trained and competent to safely deliver the activity they are employed to provide under this protocol and that adequate supervision arrangements are in place. As a minimum, competence requirements stipulated in the protocol under Characteristics of staff 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, who must be a registered healthcare professional 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. If a vaccination service is being provided at scale, the clinical supervisor should only take on specific supervision requirements in relation to the drawing up of the vaccine if this can be done safely alongside their overarching role. Any time the protocol is used, the name of the clinical supervisor taking responsibility and all the people working under different stages of the protocol must be recorded for the session. The clinical supervisor has ultimate responsibility for safe care being provided under the terms of the protocol. Staff working under the protocol may be supported by additional registered healthcare professionals,

but the clinical supervisor retains responsibility. Staff working to the protocol must understand who the clinical supervisor for their practice at any time is and can only proceed with their authority. The clinical supervisor may withdraw this authority for all members of staff or individual members of staff at any time and has authority to stop and start service provision under the protocol as necessary. Every member of staff has a responsibility to, and should, report immediately to the clinical supervisor any concerns they have about working under the protocol in general or about a specific individual, process, issue or event.

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

Operation under this protocol is the responsibility of service providers/contractors. Provider organisations/contractors using this protocol should retain copies, along with the details of those authorised to work under it, for 10 years after the protocol expires.

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

Change history

Version number	Change details	Date
V01.00	New national protocol for COVID-19 mRNA Vaccine BNT162b2 Pfizer/BioNTech [DoH Reference HE1/21/233945]	26 April 2021
V02.00	Vaccination protocol revised to align content with regional PGD v01.14	20 August 2021

1. Ministerial and clinical authorisation

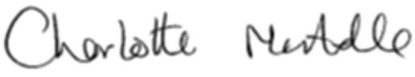
This protocol is not legally valid, in accordance with regulation 247A of the HMR 2012, inserted by the Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020, until it is approved by the Minister for Health.

On 20/08/2021 the Minister for Health, Robin Swann MLA, approved this protocol in accordance with regulation 247A of HMR 2012.

Ministerial Authorisation			
Role	**Name**	**Sign**	**Date**
Minister for Health	Robin Swann MLA		20/08/2021

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

This protocol provides clinical authorisation for the delivery of the national COVID-19 vaccination programme

Clinical Authorisation			
Role	**Name**	**Sign**	**Date**
Chief Medical Officer	Dr Michael McBride		20/08/2021
Chief Nursing Officer	Professor Charlotte McArdle		20/08/2021
Chief Pharmaceutical Officer	Mrs Cathy Harrison		20/08/2021

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

Assembly, preparation and administration of vaccines supplied and administered under this protocol must be subject to all HSC governance arrangements and standard operating procedures that ensure that the safety, quality or efficacy of the product is not compromised. The assembly, preparation and administration of the vaccines must also be in accordance with the general requirements of the Human Medicines Regulations 2012 and Medicines Act 1968, and with the Regulation 174 Information for Healthcare Professionals for the product as issued by the Medicines and Healthcare products Regulatory Agency (MHRA).

Note: The national COVID-19 vaccination programme may also be provided under a patient group direction (PGD) or on a patient specific basis (that is, by or on the directions of an appropriate independent prescriber, such as under a patient specific direction (PSD)). Supply and administration

in these instances should be in accordance with contractual arrangements with the commissioner for the delivery of the national COVID-19 vaccination programme and are not related to this protocol.

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 persons are trained and competent to safely deliver the activity they are employed to provide under this protocol. As a minimum, competence requirements stipulated in the protocol must be adhered to.

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

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

The clinical supervisor must be a registered healthcare professional 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[1] c. Provide advice to the individual	Registered Healthcare Professionals Only
Stage 2	• Vaccine Preparation	Registered Healthcare Professionals or specified non-registered persons
Stage 3	• Vaccine Administration	Registered Healthcare Professionals or specified non-registered persons
Stage 4	• Record Keeping	Registered Healthcare Professionals or specified non-registered persons

The following specified registered healthcare professionals are permitted to practice under the protocol subject to the requirements set out below:

- Nurses and midwives currently registered with the Nursing and Midwifery Council (NMC).
- Pharmacists currently registered with the Pharmaceutical Society of Northern Ireland (PSNI).
- Chiropodists/podiatrists, dieticians, occupational therapists, operating department practitioners, orthoptists, orthotists/prosthetists, paramedics, physiotherapists, radiographers and speech and language therapists currently registered with the Health and Care Professions Council (HCPC).
- Dental hygienists and dental therapists registered with the General Dental Council.
- Optometrists registered with the General Optical Council.
- Doctors currently registered with a licence to practice with the General Medical Council.
- Dentists currently registered with the General Dental Council.

The following professionals (who are in the main non-registered) are permitted to practice under the protocol with appropriate supervision as set out below, subject to the requirements set out below

[1] For those lacking mental capacity, a decision may be made in the individual's best interests in accordance with the common law in Northern Ireland in relation to the best interests of the incapacitous individual

- Veterinary surgeons currently registered with the Royal College of Veterinary Surgeons.
- Pharmacy technicians, pre-registration pharmacists and other pharmacy support practitioners.
- Retired clinical practitioners who have left the register in good standing such as doctors, dentists, pharmacists, nurses, optometrists, chiropodists/podiatrists, dieticians, occupational therapists, orthoptists, orthotists/prosthetists, paramedics, pharmacy technicians, physiotherapists, radiographers, speech and language therapists, dental hygienists and dental therapists not currently registered.
- Student doctors, dentists, pharmacists, nurses, midwives, optometrists, chiropodists/podiatrists, dieticians, occupational therapists, orthoptists, orthotists/prosthetists, paramedics, physiotherapists, radiographers, speech and language therapists, dental hygienists and dental therapists not currently registered.
- Healthcare Scientists.
- Dental nurses.
- Physician's assistants.

The following non-registered Armed Forces staff are permitted to administer under the protocol with appropriate supervision as set out below, subject to the requirements set out below:

- Combat Medical Technician – Class 1,2 & 3 (CMT)
- Royal Navy Medical Assistant (RN MA)
- Royal Air Forces Medic
- Defence Medic

Requirements

All those working under this protocol must have undertaken training, be assessed as competent and receive supervision appropriate to the stage of activity they are undertaking. Where multiple person models are used, the provider must ensure that all elements of the protocol are complied with in the provision of vaccination to each individual. The provider is responsible for ensuring that persons are trained and competent to safely deliver the activity they are employed to provide under this protocol. As a minimum, competence requirements stipulated in the protocol must be adhered to.

All persons must be designated by name by the provider as an approved person under the current terms of this protocol before working to it, and listed on the practitioner authorisation sheet in Appendix A. Protocols do not remove inherent obligations or accountability. All practitioners operating under this protocol must work within their terms of employment at all times; registered healthcare professionals should also abide by their professional code of conduct. There are three underpinning principles to which every person undertaking activities under the remit of this protocol must adhere:

1. Training
    - They must have undertaken training appropriate to this protocol and relevant to their role, as required by local policy and national standard operating procedures and in line with the Training recommendations for COVID-19 vaccinators
    - They 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

2. Competency
    - Those providing clinical supervision to those administering the vaccine must be competent to assess individuals for suitability for vaccination, identify any contraindications/exclusions or precautions, discuss issues related to vaccination and obtain informed consent from the individuals being vaccinated.
    - They 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 month). They should be observed administering the vaccine until both they, and their supervisor or trainer, feel confident

that they have the necessary knowledge and skills to administer vaccines safely and competently.

In addition and where indicated as relevant to the role -

- They must be familiar with the vaccine product and alert to any changes in the manufacturers summary of product characteristics (SPC), should it become licensed, or the Regulation 174 Information for UK Healthcare Professionals and familiar with the national recommendations for the use of this vaccine
- They must be familiar with, and alert to changes in relevant chapters of Immunisation Against Infectious Disease: the Green Book COVID-19: the green book, chapter 14a - GOV.UK
- They must be familiar with, and alert to changes in the relevant provider's standard operating procedures (SOPs) and provider's arrangements for the national COVID-19 vaccination programme
- They 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.
- They 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.
- They must have access to the provider's protocols and relevant COVID-19 vaccination programme online resources.
- They must be competent in intramuscular injection technique if they are administering the vaccine, this should include a practical element.
- For those preparing the vaccine, they must be competent in the handling of the vaccine product and use of the correct technique for drawing up the correct dose.
- For those in record keeping roles, they must understand the importance of making sure vaccine information is recorded on the vaccination management system
- They should fulfil any additional requirements defined by local policies developed in accordance with any national guidance.

3. Supervision
    - A period of supervised practice to allow observation of, and development of skills in vaccine administration and application of knowledge to practice is essential. Supervision for new immunisers and support for all immunisers is critical to the safe and successful delivery of the COVID-19 immunisation programme.
    - Non-registered professionals and non-registered Armed Forces staff must be supervised and supported by a registered healthcare professional at all times.
    - The clinical supervisor must be a registered healthcare professional trained and competent in all aspects of the protocol and provide clinical supervision for the overall provision of clinical care provided under the protocol.

3. Clinical condition or situation to which this Protocol applies

COVID-19 mRNA Vaccine BNT162b2 Pfizer/BioNTech is indicated for the active immunisation of individuals for the prevention of COVID-19 infection caused by SARS-CoV-2, in accordance with the national immunisation programme and recommendations given in Chapter 14a of the Immunisation Against Infectious Disease: the 'Green Book', JCVI statement on Priority groups for coronavirus (COVID-19 vaccination), 30 December 2020 and subsequent correspondence/publications from Northern Ireland Department of Health.

4. Clinical information

STAGE 1: Assessment of the individual presenting for vaccination

<table>
<tr><th>ACTIVITY STAGE 1a:</th><th>Assess the individual presenting for vaccination against the inclusion and exclusion criteria below. If they are not eligible for vaccination or need to return at a later date, advise them accordingly.</th></tr>
<tr><td>Clinical condition or situation to which this Protocol applies</td><td>COVID-19 mRNA BNT162b2 vaccine is indicated for the active immunisation of individuals for the prevention of COVID-19 infection caused by SARS-CoV-2, in accordance with the national immunisation programme and recommendations given in Chapter 14a of the Immunisation Against Infectious Disease: the 'Green Book', JCVI Priority groups for coronavirus (COVID-19 vaccination), 30 December 2020 and subsequent correspondence/publications from Northern Ireland Department of Health.</td></tr>
<tr><td>Criteria for inclusion</td><td>National policy must be followed in relation to the priority groups eligible for vaccination at a particular point in time.

JCVI Phase One
COVID-19 mRNA BNT162b2 vaccine should be offered to individuals in accordance with JCVI guidance 'Priority groups for coronavirus (COVID-19 vaccination), 30 December 2020.'

JCVI guidance on Priority groups for coronavirus (COVID-19) vaccination recommends vaccination in the following order of priority, starting with those to be vaccinated first:

<table>
<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
Health and social care workers (see HSS(MD)82/2020 for prioritisation of staff in current phase of vaccine deployment)</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 individuals (see Definition of clinically extremely vulnerable[2] 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 heath conditions which put them at higher risk of serious disease and mortality, as per JCVI advice[3]</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>

JCVI Phase Two

Phase 2 of the COVID 19 vaccination programme should be offered in accordance with national recommendations and JCVI guidance on the 'Priority groups for phase 2 of the coronavirus (COVID-19) vaccination</td></tr>
</table>

[2] Individuals identified as clinically extremely vulnerable should have this status flagged in their GP record.
[3] This also includes those who are eligible for a carer's allowance, or those who are the sole or primary carer of an elderly or disabled person who is at increased risk of COVID-19 mortality and therefore clinically vulnerable.

Criteria for inclusion (continued)	programme' in the following age-based order of priority, starting with the oldest adults first and proceeding in the following order: • all those aged 40 to 49 years • all those aged 30 to 39 years • all those aged 18 to 29 years olds **Children eligible for vaccination:** • 12 to 15 year olds with severe neurodisabilities, Down's syndrome, immunosuppression and multiple or severe learning disabilities • 12 to 17 year olds who live with an immunosuppressed person • 17 year olds who are within 3 months of their 18th birthday. • 16 and 17 year olds not in 'at risk' groups or a health and social care worker. Please see note in Dose and Frequency of Administration. This includes those born between 1 August 2003 and the 31 August 2005. **Note:** all those attending for vaccination must have reached their 16th birthday. See **JCVI Phase One** for advice on young people aged 16 to 17 years with underlying health conditions which put them at higher risk of serious COVID-19 and for 16 to 17 year olds who are health and social care workers. Implementation of the COVID-19 vaccination programme should aim to achieve high vaccine uptake whilst prioritising those most at risk. The priority order should be followed if it is reasonably practicable to do so. Implementation should also involve flexibility in vaccine deployment at a local level. Operational considerations, such as minimising wastage, may require a flexible approach to prioritisation, such as advised for detained settings[4], where decisions are taken in consultation with national or local public health experts. JCVI advises that local teams exercise operational judgment and consider a universal offer to people experiencing homelessness and rough sleeping, alongside delivery of the programme to priority group 6, where appropriate.[5]
Criteria for exclusion[5]	Individuals for whom valid consent or a 'best-interests' decision in accordance with the common law in Northern Ireland in relation to the best interests of the incapacitous individual has not been received (for further information on consent see Reference guide to consent for examination or treatment). 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 the COVID-19 mRNA BNT162b2 (Pfizer BioNTech) vaccine or have had a previous systemic allergic reaction (including immediate-onset anaphylaxis) to any component (excipient)[7] of the COVID-19 mRNA BNT162b2 (Pfizer BioNTech) vaccine.

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

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

[7] Excipients include ALC-0315 = (4-hydroxybutyl) azanediyl)bis (hexane-6,1-diyl)bis(2-hexyldecanoate), ALC-0159 = 2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide, 1,2-Distearoyl-sn-glycero-3-phosphocholine, cholesterol, potassium chloride, potassium dihydrogen phosphate, sodium chloride,

Criteria for exclusion[6] (continued)	• have had a previous allergic reaction (including immediate onset anaphylaxis) to COVID-19 vaccine Moderna • have a history of immediate anaphylaxis to multiple, different drug classes, with the trigger unidentified (this may indicate PEG allergy) • have a history of anaphylaxis to a vaccine, injected antibody preparation or a medicine likely to contain PEG (e.g. depot steroid injection, laxative) • have a history of idiopathic (unexplained) anaphylaxis (see Cautions including any relevant action to be taken) • are suffering from acute severe febrile illness (the presence of a minor infection is not a contraindication for immunisation) • have received a full dose of COVID-19 vaccine in the preceding 21 days • have completed a course of COVID-19 vaccination • are participating in a COVID-19 vaccine clinical trial; unless they have consulted the trial team and have been provided with written advice that they can be safely vaccinated in the routine COVID-19 vaccination programme. **Note:** People participating in a COVID-19 research trial other than a vaccine trial (e.g. survey / questionnaire) can receive the COVID-19 vaccination, provided they fulfil the other inclusion criteria at the time of offer. If there is any doubt please refer to the appropriate clinical trial leads. • are advised by the UK regulator, the Medicines & Healthcare products Regulatory Agency (MHRA), not to receive COVID-19 mRNA vaccine BNT162b2 (see Cautions including any relevant action to be taken).
Cautions including any relevant action to be taken	The COVID-19 chapter of the Green Book advises that there are very few individuals who cannot receive COVID vaccine. Where there is doubt, rather than withholding vaccination, appropriate advice should be sought from the relevant specialist, or from the PHA Duty Room (tel 0300 555 0119). **Patients with a history of allergy** Facilities for management of anaphylaxis should be available at all vaccination sites (see Chapter 8 of the Green Book). The Pfizer BioNTech and Moderna mRNA vaccines contain polyethylene glycol (PEG). PEGs (also known as macrogols) are a group of known allergens commonly found in medicines, many household products and cosmetics. Medicines containing PEG include some tablets, laxatives, depot steroid injections, and some bowel preparations used for colonoscopy. Known allergy to PEG is rare but would contraindicate receipt of this vaccine. (Sellaturay P et al, 2020). Patients who have: a previous allergic reaction (including anaphylaxis) to a food, insect sting and most medicines (where trigger has been identified); a family history of allergies; a previous non-systemic reaction to a vaccine; a hypersensitivity to nonsteroidal anti-inflammatory drugs, e.g. aspirin, ibuprofen; a history of mastocytosis may proceed with vaccination as normal, according to local guidelines. All recipients of the COVID-19 mRNA BNT162b2 vaccine should be kept for observation and monitored for a minimum of 15 minutes.

disodium hydrogen phosphate dihydrate, sucrose, water for injections.

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

Cautions including any relevant action to be taken (continued)	Special precautions as described in Chapter 14a, and consideration of the possibility of undiagnosed PEG-allergy, is required for individuals with: • history of immediate anaphylaxis to multiple, different drug classes, with the trigger unidentified (this may indicate PEG allergy) • history of anaphylaxis to a vaccine, injected antibody preparation or a medicine likely to contain PEG (such as depot steroid injection, laxative) • history of idiopathic anaphylaxis Such individuals should not be vaccinated with COVID-19 mRNA vaccine BNT162b2, except on the expert advice of an allergy specialist and under a PSD. The AstraZeneca COVID-19 vaccine can be used as an alternative (unless otherwise contraindicated), particularly if they previously tolerated an injected influenza vaccine. In these circumstances, the AstraZeneca COVID-19 vaccine should be administered in a setting with full resuscitation facilities (such as a hospital), and a 30 minute observation period is recommended. Patients with a prior systemic allergic reaction to COVID-19 mRNA BNT162b2 vaccine; prior allergic reaction to another mRNA vaccine (e.g. Moderna mRNA-1273 COVID-19 Vaccine); prior allergic reaction to a component of the vaccine, including PEG should not receive the COVID-19 mRNA BNT162b2 vaccine and should be referred to an allergist. A person should have their second dose at the same location as they had their first dose. The location of administration is important for those with a history of previous allergy, because this history of a reaction remains important even if a patient has no reaction to their first dose of a COVID-19 vaccine which provides no guarantee they will not have a reaction to their second dose of vaccine. Patients who experienced an immediate-type allergic reaction to the first dose of COVID-19 vaccine, where symptoms were limited to swelling or rash local to the injection site only, can have the second dose using the same vaccination in any vaccination setting. Observe the patient for 30 minutes. Patients who experienced delayed urticaria / angioedema to the first dose of COVID-19 vaccine, where the reaction was self-limiting or resolved with oral antihistamine, can have the second dose using the same vaccination in any setting. Consider pre-treatment with non-sedating antihistamine, 30 minutes prior to vaccination. Patients who experienced delayed urticaria / angioedema to the first dose of COVID-19 vaccine, where medical attention was required, should be referred to an allergy specialist for advice on the second dose. 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. **Myocarditis and pericarditis** 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

Cautions including any relevant action to be taken (continued)	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. Vaccinated individuals should also seek immediate medical attention should they experience new onset of chest pain, shortness of breath, palpitations or arrhythmias. **Guillain-Barre Syndrome (GBS)** Individuals who have a history of GBS should be vaccinated as recommended for their age and underlying risk status. Cases of GBS that occur following vaccination may occur by chance (the rate of GBS is 2 per 100000 per year in the population); no causal link with vaccination has been proven. As there is no evidence to suggest that having had a prior diagnosis of GBS predisposes an individual to further episodes, 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. Based on an understanding of the natural history of GBS, the same vaccine product may be used to complete the course; using an alternative product may increase the chance of experiencing known side effects. **Pregnancy** Vaccination in pregnancy should be offered in accordance with recommendations in Chapter 14a of the Green Book. 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. There is now extensive post-marketing experience of the use of the Pfizer BioNTech and Moderna vaccines in the USA with no safety signals so far (https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafepregnancyregistry.html). These vaccines are therefore the preferred vaccines to offer to pregnant women. Clinicians should discuss the risks and benefits of vaccination with the woman, who should be told about the limited evidence of safety for the vaccine in pregnancy. COVID-19 Pfizer and Moderna vaccines are the preferred vaccines for pregnant women of any age, because of more extensive experience of their use in pregnancy. Pregnant women who commenced vaccination with AstraZeneca, however, are advised to complete with the same vaccine. See Special Considerations / Additional Information section. **Bleeding disorders** Individuals with a bleeding disorder may develop a haematoma at the injection site (see Route of Administration). **Past history of COVID-19 infection** There is no evidence of any safety concerns from vaccinating individuals with a past history of COVID-19 infection, or with detectable COVID-19 antibody. Vaccination of individuals who may be infected but asymptomatic or incubating COVID-19 infection is unlikely to have a detrimental effect on the illness. Vaccination should be deferred in those with confirmed infection to avoid onward transmission and confusing the differential diagnosis. As clinical deterioration can occur up to two weeks after infection, ideally vaccination should be deferred until clinical recovery to around four weeks

Cautions including any relevant action to be taken (continued)	after onset of symptoms or four weeks from the first confirmed positive specimen in those who are asymptomatic. Having prolonged COVID-19 symptoms is not a contraindication to receiving COVID-19 vaccine but if the 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 vaccination protocol must be in accordance with the most up to date advice or amendments (see Green Book Chapter 14a or Regulatory approval of Pfizer/BioNTech vaccine for COVID-19).
Action to be taken if the patient is excluded	In a GP practice setting, inform or refer to the GP or a prescriber as appropriate. The risk to the individual of not being immunised must be considered. The indications for risk groups are not exhaustive, and the healthcare practitioner should consider the risk of COVID-19 exacerbating any underlying disease that an individual may have, as well as the risk of serious illness from COVID-19 itself. Where appropriate, such individuals should be referred for assessment of clinical risk. Where risk is identified as equivalent to those currently eligible for immunisation, vaccination may be provided by an appropriate prescriber or on a patient specific basis, under a PSD. In case of postponement due to acute illness, advise when the individual can be vaccinated and ensure another appointment is arranged. Individuals who have had a previous systemic allergic reaction (including immediate onset anaphylaxis) to a previous dose of Moderna mRNA-1273 COVID-19 Vaccine or COVID-19 mRNA vaccine BNT162b2 Pfizer/BioNTech or any component of the vaccine should not receive further COVID-19 mRNA vaccine BNT162b2 Pfizer/BioNTech (or Moderna mRNA-1273 COVID-19 Vaccine). Seek advice from an allergy specialist. Individuals who suffer from milder reactions following the first dose of COVID-19 mRNA vaccine BNT162b2 Pfizer/BioNTech may proceed to a second dose in an appropriate setting (see Cautions including any relevant action to be taken). Individuals who have a history of immediate-onset anaphylaxis to multiple classes of drugs or unexplained anaphylaxis, should not be vaccinated with COVID-19 mRNA vaccine BNT162b2. The AstraZeneca COVID-19 vaccine (ChAdOx1-S [recombinant]) can be used as an alternative (if not otherwise contraindicated) following the advice of an allergy specialist and in a setting with full resuscitation facilities (e.g. a hospital), and a 30 minute observation period is recommended. Children and young people have a very low risk of COVID-19, severe disease or death due to SARS CoV-2 compared to adults and so COVID-19 vaccines are not routinely recommended for children and young people under 16 years of age. Refer to Green Book Chapter 14a for up-to-date advice on COVID-19 vaccination in children. The Pfizer BioNTech vaccine has approval for use from 12 years of age and

Action to be taken if the patient is excluded (continued)	is therefore the preferred vaccine in this age group. Young people who have had a first dose of AstraZeneca vaccine, however, should complete with the same vaccine. **Note:** vaccination in children under 12 years of age is not covered by this vaccination protocol (a PSD would be required). Individuals who are participating in a clinical trial of COVID-19 vaccines who present for vaccination should be referred back to the investigators unless they have written advice in relation to receiving the COVID-19 vaccine in the routine programme. Document the reason for exclusion and any action taken in the individual's clinical records. Advice should be sought from the individual's clinician in the first instance. Further advice also may be provided from the PHA Immunisation Team: pha.immunisation@hscni.net.
Action to be taken if the patient or carer declines treatment	Informed consent, from the individual or a person legally able to act on the person's behalf, must be obtained for each administration and recorded appropriately. Where a person lacks the capacity, in accordance with the common law in Northern Ireland in relation to the best interests of the incapacitous individual, a decision to vaccinate may be made in the individual's best interests. Advise individual/parent/carer about the protective effects of the vaccine, the risks of infection and potential complications if not immunised. Advise how future immunisation may be accessed if they subsequently decide to receive the COVID-19 vaccine. Document advice given and the decision reached. Inform or refer to the GP or a prescriber as appropriate.
Arrangements for referral for medical advice	Seek appropriate advice from the individual's clinician as required.

STAGE 1b: Description of treatment

ACTIVITY STAGE 1b:	**Consider any relevant cautions, interactions or adverse drug reactions.** **Provide advice to the individual and obtain informed consent[1].** **Record individual's consent[1] and ensure vaccinator, if another person, is informed of the vaccine product to be administered.**
Name, strength & formulation of drug	COVID-19 mRNA BNT162b2 vaccine in a multidose vial. Each vial contains 0.45ml frozen liquid drug product which must be diluted with 1.8ml of 0.9% sodium chloride solution to provide a total of six doses of 30 micrograms in 0.3ml (see Route / Method of Administration)
Legal category	COVID-19 mRNA BNT162b2 vaccine is provided temporary authorisation by the Medicines and Healthcare products Regulatory Agency (MHRA) for supply in the UK under regulation 174 and 174A, pending UK marketing authorisation. The regulation 174 authorised product is categorised as a prescription only medicine (POM).
Black triangle▼	COVID-19 mRNA BNT162b2 vaccine did not have a UK marketing authorisation at the time this protocol was written and 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 BNT162b2 vaccine is supplied in the UK in accordance with regulation 174 and did not have a UK marketing authorisation at the time of writing this protocol. As part of the consent process, healthcare professionals must inform the individual/carer that this vaccine does not have a UK marketing authorisation but has been authorised for temporary supply in the UK by the MHRA and that it is being offered in accordance with national guidance.
Drug interactions	**Immunosuppression** Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to the vaccine. No data are available about concomitant use of immunosuppressants. It is important to still immunise this group. The small number of patients who are about to receive planned immunosuppressive therapy should be considered for vaccination prior to commencing therapy (ideally at least two weeks before), when their immune system is better able to make a response. Where possible, it would also be preferable for the 2-dose schedule to be completed prior to commencing immunosuppression. This would entail offering the second dose at the recommended minimum for that vaccine (three or four weeks from the first dose) to provide maximum benefit that may not be received if the second dose was given during the period of immunosuppression. Any decision to defer immunosuppressive therapy or to delay possible benefit from vaccination until after therapy should not be taken without due consideration of the risks from COVID-19 and from their underlying condition. **Co-administration with other vaccines**

Drug interactions (continued)	Where individuals in an eligible cohort present having recently received another inactivated or live vaccine, 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 a patient presents requiring two vaccines. It is generally better for vaccination to proceed to avoid any further delay in protection and to avoid the risk of the patient not returning for a later appointment. An exception to this is shingles vaccination, where a seven day interval should ideally be observed given the potential for an inflammatory response to COVID-19 vaccine to reduce the response to the live virus.
Identification & management of adverse reactions	The most frequent adverse reactions in participants 16 years of age and older were pain at the injection site, fatigue, headache, myalgia, chills, arthralgia and pyrexia, and were usually mild or moderate in intensity and resolved within a few days after vaccination. Redness at the injection site, injection site swelling, and nausea are reported as common. Lymphadenopathy was reported in less than 1%. **Lymphadenopathy** Swollen axilla or neck glands on the same side as the vaccination site can occur as an uncommon reaction, which can last for up to 10 days. If the vaccine recipient is due to attend for a mammogram, they should be advised to inform clinicians regarding date of vaccine administration. **Myocarditis and pericarditis** Recently a number of cases of myocarditis and pericarditis have been reported after Pfizer BioNTech vaccine from Israel and the USA. The reported rate appears to be highest in those under 25 years of age and in males, and after the second dose. Onset is within a few days of vaccination and most cases are mild and have recovered without any sequalae. The MHRA has advised the benefits of vaccination still outweigh any risk in most individuals. **Guillain-Barre Syndrome** A very small number of cases of Guillain-Barre Syndrome (GBS) have been reported after COVID-19 mRNA (Pfizer/BioNTech) vaccination but these reports have not reached the number expected to occur by chance in the immunised population. 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 As with all vaccines there is a very small possibility of anaphylaxis and facilities for its management must be available. A protocol for the management of anaphylaxis and an anaphylaxis pack must always be available whenever the COVID-19 mRNA Vaccine BNT162b2 (Pfizer BioNTech) vaccine is given. Immediate treatment should include early

Identification & management of adverse reactions (continued)	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. In the event of a severe adverse reaction individual should be advised to seek medical advice.
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 Yellow Card reporting scheme on: http://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 adverse drug reactions for this product, see https://yellowcard.mhra.gov.uk/the-yellow-card-scheme/. There is also a specific reporting page for COVID-19 vaccinations: https://coronavirus-yellowcard.mhra.gov.uk/ Any adverse reaction to a vaccine should be documented in the individual's record and the individual's GP should be informed. Anaphylaxis is a very rare, recognised side effect of most vaccines and suspected cases should be reported via the Coronavirus Yellow Card Scheme. Chapter 8 of the Green Book gives detailed guidance on distinguishing between faints, panic attacks and the signs and symptoms of anaphylaxis. If a case of suspected anaphylaxis meets the clinical features described in Chapter 8, this should be reported via the Yellow Card Scheme as a case of 'anaphylaxis' (or if appropriate 'anaphylactoid reaction'). Cases of less severe allergic reactions (i.e. not including the clinical features of anaphylaxis) should not be reported as anaphylaxis but as 'allergic reaction'. Programmatic Adverse Events should be recorded in line with local procedures and where appropriate escalated in accordance with national framework.
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 Vaccine Pfizer / BioNTech • COVID-19 Vaccination Record Card • What to expect after your COVID-19 vaccination • COVID-19 vaccination: women of childbearing age, currently pregnant, or breastfeeding
Patient advice / follow up treatment	Immunosuppressed individuals should be advised that they may not make a full immune response to the vaccine. Inform the individual/carer of possible side effects and their management. The individual/carer should be advised to seek medical advice in the event of an adverse reaction. Vaccinated individuals should be advised that it is common to develop a fever after vaccination and that this normally happens within 48 hours after

Patient advice / follow up treatment Continued	the vaccination and usually goes away within 48 hours. This is a common, expected reaction, and self-isolation and testing for COVID-19 are not required unless the individual has other COVID-19 symptoms; has been told by PHA Contact Tracing Services they are a close contact of someone who has tested positive for COVID-19; they live with someone who has recently tested positive for COVID-19; or they live with someone who has symptoms of COVID-19. Vaccinated individuals should be advised that if the fever started 48 hours after the vaccination or lasts longer than 48 hours, they should self-isolate and book a test. Vaccinated individuals should be advised that feeling generally unwell, shivery, achy and tired were also symptoms commonly reported by vaccine recipients in the clinical trials. Generally, these symptoms were found to resolve within one to two days without treatment but paracetamol can be taken if necessary to relieve any of these symptoms. Vaccinated individuals should be advised to seek immediate medical attention should they experience new onset of chest pain, shortness of breath, palpitations or arrhythmias. Very rare reports have been received of Guillain-Barre Syndrome (GBS) following COVID-19 vaccination, so 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. As has always been recommended, any fever after vaccination should be monitored and if individuals are concerned about their health at any time, they should seek advice from their GP. The individual should be advised to seek medical advice in the event of a severe adverse reaction. Inform the individual that they can report suspected adverse reactions to the MHRA using the Yellow Card reporting scheme on: https://coronavirus-yellowcard.mhra.gov.uk 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 administration is postponed advise the individual how future vaccination may be accessed. When applicable, advise the individual/carer when to return for vaccination or when a subsequent vaccine dose is due.
Special considerations / additional information	Ensure there is immediate access to adrenaline (epinephrine) 1 in 1,000 injection and access to a telephone at the time of vaccination. A protocol for the management of anaphylaxis and an anaphylaxis pack must be readily available in case of an anaphylactic event. Immediate treatment should include early treatment with 500 micrograms intramuscular adrenaline (0.5ml of 1:1000 or 1mg/ml adrenaline), with an early call for help and further IM adrenaline every 5 minutes if features of anaphylaxis do not resolve. Minor illnesses without fever or systemic upset are not valid reasons to postpone immunisation. If an individual is acutely unwell, immunisation may 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.

Special considerations / additional information (continued)	**Pregnancy** There is no known risk associated with giving inactivated, recombinant viral or bacterial vaccines or toxoids during pregnancy or whilst breast-feeding. Since inactivated vaccines cannot replicate they cannot cause infection in either the mother or the fetus. As with most pharmaceutical products, specific clinical trials of coronavirus vaccines in pregnant women have not been carried out. Developmental and reproductivity testing of the Pfizer BioNTech, Moderna and AstraZeneca COVID-19 vaccines have not raised any concerns. 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. There is now extensive post-marketing experience of the use of the Pfizer BioNTech and Moderna vaccines in the USA with no safety signals so far (https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafepregnancyregistry.html). These vaccines are therefore the preferred vaccines to offer to pregnant women. Clinicians should discuss the risks and benefits of vaccination with the woman, who should be told about the limited evidence of safety for the vaccine in pregnancy. 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 can 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 may complete vaccination during pregnancy using the same vaccine product (unless contraindicated). Alternatively, vaccination should be offered as soon as possible after pregnancy. Note: The Royal College of Obstetricians and Gynaecologists has produced a decision aid to support women to make a personal informed choice, in discussion with a healthcare professional, about whether to accept a COVID-19 vaccination in pregnancy (see https://www.rcog.org.uk/covid-vaccine). Termination of pregnancy following inadvertent immunisation should not be recommended. Surveillance of the inadvertent administration of COVID-19 vaccines in early pregnancy is being conducted for the UK by the PHE Immunisation Department, to whom such cases should be reported at this link: https://www.gov.uk/guidance/vaccination-in-pregnancy-vip. As above, women who are inadvertently vaccinated in early pregnancy should be offered the second dose of the same product. **Breastfeeding** It is unknown whether COVID-19 mRNA vaccine BNT162b2 (Pfizer BioNtech) is excreted in human milk. There is no known risk associated with giving non-live vaccines whilst breastfeeding. JCVI advises that breastfeeding women may be offered vaccination with the Pfizer-BioNTech or AstraZeneca COVID-19 vaccines. The developmental and health benefits of breastfeeding should be considered along with the woman's clinical need for immunisation against COVID-19, and the woman should be informed about the absence of safety data for the vaccine in breastfeeding women.

Special considerations / additional information (continued)	**Previous incomplete vaccination** If the course is interrupted or delayed, it should be resumed using the same vaccine but the first dose should not be repeated. Evidence from trials of co-administration suggests 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 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, this vaccination protocol may be used. **Non-responders / immunosuppressed** Immunological response may be lower in immunocompromised individuals, but they should still be vaccinated. Emerging evidence suggests many individuals with immunosuppression are protected after two doses of vaccination. Despite the overall reassuring evidence, some individuals with more severe immunosuppression do not make a good immune response to a complete course of vaccine and may therefore remain at high risk. Post-vaccination testing for spike antibody may be considered by specialists managing individuals with severe immunosuppression. Individuals can then be advised whether to take precautions to reduce their chance of exposure, taking into account their underlying immune defect and any test results. Individuals who have received a bone marrow transplant after COVID-19 vaccination should be considered for re-immunisation.

STAGE 2: Vaccine Preparation

ACTIVITY STAGE 2:	Vaccine preparation
Vaccine presentation	COVID-19 mRNA Vaccine BNT162b2 30micrograms/0.3ml dose concentrate for solution for injection multi-dose vials COVID-19 mRNA Vaccine BNT162b2 is a multi-dose vial and must be diluted with 1.8mL of 0.9% sodium chloride before use. 1 vial contains 6 doses of 30 micrograms of BNT162b2 RNA (embedded in lipid nanoparticles).
Supplies	A central supply of COVID-19 mRNA Vaccine BNT162b2 has been procured in response to the COVID-19 pandemic. HSC standard operating procedures should be followed for appropriate ordering, storage, handling, preparation, administration and waste minimisation of COVID-19 mRNA Vaccine BNT162b2, which ensure use is in accordance with Regulation 174 Information for UK Healthcare Professionals and Conditions of Authorisation for Pfizer/BioNTech COVID-19 vaccine BNT162b2.
Storage	Vials of COVID-19 mRNA BNT162b2 vaccine are supplied frozen and require storage in an ultra-low temperature freezer at -75°C (+/-15°C). Once removed from the freezer, COVID-19 mRNA BNT162b2 vaccine is stable for 31 days in a fridge at 2 to 8°C, and up to 2 hours at temperatures up to 25°C, prior to dilution. COVID-19 mRNA Vaccine BNT162b2 should be diluted as close to use as possible. However, reconstituted vaccine which is not required immediately must be used within 6 hours from the time of dilution and stored between 2°C to 25°C. The vaccine vial has space to write the date and time of dilution; write this on the vial label. Store in original packaging in order to protect from light. 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. The most up to date manufacturer's recommendations in the current Conditions of Authorisation for Pfizer/BioNTech COVID-19 vaccine and Information for Healthcare Professionals on Pfizer/BioNTech COVID-19 vaccine may be followed. Breaches in the cold-chain should be reported in line with local arrangements. Vaccines that have been stored outside of the cold-chain should be quarantined and further advice re use should be sought from the local Trust's Pharmacy Department or Medicines Information Service. Vaccine losses outside of secondary care should be reported to the PHA Duty Room (0300 555 0119) for further risk assessment, including whether patients need revaccination following a cold chain breach.
Vaccine preparation	Using aseptic technique, thawed COVID-19 mRNA Vaccine BNT162b2 requires dilution in its original vial with 1.8ml of unpreserved sodium chloride 0.9% solution for injection, prior to withdrawing a 0.3ml dose for administration.

Vaccine preparation (continued)	Vaccine should be prepared in accordance with manufacturer's recommendations (see Regulation 174 Information for UK Healthcare Professionals) and HSC standard operating procedures for the service. Gently invert the diluted solution 10 times. Do not shake the vaccine. The vaccine dose should be drawn up from the diluted vial immediately prior to administration. Inspect visually prior to administration and ensure appearance is consistent with the description in the Regulation 174 Information for UK Healthcare Professionals, that is an off-white solution with no particulates visible. Discard the vaccine if particulates or discolouration are present. In order to extract at least 6 doses from a single vial, low dead-volume syringes and/or needles should be used. Each dose must contain 0.3ml of vaccine. If the amount of vaccine remaining in the vial cannot provide a full dose of 0.3 ml, discard the vial and any excess volume. Do not pool excess vaccine from multiple vials. Any unused vaccine should be discarded 6 hours after dilution. The vaccine may be diluted, drawn up and administered by the same person or separate persons with the required competence and supervision. If the vaccine is to be administered by a person other than the person preparing it, ensure that there are clear procedures for transferring the vaccine to the vaccinator in a safe way, allowing for appropriate checks of vaccine particulars, batch number and expiry by both parties.
Disposal	Equipment used for immunisation, including used vials, ampoules, or discharged vaccines in a syringe or applicator, should be disposed of safely in a UN-approved puncture-resistant 'sharps' box, according to local authority regulations and guidance in the technical memorandum 07-01: Safe management of healthcare waste (Department of Health, 2013).

STAGE 3: Vaccine Administration

ACTIVITY STAGE 3:	**Before administering the vaccine, ensure:** **1. the individual has been assessed in accordance with stage one of this protocol** **2. the vaccine to be administered has been identified, by the registered practitioner consenting the individual, as COVID-19 Vaccine BNT162b2 (Pfizer / BioNTech)** **3. consent for vaccination has been provided and documented[1]** **Administer COVID-19 Vaccine BNT162b2 (Pfizer / BioNTech) and provide any post-vaccination advice.**
Vaccine to be administered	COVID-19 mRNA Vaccine BNT162b2, COVID-19 mRNA vaccine BNT162b2 30micrograms in 0.3ml dose
Dose and frequency of administration	A two-dose course should be administered consisting of 30micrograms in 0.3ml followed by a second dose of 30micrograms in 0.3ml after an interval of at least 21 days, or in accordance with official national guidance at the time. See note below for 16 to 17 year olds not in 'at risk' groups or a health and social care worker. 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. At the time of writing, 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. Operationally, this consistent interval should be used for all vaccines with a two-dose primary schedule to avoid confusion and simplify booking, and this will help to ensure a good balance between achieving rapid and long lasting protection. See Drug Interactions section for advice on dosing interval for individuals who are about to receive planned immunosuppressive therapy. If an interval longer than the recommended interval is left between doses, the second dose should still be given (preferably using the same vaccine as was given for the first dose if possible). The course does not need to be restarted. If the course is interrupted, it should be resumed (using the same vaccine) but not repeated. In these eventualities, the second dose can still be given under this vaccination protocol. Individuals may not be fully protected until at least 7 days after their second dose of the vaccine. **Note:** At this time, JCVI advises that all 16 to 17-year-olds who are not in 'at risk' groups or who are not a health and social care worker should be offered a **first dose** of Pfizer-BNT162b2 vaccine. Pending further evidence on effectiveness and safety in this age group, a second vaccine dose is anticipated to be offered later to increase the level of protection and contribute towards longer term protection. Further data and the potential availability of alternative vaccine options will inform exact details. Further advice from JCVI is expected before second doses are due at approximately 12 weeks after the first dose.
Duration of treatment	See Dose and frequency of administration above. The duration of immunity provided by COVID-19 mRNA BNT162b2 vaccine is currently unclear and future vaccination should be advised in accordance with national recommendations.

Quantity to be supplied / administered	Administer 30micrograms in 0.3ml. A two-dose* course with a minimum interval of 21 days should be provided (see Dose and frequency of administration). * See note in Dose and frequency of administration regarding 16 to 17 year olds who are not in 'at risk' groups or who are not a health and social care worker.
Route / method of administration	COVID-19 mRNA Vaccine BNT162b2 30micrograms in 0.3ml, is for administration by intramuscular injection only, preferably into deltoid region of the upper arm. Vaccinators should administer a 0.3ml dose prepared in accordance with Stage 2 above. Where it is within their competence, experienced vaccinators may draw the required 0.3ml dose from a vial diluted by another person, under the supervision of a doctor, nurse, or pharmacist, in accordance with Stage 2. If vaccine is not prepared by the vaccinator, safe procedures must be in place for the vaccinator to safely receive, check, and use the vaccine immediately after preparation. Do not shake the vaccine. Check product name, batch number and expiry prior to administration. Inspect visually prior to administration and ensure appearance is consistent with the description in the Regulation 174 Information for UK Healthcare Professionals, that is an off-white solution with no particulates visible. Discard the vaccine if particulates or discolouration are present. Where the individual has been identified by the assessing registered professional as being at increased risk of bleeding, a fine needle (equal to 23 gauge or finer calibre such as 25 gauge) should be used for the vaccination, followed by firm pressure applied to the site (without rubbing) for at least 2 minutes. The individual/carer should be informed about the risk of haematoma from the injection.
Disposal	Equipment used for immunisation, including used vials, ampoules, or discharged vaccines in a syringe or applicator, should be disposed of safely in a UN-approved puncture-resistant 'sharps' box, according to local authority regulations and guidance in the technical memorandum 07-01: Safe management of healthcare waste (Department of Health, 2013).
Observation following vaccination	Recipients of COVID-19 vaccine should be observed for any immediate reactions during the period they are receiving any post-immunisation information and subsequent appointment if required. COVID-19 mRNA Vaccine BNT162b2 (Pfizer BioNtech) vaccine recipients should be monitored for 15 mins after vaccination, with a longer observation period when indicated after clinical assessment. Patients who experienced an immediate-type allergic reaction to the first dose of COVID-19 vaccine, where symptoms were limited to swelling or rash local to the injection site only, can have the second dose using the same vaccination in any vaccination setting. Observe the patient for 30 minutes. Patients who experienced delayed urticaria / angioedema to the first dose of COVID-19 vaccine, where the reaction was self-limiting or resolved with oral antihistamine, can have the second dose using the same vaccination

	in any setting. Consider pre-treatment with non-sedating antihistamine, 30 minutes prior to vaccination. As syncope (fainting) can occur following vaccination, all vaccinees should either be driven by someone else or should not drive for 15 minutes after vaccination.
Post-vaccination advice	Vaccine recipients should be monitored for 15 mins after vaccination, with a longer observation period when indicated after clinical assessment (see Green Book Chapter 14a). Ensure the individual has been provided appropriate written information such as the: • Regulation 174 Information for UK recipients for COVID-19 mRNA vaccine BNT162b2 • COVID-19 Vaccination Record Card • What to expect after your COVID-19 vaccination

STAGE 4: Recording vaccine adminstration

ACTIVITY STAGE 4:	**Complete a record of vaccination for the individual and in accordance with local policy.** **The required records should be completed by the person who is undertaking the recorded activity or a designated record keeper who is a witness to the activity undertaken.**
Records	Verbally confirm individual's name, address, date of birth, HSC number (for healthcare professionals) and Record data required by the data capture form (including): • that valid informed consent was given or a decision to vaccinate made in the individual's best interests in accordance with the common law in Northern Ireland in relation to the best interests of the incapacitous individual • clinical risk group indication for immunisation if applicable • 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 immunisation • details of any adverse drug reactions and actions taken • supplied and administered via vaccination protocol Records should be signed and dated by the practitioner. All records should be clear, legible and contemporaneous. It is important that vaccinations given either at a general practice or elsewhere are recorded on appropriate health records for the individual (using the appropriate clinical code) in a timely manner. If given elsewhere, systems should be in place to ensure a record of vaccination is returned to the individual's general practice to allow clinical follow up and to avoid duplicate vaccination. A record of all individuals receiving treatment under this vaccination protocol should also be kept for audit purposes in accordance with local policy.

5. Key references

Key references	COVID-19 mRNA BNT162b2 Vaccination

- Immunisation Against Infectious Disease: The Green Book, Chapter 14a. Published 27 November 2020. https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book
- Priority groups for coronavirus (COVID-19) vaccination: advice from the JCVI, 30 December 2020
- https://www.gov.uk/government/publications/priority-groups-for-coronavirus-covid-19-vaccination-advice-from-the-jcvi-30-december-2020
- Coronavirus (Covid-19): Shielded patients list. NHS Digital. Updated 18 August 2020. https://digital.nhs.uk/coronavirus/shielded-patient-list
- Coronavirus (COVID-19): definitions of 'clinically extremely vulnerable' and 'vulnerable' https://www.nidirect.gov.uk/articles/coronavirus-covid-19-definitions-clinically-extremely-vulnerable-and-vulnerable
- Information for Healthcare Professionals on Pfizer/BioNTech COVID-19 vaccine (Manufacturer's product information) https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/948101/Temporary_Authorisation_HCP_Information.pdf
- Clinical guidance for healthcare professionals on maintaining immunisation programmes during COVID-19. https://www.england.nhs.uk/coronavirus/publication/preparedness-letters-for-general-practice/
- Immunisation training, Public Health Agency https://www.publichealth.hscni.net/directorate-public-health/health-protection/immunisationvaccine-preventable-diseases
- COVID-19 Vaccination e-learning programme https://www.e-lfh.org.uk/covid-19-vaccination-e-learning-programme-now-live/
- Joint Committee on Vaccination and Immunisation (JCVI). https://www.gov.uk/government/groups/joint-committee-on-vaccination-and-immunisation#influenza-vaccines-jcvi-advice
- JCVI final statement on phase 2 of the COVID-19 vaccination programme, 13 April 2021 https://www.gov.uk/government/publications/priority-groups-for-phase-2-of-the-coronavirus-covid-19-vaccination-programme-advice-from-the-jcvi/jcvi-final-statement-on-phase-2-of-the-covid-19-vaccination-programme-13-april-2021
- Department of Health NI. Deployment of the Covid-19 vaccine in Northern Ireland, 7th Dec 2020. https://www.health-ni.gov.uk/sites/default/files/publications/health/doh-hss-md-82-2020.pdf
- Joint Committee on Vaccination and Immunisation (JCVI). Optimising the COVID-19 vaccination programme for maximum short-term impact, 26 January 2021 https://www.gov.uk/government/publications/prioritising-the-first-covid-19-vaccine-dose-jcvi-statement/optimising-the-covid-19-vaccination-programme-for-maximum-short-term-impact

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Key references
(continued)

- HSS(MD)13/2021. Updated guidance on timing of COVID-19 vaccine dosing interval in patients due to receive treatment with immunosuppressants, 28 January 2021 https://www.health-ni.gov.uk/publications/letters-and-urgent-communications-2020
- MHRA. Regulatory approval of Pfizer / BioNTech vaccine for COVID-19. https://www.gov.uk/government/publications/regulatory-approval-of-pfizer-biontech-vaccine-for-covid-19
- MHRA. Confirmation of guidance to vaccination centres on managing allergic reactions following COVID-19 vaccination with the Pfizer/BioNTech vaccine 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
- Resuscitation Council UK. Management of anaphylaxis in the vaccination setting. https://www.resus.org.uk/about-us/news-and-events/rcuk-publishes-anaphylaxis-guidance-vaccination-settings
- Public Health England. JCVI issues interim advice on COVID-19 booster vaccination, 19 July 2021 https://www.gov.uk/government/news/jcvi-issues-interim-advice-on-covid-19-booster-vaccination
- Public Health England. JCVI issues updated advice on COVID-19 vaccination of young people aged 16 to 17, 4 August 2021. https://www.gov.uk/government/news/jcvi-issues-updated-advice-on-covid-19-vaccination-of-young-people-aged-16-to-17
- Department of Health and Social Care. JCVI statement on COVID-19 vaccination of children and young people aged 12 to 17 years, 4 August 2021 https://www.gov.uk/government/publications/jcvi-statement-august-2021-covid-19-vaccination-of-children-and-young-people-aged-12-to-17-years/jcvi-statement-on-covid-19-vaccination-of-children-and-young-people-aged-12-to-17-years-4-august-2021
- HSS(MD)56 /2021. Further updated advice from JCVI regarding children aged 16 and 17 years of age. 6 August 2021. https://www.health-ni.gov.uk/sites/default/files/publications/health/doh-hss-md-56-2021.pdf

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
- National Minimum Standards for Immunisation Training (2018) https://www.gov.uk/government/publications/national-minimum-standards-and-core-curriculum-for-immunisation-training-for-registered-healthcare-practitioners
- PHE Guidance on immunisation training during the COVID-19 pandemic. 26 June 2020. https://www.gov.uk/government/publications/immunisation-training-guidance-during-the-covid-19-pandemic/guidance-on-immunisation-training-during-the-covid-19-pandemic

	• 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. Published 4 August 2009. https://www.gov.uk/government/publications/reference-guide-to-consent-for-examination-or-treatment-second-edition • Immunisation knowledge and skills competence assessment tool. Royal College of Nursing (RCN) 2018 https://www.rcn.org.uk/professional-development/publications/pdf-006943 • Guidance on vaccine handling and storage in GP practices. PHA and HSCB, January 2020 http://primarycare.hscni.net/pharmacy-and-medicines-management/resources/vaccines/ • Regulation 247A, UK Statutory Instrument 2012 No. 1916, The Human Medicines Regulations 2012 https://www.legislation.gov.uk/uksi/2012/1916/regulation/247A

APPENDIX A

COVID-19 mRNA BNT162b2 vaccine protocol v02.00
Valid from: 20/08/2021 Expiry: 31/03/2022

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

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

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

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

I confirm that I have read and understood the content of this protocol and that I am willing and competent to work to it.

Name	Designation	Activity Stage:				Signature	Date
		1	2	3	4		

Authorising registered healthcare professional

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

Name	Designation	Signature	Date

Note to authorising registered healthcare professional

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

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