

COVID-19 mRNA Vaccine BNT162b2 Pfizer/BioNTech Vaccine

National Protocol

Reference no: COVID-19 mRNA Vaccine BNT162b2 Pfizer/BioNTech Vaccine Protocol
Version no: v02
Valid from: 02 February 2021
Review date: 30 November 2021
Expiry date: 31 December 2021

1. About the National Protocol

This protocol is for the supply and administration of COVID-19 mRNA Vaccine BNT162b2 Pfizer/BioNTech to individuals in accordance with the national COVID-19 vaccination programme. This protocol only allows administration during or in anticipation of COVID-19 pandemic where the disease represents a serious risk or potentially serious risk to human health.

This protocol is for the supply and administration of COVID-19 mRNA Vaccine BNT162b2 Pfizer/BioNTech by appropriately trained persons in accordance with [regulation 247A](#) of the [Human Medicines Regulation 2012](#), as inserted by [The Human Medicines \(Coronavirus and Influenza\) \(Amendment\) Regulations 2020](#)

The Scottish Government has developed this protocol which has been approved by the Scottish Ministers to facilitate the delivery of the national COVID-19 vaccination programme by Health Boards in Scotland and any organisation a Health Board makes arrangements with to deliver such services on its behalf, referred to as “the provider”. Please note that in the context of this protocol, “the provider” means:

- (a) a Health Board,
- (b) a Health Board working with Armed Forces staff where Armed Forces staff are working in Health Board settings, or
- (c) an organisation delivering services on behalf of a Health Board.

This protocol may be followed wholly from patient assessment through to post-vaccination by a single person. Alternatively, obtaining consent and patient assessment may be undertaken by a registered healthcare professional with the process of administration undertaken by a non-registered professional or a non-registered Armed Forces staff member under clinical supervision.

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 patient.

The provider is responsible for ensuring that persons are trained and competent to safely deliver the activity they are authorised to provide under this protocol. As a minimum, competence requirements stipulated in the protocol under ‘Characteristics of staff’ must be adhered to.

The provider must identify a clinical supervisor who has overall responsibility for provision of vaccinations under the protocol at all times. This includes overall responsibility for the activities of any Armed Forces staff working under the protocol.

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.

The clinical supervisor must be identifiable to service users. Whenever the protocol is used, the name of the clinical supervisor taking responsibility and all of the people working under different activity stages of the protocol must be recorded for the session using the schedule in Annex C or maintaining an equivalent electronic record. The clinical supervisor has ultimate responsibility for safe care being provided under the terms of the protocol. Persons working under the protocol may be supported by additional registered healthcare professionals, but the clinical supervisor retains responsibility.

Persons working to the protocol must understand who the clinical supervisor for their practice is at any time and can only work under their authority. The clinical supervisor may withdraw this authority for all persons or individual persons at any time and has authority to stop and start service provision under the protocol as necessary. All members of staff have 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.

Individual practitioners must be designated by name to work to this protocol. Individuals working in accordance with this protocol must ensure they meet the staff characteristics for the activity they are undertaking, make a declaration of competence and be authorised in writing by the provider. This can be done by completing Annex B of this protocol or maintaining an equivalent electronic record.

It is a Health Board's responsibility to adhere to this protocol. Where the Health Board is not the provider, it is the Health Board's responsibility to ensure that the provider adheres to this protocol. The final authorised copy of this protocol should be kept, by Health Boards for 8 years after the protocol expires. Providers adopting authorised versions of this protocol should also retain copies, along with the details of those authorised to work under it, for 8 years after the protocol expires.

Providers must check that they are using the current version of this protocol. Amendments may become necessary prior to the published expiry date. Current versions of protocols authorised by the Scottish Ministers in accordance with

regulation 247A of the Human Medicines Regulations 2012 can be found on the Scottish Government website: (tbc)

Any concerns regarding the content of this protocol should be addressed to:




VaccinationsDelivery@gov.scot

2. Approval and Clinical Authorisation

This protocol is not legally valid, in accordance with [regulation 247A](#) of [Human Medicines Regulation 2012](#), as inserted by [The Human Medicines \(Coronavirus and Influenza\) \(Amendment\) Regulations 2020](#), until approved by the Scottish Ministers.

On 2 February 2021 the Scottish Ministers, approved this protocol in accordance with [regulation 247A](#) of Human Medicines Regulation 2012. Approval of clinical information in Annex A is via the Scottish Government Chief Medical Officer, Chief Pharmaceutical Officer and Chief Nursing Officer for the delivery of the national COVID-19 vaccination programme, with defined limitations to authorisation that may be updated from time to time as may be required.

Authorised for use by the following organisations and/or services
All Health Boards in Scotland, and organisations Health Boards make arrangements with to deliver services on their behalf.
Limitations to authorisation
This authorisation applies to the supply and administration of the vaccine(s) only under the conditions set out in the authorisation for supply or license set out by the Medicines and Healthcare products Regulatory Agency

Clinical authorisation			
Role	Name	Sign	Date
CMO	Gregor Smith		02 February 2021
CNO	Fiona Mcqueen		02 February 2021
CPO	Alison Strath		02 February 2021

It is Health Boards' responsibility to ensure they and any organisations they make arrangements with to deliver services on their behalf operate the specified vaccination services in accordance with the protocol. Any provider administering COVID-19 mRNA Vaccine BNT162b2 Pfizer/BioNTech vaccine under protocol must work strictly within the terms of this protocol.

The national COVID-19 vaccination programme may also be provided under patient group direction, under written instruction for supply and administration in the course of an occupational health scheme, or on a patient specific basis, by or on the directions of an appropriate prescriber. Supply and administration in these instances are not related to this protocol.

3. Change history

Version number	Change details	Date
V01.00	New protocol for COVID-19 mRNA Vaccine BNT162b2 Pfizer/BioNTech vaccine.	21 January 2021
V02.00	Updated protocol to reflect Armed Services staff roles	02 February 2021

4. Characteristics of staff

The Provider is responsible for the designation and authorisation of persons within the classes set out below permitted to administer medicinal products under this protocol. In doing so the provider must establish that those persons

- a) demonstrate appropriate knowledge and skills to work under the National Protocol for the supply/administration of COVID-19 vaccine.
- b) have met the requirements of the NES Proficiency document -COVID-19 vaccine administration for registered staff or the NES Proficiency document – COVID-19 vaccine administration - Healthcare support workers as appropriate <https://learn.nes.nhs.scot/37676/immunisation/covid-19-vaccines>

Classes of persons permitted to administer medicinal products under this protocol

This protocol may be adhered to wholly from assessment through to post-vaccination by a single appropriately specified registered healthcare professional. Alternatively, multiple persons may undertake specific activity stages in the vaccination pathway in accordance with this protocol.

Activity stages of the vaccination pathway under this protocol

Stage 1	a. Assessment of the individual presenting for vaccination b. Provide information and obtain informed consent c. Provide advice to the individual	Registered Healthcare Professionals Only
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Stage 2	• Vaccine Preparation	Registered Healthcare Professionals, non-registered professionals or non-registered Armed Forces staff
Stage 3	• Vaccine Administration	Registered Healthcare Professionals, non-registered professionals or non-registered Armed Forces staff
Stage 4	• Record Keeping	Registered Healthcare Professionals, non-registered professionals or non-registered Armed Forces staff

Providers are responsible for assessing the competency of, designating and recording the names of all those persons permitted to supply and administer under this protocol.

The following specified registered healthcare professionals are permitted to administer 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 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.
- Doctors currently registered with General Medical Council.
- Dentists currently registered with General Dental Council.

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

- Healthcare support workers.
- Pharmacy technicians, provisionally registered pharmacists, pre-registration pharmacists and other pharmacy support practitioners.
- Retired clinical practitioners 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
- Healthcare Assistant (HCA)

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 Annex B. All staff listed on the sheet will be covered by NHS indemnity extended by the Health Board who is responsible for the COVID 19 vaccination programme in that locality. 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 health board standard operating procedures and in line with the training recommendations for COVID-19 vaccinators.
- They must have met the requirements set out in the NES Proficiency document - COVID-19 vaccine administration for registered staff or the NES Proficiency document –COVID-19 vaccine administration- Healthcare support workers

2. Competency

- Those providing clinical supervision to those administering the vaccine must be competent to assess individuals for suitability for vaccination, identify any contraindications or precautions, discuss issues related to vaccination and obtain informed consent from the individuals being vaccinated.
- All persons must either be an appropriate prescriber or one of above noted registered professionals. Those that are not registered professionals, and those returning to immunisation after a prolonged interval (more than 12 months), should be assessed and signed off as meeting the requirements of the relevant NES Proficiency document -COVID-19 vaccine administration. 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.
- Experienced vaccinators should use the relevant NES Proficiency document to self-assess that they are able to meet all the competencies listed and confirm that they have the knowledge and skills necessary to administer COVID-19 vaccine.
- They must have completed local IPC training and comply with the vaccination guidance with the National COVID-19 IPC guidelines available: [National Infection Prevention and Control Manual: Scottish COVID-19 Infection Prevention and Control Addendum for Acute Settings](#)

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 \(www.gov.uk\)](#).
- 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, procedure for dilution of the vaccine 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 app.

- 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.

5. Clinical condition or situation to which this Protocol applies

COVID-19 mRNA Vaccine BNT162b2 Pfizer/BioNTech is indicated for active immunisation against COVID-19 disease caused by SARS-CoV-2 virus in accordance with Scottish Government COVID-19 immunisation programme and recommendations given in Chapter 14a of the Immunisation Against Infectious Disease: the 'Green Book' [COVID-19: the green book, chapter 14a - GOV.UK \(www.gov.uk\)](https://www.gov.uk/government/publications/covid-19-the-green-book-chapter-14a) and Scottish Government CMO letters relating to COVID-19 vaccination.

ANNEX A: Clinical Information

This Annex provides information about the clinical situation or condition and treatment in relation to the National Protocol.

Annex Version history

Version	Date	Summary of changes
1.0	21/01/21	Version 1.0 new Annex A
1.1	01/02/21	<p>The following sections have been updated</p> <ul style="list-style-type: none">• Exclusion section updated to align with wording in Green Book on previous systemic allergic reaction (including immediate-onset anaphylaxis and an additional exclusion for those patients with history of systemic reaction to biologics/monoclonals except on the advice an allergy specialist.• Cautions section updated to include advice from Green Book on second doses following non allergic reactions or localised urticarial skin reactions without systemic symptoms following first dose.• Form/strength section updated to reflect number of doses in a vial• Route of administration section updated to align with wording in information for UK health professionals on number of doses in a vial.• Frequency section updated to align with advice in Green Book on timing of second dose for those commencing immunosuppressive treatment.• Observation following vaccination section updated with advice on post vaccine observation of second doses in those who had localised urticarial skin rashes (without systemic symptoms to the first dose.

1. Clinical condition or situation to which this Protocol applies

Category	Description
Indication	COVID-19 mRNA Vaccine BNT162b2 is indicated for active immunisation against COVID-19 disease caused by SARS-CoV-2 virus in accordance with Scottish Government COVID-19 immunisation programme and recommendations given in Chapter 14a of the Immunisation Against Infectious Disease: the 'Green Book', JCVI statement on priority groups for COVID-19 vaccination from 30th December 2020 and subsequent correspondence/publications from Scottish Government.
Inclusion criteria	National policy must be followed in relation to the priority groups eligible for vaccination at a particular point in time.

Category	Description
	<p>COVID-19 vaccine should be offered to the following individuals:</p> <ul style="list-style-type: none"> • Residents in a care home for older adults and their carers • All those 80 years of age and over • Frontline health and social care workers (as included in COVID-19 –SARS-Cov-2 chapter of Green Book, JCVI statement and Scottish Government CMO letters) • All those 75 years of age and over • All those 70 years of age and over • Clinically extremely vulnerable (CEV) individuals (not including all pregnant women and those under 16 years) as defined by Scottish Government at https://www.gov.scot/publications/covid-shielding/pages/highest-risk-classification/ • All those 65 years of age and over • Individuals aged 16 years to 64 years with underlying health conditions which puts them at higher risk of serious disease and mortality included in Table 3 COVID-19 –SARS-Cov-2 chapter 14a of Green Book* • All those 60 years of age and over • All those 55 years of age and over • All those 50 years of age and over • Further guidance for those under age 50 years not included in the above groups will follow in phase 2. <p>*This also includes those who are in receipt of a carer’s allowance, or those who are the main carer of an elderly or disabled person whose welfare may be at risk if the carer falls ill.</p> <p>The list above is not exhaustive, and clinician should apply clinical judgment to take into account the risk of COVID-19 exacerbating any underlying disease that a patient may have, as well as the risk of serious illness from COVID-19 itself. COVID-19 vaccine should be offered in such cases even if the individual is not in the clinical risk groups specified above, this may be provided under a Patient Specific Direction (PSD).</p>
<p>Exclusion criteria</p>	<p>The vaccine should not be given to:</p> <ul style="list-style-type: none"> • Those who have had a previous systemic allergic reaction (including immediate-onset anaphylaxis) to a previous dose of this COVID-19 vaccine • Those who have had a previous systemic allergic reaction (including immediate-onset anaphylaxis) to any components of this vaccine

Category	Description
	<ul style="list-style-type: none"> • Those with a history of immediate-onset anaphylaxis to multiple classes of drugs or unexplained anaphylaxis. • Those with a history of systemic allergic reactions to biologics/monoclonal preparations. Such individuals should not receive the COVID-19 mRNA Vaccine BNT162b2 vaccine except on the expert advice of an allergy specialist • Those in whom no valid consent has been received • Those who are under 16 years of age • Women who are known to be pregnant (routine questioning about last menstrual period and/or pregnancy testing is not required before offering the vaccine) • Those with confirmed COVID-19 infection to avoid confusing the differential diagnosis. As clinical deterioration can occur up to two weeks after infection, ideally vaccination should be deferred until around four weeks after onset of symptoms or from the first PCR positive specimen in those who are asymptomatic. • Those with evidence of current deterioration of COVID-19 symptoms, deferral of vaccination may be considered to avoid incorrect attribution of any change in the person's underlying condition to the vaccine. • Those who are participating in a clinical trial of COVID-19 vaccines • Those with acute febrile illness – consider postponing immunisation until individual has fully recovered. • Those with evolving neurological condition – consider postponing immunisation until individual has stabilised.
<p>Cautions/need for further advice/ circumstances when further advice should be sought from a doctor</p>	<p>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 local immunisation or health protection team.</p> <p>Individuals with a bleeding disorder may develop a haematoma at the injection site (see Route of Administration).</p> <p>The MHRA has advised that individuals with a history of anaphylaxis to food, an identified drug or vaccine, or an insect sting can receive any COVID-19 vaccine, as long as they are not known to be allergic to any component of the vaccine.</p> <p>The COVID-19 chapter of the Green Book states that individuals with a localised urticarial (itchy) skin reaction (without systemic symptoms) to the first dose of a COVID-19 vaccine should receive the second dose of vaccine with prolonged observation (30 minutes) in a setting with full resuscitation facilities (e.g. a hospital).</p>

Category	Description
	<p data-bbox="485 230 1377 371">The COVID-19 chapter of the Green Book states individuals with non-allergic reactions (vasovagal episodes, non-urticarial skin reaction or non-specific symptoms) to the first dose of a COVID-19 vaccine can receive the second dose of vaccine in any vaccination setting.</p> <p data-bbox="485 398 1377 607">Because of the absence of data on co-administration with COVID-19 vaccines, it should not be routine to offer appointments to give this vaccine at the same time as other vaccines. Based on current information about the first COVID-19 vaccines being deployed, scheduling should ideally be separated by an interval of at least 7 days to avoid incorrect attribution of potential adverse events.</p> <p data-bbox="485 633 1377 954">As COVID-19 mRNA Vaccine BNT162b2 is considered inactivated, where individuals in an eligible cohort present having received another inactivated or live vaccine, COVID-19 vaccination should still be considered. The same applies for other live and inactivated vaccines where COVID-19 vaccination has been received first. In many cases, vaccination should proceed to avoid any further delay in protection and to avoid the risk of the patient not returning for a later appointment. In such circumstances, patients should be informed about the likely timing of potential adverse events relating to each vaccine.</p> <p data-bbox="485 981 1377 1189">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.</p> <p data-bbox="485 1216 1377 1323">JCVI advise there is no known risk associated with giving these types of vaccines during pregnancy. These vaccines cannot replicate, so they cannot cause infection in either the woman or the unborn child.</p> <p data-bbox="485 1350 1377 1458">Although the available data do not indicate any safety concern or harm to pregnancy, there is insufficient evidence to recommend routine use of COVID-19 vaccines during pregnancy.</p> <p data-bbox="485 1485 1377 1805">JCVI advises that, for women who are offered vaccination with the Pfizer-BioNTech or AstraZeneca COVID-19 vaccines, vaccination in pregnancy should be considered where the risk of exposure to Severe Acute Respiratory Syndrome coronavirus 2 (SARS-CoV2) infection is high and cannot be avoided, or where the woman has underlying conditions that put them at very high risk of serious complications of COVID-19. In these circumstances, clinicians should discuss the risks and benefits of vaccination with the woman, who should be told about the absence of safety data for the vaccine in pregnant women.</p> <p data-bbox="485 1832 1377 1939">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.</p> <p data-bbox="485 1966 1377 2022">The developmental and health benefits of breastfeeding should be considered along with the woman's clinical need for immunisation against</p>

Category	Description
	COVID-19, and the woman should be informed about the absence of safety data for the vaccine in breastfeeding women.
Action if excluded	<p>Specialist advice should be sought on the vaccine and circumstances under which it could be given as vaccination using a patient specific direction may be indicated.</p> <p>Individuals who are participating in a clinical trial of COVID-19 vaccines who present for vaccination should be referred back to the investigators.</p> <p>In case of postponement due to acute illness or evolving neurological condition, advise when the individual can be vaccinated and ensure another appointment is arranged.</p> <p>In case of postponement due to COVID-19 symptoms or positive COVID test in the last four weeks advise when the individual can be vaccinated and how future vaccination may be accessed.</p> <p>Document the reason for exclusion and any action taken in accordance with local procedures.</p>
Action if patient declines	<p>Advise the individual/carer about the protective effects of the vaccine, the risks of infection and potential complications if not immunised.</p> <p>Advise how future immunisation may be accessed if they subsequently decide to receive the COVID-19 vaccine</p> <p>Document patient's declined consent and advice given.</p>

2. Description of treatment

Category	Description
Name of medicine	COVID-19 mRNA Vaccine BNT162b2 concentrate for solution for injection
Form/strength	<p>COVID-19 mRNA Vaccine BNT162b2 30micrograms/0.3ml dose concentrate for solution for injection multidose vials</p> <p>COVID-19 mRNA Vaccine BNT162b2 is a multidose 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).</p>
Route of administration	<p>After dilution, vials of COVID-19 mRNA Vaccine BNT162b2 contain 6 doses of 0.3 mL of vaccine. In order to extract 6 doses from a single vial, low dead-volume syringes and/or needles should be used. If standard syringes and needles are used, there may not be sufficient volume to extract a sixth dose from a single vial. Irrespective of the type of syringe and needle</p> <p>Each dose must contain 0.3 mL of vaccine.</p>

Category	Description
	<p data-bbox="499 232 1378 300">If the amount of vaccine remaining in the vial cannot provide a full dose of 0.3mL, discard the vial and any excess volume.</p> <p data-bbox="499 324 1050 353">Do not pool excess vaccine from multiple vials</p> <p data-bbox="499 378 1246 407">Any unused vaccine should be discarded 6 hours after dilution.</p> <p data-bbox="499 432 1378 573">COVID-19 mRNA Vaccine BNT162b2 must be administered by intramuscular (IM) injection preferably into the deltoid area of the upper arm. Where administration into the deltoid is not possible the anterolateral thigh can be considered.</p> <p data-bbox="499 598 1358 703">Inspect visually prior to administration and ensure appearance is consistent with the description in the manufacturer's product literature or summary of product characteristics.</p> <p data-bbox="499 728 1385 1234">Individuals with bleeding disorders may be vaccinated intramuscularly if, in the opinion of a doctor familiar with 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 is below the upper level of the therapeutic range, can receive intramuscular vaccination. A fine needle (23 or 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/parent/carer should be informed about the risk of haematoma from the injection.</p> <p data-bbox="499 1258 1265 1326">The site at which each vaccine was given should be noted in the individual's records.</p>
<p data-bbox="288 1368 389 1397">Dosage</p>	<p data-bbox="499 1368 1310 1435">The dose of COVID-19 mRNA Vaccine BNT162b2 is 30 micrograms contained in 0.3mL of the diluted vaccine.</p>
<p data-bbox="272 1480 405 1509">Frequency</p>	<p data-bbox="499 1480 1334 1547">COVID-19 mRNA Vaccine BNT162b2 course consists of two separate doses of 0.3ml each, a minimum of 21 days apart.</p> <p data-bbox="499 1572 1385 1789">Operationally, it is recommended in the COVID-19 chapter of Green Book that the second dose of both vaccines should be routinely scheduled between four and 12 weeks after the first dose. This will allow more people to benefit from the protection provided from the first dose during the roll out phase. Longer term protection will then be provided by the second dose.</p> <p data-bbox="499 1814 1378 2029">Individuals 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</p>

Category	Description
	<p data-bbox="497 232 1362 338">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.</p> <p data-bbox="497 360 1386 499">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.</p> <p data-bbox="497 524 1355 629">JCVI advises that the second vaccine dose should be with the same vaccine as for the first dose. Switching between vaccines or missing the second dose is not advised as this may affect the duration of protection.</p> <p data-bbox="497 654 1382 1088">There is no evidence on the interchangeability of the COVID-19 vaccines although studies are underway. Therefore, every effort should be made to determine which vaccine the individual received and to complete 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 a single dose of the locally available product. This option is preferred if the individual is likely to be at immediate high risk or is considered unlikely to attend again. In these circumstances, as both the vaccines are based on the spike protein, it is likely the second dose will help to boost the response to the first dose. For this reason, until additional information becomes available, further doses are not required.</p>
<p data-bbox="268 1133 413 1196">Duration of treatment</p>	<p data-bbox="497 1133 1086 1167">See Dose and frequency of administration above.</p> <p data-bbox="497 1189 1355 1256">Booster doses of COVID-19 vaccine are not yet recommended because the need for, and timing of, boosters has not yet been determined.</p>
<p data-bbox="213 1301 467 1406">Maximum or minimum treatment period</p>	<p data-bbox="497 1301 975 1335">See Frequency of administration above.</p>
<p data-bbox="225 1451 456 1514">Quantity to supply/administer</p>	<p data-bbox="497 1451 1150 1485">Administer 30 micrograms in 0.3mL per administration.</p>
<p data-bbox="236 1563 445 1626">▼ black triangle medicines</p>	<p data-bbox="497 1563 1334 1704">COVID-19 mRNA Vaccine BNT162b2 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.</p> <p data-bbox="497 1727 1366 1868">All adverse reactions occurring in individuals of any age after vaccination should be reported to the MHRA using the Coronavirus Yellow Card Scheme. Anyone can report a suspected adverse reaction to the MHRA using the Coronavirus Yellow Card reporting scheme</p> <p data-bbox="497 1890 1019 1924">https://coronavirus-yellowcard.mhra.gov.uk/</p>
<p data-bbox="244 1973 437 2007">Legal category</p>	<p data-bbox="497 1973 1378 2033">COVID-19 mRNA Vaccine BNT162b2 is provided temporary authorisation by the Medicines & Healthcare products Regulatory Agency (MHRA) for</p>

Category	Description
	<p>supply in the UK under regulation 174 and 174A, pending UK marketing authorisation.</p> <p>The regulation 174 authorised product is categorised as a prescription only medicine (POM).</p>
<p>Is the use out with the SPC?</p>	<p>COVID-19 mRNA Vaccine BNT162b2 is supplied in the UK in accordance with regulation 174 and did not have a UK marketing authorisation at the time of writing this protocol.</p> <p>As part of the consent process, 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.</p> <p>The vaccine manufacturer's information for UK healthcare professionals states that the vaccine should be given as a series of two doses (0.3mL, each) 21 days apart. This is superseded by the JCVI advice that the second dose of both vaccines should be routinely scheduled between four and 12 weeks after the first dose. This will allow more people to benefit from the protection provided from the first dose during the roll out phase. Longer term protection will then be provided by the second dose.</p>
<p>Storage requirements</p>	<p>COVID-19 mRNA Vaccine BNT162b2 must be stored frozen at ultra-low temperature in accordance with manufacturer's advice.</p> <p>Once removed from the freezer BNT162b2 vaccine can be stored for 5 days in a fridge between +2 to +8°C prior to dilution.</p> <p>NHS Board guidance on Storage and Handling of vaccines should be observed.</p> <p>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.</p> <p>The vaccine vial has space to write the date and time of dilution; write this on the vial label.</p> <p>During storage, minimise exposure to room light and avoid exposure to direct sunlight and ultraviolet light.</p> <p>In the event of an inadvertent or unavoidable deviation of these conditions, vaccine that has been stored outside the conditions stated above should be quarantined and risk assessed for suitability of continued use or appropriate disposal.</p> <p>The manufacturer may advise of updated storage requirements and product stability as new data becomes available, vaccine may be stored in accordance with updated recommendations from the manufacturer.</p>

Category	Description
<p>Additional information</p>	<p>Minor illnesses without fever or systemic upset are not valid reasons to postpone immunisation. If an individual is acutely unwell, immunisation should be postponed until they have fully recovered.</p> <p>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. Inclusion of antibody positive individuals in the Pfizer phase 3 analysis did not give any safety signals.</p> <p>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, ideally vaccination should be deferred until around four weeks after onset of symptoms or from the first PCR positive specimen in those who are asymptomatic.</p> <p>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.</p>

3. Adverse reactions

Category	Description
<p>Warnings including possible adverse reactions and management of these</p>	<p>Local reactions at the injection site are fairly common after COVID-19 mRNA Vaccine BNT162b2 primarily pain at the injection site, usually without redness and swelling. Systemic events reported were generally mild and short lived. In the final safety analysis of over 21,000 participants 16 years and older, the most common events were injection site pain (>80%), fatigue (>60%), and headache (>50%). Myalgia, arthralgia and chills were also common with fever in 10-20%. Most were classified as mild or moderate. Lymphadenopathy was reported in less than 1%.</p> <p>In an earlier analysis of around 8,000 recipients, severe side effects, defined as those that interfere with daily activity, included fatigue in around 4% and headache in 2%. Older adults tend to report fewer adverse events following vaccination. This earlier analysis also showed no signal for enhanced disease in vaccine recipients with only 1 case of severe COVID in the 8 vaccine failures at that time.</p> <p>A protocol for the management of anaphylaxis and an anaphylaxis pack must always be available whenever COVID-19 mRNA Vaccine BNT162b2 is given. Immediate treatment should include early treatment with 0.5mg intramuscular adrenaline (0.5ml of 1:1000 or 1mg/ml adrenaline), with an early call for help and further IM adrenaline every 5 minutes. The health professionals overseeing the immunisation service must be trained to</p>

Category	Description
	<p>recognise an anaphylactic reaction and be familiar with techniques for resuscitation of a patient with anaphylaxis.</p> <p>In the event of a severe adverse reaction individual should be advised to seek medical advice.</p> <p>For full details/information on possible adverse reaction, refer to manufacturer's product literature or summary of product characteristics.</p>
<p>Reporting procedure for adverse reactions</p>	<p>Healthcare professionals and individuals/carers should report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Coronavirus Yellow Card reporting scheme on: https://coronavirus-yellowcard.mhra.gov.uk/</p> <p>As this vaccine is labelled with a black triangle, all adverse reactions occurring in individuals of any age after vaccination should be reported to the MHRA using the Coronavirus Yellow Card Scheme. Anyone can report a suspected adverse reaction to the MHRA using the Coronavirus Yellow Card reporting scheme https://coronavirus-yellowcard.mhra.gov.uk/</p> <p>Any adverse reaction to a vaccine should be documented in accordance with locally agreed procedures in the individual's record and the individual's GP should be informed.</p> <p>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'.</p> <p>Programmatic Adverse Events should be recorded in line with local procedures and where appropriate escalated in accordance with the national framework.</p>
<p>Advice to patient or carer including written information</p>	<p>Written information to be given to individual</p> <ul style="list-style-type: none"> • Provide manufacturer's consumer information leaflet/patient information leaflet (PIL) provided with the vaccine. • Provide copy of Public Health Scotland post- vaccination leaflet • Provide copy of Pregnant, planning a pregnancy or breastfeeding, a guide to COVID-19 vaccine to women of child bearing years <p>Individual advice / follow up treatment</p> <ul style="list-style-type: none"> • Inform the individual/carers of possible side effects and their management.

Category	Description
	<ul style="list-style-type: none"> • Vaccinated individuals should be advised that it is common to develop a fever after vaccination and that this normally happens within 48 hours after 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 NHS Test and Protect 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. • 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 or NHS24 • 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: http://yellowcard.mhra.gov.uk. • Immunosuppressed individuals should be advised that they may not make a full immune response to the vaccine and they should continue to take appropriate measures to protect themselves against this infection. • 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.
<p>Observation following vaccination</p>	<p>Vaccine recipients should be monitored for 15 minutes after vaccination, with a longer observation period when indicated after clinical assessment.</p> <p>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.</p> <p>Individuals with a localised urticarial (itchy) skin reaction (without systemic symptoms) to the first dose of a COVID-19 vaccine should receive the</p>

Category	Description
	second dose of vaccine with prolonged observation (30 minutes) in a setting with full resuscitation facilities (e.g. a hospital)
Follow up	Not applicable
Additional facilities	A protocol for the management of anaphylaxis and an anaphylaxis pack must always be available whenever COVID-19 mRNA Vaccine BNT162b2 is given. Immediate treatment should include early treatment with 0.5mg intramuscular adrenaline (0.5ml of 1:1000 or 1mg/ml adrenaline), with an early call for help and further IM adrenaline every 5 minutes. The health professionals overseeing the immunisation service must be trained to recognise an anaphylactic reaction and be familiar with techniques for resuscitation of a patient with anaphylaxis.

4. Audit Trail/Records

Name	Description
Record/ audit trail	<p>Record:</p> <ul style="list-style-type: none"> • that valid informed consent was given • name of individual, address, date of birth and GP with whom the individual is registered • name of person that undertook assessment of individual's clinical suitability for vaccine • name of person that administered the vaccine • name and brand of vaccine • date of administration • dose, form and route of administration of vaccine • batch number • where possible 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 • administered under protocol <p>Records should kept line with local procedures. Ideally records should be kept within the NHS Scotland COVID-19 vaccine administration app.</p> <p>Local policy should be followed to encourage information sharing with the individual's General Practice.</p> <p>All records should be clear, legible and contemporaneous.</p>

5. References

Name	Description
Additional references	<p>Immunisation against Infectious Disease [Green Book] https://www.gov.uk/government/organisations/public-health-england/series/immunisation-against-infectious-disease-the-green-book</p> <p>Immunisation against Infectious Disease [Green Book] COVID-19 https://www.gov.uk/government/publications/covid-19-the-green-book-chapter-14a</p> <p>JCVI: advice on priority groups for COVID-19 vaccine 30th December 2020 https://www.gov.uk/government/publications/priority-groups-for-coronavirus-covid-19-vaccination-advice-from-the-jcvi-30-december-2020</p> <p>Manufacturer's product information/ Summary of Product Characteristics https://www.gov.uk/government/publications/regulatory-approval-of-pfizer-biontech-vaccine-for-covid-19</p> <p>Educational resources for registered professionals produced by National Education for Scotland https://learn.nes.nhs.scot/37676/immunisation/covid-19-vaccines</p> <p>All relevant Scottish Government advice including the relevant CMO letter(s)</p>

ANNEX B: Practitioner authorisation sheet

COVID-19 mRNA Vaccine BNT162b2 Pfizer/BioNTech Vaccine Protocol v00.01 Valid from: DDDDDD Expiry: DDDDDD

Before signing this Protocol, check that the document has had the necessary authorisations in section 1 and 2. Without these, this Protocol is not lawfully valid.

Practitioner

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.

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

I confirm that I have read and understood the content of this Protocol and that I am willing and competent to work to it within my professional code of conduct.

Name	Designation	Signature	Date

Person authorising on behalf of Provider

I confirm that the practitioners named above have declared themselves suitably trained and competent to work under this Protocol. I give authorisation on behalf of **insert name of organisation** for the above named health care professionals who have signed the Protocol to work under it.

Name	Designation	Signature	Date

Note to person authorising on behalf of Provider

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

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

ANNEX C: Clinical Supervision sheet

COVID-19 mRNA Vaccine BNT162b2 Pfizer/BioNTech Vaccine Protocol v02.0 Valid from: DDDDDD Expiry: DDDDDD

This sheet must record the name of the clinical supervisor taking responsibility and all of the people working under different activity stages of the protocol.

Activity stages of the vaccination pathway under this protocol:

Stage 1	a. Assessment of the individual presenting for vaccination b. Provide information and obtain informed consent c. Provide advice to the individual	Registered Healthcare Professionals Only
Stage 2	•Vaccine Preparation	Registered Healthcare Professionals, non-registered professionals or non-registered Armed Forces staff
Stage 3	•Vaccine Administration	Registered Healthcare Professionals, non-registered professionals or non-registered Armed Forces staff
Stage 4	•Record Keeping	Registered Healthcare Professionals, non-registered professionals or non-registered Armed Forces staff

The clinical supervisor has ultimate responsibility for safe care being provided under the terms of the protocol. Persons working under the protocol may be supported by additional registered healthcare professionals, but the clinical supervisor retains responsibility.

Before signing this Protocol, check that the document has had the necessary authorisations. Without these, this Protocol is not lawfully valid.

Clinical Supervisor

Name	Designation	Signature	Date

Practitioner(s) and Activity Stages

Name	Activity Stage(s)	Signature	Date

Note to Clinical Supervisor

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

This authorisation sheet should be retained to serve as a record of clinical supervision arrangements for those working under this Protocol.