Comirnaty® (COVID-19 mRNA Vaccine, Pfizer/BioNTech) National Protocol

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Scottish Government
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Comirnaty® 10 micrograms/dose (COVID-19 mRNA Vaccine, Pfizer/BioNTech)

National Protocol

Reference no: Comirnaty® 10 micrograms/dose (COVID-19 mRNA Vaccine, Pfizer/BioNTech) Protocol

Version no: v1. 0
Valid from: 26 January 2022
Review date: 01 March 2022
Expiry date: 31 March 2022

1. About the National Protocol

This protocol is for the supply and administration of Comirnaty® 10 micrograms/dose (COVID-19 mRNA Vaccine, 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 Comirnaty® 10 micrograms/dose (COVID-19 mRNA Vaccine, 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.

This issue of consent for children and young people under the age of 16 is complex. In Scotland, the legal age of capacity is 16. However, children under the age of 16 can consent to medical treatment if they understand what is being proposed. Providers should ensure that capacity is assessed in line with current established practice, seeking advice from their legal advisers on consent as required.

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: vaccineoperationaloversight@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 20 January 2022 the Scottish Ministers, approved this protocol in accordance with regulation 247A of the Human Medicines Regulation 2012. Approval of clinical information in Annex A is via the Scottish Government Chief Medical Officer, Chief Pharmaceutical Officer and Deputy 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**		**26 January 2022**

CNO	**Alex McMahon**		**26 January 2022**
CPO	**Alison Strath**		**26 January 2022**

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 Comirnaty® (COVID-19 mRNA Vaccine, Pfizer/BioNTech) 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 Comirnaty® 10 micrograms/dose (COVID-19 mRNA Vaccine, Pfizer/BioNTech).	14 January 2022
V01.00	Clinical annex updated	25 January 2022

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 d. Capacity for under 16's should be assessed in line with current practices for existing childhood vaccination programmes	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

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)
- Military General Duties Vaccinators

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.
   - The issue of consent when offering vaccination to children and young people is complex. In Scotland, the legal age of capacity is 16. However, children under the age of 16 can consent to medical treatment if they understand what is being proposed. Capacity should be assessed in line with current established practice, with persons undertaking activities under the remit of this protocol seeking advice from their Immunisation Co-ordinator as required.
   - 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) 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

Comirnaty® 10 micrograms/dose (COVID-19 mRNA Vaccine, 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) 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.

Most Recent Changes

Version	Date	Summary of changes
1.0	25/01/22	The following sections have been updated: Frequency section updated to include course consisting of two separate doses of 0.2ml each, a minimum of 21 days apart.

1. Clinical condition or situation to which this Protocol applies

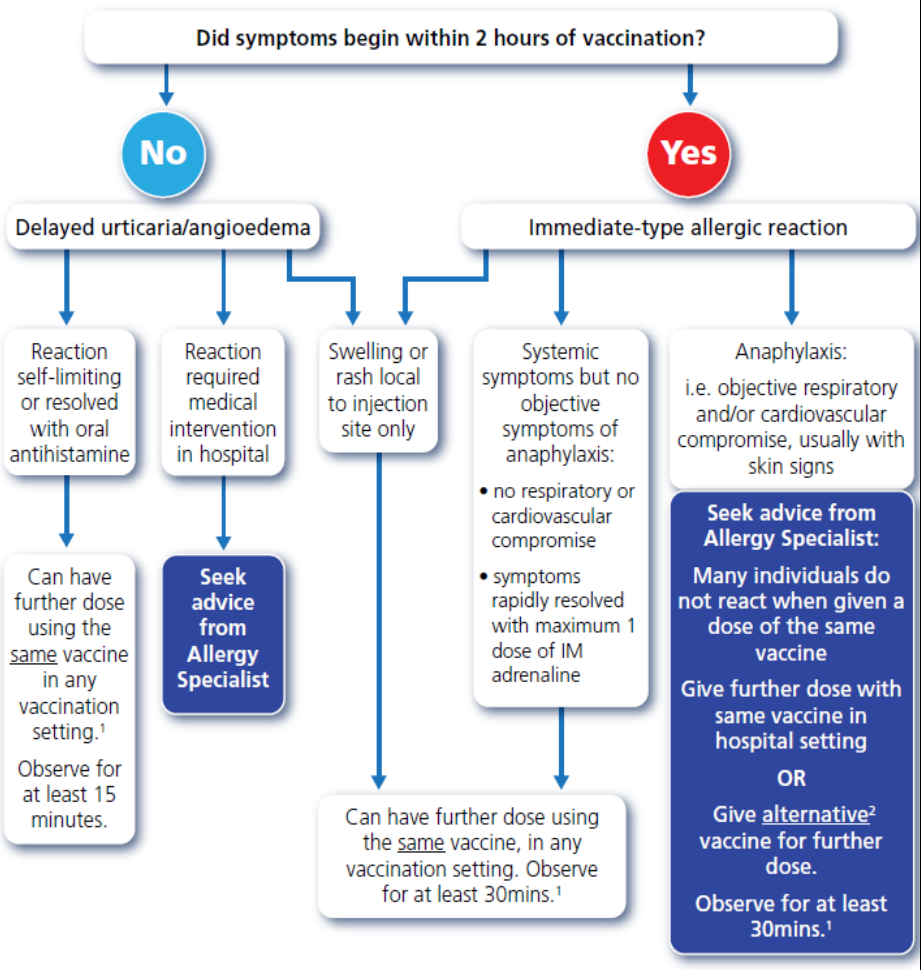
Category	Description
Indication	Comirnaty® 10 micrograms/dose (COVID-19 mRNA vaccine, Pfizer/BioNTech) is indicated for active immunisation against COVID-19 disease caused by SARS-CoV-2 virus in accordance with Scottish Government COVID-19 immunisation programme and recommendations given in Chapter 14a of the Immunisation Against Infectious Disease: the 'Green Book'; statements from Joint Committee on Vaccination and Immunisation (JCVI); and subsequent correspondence/publications from Scottish Government.
Inclusion criteria	Comirnaty® 10 micrograms/dose (COVID-19 mRNA vaccine, Pfizer/BioNTech should be offered to individuals aged 5-11 years in accordance with the recommendations in Chapter 14a of the Green Book and JCVI advice. National policy must be followed in relation to the priority groups eligible for vaccination at a particular point in time. Individuals are eligible for different dose schedules based on their age and recognised risk group (see the frequency section).
Exclusion criteria	The vaccine should not be given to: • Those who have had a previous systemic anaphylaxis reaction to any COVID-19 vaccine.

Category	Description
	• Those who have had a prior systemic allergic reaction to any component (excipient) of Comirnaty® 10 micrograms/dose (COVID-19 mRNA vaccine, Pfizer/BioNTech) e.g. polyethylene glycol • Those with a history of immediate anaphylaxis to multiple, different drug classes, with the trigger unidentified (this may indicate PEG allergy) unless the advice from relevant specialist, local immunisation or health protection team is that vaccination should proceed • Those with a history of anaphylaxis to a vaccine, injected antibody preparation or a medicine likely to contain PEG (e.g. depot steroid injection, laxative) unless the advice from relevant specialist, local immunisation or health protection team is that vaccination should proceed • Those with a history of idiopathic (unexplained) anaphylaxis unless the advice from relevant specialist, local immunisation or health protection team is that vaccination should proceed • Those in whom no valid consent has been received • Those who are under 5 years of age or over 12 years of age • 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 with acute febrile illness – consider postponing immunisation until individual has fully recovered. • Those bone marrow and peripheral blood stem cell donors who have commenced GCSF, the vaccination (first or second dose) must be delayed at least until 72 hours after stem cell collection (both peripheral blood stem cell and bone marrow donation). This is a precautionary advice to avoid vaccination when receiving Granulocyte-colony stimulating factor (GCSF) and allow for post donation recovery period. • Those who developed myocarditis or pericarditis following a previous dose of COVID-19 vaccination

Category	Description
Cautions/need for further advice/ circumstances when further advice should be sought from a doctor	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. Individuals with a history of allergy The Pfizer BioNTech (Comirnaty® 10 micrograms/dose) 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 mRNA vaccines. Published data now show that some individuals with prior allergic reaction to PEG containing medicines (e.g. PEG-asparaginase) can tolerate the PfizerBioNTech vaccine (although the historical reaction may have been due a non-PEG component). Expert advice should be obtained and if a decision is made to administer an mRNA vaccine, then this should only be done in hospital under medical supervision under a patient specific direction. There is now evidence that many individuals with initial apparent allergic reaction to an mRNA vaccine can tolerate a second dose of the same vaccine. Where there were no objective signs of anaphylaxis and symptoms rapidly resolved (with no more than 1 dose of IM adrenaline), a further dose of the same vaccine can be given in any vaccination setting. Observe for 30 minutes. If the reaction might have been anaphylaxis, obtain expert advice; if a decision is made to administer the same vaccine, then this should be done under medical supervision in the hospital setting under a patient specific direction. 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. Observation for 15 minutes is recommended.

Category	Description
	No specific management is required for individuals with a family history of allergies. Figure 1 summarises the management of patients with a history of allergy. **Figure 1: Management of patients with a history of allergy**

	Proceed with vaccination	Special precautions	Vaccination contra-indicated
PATIENT CHARACTERISTICS	• previous allergic reaction (including anaphylaxis) to a food, insect sting and most medicines (where trigger has been identified) • previous non-systemic reaction to a vaccine • hypersensitivity to non-steroidal anti-inflammatory drugs e.g. aspirin, ibuprofen • mastocytosis	• prior non-anaphylaxis allergic reaction to COVID-19 vaccine • 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 (e.g. depot steroid injection, laxative) • history of idiopathic anaphylaxis	• prior anaphylaxis reaction to COVID-19 vaccine • prior systemic allergic reaction to a component of the vaccine (for known PEG allergy see text above)
ACTIONS	• proceed with vaccination in any setting • consider observation for 15 minutes (may not be required if previous tolerated the same vaccine)	• consider possibility of PEG allergy and seek allergy advice if needed • consider observation for 30 minutes • some patients may benefit from pretreatment with antihistamine, however this may mask initial symptoms of a reaction	• refer to allergist or other appropriate specialist • consider administration of the implicated mRNA vaccine under medical supervision in hospital, or, where reaction was to AstraZeneca vaccine give alternative vaccine in any setting • consider observation for 30 minutes

Category	Description
	Figure 2 shows the Green Chapter flowchart for managing patients who have allergic reactions to the first dose of COVID-19 vaccine. **Figure 2: Flowchart for managing patients who have allergic reactions to the first dose of COVID-19 vaccine**  [1] Consider pre-treatment with non-sedating antihistamine, at least 30 mins prior to vaccination [2] If reaction was to AstraZeneca vaccination, complete or boost with an mRNA vaccine. If reaction was to an mRNA vaccine, give the same or alternative mRNA vaccine in hospital setting. Those with an anaphylaxis immediate-type allergic reaction are excluded from receiving vaccination under this protocol– a patient specific direction is required if further doses are offered. Individuals with a bleeding history

Category	Description
	Individuals with a bleeding disorder may develop a haematoma at the injection site (see Route of Administration). Co-administration with other vaccines As all of the early COVID-19 vaccines are considered inactivated, 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 or more 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. This includes but is not limited to vaccines commonly administered around the same time or in the same settings (including influenza and pneumococcal polysaccharide vaccine in those aged over 65 years, pertussis-containing vaccines and influenza vaccines in pregnancy, and LAIV, HPV, MenACWY and Td-IPV vaccines in the schools programmes). A UK study of co-administration of AstraZeneca and Pfizer BioNTech COVID-19 vaccines with inactivated influenza vaccines confirmed acceptable immunogenicity and reactogenicity. Where co-administration does occur, patients should be informed about the likely timing of potential adverse events relating to each vaccine. If the vaccines are not given together, they can be administered at any interval, although separating the vaccines by a day or two will avoid confusion over systemic side effects. Syncope 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. Clinical trial participants Individuals who have participated in a clinical trial of COVID-19 vaccines should be provided with written advice on whether and when they should be safely vaccinated in the routine programme. Advice should also be provided from the trial investigators on

Category	Description
	whether any individual could receive additional doses for the purposes of vaccine certification. Trial participants who are eligible for boosters should be offered vaccination in line with the general population, at least three months after the dose considered as the final primary dose or the final revaccination (if the latter is required for certification purposes). Individuals with a past history of COVID-19 infection There is no convincing evidence of any safety concerns from vaccinating individuals with a past history of COVID-19 infection, or with detectable COVID-19 antibody. Vaccination of individuals who may be infected or asymptomatic or incubating COVID-19 infection is unlikely to have a detrimental effect on the illness. Vaccination should ideally be deferred in those with confirmed infection to avoid confusing the differential diagnosis. As clinical deterioration can occur up to two weeks after infection, vaccination of adults and high risk children should be deferred until clinical recovery to around four weeks after onset of symptoms or four weeks from the first confirmed positive specimen for that episode in those who are asymptomatic. The four-week interval may be reduced in periods of high incidence or where there is concern about vaccine effectiveness (for example a new variant). In younger people, protection from serious complications of COVID-19 infection is likely to be high for a period of months. Limited evidence suggests that countries with longer intervals between primary doses (eight to twelve weeks) may have a lower rate of myocarditis after the second dose. Based on extrapolation from this limited evidence, JCVI have taken a precautionary approach to mitigate the very rare risk of post-vaccine myocarditis. Therefore, vaccination should ideally be deferred until twelve weeks from onset (or sample date) in children and young people under 18 years who are not in high risk groups. This interval may be reduced to eight weeks in healthy under 18 year olds during periods of high incidence or where there is concern about vaccine effectiveness (for example a new variant). Current advice in PIMS-TS cases also suggests that an interval of 12 weeks should be observed, although earlier administration can be considered in those at risk of infection and/or who are fully recovered.

Category	Description
Action if excluded	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. In case of postponement due to acute illness advise when the individual can be vaccinated and ensure another appointment is arranged. In case of deferral due to COVID-19 symptoms or recent positive COVID test advise when the individual can be vaccinated and how future vaccination may be accessed. Document the reason for exclusion and any action taken in accordance with local procedures.
Action if patient declines	Advise the individual/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 patient's declined consent and advice given.

2. Description of treatment

Category	Description
Name of medicine	Comirnaty® 10 micrograms/dose concentrate for dispersion for injection COVID-19 mRNA Vaccine (nucleoside modified) Comirnaty® 10 micrograms/dose (COVID-19 mRNA vaccine, Pfizer/BioNTech)
Form/strength	Comirnaty® 10 micrograms/dose (COVID-19 mRNA vaccine, Pfizer/BioNTech) 10 micrograms/0.2mL dose concentrate for dispersion for injection multidose vials Comirnaty® 10 micrograms/dose (COVID-19 mRNA vaccine, Pfizer/BioNTech) is a multidose vial and must be diluted with

Category	Description
	1.3mL of 0.9% sodium chloride before use. 1 vial contains 10 doses of 10 micrograms of COVID-19 mRNA vaccine (embedded in lipid nanoparticles).
Route of administration	After dilution, vials of Comirnaty® 10 micrograms/dose (COVID-19 mRNA vaccine, Pfizer/BioNTech) contain 10 doses of 0.2 mL of vaccine. In order to extract 10 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 ten doses from a single vial. Each dose must contain 0.2 mL of vaccine. If the amount of vaccine remaining in the vial cannot provide a full dose of 0.2 mL, discard the vial and any excess volume. Any unused vaccine should be discarded 12 hours after dilution. Comirnaty® 10 micrograms/dose (COVID-19 mRNA vaccine, Pfizer/BioNTech) 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. Inspect visually prior to administration and ensure appearance is consistent with the description in the manufacturer's product literature or summary of product characteristics. 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

Category	Description
	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. The site at which each vaccine was given should be noted in the individual's records.
Dosage	The dose of Comirnaty® 10 micrograms/dose COVID-19 mRNA vaccine is 10 micrograms contained in 0.2 mL of the diluted vaccine

Frequency	**Primary Vaccination** Comirnaty® 10 micrograms/dose (COVID-19 mRNA Vaccine, Pfizer/BioNTech) course consists of two separate doses of 0.2ml each, a minimum of 21 days apart. For Comirnaty® 10 micrograms/dose (COVID-19 mRNA vaccine, Pfizer/BioNTech), there is evidence of better immune response and/or protection where longer intervals between doses in the primary schedule are used. Based on this evidence, longer intervals are likely to provide more durable protection. JCVI is currently recommending a minimum interval of eight weeks between doses of all the available COVID-19 vaccines where a two-dose primary schedule is used. Operationally, using the same minimum interval for all products will simplify booking, and will help to ensure a good balance between achieving rapid and long-lasting protection. If an interval longer than the recommended interval is left between doses in the two dose primary schedule, 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. The main exception to the eight-week lower interval would be those about to commence immunosuppressive treatment. In these individuals, the minimal intervals outlined above may be followed to enable the vaccine to be given whilst their immune system is better able to respond. 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 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. 5-11 year olds

	Children aged 5 - 11 years in a clinical risk group (as defined in the COVID-19 chapter of Green Book), or who are about to commence immunosuppression or who are a household contact of someone who is immunosuppressed (as defined in the Green Book), should be offered two 10 micrograms doses of Comirnaty® (COVID-19 mRNA vaccine, Pfizer/BioNTech) with an interval of 8 weeks between the first and second doses. Children aged 5-11 years who have commenced immunisation with the 10 microgram paediatric dose of Pfizer BioNTech should complete vaccination with the paediatric dose (although an adult/ adolescent dose is an alternate in those who turn 12 years of age between doses). Those who present for the second dose over the age of 12 years should be given an adult/ adolescent dose of vaccine. Severe immunosuppression For those identified as meeting the definition for severe immunosuppression in proximity of their first or second vaccine doses in the primary schedule, in line with specialist advice, for a third primary dose (as defined in COVID-19 chapter of Green Book) in accordance with recommendations in the JCVI advice on third dose primary vaccine. The third primary dose should be given at least 8 weeks after the second dose, with special attention paid to current or planned immunosuppressive therapies guided by the following principles: a) where possible the third primary dose should be delayed until two weeks after the period of immunosuppression, in addition to the time period for clearance of the therapeutic agent, b) if not possible, consideration should be given to vaccination during a treatment 'holiday' or at a nadir of immunosuppression between doses of treatment. For those aged over 18 years, JCVI advises a preference for mRNA vaccines - Pfizer BioNTech (Comirnaty®) or Moderna (Spikevax®) - for the third primary dose for those with severe immunosuppression. Pfizer BioNTech (Comirnaty® 10 micrograms/dose) is preferred for 5-11 year olds.

Category	Description
Duration of treatment	See Dose and frequency of administration above.
Maximum or minimum treatment period	See Frequency of administration above.
Quantity to supply/administer	Administer 10 micrograms in 0.2mL per administration.
▼ black triangle medicines	Yes, Comirnaty® 10 micrograms/dose (COVID-19 mRNA vaccine, Pfizer/BioNTech) has been designated ▼ 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/
Legal category	Prescription only medicine (POM).
Is the use out with the SPC?	The vaccine marketing authorisation holder's summary of product characteristics states that the vaccine should be given as a series of two doses (0.2mL, each) 21 days apart. This is superseded by the JCVI recommendation of a minimum interval of eight weeks between doses of all the available COVID-19 vaccines where a two-dose primary schedule is used. The vaccine marketing authorisation holder's summary of product characteristics states that close observation for at least 15 minutes is recommended following vaccination. In recognition of the need to accelerate delivery of the programme in response to the emergence of the Omicron variant, the UK Chief Medical Officers have recommended temporary suspension of this requirement. This temporary suspension in individuals without a history of allergy has also been agreed by the Commission on Human Medicines

Category	Description
	The Scottish Government has made further recommendations that all doses of COVID-19 vaccines be followed by a 5 minute observation period. The vaccine marketing authorisation holder's summary of product characteristics states that the vaccine is indicated in children aged 5 to 11 years. The use in children aged 5-11 years who commence immunisation with the 10 microgram paediatric dose of Pfizer BioNTech and then turn 12 years of age should complete vaccination with the 10 microgram paediatric dose is outwith the SPC but is aligned with advice from JCVI. Vaccine should be stored according to the conditions detailed below. However, in the event of a deviation of these conditions where vaccine is assessed as appropriate for continued use, administration under this PGD is allowed.
Storage requirements	Comirnaty® 10 micrograms/dose (COVID-19 mRNA vaccine, Pfizer/BioNTech) must be stored in accordance with manufacturer's advice. NHS Board guidance on Storage and Handling of vaccines should be observed. Comirnaty® (COVID-19 mRNA vaccine, Pfizer/BioNTech) should be diluted as close to use as possible. However, reconstituted vaccine which is not required immediately must be used within 12 hours from the time of dilution and stored between +2°C to +30°C. The vaccine vial has space to write the date and time that the vial should be discarded following dilution (calculation: time of dilution + 12 hours); write this on the vial label. During storage, minimise exposure to room light and avoid exposure to direct sunlight and ultraviolet light. 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.

Category	Description
	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.
Additional information	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. 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.

3. Adverse reactions

Category	Description
Warnings including possible adverse reactions and management of these	The overall safety profile of Comirnaty in participants 5 to 15 years of age was similar to that seen in participants 16 years of age and older. The most frequent adverse reactions in children 5 to 11 years of age were injection site pain (>80%), fatigue (>50%), headache (>30%), injection site redness and swelling (>20%), myalgia and chills (>10%). Recently a number of cases of myocarditis and pericarditis have been reported after Pfizer BioNTech (Comirnaty®) 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. Individuals who have had myocarditis or pericarditis should be investigated, and a second or booster dose can be given once they are fully recovered in line with advice in the COVID-19 chapter of the Green Book, under a PSD.

Category	Description
	A protocol for the management of anaphylaxis and an anaphylaxis pack must always be available whenever vaccines are given. Immediate treatment should include early treatment with intramuscular 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. For full details/information on possible adverse reaction, refer to manufacturer's product literature or summary of product characteristics.
Reporting procedure for adverse reactions	Healthcare professionals and individuals/carers should report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Coronavirus Yellow Card reporting scheme on: https://coronavirus-yellowcard.mhra.gov.uk/ 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/ 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. 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)

Category	Description
	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 the national framework.
Advice to patient or carer including written information	Written information to be given to individual • Provide manufacturer's consumer information leaflet/patient information leaflet (PIL) provided with the vaccine. • Provide copy of Public Health Scotland post-vaccination leaflet • For eligible children and young people under the age of 16, clear information on the potential risks and benefits of vaccination should be provided to the parent/carer of the eligible child or young person prior to vaccination. Information provided should be accessible for children and young people under the age of 16 should they wish to consent for vaccination. Individual advice / follow up treatment • Inform the individual/carer of possible side effects and their management. • 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

Category	Description
	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. • Inform the individual/carer that anyone who has any of the following symptoms after vaccination should seek medical advice urgently: ➢ chest pain ➢ shortness of breath ➢ feelings of having a fast-beating, fluttering, or pounding heart • 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.

Category	Description
Observation following vaccination	Following COVID-19 vaccine administration, individuals should be observed for any immediate reactions whilst they are receiving any verbal post vaccination information and exiting the centre. According to the Summaries of Product Characteristics, it is recommended that all recipients of the Pfizer BioNTech and Moderna vaccines are kept for observation and monitored for a minimum of 15 minutes. In recognition of the need to accelerate delivery of the programme in response to the emergence of the Omicron variant, the UK Chief Medical Officers have recommended suspension of this requirement. This temporary suspension in individuals without a history of allergy has also been agreed by the Commission on Human Medicines. There is no routine requirement for observation following COVID-19 Vaccine AstraZeneca. The Scottish Government has made further recommendations that all doses of mRNA COVID-19 vaccines be followed by a 5 minute observation period. A longer observation period should be observed when indicated after clinical assessment as set out in Figure 1 and Figure 2 (above). Vaccinated individuals should be informed about how to access immediate healthcare advice in the event of displaying any symptoms. In some settings, for example domiciliary vaccination, this may require a responsible adult to be present for at least 15 minutes after vaccination.
Follow up	Not applicable
Additional facilities	A protocol for the management of anaphylaxis and an anaphylaxis pack must always be available whenever vaccines are given. Immediate treatment should include early treatment with intramuscular 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	Record: • 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 Records should kept in line with local procedures. Ideally records should be kept within the NHS Scotland COVID-19 vaccine administration app. Local policy should be followed to encourage information sharing with the individual's General Practice. All records should be clear, legible and contemporaneous.

5. References

Name	Description
Additional references	Immunisation against Infectious Disease [Green Book] https://www.gov.uk/government/organisations/public-health-england/series/immunisation-against-infectious-disease-the-green-book Immunisation against Infectious Disease [Green Book] COVID-19 https://www.gov.uk/government/publications/covid-19-the-green-book-chapter-14a 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 JCVI: Final statement on phase 2 of the COVID-19 vaccination programme: 13 April 2021 JCVI final statement on phase 2 of the COVID-19 vaccination programme: 13 April 2021 JCVI: JCVI statement on COVID-19 vaccination of children and young people aged 12 to 17 years: 15 July 2021 https://www.gov.uk/government/publications/covid-19-vaccination-of-children-and-young-people-aged-12-to-17-years-jcvi-statement/jvci-statement-on-covid-19-vaccination-of-children-and-young-people-aged-12-to-17-years-15-july-2021 Updated JCVI statement on COVID-19 vaccination of children and young people aged 12 to 17 years: 04 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 JCVI: Third primary COVID-19 vaccine dose for people who are immunosuppressed: 1st September 2021

Name	Description
	https://www.gov.uk/government/publications/third-primary-covid-19-vaccine-dose-for-people-who-are-immunosuppressed-jcvi-advice JCVI: COVID-19 vaccination of children aged 12 to 15 years: 3rd September 2021 https://www.gov.uk/government/publications/jcvi-statement-september-2021-covid-19-vaccination-of-children-aged-12-to-15-years JCVI: Statement regarding a COVID-19 booster vaccine programme for winter 2021/22; 14th September 2021 https://www.gov.uk/government/publications/jcvi-statement-september-2021-covid-19-booster-vaccine-programme-for-winter-2021-to-2022/jcvi-statement-regarding-a-covid-19-booster-vaccine-programme-for-winter-2021-to-2022 Universal vaccination of children and young people aged 12 to 15 years against COVID-19. Letter from the UK Chief Medical Officers: 13th September. https://www.gov.uk/government/publications/universal-vaccination-of-children-and-young-people-aged-12-to-15-years-against-covid-19 JCVI advice on the UK vaccine response to the Omicron variant: 29 November 2021 **https://www.gov.uk/government/publications/uk-vaccine-response-to-the-omicron-variant-jcvi-advice** JCVI statement on COVID-19 vaccination of children and young people: 22 December 2021: **https://www.gov.uk/government/publications/jcvi-update-on-advice-for-covid-19-vaccination-of-children-and-young-people/jcvi-statement-on-covid-19-vaccination-of-children-and-young-people-22-december-2021** Manufacturer's product information/ Summary of Product Characteristics

Name	Description
	https://www.gov.uk/government/publications/regulatory-approval-of-pfizer-biontech-vaccine-for-covid-19 Educational resources for registered professionals produced by National Education for Scotland https://learn.nes.nhs.scot/37676/immunisation/covid-19-vaccines All relevant Scottish Government advice including the relevant CMO letter(s)

ANNEX B: Practitioner authorisation sheet

Comirnaty® 10 micrograms/dose (COVID-19 mRNA Vaccine, Pfizer/BioNTech) Protocol
Valid from: Expiry:

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

Comirnaty® 10 micrograms/dose (COVID-19 mRNA Vaccine, Pfizer/BioNTech) Protocol
Valid from: Expiry:

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 d. Capacity for under 16s should be assessed in line with current practices for existing childhood vaccination programmes	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.

ANNEX C: Continued

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.

Annex Version History

Version	Date	Summary of changes
1.0	14.01.22	Version 1.0 new Annex A
1.0	25/01/22	The following sections have been updated: Frequency section updated to include course consisting of two separate doses of 0.2ml each, a minimum of 21 days apart.

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