Patient Group Direction (PGD) Template

Administration of COVID-19 mRNA Vaccine BNT162b2 Pfizer/BioNTech

Note other COVID19 vaccines are not covered by this PGD – separate PGDs will be available.

Publication date: 31 December 2020

Version history

Version	Date	Summary of changes
1.0	04/12/20	Version 1.0 new PGD
1.1	10/12/20	The following sections have been updated following the publication of updated COVID-19 –SARS-Cov-2 chapter 14a of Green Book and updated guidance from Medicines & Healthcare products Regulatory Agency on managing allergic reactions. • Inclusion criteria updated to include reference to Table 3 COVID-19 – SARS-Cov-2 chapter 14a of Green Book for individuals aged 16 years to 64 years with underlying health conditions. • Exclusion criteria updated to align with MHRA guidance that any person with a history of immediate-onset anaphylaxis to a vaccine, medicine or food should not receive COVID-19 mRNA Vaccine BNT162b2. • Frequency section updated to align with wording in chapter 14a of Green Book that scheduling the second dose of COVID-19 mRNA Vaccine BNT162b2 from 28 days after the first is may be preferred rather than is recommended. • Additional monitoring section updated to refer to MHRA Coronavirus Yellow Card Scheme. • Use out with the SPC section updated to align with wording in chapter 14a of Green Book that scheduling the second dose of COVID-19 mRNA Vaccine BNT162b2 from 28 days after the first is may be preferred rather than is recommended. • Additional information section updated to align with wording chapter 14a of Green Book for those with prolonged COVID-19 symptoms. • Warnings and ADR section updated to align with wording in chapter 14a of Green Book for adverse reactions to COVID-19 mRNA Vaccine BNT162b2 • Warnings and ADR section updated to align with MHRA guidance on anaphylaxis recognition and treatment. • Additional facilities section updated to align with MHRA guidance on

Version	Date	Summary of changes
		anaphylaxis recognition and treatment. • Reporting ADR section updated to refer to MHRA Coronavirus Yellow Card Scheme. • Observation following vaccination section updated to align with MHRA guidance that vaccine recipients should be monitored for 15 minutes after vaccination
1.2	31/12/20	The following sections have been updated following the publication of updated advice from JCVI. • Indication section updated to include JCVI statement 30 December 2020 • Inclusion criteria updated to align with wording of JCVI statement 30 December 2020 • Exclusion criteria updated wording on pregnancy and history of anaphylaxis • Cautions section updated with additional wording on pregnancy and breastfeeding • Form/strength section updated with updated description of vaccine • Route of administration section updated with updated description of vaccine; advice on sixth dose and reference that preferred site of injection is the deltoid area of the upper arm. • Frequency section updated to reflect JCVI advice on scheduling second dose and that the second vaccine dose should be with the same vaccine as for the first dose. • Use out with the SPC section updated to reflect JCVI advice on scheduling second dose. • Advice to patient section updated to remove reference advice on avoiding pregnancy after vaccination.

Clinical situation

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. COVID-19 vaccine should be offered to the following individuals: • 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. *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. 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

Category	Description
	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).
Exclusion criteria	The vaccine should not be given to: • Those who have had a confirmed anaphylactic reaction to a previous dose of this COVID-19 vaccine • Those who have had a confirmed anaphylactic reaction to any components of this vaccine • Those with a history of immediate-onset anaphylaxis to multiple classes of drugs or unexplained anaphylaxis. • 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.
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 bleeding disorder may develop a haematoma at the injection site (see Route of Administration). 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

Category	Description
	component of the vaccine. 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. 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. 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. 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. 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. 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. There is no known risk associated with giving non-live vaccines whilst breastfeeding. JCVI advises that breastfeeding women may be offered vaccination with the Pfizer-BioNTech or AstraZeneca COVID-19 vaccines. The developmental and health benefits of breastfeeding should be considered along with the woman's clinical need for immunisation against COVID-19, and the woman should be informed about the absence of safety data for the vaccine in breastfeeding women.
Action if excluded	Specialist advice should be sought on the vaccine and circumstances under

Category	Description
	which it could be given as vaccination using a patient specific direction may be indicated. Individuals who are participating in a clinical trial of COVID-19 vaccines who present for vaccination should be referred back to the investigators. 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. 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. 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.

Description of treatment

Category	Description
Name of medicine	COVID-19 mRNA Vaccine BNT162b2 concentrate for solution for injection
Form/strength	COVID-19 mRNA Vaccine BNT162b2 30micrograms/0.3ml dose concentrate for solution for injection multidose vials 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 5 doses of 30 micrograms of BNT162b2 RNA (embedded in lipid nanoparticles).
Route of administration	After dilution, the vial contains 5 doses of 0.3 ml. Withdraw the required 0.3 mL dose of diluted vaccine using a sterile needle and syringe and administer. Vial volume was optimized to reliably obtain 5 doses regardless of syringe type used as most syringe and needle combinations require withdrawal of excess volume in order to ensure the full 0.3 mL dose of vaccine can be administered. When low dead-volume syringes and/or needles are used, the amount remaining in the vial after 5 doses have been extracted may be sufficient for an additional (sixth) dose. Care should be taken to ensure a full 0.3 mL will be administered to the subject and that all doses from a single prepared vial are administered within 6 hours of the time of dilution. Where a full 0.3 mL dose

Category	Description
	cannot be extracted the contents should be discarded. Any unused vaccine should be discarded 6 hours after dilution. 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. 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 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 COVID-19 mRNA Vaccine BNT162b2 is 30 micrograms contained in 0.3mL of the diluted vaccine.
Frequency	COVID-19 mRNA Vaccine BNT162b2 course consists of two separate doses of 0.3ml each, a minimum of 21 days apart. 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. 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. 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. There is no evidence on the interchangeability of the COVID-19 vaccines although studies are underway. Therefore, every effort should be made to

Category	Description
	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.
Duration of treatment	See Dose and frequency of administration above. Booster doses of COVID-19 vaccine are not yet recommended because the need for, and timing of, boosters has not yet been determined.
Maximum or minimum treatment period	See Frequency of administration above.
Quantity to supply/administer	Administer 30 micrograms in 0.3mL per administration.
▼ black triangle medicines	COVID-19 mRNA Vaccine BNT162b2 did not have a UK marketing authorisation at the time this PGD was written and is authorised for temporary supply in the UK in accordance with a Regulation 174 authorisation. 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	COVID-19 mRNA Vaccine BNT162b2 is provided temporary authorisation by the Medicines & Healthcare products Regulatory Agency (MHRA) for supply in the UK under regulation 174 and 174A, pending UK marketing authorisation. The regulation 174 authorised product is categorised as a prescription only medicine (POM).
Is the use out with the SPC?	COVID-19 mRNA Vaccine BNT162b2 is supplied in the UK in accordance with regulation 174 and did not have a UK marketing authorisation at the time of writing this PGD. As part of the consent process, 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.

Category	Description
	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.
Storage requirements	COVID-19 mRNA Vaccine BNT162b2 must be stored frozen at ultra-low temperature in accordance with manufacturer's advice. Once removed from the freezer BNT162b2 vaccine can be stored for 5 days in a fridge between +2 to +8°C prior to dilution. NHS Board guidance on Storage and Handling of vaccines should be observed. COVID-19 mRNA Vaccine BNT162b2 should be diluted as close to use as possible. However, reconstituted vaccine which is not required immediately must be used within 6 hours from the time of dilution and stored between +2°C to +25°C. The vaccine vial has space to write the date and time of dilution; write this on the vial label. 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. 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. 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. 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

Category	Description
	those who are asymptomatic. Having prolonged COVID-19 symptoms is not a contraindication to receiving COVID-19 vaccine but if the patient is seriously debilitated, still under active investigation, or has evidence of recent deterioration, deferral of vaccination may be considered to avoid incorrect attribution of any change in the person's underlying condition to the vaccine.

Adverse reactions

Category	Description
Warnings including possible adverse reactions and management of these	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%. 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. 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. 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/**

Category	Description
	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) 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 • Provide copy of Pregnant, planning a pregnancy or breastfeeding, a guide to COVID-19 vaccine to women of child bearing years 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 longer than 48 hours, they should self-isolate and book a test.

Category	Description
	• 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.
Observation following vaccination	Vaccine recipients should be monitored for 15 minutes after vaccination, with a longer observation period when indicated after clinical assessment. As syncope (fainting) can occur following vaccination, all vaccines should either be driven by someone else or should not drive for 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 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.

Characteristics of staff authorised under the PGD

Category	Description
Professional qualifications	The following classes of registered healthcare practitioners are permitted to administer COVID-19 mRNA Vaccine BNT162b2 • nurses and midwives currently registered with the Nursing and Midwifery Council (NMC) • pharmacists currently registered with the General Pharmaceutical Council (GPhC) • chiropodists/podiatrists, dieticians, occupational therapists, orthoptists, orthotists/prosthetists, paramedics, physiotherapists, radiographers and speech and language therapists currently registered with the Health and Care Professions Council (HCPC) • dental hygienists and dental therapists registered with the General Dental Council • optometrists registered with the General Optical Council.
Specialist competencies or qualifications	Persons must only work under this PGD where they are competent to do so. All practitioners operating this PGD must: a. demonstrate appropriate knowledge and skills to work under the PGD for the 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. This NES Proficiency document can be found at TURAS Learn at: **https://learn.nes.nhs.scot/37676/immunisation/covid-19-vaccines** All persons operating this PGD: • must be authorised by name by their employer as an approved person under the current terms of this PGD before working to it • must be familiar with the vaccine product and alert to changes in the manufacturers product information/summary of product information, • must be competent to undertake immunisation and to discuss issues related to immunisation to assess patients for vaccination and obtain consent • must be competent in the correct storage of vaccines and management of the cold chain if receiving, responsible for, or handling the vaccine • must be competent in the recognition and management of anaphylaxis or under the supervision of persons able to respond appropriately to immediate adverse reactions

Category	Description
	• must have access to the PGD and associated online resources • should fulfil any additional requirements defined by local policy All practitioners operating under the PGD are responsible for ensuring they remain up to date with the use of COVID-19 vaccines included. If any training needs are identified these should be discussed with the individuals in the organisation responsible for authorising individuals to act under the PGD Employer The employer is responsible for ensuring that persons have the required knowledge and skills to safely deliver the activity they are employed to provide under this PGD As a minimum, competence requirements stipulated in the PGD must be adhered to.
Continuing education and training	All practitioners operating under the PGD are responsible for ensuring they remain up to date with the use of COVID-19 vaccines included. If any training needs are identified these should be discussed with the individuals in the organisation responsible for authorising individuals to act under this PGD.

Audit trail

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 PGD Records should kept 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.

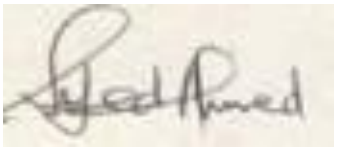
Additional references

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** Manufacturer's product information/ Summary of Product Characteristics **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)

This Patient Group Direction must be agreed to and signed by all healthcare professionals involved in its use. The original signed copy will be held at Pharmacy Services, Clarkston Court, 56 Busby Road, Glasgow. The PGD must be easily accessible in the clinical setting.

Organisation:	**NHS Greater Glasgow & Clyde**

Professionals drawing up PGD/Authors

	Designation and Contact Details
*Name: Syed Ahmed  Signature: Date:31/12/2020	Designation: Senior Medial Officer, Vaccination, Immunisation & Respiratory Viral Infections, Scottish Government E-mail address: syed.ahmed@gov.scot
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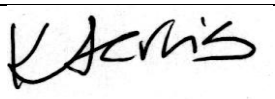
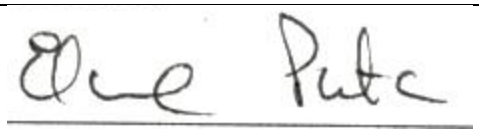
AUTHORISATION:

NHSGG&C PGD Sub-Committee of ADTC		
Chairman in BLOCK CAPITALS	**Signature:**	**Date:**
Dr Craig Harrow		**31/12/2020**

NHSGG&C PGD Sub-Committee of ADTC		
Chief Nurse, Renfrewshire HSCP in BLOCK CAPITALS	**Signature:**	**Date:**
Karen Jarvis		**31/12/2020**

Pharmacist representative of PGD Sub-Committee of ADTC		
Name: in BLOCK CAPITALS	**Signature:**	**Date:**
Elaine Paton		**21/12/2020**

Antimicrobial use

If the PGD relates to an antimicrobial agent, the use must be supported by the NHS GG&C Antimicrobial Management Team (AMT). A member of this team must sign the PGD on behalf of the AMT.

Microbiology approval	Name:	Designation:
	Signature: (on behalf of NHS GG&C AMT)	Date:

Local Authorisation:

Service Area for which PGD is applicable:			
I authorise the supply/administer medicines in accordance with this PGD to patients cared for in this service area.			
Lead Clinician for the service area (Doctor)			
Name:	**Signature:**	**Designation:**	**Date:**
E-Mail contact address:			

I agree that only fully competent, qualified and trained professionals are authorised to operate under the PGD. Records of nominated individuals will be kept for audit purposes.			
Name (Lead Professional)**:**	**Signature:**	**Designation:**	**Date:**
E-Mail contact address:			

Description of Audit arrangements:			
Frequency of checks: **(Generally annually)**		**Names of auditor(s):**	

PGDs DO NOT REMOVE INHERENT PROFESSIONAL OBLIGATIONS OR ACCOUNTABILITY.

It is the responsibility of each professional to practice only within the bounds of their own competence and in accordance with their own Code of Professional Conduct.

Note to Authorising Managers: authorised staff should be provided with an individual copy of the clinical content of the PGD and a photocopy of the document showing their authorisation.

I have read and understood the Patient Group Direction. I acknowledge that it is a legal document and agree to supply/administer this medicine only in accordance with this PGD.

Name of Professional	**Signature**	**Date**

Patient Group Direction Audit Form

Form for the audit of compliance with PGD or PGDs

To ensure best practice all PGDs should be audited on a 6 monthly basis.

Name and post of Designated Lead person within each practice/clinic base:			
Location/Clinic Base: **Date of audit:**			
Tick as appropriate. If 'no', state action required	**Y**	**N**	**Action**
Is the PGD or PGDs utilised within the clinical area?			
Has the PGD or PGDs been reviewed within the 2 year limit?			
Do the managers listed on the PGD or PGDs hold a current list of authorised staff?			
Are all staff authorised to work under the PGD or PGDs members of one of the health professions listed in the PGD?			
Do all staff meet the training requirements identified within the PGD?			
Are you confident that all medicines supplied or administered under the PGD or PGDs are stored according to the PGD where this is specified?			
Do the staff working under the PGD or PGDs have a copy of the PGD which has governance sign off and is in date and, available for reference at the time of consultation?			
Where the medicine requires refrigeration. (Delete if not required).			
Is there a designated person responsible for ensuring that the cold chain is maintained?			
Is there a record that the fridge temperature has been monitored to required levels?			
If there is regular and sustained reliance on PGDs for service provision has a Non Medical Prescribing approach been considered as an alternative? (Please note reasons for either a Y/N response).			

Name:	Date of audit:

Keep copies of completed audits alongside your PGD for local reference.

Please retain at local level and ensure audit forms are readily available as they may be required for clinical governance audit purposes.