NHS
Greater Glasgow and Clyde

Patient Group Direction (PGD)

Administration of

AstraZeneca COVID-19 Vaccine (ChAdOx1-S [Recombinant])

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

Publication date: 19 April 2021

PGD 2121/2142

NHS Greater Glasgow and Clyde

Version history

Version	Date	Summary of changes
1.0	31/12/20	New PGD
1.1	28/01/21	The following sections have been updated: • Inclusion section updated to advise that in individuals who had systemic allergic symptoms after the first dose of Pfizer-BioNTech vaccine may be considered for a second dose using the AstraZeneca vaccine • Exclusion section updated to align with wording in Green Book on previous systemic allergic reaction (including immediate-onset anaphylaxis) • Cautions section updated to include advice from Green Book on second doses following non allergic reactions or localised urticarial skin reactions without systemic symptoms following first dose. • Route of administration updated to align with manufacturer's advice on obtaining additional dose from vial • Frequency section updated to align with advice in Green Book on timing of second dose for those commencing immunosuppressive treatment • Observation following vaccination section updated with advice on post vaccine observation of second doses in those who had systemic allergic symptoms after the first dose of Pfizer-BioNTech vaccine
1.2	25/2/21	The following sections have been updated: • Inclusion section updated to include women who are pregnant where the risk of exposure to 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 and to remove statement not including pregnant women from clinically extremely vulnerable individuals • Exclusion section updated to remove pregnancy and evolving neurological conditions • Exclusion section updated to include those patient characteristics which warrant special precautions as per the

Version	Date	Summary of changes
		Green Book • Cautions section updated to detail the potential for cross-reactivity between patients allergic to polyethylene glycol and polysorbate 80. This section includes advice on inclusion of patients who have no history of systematic allergic reactions to other polysorbate 80-containing injectable vaccines • Cautions section updated to include Management of patients with a history of allergy and Flowchart for managing patients who have allergic reactions to the first dose of COVID-19 vaccine • Action if excluded section updated to remove reference to evolving neurological conditions • Frequency section updated to align with Green Book advice on scheduling of second dose. • Observation following vaccination section updated for patients who had swelling or rash local to the injection site only.
1.3	19/04/21	The following sections have been updated: • Indication section updated to include JCVI statement from 7 April 2021 and statement on phase 2 from 13 April 2021. • Inclusion section updated to highlight that the inclusion criteria refer to COVID-19 Vaccine AstraZeneca. • Inclusion section updated to include those aged from 18 years and adult household contacts of adults with severe immunosuppression • Inclusion section updated to highlight that JCVI currently advises that it is preferable for adults aged less than 30 years without underlying health conditions to be offered an alternative COVID-19 vaccine, if available. People may make an informed choice to receive the AstraZeneca COVID-19 vaccine to receive earlier protection and in such cases vaccination using this PGD is permitted • Inclusion section updated to advise that individuals aged 18 to 29 years who have received their first dose with AstraZeneca COVID-19 vaccine with no clotting episode with concomitant thrombocytopenia are permitted to receive their second dose of AstraZeneca COVID-19 vaccine using this PGD. • Inclusion section updated to align with JCVI advice on the use of

Version	Date	Summary of changes
		vaccination in pregnancy. • Exclusion section updated with additional exclusions related to heparin-induced thrombocytopenia and thrombosis (HITT or HIT type 2). • Exclusion section updated with additional exclusion for patients who experience a clotting episode with concomitant thrombocytopenia following the first dose of AstraZeneca COVID-19 Vaccine (ChAdOx1-S [Recombinant]). • Cautions section updated to reflect JCVI advice for adults aged less than 30 years without underlying health conditions. • Cautions section updated to reflect JCVI advice that those with a prior history of thrombosis or known risk factors for thrombosis are no more at risk of developing the immune-mediated condition of thrombosis in combination with thrombocytopenia after AstraZeneca COVID-19 Vaccine (ChAdOx1-S [Recombinant]) vaccination. • Cautions section updated to recommend the use of alternative COVID-19 vaccines in pregnant women, other than those who have received the first dose of AstraZeneca COVID-19 Vaccine (ChAdOx1-S [Recombinant]). • Frequency section updated to reflect JCVI advice on intervals between doses. • Is this use out with the SPC section updated to highlight difference between Green Book Chapter and information for Health Care Professionals. • Warnings section updated to align with Green Book Chapter. • Warnings section updated to align with JCVI on the nature of, and rarity of thrombosis with thrombocytopenia risk and the relative benefits of vaccination for adults aged 30 years and over, adults who are clinically extremely vulnerable and those with underlying clinical risks • Advice to patient or carer including written information section updated to align with advice from MHRA on the importance to seek urgent medical advice following vaccination in the event of specific symptoms and to provide the associated leaflet.

NHS
Greater Glasgow and Clyde

Contents

Authorisation 5
Clinical situation 6
Description of treatment 12
Adverse reactions 16
Characteristics of staff authorised under the PGD 19
Audit trail 21
Additional references 22
PGD for administration of COVID-19 Vaccine (ChAdOx1-S [recombinant]) AstraZeneca PGD v1.3 Valid from: 19/04/2021 Expiry: 30/11/2021 - authorisation 23

NHS
Greater Glasgow and Clyde

Authorisation

PGD COVID-19 AstraZeneca COVID-19 Vaccine (ChAdOx1-S [Recombinant])

Date approved: 21/04/2021

Effective from: 19/04/2021 **Review date:** 30/11/2021

NHS Greater Glasgow and Clyde

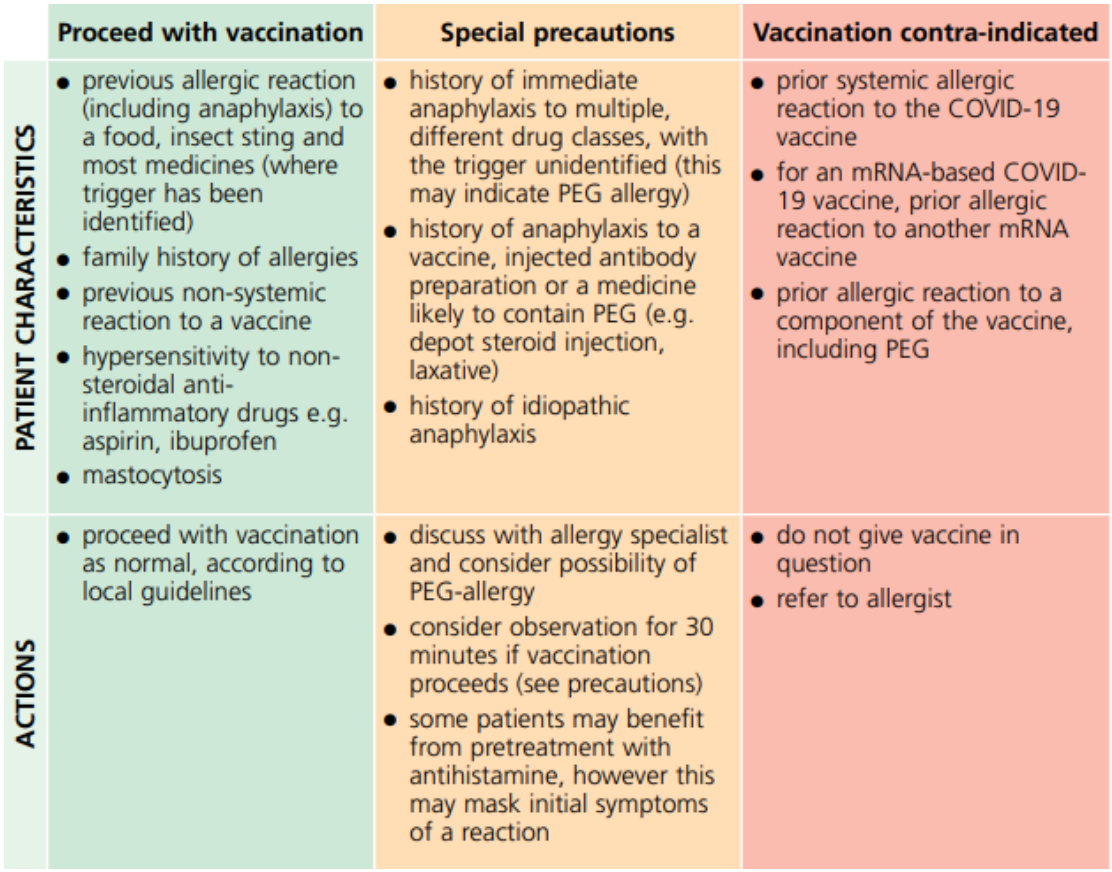
Clinical situation

Category	Description
Indication	AstraZeneca COVID-19 Vaccine (ChAdOx1-S [Recombinant]) 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, JCVI statement on use of the AstraZeneca COVID-19 vaccine: 7 April 2021, JCVI final statement on phase 2 of the COVID-19 vaccination programme from 13 April 2021 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. AstraZeneca COVID-19 Vaccine (ChAdOx1-S [Recombinant]) 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 those under 18 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 18 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* this also includes adult household contacts of adults with severe immunosuppression**

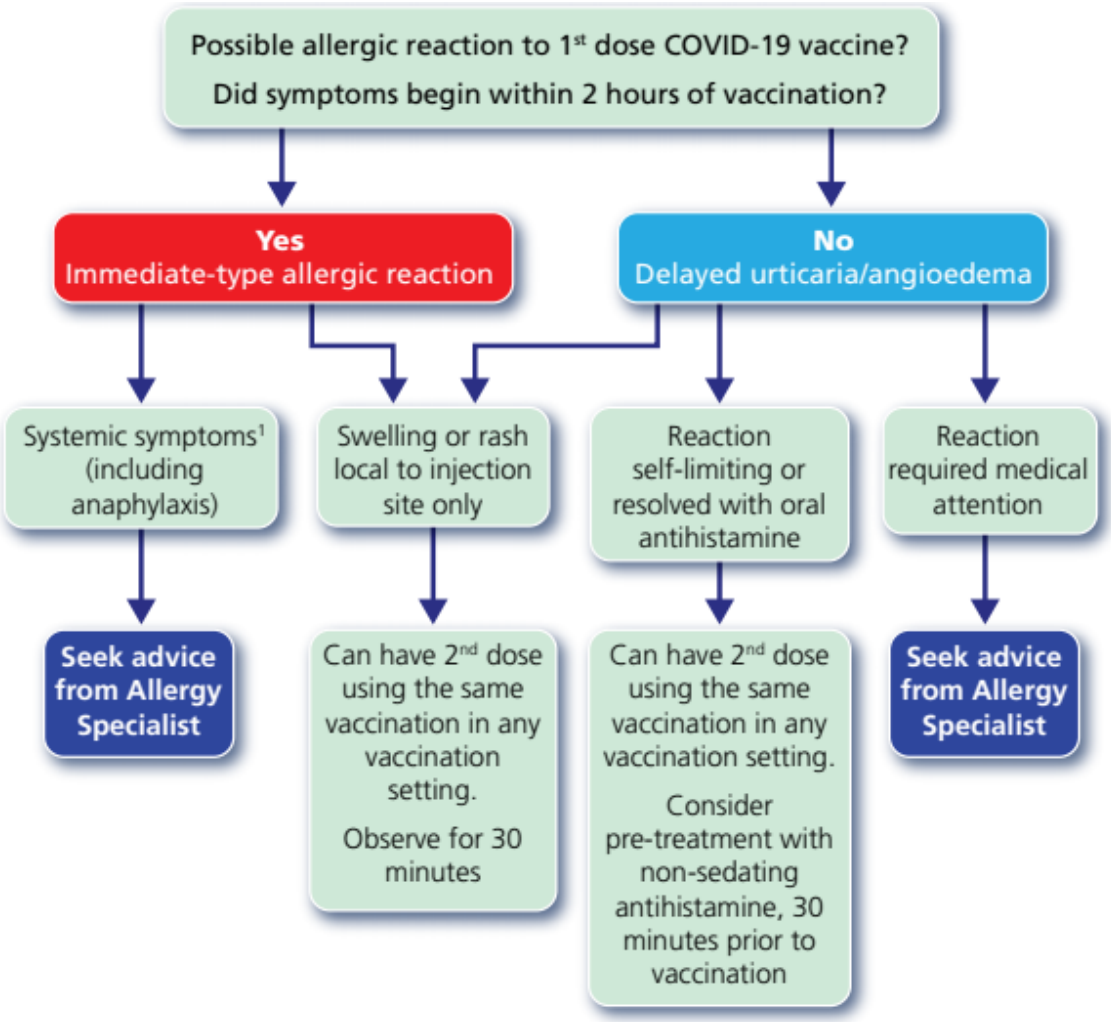
Category	Description
	• All those 60 years of age and over • All those 55 years of age and over • All those 50 years of age and over • All those 40 years of age and over • All those 30 years of age and over • All those aged 18 years to 29 years** • Pregnant women should be offered vaccination at the same time as non-pregnant women, based on their age and clinical risk group. Pfizer and Moderna vaccines are the preferred vaccines for pregnant women of any age, because of more extensive experience of their use in pregnancy. Pregnant women who commenced vaccination with AstraZeneca COVID-19 (ChAdOx1-S [Recombinant]) vaccine, however, are advised to complete with the same vaccine. Clinicians (such as obstetricians, mid-wives, GPs or other healthcare professionals authorised to offer COVID-19 vaccination) should discuss the risks and benefits of vaccination with the woman, who should be told about the limited evidence of safety for the vaccine in pregnancy. *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. ** JCVI currently advises that it is preferable for adults aged less than 30 years without underlying health conditions to be offered an alternative COVID-19 vaccine, if available. People may make an informed choice to receive the AstraZeneca COVID-19 Vaccine (ChAdOx1-S [Recombinant]) to receive earlier protection and in such cases vaccination using this PGD is permitted. Individuals aged 18 years to 29 years who have received their first dose with AstraZeneca COVID-19 Vaccine (ChAdOx1-S [Recombinant]) with no clotting episode with concomitant thrombocytopenia are permitted to receive their second dose of AstraZeneca COVID-19 Vaccine (ChAdOx1-S [Recombinant]) using this PGD. The list above is not exhaustive, and clinician should apply clinical judgment to take into account the risk of COVID-19 exacerbating any underlying disease that a patient may have, as well as the risk of serious illness from COVID-19 itself. AstraZeneca COVID-19 Vaccine (ChAdOx1-S [Recombinant]) 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) or an alternative COVID-19 vaccine should be considered.
Exclusion criteria	The vaccine should not be given to: • Those who have had a previous systemic allergic reaction (including immediate-onset anaphylaxis) to a previous dose of AstraZeneca COVID-19 Vaccine (ChAdOx1-S [Recombinant])

Category	Description
	• Those who have had a previous systemic allergic reaction (including immediate-onset anaphylaxis) to any components of AstraZeneca COVID-19 Vaccine (ChAdOx1-S [Recombinant]) • 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 18 years of age • 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 who have a history of a previous episode of heparin-induced thrombocytopenia and thrombosis (HITT or HIT Type 2). These individuals should be offered vaccination with an alternative COVID-19 vaccine. • Those who experience a clotting episode with concomitant thrombocytopenia following the first dose of AstraZeneca COVID-19 Vaccine (ChAdOx1-S [Recombinant]).
Cautions/ **need for further advice/ circumstances when further advice should**	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. Based on current evidence JCVI are advising a preference for a vaccine other than AstraZeneca COVID-19 Vaccine (ChAdOx1-S [Recombinant]) to be offered to healthy people under 30 years of age,

Category	Description
be sought from a doctor	including health and social care workers, unpaid carers and household contacts of immunosuppressed individuals. In the absence of a suitable alternative these individuals may defer or choose to receive the AstraZeneca COVID-19 Vaccine (ChAdOx1-S [Recombinant]) provided they have been informed and understand the relative risks and benefits. In such cases vaccination using this PGD is permitted. Individuals over 30 years of age with past clotting episodes and those diagnosed with thrombophilia, whether or not they are on long term anti-coagulation, remain at risk of COVID-19 disease. There is no evidence that those with a prior history of thrombosis or known risk factors for thrombosis are more at risk of developing this immune-mediated condition of thrombosis in combination with thrombocytopenia after the AstraZeneca COVID-19 Vaccine (ChAdOx1-S [Recombinant]). For most of these individuals, the risk of recurrent thrombosis due to COVID-19 infection, remains far greater than the risk of this syndrome. Therefore, individuals with such a history should be vaccinated with any of the available vaccines (provided they are not otherwise contra-indicated). The same consideration applies to those who experience common clotting episodes after the first dose of AstraZeneca COVID-19 Vaccine (ChAdOx1-S [Recombinant]) but without concomitant thrombocytopenia. Figure 1 summarises the management of patients with a history of allergy. The Pfizer BioNTech and Moderna mRNA vaccines contain polyethylene glycol (PEG). PEGs (also known as macrogols) are a group of known allergens commonly found in medicines, many household products and cosmetics. Medicines containing PEG include some tablets, laxatives, depot steroid injections, and some bowel preparations used for colonoscopy. Known allergy to PEG is rare but would contraindicate receipt of mRNA vaccines. It is unclear whether PEG is the only cause of allergic reactions in patients with systemic allergic symptoms after the first dose of Pfizer-BioNTech vaccine. The rate of anaphylaxis reported to date to the AstraZeneca vaccine is in line with the expected rate of anaphylaxis to non-COVID vaccines. The AstraZeneca vaccine does not contain PEG but does contain a related compound called polysorbate 80. Some people with PEG allergy may also be allergic to polysorbate 80. However, polysorbate 80 is widely used in medicines and foods, and is present in many medicines including monoclonal antibody preparations. Some injected influenza vaccines (including the main vaccine used in over 65 year olds) contain polysorbate 80. Individuals who have tolerated injections that contain polysorbate 80 (such as certain influenza vaccines) are likely to tolerate the AstraZeneca vaccine.

Category	Description
	Figure 1: Management of patients with a history of allergy  Figure 2 shows the Green Chapter flowchart for managing patients who have allergic reactions to the first dose of COVID-19 vaccine.

Category	Description
	Figure 2: Flowchart for managing patients who have allergic reactions to the first dose of COVID-19 vaccine



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.

Individuals with a bleeding disorder may develop a haematoma at the injection site (see Route of Administration).

Category	Description
	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 AstraZeneca COVID-19 Vaccine (ChAdOx1-S [Recombinant]) 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 clinical trials on the use of COVID-19 vaccines during pregnancy are not advanced, the available data do not indicate any harm to pregnancy. JCVI has therefore advised that women who are pregnant should be offered vaccination at the same time as non-pregnant women, based on their age and clinical risk group. There is now extensive post-marketing experience of the use of the Pfizer BioNTech and Moderna vaccines in the USA with no safety signals so far. These vaccines are therefore the preferred vaccines to offer to pregnant women. Clinicians (such as obstetricians, mid-wives, GPs or other healthcare professionals authorised to offer COVID-19 vaccination) should discuss the risks and benefits of vaccination with the woman, who should be told about the limited evidence of safety for the vaccine in pregnancy. Pregnant women who commenced vaccination with AstraZeneca COVID-19 Vaccine (ChAdOx1-S [Recombinant]), however, are advised to complete with the same vaccine. There is no known risk associated with giving non-live vaccines whilst breastfeeding. JCVI advises that breastfeeding women may be offered any suitable COVID-19 vaccine. 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.

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. 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, 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	AstraZeneca COVID-19 Vaccine (ChAdOx1-S [Recombinant]), solution for injection in a multidose container AstraZeneca COVID-19 Vaccine (ChAdOx1-S [Recombinant])
Form/strength	AstraZeneca COVID-19 Vaccine (ChAdOx1-S [Recombinant]) solution for injection multidose vials containing: 5mL of solution in a 10-dose vial; or 4mL of solution in an 8-dose vial
Route of administration	Each vial contains at least the number of doses stated. It is normal for liquid to remain in the vial after withdrawing the final dose. When low dead volume syringes and/or needles are used, the amount remaining in the vial may be sufficient for an additional dose. Care should be taken to ensure a full 0.5 mLdose is administered. Where a full 0.5 mL dose cannot be extracted, the remaining volume should be discarded. AstraZeneca COVID-19 Vaccine (ChAdOx1-S [Recombinant]) must be administered by intramuscular (IM) injection preferably into the deltoid area of

Category	Description
	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 AstraZeneca COVID-19 Vaccine (ChAdOx1-S [Recombinant]) is 0.5mL
Frequency	AstraZeneca COVID-19 Vaccine (ChAdOx1-S [Recombinant]) course consists of two separate doses of 0.5mL each, a minimum of 28 days apart. Based on good evidence of higher clinical protection, JCVI currently recommend that, ideally, an eight-week minimum interval should be observed for this vaccine. An interval of 28 days may be observed when rapid protection is required (for example for those about to receive immunosuppressive treatment). Operationally, it is recommended in the COVID-19 chapter of Green Book that a consistent interval should be used; currently a schedule of 12 weeks is being followed. This will reduce confusion and 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. 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

Category	Description
	received if the second dose was given during the period of immunosuppression. 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 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 all the authorised COVID-19 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 0.5mL per administration.
▼ black triangle medicines	AstraZeneca COVID-19 Vaccine (ChAdOx1-S [Recombinant]) 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 Medicines & Healthcare products Regulatory Agency (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	AstraZeneca COVID-19 Vaccine (ChAdOx1-S [Recombinant]) is provided temporary authorisation by the MHRA for supply in the UK under regulation

Category	Description
	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?	AstraZeneca COVID-19 Vaccine (ChAdOx1-S [Recombinant]) 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. The vaccine manufacturer's information for UK healthcare professionals states that the vaccine should be used with caution in those with a history of cerebral venous sinus thrombosis or antiphospholipid syndrome. The JCVI has further advised that there is no evidence that those with a prior history of thrombosis or known risk factors for thrombosis are more at risk of developing this immune-mediated condition of thrombosis in combination with thrombocytopenia after the AstraZeneca COVID-19 Vaccine (ChAdOx1-S [Recombinant]).
Storage requirements	AstraZeneca COVID-19 Vaccine (ChAdOx1-S [Recombinant]) must be stored in a fridge between +2 to +8°C in accordance with manufacturer's advice. During storage it is recommended that the vials are stored in the original packaging/cartons, away from direct sunlight to protect from light and kept upright. NHS Board guidance on Storage and Handling of vaccines should be observed. 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. After first use – use as soon as practically possible and within six hours. The vaccine may be stored between +2 and +25°C during the in-use period in accordance with manufacturer's advice. The vaccine vial has space to write the date and time that the vial was first punctured; write this on the vial label. 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.

Category	Description
	There is no evidence of any safety concerns from vaccinating individuals with a past history of COVID-19 infection, or with detectable COVID-19 antibody. Vaccination of individuals who may be infected but asymptomatic or incubating COVID-19 infection is unlikely to have a detrimental effect on the illness. Vaccination should be deferred in those with confirmed infection to avoid 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. 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	From early phase trials, mild pain and tenderness at the injection site was common with COVID-19 Vaccine (ChAdOx1-S [recombinant]) AstraZeneca occurring in 88% of 18-55 year olds, 73% of 56-69 year olds and 61% of people aged 70 years or over; similar levels were reported after each dose. Short lived systemic symptoms including fatigue and headache were also common but decreased with age, being reported in 86%, 77%, and 65% of those aged 18-55, 56-69 and 70 years or over respectively; most of these were classified as mild or moderate. These reactions were unusual after the second dose. Mild fever (>38˚C) was recorded in the first 48 hours for around a quarter of younger participants but was not reported in those over 55 years of age or in any age group after the second dose. Fever can be modified by the prophylactic use of paracetamol, which does not affect the immune response to this vaccine. In the phase 3 study, injection site reactions, mild fever, headache, myalgia and arthralgia occurred in more than 10% of vaccinees. Less than 1% reported lymphadenopathy or an itchy rash. Only one serious adverse event was reported as possibly linked to the vaccine; this was a case of transverse myelitis which occurred 14 days after dose 2. There was no signal to suggest that prior vaccination led to enhanced disease. Recently, a rare condition involving serious thromboembolic events accompanied by thrombocytopenia, has been reported after AstraZeneca COVID-19 Vaccine (ChAdOx1-S [Recombinant]) vaccination. The condition presents with unusual venous thrombosis, including cerebral venous sinus thrombosis, portal vein thrombosis, and sometimes arterial thrombosis, with

Category	Description
	low platelet count and high D-dimer measurements. The condition has similarities to heparin-induced thrombocytopenia and thrombosis (HITT or HIT type 2) and patients usually have positive antibody to platelet factor 4. The majority of the events occurred between 5 and 16 days following vaccination. Overall, JCVI, MHRA and the WHO remain clear that the benefits of vaccination outweigh this small risk for adults aged 30 years and over, adults who are clinically extremely vulnerable and those with underlying clinical risks. A protocol for the management of anaphylaxis and an anaphylaxis pack must always be available whenever AstraZeneca COVID-19 Vaccine (ChAdOx1-S [Recombinant]) 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 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) 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.

Category	Description
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 • Provide copy of COVID-19 AstraZeneca vaccine and rare blood clots leaflet Individual advice / follow up treatment • Inform the individual/carer of possible side effects and their management. • Inform the individual/carer that anyone who has any of the following symptoms from around four days to four weeks after vaccination should seek medical advice urgently: ➢ a new, severe headache which is not helped by usual painkillers or is getting worse ➢ an unusual headache which seems worse when lying down or bending over or may be accompanied by: blurred vision, nausea and vomiting; difficulty with your speech; weakness, drowsiness or seizures. ➢ new, unexplained pinprick bruising or bleeding ➢ shortness of breath, chest pain, leg swelling or persistent abdominal pain • Vaccinated individuals should be advised that it is common to develop a fever after vaccination and that this normally happens within 48 hours after the vaccination and usually goes away within 48 hours. This is a common, expected reaction, and self-isolation and testing for COVID-19 are not required unless the individual has other COVID-19 symptoms; has been told by NHS Test and Protect they are a close contact of someone who has tested positive for COVID-19; they live with someone who has recently tested positive for COVID-19; or they live with someone who has symptoms of COVID-19. • Vaccinated individuals should be advised that if the fever started 48 hours after the vaccination or lasts longer than 48 hours, they should self-isolate and book a test. • Vaccinated individuals should be advised that feeling generally unwell, shivery, achy and tired were also symptoms commonly reported by vaccine recipients in the clinical trials. Generally, these symptoms were

Category	Description
	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	As syncope (fainting) can occur following vaccination, all vaccinees should either be driven by someone else or should not drive for 15 minutes after vaccination. Individuals with swelling or a localised urticarial (itchy) skin reaction (without systemic symptoms) to the first dose of a COVID-19 vaccine should receive the second dose of vaccine with prolonged observation (30 minutes) in any setting.
Follow up	Not applicable
Additional facilities	A protocol for the management of anaphylaxis and an anaphylaxis pack must always be available whenever AstraZeneca COVID-19 Vaccine (ChAdOx1-S [Recombinant]) 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.

NHS Greater Glasgow and Clyde

Characteristics of staff authorised under the PGD

Category	Description
Professional qualifications	The following classes of registered healthcare practitioners are permitted to administer AstraZeneca COVID-19 Vaccine (ChAdOx1-S [Recombinant]) • 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

Category	Description
	immediate adverse reactions • 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.

NHS Greater Glasgow and Clyde

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.

NHS Greater Glasgow and Clyde

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 30 December 2020 https://www.gov.uk/government/publications/priority-groups-for-coronavirus-covid-19-vaccination-advice-from-the-jcvi-30-december-2020 JCVI statement on use of the AstraZeneca COVID-19 vaccine: 7 April 2021 https://www.gov.uk/government/publications/use-of-the-astrazeneca-covid-19-vaccine-jcvi-statement/jcvi-statement-on-use-of-the-astrazeneca-covid-19-vaccine-7-april-2021 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 https://www.gov.uk/government/publications/priority-groups-for-phase-2-of-the-coronavirus-covid-19-vaccination-programme-advice-from-the-jcvi Manufacturer's product information/ Summary of Product Characteristics https://www.gov.uk/government/publications/regulatory-approval-of-covid-19-vaccine-astrazeneca 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)

NHS Greater Glasgow & Clyde Patient Group Direction (PGD) for Health Care Professionals	

AstraZeneca COVID-19 Vaccine (ChAdOx1-S [Recombinant])

Organisation:	**NHS Greater Glasgow & Clyde**

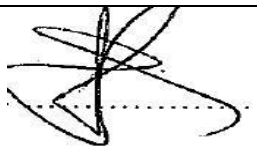
Professionals drawing up PGD/Authors

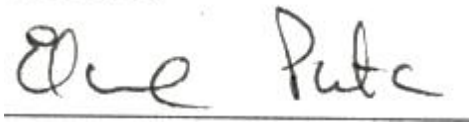
	Designation and Contact Details
*Name: Gillian Penrice  Signature: Date: 20/04/2021	Designation: Consultant in Public Health Medicine, NHS GG&C E-mail address: Gillian.penrice@ggc.scot.nsh.uk
Name: Val Reilly  Signature: Date: 20/04/2021	Designation: Public Health Pharmacist, Pharmaceutical Public Health West House, NHS GG&C E-mail address: val.reilly@ggc.scot.nhs.uk
Na me: Hilda Crookshanks  Signature: Date: 20/04/2021	Designation: Health Protection Nurse Specialist, Public Health Protections, West House, NHS GG&C E-mail address: Hilda.crookshanks@ggc.scot.nhs.uk
Name: Signature: Date:	Designation: E-mail address:

*** Lead Author**

AUTHORISATION:

NHSGG&C PGD & Non-medical Prescribing Sub-Committee of ADTC		
Chairman in BLOCK CAPITALS	**Signature:**	**Date:**
Dr Craig Harrow		**20/04/2021**

NHSGG&C PGD Sub-Committee of ADTC		
Lead Nurse, North Sector, NHS GG&C in BLOCK CAPITALS	**Signature:**	**Date:**
John Carson		**20/04/2021**

Pharmacist representative of PGD & Non-Medical Sub-Committee of ADTC		
Name: in BLOCK CAPITALS	**Signature:**	**Date:**
Elaine Paton		**20/04/2021**

PGD for administration of AstraZeneca COVID-19 Vaccine (ChAdOx1-S [Recombinant]) PGD v1.3 Valid from: 19/04/2021 Expiry: 30/11/2021 - authorisation

Practitioner

This PGD does not remove professional obligations and accountability. It is the responsibility of each professional to practice within the bounds of their own competence and in accordance with their Code of Professional Conduct and to ensure familiarity with the marketing authorisation holder's summary of product characteristics for all vaccines administered in accordance with this PGD.

By signing this PGD you are indicating that you agree to its contents and that you will work within it. I agree to administer AstraZeneca COVID-19 Vaccine (ChAdOx1-S [Recombinant]) only in accordance with this PGD.

Name of professional	Signature	Date

Authorising Manager

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

Lead clinician for the service area

Name ……..

Signature ……..

Date ……

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