

Patient Group Direction (PGD) Template

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: 05 July 2021

PGD No: 2021/2179

Version history

Version	Date	Summary of changes
1.0	31/12/20	New PGD
1.1	28/01/21	<p>The following sections have been updated:</p> <ul style="list-style-type: none"> • 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	<p>The following sections have been updated:</p> <ul style="list-style-type: none"> • 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 Green Book

Version	Date	Summary of changes
		<ul style="list-style-type: none"> • 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	<p>The following sections have been updated:</p> <ul style="list-style-type: none"> • 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 vaccination in pregnancy.

Version	Date	Summary of changes
		<ul style="list-style-type: none"> • 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.
1.4	10/05/21	<p>The following sections have been updated:</p> <ul style="list-style-type: none"> • Indication section updated to include reference to JCVI statement of 7 May 2021

Version	Date	Summary of changes
		<ul style="list-style-type: none"> • Inclusion section updated to highlight that JCVI currently advises that it is preferable for adults aged less than 40 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 include those requiring a different type of COVID-19 vaccine for the second dose than that given as the first dose when clinically indicated. • Exclusion section update to remove exclusions related to possibility of PEG allergy. • Exclusion section updated to include 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). • Cautions section updated to reflect JCVI advice for adults aged less than 40 years without underlying health conditions. • Cautions section updated with updated information on possibility of undiagnosed PEG-allergy • Frequency section updated to remove advice that the second vaccine dose should be with the same vaccine as for the first dose. • Warnings section updated to reflect JCVI advice for adults aged less than 30 years without underlying health conditions.
1.5	24/05/21	<p>The following sections have been updated:</p> <ul style="list-style-type: none"> • Frequency section updated to include JCVI advice that second doses of all vaccines should be brought forward from 12 to 8 weeks for all priority groups, with priority given to those areas where the B.1.617.2 variant is of the highest threat.
1.6	05/07/21	<p>The following sections have been updated:</p> <ul style="list-style-type: none"> • Exclusion section updated to add those individuals with a previous history of capillary leak syndrome.

Version	Date	Summary of changes
		<ul style="list-style-type: none">• Cautions section updated to align with Green Book chapter on co-administration with other vaccines.• Frequency section updated to align with Green Book chapter advice on scheduling.• Frequency section updated to align with Green Book chapter on interchangeability between COVID-19 vaccines.• Duration of treatment section updated to align with Green Book chapter on reinforcing immunisation.

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Effective from: 05/07/2021

Review date: 30/11/2021

Clinical situation

Category	Description
Indication	<p>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 JCVI statement on 7 May 2021 and subsequent correspondence/publications from Scottish Government.</p>
Inclusion criteria	<p>National policy must be followed in relation to the priority groups eligible for vaccination at a particular point in time.</p> <p>AstraZeneca COVID-19 Vaccine (ChAdOx1-S [Recombinant]) should be offered to the following individuals:</p> <ul style="list-style-type: none"> • Residents in a care home for older adults and their carers • All those 80 years of age and over • Frontline health and social care workers (as included in COVID-19 –SARS-Cov-2 chapter of Green Book, JCVI statement and Scottish Government CMO letters) • All those 75 years of age and over • All those 70 years of age and over • Clinically extremely vulnerable (CEV) individuals (not including 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** • All those 60 years of age and over • All those 55 years of age and over • All those 50 years of age and over

Category	Description
	<ul style="list-style-type: none"> • All those 40 years of age and over • All those aged 30 years to 39 years ** • 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. • Those requiring a different type of COVID-19 vaccine for the second dose than that given as the first dose when clinically indicated. <p>*This also includes those who are in receipt of a carer’s allowance, or those who are the main carer of an elderly or disabled person whose welfare may be at risk if the carer falls ill.</p> <p>** JCVI currently advises that it is preferable for adults aged less than 40 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.</p> <p>Individuals aged 18 years to 39 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.</p> <p>The list above is not exhaustive, and clinician should apply clinical judgment to take into account the risk of COVID-19 exacerbating any underlying disease that a patient may have, as well as the risk of serious illness from COVID-19 itself. 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.</p>
Exclusion criteria	<p>The vaccine should not be given to:</p> <ul style="list-style-type: none"> • Those who have had a previous systemic allergic reaction (including immediate-onset anaphylaxis) to a previous dose of AstraZeneca COVID-19 Vaccine (ChAdOx1-S [Recombinant])

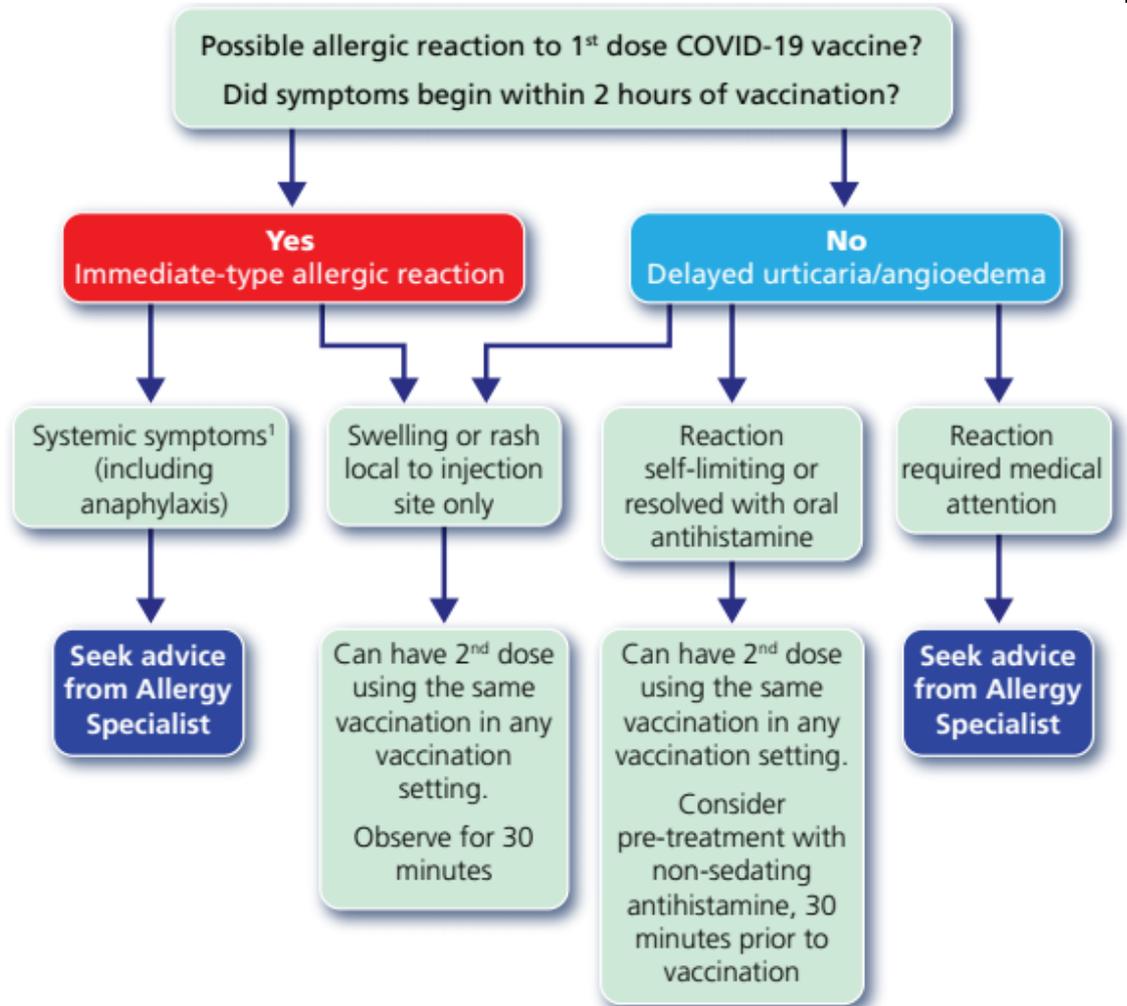
Category	Description
	<ul style="list-style-type: none"> • Those who have had a previous systemic allergic reaction (including immediate-onset anaphylaxis) to any components of AstraZeneca COVID-19 Vaccine (ChAdOx1-S [Recombinant]) • Those in whom no valid consent has been received • Those who are under 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]). • 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 with a previous history of capillary leak syndrome. These individuals may be offered vaccination with an alternative COVID-19 vaccine.
<p>Cautions/ need for further advice/ circumstances when further advice should be sought from a doctor</p>	<p>The COVID-19 chapter of the Green Book advises that there are very few individuals who cannot receive COVID vaccine. Where there is doubt, rather than withholding vaccination, appropriate advice should be sought from the relevant specialist, or from the local immunisation or health protection team.</p> <p>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 40 years of age, 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</p>

Category	Description
	<p>have been informed and understand the relative risks and benefits. In such cases vaccination using this PGD is permitted.</p> <p>Individuals over 40 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.</p> <p>Figure 1 summarises the management of patients with a history of allergy.</p> <p>The AstraZeneca COVID-19 Vaccine (ChAdOx1-S [Recombinant]) does not contain polyethylene glycol (PEG) but does contain a related compound called polysorbate 80. Some people with PEG allergy may also be allergic to polysorbate 80. Individuals who have tolerated injections that contain polysorbate 80 (such as certain influenza vaccines) are likely to tolerate COVID-19 Vaccine AstraZeneca.</p> <p>Special precautions as described in the COVID-19 chapter of the Green Book, and consideration of the possibility of undiagnosed PEG-allergy, is required for individuals with:</p> <ul style="list-style-type: none"> • history of immediate anaphylaxis to multiple, different drug classes, with the trigger unidentified (this may indicate PEG allergy) • history of anaphylaxis to a vaccine, injected antibody preparation or a medicine likely to contain PEG (such as depot steroid injection, laxative) • history of idiopathic anaphylaxis <p>Individuals with the possibility of undiagnosed PEG-allergy (as above) should not be vaccinated with COVID-19 mRNA vaccine (Pfizer or Moderna), except on the expert advice of a relevant specialist, local immunisation or health protection team is that vaccination should proceed. AstraZeneca COVID-19 Vaccine (ChAdOx1-S [Recombinant]). can be used as an alternative (unless otherwise contraindicated), particularly if they previously tolerated an injected influenza vaccine. In these circumstances, AstraZeneca COVID-19 Vaccine (ChAdOx1-S [Recombinant]). should be administered in a setting with full resuscitation facilities (such as a hospital), and a 30-minute observation period is recommended.</p> <p>Appendix 1 provides an accessible version of Figure 1.</p>

Category	Description											
	<p>Figure 1: Management of patients with a history of allergy</p>											
	<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th data-bbox="357 483 730 539"></th> <th data-bbox="730 483 1098 539" style="background-color: #fce4d6;">Special precautions</th> <th data-bbox="1098 483 1469 539" style="background-color: #ffe0b2;">Vaccination contra-indicated</th> </tr> </thead> <tbody> <tr> <td data-bbox="357 539 730 992" style="background-color: #e2efda; vertical-align: middle; text-align: center;">PATIENT CHARACTERISTICS</td> <td data-bbox="730 539 1098 992" style="background-color: #fce4d6;"> <ul style="list-style-type: none"> ● 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 </td> <td data-bbox="1098 539 1469 992" style="background-color: #ffe0b2;"> <ul style="list-style-type: none"> ● prior systemic allergic reaction to the COVID-19 vaccine ● for an mRNA-based COVID-19 vaccine, prior allergic reaction to another mRNA vaccine ● prior allergic reaction to a component of the vaccine, including PEG </td> </tr> <tr> <td data-bbox="357 992 730 1346" style="background-color: #e2efda; vertical-align: middle; text-align: center;">ACTIONS</td> <td data-bbox="730 992 1098 1346" style="background-color: #fce4d6;"> <ul style="list-style-type: none"> ● discuss with allergy specialist and consider possibility of PEG-allergy ● consider observation for 30 minutes if vaccination proceeds (see precautions) ● some patients may benefit from pretreatment with antihistamine, however this may mask initial symptoms of a reaction </td> <td data-bbox="1098 992 1469 1346" style="background-color: #ffe0b2;"> <ul style="list-style-type: none"> ● do not give vaccine in question ● refer to allergist </td> </tr> </tbody> </table>				Special precautions	Vaccination contra-indicated	PATIENT CHARACTERISTICS	<ul style="list-style-type: none"> ● 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 	<ul style="list-style-type: none"> ● prior systemic allergic reaction to the COVID-19 vaccine ● for an mRNA-based COVID-19 vaccine, prior allergic reaction to another mRNA vaccine ● prior allergic reaction to a component of the vaccine, including PEG 	ACTIONS	<ul style="list-style-type: none"> ● discuss with allergy specialist and consider possibility of PEG-allergy ● consider observation for 30 minutes if vaccination proceeds (see precautions) ● some patients may benefit from pretreatment with antihistamine, however this may mask initial symptoms of a reaction 	<ul style="list-style-type: none"> ● do not give vaccine in question ● refer to allergist
	Special precautions	Vaccination contra-indicated										
PATIENT CHARACTERISTICS	<ul style="list-style-type: none"> ● 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 	<ul style="list-style-type: none"> ● prior systemic allergic reaction to the COVID-19 vaccine ● for an mRNA-based COVID-19 vaccine, prior allergic reaction to another mRNA vaccine ● prior allergic reaction to a component of the vaccine, including PEG 										
ACTIONS	<ul style="list-style-type: none"> ● discuss with allergy specialist and consider possibility of PEG-allergy ● consider observation for 30 minutes if vaccination proceeds (see precautions) ● some patients may benefit from pretreatment with antihistamine, however this may mask initial symptoms of a reaction 	<ul style="list-style-type: none"> ● do not give vaccine in question ● refer to allergist 										
	<p>Figure 2 shows the Green Chapter flowchart for managing patients who have allergic reactions to the first dose of COVID-19 vaccine.</p>											

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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).

As all of the early COVID-19 vaccines are considered inactivated (including the AstraZeneca COVID-19 Vaccine (ChAdOx1-S [Recombinant])), where individuals in an eligible cohort present having recently received another inactivated or live vaccine, COVID-19 vaccination should still be given. The same applies for most other live and inactivated vaccines where COVID-19 vaccination has been received first or where a patient presents requiring two vaccines. It is generally better for vaccination to proceed to avoid any further delay in protection and to avoid the risk

Category	Description
	<p>of the patient not returning for a later appointment. An exception to this is shingles vaccination, where a seven-day interval should ideally be observed given the potential for an inflammatory response to COVID-19 vaccine to reduce the response to the live virus.</p> <p>Syncope (fainting) can occur following, or even before, any vaccination especially in adolescents as a psychogenic response to the needle injection. This can be accompanied by several neurological signs such as transient visual disturbance, paraesthesia and tonic-clonic limb movements during recovery. It is important that procedures are in place to avoid injury from faints.</p> <p>JCVI advise there is no known risk associated with giving these types of vaccines during pregnancy. These vaccines cannot replicate, so they cannot cause infection in either the woman or the unborn child.</p> <p>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.</p> <p>Pregnant women who commenced vaccination with AstraZeneca COVID-19 Vaccine (ChAdOx1-S [Recombinant]), however, are advised to complete with the same vaccine.</p> <p>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.</p> <p>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.</p>
<p>Action if excluded</p>	<p>Specialist advice should be sought on the vaccine and circumstances under which it could be given as vaccination using a patient specific direction may be indicated.</p> <p>Individuals who are participating in a clinical trial of COVID-19 vaccines who present for vaccination should be referred back to the investigators.</p> <p>In case of postponement due to acute illness, advise when the individual can be vaccinated and ensure another appointment is arranged.</p>

Category	Description
	<p>In case of postponement due to COVID-19 symptoms or positive COVID test in the last four weeks advise when the individual can be vaccinated and how future vaccination may be accessed.</p> <p>Document the reason for exclusion and any action taken in accordance with local procedures.</p>
Action if patient declines	<p>Advise the individual/carer about the protective effects of the vaccine, the risks of infection and potential complications if not immunised.</p> <p>Advise how future immunisation may be accessed if they subsequently decide to receive the COVID-19 vaccine</p> <p>Document patient's declined consent and advice given.</p>

Description of treatment

Category	Description
Name of medicine	<p>AstraZeneca COVID-19 Vaccine (ChAdOx1-S [Recombinant]), solution for injection in a multidose container</p> <p>AstraZeneca COVID-19 Vaccine (ChAdOx1-S [Recombinant])</p>
Form/strength	<p>AstraZeneca COVID-19 Vaccine (ChAdOx1-S [Recombinant]) solution for injection multidose vials containing:</p> <p>5mL of solution in a 10-dose vial; or</p> <p>4mL of solution in an 8-dose vial</p>
Route of administration	<p>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 mL dose is administered. Where a full 0.5 mL dose cannot be extracted, the remaining volume should be discarded.</p> <p>AstraZeneca COVID-19 Vaccine (ChAdOx1-S [Recombinant]) must be administered by intramuscular (IM) injection preferably into the deltoid area of the upper arm. Where administration into the deltoid is not possible the anterolateral thigh can be considered.</p> <p>Inspect visually prior to administration and ensure appearance is consistent with the description in the manufacturer's product literature or summary of product characteristics.</p> <p>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</p>

Category	Description
	<p>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.</p> <p>Individuals on stable anticoagulation therapy, including individuals on warfarin who are up-to-date with their scheduled INR testing and whose latest INR is below the upper level of the therapeutic range, can receive intramuscular vaccination. A fine needle (23 or 25 gauge) should be used for the vaccination, followed by firm pressure applied to the site without rubbing for at least 2 minutes. The individual/parent/carer should be informed about the risk of haematoma from the injection.</p> <p>The site at which each vaccine was given should be noted in the individual's records.</p>
Dosage	<p>The dose of AstraZeneca COVID-19 Vaccine (ChAdOx1-S [Recombinant]) is 0.5mL</p>
Frequency	<p>AstraZeneca COVID-19 Vaccine (ChAdOx1-S [Recombinant]) course consists of two separate doses of 0.5mL each, a minimum of 28 days apart.</p> <p>For both AstraZeneca COVID-19 Vaccine (ChAdOx1-S [Recombinant]) and mRNA vaccines, there is evidence of better immune response and/or protection where longer intervals between doses are used.</p> <p>Currently, JCVI is recommending an interval of 8 to 12 weeks between doses of all the available COVID-19 vaccines. Operationally, this consistent interval should be used for all two dose vaccines to avoid confusion and simplify booking, and will help to ensure a good balance between achieving rapid and long-lasting protection.</p> <p>The main exception to the eight week lower interval would be those about to commence immunosuppressive treatment. In these individuals, the minimal intervals outlined below may be followed to ensure that the vaccine is given whilst their immune system is better able to respond</p> <p>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.</p> <p>If an interval longer than the recommended interval is left between doses, the second dose should still be given (preferably using the same vaccine as was given for the first dose if possible). The course does not need to be restarted.</p>

Category	Description
	<p>Evidence from trials of co-administration suggest that those who receive mixed schedules, including mRNA and AstraZeneca COVID-19 Vaccine (ChAdOx1-S [Recombinant]) make a good immune response, although rates of side effects at the second dose are higher. Therefore, every effort should be made to determine which vaccine the individual received and to complete with the same vaccine. For individuals who started the schedule and who attend for vaccination at a site where the same vaccine is not available, or if the first product received is unknown, it is reasonable to offer one dose of the locally available product to complete the schedule. This option is preferred if the individual is likely to be at immediate high risk or is considered unlikely to attend again. Further doses would not then be required.</p>
<p>Duration of treatment</p>	<p>See Dose and frequency of administration above.</p> <p>The need for booster doses is still under consideration by JCVI as the need for, and timing of boosters has not yet been determined.</p>
<p>Maximum or minimum treatment period</p>	<p>See Frequency of administration above.</p>
<p>Quantity to supply/administer</p>	<p>Administer 0.5mL per administration.</p>
<p>▼ black triangle medicines</p>	<p>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.</p> <p>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/</p>
<p>Legal category</p>	<p>AstraZeneca COVID-19 Vaccine (ChAdOx1-S [Recombinant]) is provided temporary authorisation by the MHRA for supply in the UK under regulation 174 and 174A, pending UK marketing authorisation.</p> <p>The regulation 174 authorised product is categorised as a prescription only medicine (POM).</p>
<p>Is the use out with the SPC?</p>	<p>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.</p> <p>As part of the consent process, inform the individual/carer that this vaccine does not have a UK marketing authorisation but has been authorised for</p>

Category	Description
	<p>temporary supply in the UK by the MHRA and that it is being offered in accordance with national guidance.</p> <p>The vaccine manufacturer's information for UK healthcare professionals states that the vaccine should be 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]).</p>
<p>Storage requirements</p>	<p>AstraZeneca COVID-19 Vaccine (ChAdOx1-S [Recombinant]) must be stored in a fridge between +2 to +8°C in accordance with manufacturer's advice.</p> <p>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.</p> <p>NHS Board guidance on Storage and Handling of vaccines should be observed.</p> <p>In the event of an inadvertent or unavoidable deviation of these conditions, vaccine that has been stored outside the conditions stated above should be quarantined and risk assessed for suitability of continued use or appropriate disposal.</p> <p>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.</p> <p>The manufacturer may advise of updated storage requirements and product stability as new data becomes available, vaccine may be stored in accordance with updated recommendations from the manufacturer.</p>
<p>Additional information</p>	<p>Minor illnesses without fever or systemic upset are not valid reasons to postpone immunisation. If an individual is acutely unwell, immunisation should be postponed until they have fully recovered.</p> <p>There is no evidence of any safety concerns from vaccinating individuals with a past history of COVID-19 infection, or with detectable COVID-19 antibody.</p> <p>Vaccination of individuals who may be infected but asymptomatic or incubating COVID-19 infection is unlikely to have a detrimental effect on the illness. Vaccination should be deferred in those with confirmed infection to avoid confusing the differential diagnosis. As clinical deterioration can occur up to two weeks after infection, ideally vaccination should be deferred until around four weeks after onset of symptoms or from the first PCR positive specimen in those who are asymptomatic.</p>

Category	Description
	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
<p>Warnings including possible adverse reactions and management of these</p>	<p>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.</p> <p>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 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.</p> <p>Overall, JCVI, MHRA and the WHO remain clear that the benefits of vaccination outweigh this small risk for adults aged 40 years and over, adults who are clinically extremely vulnerable and those with underlying clinical risks.</p> <p>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</p>

Category	Description
	<p>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.</p> <p>In the event of a severe adverse reaction individual should be advised to seek medical advice.</p> <p>For full details/information on possible adverse reaction, refer to manufacturer's product literature or summary of product characteristics.</p>
<p>Reporting procedure for adverse reactions</p>	<p>Healthcare professionals and individuals/carers should report suspected adverse reactions to the MHRA using the Coronavirus Yellow Card reporting scheme on: https://coronavirus-yellowcard.mhra.gov.uk/</p> <p>As this vaccine is labelled with a black triangle, all adverse reactions occurring in individuals of any age after vaccination should be reported to the MHRA using the Coronavirus Yellow Card Scheme. Anyone can report a suspected adverse reaction to the MHRA using the Coronavirus Yellow Card reporting scheme https://coronavirus-yellowcard.mhra.gov.uk/</p> <p>Any adverse reaction to a vaccine should be documented in accordance with locally agreed procedures in the individual's record and the individual's GP should be informed.</p> <p>Anaphylaxis is a very rare, recognised side effect of most vaccines and suspected cases should be reported via the Coronavirus Yellow Card Scheme. Chapter 8 of the Green Book gives detailed guidance on distinguishing between faints, panic attacks and the signs and symptoms of anaphylaxis. If a case of suspected anaphylaxis meets the clinical features described in Chapter 8, this should be reported via the Yellow Card Scheme as a case of 'anaphylaxis' (or if appropriate 'anaphylactoid reaction'). Cases of less severe allergic reactions (i.e. not including the clinical features of anaphylaxis) should not be reported as anaphylaxis but as 'allergic reaction'.</p> <p>Programmatic Adverse Events should be recorded in line with local procedures and where appropriate escalated in accordance with the national framework.</p>
<p>Advice to patient or carer including written information</p>	<p>Written information to be given to individual</p> <ul style="list-style-type: none"> • Provide manufacturer's consumer information leaflet/patient information leaflet (PIL) provided with the vaccine. • Provide copy of Public Health Scotland post-vaccination leaflet • Provide copy of Pregnant, planning a pregnancy or breastfeeding, a guide to COVID-19 vaccine to women of child bearing years • Provide copy of COVID-19 AstraZeneca vaccine and rare blood clots leaflet

Category	Description
	<p data-bbox="432 197 927 226">Individual advice / follow up treatment</p> <ul style="list-style-type: none"> <li data-bbox="480 255 1299 327">• Inform the individual/carer of possible side effects and their management. <li data-bbox="480 356 1461 468">• 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: <ul style="list-style-type: none"> <li data-bbox="528 497 1449 568">➤ a new, severe headache which is not helped by usual painkillers or is getting worse <li data-bbox="528 598 1445 745">➤ 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. <li data-bbox="528 775 1182 804">➤ new, unexplained pinprick bruising or bleeding <li data-bbox="528 833 1465 904">➤ shortness of breath, chest pain, leg swelling or persistent abdominal pain <li data-bbox="480 934 1458 1285">• 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. <li data-bbox="480 1314 1426 1426">• 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. <li data-bbox="480 1456 1458 1695">• 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. <li data-bbox="480 1724 1449 1836">• 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 <li data-bbox="480 1865 1458 1937">• The individual should be advised to seek medical advice in the event of a severe adverse reaction.

Category	Description
	<ul style="list-style-type: none"> • 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	<p>As syncope (fainting) can occur following vaccination, all vaccinees should either be driven by someone else or should not drive for 15 minutes after vaccination.</p> <p>Individuals with 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.</p>
Follow up	Not applicable
Additional facilities	<p>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.</p>

Characteristics of staff authorised under the PGD

Category	Description
<p>Professional qualifications</p>	<p>The following classes of registered healthcare practitioners are permitted to administer AstraZeneca COVID-19 Vaccine (ChAdOx1-S [Recombinant])</p> <ul style="list-style-type: none"> • 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.
<p>Specialist competencies or qualifications</p>	<p>Persons must only work under this PGD where they are competent to do so.</p> <p>All practitioners operating this PGD must:</p> <ol style="list-style-type: none"> 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 <p>All persons operating this PGD:</p> <ul style="list-style-type: none"> • 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
	<ul style="list-style-type: none"> • must have access to the PGD and associated online resources • should fulfil any additional requirements defined by local policy <p>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</p> <p>Employer</p> <p>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</p> <p>As a minimum, competence requirements stipulated in the PGD must be adhered to.</p>
<p>Continuing education and training</p>	<p>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.</p>

Audit trail

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

Additional references

Name	Description
Additional references	<p>Immunisation against Infectious Disease [Green Book] https://www.gov.uk/government/organisations/public-health-england/series/immunisation-against-infectious-disease-the-green-book</p> <p>Immunisation against Infectious Disease [Green Book] COVID-19 https://www.gov.uk/government/publications/covid-19-the-green-book-chapter-14a</p> <p>JCVI: advice on priority groups for COVID-19 vaccine 30 December 2020 https://www.gov.uk/government/publications/priority-groups-for-coronavirus-covid-19-vaccination-advice-from-the-jcvi-30-december-2020</p> <p>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</p> <p>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</p> <p>Use of the AstraZeneca COVID-19 (AZD1222) vaccine: updated JCVI statement, 7 May 2021 https://www.gov.uk/government/publications/use-of-the-astrazeneca-covid-19-vaccine-jcvi-statement-7-may-2021/use-of-the-astrazeneca-covid-19-azd1222-vaccine-updated-jcvi-statement-7-may-2021</p> <p>Manufacturer's product information/ Summary of Product Characteristics https://www.gov.uk/government/publications/regulatory-approval-of-covid-19-vaccine-astrazeneca</p> <p>Educational resources for registered professionals produced by National Education for Scotland https://learn.nes.nhs.scot/37676/immunisation/covid-19-vaccines</p> <p>All relevant Scottish Government advice including the relevant CMO letter(s)</p>

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

Organisation: NHS Greater Glasgow & Clyde

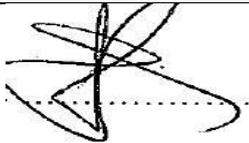
Professionals drawing up PGD/Authors

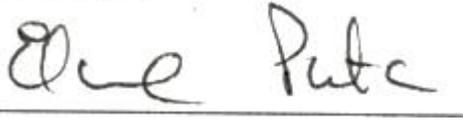
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* Lead Author

AUTHORISATION

NHS GG&C PGD & Non-medical Prescribing Sub-Committee of ADTC		
Chairman in BLOCK CAPITALS	Signature:	Date:
Dr Craig Harrow		09/07/2021

NHS GG&C PGD Sub-Committee of ADTC		
Lead Nurse, North Sector, NHS GG&C in BLOCK CAPITALS	Signature:	Date:
John Carson		09/07/2021

Pharmacist representative of PGD & Non-Medical Sub-Committee of ADTC		
Name: in BLOCK CAPITALS	Signature:	Date:
Elaine Paton		09/07/2021

PGD for administration of AstraZeneca COVID-19 Vaccine (ChAdOx1-S [Recombinant]) PGD v1.6 Valid from: 05/07/2021 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.

Appendix 1 – management of patients with a history of allergy

	Proceed with vaccination	Special precautions	Vaccination contra-indicated
Patient characteristics	<ul style="list-style-type: none"> • previous allergic reaction (including anaphylaxis) to a food, insect sting and most medicines (where trigger has been identified) • family history of allergies • previous non-systemic reaction to a vaccine • hypersensitivity to nonsteroidal antiinflammatory drugs e.g. aspirin, ibuprofen • mastocytosis 	<ul style="list-style-type: none"> • history of immediate anaphylaxis to multiple different drug classes, with the trigger unidentified (this may indicate a 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 	<ul style="list-style-type: none"> • prior systemic allergic reaction to the COVID-19 vaccine • for an mRNA-based COVID-19 vaccine, prior allergic reaction to another mRNA vaccine • prior allergic reaction to a component of the vaccine, including PEG
Actions	<ul style="list-style-type: none"> • proceed with vaccination as normal, according to local guidelines 	<ul style="list-style-type: none"> • discuss with allergy specialist and consider possibility of PEG allergy • consider observation for 30 minutes if vaccination proceeds (see precautions – p17 in Green Book COVID-19 chapter 14a) • some patients may benefit from pre-treatment with antihistamine, however this may mask initial symptoms of a reaction 	<ul style="list-style-type: none"> • do not give vaccine in question • refer to allergist