NHS Grampian NHS Highland NHS Orkney NHS Shetland NHS Tayside NHS Eileanan Siar Western Isles

Patient Group Direction For The Administration of Vaxzevria® (AstraZeneca COVID-19 Vaccine ChAdOx1-S [Recombinant]) by Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles

Version 1.1

Effective from 11th May 2022

NoS/PGD/COVID19_Vaxzevria/MGPG1268

Note: Other COVID19 vaccines are not covered by this PGD – separate PGDs will be available

This Patient Group Direction (PGD) has been adopted from the PGD template produced by Public Health Scotland on 11th May 2022. Note Version 1.0 not issued, first published Version 1.1.

Version history

Version	Date	Summary of changes
1.0	11.05.22	Version 1.0 new PGD The changes from version 2.8 of PGD for AstraZeneca COVID-19 Vaccine (ChAdOx1-S [Recombinant]) (supplied under regulation 174 approval include: Update to include brand name Vaxzevria® throughout Form/strength updated to be suspension for injection in 8 dose multidose vial Frequency section updated to include wording on vaccine in Spring 2022 booster Black triangle section wording updated to reflect vaccine now has conditional marketing authorisation Legal classification section updated to state prescription only medicine Is use with SPC section updated to reflect vaccine now has conditional marketing authorisation and highlighting the differences to JCVI advice as set out in the COVID-19 chapter of Green Book.
1.1	11.05.22	Version 1.1 with change to spelling of name of vaccine.

Contents

Authorisation

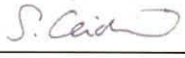
Vaxzevria® (AstraZeneca COVID-19 Vaccine ChAdOx1-S [Recombinant])

This specimen Patient Group Direction (PGD) template has been produced by Public Health Scotland to assist NHS Boards. NHS Boards should amend/adapt this PGD template and must ensure that the PGD is considered and approved in line with local clinical governance arrangements for PGDs

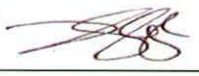
The qualified health professionals who may administer Vaxzevria® (AstraZeneca COVID-19 Vaccine ChAdOx1-S [Recombinant]) under this PGD can only do so as named individuals. **It is the responsibility of each professional to practice within the bounds of their own competence and in accordance with their own Code of Professional Conduct, and to ensure** familiarity with the manufacturer's product information/summary of product characteristics (SPC) for the vaccine administered in accordance with this PGD.

NHS Board governance arrangements will indicate how records of staff authorised to operate this PGD will be maintained. Under PGD legislation there can be no delegation. Administration of the vaccine has to be by the same registered healthcare practitioner who have assessed the patient under the PGD.

This PGD template has been adopted by NoS for use across all 6 NoS Health Boards.

This PGD has been produced for NoS by					
Doctor	Dr Susan Laidlaw	Signature		Date Signed	19/05/2022
Pharmacist	Russel Mackay	Signature		Date Signed	17/05/2022
Nurse	Alison Smart	Signature		Date Signed	17/05/2022

Approved for use within NoS Boards by;

North of Scotland (NoS) PGD Group Chair	**Signature**	**Date Signed**
Lesley Coyle		17/05/2022

Authorised and executively signed for use within NoS Boards by;

NHS Grampian Chief Executive	**Signature**	**Date Signed**
Professor Caroline Hiscox		20/05/2022

Version 1.1 valid from 11th May 2022 review date 31st December 2022.

Clinical situation

Category	Description
Indication	Vaxzevria® (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'; statements from Joint Committee on Vaccination and Immunisation (JCVI); and subsequent correspondence/publications from Scottish Government.
Inclusion criteria	Vaxzevria® (AstraZeneca COVID-19 Vaccine ChAdOx1-S [Recombinant]) should be offered to all individuals aged 18 years and over in accordance with the recommendations in Chapter 14a of the Green Book and JCVI advice. National policy must be followed in relation to the priority groups eligible for vaccination at a particular point in time. Individuals are eligible for different dose schedules based on their age and recognised risk group (see the frequency section). 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. Individuals may make an informed choice to receive the Vaxzevria® (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 39 years who have received their first dose with Vaxzevria® (AstraZeneca COVID-19 Vaccine ChAdOx1-S [Recombinant]) with no clotting episode with concomitant thrombocytopenia are permitted to receive their subsequent doses of Vaxzevria® (AstraZeneca COVID-19 Vaccine ChAdOx1-S [Recombinant]) using this PGD.
Exclusion criteria	The vaccine should not be given to: • Those who have had a previous systemic anaphylaxis reaction to any COVID-19 vaccine. • Those who have had a prior systemic allergic reaction to any component (excipient) of Vaxzevria® (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 evidence of current deterioration of COVID-19 symptoms, deferral of vaccination may be considered to avoid incorrect attribution of any change in the person's underlying condition to the vaccine.

	• Those with acute febrile illness – consider postponing immunisation until individual has fully recovered. • Those 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 Vaxzevria® (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. • Those in whom a third primary dose for immunosuppression or a COVID-19 booster dose is required and where the individual received mRNA vaccines in the primary course. In such cases vaccination using a patient specific direction should be considered. • Those who developed myocarditis or pericarditis following a previous dose of COVID-19 vaccination • Those in whom Guillain Barre Syndrome has occurred within six weeks of a previous dose of Vaxzevria® (AstraZeneca COVID-19 Vaccine ChAdOx1-S [Recombinant]). In such cases, for any future doses Pfizer or Moderna COVID-19 vaccines are preferred. • Those in whom immune thrombocytopenia has occurred in the four weeks after the first dose of Vaxzevria® (AstraZeneca COVID-19 Vaccine ChAdOx1-S [Recombinant]). Such individuals should be assessed by a haematologist and the risk benefit of further vaccination and with which product should be considered on an individual basis.
Cautions/ **need for further advice/ circumstances when further advice should be sought from a doctor**	The COVID-19 chapter of the Green Book advises that there are very few individuals who cannot receive COVID vaccine. Where there is doubt, rather than withholding vaccination, appropriate advice should be sought from the relevant specialist, or from the local immunisation or health protection team. Based on current evidence JCVI are advising a preference for a vaccine other than Vaxzevria® (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 for the primary course. In the absence of a suitable alternative, these individuals may defer or choose to receive the

Vaxzevria® (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 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 Vaxzevria® (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 Vaxzevria® (AstraZeneca COVID-19 Vaccine ChAdOx1-S [Recombinant]) but without concomitant thrombocytopenia.

Individuals with a history of allergy

Figure 1 summarises the management of patients with a history of allergy.

The Vaxzevria® (AstraZeneca COVID-19 Vaccine ChAdOx1-S [Recombinant]) does not contain polyethylene glycol (PEG) but does contain a related compound called polysorbate 80. Rarely 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 (including the adjuvanted influenza vaccine, Fluad® and the GlaxoSmithKline vaccine Fluarix®) are likely to tolerate the AstraZeneca vaccine. Advice on the management of patients with allergy is summarised in figure 1.

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:

- 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

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 the

adjuvanted influenza vaccine. In these circumstances, Vaxzevria® (AstraZeneca COVID-19 Vaccine ChAdOx1-S [Recombinant]) should be administered in a setting with full resuscitation facilities (such as a hospital), and observe for 30-minutes.

The COVID-19 chapter of the Green Book states individuals with non-allergic reactions (vasovagal episodes, non-urticarial skin reaction or non-specific symptoms) to the first dose of a COVID-19 vaccine can receive the second dose of vaccine in any vaccination setting. Observation for 15 minutes is recommended.

Appendix 3 provides an accessible version of Figure 1.

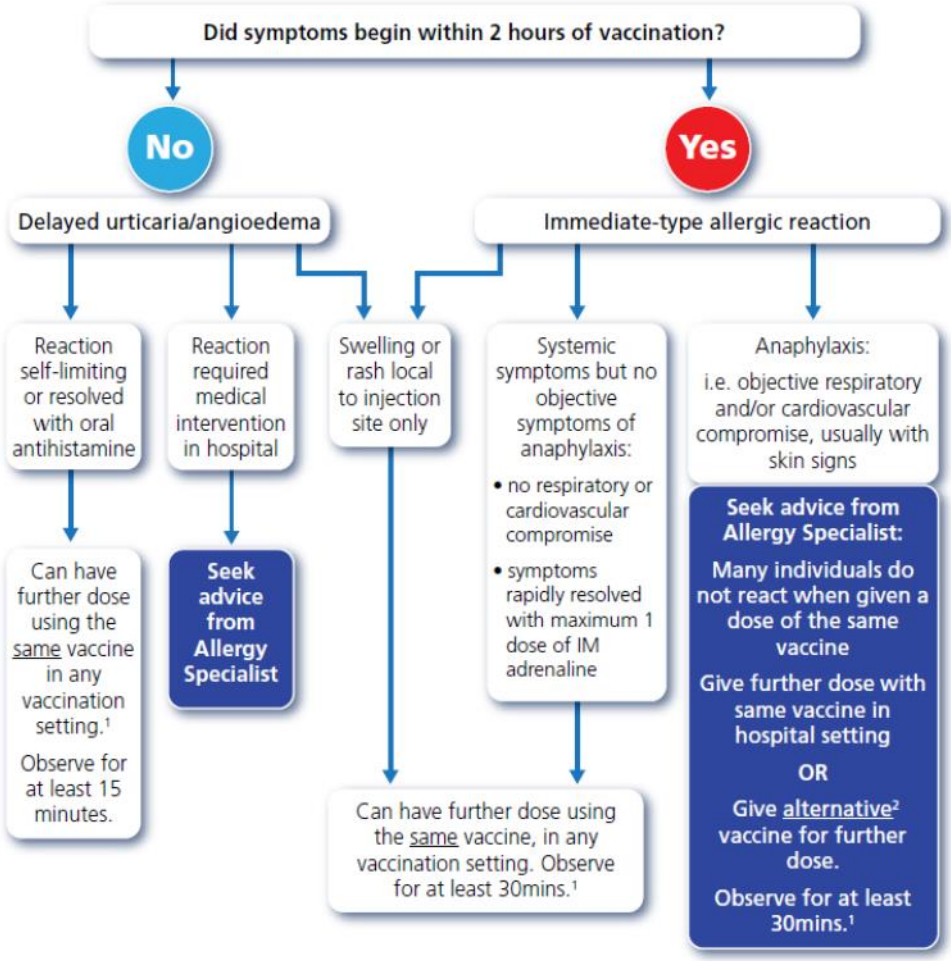
No specific management is required for individuals with a family history of allergies

Figure 1: Management of patients with a history of allergy

	Proceed with vaccination (no special precautions)	Special precautions	Vaccination contra-indicated
PATIENT CHARACTERISTICS	• previous allergic reaction (including anaphylaxis) to a food, insect sting and most medicines (where trigger has been identified) • previous non-systemic reaction to a vaccine • hypersensitivity to non-steroidal anti-inflammatory drugs e.g. aspirin, ibuprofen • mastocytosis	• prior non-anaphylaxis allergic reaction to COVID-19 vaccine • history of immediate anaphylaxis to multiple, different drug classes, with the trigger unidentified (this may indicate PEG allergy) • history of anaphylaxis to a vaccine, injected antibody preparation or a medicine likely to contain PEG (e.g. depot steroid injection, laxative) • history of idiopathic anaphylaxis	• prior anaphylaxis reaction to COVID-19 vaccine • prior systemic allergic reaction to a component of the vaccine (for known PEG allergy see text above)
ACTIONS	• proceed with vaccination in any setting • some individuals may be reassured by being observed for 15 minutes (may not be required if previously tolerated the same vaccine) • some patients (e.g. those with mastocytosis) may benefit from pretreatment with anti-histamine to reduce allergic symptoms	• consider possibility of PEG allergy and seek allergy advice if needed • a person has previously tolerated a dose of the same vaccine, it is safe to administer in any setting. Otherwise - consider giving vaccine and observe for 30 minutes	• refer to allergist or other appropriate specialist • consider administration of the implicated mRNA vaccine under medical supervision in hospital, or, where reaction was to AstraZeneca vaccine give alternative vaccine in any setting • consider observation for 30 minutes

Figure 2 shows the Green Book Chapter flowchart for managing patients who have allergic reactions to the first dose of COVID-19 vaccine.

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



[1] Consider pre-treatment with non-sedating antihistamine, at least 30mins prior to vaccination

[2] If reaction was to AstraZeneca vaccination, complete or boost with an mRNA vaccine. If reaction was to an mRNA vaccine, give the same or alternative mRNA vaccine in hospital setting.

Those with an anaphylaxis immediate-type allergic reaction are excluded from receiving vaccination under this PGD – a patient specific direction is required if further doses are offered.

Individuals with a bleeding history

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

Co-administration with other vaccines

As all of the early COVID-19 vaccines are considered inactivated (including the Vaxzevria® (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 or more vaccines. It is generally better for vaccination to proceed to avoid any further delay in protection and to avoid the risk of the patient not returning for a later appointment. This includes but is not limited to vaccines commonly administered around the same time or in the same settings (including influenza and pneumococcal polysaccharide vaccine in those aged over 65 years, pertussis-containing vaccines and influenza vaccines in pregnancy, and LAIV, HPV, MenACWY and Td-IPV vaccines in the schools programmes). 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 interfere the response to the live virus in the older population and because of the potential difficulty of attributing systemic side effects to the newer adjuvanted shingles vaccine. A UK study of co-administration of AstraZeneca and Pfizer BioNTech COVID-19 vaccines with inactivated influenza vaccines confirmed acceptable immunogenicity and reactogenicity. Where co-administration does occur, patients should be informed about the likely timing of potential adverse events relating to each vaccine. If the vaccines are not given together, they can be administered at any interval, although separating the vaccines by a day or two will avoid confusion over systemic side effects. Syncope Syncope (fainting) can occur following, or even before, any vaccination especially in adolescents as a psychogenic response to the needle injection. This can be accompanied by several neurological signs such as transient visual disturbance, paraesthesia and tonic-clonic limb movements during recovery. It is important that procedures are in place to avoid injury from faints. Pregnancy and breastfeeding 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 be considered as falling into a clinical risk group (JCVI Priority Cohort 6 for COVID-19 vaccination. 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 (for those under 18 years Comirnaty® (COVID-19 mRNA vaccine, Pfizer/BioNTech) is preferred). 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 have already received a dose of Vaxzevria® (AstraZeneca COVID-19 Vaccine ChAdOx1-S [Recombinant]) can complete with the same vaccine or with an mRNA product. 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. Emerging safety data is reassuring: mRNA was not detected in the breast milk of recently vaccinated and protective antibodies have been detected in breast milk. The developmental and health benefits of breastfeeding should be considered along with the woman's clinical need for immunisation against COVID-19. Clinical trial participants Individuals who have participated in a clinical trial of either primary or booster COVID-19 vaccines should be provided with written advice on whether and when they should be safely vaccinated in the routine programme. Advice should also be provided from the trial investigators on whether any individual could receive additional doses for the purposes of vaccine certification. Trial participants who are eligible for boosters should be offered vaccination in line with the general population, at least three months after the dose considered as the final primary dose or the final revaccination (if the latter is required for certification purposes). Individuals with a past history of COVID-19 infection There is no convincing evidence of any safety concerns from vaccinating individuals with a past history of COVID-19 infection, or with detectable COVID-19 antibody. Vaccination of individuals who may be infected or asymptomatic or incubating COVID-19 infection is unlikely to have a detrimental effect on the illness. As clinical deterioration can occur up to two weeks after infection, vaccination of adults and high risk children should ideally be deferred until clinical recovery to around four weeks after onset of symptoms or four weeks from the first confirmed positive specimen to avoid confusing the differential diagnosis. There is no need to defer immunisation in individuals after recovery from a recent episode with compatible symptoms who were not tested unless there are strong clinical or epidemiological features to suggest the episode was COVID-19 infection. The four week interval may be reduced to ensure operational flexibility when rapid protection is required, for example high incidence or circulation of a new variant in a vulnerable population. Currently, the JCVI consider that, in care home residents and the housebound, there may be an advantage in offering vaccination to some individuals with recent confirmed COVID-19, without a four-week deferral, where individuals are clinically stable and when infection control procedures can be maintained. These populations are likely to be highly vulnerable and will facilitate vaccination without the need for multiple visits.

Action if excluded	Specialist advice should be sought on the vaccine and circumstances under which it could be given as vaccination using a patient specific direction may be indicated. In case of postponement due to acute illness, advise when the individual can be vaccinated and ensure another appointment is arranged. In case of deferral due to COVID-19 symptoms or recent positive COVID test advise when the individual can be vaccinated and how future vaccination may be accessed. Document the reason for exclusion and any action taken in accordance with local procedures.
Action if patient declines	Advise the individual/carer about the protective effects of the vaccine, the risks of infection and potential complications if not immunised. Advise how future immunisation may be accessed if they subsequently decide to receive the COVID-19 vaccine Document patient's declined consent and advice given.

Description of treatment

Category	Description
Name of medicine	Vaxzevria® (AstraZeneca COVID-19 Vaccine ChAdOx1-S [Recombinant])
Form/strength	Vaxzevria® (AstraZeneca COVID-19 Vaccine ChAdOx1-S [Recombinant]) suspension for injection multidose vials containing: 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 mL dose is administered. Where a full 0.5 mL dose cannot be extracted, the remaining volume should be discarded. Vaxzevria® (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. 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

Category	Description
	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 Vaxzevria® (AstraZeneca COVID-19 Vaccine ChAdOx1-S [Recombinant]) is 0.5mL
Frequency	Vaxzevria® (AstraZeneca COVID-19 Vaccine ChAdOx1-S [Recombinant]) course consists of two separate doses of 0.5mL each, a minimum of 28 days apart. For both Vaxzevria® (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 in the primary schedule are used. Based on this evidence, longer intervals are likely to provide more durable protection. JCVI is currently recommending a minimum interval of eight weeks between doses of all the available COVID-19 vaccines where a two-dose primary schedule is used. Operationally, using the same minimum interval for all products will simplify booking, and will help to ensure a good balance between achieving rapid and long-lasting protection. If an interval longer than the recommended interval is left between doses in the two dose primary schedule, the second dose should still be given (preferably using the same vaccine as was given for the first dose if possible). The course does not need to be restarted. The main exception to the eight-week lower interval would be those about to commence immunosuppressive treatment. In these individuals, the minimal intervals outlined above may be followed to enable the vaccine to be given whilst their immune system is better able to respond. Individuals who are about to receive planned immunosuppressive therapy should be considered for vaccination prior to commencing therapy (ideally at least two weeks before), when their immune system is better able to make a response. Where possible, it would also be preferable for the 2-dose schedule to be completed prior to commencing immunosuppression. This would entail offering the second dose at the recommended minimum for that vaccine (three

Category	Description
	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. Evidence suggests that those who receive mixed schedules, including mRNA and Vaxzevria® (AstraZeneca COVID-19 Vaccine ChAdOx1-S [Recombinant]) make a good immune response, although rates of side effects with a heterologous second dose are higher. Accumulating evidence now supports the use of heterologous schedules for primary immunisation, and these are now recognised by the European Medicines Agency. For individuals who started the schedule and who attend for vaccination where the same vaccine is not available or suitable, or if the first product received is unknown or not available, one dose of the locally available product should be given to complete the primary course. Individuals who experienced severe expected reactions after a first dose of AstraZeneca or Pfizer BioNTech vaccines should be informed about the higher rate of such reactions when they receive a second dose of an alternate vaccine. Severe immunosuppression Those who have this vaccine previously and identified as meeting the definition for severe immunosuppression in proximity of their first or second vaccine doses in the primary schedule , in line with specialist advice, for a third primary dose (as defined in COVID-19 chapter of Green Book) The third primary dose should be given at least 8 weeks after the second dose, with special attention paid to current or planned immunosuppressive therapies guided by the following principles: a) where possible the third primary dose should be delayed until two weeks after the period of immunosuppression, in addition to the time period for clearance of the therapeutic agent, b) if not possible, consideration should be given to vaccination during a treatment 'holiday' or at a nadir of immunosuppression between doses of treatment. For those aged over 18 years, JCVI advises a preference for mRNA vaccines - Pfizer BioNTech (Comirnaty®) or Moderna (Spikevax®) - for the third primary dose for those with severe immunosuppression. Pfizer BioNTech (Comirnaty®) is preferred for 12-17 year olds. AstraZeneca COVID-19 vaccine (Vaxzevria®) is an option for individuals who have received this vaccine previously where mRNA vaccines are clinically contraindicated. In exceptional circumstances, persons aged 40 years or over who received a mRNA COVID-19 vaccine previously may be offered a third dose of AstraZeneca Vaxzevria® vaccine following a decision by a health professional on a case-by-case basis. Booster vaccination Booster vaccination should not be given within three months (12 weeks) of completion of the primary course. The JCVI have advised that a full dose (30µg) of Pfizer-BioNTech vaccine or a half dose (50µg) of the Moderna COVID-19 vaccine should be offered for boosting irrespective of the vaccine used for the primary course. Both vaccines are suitable for boosting adults aged 18 years or over, with Pfizer

Category	Description
	BioNTech preferred for those aged 16-17 years and those aged 12-15 years in clinical risk groups. Both vaccines have been shown to give good immune responses in those already primed. The half dose of Moderna and is expected to have a lower rate of side effects (including myocarditis) than a full dose. Where mRNA vaccines are clinically contra-indicated, vaccination with AstraZeneca vaccine may be considered in those who had received at least one dose of this vaccine previously. Severely immunosuppressed individuals (aged 12 years and over) who have completed their primary course (three doses) should be offered a booster dose with a minimum of three months between the third primary and booster dose. Those who have not yet received their third dose may be given the third dose now (provided there has been an interval of at least 8 weeks since the second primary dose) to avoid further delay. A fourth dose can be given in three months, in line with the clinical advice on optimal timing. Spring booster 2022 JCVI have advised a further booster dose should be given around six months after the last dose to adults aged 75 years and over*; residents of any age in a care home for older adults, and; individuals aged 12 years and over who are immunosuppressed (as defined in COVID-19 chapter of Green Book). *or who will turn 75 years by 30 June 2022 The vast majority of people aged over 75 will reach an interval of around six months from their previous dose between March and June 2022. Although vaccination should ideally be offered around six months from any previous dose, operational flexibility may be used. For example, individuals in care homes or housebound patients may be offered the booster alongside other residents providing there is at least three months (12 weeks) from the previous dose. Immunosuppressed individuals who have received an additional primary dose may have received the booster (fourth) dose more recently. These latter individuals and other eligible people who received their last vaccine more recently should also be offered the booster during the spring campaign providing there is at least three months (12 weeks) from the previous dose. This will ensure they have additional protection against a potential summer wave and will align with their peers to facilitate an autumn programme. Someone in an eligible group who has received a full course of primary vaccination (two or three doses) but has not received their first booster by March 2022, may be given the spring booster in the campaign provided there is at least three months from the previous dose. An additional dose is not then recommended before the autumn. The vaccines offered should follow the age-appropriate advice as for other reinforcing doses (as set out in COVID-19 chapter of Green Book). The JCVI have advised that a full dose (30µg) of Pfizer-BioNTech vaccine or a half dose (50µg) of the Moderna COVID-19 vaccine should be offered for the additional booster irrespective of the vaccine

Category	Description
	used previously. Both vaccines are suitable for boosting adults aged 18 years or over, with Pfizer BioNTech preferred for those aged 12-17 years in clinical risk groups. Where mRNA vaccines are clinically contra-indicated, vaccination with AstraZeneca vaccine may be considered in those who had received at least one dose of this vaccine previously.
Duration of treatment	See Dose and frequency of administration above.
Maximum or minimum treatment period	See Frequency of administration above.
Quantity to supply/administer	Administer 0.5mL per administration.
▼ black triangle medicines	Vaxzevria® (AstraZeneca COVID-19 Vaccine ChAdOx1-S [Recombinant]) has been designated ▼ 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	Prescription only medicine (POM).
Is the use out with the SPC?	The vaccine manufacturer's marketing authorisation holder's summary of product characteristics states that a booster/third dose may be administered at least six months after completing the primary course. This is superseded by the JCVI advice as set out in the COVID-19 chapter of Green Book for third primary dose vaccination or booster vaccination and spring 2022 booster vaccination.
Storage requirements	Vaxzevria® (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

Category	Description
	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. There is no convincing evidence of any safety concerns from vaccinating individuals with a past history of COVID-19 infection, or with detectable COVID-19 antibody. 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 Vaxzevria® (AstraZeneca COVID-19 Vaccine ChAdOx1-S [Recombinant]) 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 Vaxzevria® (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. 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. A protocol for the management of anaphylaxis and an anaphylaxis pack must always be available whenever vaccines are given. Immediate treatment should include early treatment with intramuscular adrenaline, with an early call for help and further IM adrenaline every 5 minutes. The health professionals overseeing the immunisation service must be trained to recognise an anaphylactic reaction and be familiar with techniques for resuscitation of a patient with anaphylaxis. In the event of a severe adverse reaction individual should be advised to seek medical advice. For full details/information on possible adverse reaction, refer to manufacturer's product literature or summary of product characteristics.

Category	Description
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.
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

Category	Description
	▪ 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. • Vaccinated individuals should be advised that if the fever started 48 hours after the vaccination or lasts longer than 48 hours, they should seek medical advice as they may have COVID-19 or another infection. They may be advised to take a COVID-19 test. • Vaccinated individuals should be advised that feeling generally unwell, shivery, achy and tired were also symptoms commonly reported by vaccine recipients in the clinical trials. Generally, these symptoms were found to resolve within one to two days without treatment but paracetamol can be taken if necessary to relieve any of these symptoms. • As has always been recommended, any fever after vaccination should be monitored and if individuals are concerned about their health at any time, they should seek advice from their GP or NHS24 • The individual should be advised to seek medical advice in the event of a severe adverse reaction. • Inform the individual that they can report suspected adverse reactions to the MHRA using the Yellow Card reporting scheme on: **http://yellowcard.mhra.gov.uk** • Immunosuppressed individuals should be advised that they may not make a full immune response to the vaccine and they should continue to take appropriate measures to protect themselves against this infection. • When administration is postponed advise the individual how future vaccination may be accessed • When applicable, advise the individual/carer when to return for vaccination or when a subsequent vaccine dose is due.

Category	Description
Observation following vaccination	Following COVID-19 vaccine administration, individuals should be observed for any immediate reactions whilst they are receiving any verbal post vaccination information and exiting the centre. According to the Summaries of Product Characteristics, it is recommended that all recipients of the Pfizer BioNTech and Moderna vaccines are kept for observation and monitored for a minimum of 15 minutes. In recognition of the need to accelerate delivery of the programme in response to the emergence of the Omicron variant, the UK Chief Medical Officers have recommended suspension of this requirement. This temporary suspension in individuals without a history of allergy has also been agreed by the Commission on Human Medicines. There is no routine requirement for observation following Vaxzevria® (AstraZeneca COVID-19 Vaccine ChAdOx1-S [Recombinant]). The Scottish Government has made further recommendations that all doses of mRNA COVID-19 vaccines be followed by a 5 minute observation period. A longer observation period when indicated after clinical assessment as set out in Figure 1 and Figure 2 (above). Vaccinated individuals should be informed about how to access immediate healthcare advice in the event of displaying any symptoms. In some settings, for example domiciliary vaccination, this may require a responsible adult to be present for at least 15 minutes after vaccination. 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.
Follow up	Not applicable
Additional facilities	A protocol for the management of anaphylaxis and an anaphylaxis pack must always be available whenever vaccines are given. Immediate treatment should include early treatment with intramuscular adrenaline, with an early call for help and further IM adrenaline every 5 minutes. The health professionals overseeing the immunisation service must be trained to recognise an anaphylactic reaction and be familiar with techniques for resuscitation of a patient with anaphylaxis.

Characteristics of staff authorised under the PGD

Category	Description
Professional qualifications	The following classes of registered healthcare practitioners are permitted to administer Vaxzevria® (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: • demonstrate appropriate knowledge and skills to work under the PGD for the administration of COVID-19 vaccine. • 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

Category	Description
	• must be competent in the recognition and management of anaphylaxis or under the supervision of persons able to respond appropriately to 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.

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

Name	Description
	• anatomical site of vaccination • advice given, including advice given if excluded or declines immunisation • details of any adverse drug reactions and actions taken • administered under PGD Records should kept line with local procedures. Ideally records should be kept within the NHS Scotland COVID-19 vaccine administration app. Local policy should be followed to encourage information sharing with the individual's General Practice. All records should be clear, legible and contemporaneous.

Additional references

Name	Description
Additional references	Immunisation against Infectious Disease [Green Book] **https://www.gov.uk/government/organisations/public-health-england/series/immunisation-against-infectious-disease-the-green-book** Immunisation against Infectious Disease [Green Book] COVID-19 **https://www.gov.uk/government/publications/covid-19-the-green-book-chapter-14a** 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 JCVI statements All relevant Scottish Government advice including the relevant CMO letter(s)

Appendix 1

Healthcare Professional Agreement to Administer Vaccine Under Patient Group Direction

I:

_____ (Insert name)

Working within: _____ e.g. Health Board, Area Practice

Agree to administer the vaccine contained within the following Patient Group Direction:

Patient Group Direction For The Administration of Vaxzevria® (AstraZeneca COVID-19 Vaccine ChAdOx1-S [Recombinant]) by Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles (Version 1.1 valid from 11th May 2022)

I have completed the appropriate training to my professional standards enabling me to administer the vaccine under the above direction. I agree not to act beyond my professional competence, nor out with the recommendations of the direction. **PGDs do not remove inherent professional obligations or accountability.**

Signed: _____

Print Name: _____

Date: _____

Profession: _____

Professional Registration number/PIN _____

NHS Grampian NHS Highland NHS Orkney NHS Shetland NHS Tayside NHS Eileanan Siar Western Isles

Appendix 2

Healthcare Professionals Authorisation to Administer Vaccine Under Patient Group Direction

The Lead manager/Professional of each clinical area is responsible for maintaining records of all clinical areas where this PGD is in use, and to whom it has been disseminated.
The Senior Nurse/Professional who approves a healthcare professional to administer the vaccine under this PGD is responsible for ensuring that he or she is competent, qualified and trained to do so, and for maintaining an up-to-date record of such approved persons.
The Healthcare Professional that is approved to administer the vaccine under this PGD is responsible for ensuring that he or she understands and is qualified, trained and competent to undertake the duties required. The approved person is also responsible for ensuring that administration is carried out within the terms of the direction, and according to his or her individual code of professional practice and conduct.
Patient Group Direction For The Administration of Vaxzevria® (AstraZeneca COVID-19 Vaccine ChAdOx1-S [Recombinant]) by Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles (Version 1.1 valid from 11th May 2022)
Local clinical area(s) where the listed healthcare professionals will operate under this PGD:

Name of Healthcare Professional	Signature	Date	Name of Manager	Signature	Date

Patient Group Direction For The Administration of Vaxzevria® (AstraZeneca COVID-19 Vaccine ChAdOx1-S [Recombinant]) by Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles (Version 1.1 valid from 11th May 2022)

Name of Healthcare Professional	Signature	Date	Name of Manager	Signature	Date

Appendix 3 – Management of Patients with a History of Allergy

	Proceed with vaccination (no special precautions)	Special precautions	Vaccination contra-indicated
Patient characteristics	• previous allergic reaction (including anaphylaxis) to a food, insect sting and most medicines (where trigger has been identified) • previous non-systemic reaction to a vaccine • hypersensitivity to non-steroidal anti-inflammatory drugs e.g. aspirin, ibuprofen • mastocytosis	• prior non-anaphylaxis allergic reaction to COVID-19 vaccine • history of immediate anaphylaxis to multiple different drug classes, with the trigger unidentified (this may indicate 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	• prior anaphylaxis to the COVID-19 vaccine • prior systemic allergic reaction to a component of the vaccine, (for known PEG allergy see Green Book chapter 14a COVID-19)
Actions	• proceed with vaccination as normal, according to local guidelines • some individuals may be reassured by being observed for 15 minutes (may not be required if previously tolerated the same vaccine) • some patients (e.g. those with mastocytosis) may benefit from pre-treatment with anti-histamine to reduce allergic symptoms	• consider possibility of PEG allergy and seek allergy advice if needed • a patient has previously tolerated a dose of the same vaccine, it is safe to administer in any setting Otherwise • Consider giving vaccine and observe for 30 minutes	• refer to allergist or other appropriate specialist • consider administration of the implicated mRNA vaccine under medical supervision in hospital, or, where the reaction was to AstraZeneca vaccine give an alternative vaccine in any setting • consider observation for 30 minutes