Public Health England

Publications approval reference: 001559

Patient Group Direction for COVID-19 Vaccine AstraZeneca, (ChAdOx1-S [recombinant])

This Patient Group Direction (PGD) is for the administration of COVID-19 Vaccine AstraZeneca (ChAdOx1-S [recombinant]) to individuals in accordance with the national COVID-19 vaccination programme.

This PGD is for the administration of COVID-19 Vaccine AstraZeneca by registered healthcare practitioners identified in Section 3.

The national COVID-19 vaccination programme may also be provided under national protocol or on a patient specific basis (that is by or on the direction of an appropriate independent prescriber). Supply and administration in these instances are not covered by this PGD.

Reference no:	COVID-19 Vaccine AstraZeneca PGD
Version no:	v02.00
Valid from:	22 March 2021
Review date:	1 October 2021
Expiry date:	31 March 2022

Public Health England (PHE) has developed this PGD for authorisation by NHS England and NHS Improvement to facilitate the delivery of the national COVID-19 vaccination programme.

NHS England and NHS Improvement and those providing services in accordance with this PGD must not alter, amend or add to the clinical content of this document (sections 3, 4, 5 and 6); such action will invalidate the clinical sign-off with which it is provided. Section 2 may be amended only by the person(s) authorising the PGD, in accordance with Human Medicines Regulations 2012 (HMR2012)[1] Schedule 16 Part 2, on behalf of NHS England and NHS Improvement. Section 7 is to be completed by registered practitioners providing the service and their authorising/line manager.

Operation of this PGD is the responsibility of NHS England and NHS Improvement and service providers. The final authorised copy of this PGD should be kept by NHS England and NHS Improvement for 8 years after the PGD expires. Provider organisations adopting authorised versions of this PGD should also retain copies for 8 years.

Individual registered practitioners must be authorised by name to work according to the current version of this PGD by signing section 7. A manager with the relevant level of authority should also provide a counter signature, unless there are contractual arrangements for self-declaration.

Providers must check that they are using the current version of the PGD. Amendments may become necessary prior to the published expiry date. Current versions of PHE developed COVID-19 vaccine PGDs can be found via:
https://www.gov.uk/government/collections/covid-19-vaccination-programme

The most current national recommendations should be followed. This may mean that a Patient Specific Direction (PSD) is required to administer the vaccine in line with updated recommendations that are outside the criteria specified in this PGD. Any concerns regarding the content of this PGD should be addressed to: immunisation@phe.gov.uk

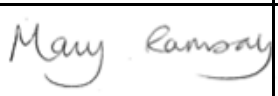
[1] This includes any relevant amendments to legislation (such as 2013 No.235, 2015 No.178, 2015 No.323 and 2020 No.1125).

Change history

Version	Change details	Date
V01.00	New COVID-19 Vaccine AstraZeneca PGD	5 January 2021
V02.00	COVID-19 Vaccine AstraZeneca PGD amended to: • identify the national protocol or patient specific provision as an alternative to use of this PGD • cover JCVI recommendations for phase 2 • include vaccination in pregnancy in accordance with the Green Book Chapter 14a, remove additional information on pregnancy and in cautions refer to Chapter 14a and the Royal College of Obstetricians and Gynaecologists (RCOG) decision aid • include JCVI advice for homelessness and detained settings • update of cautions which pertain to anaphylaxis, allergy and reactions to 1st dose • add paragraph about post vaccination observation • move participation in a clinical trial from the criteria for exclusion section to the caution section • move recommendations for individuals with bleeding disorder to the cautions section • include a paragraph in the legal category section to allow for PGD use to continue should the vaccine be provided a marketing authorisation in the future, so long as the PGD remains clinically appropriate • include JCVI advice that the second dose of COVID-19 Vaccine AstraZeneca should be given between 8 and 12 weeks after the first dose • reword advice pertaining to the extraction of full doses from a vial and not pooling excess vaccine • remove specific reference to supply via ImmForm • remove detail on management of anaphylaxis which is outside the required scope of this PGD • update key references • remove Appendix A and refer directly to the Green Book Chapter 14a	17 March 2021

1. PGD development

This PGD has been developed by the following health professionals on behalf of Public Health England:

Developed by:	Name	Signature	Date
Pharmacist (Lead Author)	Elizabeth Graham Lead Pharmacist Immunisation Services, Immunisation and Countermeasures, PHE		17/03/2021
Doctor	Mary Ramsay Consultant Epidemiologist and Head of Immunisation and Countermeasures, PHE		17/03/2021
Registered Nurse (Chair of Expert Panel)	David Green Nurse Consultant, Immunisation and Countermeasures, PHE		17/03/2021

In addition to the signatories above the working group included:

Name	Designation
Jane Horsfall	Senior Policy Manager, Primary Care Group, NHS England and NHS Improvement
Jo Jenkins	Specialist Pharmacist (Patient Group Directions), NHS Specialist Pharmacy Service
Jill Loader	Deputy Director, Primary Care Group, NHS England and NHS Improvement
Bhavana Reddy	Lead Pharmacy Adviser - Clinical Workstream, Flu and COVID-19 Vaccination Programme, NHS England and NHS Improvement
Gul Root	Principal Pharmaceutical Officer, Department of Health & Social Care and National lead pharmacy public health, Public Health England

This PGD has been peer reviewed by the PHE Immunisations PGD Expert Panel in accordance with PHE PGD Policy. It has been ratified by the PHE Medicines Governance Group and the PHE Quality and Clinical Governance Delivery Board.

Expert Panel

Name	Designation
Nicholas Aigbogun	Consultant in Communicable Disease Control, Yorkshire and Humber Health Protection Team, Public Health England
Sarah Dermont	Clinical Project Coordinator and Registered Midwife, NHS Infectious Diseases in Pregnancy Screening Programme, Public Health England
Ed Gardner	Advanced Paramedic Practitioner/Emergency Care Practitioner, Medicines Manager, Proactive Care Lead
Michelle Jones	Senior Medicines Optimisation Pharmacist, NHS Bristol North Somerset & South Gloucestershire CCG
Jacqueline Lamberty	Lead Pharmacist Medicines Management Services, Public Health England
Vanessa MacGregor	Consultant in Communicable Disease Control, Public Health England, East Midlands Health Protection Team

Alison MacKenzie	Consultant in Public Health Medicine, Screening and Immunisation Lead, Public Health England (South West) / NHS England and NHS Improvement South (South West)
Gill Marsh	Senior Screening and Immunisation Manager, Public Health England / NHS England and NHS Improvement (North West)
Lesley McFarlane	Screening and Immunisation Manager: Clinical (COVID-19 and Influenza), Public Health England / NHS England and NHS Improvement (Midlands)
Tushar Shah	Lead Pharmacy Advisor, NHS England and NHS Improvement (London Region)

2. Organisational authorisation

The PGD is not legally valid until it has had the relevant organisational authorisation from NHS England and NHS Improvement completed below.

NHS England and NHS Improvement accepts governance responsibility for this PGD. Any provider delivering the national COVID-19 vaccination programme under PGD must work strictly within the terms of this PGD, relevant NHS standard operating procedures (SOPs) and contractual arrangements with the commissioner for the delivery of the national COVID-19 vaccination programme.

NHS England and NHS Improvement authorises this PGD for use by the services or providers delivering the national COVID-19 vaccination programme.

Organisational approval (legal requirement)			
Role	**Name**	**Sign**	**Date**
Medical Director, COVID-19 Vaccination Programme, NHS England and NHS Improvement	Dr Jonathan Leach OBE		22 March 2021

Section 7 provides a practitioner authorisation sheet. Individual practitioners must be authorised by name to work to this PGD. Alternative practitioner authorisation records, specifying the PGD and version number, may be used where appropriate in accordance with local policy. This may include the use of electronic records.

Assembly, final preparation and administration of vaccines supplied and administered under this PGD must be subject to NHS governance arrangements and standard operating procedures that ensure that the safety, quality or efficacy of the product is not compromised. The assembly, final preparation and administration of the vaccines must also be in accordance with the instructions for usage that are conditions of the authorisation to supply the product. These conditions for usage are in the Information for UK Healthcare Professionals, published alongside the conditions of authorisation and available at: https://www.gov.uk/government/publications/regulatory-approval-of-covid-19-vaccine-astrazeneca

3. Characteristics of staff

Qualifications and professional registration	Practitioners must only work under this PGD where they are competent to do so. Practitioners working to this PGD must also be one of the following registered professionals who can legally supply and administer under a PGD (see Patient Group Directions: who can administer them): • 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. Practitioners must also fulfil all the Additional requirements.
Additional requirements	Additionally, practitioners: • must be authorised by name as an approved practitioner under the current terms of this PGD before working to it • must have undertaken appropriate training for working under PGDs for supply/administration of medicines • must be competent in the use of PGDs (see NICE Competency framework for health professionals using PGDs) • must be familiar with the vaccine product and alert to changes in the Summary of Product Characteristics (SPC), should it become licensed, or the Regulation 174 Information for UK Healthcare Professionals for the vaccine and familiar with the national recommendations for the use of this vaccine • must be familiar with, and alert to changes in relevant chapters of Immunisation Against Infectious Disease: the Green Book • must be familiar with, and alert to changes in the relevant NHS standard operating procedures (SOPs) and commissioning arrangements for the national COVID-19 vaccination programme • must have undertaken training appropriate to this PGD as required by local policy and national NHS standard operating procedures and in line with the Training recommendations for COVID-19 vaccinators. • must have completed the national COVID-19 vaccination e-learning programme, including the relevant vaccine specific session, and/or locally-provided COVID-19 vaccine training • must be competent to assess individuals for suitability for vaccination, identify any contraindications or precautions, obtain informed consent (or 'best interests' decision in accordance with the Mental Capacity Act 2005) and to discuss issues related to vaccination • must be competent in the correct handling and storage of vaccines, and management of the cold chain • must be competent in the handling of the vaccine product and use of aseptic technique for drawing up the correct dose • must be competent in the intramuscular injection technique

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Additional requirements (continued)	• must be competent in the recognition and management of anaphylaxis, have completed basic life support training and be able to respond appropriately to immediate adverse reactions • must have access to the PGD and relevant COVID-19 vaccination programme online resources such as the Green Book and PHE COVID-19 vaccination programme: Information for healthcare practitioners • must have been signed off as competent using the COVID-19 vaccinator competency assessment tool if new to or returning to immunisation after a prolonged period (more than 12 months) or have used the tool for self-assessment if experienced vaccinator (vaccinated within past 12 months) • should fulfil any additional requirements defined by local or national policy **The individual practitioner must be authorised by name, under the current version of this PGD before working according to it.**
Continued training requirements	Practitioners must ensure they are up to date with relevant issues and clinical skills relating to vaccination and management of anaphylaxis. Practitioners should be constantly alert to any subsequent recommendations from Public Health England and/or NHS England and NHS Improvement and other sources of medicines information.

4. Clinical condition or situation to which this PGD applies

<table>
<tr><td>Clinical condition or situation to which this PGD applies</td><td>COVID-19 Vaccine AstraZeneca is indicated for the active immunisation of individuals for the prevention of coronavirus disease (COVID-19) caused by the SARS-CoV-2 virus, in accordance with the national COVID-19 vaccination programme (see COVID-19 vaccination programme page) and recommendations given in Chapter 14a of the Immunisation Against Infectious Disease: the ‘Green Book’, and subsequent correspondence/publications from PHE and/or NHS England and NHS Improvement.</td></tr>
<tr><td>Criteria for inclusion

Continued over page</td><td>COVID-19 Vaccine AstraZeneca should be offered to individuals, aged 18 years and over, in accordance with Joint Committee on Vaccination and Immunisation (JCVI) guidance in the following order of priority, starting with those to be vaccinated first:
<table>
<tr><th>Priority</th><th>Risk group</th></tr>
<tr><td>1</td><td>Residents in a care home for older adults and their carers</td></tr>
<tr><td>2</td><td>All those 80 years of age and over
Frontline health and social care workers (see Chapter 14a)</td></tr>
<tr><td>3</td><td>All those 75 years of age and over</td></tr>
<tr><td>4</td><td>All those 70 years of age and over
Clinically extremely vulnerable[2] individuals (see Definition of clinically extremely vulnerable groups)</td></tr>
<tr><td>5</td><td>All those 65 years of age and over</td></tr>
<tr><td>6</td><td>Adults aged 16 years[3] to 65 in an at-risk group (see the table ‘Clinical risk groups 16 years of age and over who should receive COVID-19 immunisation’ in Chapter 14a)[4]</td></tr>
<tr><td>7</td><td>All those 60 years of age and over</td></tr>
<tr><td>8</td><td>All those 55 years of age and over</td></tr>
<tr><td>9</td><td>All those 50 years of age and over</td></tr>
</table>
Vaccination in pregnancy should be offered, in accordance with Chapter 14a, following a discussion of the risks and benefits of vaccination with the woman, who should be told about the absence of safety data for the vaccine in pregnancy (see Cautions).

Phase 2 of the COVID 19 vaccination programme should be offered in accordance with national recommendations and JCVI guidance on the ‘Priority groups for phase 2 of the coronavirus (COVID-19) vaccination programme’ in the following age-based order of priority, starting with the oldest adults first and proceeding in the following order:
• all those aged 40 to 49 years
• all those aged 30 to 39 years
• all those aged 18 to 29 years</td></tr>
</table>

[2] Individuals identified as clinically extremely vulnerable should have this status flagged in their GP record.
[3] COVID-19 Vaccine AstraZeneca is only authorised for use in those 18 years of age and over (see Criteria for exclusion). COVID-19 mRNA vaccine BNT162b2 (Pfizer/BioNTech) may be a suitable alternative for those 16-17 years of age. If COVID-19 mRNA vaccine BNT162b2 (Pfizer/BioNTech) is not available a PSD will be required to provide COVID-19 Vaccine AstraZeneca to individuals under 18 years of age.
[4] This also includes adult carers.

Criteria for inclusion (continued)	Implementation of the COVID-19 vaccination programme should aim to achieve high vaccine uptake whilst prioritising those most at risk. The priority order should be followed if it is reasonably practicable to do so. Implementation should also involve flexibility in vaccine deployment at a local level. Operational considerations, such as minimising wastage, may require a flexible approach to prioritisation, such as advised for detained settings[5], where decisions are taken in consultation with national or local public health experts. JCVI advises that local teams exercise operational judgment and consider a universal offer to people experiencing homelessness and rough sleeping, alongside delivery of the programme to priority group 6, where appropriate.[5]
Criteria for exclusion[6]	Individuals for whom valid consent, or a 'best-interests' decision in accordance with the Mental Capacity Act 2005, has not been obtained. The Regulation 174 Information for UK recipients for COVID-19 vaccine AstraZeneca should be available to inform consent. Individuals who: • are less than 18 years of age • have had a previous systemic allergic reaction (including immediate onset anaphylaxis) to a previous dose of COVID-19 Vaccine AstraZeneca or to any component of the vaccine or residues from the manufacturing process[7] • are suffering from acute severe febrile illness (the presence of a minor infection is not a contraindication for vaccination) • have received a full dose of COVID-19 vaccine in the preceding 28 days • have completed a course of COVID-19 vaccination
Cautions, including any relevant action to be taken Continued over page	The COVID-19 Vaccine AstraZeneca 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. Special precautions as described in Chapter 14a, 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 Such individuals should not be vaccinated with COVID-19 mRNA vaccine, except on the expert advice of an allergy specialist and under a PSD. COVID-19 Vaccine AstraZeneca can be used as an alternative (unless otherwise contraindicated), particularly if they previously tolerated an injected influenza vaccine. In these circumstances, COVID-

[5] https://www.gov.uk/government/publications/letter-from-the-health-and-social-care-secretary-on-covid-19-vaccination-phase-1-advice

[6] Exclusion under this PGD does not necessarily mean the medication is contraindicated, but it would be outside its remit and another form of authorisation will be required

[7] Contains polysorbate 80. Refer to Regulation 174 Information for UK Healthcare Professionals for a full list of excipients.

Cautions, including any relevant action to be taken (continued)	19 Vaccine AstraZeneca should be administered in a setting with full resuscitation facilities (such as a hospital), and a 30 minute observation period is recommended. Where individuals experienced a possible allergic reaction to a first dose of COVID-19 vaccine follow the guidance in Chapter 14a of the Green Book in relation to the administration of subsequent doses. 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. 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. There is no routine requirement for 15 minutes observation following COVID-19 Vaccine AstraZeneca. However, as fainting can occur following vaccination, all those vaccinated with any of the COVID-19 vaccines should either be driven by someone else or should not drive for 15 minutes after vaccination. Vaccination in pregnancy should be offered in accordance with recommendations in Chapter 14a, following a discussion of the risks and benefits of vaccination with the woman. The Royal College of Obstetricians and Gynaecologists has produced a decision aid to support women to make a personal informed choice, in discussion with a healthcare professional, about whether to accept a COVID-19 vaccination in pregnancy (see https://www.rcog.org.uk/covid-vaccine). Individuals with a bleeding disorder may develop a haematoma at the injection site. Individuals with bleeding disorders may be vaccinated intramuscularly if, in the opinion of a doctor familiar with the individual's bleeding risk, vaccines or similar small volume intramuscular injections can be administered with reasonable safety by this route. If the individual receives medication/treatment to reduce bleeding, for example treatment for haemophilia, intramuscular vaccination can be scheduled shortly after such medication/treatment is administered. Individuals on stable anticoagulation therapy, including individuals on warfarin who are up to date with their scheduled INR testing and whose latest INR was below the upper threshold of their therapeutic range, can receive intramuscular vaccination. A fine needle (equal to 23 gauge or finer calibre such as 25 gauge) should be used for the vaccination, followed by firm pressure applied to the site (without rubbing) for at least 2 minutes. If in any doubt, consult with the clinician responsible for prescribing or monitoring the individual's anticoagulant therapy. The individual/carer should be informed about the risk of haematoma from the injection. Individuals who are participating in a clinical trial of COVID-19 vaccines who present for vaccination should be referred back to the trial investigators. Eligible individuals who are enrolled in vaccine trials should then be provided with written advice on whether and when they can be safely vaccinated in the routine programme.
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Cautions, including any relevant action to be taken (continued)	**Past history of COVID-19 infection** There is no evidence of any safety concerns from vaccinating individuals with a past history of COVID-19 infection, or with detectable COVID-19 antibody. Vaccination of individuals who may be infected but asymptomatic or incubating COVID-19 infection is unlikely to have a detrimental effect on the illness. Vaccination should be deferred in those with confirmed infection to avoid onward transmission and confusing the differential diagnosis. As clinical deterioration can occur up to two weeks after infection, ideally vaccination should be deferred until clinical recovery to around four weeks after onset of symptoms or four weeks from the first confirmed positive specimen in those who are asymptomatic. Having prolonged COVID-19 symptoms is not a contraindication to receiving COVID-19 vaccine but if the individual 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. **Vaccine Surveillance** The UK regulator will maintain real-time surveillance post deployment of COVID-19 vaccines in the UK. In response to any safety signals, MHRA may provide temporary advice or make substantive amendments to the authorised conditions of the vaccine product's supply in the UK. Administration under this PGD must be in accordance with the most up-to-date advice or amendments (see Green Book Chapter 14a and Regulatory approval of COVID-19 Vaccine AstraZeneca).
Action to be taken if the patient is excluded	The risk to the individual of not being immunised must be considered. The indications for risk groups are not exhaustive, and the healthcare practitioner should consider the risk of COVID-19 exacerbating any underlying disease that an individual may have, as well as the risk of serious illness from COVID-19 itself. Where appropriate, such individuals should be referred for assessment of clinical risk. Where risk is identified as equivalent to those currently eligible for immunisation, vaccination may be provided by an appropriate prescriber or on a patient specific basis, under a PSD. Children at very high risk of exposure and serious outcomes such as older children with severe neuro-disabilities that require residential care should be referred to specialists for consideration for vaccination, by an appropriate prescriber or under PSD, following assessment of the individual's risk. For individuals who have had a previous systemic allergic reaction (including immediate onset anaphylaxis) to a previous dose of COVID-19 Vaccine AstraZeneca or any component of the vaccine, advice should be sought from an allergy specialist. In case of postponement due to acute illness, advise when the individual can be vaccinated and, if possible, ensure another appointment is arranged. Document the reason for exclusion and any action taken.
Action to be taken if the patient or carer declines treatment Continued over page	Informed consent, from the individual or a person legally able to act on the person's behalf, must be obtained for each administration and recorded appropriately. Where a person lacks the capacity, in

Action to be taken if the patient or carer declines treatment (continued)	accordance with the Mental Capacity Act 2005, a decision to vaccinate may be made in the individual's best interests. Advise the individual/carer about the protective effects of the vaccine, the risks of infection and potential complications if not immunised. Document advice given and the decision reached.
Arrangements for referral for medical advice	As per local policy.

5. Description of treatment

Name, strength & formulation of drug	COVID-19 Vaccine AstraZeneca, solution for injection in multidose container COVID-19 Vaccine (ChAdOx1-S [recombinant]): • 5ml of solution in a 10-dose vial • 4ml of solution in an 8-dose vial One dose (0.5 ml) contains COVID-19 Vaccine (ChAdOx1-S* recombinant) 5 x 10^{10} viral particles. *Recombinant, replication-deficient chimpanzee adenovirus vector encoding the SARS-CoV-2 Spike (S) glycoprotein. Produced in genetically modified human embryonic kidney (HEK) 293 cells.
Legal category	COVID-19 Vaccine AstraZeneca did not have a UK marketing authorisation at the time of writing this PGD. COVID-19 Vaccine AstraZeneca has been provided temporary authorisation by the Medicines & Healthcare products Regulatory Agency (MHRA) for supply in the UK under regulation 174 and 174A of HMR 2012, see https://www.gov.uk/government/publications/regulatory-approval-of-covid-19-vaccine-astrazeneca In accordance with the UK Statutory Instrument 2020 No. 1125, The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020, a PGD may now be used to supply and/or administer a medicine authorised under regulation 174. Should COVID-19 Vaccine AstraZeneca be issued a marketing authorisation in the future, this PGD may be used to administer licensed product so long as it remains clinically appropriate to do so and in accordance with the manufacturer's product information. COVID-19 Vaccine AstraZeneca is categorised as a prescription only medicine (POM).
Black triangle▼	As a new vaccine product, MHRA has a specific interest in the reporting of adverse drug reactions for this product.
Off-label use	COVID-19 Vaccine AstraZeneca is supplied in the UK in accordance with regulation 174 and did not have a UK marketing authorisation at the time of writing this PGD. As part of the consent process, healthcare professionals must inform the individual/carer that this vaccine has been authorised for temporary supply in the UK by the regulator, MHRA, and that it is being offered in accordance with national guidance. The Regulation 174 Information for UK recipients for COVID-19 Vaccine AstraZeneca should be available to inform consent.
Route / method of administration Continued over page	COVID-19 Vaccine AstraZeneca is for administration by intramuscular injection only, preferably into deltoid region of the upper arm. Vaccine should be prepared in accordance with the manufacturer's recommendations (see Regulation 174 Information for UK Healthcare Professionals) and NHS standard operating procedures for the service. Inspect visually prior to administration and ensure appearance is consistent with the description in the Regulation 174 Information for UK Healthcare Professionals, that is a colourless to slightly brown,

Route / method of administration (continued)	clear to slightly opaque solution. Discard the vaccine if particulate matter or differences to the described appearance are observed. Do not shake the vial. Check product name, batch number and expiry date prior to administration. Aseptic technique should be used for withdrawing each vaccine dose of 0.5ml into a syringe for injection to be administered intramuscularly. Use a separate sterile needle and syringe for each individual. COVID-19 Vaccine AstraZeneca vials are multidose and, if low dead volume syringes and/or needles are used, one vial contains at least the number of doses stated. Care should be taken to ensure a full 0.5ml dose is administered. Where a full 0.5ml dose cannot be extracted, the remaining volume should be discarded. Do not pool excess vaccine from multiple vials. The vaccine does not contain any preservative. After first dose withdrawal, use the vial as soon as practicably possible and within 6 hours (stored at 2°C to 25°C). Discard any unused vaccine.
Dose and frequency of administration	A two-dose course should be administered consisting of 0.5ml followed by a second dose of 0.5ml administered in accordance with official national guidance and at a minimum of 4 weeks after the first dose. Published data indicate that the booster response to the second dose of COVID-19 Vaccine AstraZeneca improves as the interval between doses increases. Given these data, JCVI now advise that the second dose of COVID-19 Vaccine AstraZeneca should be given between 8 and 12 weeks after the first dose.[5] If an interval longer than the recommended interval is left between doses, the second dose should still be given (using the same vaccine as was given for the first dose if possible, see Additional Information). The course does not need to be restarted.
Duration of treatment	See Dose and frequency of administration above. Booster doses of COVID-19 vaccines are not yet recommended because the need for, and timing of, boosters has not yet been determined.
Quantity to be supplied / administered	Administer 0.5ml A two-dose course should be completed.
Supplies	Providers should order/receive COVID-19 vaccines via the national appointed supply route for the provider. NHS standard operating procedures should be followed for appropriate ordering, storage, handling, preparation, administration and waste minimisation of COVID-19 Vaccine AstraZeneca, which ensure use is in accordance with Regulation 174 Information for UK Healthcare Professionals and Conditions of Authorisation for COVID-19 Vaccine AstraZeneca.
Storage Continued over page	COVID-19 Vaccine AstraZeneca unopened multidose vial: • Store in a refrigerator (2 to 8°C). • Do not freeze. • Keep vials in outer carton to protect from light. • Shelf life is 6 months.

Storage (continued)	After the first dose is withdrawn, administer remaining doses from the vial as soon as practicably possible and within 6 hours of first use of the vial. The vaccine may be stored between 2°C and 25°C during this in-use period. Once a dose is withdrawn from the vial it should be administered immediately. The vaccine does not contain preservative. The above details relate to storage requirements and available stability data at the time of product authorisation. This may be subject to amendment as more data becomes available. Refer to NHS standard operating procedures for the service and the most up to date manufacturer's recommendations in the Conditions of Authorisation for COVID-19 Vaccine AstraZeneca and Regulation 174 Information for UK Healthcare Professionals.
Disposal	Follow local clinical waste policy and NHS standard operating procedures and ensure safe and secure waste disposal. Equipment used for vaccination, including used vials, ampoules, or discharged vaccines in a syringe or applicator, should be disposed of safely and securely according to local authority regulations and guidance in the technical memorandum 07-01: Safe management of healthcare waste (Department of Health, 2013). COVID-19 Vaccine AstraZeneca contains genetically modified organisms (GMOs). Sharps waste and empty vials should be placed into yellow lidded waste bins and sent for incineration; there is no need for specific designation as GMO waste. An appropriate virucidal disinfectant should be available for managing spills in all settings where vaccination is administered.
Drug interactions	Immunological response may be diminished in those receiving immunosuppressive treatment, but it is important to still immunise this group. Although no data for co-administration of COVID-19 vaccine with other vaccines exists, in the absence of such data, first principles would suggest that interference between inactivated vaccines with different antigenic content is likely to be limited. Based on experience with other vaccines, any potential interference is most likely to result in a slightly attenuated immune response to one of the vaccines. There is no evidence of any safety concerns, although it may make the attribution of any adverse events more difficult. It should not be routine to offer appointments to give this vaccine at the same time as other vaccines. Scheduling should ideally be separated by an interval of at least 7 days to avoid incorrect attribution of potential adverse events. Where individuals in an eligible cohort present having received another inactivated or live vaccine, COVID-19 vaccination should still be considered. The same applies for other live and inactivated vaccines where COVID-19 vaccination has been received first or where an individual presents requiring two vaccines. In most cases, vaccination should proceed, and may be provided under the PGD, to avoid any further delay in protection and to avoid the risk of the individual not returning for a later appointment. In such circumstances, individuals should be informed about the likely timing of potential adverse events relating to each vaccine.

Identification & management of adverse reactions	The most frequently reported adverse reactions were injection site tenderness, injection site pain, headache, fatigue, myalgia, malaise, pyrexia, chills, arthralgia and nausea. The majority of adverse reactions were mild to moderate in severity and usually resolved within a few days of vaccination. By day 7 the incidence of subjects with at least one local or systemic reaction was 4% and 13% respectively. When compared with the first dose, adverse reactions reported after the second dose were milder and reported less frequently. Adverse reactions were generally milder and reported less frequently in older adults (≥65 years old). Individuals should be provided with the advice within the leaflet What to expect after your COVID-19 vaccination, which covers the reporting of adverse reactions and their management, such as with analgesic and/or antipyretic medication. Vaccinated individuals should be advised that the COVID-19 vaccine may cause a mild fever, which usually resolves within 48 hours. This is a common, expected reaction and isolation is not required unless COVID-19 is suspected. A detailed list of adverse reactions is available in the Regulation 174 Information for UK Healthcare Professionals.
Reporting procedure of adverse reactions	Healthcare professionals and individuals/carers should report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Coronavirus Yellow Card reporting scheme on: https://coronavirus-yellowcard.mhra.gov.uk/. Or search for MHRA Yellow Card in the Google Play or Apple App Store. As a new vaccine product, MHRA has a specific interest in the reporting of all adverse drug reactions for this product, see https://yellowcard.mhra.gov.uk/the-yellow-card-scheme/ Any adverse reaction to a vaccine should also be documented in the individual's record and the individual's GP should be informed. The Green Book Chapter 14a and Chapter 8 provide further details regarding the clinical features of reactions to be reported as 'anaphylaxis'. Allergic reactions that do not include the clinical features of anaphylaxis should be reported as 'allergic reaction'.
Written information to be given to patient or carer	Ensure the individual has been provided appropriate written information such as the: • Regulation 174 Information for UK recipients for COVID-19 Vaccine AstraZeneca • COVID-19 Vaccination Record Card • What to expect after your COVID-19 vaccination • COVID-19 vaccination: women of childbearing age, currently pregnant, or breastfeeding
Patient advice / follow up treatment Continued over page	As with all vaccines, immunisation may not result in protection in all individuals. Immunosuppressed individuals should be advised that they may not make a full immune response to the vaccine. Nationally recommended protective measures should still be followed. Inform the individual/carer of possible side effects and their management.

Patient advice / follow up treatment (continued)	The individual/carer should be advised to seek appropriate advice from a healthcare professional in the event of an adverse reaction. Advise the individual/carer that they can report side effects directly via the national reporting system run by the MHRA known as the Coronavirus Yellow Card reporting scheme on: https://coronavirus-yellowcard.mhra.gov.uk/ . Or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, they can help provide more information on the safety of medicines. When applicable, advise the individual/carer when to return for vaccination or when a subsequent vaccine dose is due.
Special considerations / additional information	Ensure there is immediate access to an anaphylaxis pack including adrenaline (epinephrine) 1 in 1,000 injection and easy access to a telephone at the time of vaccination. Minor illnesses without fever or systemic upset are not valid reasons to postpone vaccination. If an individual is acutely unwell, vaccination should be postponed until they have fully recovered. This is to avoid confusing the differential diagnosis of any acute illness (including COVID-19) by wrongly attributing any signs or symptoms to the adverse effects of the vaccine. **Breastfeeding** There is no known risk associated with giving non-live vaccines whilst breastfeeding. JCVI advises that breastfeeding women may be offered vaccination with the COVID-19 Vaccine AstraZeneca. Breastfeeding women may be vaccinated under this PGD. The developmental and health benefits of breastfeeding should be considered along with the mother'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. **Previous incomplete vaccination** There is no evidence on the interchangeability of the COVID-19 vaccines although studies are underway. Therefore, every effort should be made to determine which vaccine the individual received and to complete the course 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. In these circumstances, this PGD may be used and, as COVID-19 vaccines are based on the spike protein, it is likely the second dose will help to boost the response to the first dose. For this reason, until additional information becomes available, further doses would not then be required.
Records Continued over page	Record: • that valid informed consent was given or a decision to vaccinate made in the individual's best interests in accordance with the Mental Capacity Act 2005 • name of individual, address, date of birth and GP with whom the individual is registered (or record where an individual is not registered with a GP) • name of immuniser

Records (continued)	• name and brand of vaccine • date of administration • dose, form and route of administration of vaccine • quantity administered • batch number and expiry date • anatomical site of vaccination • advice given, including advice given if excluded or declines vaccination • details of any adverse drug reactions and actions taken • supplied via PGD Records should be signed and dated (or password-controlled immuniser's record on e-records). All records should be clear, legible and contemporaneous. As a variety of COVID-19 vaccines are available, it is especially important that the exact brand of vaccine, batch number and site at which each vaccine is given is accurately recorded in the individual's records. It is important that vaccinations are recorded in a timely manner on appropriate health care records for the individual. Systems should be in place to ensure this information is returned to the individual's general practice record in a timely manner to allow clinical follow up and to avoid duplicate vaccination. A record of all individuals receiving treatment under this PGD should also be kept for audit purposes.

6. Key references

Key references	COVID-19 Vaccine AstraZeneca vaccination • Immunisation Against Infectious Disease: The Green Book, Chapter 14a. Published 12 February 2021. https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book • COVID-19 vaccination programme. Updated 20 February 2021. https://www.gov.uk/government/collections/covid-19-vaccination-programme • Priority groups for phase 2 of the coronavirus (COVID-19) vaccination programme: advice from the JCVI. Published 26 February 2021. https://www.gov.uk/government/publications/priority-groups-for-phase-2-of-the-coronavirus-covid-19-vaccination-programme-advice-from-the-jcvi • Definition of clinically extremely vulnerable groups https://www.gov.uk/government/publications/guidance-on-shielding-and-protecting-extremely-vulnerable-persons-from-covid-19/guidance-on-shielding-and-protecting-extremely-vulnerable-persons-from-covid-19#cev • Training recommendations for COVID-19 vaccinators. Published 08 December 2020. https://www.gov.uk/government/publications/covid-19-vaccinator-training-recommendations/training-recommendations-for-covid-19-vaccinators • National COVID-19 vaccination e-learning programme https://www.e-lfh.org.uk/programmes/covid-19-vaccination/ • COVID-19 vaccinator competency assessment tool. Published 8 December 2020. https://www.gov.uk/government/publications/covid-19-vaccinator-competency-assessment-tool • COVID-19: vaccination programme guidance for healthcare practitioners. Published 12 February 2021. https://www.gov.uk/government/publications/covid-19-vaccination-programme-guidance-for-healthcare-practitioners • Regulation 174 Information for UK Healthcare Professionals and Regulation 174 Information for UK recipients for COVID-19 Vaccine AstraZeneca and Conditions of Authorisation for COVID-19 Vaccine AstraZeneca. Published 23 February 2021. https://www.gov.uk/government/publications/regulatory-approval-of-covid-19-vaccine-astrazeneca **General** • Health Technical Memorandum 07-01: Safe Management of Healthcare Waste. Department of Health 20 March 2013 https://www.gov.uk/government/publications/guidance-on-the-safe-management-of-healthcare-waste • NICE Medicines Practice Guideline 2 (MPG2): Patient Group Directions. Published March 2017. https://www.nice.org.uk/guidance/mpg2 • NICE MPG2 Patient group directions: competency framework for health professionals using patient group directions. Updated March 2017.

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Key references (continued)	https://www.nice.org.uk/guidance/mpg2/resources • Patient Group Directions: who can use them. Medicines and Healthcare products Regulatory Agency. 4 December 2017. https://www.gov.uk/government/publications/patient-group-directions-pgds/patient-group-directions-who-can-use-them • PHE Immunisation Collection https://www.gov.uk/government/collections/immunisation • UK Statutory Instrument 2012 No. 1916, The Human Medicines Regulations 2012 https://www.legislation.gov.uk/uksi/2012/1916/contents • UK Statutory Instrument 2020 No. 1125, The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 https://www.legislation.gov.uk/uksi/2020/1125/contents/made

7. Practitioner authorisation sheet

COVID-19 Vaccine AstraZeneca PGD v02.00 Valid from: 22/03/2021 Expiry: 31/03/2022

By signing this Patient Group Direction (PGD) you are indicating that you agree to its contents and that you will work within it.

PGDs do not remove inherent professional obligations or accountability.

It is the responsibility of each professional to practise only within the bounds of their own competence and professional code of conduct.

I confirm that I have read and understood the content of this PGD and that I am willing and competent to work to it within my professional code of conduct.			
Name	Designation	Signature	Date

Authorising manager

I confirm that the registered healthcare professionals 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 healthcare professionals who have signed the PGD to work under it.			
Name	Designation	Signature	Date

Note to authorising manager

Score through unused rows in the list of practitioners to prevent practitioner additions post managerial authorisation.

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