UK Health Security Agency

NHS

Publications approval reference: C1642

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

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

This PGD is for the administration of Vaxzevria, COVID-19 Vaccine (ChAdOx1-S [recombinant]), 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:	Vaxzevria PGD
Version no:	V01.00
Valid from:	5 May 2022
Expiry date:	1 April 2023

The UK Health Security Agency (UKHSA) has developed this PGD for authorisation by NHS England and NHS Improvement (NHSEI) to facilitate the delivery of the national COVID-19 vaccination programme.

NHSEI 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 NHSEI 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 UKHSA developed COVID-19 vaccine PGDs can be found via: 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

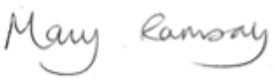
[1] This includes any relevant amendments to legislation (such as 2013 No.235, 2015 No.178, 2015 No.323 and 2020 No.1125).

Change History

Version	Change details	Date
V01.00	New PGD for Vaxzevria	29/04/2022

1. PGD development

This PGD has been developed by the following health professionals on behalf of the UKHSA:

Developed by:	Name	Signature	Date
Pharmacist (Lead Author)	Beth Graham Lead Pharmacist Immunisation Services, Immunisation and Vaccine Preventable Diseases Division, UKHSA		29/04/2022
Doctor	Mary Ramsay Consultant Epidemiologist, Immunisation and Vaccine Preventable Diseases Division, UKHSA		29/04/2022
Registered Nurse (Chair of Expert Panel)	David Green Nurse Consultant for Immunisation, Immunisation and Vaccine Preventable Diseases Division UKHSA		29/04/2022

In addition to the signatories above the working group included:

Name	Designation
Suki Hunjunt	Lead Pharmacist Immunisation Services, Immunisation and Vaccine Preventable Diseases Division, UKHSA
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, NHSEI
Jane Freeguard	Director of Pharmacy – COVID-19 Vaccination Programme, NHSEI
Gul Root	Principal Pharmaceutical Officer, Department of Health and Social Care and National lead pharmacy public health, Office for Health Improvement and Disparities
Naveen Dosanjh	Senior Clinical Advisor, Clinical Workstream, COVID-19 Vaccination Programme, NHSEI

This PGD has been peer reviewed by the UKHSA Immunisations PGD Expert Panel (see below) in accordance with UKHSA PGD Policy. It has been approved by the UKHSA Medicines Governance Group and ratified by the UKHSA Clinical Quality and Oversight Board.

Expert Panel

Name	Designation
Nicholas Aigbogun	Consultant in Communicable Disease Control, Yorkshire and Humber Health Protection Team, UKHSA
Sarah Dermont	Clinical Project Coordinator and Registered Midwife, NHS Infectious Diseases in Pregnancy Screening Programme, NHSEI
Ed Gardner	Advanced Paramedic Practitioner/Emergency Care Practitioner, Medicines Manager, Proactive Care Lead
Michael Gregory	Medical Director for Commissioning, NHSEI (North West)
Michelle Jones	Principal Medicines Optimisation Pharmacist, NHS Bristol North Somerset and South Gloucestershire CCG
Jacqueline Lamberty	Lead Pharmacist Medicines Governance, UKHSA
Vanessa MacGregor	Consultant in Communicable Disease Control, East Midlands Health Protection Team, UKHSA
Alison Mackenzie	Consultant in Public Health Medicine, Screening and Immunisation Lead, NHSEI (South West)
Gill Marsh	Principal Screening and Immunisation Manager, NHSEI (North West)
Lesley McFarlane	Screening and Immunisation Manager: Clinical (COVID-19 and Influenza), NHSEI (Midlands)
Tushar Shah	Lead Pharmacy Advisor, NHSEI (London Region)

2. Organisational authorisation

The PGD is not legally valid until it has had the relevant organisational authorisation from NHSEI completed below.

NHSEI 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.

NHSEI 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		5 May 2022

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 should also be in accordance with the manufacturer's instructions in the product's UK Summary of Product Characteristics (SPC) or in accordance with official national recommendations.

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 of 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 SPC, 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 SOPs 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. For further information on consent see Chapter 2 of the Green Book. • 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 • 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

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Additional requirements (continued)	• must have access to the PGD and relevant COVID-19 vaccination programme online resources such as the Green Book and 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 the UKHSA and/or NHSEI and other sources of medicines information.

4. Clinical condition or situation to which this PGD applies

Clinical condition or situation to which this PGD applies	Vaxzevria, COVID-19 Vaccine (ChAdOx1-S [recombinant]), hereafter referred to a Vaxzevria, is indicated for the active immunisation of individuals for the prevention of coronavirus disease (COVID-19) caused by the SARS-CoV-2 virus. This PGD is for administration of Vaxzevria 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 (hereafter referred to as Chapter 14a), and subsequent correspondence or publications from the UKHSA or NHSEI.
Criteria for inclusion	Vaxzevria should be offered to all individuals aged 18 years and over in accordance with the national COVID-19 vaccination programme and the recommendations in Chapter 14a. Individuals are eligible for different dose schedules based on their age and recognised risk group (see the Dose and frequency of administration section).
Criteria for exclusion[2]	Individuals for whom valid consent, or a 'best-interests' decision in accordance with the Mental Capacity Act 2005, has not been obtained (for further information on consent see Chapter 2 of the Green Book). The Patient Information Leaflet for Vaxzevria 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 Vaxzevria (or COVID-19 Vaccine AstraZeneca) or to any component of the vaccine or residues from the manufacturing process[3] • have experienced thrombosis with thrombocytopenia syndrome (TTS) following vaccination with an AstraZeneca COVID-19 vaccine • have previously experienced episodes of capillary leak syndrome (CLS) • are suffering from acute severe febrile illness or acute infection (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
Cautions, including any relevant action to be taken Continued over page	Facilities for management of anaphylaxis should be available at all vaccination sites (see Chapter 8 of the Green Book) and advice issued by the Resuscitation Council. JCVI issues advice on vaccine preference specific to the current UK context and available data. Vaxzevria is an AstraZeneca COVID-19 vaccine. An alternative to an AstraZeneca COVID-19 vaccine may be advised as preferable for some groups eligible for COVID-19 vaccination. Recommendations current at the time of vaccination should be followed (see Chapter 14a). A very rare condition involving serious thromboembolic events accompanied by thrombocytopenia (TTS), has been reported after COVID-19 AstraZeneca vaccination (see Chapter 14a). Although it is very rare, a higher incidence is seen in younger individuals.

[2] 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

[3] Contains polysorbate 80. Refer to the product's SPC for a full list of excipients.

Cautions, including any relevant action to be taken (continued)	JCVI currently advises a preference for a vaccine other than Vaxzevria 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. This advice may change if there is a change in the epidemiology or an interruption in the supply of the alternative vaccines. Within this group of healthy adults aged 18 to 39 years, those who are older (over 30 years of age), male, from certain minority ethnic backgrounds, in certain occupations at high risk of exposure, and those who are obese, remain at high risk of COVID-19. In the absence of a suitable alternative, these individuals should still be offered the AstraZeneca vaccine (Vaxzevria) and may choose to receive the vaccine, provided they have been informed and understand the relative risks and benefits. They should be given the latest version of the COVID-19 vaccination and blood clotting leaflet. Those who have already received a dose of an AstraZeneca COVID-19 vaccine should complete the primary course with the same vaccine. Where the same vaccine is not available or suitable, or if the first product received is unknown, one dose of the locally available product should be given to complete the primary course. The SPC for Vaxzevria currently states that, as a precautionary measure, administration of Vaxzevria in individuals with a history of heparin-induced thrombocytopenia and thrombosis (HITT or HIT type 2) or cerebral venous sinus thrombosis should only be considered when the benefit outweighs any potential risks. Individuals 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 an AstraZeneca COVID-19 vaccine. 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 aged 40 years and over 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 an AstraZeneca COVID-19 vaccine but without concomitant thrombocytopenia. Individuals who have received the first dose of an AstraZeneca COVID-19 vaccine without developing this rare condition, TTS, are advised to receive the second dose of the same vaccine at the currently recommended interval. To date, there is no signal of an increased risk of this condition after the second dose and the rate of other reactions is lower after the second dose than after the first dose of this vaccine. Using an alternative product for the second dose is more likely to lead to common side effects. Previous immune thrombocytopenia (ITP) is not a contra-indication for vaccination but platelet monitoring is advised for individuals with a history of ITP who receive an AstraZeneca COVID-19 vaccine. Cases of thrombocytopenia, including ITP, have been reported, typically within the first four weeks after vaccination. Individuals who experience ITP in the four weeks after the first dose of an AstraZeneca COVID-19 vaccine should be assessed by a haematologist and the risk benefit of further vaccination and with which product should be considered on an individual basis. If receiving further vaccination, the platelet count should be monitored.

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Cautions, including any relevant action to be taken (continued)	Guidance produced by the UK Immune Thrombocytopenia (ITP) Forum Working Party advises discussing the potential for a fall in platelet count in individuals with a history of ITP receiving any COVID-19 vaccine and recommends a platelet count check 2-5 days after the vaccine (British Society for Haematology-COVID-19). There is no routine requirement for observation following Vaxzevria. 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 • informed about the signs and symptoms of anaphylaxis and 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. Individuals with a personal history of allergy should be managed in line with Chapter 14a Table 5. Special precautions are advised for individuals with a personal history of allergy including a: • 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 polyethylene glycol (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 undiagnosed PEG allergy often have a history of immediate onset-unexplained anaphylaxis or anaphylaxis to multiple classes of drugs or an unexplained anaphylaxis. Vaxzevria does not contain PEG but does contain a related compound called polysorbate 80. Rarely, people with PEG allergy may also be allergic to polysorbate 80. Individuals with PEG allergy who have tolerated injections that contain polysorbate 80 (including the adjuvanted influenza vaccine, Fluad® and the GlaxoSmithKline vaccine Fluarix®) are likely to tolerate Vaxzevria. The vaccine 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 dose of COVID-19 vaccine follow the guidance in Chapter 14a in relation to the administration of subsequent doses. Individuals with non-allergic reactions (vasovagal episodes, non-urticarial skin reaction or non-specific symptoms) to a COVID-19 vaccine can receive subsequent doses of vaccine in any vaccination setting. Observation for 15 minutes is recommended for these individuals. No specific management is required for individuals with a family history of allergies. Syncope (fainting) can occur following, or even before, any vaccination 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 Vaxzevria. 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

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Cautions, including any relevant action to be taken (continued)	vaccination.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 two 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. Very rare reports have been received of Guillain-Barre Syndrome (GBS) following COVID-19 vaccination (further information is available in Chapter 14a). Healthcare professionals should be alert to the signs and symptoms of GBS to ensure correct diagnosis and to rule out other causes, in order to initiate adequate supportive care and treatment. Individuals who have a history of GBS should be vaccinated as recommended for their age and underlying risk status. In those who are diagnosed with GBS after the first dose of vaccine, the balance of risk benefit is in favour of completing a full COVID-19 vaccination schedule. On a precautionary basis, however, where GBS occurs within six weeks of an Astra Zeneca COVID-19 vaccine, for any future doses Comirnaty® and Spikevax® vaccines are preferred. **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 or asymptomatic or incubating COVID-19 infection is unlikely to have a detrimental effect on the illness. For adults, vaccination after COVID-19 infection, should ideally be deferred until clinical recovery to around four weeks after onset of symptoms or four weeks from the first confirmed positive specimen. This is to avoid confusing the differential diagnosis as clinical deterioration can occur up to two weeks after infection. This recommended interval after COVID-19 infection may be reduced to ensure operational flexibility when rapid protection is required, for example in periods of high incidence or circulation of a new variant in a vulnerable population. When rapid protection is required, any reduction in the recommended interval after COVID-19 infection will be advised by the JCVI or UKHSA and published in NHSEI operational guidance. 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 and epidemiological features to suggest the episode was COVID-19 infection. 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.

Action to be taken if the patient is excluded	This PGD is for individuals aged 18 years and over in accordance with recommendations in Chapter 14a for the use of an AstraZeneca COVID-19 vaccine. For individuals under 18 years of age, Comirnaty® vaccine is recommended (see the appropriate Comirnaty® PGD). 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. Individuals who have had a previous systemic allergic reaction (including immediate onset anaphylaxis) to a previous dose of Vaxzevria (or COVID-19 Vaccine AstraZeneca) may be given an alternate mRNA COVID-19 vaccine in any setting, with observation for 30 minutes, for subsequent doses of COVID-19 vaccine indicated. Individuals who experience a clotting episode with concomitant thrombocytopenia following the first dose of an AstraZeneca COVID-19 vaccine should be properly assessed. If they are considered to have TTS, further vaccination should be deferred until their clotting has completely stabilised. Current evidence would support a decision to complete the primary course or boost individuals with a history of TTS with an mRNA vaccine, provided at least 12 weeks has elapsed from the implicated dose. Individuals who have previously experienced episodes of CLS may be offered vaccination with an appropriate alternative COVID-19 vaccine. 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	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 accordance with the Mental Capacity Act 2005, a decision to vaccinate may be made in the individual's best interests. For further information on consent see Chapter 2 of the Green Book. 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	As per local policy.

5. Description of treatment

Name, strength and formulation of drug	Vaxzevria, suspension for injection COVID-19 Vaccine (ChAdOx1-S [recombinant]) in multidose vial: • 5ml of suspension in a 10-dose vial • 4ml of suspension in an 8-dose vial One dose (0.5 ml) contains COVID-19 Vaccine (ChAdOx1-S* recombinant) not less than 2.5×10^8 infectious units (Inf.U). *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	Prescription only medicine (POM).
Black triangle▼	Yes. As a new vaccine product, MHRA has a specific interest in the reporting of adverse drug reactions for this product.
Off-label use	Where a vaccine is recommended off-label consider, as part of the consent process, informing the individual/carer that the vaccine is being offered in accordance with national guidance but that this is outside the product licence. **Primary immunisation** The Vaxzevria SPC describes a 2-dose primary course. A third primary dose may be administered under this PGD to individuals who had severe immunosuppression in proximity to their first or second COVID-19 doses in the primary schedule in accordance with the recommendations from the JCVI and Chapter 14a. **Booster immunisation** The Vaxzevria SPC recommends a booster dose may be administered 6 months after the second dose. Booster vaccination may be offered under this PGD at a minimum interval of 3 months from the previous dose, completion of the primary course or previous booster dose, in accordance with the recommendations from the JCVI and Chapter 14a. **Storage** Vaccine should be stored according to the conditions detailed in the Storage section below. However, in the event of an inadvertent or unavoidable deviation of these conditions refer to Vaccine Incident Guidance. Where vaccine is assessed in accordance with these guidelines as appropriate for continued use this would constitute off-label administration under this PGD. In the event that available data supports extension to the vaccine shelf life, any resulting off-label use of expiry extended vaccine under this PGD should be supported by NHS operational guidance or standard operating procedure.
Route / method of administration Continued over page	Vaxzevria 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 SPC) and NHS standard operating procedures for the service. Inspect visually prior to administration and ensure appearance is consistent with the description in the SPC, that is a colourless to slightly brown, clear to slightly opaque suspension. Discard the vaccine if particulate matter or differences to the described appearance are observed.

Route / method of administration (continued)	Do not shake the vial. Do not dilute the suspension. The vaccine should not be mixed in the same syringe with any other vaccines or medicinal products. 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. Vaxzevria 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 practically possible and within 6 hours (stored at 2°C to 25°C). Discard any unused vaccine.
Dose and frequency of administration Continued over page	**Interval post SARS-CoV-2 infection** For adults, vaccination after COVID-19 infection 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. The recommended interval after COVID-19 infection 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. When rapid protection is required, any reduction in the recommended interval after COVID-19 infection will be advised by the JCVI or UKHSA and published in NHSEI operational guidance. 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 and epidemiological features to suggest the episode was COVID-19 infection. **Primary vaccination** A two-dose course should be administered to eligible individuals, with the exception of individuals who were severely immunosuppressed when they received their first or second dose of COVID- 19 vaccination for whom JCVI have provided recommendations for a third primary dose. The two-dose course consists of 0.5ml followed by a second dose of 0.5ml after an interval of at least 28 days. However, the programme schedule, including both the number of doses and the intervals between them, should be administered in accordance with official national guidance which, at the time of writing, recommends a minimum interval of eight weeks between primary doses for adults, as set out in Chapter 14a. 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. At the time of writing, 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 supply and booking, and this will help to ensure a good balance between achieving rapid and long-lasting protection.

Dose and frequency of administration (continued)	If the primary course is interrupted or delayed, it should be resumed (using the same vaccine as was given for the first dose if possible, see Additional Information) but doses should not be repeated. The main exception to the eight-week lower interval would be those about to commence immunosuppressive treatment. In these individuals, the licensed minimal interval of at least 28 days may be followed to enable the vaccine to be given whilst their immune system is better able to respond. **Primary vaccination of severely immunosuppressed individuals** JCVI advises a preference for mRNA vaccines for the third primary dose. Vaxzevria is an option for individuals who have received an AstraZeneca COVID-19 vaccine previously, where mRNA vaccines are clinically contra-indicated. JCVI advises that a third primary dose be offered to individuals who had severe immunosuppression in proximity to their first or second COVID-19 doses in the primary schedule (see 'Box 1: Criteria for a third primary dose of COVID-19 vaccine in Chapter 14a). The third dose should be given ideally at least 8 weeks after the second dose, with special attention paid to current or planned immunosuppressive therapies. Where possible the third dose should be delayed until two weeks after the period of immunosuppression, in addition to the time period for clearance of the therapeutic agent. If not possible, consideration should be given to vaccination during a treatment 'holiday' or when the degree of immunosuppression is at a minimum (see Additional information). **Booster vaccination** Boosters should be offered to individuals eligible as part of the national COVID19 vaccination programme in accordance with the recommendations from the JCVI and Chapter 14a. The JCVI have advised that a full dose (30 micrograms) of Comirnaty® or a half dose (50 micrograms) of Spikevax® should be offered for boosting irrespective of the vaccine used for the primary course (see PGDs for COVID-19 vaccines). Where mRNA vaccines are clinically contra-indicated, Vaxzevria may be considered for those who had received at least one dose of an AstraZeneca COVID-19 vaccine previously. Individuals should complete a primary course of COVID-19 vaccination before receiving any boosters. Boosters should be given at a minimum interval of three months from the previous dose.
Duration of treatment	See Dose and frequency of administration above.
Quantity to be supplied / administered	Administer 0.5ml per dose.
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 Vaxzevria, which ensure use is in accordance with the product's SPC and official national recommendations.

Storage	Vaxzevria 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. 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 product's SPC. In the event of an inadvertent or unavoidable deviation of these conditions, vaccine that has been stored outside the conditions stated above should be quarantined and risk assessed for suitability of continued off-label use or appropriate disposal. Refer to Vaccine Incident Guidance.
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 arrangements and guidance in the technical memorandum 07-01: Safe management of healthcare waste (Department of Health, 2013). Vaxzevria 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, with activity against adenovirus, should be available for managing spills in all settings where vaccine 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. Similar considerations apply to co-administration of inactivated (or non-replicating) COVID-19 vaccines with live vaccines such as MMR. In particular, live vaccines which replicate in the mucosa, such as live attenuated influenza vaccine (LAIV) are unlikely to be seriously affected by concomitant COVID-19 vaccination. For further information about co-administration with other vaccines see Additional Information section.

Identification and management of adverse reactions	The most frequently reported adverse reactions are injection site tenderness, injection site pain, headache, fatigue, myalgia, malaise, pyrexia (including feverishness and fever), chills, arthralgia and nausea. The majority of adverse reactions are mild to moderate in severity and usually resolved within a few days of vaccination. When compared with the first dose, adverse reactions reported after the second dose are milder and reported less frequently. The reactogenicity observed in individuals who received a booster dose was consistent with the known reactogenicity profile of Vaxzevria and was lower than that of the first dose. Reactogenicity events are 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 antipyretic medication. Serious thromboembolic events with concurrent thrombocytopenia, sometimes accompanied by bleeding, have occurred very rarely following vaccination with an AstraZeneca COVID-19 vaccine during post-authorisation use. The majority of the events occurred within the first 3 weeks following vaccination but have also been reported after this period. Risk factors have not been identified. Healthcare professionals should be alert to the signs and symptoms of thromboembolism and/or thrombocytopenia. Vaccinated individuals should also be instructed to seek immediate medical attention if four or more days after vaccination they develop new onset or worsening severe or persistent headaches with blurred vision, which do not respond to simple painkillers, or if they develop new symptoms such as shortness of breath, chest pain, leg swelling, leg pain, persistent abdominal pain, any neurological symptoms or signs such as confusion or seizures, or unusual skin bruising and/or petechiae beyond the site of vaccination. Individuals diagnosed with thrombocytopenia within 3 weeks after vaccination with an AstraZeneca COVID-19 vaccine should be actively investigated for signs of thrombosis. Similarly, individuals who present with thrombosis within 3 weeks of vaccination should be evaluated for thrombocytopenia. Individuals with TTS require specialised clinical management and should be urgently referred to a secondary healthcare centre and to a specialist in haematology for advice on further management. Individuals should be provided with the advice within the leaflet COVID-19 vaccination and blood clotting. Very rare cases of CLS have been reported in the first days after vaccination with Vaxzevria. CLS is a rare disorder characterised by acute episodes of oedema mainly affecting the limbs, hypotension, haemoconcentration and hypoalbuminaemia. Individuals with an acute episode of CLS following vaccination require prompt recognition and treatment. Intensive supportive therapy is usually warranted. GBS has been reported very rarely within six weeks of AstraZeneca COVID-19 vaccination, although it is not yet certain whether these are caused by the vaccine. Individuals should be advised to seek immediate medical attention if they develop weakness and paralysis in the extremities that can progress to the chest and face. A detailed list of adverse reactions is available in the product's SPC.

Reporting procedure of adverse reactions	Healthcare professionals and individuals/carers should report suspected adverse reactions to the MHRA using the Coronavirus Yellow Card reporting scheme 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. 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: • Patient Information Leaflet for Vaxzevria • COVID-19 Vaccination Record Card • What to expect after your COVID-19 vaccination • COVID-19 vaccination: women of childbearing age, currently pregnant, or breastfeeding • COVID-19 vaccination and blood clotting • COVID-19 vaccination: a guide to booster vaccination For other leaflets available see Leaflets, posters and resources on the UKHSA Covid-19 vaccination programme webpage.
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. Inform the individual/carer of possible side effects and their management. As fainting can occur following vaccination, all those vaccinated with any of the COVID-19 vaccines should be advised not to drive for 15 minutes after vaccination. The individual/carer should be advised to seek appropriate advice from a healthcare professional in the event of an adverse reaction. Vaccinated individuals should be advised to seek immediate medical attention if four or more days after vaccination they develop new onset or worsening severe or persistent headaches with blurred vision, which do not respond to simple painkillers or if they develop new symptoms such as shortness of breath, chest pain, leg swelling, persistent abdominal pain, any neurological symptoms or signs (such as confusion or seizures) or unusual skin bruising and/or petechiae. Individuals with thromboembolic events and concurrent thrombocytopenia should be urgently referred to a secondary healthcare centre and to a specialist in haematology for advice on further management. Vaccinated individuals should be advised to seek immediate medical attention if they develop weakness and paralysis in the extremities that can progress to the chest and face (Guillain-Barré syndrome). This has been reported very rarely after vaccination. 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 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.

Patient advice / follow up treatment (continued)	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. JCVI advises a preference for mRNA vaccines for the third primary dose, with the option of the AstraZeneca vaccine for individuals who have received this vaccine previously where mRNA vaccines are clinically contra-indicated. In exceptional circumstances, persons who received a mRNA COVID-19 vaccine previously may be offered a third primary dose of AstraZeneca vaccine following a decision by a health professional on a case-by-case, individualised basis. In such instances a prescriber or PSD would be required for administration. For those under 18 years the Comirnaty® vaccine remains the preferred choice, as set out in JCVI advice of 4 August 2021 and 16 February 2022. Where mRNA vaccines are clinically contra-indicated, AstraZeneca vaccine may be considered for a booster dose in those who had received at least one dose of this vaccine previously. In exceptional circumstances, persons aged 40 years or over who received an mRNA COVID-19 vaccine primary course may be offered boosting with AstraZeneca vaccine following a decision by a health professional on a case-by-case basis. In such instances a prescriber or PSD would be required for administration (see Chapter 14a). **Pregnancy** Comirnaty® and Spikevax® vaccines are the preferred vaccines for eligible pregnant women, because of more extensive experience of their use in pregnancy. Pregnant women who have already received a dose of AstraZeneca vaccine can complete with the same vaccine or with an mRNA product. 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. In December 2021, following the recognition of pregnancy as a risk factor for severe COVID-19 infection and poor pregnancy outcomes during the Delta wave, pregnancy was added to the clinical risk groups recommended COVID-19 vaccination. If a woman finds out she is pregnant after she has started a course of vaccine, she should complete vaccination during pregnancy using the same vaccine product (unless contra-indicated). **Breastfeeding** There is no known risk associated with being given a non-live vaccine whilst breastfeeding. JCVI advises that breastfeeding women should be offered any suitable COVID-19 vaccine. Emerging safety data is reassuring; mRNA was not detected in the breast milk of recently vaccinated women and protective antibodies have been detected in breast milk.

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Special considerations / additional information (continued)	The developmental and health benefits of breastfeeding are clear and should be discussed with the woman, along with her clinical need for immunisation against COVID-19. **Previous incomplete vaccination** If the primary course is interrupted or delayed, it should be resumed using the same vaccine, if possible, but the earlier doses should not be repeated. Evidence suggests that those who receive mixed schedules, including mRNA and adenovirus vectored vaccines make a good immune response, although rates of side effects with heterologous doses are higher. Accumulating evidence now supports the use of heterologous schedules for primary immunisation, and these are now recognised by the European Medicines Agency (EMA). 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 (Comirnaty®) vaccines should be informed about the higher rate of such reactions when they receive a second dose of an alternate vaccine. In these circumstances, this PGD may be used. For individuals with a history of thrombosis combined with thrombocytopenia following vaccination with an AstraZeneca COVID-19 vaccine, current evidence would support completion of the course with an mRNA vaccine, provided a period of at least 12 weeks has elapsed from the implicated dose. Individuals who have participated in a clinical trial of either primary or booster COVID-19 vaccination 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 3 months after the dose considered as the final primary dose or the final revaccination (if the latter is required for certification purposes). Individuals who have been vaccinated abroad are likely to have received an mRNA or vector vaccine based on the spike protein, or an inactivated whole viral vaccine. Specific advice on Vaccination of those who received COVID-19 vaccine overseas is available from the UKHSA. **Co-administration with other vaccines** Where individuals in an eligible cohort present having recently received one or more inactivated or live vaccines, 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 an individual presents requiring two or more vaccines. It is generally better for vaccination to proceed and it may be provided under this PGD, to avoid any further delay in protection and to avoid the risk of the individual 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 HPV, MenACWY and Td-IPV vaccines). The only exceptions to this are the shingles vaccines, where a seven-day interval should ideally be observed. This is based on the potential for an inflammatory response

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Special considerations / additional information (continued)	to COVID-19 vaccine to interfere with 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, individuals 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. **Non-responders / immunosuppressed** Immunological response may be lower in immunocompromised individuals, but they should still be vaccinated. JCVI advises that a third primary vaccine dose be offered to individuals who had severe immunosuppression in proximity to their first or second COVID-19 doses in the primary schedule (see 'Box 1: Criteria for a third primary dose of COVID-19 vaccine in Chapter 14a). Most individuals whose immunosuppression commenced at least two weeks after the second dose of vaccination do not require an additional primary vaccination at this stage. Individuals who had received brief immunosuppression (≤40mg prednisolone per day) for an acute episode (for example, asthma / COPD / COVID-19) and individuals on replacement corticosteroids for adrenal insufficiency are not considered severely immunosuppressed sufficient to have prevented response to the primary vaccination. JCVI advises a preference for mRNA vaccines for the third primary dose. Vaxzevria is an option for individuals who have received an AstraZeneca COVID-19 vaccine previously, where mRNA vaccines are clinically contra-indicated. Third primary doses should be given ideally at least 8 weeks after the second dose, with special attention paid to current or planned immunosuppressive therapies. Where possible the third dose should be delayed until two weeks after the period of immunosuppression, in addition to the time period for clearance of the therapeutic agent. If not possible, consideration should be given to vaccination during a treatment 'holiday' or when the degree of immunosuppression is at a minimum. Individuals who have received a bone marrow transplant after vaccination should be considered for a re-immunisation programme for all routine vaccinations and for COVID-19 (see Chapter 7 of the Green Book). This is not covered by this PGD and should be provided on a patient specific basis.
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 • name and brand of vaccine • date of administration • dose, form and route of administration of vaccine • quantity administered • batch number and expiry date

Records (continued)	• 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 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	**Vaxzevria vaccination** • Immunisation Against Infectious Disease: The Green Book, Chapter 14a. Updated 28 February 2022 https://www.gov.uk/government/publications/covid-19-the-green-book-chapter-14a • COVID-19 Vaccination and blood clotting. https://www.gov.uk/government/collections/covid-19-vaccination-and-blood-clotting • COVID-19 vaccination programme. Updated 17 March 2022. https://www.gov.uk/government/collections/covid-19-vaccination-programme • Training recommendations for COVID-19 vaccinators. Updated 4 October 2021. 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. Updated 16 March 2021. https://www.gov.uk/government/publications/covid-19-vaccinator-competency-assessment-tool • COVID-19: vaccination programme guidance for healthcare practitioners. Updated 10 March 2022. https://www.gov.uk/government/publications/covid-19-vaccination-programme-guidance-for-healthcare-practitioners • Summary of Product Characteristics and Patient information leaflet for Vaxzevria. Published 26 January 2022. 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.england.nhs.uk/publication/management-and-disposal-of-healthcare-waste-htm-07-01/ • 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. 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 • UK Statutory Instrument 2012 No. 1916, The Human Medicines Regulations 2012, as amended. https://www.legislation.gov.uk/uksi/2012/1916/contents • UK Statutory Instrument 2022 No. 350, The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2022. https://www.legislation.gov.uk/uksi/2022/350/made

7. Practitioner authorisation sheet

Vaxzevria PGD v01.00 Valid from: 5 May 2022 Expiry: 1 April 2023

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.