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National protocol for COVID-19 Vaccine AstraZeneca, (ChAdOx1-S [recombinant])

Reference no: COVID-19 Vaccine AstraZeneca protocol
Version no: v07.00 (Expiry extension of V06.00)
Valid from: 31 March 2022
Expiry date: 1 October 2022

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

This protocol is for the administration of COVID-19 Vaccine AstraZeneca by appropriately trained persons in accordance with [regulation 247A](#) of the [Human Medicines Regulations 2012](#) (HMR 2012), inserted by [The Human Medicines \(Coronavirus and Influenza\) \(Amendment\) Regulations 2020](#)

The UK Health Security Agency (UKHSA) has developed this protocol for authorisation by or on behalf of the Secretary of State for Health and Social Care to facilitate the delivery of the national COVID-19 vaccination programme commissioned by NHS England and NHS Improvement (NHSEI).

This protocol may be followed wholly from assessment through to post-vaccination by an appropriately registered healthcare professional (see [Characteristics of staff](#)). Alternatively, multiple persons may undertake stages in the vaccination pathway in accordance with this protocol. Where multiple person models are used, the service provider/contractor must ensure that all elements of the protocol are complied with, in the provision of vaccination to each individual. The provider/contractor is responsible for ensuring that persons are trained and competent to safely deliver the activity they are employed to provide under this protocol. As a minimum, competence requirements stipulated in the protocol under [Characteristics of staff](#) must be adhered to.

The provider/contractor and registered healthcare professionals are responsible for ensuring that they have adequate and appropriate indemnity cover.

Persons must be authorised by name to work under this protocol. They must ensure they meet the staff characteristics for the activity they are undertaking, make a declaration of competence and be authorised in writing. This can be done by completing [Section 4](#) of this protocol or maintaining an equivalent electronic record.

A clinical supervisor¹, who must be a registered doctor, nurse or pharmacist trained and competent in all aspects of the protocol, must be present and take overall responsibility for provision of vaccination under the protocol at all times and be identifiable to service users. The drawing up of the vaccine has its own supervision requirements in accordance with [Part 1](#) of the HMR 2012 and will need to be done by, or under the supervision of, a registered doctor, nurse or pharmacist. If a vaccination service is being provided at scale, the clinical supervisor should only take on specific supervision requirements in relation to the drawing up of the vaccine if this can be done safely alongside their overarching role. Any time the protocol is used, the name of the clinical supervisor taking responsibility and all the people working under different stages of the protocol

¹ This role is different to the Band 6 'COVID-19 Vaccination Programme - RHCP Clinical Supervisor (Vaccinations)' (see [Accountability and delegation under the national protocols for COVID-19 vaccines: visual diagram](#)).

must be recorded for the session. The clinical supervisor has ultimate responsibility for safe care being provided under the terms of the protocol. Staff working under the protocol may be supported by additional registered healthcare professionals, but the clinical supervisor retains overall responsibility. Staff working to the protocol must understand who the clinical supervisor for their practice at any time is and can only proceed with their authority. The clinical supervisor may withdraw this authority for all members of staff or individual members of staff at any time and has authority to stop and start service provision under the protocol as necessary. Every member of staff has a responsibility to, and should, report immediately to the clinical supervisor any concerns they have about working under the protocol in general or about a specific individual, process, issue or event.

Operation under this protocol is the responsibility of service providers/contractors. Provider organisations/contractors using this protocol should retain copies, along with the details of those authorised to work under it, for 8 years after the protocol expires.

Persons must check that they are using the current version of this protocol and current versions of any documents this protocol refers to. Amendments may become necessary prior to the published expiry date. Current versions of national protocols for COVID-19 vaccines, authorised by or on behalf of the Secretary of State for Health and Social Care in accordance with regulation 247A of the HMR 2012, can be found via:

[COVID-19 vaccination programme - GOV.UK \(www.gov.uk\)](https://www.gov.uk/government/covid-19/vaccines)

Any concerns regarding the content of this protocol should be addressed to:
immunisation@phe.gov.uk

Change History

Change history Version	Change details	Date
V01.00	New national protocol for COVID-19 Vaccine AstraZeneca	05/01/2021
V02.00	National protocol for COVID-19 Vaccine AstraZeneca amended to: <ul style="list-style-type: none"> • add footnote to front page pertaining to the clinical supervisor role • delete clinical supervisor column from Table 2 • cover JCVI recommendations for phase 2 • include vaccination in pregnancy in accordance with 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 and actions if excluded 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 • include a paragraph in the legal category section to allow for protocol use to continue should the vaccine be provided a marketing authorisation in the future, so long as the protocol remains clinically appropriate • 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 protocol • update key references • remove Appendix A and refer directly to the Green Book Chapter 14a 	17/03/2021
V03.00	National protocol for COVID-19 Vaccine AstraZeneca amended to: <ul style="list-style-type: none"> • inclusions, exclusions, cautions, identification and management of adverse reactions, written information and advice sections, relating to vaccination and thromboembolic events • recommend that those under 30 years of age commence COVID-19 vaccination with an alternative COVID-19 vaccine where possible 	22/04/2021
V04.00	National protocol for COVID-19 Vaccine AstraZeneca amended to: <ul style="list-style-type: none"> • identify in the Criteria for inclusion and Cautions sections the preference for an alternative COVID-19 Vaccine for healthy individuals under 40 years of age • identify in the Cautions section COVID-19 mRNA vaccine BNT162b2 (Pfizer BioNTech) or COVID-19 Vaccine Moderna as the preferred vaccines to offer to pregnant women • minor rewording of breastfeeding paragraph 	12/05/2021
V05.00	National protocol for COVID-19 Vaccine AstraZeneca amended to: <ul style="list-style-type: none"> • align with the current national programme recommendations, latest guidance and regulatory approval and this includes significant update to the criteria for inclusion, criteria for exclusion, cautions, actions if excluded, dose, interactions, adverse reactions and additional information sections • signpost to a Patient Group Direction for Vaxzevria Covid-19 vaccine when available, for administration of Vaxzevria, conditional marketing authorisation approved supplies 	17/10/2021

	<ul style="list-style-type: none"> • update from PHE to UKHSA and include further minor update in other sections to align with update and for consistency with other protocol where appropriate 	
V06.00	<p>COVID-19 Vaccine AstraZeneca protocol v05.00 amended to:</p> <ul style="list-style-type: none"> • update Criteria for inclusion in line with the updated Chapter 14a of the Green Book 11 January 2022 • update Cautions link to Regulation 174 and section to include immune thrombocytopenia (ITP), Past history of COVID-19 infection in line with the updated Chapter 14a of the Green Book 11 January 2022 • update Dose and frequency of administration, Action to be taken if the individual is excluded and Off-label sections in line with the updated Chapter 14a of the Green Book 11 January 2022 • update Special consideration and additional information section to be in line with the updated Chapter 14a of the Green Book 11 January 2022 • update wording 'expiry' to 'date' in the Vaccine preparation section • update Written information to be given to patient or carer section to include COVID-19 vaccination: A guide to booster vaccination • update to Key references to link to most recent published documents • update 'the' before UKHSA, wording 'PGD' to 'protocol', 'patient' to 'individual' and Pfizer and Moderna vaccines as per licensed brand names 	31/01/2022
V07.00	<p>COVID-19 Vaccine AstraZeneca protocol v06.00 with expiry extension to 1 October 2022 approved by Minister on 28 Month 2022</p>	28/03/2022

1. Ministerial authorisation

This protocol is not legally valid, in accordance with [regulation 247A](#) of the [HMR 2012](#), inserted by the [Human Medicines \(Coronavirus and Influenza\) \(Amendment\) Regulations 2020](#), until it is approved by or on behalf of the Secretary of State for Health and Social Care.

On 28 March 2022 TBC on expiry extension, Department of Health and Social Care Ministers approved this protocol in accordance [regulation 247A](#) of HMR 2012.

Any provider/contractor administering COVID-19 Vaccine AstraZeneca under this protocol must work strictly within the terms of this protocol and contractual arrangements with the commissioner, for the delivery of the national COVID-19 vaccination programme.

Assembly, final preparation and administration of vaccines supplied and administered under this protocol 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 Healthcare Professionals on COVID-19 Vaccine AstraZeneca \(Regulation 174\)](#), published alongside the [Conditions of Authorisation for COVID-19 Vaccine AstraZeneca \(Regulation 174\)](#).

Note: The national COVID-19 vaccination programme may also be provided under a patient group direction or on a patient specific basis (that is, by or on the directions of an appropriate independent prescriber, such as under a patient specific direction (PSD)). Supply and administration in these instances should be in accordance with contractual arrangements with the commissioner for the delivery of the national COVID-19 vaccination programme and are not related to this protocol.

2. Characteristics of staff

Classes of persons permitted to administer medicinal products under this protocol

This protocol may be followed wholly from assessment through to post-vaccination by an appropriately registered healthcare professional (see [Table 2](#)). Alternatively, multiple persons may undertake stages in the vaccination pathway in accordance with this protocol. Where multiple person models are used, the service provider/contractor must ensure that all elements of the protocol are complied with, in the provision of vaccination to each individual. The service provider/contractor is responsible for ensuring that there is a clinical supervisor present at all times and that persons are trained and competent to safely deliver the activity they are employed to provide under this protocol. As a minimum, competence requirements stipulated in the protocol must be adhered to.

The provider/contractor and registered healthcare professionals are responsible for ensuring that they have adequate and appropriate indemnity cover.

This protocol is separated into operational stages of activity as outlined in [Table 1](#).

The clinical supervisor¹ must be a registered doctor, nurse or pharmacist trained and competent in all aspects of the protocol and provide clinical supervision, see [page 1](#), for the overall provision of clinical care provided under the legal authority of the protocol.

Table 1: Operational stages of activity under this protocol

Stage 1	a. Assessment of the individual presenting for vaccination b. Provide information and obtain informed consent ² c. Provide advice to the individual	Specified Registered Healthcare Professionals Only (see Table 2)
Stage 2	• Vaccine Preparation	Registered or non-registered persons
Stage 3	• Vaccine Administration	Registered or non-registered persons
Stage 4	• Record Keeping	Registered or non-registered persons

Persons must only work under this protocol where they are competent to do so.

Non-professionally qualified persons operating under this protocol must be adequately supervised by experienced registered healthcare professionals.

Protocols do not remove inherent professional obligations or accountability. All persons operating under this protocol must work within their terms of employment at all times; registered healthcare professionals must also abide by their professional code of conduct.

To undertake the assigned stage(s) of activity under this protocol, persons working to this protocol must meet the criteria specified in [Table 2](#) (see below).

Table 2: Protocol stages and required characteristics of persons working under it

Persons working to this protocol must meet the following criteria, as applicable to undertake their assigned stage(s) of activity under this protocol:	Stage 1	Stage 2	Stage 3	Stage 4
must be authorised by name as an approved person under the current terms of this protocol before working to it, see Section 4	Y	Y	Y	Y
must be competent to assess individuals for suitability for vaccination, identify any contraindications or precautions, discuss issues related to vaccination and obtain informed consent ² and must be an appropriately qualified prescriber or one of the following registered professionals who can operate under a PGD or as an occupational health vaccinator in accordance with HMR 2012:	Y	N	N	N

² For those lacking mental capacity, a decision may be made in the individual's best interests in accordance with the [Mental Capacity Act 2005](#) (for further information on consent see [Chapter 2](#) of 'The Green Book').

<ul style="list-style-type: none"> nurses, nursing associates 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, operating department practitioners, 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. 				
must be a doctor, nurse or pharmacist or a person who is under the supervision of, a doctor, nurse or pharmacist (see Page 1)	N	Y	N	N
must be competent in the handling of the vaccine product and use of aseptic technique for drawing up the correct dose	N	Y	Y	N
must be familiar with the vaccine product and alert to any changes in the Regulation 174 Information for UK Healthcare Professionals and familiar with the national recommendations for the use of this vaccine	Y	Y	Y	N
must be familiar with, and alert to changes in relevant chapters of Immunisation Against Infectious Disease: the Green Book	Y	Y	Y	N
must be familiar with, and alert to changes in the relevant standard operating procedures (SOPs) and commissioning arrangements for the national COVID-19 vaccination programme	Y	Y	Y	Y
must have undertaken training appropriate to this protocol and relevant to their role, as required by local policy and SOPs and in line with the Training recommendations for COVID-19 vaccinators	Y	Y	Y	N
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	Y	Y	Y	N
must be competent in the correct handling and storage of vaccines and management of the cold chain if receiving, responsible for, or handling the vaccine	N	Y	Y	N
must be competent in intramuscular injection technique if they are administering the vaccine	N	N	Y	N
must be competent in the recognition and management of anaphylaxis, have completed basic life support training and able to respond appropriately to immediate adverse reactions	Y	N	Y	N
must have access to the protocol and relevant COVID-19 vaccination programme online resources such as the Green Book , particularly Chapter 14a , and the COVID-19 vaccination programme: Information for healthcare practitioners document	Y	Y	Y	N
must understand the importance of making sure vaccine information is recorded on the relevant data system, meeting the relevant competencies of the COVID-19 vaccinator competency assessment tool	Y	Y	Y	Y
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 an experienced vaccinator (vaccinating within past 12 months)	Y	Y	Y	Y
should fulfil any additional requirements defined by local or national policy	Y	Y	Y	Y

STAGE 1: Assessment of the individual presenting for vaccination

ACTIVITY STAGE 1a:	Assess the individual presenting for vaccination. If they are not eligible for vaccination or need to return at a later date, advise them accordingly.
Clinical condition or situation to which this Protocol applies	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 Immunisation Against Infectious Disease: the 'Green Book' and subsequent correspondence/publications from the UKHSA and/or NHSEI.
Criteria for inclusion	<p>COVID-19 Vaccine AstraZeneca 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 of the Green Book.</p> <p>Individuals are eligible for different dose schedules based on their age and recognised risk group (see the Dose and frequency of administration section).</p>
Criteria for exclusion³	<p>Individuals for whom valid consent, or '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 Regulation 174 Information for UK recipients for COVID-19 vaccine AstraZeneca should be available to inform consent.</p> <p>Individuals who:</p> <ul style="list-style-type: none"> • 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 process⁴ • have experienced thrombosis with thrombocytopenia syndrome (TTS) following vaccination with COVID-19 Vaccine AstraZeneca • 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	<p>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.</p> <p>JCVI issues advice on vaccine preference specific to the current UK context and available data. An alternative COVID-19 vaccine to COVID-19 Vaccine AstraZeneca 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 of the Green Book).</p> <p>Serious thromboembolic events with concurrent thrombocytopenia, sometimes accompanied by bleeding, have occurred very rarely following</p>

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³ Exclusion under this protocol does not necessarily mean the medication is contraindicated, but it would be outside its remit and another form of authorisation will be required

⁴ Contains polysorbate 80. Refer to [Regulation 174 Information for UK Healthcare Professionals](#) for a full list of excipients.

<p>Cautions including any relevant action to be taken (continued)</p>	<p>pressure to the injection site for at least two minutes. The individual/carer should be informed about the risk of haematoma from the injection.</p> <p>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 vaccine, for any future doses Comirnaty® and Spikevax® vaccines are preferred. Where GBS occurs following either of the mRNA vaccines, further vaccination can proceed as normal, once recovered.</p> <p>Past history of COVID-19 infection</p> <p>There is no evidence of any safety concerns from vaccinating individuals with a past history of COVID-19 infection, or with detectable COVID-19 antibody.</p> <p>Vaccination of individuals who may be infected but asymptomatic or incubating COVID-19 infection is unlikely to have a detrimental effect on the illness. Vaccination should be deferred in those with confirmed infection to avoid 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 for that episode in those who are asymptomatic. This interval may be reduced in periods of high incidence or where there is concern about vaccine effectiveness (for example a new variant). The timing of any change will be advised by JCVI or the UKHSA and published in operational guidance agreed by DHSC and NHSEI.</p> <p>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.</p> <p>Vaccine Surveillance</p> <p>The UK regulator will maintain real-time surveillance post deployment of COVID-19 vaccines in the UK. In response to any safety signals, the Medicines and Healthcare products Regulatory Agency (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 protocol 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). These documents take precedence for the purposes of compliance with this protocol, if there is a delay in updating other provisions of this protocol that cut across them.</p>
<p>Dose and frequency of administration</p> <p>Continued over page</p>	<p>Primary vaccination</p> <p>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.</p>

<p>Dose and frequency of administration (continued)</p>	<p>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.</p> <p>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, this consistent interval should be used for all vaccines with a two-dose primary schedule to avoid confusion and simplify booking, and this will help to ensure a good balance between achieving rapid and long-lasting protection.</p> <p>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.</p> <p>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.</p> <p>Primary vaccination of severely immunosuppressed individuals</p> <p>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 decision on the timing of the third dose should be undertaken by the specialist involved in the care of the individual. 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 (see Additional information).</p> <p>Booster vaccination</p> <p>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 of the Green Book. Where mRNA vaccines are clinically contra-indicated, AstraZeneca vaccine may be considered in those who had received at least one dose of this vaccine previously.</p> <p>Individuals should complete a primary course of COVID-19 vaccination before receiving any boosters.</p> <p>Boosters should be given at a minimum interval of three months from the previous dose.</p>
<p>Action to be taken if the individual is excluded</p> <p>Continued over page</p>	<p>This protocol is for individuals aged 18 years and over in accordance with recommendations in Chapter 14a for the use of COVID-19 Vaccine AstraZeneca. For individuals under 18 years of age, Comirnaty® vaccine is recommended (see the appropriate Comirnaty® protocol).</p> <p>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</p>

Actions to be taken if the individual is excluded (continued)	<p>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 only be provided by an appropriate prescriber or on a patient specific basis, under a PSD.</p> <p>Individuals who have had a previous systemic allergic reaction (including immediate onset anaphylaxis) to a previous dose of 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.</p> <p>Individuals who experience a clotting episode with concomitant thrombocytopenia following the first dose of AstraZeneca 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.</p> <p>Individuals who have previously experienced episodes of CLS syndrome may be offered vaccination with an alternative, mRNA, COVID-19 vaccine.</p> <p>In case of postponement due to acute illness, advise when the individual can be vaccinated and, if possible, ensure another appointment is arranged.</p> <p>Document the reason for exclusion and any action taken.</p>
Action to be taken if the individual or carer declines treatment	<p>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'.</p> <p>Advise the individual/carers about the protective effects of the vaccine, the risks of infection and potential complications if not immunised.</p> <p>Document advice given and the decision reached.</p>
Arrangements for referral	<p>As per local policy.</p>

STAGE 1b: Description of treatment

ACTIVITY STAGE 1b:	<p>Consider any relevant cautions, interactions or adverse drug reactions.</p> <p>Provide advice to the individual and obtain informed consent².</p> <p>Record individual's consent² and ensure vaccinator, if another person, is informed of the vaccine product to be administered.</p>
Name, strength and formulation of drug	<p>COVID-19 Vaccine AstraZeneca, solution for injection in multidose container COVID-19 Vaccine (ChAdOx1-S [recombinant]):</p> <ul style="list-style-type: none"> • 5ml of solution in a 10-dose vial • 4ml of solution in an 8-dose vial <p>One dose (0.5 ml) contains COVID-19 Vaccine (ChAdOx1-S* recombinant) 5×10^{10} viral particles.</p> <p>*Recombinant, replication-deficient chimpanzee adenovirus vector encoding the SARS-CoV-2 Spike (S) glycoprotein. Produced in genetically modified human embryonic kidney (HEK) 293 cells.</p>
Legal category	<p>COVID-19 Vaccine AstraZeneca has been provided temporary authorisation by the MHRA for supply in the UK under Regulation 174 and 174A of HMR 2012.</p> <p>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.</p> <p>COVID-19 Vaccine AstraZeneca is categorised as a prescription only medicine (POM).</p> <p>Note: For administration of Vaxzevria COVID-19 vaccine (ChAdOx1 S [recombinant]), which has been granted a conditional marketing authorisation, see the Patient Group Direction for Vaxzevria Covid-19 vaccine when available.</p>
Black triangle▼	<p>As a new vaccine product, MHRA has a specific interest in the reporting of adverse drug reactions for this product.</p>
Off-label use	<p>COVID-19 Vaccine AstraZeneca is supplied in the UK in accordance with Regulation 174.</p> <p>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.</p>
Drug interactions	<p>Immunological response may be diminished in those receiving immunosuppressive treatment, but it is important to still immunise this group.</p> <p>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</p>

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Drug interactions (continued)	<p>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.</p> <p>For further information about co-administration with other vaccines see Additional Information section.</p>
Identification and management of adverse reactions	<p>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. By day 7 the incidence of subjects with at least one local or systemic reaction is 4% and 13% respectively. When compared with the first dose, adverse reactions reported after the second dose are milder and reported less frequently.</p> <p>Reactogenicity events are generally milder and reported less frequently in older adults (≥65 years old).</p> <p>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.</p> <p>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.</p> <p>Serious thromboembolic events with concurrent thrombocytopenia, sometimes accompanied by bleeding, have occurred very rarely following vaccination with COVID-19 Vaccine AstraZeneca during post-authorisation use. The majority of the events occurred within the first 14 days following vaccination but have also been reported after this period. Risk factors have not been identified.</p> <p>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.</p> <p>Individuals diagnosed with thrombocytopenia within 3 weeks after vaccination with COVID-19 Vaccine AstraZeneca should be actively investigated for signs of thrombosis. Similarly, individuals who present with thrombosis within 3 weeks of vaccination should be evaluated for thrombocytopenia.</p> <p>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.</p> <p>Very rare cases of Capillary Leak Syndrome (CLS) have been reported in the first days after vaccination with COVID-19 Vaccine AstraZeneca/Vaxzevria. CLS is a rare disorder characterised by acute episodes of oedema mainly affecting the limbs, hypotension, haemoconcentration and hypoalbuminaemia. Individuals with an acute</p>

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Identification and management of adverse reactions (continued)	<p>episode of CLS following vaccination require prompt recognition and treatment. Intensive supportive therapy is usually warranted.</p> <p>GBS has been reported very rarely within six weeks of AstraZeneca 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.</p> <p>A detailed list of adverse reactions is available in the Regulation 174 Information for UK Healthcare Professionals.</p>
Reporting procedure of adverse reactions	<p>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.</p> <p>As a new vaccine product, MHRA has a specific interest in the reporting of all adverse drug reactions for this product.</p> <p>Any adverse reaction to a vaccine should also be documented in the individual's record and the individual's GP should be informed.</p> <p>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'.</p>
Written information to be given to individual or carer	<p>Ensure the individual has been provided appropriate written information such as the:</p> <ul style="list-style-type: none"> • 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 • COVID-19 vaccination and blood clotting • COVID-19 vaccination: a guide to booster vaccination
Advice / follow up treatment Continued over page	<p>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.</p> <p>Inform the individual/carers of possible side effects and their management.</p> <p>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.</p> <p>The individual/carers should be advised to seek appropriate advice from a healthcare professional in the event of an adverse reaction.</p> <p>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</p>

Advice / follow up treatment (continued)	<p>on further management.</p> <p>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.</p> <p>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.</p> <p>When applicable, advise the individual/carer when to return for vaccination or when a subsequent vaccine dose is due.</p>
Special considerations / additional information	<p>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.</p> <p>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.</p> <p>For those aged 16 years and over, 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.</p> <p>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).</p> <p>Pregnancy</p> <p>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.</p> <p>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. Although clinical trials on the use of COVID-19 vaccines during pregnancy are not advanced, the available data do not indicate any harm to pregnancy. JCVI has therefore advised that women who are pregnant should be offered vaccination at the same time as non-pregnant women, based on their age and clinical risk group.</p>

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<p>Special considerations / additional information (continued)</p> <p>Continued over page</p>	<p>Routine questioning about last menstrual period and/or pregnancy testing is not required before offering the vaccine. Women who are planning pregnancy or in the immediate postpartum should be vaccinated with a suitable product for their age and clinical risk group.</p> <p>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).</p> <p>Breastfeeding</p> <p>There is no known risk associated with being given a non-live vaccine whilst breastfeeding. JCVI advises that breastfeeding women may be offered any suitable COVID-19 vaccine.</p> <p>The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for immunisation against COVID-19; at the same time, women should be informed about the emerging safety data for the vaccine in breastfeeding.</p> <p>Previous incomplete vaccination</p> <p>If the primary course is interrupted or delayed, it should be resumed using the same vaccine 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 after the second dose are higher. Accumulating evidence now supports the use of heterologous schedules for primary immunisation, and these are now recognised by the European Medicines Agency (EMA).</p> <p>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.</p> <p>For individuals with a history of thrombosis combined with thrombocytopenia following vaccination with the 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.</p> <p>Individuals with a history of CLS should be carefully counselled about the risks and benefits of vaccination and may be offered an alternative vaccine to complete a vaccination course.</p> <p>Individuals who are participating in a clinical trial of COVID-19 vaccines who present for vaccination should be referred back to the investigators. Eligible individuals who are enrolled in vaccine trials should then be provided with written advice on whether and when they should be safely vaccinated in the routine programme. Advice should also be provided from the trial investigators on whether any individual could receive additional doses for the purposes of vaccine certification. Trial participants who are eligible for boosters should be offered vaccination in line with the general population, at least three months after the dose considered as the final primary dose or the final revaccination (if the latter is required for certification purposes).</p> <p>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</p>
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Special considerations / additional information
(continued)

[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 protocol, 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 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.

JCVI has previously advised that, the decision on the timing of the third primary dose should be undertaken by the specialist involved in the care of the individual. In general, vaccines administered during periods of minimum immunosuppression (where possible) are more likely to generate better immune responses. However, following the recognition of the Omicron variant, JCVI has now advised that boosters should be offered from three months after the third dose. Those who have not yet received their third primary dose may be given their third dose now (8 weeks after the second dose) to avoid further delay. Boosters should be given at a minimum interval of three months from the previous dose in line with the clinical advice on optimal timing.

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.

STAGE 2: Vaccine preparation

ACTIVITY STAGE 2:	Vaccine preparation
Vaccine presentation	<p>COVID-19 Vaccine AstraZeneca, solution for injection in multidose container COVID-19 Vaccine (ChAdOx1-S [recombinant]):</p> <ul style="list-style-type: none"> • 5ml of solution in a 10-dose vial • 4ml of solution in an 8-dose vial
Supplies	<p>Providers should order/receive COVID-19 vaccines via the national appointed supply route for the provider.</p> <p>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.</p>
Storage	<p>COVID-19 Vaccine AstraZeneca unopened multidose vial:</p> <ul style="list-style-type: none"> • 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. <p>After first dose 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.</p> <p>Once a dose is withdrawn from the vial it should be administered immediately.</p> <p>The vaccine does not contain preservative.</p> <p>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.</p>
Vaccine preparation	<p>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.</p> <p>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, clear to slightly opaque solution. Discard the vaccine if particulate matter or differences to the described appearance are observed.</p> <p>Do not shake the vial. Do not dilute the solution.</p> <p>The vaccine should not be mixed in the same syringe with any other vaccines or medicinal products.</p> <p>Check product name, batch number and expiry date prior to administration.</p> <p>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.</p>

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Vaccine preparation (continued)	<p>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.</p> <p>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.</p> <p>The vaccine may be drawn up and administered by the same person or separate persons with the required competence and supervision. If the vaccine is to be administered by a person other than the person preparing it, ensure that there are clear procedures for transferring the vaccine to the vaccinator in a safe way, allowing for appropriate checks of vaccine particulars, batch number and date by both parties.</p>
Disposal	<p>Follow local clinical waste policy and NHS standard operating procedures and ensure safe and secure waste disposal.</p> <p>Equipment used for vaccine preparation, 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).</p> <p>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, with activity against adenovirus, should be available for managing spills in all settings where vaccine is administered.</p>

STAGE 3: Vaccine administration

ACTIVITY STAGE 3:	<p>Before administering the vaccine, ensure:</p> <ol style="list-style-type: none"> 1. The individual has been assessed in accordance with stage one of this protocol. 2. The vaccine to be administered has been identified, by the registered practitioner consenting the individual, as COVID-19 Vaccine AstraZeneca. 3. Consent for vaccination has been provided and documented². <p>Administer COVID-19 Vaccine AstraZeneca and provide any post-vaccination advice.</p>
Vaccine to be administered	COVID-19 Vaccine AstraZeneca 0.5ml dose
Quantity to be supplied / administered	Administer 0.5ml per dose.
Route / method of administration	<p>COVID-19 Vaccine AstraZeneca is for administration by intramuscular injection only, preferably into deltoid region of the upper arm.</p> <p>Vaccinators should administer a 0.5ml dose prepared in accordance with Stage 2 above.</p> <p>If vaccine is not drawn up by the vaccinator, safe procedures must be in place for the vaccinator to safely receive, check, and use the vaccine immediately after preparation.</p> <p>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, clear to slightly opaque solution. Discard the vaccine if particulate matter or differences to the described appearance are observed.</p> <p>Do not shake the vaccine. Do not dilute the solution.</p> <p>The vaccine should not be mixed in the same syringe with any other vaccines or medicinal products.</p> <p>Check product name, batch number and expiry prior to administration.</p> <p>Where the individual has been identified by the assessing registered professional as being at increased risk of bleeding, 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. The individual/carer should be informed about the risk of haematoma from the injection.</p>
Disposal	<p>Follow local clinical waste policy and NHS standard operating procedures and ensure safe and secure waste disposal.</p> <p>Equipment used for immunisation, 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).</p> <p>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, with activity against adenovirus, should be available for managing spills in all settings where vaccination is administered.</p>

Post-vaccination advice	<p>Ensure the individual has been provided appropriate written information such as the:</p> <ul style="list-style-type: none"> • 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 • COVID-19 vaccination and blood clotting • COVID-19 vaccination: a guide to booster vaccination
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STAGE 4: Recording vaccine administration

ACTIVITY STAGE 4:	<p>Complete a record of vaccination for the individual and in accordance with local policy.</p> <p>The required records should be completed by the person who is undertaking the recorded activity or a designated record keeper who is a witness to the activity undertaken.</p>
Records	<p>Record:</p> <ul style="list-style-type: none"> • 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 supervisor, immuniser and, where different from the immuniser, ensure the professional assessing the individual, person preparing the vaccine, and person completing the vaccine record are identified • 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 immunisation • details of any adverse drug reactions and actions taken • supplied via national protocol <p>All records should be clear, legible and contemporaneous.</p> <p>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.</p> <p>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.</p> <p>A record of all individuals receiving treatment under this protocol should also be kept for audit purposes in accordance with local and national policy.</p>

3. Key references

<p>Key references</p>	<p>COVID-19 Vaccine AstraZeneca vaccination</p> <ul style="list-style-type: none"> • Immunisation Against Infectious Disease: The Green Book, Chapter 14a. Published 12 January 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 24 January 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 2 February 2022. https://www.gov.uk/government/publications/covid-19-vaccination-programme-guidance-for-healthcare-practitioners • Regulatory approval of COVID-19 Vaccine AstraZeneca, including Regulation 174 Information for UK Healthcare Professionals and Regulation 174 Information for UK recipients for COVID-19 Vaccine AstraZeneca and Conditions of Authorisation. Published 9 September 2021. https://www.gov.uk/government/publications/regulatory-approval-of-covid-19-vaccine-astrazeneca <p>General</p> <ul style="list-style-type: none"> • 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/ • Regulation 247A, UK Statutory Instrument 2012 No. 1916, The Human Medicines Regulations 2012 https://www.legislation.gov.uk/ukSI/2012/1916/regulation/247A • 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
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4. Practitioner/staff authorisation sheet

COVID-19 Vaccine AstraZeneca protocol v07.00

Valid from: 31 March 2022 Expiry: 1 October 2022

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

By signing this protocol you are indicating that you agree to its contents and that you will work within it.

Protocols do not remove inherent professional obligations or accountability. All persons operating under this protocol must work within their terms of employment at all times; registered healthcare professionals must abide by their professional code of conduct.

It is the responsibility of each person operating under this protocol to do so within the bounds of their own competence.

I confirm that I have read and understood the content of this protocol and that I am willing and competent to work to it.							
Name	Designation	Activity Stage:				Signature	Date
		1	2	3	4		

Authorising registered healthcare professional

I confirm that I, as a registered healthcare professional who is familiar with the competence required in all aspects of this protocol, provide authority on behalf of the below named provider organisation, that the persons named above are competent to work under this protocol and may provide vaccination in accordance with this protocol in the course of working for insert name of organisation / service			
Name	Designation	Signature	Date

Note to authorising registered healthcare professional

Score through unused rows in the list of persons to prevent additions post authorisation.

If the clinical supervisor is also the authorising registered healthcare professional, they may make a self-declaration of competency above