Department of Health
An Roinn Sláinte
Männystrie O Poustie
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Vaccination protocol for COVID-19 Vaccine AstraZeneca (ChAdOx1-S [recombinant])

Reference no:	COVID-19 Vaccine AstraZeneca protocol
Version no:	1.1
Valid from:	26 April 2021
Review date:	1 July 2021
Expiry date:	28 February 2022

This protocol is for the administration of COVID-19 Vaccine AstraZeneca (ChAdOx1-S [recombinant]) to individuals in accordance with the 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 Department of Health has developed this protocol for authorisation by the Minister for Health to facilitate the delivery of the COVID-19 vaccination programme in Northern Ireland.

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 and the general requirements of the Human Medicines Regulations 2012 and Medicines Act 1968, as appropriate. 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 patient. 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 and that adequate supervision arrangements are in place. 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 supervisor, who must be a registered healthcare professional 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. 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 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 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 10 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 Vaccination protocols for COVID-19 Vaccines, authorised by the Minister for Health in accordance with regulation 247A of the HMR 2012, can be found via: **https://www.health-ni.gov.uk/coronavirus**

Change history

Version number	Change details	Date
V1.0	Vaccination Protocol clinically authorised by the Chief Medical Officer, the Chief Nursing Officer and the Chief Pharmaceutical Officer and approved for use by the Minister for Health [DoH document reference HE1/21/174905]	19/03/21
V1.1	➢ Criteria for inclusion updated to reflect new JCVI advice on under 30s; updated to include homeless/rough sleeping in priority group 6; remove note on pregnancy; wording updated to maintain consistency with regional PGD ➢ Criteria for exclusion updated to reflect new JCVI advice on under 30s; a history of a previous episode of heparin-induced thrombocytopenia and thrombosis (HITT or HIT type 2), experienced major venous and/or arterial thrombosis with concomitant thrombocytopenia following the first dose of any COVID-19 vaccine. ➢ Cautions including any relevant action to be taken updated to include information on thrombocytopenia and coagulation disorders; updated to recommend that the second dose should be given at the same location as the first dose; updated to include pregnancy advice from Green Book that Moderna and Pfizer are the preferred vaccines in pregnancy due to more experience/data. ➢ Action to be taken if the patient is excluded updated to include advice on 18 to 29 years olds; a history of a previous episode of heparin-induced thrombocytopenia and thrombosis (HITT or HIT type 2), experienced major venous and/or arterial thrombosis with concomitant thrombocytopenia following the first dose of any COVID-19 vaccine; updated to reflect updated Green Book advice on children. ➢ Dose and frequency of administration updated to clarify advice in the event of a delay in the second dose. ➢ Identification & management of adverse reactions updated to include information on thrombocytopenia and coagulation disorders. ➢ Special considerations / Additional information updated to reflect latest Green Book advice on pregnancy. ➢ Written information to be given to patient or carer updated to include COVID-19 vaccination and blood clotting leaflet ➢ Patient advice / follow up treatment updated to include information on thrombocytopenia and coagulation disorders. [DoH document reference HE1/21/233307]	21/04/21

1. Ministerial and clinical 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 the Minister for Health.

On 26/04/21 the Minister for Health, Robin Swann MLA, approved this protocol in accordance with regulation 247A of the HMR 2012.

Ministerial Authorisation			
Role	**Name**	**Sign**	**Date**
Minister for Health	Robin Swann MLA		26/04/2021

Unless explicitly revoked, the Minister for Health's approval of this protocol remains valid in the event of any subsequent variation to the COVID-19 Astra Zeneca vaccination specifications or key reference material set out in this vaccination protocol.

This protocol provides clinical authorisation for the delivery of the COVID-19 vaccination programme in Northern Ireland.

Clinical Authorisation			
Role	**Name**	**Sign**	**Date**
Chief Medical Officer	Dr Michael McBride		23/04/2021
Chief Nursing Officer	Professor Charlotte McArdle		22/04/2021
Chief Pharmaceutical Officer	Mrs Cathy Harrison		22/04/2021

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

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

Note: The COVID-19 vaccination programme may also be provided under a patient group direction (PGD) 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 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 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 supervisor must be a registered healthcare professional 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[1] c. Provide advice to the individual	Registered Healthcare Professionals Only
Stage 2	Vaccine Preparation	Registered Healthcare Professionals or specified non-registered persons
Stage 3	Vaccine Administration	Registered Healthcare Professionals or specified non-registered persons
Stage 4	Record Keeping	Registered Healthcare Professionals or specified non-registered persons

[1] For those lacking mental capacity, a decision may be made in the individual's best interests in accordance with the common law in Northern Ireland in relation to the best interests of the incapacitous individual

The following specified registered healthcare professionals are permitted to practice under the protocol subject to the requirements set out below:

- Nurses and midwives currently registered with the Nursing and Midwifery Council (NMC).
- Pharmacists currently registered with the Pharmaceutical Society of Northern Ireland (PSNI).
- Chiropodists/podiatrists, dietitians, 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.
- Doctors currently registered with a licence to practise with the General Medical Council.
- Dentists currently registered with the General Dental Council.

The following professionals (who are in the main non-registered) are permitted to practice under the protocol with appropriate supervision as set out below, subject to the requirements set out below:

- Veterinary surgeons currently registered with the Royal College of Veterinary Surgeons.
- Pharmacy technicians, pre-registration pharmacists and other pharmacy support practitioners.
- Retired clinical practitioners who have left the relevant register in good standing: such as doctors, dentists, pharmacists, nurses, optometrists, chiropodists/podiatrists, dietitians, occupational therapists, orthoptists, orthotists/prosthetists, paramedics, pharmacy technicians, physiotherapists, radiographers, speech and language therapists, dental hygienists and dental therapists not currently registered.
- Student doctors, dentists, pharmacists, nurses, midwives, optometrists, chiropodists/podiatrists, dietitians, occupational therapists, orthoptists, orthotists/prosthetists, paramedics, physiotherapists, radiographers, speech and language therapists, dental hygienists and dental therapists not currently registered.
- Healthcare Scientists.
- Dental nurses.
- Physician's Associates.

The following non-registered Armed Forces staff are permitted to administer under the protocol with appropriate supervision as set out below, subject to the requirements set out below:

- Combat Medical Technician – Class 1,2 & 3 (CMT)
- Royal Navy Medical Assistant (RN MA)
- Royal Air Forces Medic
- Defence Medic

Requirements

All those working under this protocol must have undertaken training, be assessed as competent and receive supervision appropriate to the stage of activity they are undertaking. Where multiple person models are used, the provider must ensure that all elements of the protocol are complied with in the provision of vaccination to each individual. The provider 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 must be adhered to.

All persons must be designated by name by the provider as an approved person under the current terms of this protocol before working to it, and listed on the practitioner authorisation sheet in Appendix A. Protocols do not remove inherent obligations or accountability. All practitioners operating under this protocol must work within their terms of employment at all times; registered healthcare professionals should also abide by their professional code of conduct. There are three underpinning principles to which every person undertaking activities under the remit of this protocol must adhere:

1. Training
   - They must have undertaken training appropriate to this protocol and relevant to their role, as required by local policy and UK standard operating procedures and in line with the Training recommendations for COVID-19 vaccinators
   - They must have completed the covid-19 vaccination e-learning programme, including the relevant vaccine specific session, and/or locally-provided COVID-19 Vaccine training

2. Competency
   - Those providing clinical supervision to those administering the vaccine must be competent to assess individuals for suitability for vaccination, identify any contraindications/exclusions or precautions, discuss issues related to vaccination and obtain informed consent from the individuals being vaccinated.
   - They 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 month). They should be observed administering the vaccine until both they, and their supervisor or trainer, feel confident that they have the necessary knowledge and skills to administer vaccines safely and competently.

In addition, and where indicated as relevant to the role:

- They must be familiar with the vaccine product and alert to any changes in the manufacturers summary of product characteristics (SPC), should it become licensed, or the Regulation 174 Information for UK Healthcare Professionals and familiar with the national recommendations for the use of this vaccine.
- They must be familiar with, and alert to changes in relevant chapters of Immunisation Against Infectious Disease: the Green Book COVID-19: the green book, chapter 14a - GOV.UK
- They must be familiar with, and alert to changes in the relevant provider's standard operating procedures (SOPs) and provider's arrangements for the COVID-19 vaccination programme
- They 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.
- They 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.
- They must have access to the provider's protocols and relevant COVID-19 vaccination programme online resources.
- They must be competent in intramuscular injection technique if they are administering the vaccine, this should include a practical element.
- For those preparing the vaccine, they must be competent in the handling of the vaccine product and use of the correct technique for drawing up the correct dose.
- For those in record keeping roles, they must understand the importance of making sure vaccine information is recorded on the vaccination management system
- They should fulfil any additional requirements defined by local policies developed in accordance with any UK guidance.

3. Supervision
   - A period of supervised practice to allow observation of, and development of skills in vaccine administration and application of knowledge to practice is essential. Supervision for new immunisers and support for all immunisers is critical to the safe and successful delivery of the COVID-19 immunisation programme.
   - Non-registered professionals and non-registered Armed Forces staff must be supervised and supported by a registered healthcare professional at all times.
   - The clinical supervisor must be a registered healthcare professional trained and competent in all aspects of the protocol and provide clinical supervision for the overall provision of clinical care provided under the protocol.

3. 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 COVID-19 infection caused by SARS-CoV-2, in accordance with the UK immunisation programme and recommendations given in Chapter 14a of the Immunisation Against Infectious Disease: the 'Green Book', JCVI statement on Priority groups for coronavirus (COVID-19 vaccination), 30 December 2020 and subsequent correspondence/publications from Northern Ireland Department of Health.

4. Clinical information

STAGE 1: Assessment of the individual presenting for vaccination

<table>
<tr><th>ACTIVITY STAGE 1a:</th><th>Assess the individual presenting for vaccination against the inclusion and exclusion criteria below. If they are not eligible for vaccination or need to return at a later date, advise them accordingly.</th></tr>
<tr><td>Clinical condition or situation to which this Protocol applies</td><td>COVID-19 Vaccine AstraZeneca is indicated for the active immunisation of individuals for the prevention of COVID-19 caused by coronavirus (SARS-CoV-2) infection, in accordance with the COVID-19 vaccination programme and recommendations given in Chapter 14a of Immunisation Against Infectious Disease: the 'Green Book' and subsequent correspondence/publications from the Department of Health.</td></tr>
<tr><td>Criteria for inclusion
(continued over page)</td><td>National policy must be followed in relation to the priority groups eligible for vaccination at a particular point in time.
JCVI Phase One
COVID-19 Vaccine AstraZeneca should be offered to individuals, aged 18 years and over, in accordance with Joint Committee on Vaccination and Immunisation (JCVI) guidance on 'Priority groups for coronavirus (COVID-19) vaccination' in the following order of priority, starting with those to be vaccinated first:
<table>
<tr><th>Priority</th><th>Risk group</th></tr>
<tr><td>1</td><td>Residents in a care home for older adults and their carers</td></tr>
<tr><td>2</td><td>All those 80 years of age and over
Frontline health and social care workers (see HSS(MD) 82/2020)</td></tr>
<tr><td>3</td><td>All those 75 years of age and over</td></tr>
<tr><td>4</td><td>All those 70 years of age and over
Clinically extremely vulnerable[2] individuals (see Definition of clinically extremely vulnerable groups)</td></tr>
<tr><td>5</td><td>All those 65 years of age and over</td></tr>
<tr><td>6</td><td>All individuals aged 16 years[3] to 64 years with underlying health conditions which put them at higher risk of serious disease and mortality (see Appendix A or Chapter 14a)[4]</td></tr>
</table></td></tr>
</table>

[2] Individuals who have been identified as clinically extremely vulnerable should have this status flagged in their GP record.
[3] COVID-19 Vaccine AstraZeneca is only authorised for use in those 18 years of age and over (see Criteria for exclusion). COVID-19 mRNA vaccine BNT162b2 may be a suitable alternative for those 16-17 years of age.
[4] This also includes those who are in receipt of a carer's allowance, or those who are the main carer of an elderly or disabled person whose welfare may be at risk if the carer falls ill.

Criteria for inclusion (continued)	

7	All those 60 years of age and over
8	All those 55 years of age and over
9	All those 50 years of age and over

JCVI Phase Two

Phase 2 of the COVID 19 vaccination programme should be offered in accordance with national recommendations and JCVI guidance on the 'Priority groups for phase 2 of the coronavirus (COVID-19) vaccination programme' in the following age-based order of priority, starting with the oldest adults first and proceeding in the following order:

- all those aged 40 to 49 years
- all those aged 30 to 39 years
- all those aged 18 to 29 years olds

Implementation of the COVID-19 vaccination programme should aim to achieve high vaccine uptake whilst prioritising those most at risk. The priority order should be followed if it is reasonably practicable to do so. Implementation should also involve flexibility in vaccine deployment at a local level. Operational considerations, such as minimising wastage, may require a flexible approach to prioritisation, such as advised for detained settings[5], where decisions are taken in consultation with national or local public health experts.

JCVI advises that local teams exercise operational judgment and consider a universal offer to people experiencing homelessness and rough sleeping, alongside delivery of the programme to priority group 6, where appropriate.[5]

Criteria for exclusion[6]

(continued over page)

Individuals for whom valid consent or a 'best-interests' decision in accordance with the common law in Northern Ireland in relation to the best interests of the incapacitous individual has not been received (for further information on consent see Reference guide to consent for examination or treatment).

Individuals who:

- are less than 18 years of age
- are aged 18 to 29 years unless:
  - they are clinically extremely vulnerable or in a clinical risk group (as per JCVI advice) that puts them at high risk of the complications of COVID-19
  - they have already received a first dose of COVID-19 AstraZeneca vaccine without suffering any serious side effects
  - an alternative COVID-19 vaccine is not available and they decide to receive the vaccine after considering all the risks and benefits. Sufficient information must be provided and documented for them to give informed consent to vaccination, including the latest version of the COVID-19 vaccination and blood clotting leaflet.
- have a history of a previous episode of heparin-induced thrombocytopenia and thrombosis (HITT or HIT type 2)

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

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

Criteria for exclusion (continued)	• experienced major venous and/or arterial thrombosis with concomitant thrombocytopenia following the first dose of any COVID-19 vaccine • have had a previous systemic allergic reaction (including immediate-onset anaphylaxis) to a previous dose of the COVID-19 vaccine AstraZeneca or to any component of the vaccine or residues from the manufacturing process[7]. • are suffering from acute severe febrile illness (the presence of a minor infection is not a contraindication for immunisation) • have received a full dose of COVID-19 vaccine in the preceding 28 days • have completed a course of COVID-19 vaccination • are participating in a COVID-19 vaccine clinical trial; unless they have consulted the trial team and have been provided with written advice that they can be safely vaccinated in the routine COVID-19 vaccination programme. **Note:** People participating in a COVID-19 research trial other than a vaccine trial (e.g. survey / questionnaire) can receive the COVID-19 vaccination, provided they fulfil the other inclusion criteria at the time of offer. If there is any doubt please refer to the appropriate clinical trial leads. • are advised by the UK regulator, the Medicines & Healthcare products Regulatory Agency (MHRA), not to receive COVID-19 vaccine AstraZeneca (see Cautions including any relevant action to be taken)
Cautions including any relevant action to be taken (Continued over page)	The COVID-19 chapter of the Green Book advises that there are very few individuals who cannot receive COVID-19 vaccine. Where there is doubt, rather than withholding vaccination, appropriate advice should be sought from the relevant specialist, or from the PHA Duty Room. **Thrombosis and thrombocytopenia occurring after COVID-19 vaccination** A recently recognised condition involving serious thromboembolic events accompanied by thrombocytopenia, has been reported after COVID-19 AstraZeneca vaccination. There is no evidence of any underlying risk factors in the individuals affected by this condition who have mainly been previously healthy. The condition is rare, tends to present with unusual forms of clotting and the mechanism is believed to be an idiosyncratic reaction related to an immune response to the COVID-19 AstraZeneca vaccine. This may be related to the recipient's polymorphisms in genes encoding Fc receptors in the immune system and is an area of active research. Because of this likely immune mechanism, there is no reason to believe that individuals with a past history of clots or of certain thrombophilic conditions would be at increased risk of this very rare condition. Similarly, although pregnancy increases the risk of clotting conditions, there is no evidence that pregnant women, those in the postpartum or women on the contraceptive pill are at higher risk of the specific condition of thrombosis in combination with thrombocytopenia after the COVID-19 AstraZeneca

[7] Excipients include L-Histidine, L-Histidine hydrochloride monohydrate, Magnesium chloride hexahydrate, Polysorbate 80, Ethanol, Sucrose, Sodium chloride, Disodium edetate dehydrate, Water for injections.

Cautions including any relevant action to be taken (continued)	vaccine. There have been no confirmed cases reported in pregnant women to date. Individuals over 30 years of age with past clotting episodes and those diagnosed with thrombophilia, whether or not they are on long term anti-coagulation, remain at risk of COVID-19 disease. There is no evidence that those with a prior history of thrombosis or known risk factors for thrombosis are more at risk of developing this immune-mediated condition of thrombosis in combination with thrombocytopenia after the AstraZeneca 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 with such a history should be vaccinated with any of the available vaccines (provided they are not otherwise contraindicated).The same consideration applies to those who experience common clotting episodes after the first dose of AstraZeneca vaccine but without concomitant thrombocytopenia. As a precautionary measure, administration of the COVID-19 Vaccine AstraZeneca in patients with a history of cerebral venous sinus thrombosis or antiphospholipid syndrome should only be considered when the benefit outweighs any potential risks. Healthcare professionals should be alert to the signs and symptoms of thromboembolism and/or thrombocytopenia. Vaccinated individuals should also 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. Patients 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. **Patients with a history of allergy** Facilities for management of anaphylaxis should be available at all vaccination sites (see Chapter 8 of the Green Book). The AstraZeneca vaccine does not contain polyethylene glycol (PEG) but does contain a related compound called polysorbate 80. Some people with PEG allergy may also be allergic to polysorbate 80. However, polysorbate 80 is widely used in medicines and foods, and is present in many medicines including monoclonal antibody preparations. Some injected influenza vaccines (including the main vaccine used in over 65 year olds) contain polysorbate 80. Individuals who have tolerated injections that contain polysorbate 80 (such as certain influenza vaccines) are likely to tolerate the AstraZeneca vaccine. Patients who have: a previous allergic reaction (including anaphylaxis) to a food, insect sting and most medicines (where trigger has been identified); a family history of allergies; a previous non-systemic reaction to a vaccine; a hypersensitivity to nonsteroidal anti-inflammatory drugs, e.g. aspirin, ibuprofen; a history of mastocytosis may proceed with vaccination as normal, according to local guidelines. Special precautions as described in Chapter 14a of the Green Book, and

Cautions including any relevant action to be taken (continued)	consideration of the possibility of undiagnosed PEG-allergy, is required for individuals with: • history of immediate anaphylaxis to multiple, different drug classes, with the trigger unidentified (this may indicate PEG allergy) • history of anaphylaxis to a vaccine, injected antibody preparation or a medicine likely to contain PEG (such as depot steroid injection, laxative) • history of idiopathic anaphylaxis Such individuals should not be vaccinated with the Moderna mRNA-1273 COVID-19 Vaccine or Pfizer/BioNTech vaccine, except on the expert advice of an allergy specialist and under a patient specific direction (PSD). The COVID-19 AstraZeneca vaccine can be used as an alternative (unless otherwise contraindicated), particularly if they previously tolerated an injected influenza vaccine. **In these circumstances, COVID-19 AstraZeneca vaccine should be administered in a setting with full resuscitation facilities (e.g. a hospital), and a 30 minute observation period is recommended.** A person should have their second dose at the same location as they had their first dose. The location of administration is important for those with a history of previous allergy, because this history of a reaction remains important even if a patient has no reaction to their first dose of a COVID-19 vaccine which provides no guarantee they will not have a reaction to their second dose of vaccine. Patients who experienced an immediate-type allergic reaction to the first dose of COVID-19 vaccine, where symptoms were limited to swelling or rash local to the injection site only, can have the second dose using the same vaccination in any vaccination setting. Observe the patient for 30 minutes. Patients who experienced delayed urticaria / angioedema to the first dose of COVID-19 vaccine, where the reaction was self-limiting or resolved with oral antihistamine, can have the second dose using the same vaccination in any setting. Consider pre-treatment with non-sedating antihistamine, 30 minutes prior to vaccination. Patients who experienced delayed urticaria / angioedema to the first dose of COVID-19 vaccine, where medical attention was required, should be referred to an allergy specialist for advice on the second dose. Syncope (fainting) can occur following, or even before, any vaccination especially in adolescents as a psychogenic response to the needle injection. This can be accompanied by several neurological signs such as transient visual disturbance, paraesthesia and tonic-clonic limb movements during recovery. It is important that procedures are in place to avoid injury from faints. **Pregnancy** Vaccination in pregnancy should be offered in accordance with recommendations in Chapter 14a of the Green Book. 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.

Cautions including any relevant action to be taken (continued)	JCVI has therefore advised that women who are pregnant should be offered vaccination at the same time as non-pregnant women, based on their age and clinical risk group. There is now extensive post-marketing experience of the use of the Pfizer BioNTech and Moderna vaccines in the USA with no safety signals so far (https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafepregnancyregistry.html). COVID-19 Pfizer and Moderna vaccines are the preferred vaccines for pregnant women of any age because of more extensive experience of their use in pregnancy. Pregnant women who commenced vaccination with AstraZeneca, however, are advised to complete with the same vaccine. Clinicians should discuss the risks and benefits of vaccination with the woman, who should be told about the limited evidence of safety for the vaccine in pregnancy. See Special considerations / Additional Information). **Bleeding disorders** Individuals with a bleeding disorder may develop a haematoma at the injection site (see Route of Administration). **Past history of COVID-19 infection** There is no evidence of any safety concerns from vaccinating individuals with a past history of COVID-19 infection, or with detectable COVID-19 antibody. Vaccination of individuals who may be infected but asymptomatic or incubating COVID-19 infection is unlikely to have a detrimental effect on the illness. Vaccination should be deferred in those with confirmed infection to avoid onward transmission and confusing the differential diagnosis. As clinical deterioration can occur up to two weeks after infection, ideally vaccination should be deferred until clinical recovery to around four weeks after onset of symptoms or four weeks from the first confirmed positive specimen in those who are asymptomatic. Having prolonged COVID-19 symptoms is not a contraindication to receiving COVID-19 vaccine but if the individual is seriously debilitated, still under active investigation, or has evidence of recent deterioration, deferral of vaccination may be considered to avoid incorrect attribution of any change in the person's underlying condition to the vaccine. **Vaccine Surveillance** The UK regulator will maintain real-time surveillance post deployment of COVID-19 vaccines in the UK. In response to any safety signals, MHRA may provide temporary advice or make substantive amendments to the authorised conditions of the vaccine product's supply in the UK. Supply under this vaccination protocol must be in accordance with the most up-to-date advice or amendments (see Green Book Chapter 14a and Information for Healthcare Professionals on COVID-19 Vaccine AstraZeneca).

Action to be taken if the patient is excluded (continued overleaf)	In a GP practice setting, inform or refer to the GP or a prescriber as appropriate. 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. In case of postponement due to acute illness, advise when the individual can be vaccinated and, if possible, ensure another appointment is arranged. Individuals who have had a previous systemic allergic reaction (including immediate onset anaphylaxis) to a previous dose of COVID-19 Vaccine AstraZeneca or any component of the vaccine should not receive further COVID-19 Vaccine AstraZeneca. Refer to an allergy specialist. Based on current evidence JCVI is advising a preference for an alternative vaccine for healthy people under 30 years of age, including health and social care workers, unpaid carers and household contacts of immunosuppressed individuals. 18 to 29 year olds should receive an alternative COVID-19 vaccine which uses a different antigen delivery mechanism unless: • they are clinically extremely vulnerable or in a clinical risk group (as per JCVI advice) that puts them at high risk of the complications of COVID-19 • they have already received a first dose of COVID-19 Vaccine AstraZeneca without suffering any serious side effects. Individuals are advised to receive the second dose at the currently recommended interval of around 12 weeks. To date, there have been no confirmed cases of this condition after the second dose and the rate of other reactions is lower at the second dose than after the first dose of this vaccine. Using an alternative product for the second dose may be more likely to lead to common side effects. • an alternative COVID-19 vaccine is not available and they decide to receive the vaccine after considering all the risks and benefits. Document that a full conversation has been had with the individual and that they have been provided with sufficient information for them to give informed consent to vaccination, including the latest version of the COVID-19 vaccination and blood clotting leaflet Individuals with a history of a previous episode of heparin-induced thrombocytopenia and thrombosis (HITT or HIT type 2) should not receive COVID-19 Vaccine AstraZeneca. An alternative COVID-19 vaccine should be considered that uses an alternative antigen delivery technology. Individuals who have experienced major venous and / or arterial thrombosis with concomitant thrombocytopenia following vaccination with any COVID-19 vaccine, should not receive COVID-19 Vaccine AstraZeneca. An alternative COVID-19 vaccine should be considered that uses an alternative antigen delivery technology. Children under 16 years of age, even if they are clinically extremely vulnerable, are at low risk of serious morbidity and mortality and, given the absence of safety and efficacy data on the vaccine, are not recommended for vaccination. Limited data suggest that children with neurological

Action to be taken if the patient is excluded (continued)	comorbidities may be at greater risk of developing severe COVID-19. Refer to Green Book Chapter 14a for up-to-date advice on COVID-19 vaccination in children. The Pfizer BioNTech vaccine has approval for use from 16 years old and currently has the most extensive safety data in those aged 12-15 years. This vaccine is therefore the preferred vaccine in this age group. It is likely that Moderna will have similar safety profile and may therefore be used as an alternate, "off-licence". Young people who have had a first dose of AstraZeneca vaccine, however, should complete with the same vaccine. **Note:** vaccination in children under 18 years of age is not covered by this vaccination protocol (a PSD would be required). Individuals who are participating in a clinical trial of COVID-19 vaccines who present for vaccination should be referred back to the investigators unless they have written advice in relation to receiving the COVID-19 vaccine in the routine programme. Document the reason for exclusion and any action taken in the individual's clinical records. Advice should be sought from the individual's clinician in the first instance. Further advice also may be provided from the PHA Immunisation Team: pha.immunisation@hscni.net.
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 the common law in Northern Ireland in relation to the best interests of the incapacitous individual, a decision to vaccinate may be made in the individual's best interests. Advise individual/parent/carer about the protective effects of the vaccine, the risks of infection and potential complications if not immunised. Advise how future immunisation may be accessed if they subsequently decide to receive the COVID-19 Vaccine. Document advice given and the decision reached. Inform or refer to the GP or a prescriber as appropriate.
Arrangements for referral for medical advice	Seek appropriate advice from the individual's clinician as required.

STAGE 1b: Description of treatment

ACTIVITY STAGE 1b:	**Consider any relevant cautions, interactions or adverse drug reactions. Provide advice to the individual and obtain informed consent[1]. Record individual's consent[1] and ensure vaccinator, if another person, is informed of the vaccine product to be administered.**
Name, strength & formulation of drug	COVID-19 Vaccine AstraZeneca, solution for injection, in a multi-dose vial. Each 4ml vial contains 8 doses and each 5ml vial contains 10 doses of vaccine. The vaccine is a colourless to slightly brown, clear to slightly opaque liquid (see Route / Method of Administration).
Legal category	COVID-19 Vaccine AstraZeneca is provided temporary authorisation by the Medicines and Healthcare products Regulatory Agency (MHRA) for supply in the UK under regulation 174 and 174A, pending UK marketing authorisation. The regulation 174 authorised product is categorised as a prescription only medicine (POM).
Black triangle▼	COVID-19 Vaccine AstraZeneca did not have a UK marketing authorisation at the time this Protocol was written and is authorised for temporary supply in the UK in accordance with a Regulation 174 authorisation. As a new vaccine product, MHRA has a specific interest in the reporting of adverse drug reactions for this product, see https://yellowcard.mhra.gov.uk/the-yellow-card-scheme/
Off-label use	COVID-19 Vaccine AstraZeneca is supplied in the UK in accordance with regulation 174 and did not have a UK marketing authorisation at the time of writing this vaccination protocol. 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 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.
Drug interactions Continued over page	**Immunosuppression** Although COVID-19 Vaccine AstraZeneca contains a live adenovirus vector, this virus is non-replicating and is considered safe in immunosuppressed people. Individuals with immunosuppression may not make a full immune response to vaccination. The small number of patients who are about to receive planned immunosuppressive therapy should be considered for vaccination prior to commencing therapy (ideally at least two weeks before), when their immune system is better able to make a response. Where possible, it would also be preferable for the 2-dose schedule to be completed prior to commencing immunosuppression. This would entail offering the second dose at the recommended minimum for that vaccine (three or four weeks from the first dose) to provide maximum benefit that may not be received if the second dose was given during the period of immunosuppression. Any decision to defer immunosuppressive therapy or to delay possible benefit from vaccination until after therapy should not be taken without due consideration of the risks from COVID-19 and from their underlying condition.

Drug interactions (continued)	**Co-administration with other vaccines** 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 (see Chapter 11 of Green Book). 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. Because of the absence of data on co-administration with COVID-19 Vaccines, it should not be routine to offer appointments to give this vaccine at the same time as other vaccines. Based on current information about the first COVID-19 Vaccines being deployed, scheduling should ideally be separated by an interval of at least 7 days to avoid incorrect attribution of potential adverse events. As COVID-19 Vaccine AstraZeneca is considered inactivated, where individuals in an eligible cohort present having received another inactivated or live vaccine, COVID-19 vaccination should still be considered. The same applies for other live and inactivated vaccines where COVID-19 vaccination has been received first. In many cases, vaccination should proceed to avoid any further delay in protection and to avoid the risk of the patient not returning for a later appointment. In such circumstances, patients should be informed about the likely timing of potential adverse events relating to each vaccine.
Identification and management of adverse reactions (continued overleaf)	From early phase trials, mild pain and tenderness at the injection site was common with COVID-19 vaccine AstraZeneca occurring in 88% of 18-55 year olds, 73% of 56-69 year olds and 61% of people aged 70 years or over; similar levels were reported after each dose. Short lived systemic symptoms including fatigue and headache were also common but decreased with age, being reported in 86%, 77%, and 65% of those aged 18-55, 56-69 and 70 years or over respectively; most of these were classified as mild or moderate. These reactions were unusual after the second dose (Ramasamy et al, 2020). In the phase 3 study only 1 serious adverse event was reported as possibly linked to the study vaccine. This was a case of transverse myelitis which occurred 14 days after dose 2. (Voysey et al, 2020). Recently, a rare condition involving serious thromboembolic events accompanied by thrombocytopenia, has been reported after AstraZeneca vaccination. The condition presents with unusual venous thrombosis, including cerebral venous sinus thrombosis, portal vein thrombosis, and sometimes arterial thrombosis, with low platelet count and high D-dimer measurements. The condition has similarities to heparin-induced thrombocytopenia and thrombosis (HITT or HIT type 2) and patients usually have positive antibody to platelet factor 4. The majority of the events occurred between 5 and 16 days following vaccination (Greinacher et al, 2021). The current reported rate of this event in the UK is around 5 per million, although a higher incidence appears to be seen in younger individuals. Overall, the JCVI, MHRA and the WHO remain clear that the benefits of vaccination outweigh this small risk for adults aged 30 years and over, adults who are clinically extremely vulnerable and those with underlying clinical risks as defined in Chapter 14a of the Green Book. As with all vaccines there is a very small possibility of anaphylaxis and facilities for its management must be available. A protocol for the management of anaphylaxis and an anaphylaxis pack must always be available whenever the COVID-19 vaccine AstraZeneca is given. Immediate treatment should include early treatment with 0.5mg intramuscular adrenaline (0.5ml of 1:1000 or

Identification and management of adverse reactions (continued)	1mg/ml adrenaline), with an early call for help and further IM adrenaline every 5 minutes. The health professionals overseeing the immunisation service must be trained to recognise an anaphylactic reaction and be familiar with techniques for resuscitation of a patient with anaphylaxis. In the event of a severe adverse reaction individual should be advised to seek medical advice. For a list of adverse reactions for the vaccine refer to Information for Healthcare Professionals on COVID-19 Vaccine AstraZeneca . 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.
Reporting procedure of adverse reactions	Healthcare professionals and individuals/carers should report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on: http://yellowcard.mhra.gov.uk or search for MHRA Yellow Card in the Google Play or Apple App Store. As a new vaccine product, MHRA have a specific interest in the reporting of adverse drug reactions for this product, see https://yellowcard.mhra.gov.uk/the-yellow-card-scheme/. There is also a specific reporting page for COVID-19 vaccinations: https://coronavirus-yellowcard.mhra.gov.uk/ Any adverse reaction to a vaccine should be documented in the individual's record and the individual's GP should be informed. Anaphylaxis is a very rare, recognised side effect of most vaccines and suspected cases should be reported via the Coronavirus Yellow Card Scheme. Chapter 8 of the Green Book gives detailed guidance on distinguishing between faints, panic attacks and the signs and symptoms of anaphylaxis. If a case of suspected anaphylaxis meets the clinical features described in Chapter 8 of the Green Book, this should be reported via the Yellow Card Scheme as a case of 'anaphylaxis' (or if appropriate 'anaphylactoid reaction'). Cases of less severe allergic reactions (i.e. not including the clinical features of anaphylaxis) should not be reported as anaphylaxis but as 'allergic reaction'. Programmatic Adverse Events should be recorded in line with local procedures and where appropriate escalated in accordance with UK frameworks.
Written information to be given to patient or carer	Ensure the individual has been provided appropriate written information such as the: • Package leaflet: Information for the user for COVID-19 Vaccine AstraZeneca (from European Medicines Agency) • 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 leaflet

Patient advice / follow up treatment	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. The individual/carer should be advised to seek medical advice in the event of an adverse reaction. Vaccinated individuals should be advised that it is common to develop a fever after vaccination and that this normally happens within 48 hours after the vaccination and usually goes away within 48 hours. This is a common, expected reaction, and self-isolation and testing for COVID-19 are not required unless the individual has other COVID-19 symptoms; has been told by PHA Contact Tracing Services they are a close contact of someone who has tested positive for COVID-19; they live with someone who has recently tested positive for COVID-19; or they live with someone who has symptoms of COVID-19. Vaccinated individuals should be advised that if the fever started 48 hours after the vaccination or lasts longer than 48 hours, they should self-isolate and book a test. Vaccinated individuals should be advised that feeling generally unwell, shivery, achy and tired were also symptoms commonly reported by vaccine recipients in the clinical trials. Generally, these symptoms were found to resolve within one to two days without treatment but paracetamol can be taken if necessary to relieve any of these symptoms. As has always been recommended, any fever after vaccination should be monitored and if individuals are concerned about their health at any time, they should seek advice from their GP. **Thrombocytopenia and coagulation disorders** Advise patients to seek urgent medical advice if they experience any of the following symptoms more than 4 days and within 28 days of coronavirus vaccination: • new onset of severe headache, which is getting worse and does not respond to simple painkillers • an unusual headache which seems worse when lying down or bending over, or may be accompanied by blurred vision, nausea and vomiting, difficulty with speech, weakness, drowsiness or seizures • new unexplained pinprick bruising or bleeding • shortness of breath, chest pain, leg swelling or persistent abdominal pain. If there is any clinical concern, patients should be urgently referred to hospital and to appropriate specialist services for further assessment, particularly if the symptoms are unexplained and present in combination with thrombocytopenia. Further guidance for secondary care is available from British Society for Haematology. The individual should be advised to seek medical advice in the event of a severe adverse reaction. Inform the individual that they can report suspected adverse reactions to the MHRA using the Yellow Card reporting scheme on: https://coronavirus-yellowcard.mhra.gov.uk When administration is postponed advise the individual how future vaccination may be accessed. When applicable, advise the individual/carer when to return for vaccination or when a subsequent vaccine dose is due.

Special considerations / additional information Continued over page	Ensure there is immediate access to adrenaline (epinephrine) 1 in 1,000 injection and access to a telephone at the time of vaccination. A protocol for the management of anaphylaxis and an anaphylaxis pack must be readily available in case of an anaphylactic event. Immediate treatment should include early treatment with 500 micrograms intramuscular adrenaline (0.5ml of 1:1000 or 1mg/ml adrenaline), with an early call for help and further IM adrenaline every 5 minutes if features of anaphylaxis do not resolve. Minor illnesses without fever or systemic upset are not valid reasons to postpone immunisation. If an individual is acutely unwell, immunisation may 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. **Pregnancy** There is no known risk associated with giving inactivated, recombinant viral or bacterial vaccines or toxoids during pregnancy or whilst breast-feeding. Since inactivated vaccines cannot replicate they cannot cause infection in either the mother or the fetus. Although COVID-19 vaccine AstraZeneca contains a live adenovirus vector, this virus is non-replicating so will not cause infection in the mother or the fetus. As with most pharmaceutical products, specific clinical trials of coronavirus vaccines in pregnant women have not been carried out. Developmental and reproductivity testing of the Pfizer BioNTech, Moderna and AstraZeneca COVID-19 vaccines have not raised any concerns. Adenovirus vectors, similar to those used in the AstraZeneca COVID-19 vaccine, have been widely used to vaccinate women against Ebola without raising any concern; formal trials of these vaccines in pregnancy are due to proceed. Although clinical trials on the use of COVID-19 vaccines during pregnancy are not advanced, the available data do not indicate any harm to pregnancy. JCVI has therefore advised that women who are pregnant should be offered vaccination at the same time as non-pregnant women, based on their age and clinical risk group. There is now extensive post-marketing experience of the use of the Pfizer BioNTech and Moderna vaccines in the USA with no safety signals so far (https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafepregnancyregistry.html). These vaccines are therefore the preferred vaccines to offer to pregnant women. Clinicians should discuss the risks and benefits of vaccination with the woman, who should be told about the limited evidence of safety for the vaccine in pregnancy. If a woman finds out she is pregnant after she has started a course of vaccine, she may complete vaccination during pregnancy using the same vaccine product (unless contraindicated). Alternatively, vaccination should be offered as soon as possible after pregnancy. Note: The Royal College of Obstetricians and Gynaecologists has produced a decision aid to support women to make a personal informed choice, in discussion with a healthcare professional, about whether to accept a COVID-19 vaccination in pregnancy (see https://www.rcog.org.uk/covid-vaccine). 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 can be vaccinated with a suitable product for their age and clinical risk group. Termination of pregnancy following inadvertent immunisation should not be recommended. Surveillance of the inadvertent administration of COVID-19 vaccines in early pregnancy is being conducted for the UK by the PHE Immunisation Department, to whom such cases should be reported at this link:

Special considerations / additional information (continued)	https://www.gov.uk/guidance/vaccination-in-pregnancy-vip. As above, women who are inadvertently vaccinated in early pregnancy should be offered the second dose of the same product. **Breastfeeding** It is unknown whether COVID-19 vaccine AstraZeneca is excreted in human milk. There is no known risk associated with giving non-live vaccines whilst breastfeeding. JCVI advises that breastfeeding women may be offered vaccination with the Pfizer-BioNTech or AstraZeneca COVID-19 vaccines. The developmental and health benefits of breastfeeding should be considered along with the woman's clinical need for immunisation against COVID-19, and the woman should be informed about the absence of safety data for the vaccine in breastfeeding women. **Previous incomplete vaccination** If the course is interrupted or delayed, it should be resumed using the same vaccine but the first dose should not be repeated. There is no evidence on the interchangeability of the COVID-19 vaccines although studies are underway. Therefore, every effort should be made to determine which vaccine the individual received and to complete the course with the same vaccine. For individuals who started the schedule and who attend for vaccination at a site where the same vaccine is not available, or if the first product received is unknown, it is reasonable to offer one dose of the locally available product to complete the schedule. This option is preferred if the individual is likely to be at immediate high risk or is considered unlikely to attend again. In these circumstances, as COVID-19 vaccines are based on the spike protein, it is likely the second dose will help to boost the response to the first dose.

STAGE 2: Vaccine Preparation

ACTIVITY STAGE 2:	Vaccine preparation
Vaccine presentation	COVID-19 Vaccine AstraZeneca, solution for injection in multi-dose container COVID-19 Vaccine (ChAdOx1-S [recombinant]): • 5ml of solution in a 10-dose vial • 4ml of solution in an 8-dose vial
Supplies	A central supply of COVID-19 Vaccine AstraZeneca has been procured in response to the COVID-19 pandemic. COVID-19 Vaccine AstraZeneca is supplied as a 4ml multi-dose vial, providing 8 doses per vial or a 5ml multi-dose vial providing 10 doses per vial, and supplied with 10 vials per pack. Standard operating procedures should be followed for appropriate storage, handling, preparation, administration and waste minimisation of vaccine.
Storage (continued overleaf)	The COVID-19 Vaccine AstraZeneca should be stored at +2ºC to +8ºC and has a shelf life of 6 months. Do not freeze. The vaccine does not contain any preservative. After first opening the vial, it should be used within 6 hours (and stored between 2ºC and 25ºC during the in-use period). After this time, the vial must be discarded.

Storage (continued)	Label vial with the expiry time after first use. Once a dose is withdrawn from the vial it should be administered immediately. Store in original packaging in order to protect from light. 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. Practitioners should follow the most up to date manufacturer's recommendations in the Information for Healthcare Professionals on COVID-19 Vaccine AstraZeneca Breaches in the cold-chain should be reported in line with local arrangements. Vaccines that have been stored outside of the cold-chain should be quarantined and further advice re use should be sought from the local Trust's Pharmacy Department or Medicines Information Service. Vaccine losses outside of secondary care should be reported to the PHA Duty Room (0300 555 0119) for further risk assessment, including whether patients need revaccination following a cold chain breach.
Vaccine preparation	Vaccine should be prepared in accordance with the manufacturer's recommendations (see Information for Healthcare Professionals on COVID-19 Vaccine AstraZeneca) and HSC standard operating procedures for the service. Inspect visually prior to administration and ensure appearance is consistent with the description in the Information for Healthcare Professionals on COVID-19 Vaccine AstraZeneca 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. Do not shake the vial. Check product name, batch number and expiry date prior to administration. Aseptic technique should be used for withdrawing each vaccine dose of 0.5 ml into a syringe for injection to be administered intramuscularly. 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. A 1ml syringe with a 23g/25g x 25mm needle will be provided for administration.
Disposal	Equipment used for immunisation, including used vials, ampoules, or discharged vaccines in a syringe or applicator, should be disposed of safely in a UN-approved puncture-resistant 'sharps' box, according to local authority regulations and guidance in the technical memorandum 07-01: Safe management of healthcare waste (Department of Health, 2013). COVID-19 Vaccine AstraZeneca contains genetically modified organisms (GMOs). Sharps waste and empty vials should be placed into purple lidded waste bins and sent for incineration; there is no need for specific designation as GMO waste. An appropriate virucidal disinfectant should be available for managing spills in all settings where vaccination is administered. Potentially contaminated gloves and aprons can be disposed in yellow/black striped offensive waste bags.

STAGE 3: Vaccine Administration

ACTIVITY STAGE 3:	**Before administering the vaccine, ensure:** **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 documented[1]** **Administer COVID-19 Vaccine AstraZeneca and provide any post-vaccination advice.**
Vaccine to be administered	COVID-19 Vaccine AstraZeneca 0.5ml dose
Dose and frequency of administration	The COVID-19 vaccine AstraZeneca vaccination course consists of two separate doses of 0.5 ml each. The second dose should be administered between 4 and 12 weeks after the first dose, or in accordance with official national guidance at the time. The second dose of the vaccine should be routinely scheduled between 4 and 12 weeks after the first dose. This will allow more people to benefit from the protection provided from the first dose during the roll out phase. Longer term protection will then be provided by the second dose. See Drug Interactions section for advice on dosing interval for individuals who are about to receive planned immunosuppressive therapy. If an interval longer than the recommended interval is left between doses, the second dose should still be given (preferably using the same vaccine as was given for the first dose if possible). The course does not need to be restarted. If the course is interrupted, it should be resumed (using the same vaccine) but not repeated. In these eventualities, the second dose can still be given under this vaccination protocol. Individuals may not be fully protected until at least 7 days after their second dose of the vaccine. There is no evidence on the interchangeability of the COVID-19 vaccines although studies are underway. Therefore, every effort should be made to determine which vaccine the individual received and to complete with the same vaccine. For individuals who started the schedule and who attend for vaccination at a site where the same vaccine is not available, or if the first product received is unknown, it is reasonable to offer a single dose of the locally available product. This option is preferred if the individual is likely to be at immediate high risk or is considered unlikely to attend again. In these circumstances, as both the vaccines are based on the spike protein, it is likely the second dose will help to boost the response to the first dose. For this reason, until additional information becomes available, further doses are not required.
Duration of treatment	See 'Dose and frequency of administration' above. Booster doses of COVID-19 Vaccines are not yet recommended because the need for, and timing of, boosters has not yet been determined.

Quantity to be supplied / administered	Administer 0.5ml A two-dose course should be completed (see Dose and frequency of administration**)**.
Route / method of administration	COVID-19 Vaccine AstraZeneca is for administration by intramuscular injection only, preferably into deltoid region of the upper arm. Vaccinators should administer a 0.5ml dose prepared in accordance with Stage 2 above. If vaccine is not drawn up by the vaccinator, safe procedures must be in place for the vaccinator to receive, check, and use the vaccine immediately after preparation. Do not shake the vaccine. Check product name, batch number and expiry prior to administration. 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. Do not shake the vial. **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. Each vial contains at least the number of doses stated. It is normal for liquid to remain in the vial after withdrawing the final dose. When low dead volume syringes and/or needles are used, the amount remaining in the vial may be sufficient for an additional dose. Care should be taken to ensure a full 0.5ml dose is administered. Where a full 0.5ml dose cannot be extracted, the remaining volume should be discarded. 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. The site at which each vaccine was given should be noted in the individual's records. As with other intramuscular injections, COVID-19 Vaccine AstraZeneca should be given with caution to individuals with thrombocytopenia, any coagulation disorder or to persons on anticoagulation therapy, because bleeding or bruising may occur following an intramuscular administration in these individuals. According to the Green Book, 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 is below the upper level of the therapeutic range, can receive intramuscular vaccination. A fine needle (23 or 25 gauge) should be used for the vaccination, followed by firm pressure applied to the site without rubbing for at least 2 minutes

	(ACIP 2019). The individual/parent/carer should be informed about the risk of haematoma from the injection.
Disposal	Equipment used for immunisation, including used vials, ampoules, or discharged vaccines in a syringe or applicator, should be disposed of safely in a UN-approved puncture-resistant 'sharps' box, according to local authority regulations and guidance in the technical memorandum 07-01: Safe management of healthcare waste (Department of Health, 2013). COVID-19 Vaccine AstraZeneca contains genetically modified organisms (GMOs). Sharps waste and empty vials should be placed into purple lidded waste bins and sent for incineration; there is no need for specific designation as GMO waste. An appropriate virucidal disinfectant should be available for managing spills in all settings where vaccination is administered. Potentially contaminated gloves and aprons can be disposed in yellow/black striped offensive waste bags.
Observation following vaccination	Recipients of COVID-19 Vaccine AstraZeneca should be observed for any immediate reactions, ideally for 15 minutes, but as a minimum recipients should be observed for the period they are receiving any post-immunisation information and subsequent appointment if required. As syncope (fainting) can occur following vaccination, all vaccinees should either be driven by someone else or should not drive for 15 minutes after vaccination. For patients with a history of immediate anaphylaxis to multiple, different drug classes, with the trigger unidentified (this may indicate PEG allergy) or a history of anaphylaxis to a vaccine, injected antibody preparation or a medicine likely to contain PEG (e.g. depot steroid injection, laxative) or a history of idiopathic anaphylaxis, the vaccine should be administered following the advice of an allergy specialist, **in a setting with full resuscitation facilities (e.g. a hospital), and a 30 minute observation period is recommended.** Patients who experienced an immediate-type allergic reaction to the first dose of COVID-19 Vaccine, where symptoms were limited to swelling or rash local to the injection site only, can have the second dose using the same vaccination in any vaccination setting. Observe the patient for 30 minutes. Patients who experienced delayed urticaria / angioedema to the first dose of COVID-19 Vaccine, where the reaction was self-limiting or resolved with oral antihistamine, can have the second dose using the same vaccination in any setting. Consider pre-treatment with non-sedating antihistamine, 30 minutes prior to vaccination.
Post-vaccination advice	Ensure the individual has been provided appropriate written information such as the: • Regulation 174 Information for UK recipients for COVID-19 Vaccine AstraZeneca • COVID-19 Vaccination Record Card • What to expect after your COVID-19 vaccination • COVID-19 vaccination and blood clotting leaflet

STAGE 4: Recording vaccine adminstration

ACTIVITY STAGE 4:	**Complete a record of vaccination for the individual and in accordance with local policy.** **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.**
Records	Verbally confirm individual's name, address, date of birth, HSC number (for healthcare professionals) and Record data required by the data capture form (including): • that valid informed consent was given or a decision to vaccinate made in the individual's best interests in accordance with the common law in Northern Ireland in relation to the best interests of the incapacitous individual • clinical risk group indication for immunisation if applicable • 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 • anatomical site of vaccination • advice given, including advice given if excluded or declines immunisation • details of any adverse drug reactions and actions taken, supplied and administered via this Vaccination Protocol Records should be signed and dated by the practitioner. All records should be clear, legible and contemporaneous. It is important that vaccinations given either at a general practice or elsewhere are recorded on appropriate health records for the individual (using the appropriate clinical code) in a timely manner. If given elsewhere, systems should be in place to ensure a record of vaccination is returned to the individual's general practice to allow clinical follow up and to avoid duplicate vaccination. A record of all individuals receiving treatment under this vaccination protocol should also be kept for audit purposes in accordance with local policy.

5. Key references

Key references	**COVID-19 (AstraZeneca) Vaccination** • Immunisation Against Infectious Disease: The Green Book, Chapter 14a. Published 27 November 2020. https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book • Priority groups for coronavirus (COVID-19) vaccination: advice from the JCVI, 30 December 2020 • https://www.gov.uk/government/publications/priority-groups-for-coronavirus-covid-19-vaccination-advice-from-the-jcvi-30-december-2020 • Coronavirus (Covid-19): Shielded patients list. NHS Digital. Updated 18 August 2020. https://digital.nhs.uk/coronavirus/shielded-patient-list • Coronavirus (COVID-19): definitions of 'clinically extremely vulnerable' and 'vulnerable' https://www.nidirect.gov.uk/articles/coronavirus-covid-19-definitions-clinically-extremely-vulnerable-and-vulnerable • Information for Healthcare Professionals on COVID-19 Vaccine AstraZeneca (Manufacturer's product information), 30 Dec 2020. https://www.gov.uk/government/publications/regulatory-approval-of-covid-19-vaccine-astrazeneca • Clinical guidance for healthcare professionals on maintaining immunisation programmes during COVID-19. https://www.england.nhs.uk/coronavirus/publication/preparedness-letters-for-general-practice/ • Immunisation training, Public Health Agency https://www.publichealth.hscni.net/directorate-public-health/health-protection/immunisationvaccine-preventable-diseases • COVID-19 Vaccination e-learning programme https://www.e-lfh.org.uk/covid-19-vaccination-e-learning-programme-now-live/ • Joint Committee on Vaccination and Immunisation (JCVI). https://www.gov.uk/government/groups/joint-committee-on-vaccination-and-immunisation#influenza-vaccines-jcvi-advice • Department of Health NI. Deployment of the Covid-19 Vaccine in Northern Ireland, 7th Dec 2020. https://www.health-ni.gov.uk/sites/default/files/publications/health/doh-hss-md-82-2020.pdf • Joint Committee on Vaccination and Immunisation (JCVI). Optimising the COVID-19 vaccination programme for maximum short-term impact, 26 January 2021 https://www.gov.uk/government/publications/prioritising-the-first-covid-19-vaccine-dose-jcvi-statement/optimising-the-covid-19-vaccination-programme-for-maximum-short-term-impact • HSS(MD)13/2021: Updated guidance on timing of COVID-19 Vaccine dosing interval in patients due to receive treatment with immunosuppressants, 28 January 2021 https://www.health-ni.gov.uk/publications/letters-and-urgent-communications-2020

	General • Health Technical Memorandum 07-01: Safe Management of Healthcare Waste. Department of Health 20 March 2013 https://www.gov.uk/government/publications/guidance-on-the-safe-management-of-healthcare-waste • National Minimum Standards for Immunisation Training (2018) https://www.gov.uk/government/publications/national-minimum-standards-and-core-curriculum-for-immunisation-training-for-registered-healthcare-practitioners • PHE Guidance on immunisation training during the COVID-19 pandemic. 26 June 2020. https://www.gov.uk/government/publications/immunisation-training-guidance-during-the-covid-19-pandemic/guidance-on-immunisation-training-during-the-covid-19-pandemic • PHE Immunisation Collection https://www.gov.uk/government/collections/immunisation • PHE Vaccine Incident Guidance https://www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors • Reference guide to consent for examination or treatment, Department of Health. Published 4 August 2009. https://www.gov.uk/government/publications/reference-guide-to-consent-for-examination-or-treatment-second-edition • Immunisation knowledge and skills competence assessment tool. Royal College of Nursing (RCN) 2018 https://www.rcn.org.uk/professional-development/publications/pdf-006943 • Guidance on vaccine handling and storage in GP practices. PHA and HSCB, January 2020 http://primarycare.hscni.net/pharmacy-and-medicines-management/resources/vaccines/ • Regulation 247A, UK Statutory Instrument 2012 No. 1916, The Human Medicines Regulations 2012 https://www.legislation.gov.uk/uksi/2012/1916/regulation/247A

APPENDIX A

COVID-19 Vaccine AstraZeneca protocol V1.0 Valid from: 26/04/2021 Expiry: 28/02/2022

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.