



COVID-19 VACCINATION OF PATIENTS AGED OVER 80 STANDARD OPERATING PROCEDURE

Initiated:	06/01/2021
Review:	15/01/2021 and as required

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Reviewed, Authorised and Signed off by: COVID-19 Vaccination Population Delivery Group

DOCUMENT HISTORY & CHANGES

- Changes necessitate reissue of the SOP incrementing the version number.
- Changes since the last version are added to the changes log below and all subsequent changes logged in chronological order.
- Changes to page 1 or headers and footers are not included in the changes log.

Changes Applied to Version	Section	Date	Brief Description of Change
V.0.1		06/01/21	New SOP
V.0.2		15/01/2021	General updates to processes

1. PURPOSE

The aim of this document is to outline the standardised approach for the delivery of the COVID-19 vaccination programme using the AstraZeneca COVID-19 Vaccine (ChAdOx1-S [Recombinant]) vaccine for the over 80s population in Greater Glasgow and Clyde.

The programme will be delivered through a mix of clinics in practice premises or locally agreed HSCP venues. On the whole this cohort will be immunised by practice employed staff with the exception of certain GP surgeries who will have local arrangements in place. A housebound programme will be run by HSCPs for those unable to attend in practice.

2. BACKGROUND

The objective of the COVID-19 immunisation programme is to protect those who are at highest risk from serious illness or death. The Joint Committee of Vaccination and Immunisation (JCVI) set out a prioritisation for persons at risk. This placed those patients aged 80 years and above as a priority.

3. DESCRIPTION

Covid-19 and Social Distancing Measures

Clinics should be set up in line with social distancing measures and should ensure appointments are arranged to support the reduction in likelihood of overcrowding or queues.

Appropriate PPE should be worn and alcohol gel/handwashing facilities should be readily available for staff and patients.

Vaccine Supply

Initial vaccine supply will be arranged for GP Practices and Movianto will confirm the exact date of delivery, which should be on your normal delivery day. Following initial delivery, the ordering process will revert to standard arrangements.

<p>First 3 weeks January 'initial supply'</p>	<p>GPs do not need to place an order for the initial batch, this is being co-ordinated on their behalf. The initial supply is enough for every practice to receive one pack of 100 doses, the 55 practices with the largest 'over 80s population' will receive a 2nd pack.</p> <p>Movianto will confirm the exact date of your delivery, which should be on your usual delivery day. Deliveries are scheduled from 6 January and in the week of 11 and 18 January. There are a number of variables which may change this timeline.</p>
<p>Subsequent supply</p>	<p>Until further notice, the Board has been asked to continue to coordinate with National Procurement. Our current expectation is that your next delivery will take place in the week of 25 January and that this should be sufficient for your remaining over 80s (to the nearest box of 100/80)</p>

PPE and Sundries

Needles & syringes will be provided with the vaccine. Leaflets will also be provided with the vaccine.

PPE and other sundries required to run a vaccination clinic should be ordered through the normal process.

Sharps Disposal

Items used for administering the COVID-19 vaccinations should be disposed of in a blue lidded sharps container. While this is correct, blue lidded sharps containers are rarely used in GP practices across Greater Glasgow & Clyde. For the foreseeable future, Tradebe will be treating **ALL** orange lidded sharps containers as blue lidded sharps containers. Therefore if you are administering COVID-19 vaccinations you can continue to use the orange lidded sharps containers you currently have, until they become routinely available.

Patient Call

GP Practices will manage all appointing, administration and contact with patients, including circumstances where the delivery venue has been organised by the HSCP. Practices should schedule appointments as soon as they possibly can with available vaccine supplies to ensure this cohort is vaccinated as early as possible. Appointments should be scheduled when Movianto confirm delivery date. The below principles should be followed:

- Patient should be invited in age order, inviting the oldest patients first.
- All Patients aged 80 and over on or before 31 March 2021

Second dose - a second dose should be scheduled 12 weeks after the first dose.

PHS have produced a generic invite letter, available in the appendix of Version 0.1

Consent

Consent must be given voluntarily and freely. The individual must be informed about the process, benefits and risks of immunisation and be able to communicate their decision. Information given should be relevant to the individual patient, properly explained. There is no legal requirement for consent to immunisation to be in writing and a signature on a consent form is not conclusive proof that consent has been given, but serves to record the decision and the discussions that have taken place with the patient or the person giving consent and questions should be answered fully. Please see Green Book Consent Chapter: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/144250/Green-Book-Chapter-2-Consent-PDF-77K.pdf

Peer Immunisation

All practices have now received details of how to book patient facing staff (in clinical and non-clinical roles) for vaccination through the NHSGGC staff vaccination programme. This is the primary route for staff vaccination and all eligible staff will be able to access appointments for first dose no later than first week of February.

GPs and practice staff should continue to book in through that process. Peer immunisation in practices using the Astra Zeneca vaccine can be considered for priority patient facing GP practice staff for example, vaccinators, if they have been unable to access vaccination prior to the programme starting in practices. Peer immunisation using the practice vaccine allocation should only be for patient facing staff in line with current priority groups: <https://www.gov.uk/government/publications/priority-groups-for-coronavirus-covid-19-vaccination-advice-from-the-jcvi-30-december-2020> or where there is likely to be vaccine wastage (see Avoiding Covid-19 Vaccine Wastage)

Where GPs or practice staff are immunised in the practice, this **MUST** be recorded using the

TURAS app which will enable the vaccination to be recorded and the staff members' own GP record to be updated.

TURAS Vaccine Management Tool (VMT)/Data recording

There are 3 options for data recording for patients over the age of 80:

1. The Scottish Government are advocating use of the TURAS Vaccine Management Tool which can be accessed via phone, tablet device or PC. Practice systems will be updated with information recorded through this tool.
 - a. For an overview: [Link to YouTube video](#)
 - b. To access the tool: [TURAS Vaccination Management Tool link](#)
 - c. Log in is with your normal TURAS account name & password.
 - d. If you do not have a Turas account, please send details of your name, designation, practice and email address to Contractor.Projects@ggc.scot.nhs.uk
 - e. User guide is available in appendix.
 - f. A contingency paper form is available in the appendix.
2. An EMIS template has been developed is now available see appendix for further detail.
3. A Vision template is being developed however it not expected to be deployed until week commencing 11/01/21. We will confirm the deployment date once available. Vision practices should use the TURAS Vaccine Management Tool for vaccine recording until this the template is available (please email Contractor.Projects@ggc.scot.nhs.uk for vaccinator accounts to be created).

Where GPs or practice staff are immunised in the practice, this MUST be recorded using the TURAS app which will enable the vaccination to be recorded and the staff members' own GP record to be updated.

Security Requirements

Practices should give consideration to storage arrangements in line with Police Scotland COVID-19 – Local Vaccine Storage Guide (Doctors Surgeries / Care Homes) available in the appendix of Version 0.1

Storage

- AstraZeneca COVID-19 Vaccine (ChAdOx1-S [Recombinant]) must be stored in a fridge between +2 to +8°C in accordance with manufacturer's advice. Do not freeze.
- During storage it is recommended that the vials are stored in the original packaging/cartons, away from direct sunlight to protect from light, and kept upright.
- NHS Board guidance on Storage and Handling of vaccines should be observed.
- In the event of an inadvertent or unavoidable deviation of these conditions, vaccine that has been stored outside the conditions stated above should be quarantined and risk assessed for suitability of continued use or appropriate disposal.
- After first use – use as soon as practically possible and within six hours. The vaccine may be stored between +2 and +25°C during the in-use period in accordance with manufacturer's advice. The vaccine vial has space to write the date and time that the vial was first punctured; write this on the vial label.
- The manufacturer may advise of updated storage requirements and product stability as new data becomes available, vaccine must be stored in accordance with updated recommendations from the manufacturer.

Practices should ensure that their existing cold chain arrangements are adequate. Advice can be sought from the HSCP pharmacy team. Best practice is to:

- Review last annual self-audit report regarding implementation of any recommendations
- Ensure sufficient space available in fridge
- Check adequacy of domestic vaccine porter (replacement of liners etc..) if use is anticipated
- Minimise opening of the fridge to avoid fluctuations in temperature

4. PLANNING AND PROCESS

All vaccinators will have read, understood and signed NHSGGC Patient Group Directive for the AstraZeneca COVID-19 Vaccine (ChAdOx1-S [Recombinant]) and will have completed all the training identified within the PGD.

Vaccination Process

- Remove one vaccine vial at a time from the refrigerator.
- Each vial contains at least the number of doses stated. The amount remaining in the vial may be sufficient for an additional dose but care should be exercised to ensure a full 0.5 ml dose is administered
- Drawing up an additional dose should be subject to an individual healthcare professional's judgement, on a case-by-case basis.
- Sufficient combined needles and syringes will be made available to support drawing up additional doses.
- The vaccine vial is a colourless to slightly brown, clear to slightly opaque solution. Visually inspect the vial prior to administration and discard if particles or any differences to the description are seen. Do not shake the vial.
- It is essential to swab the vial septum with an alcohol swab prior to *every* dose withdrawn and leave to dry for 30 seconds as the vial does not contain preservative. A detergent wipe should not be used.
- 0.5ml dose
- Storage time after first dose withdrawal – write time on the label.
- When the dose is drawn up into the syringe, this should be administered immediately.
- The administration of the vaccine should be recorded in the TURAS vaccination management tool and in any other documentation as appropriate.
- Immediate post vaccination observation only is required. However, patients should be advised not to drive until 15 minutes post vaccine.
- Those vaccinated should be issued with a post vaccine advice leaflet.
- If any issues are encountered the vaccination should be stopped/ paused and the situation clinically managed or escalated as per local processes.

Spillages of vaccine – Green Book chapter14a advises for areas administering Astra Zeneca COVID-19 vaccination an appropriate virucidal disinfectant should be available for managing spillages. The advice from ARHAI is:

A spill kit should be available in most vaccination settings for the management of blood and body fluid spillages and would also be suitable for managing vaccine spills. If a spill kit is not

available (for example when vaccinating housebound patients), a disinfectant disposable wipe with appropriate antiviral properties could be used

Avoiding Covid-19 Vaccine Wastage

Where a planned vaccination session has delivered its planned activity –the following guidance should be followed to avoid waste of vaccine.

Opportunistic vaccination should occur referring to the following order of priority:

1. Eligible patient or resident who require a first dose.
2. Front facing health or social care staff who require a first dose.
3. Health and social care staff who require a first dose.

It is recommended that those planning clinics have a local plan for how ad-hoc opportunistic vaccination should be approached to ensure fairness in terms of opportunity where the only option is to provide a second dose. Provision of second doses will be monitored to ensure that they are only provided from what would otherwise be wasted vaccine. **It remains our explicit policy that no planned second doses will be provided at this point in the programme.**

For AZ vaccine the storage window is 6 hours post first vial puncture at 2-25C. Where a vaccinator or team are faced with a situation of certain waste the guidance above should be followed. However, please bear in mind the AZ vaccine **can** be moved between doses

Where vaccination is taking place for members of the public e.g. within a GP Practice the priorities and JCVI groupings and their priority apply. This would mean a GP practice that was nearing the end of a planned >80's clinic with a number of doses of vaccine that would be otherwise wasted could attempt to recruit >75's etc to avoid wasting vaccine. Again first dose is always currently a priority over second.

Contraindications

There are very few individuals who cannot receive the AstraZeneca COVID-19 vaccine. Where there is doubt, rather than withholding vaccination, appropriate advice should be sought from the relevant specialist, or from the local immunisation or health protection team.

The vaccine should not be given to those who have had a previous systemic allergic reaction (including immediate-onset anaphylaxis) to:

- a previous dose of the same COVID-19 vaccine¹
- any component (excipient) of the COVID-19 vaccine

Cancer Patients

The overriding recommendation is for all eligible patients to be vaccinated. Reducing the risk of serious illness as a result of COVID-19 (CV-19) infection far outweighs any possible risk from the vaccine itself. Information in Appendix

Adverse Events

Adverse events should be reported in line with normal processes, including the Yellow Card Scheme. In addition please complete the adverse event template in the appendix and return to Kirsty.McCaffery@ggc.scot.nhs.uk by 10am on Monday for the previous week. This will be submitted to NHSGGC Immunisation Coordinator and returned to PHS.

Waste

Sharps containers to be disposed of as normal practice. Clinical and domestic waste will be disposed in the routine waste stream however any vaccine identifiable waste will be removed and disposed of as per NHSGGC guidance.

There is a need for secure disposal of the vaccine packaging to mitigate risks around organised crime and counterfeit medicines. The outer packaging should be placed into an orange clinical waste sack for secure disposal. This does not apply to the plain white cardboard boxes that NHS Vaccine Holding Centres are using to pack down the vaccine into smaller quantities; these can be placed in dry mixed recycling as standard.









The vaccine vials (fully used, partly used or expired/deemed unfit for use) should be placed in a blue-lidded sharps bin in vaccination centres (see previous comment on sharps)

Moving Vaccine

There are no concerns from a movement stability perspective of transporting the vaccine from house to house to support housebound patients. The vaccine should be stored at +2 to 8°C until first use. After the vial has been punctured, the vaccine should be used as soon as practically possible and within 6 hours. The vaccine may be stored between 2°C and 25°C during the in-use period

Please see 'Guidance for vaccination of housebound patients using COVID-19 vaccine AstraZeneca' in Appendix

**Appendix List – New and updated documents/links.
Refer to Version 0.1 for full list of supporting documentation.**

1. Pre-vaccination screening form	 pre vaccination screening_AZ.docx
2. Updated Resuscitation Council UK guidance on Management of Anaphylaxis in Vaccination Setting	https://www.resus.org.uk/about-us/news-and-events/rcuk-publishes-anaphylaxis-guidance-vaccination-settings
3. Paper process (contingency) if VMT app is down	 turas-vaccination-pa per-form-V1.pdf
4. Green Book Chapter	https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/948757/Greenbook_chapter_14_a_v4.pdf
5. Advice on Vaccinating Cancer Patients	 Covid Vaccination with SACT FAQs.docx  CV-19 Vaccination.docx
6. Guidance for vaccination of housebound patients using COVID-19 vaccine AstraZeneca	 Guidance for vaccination of houseb
7. Anaphylaxis Guidance	 Anaphylaxis guidance for Immunising Staff
8. Guidance on Doses per vial	 2021-01-08 - COVID-19 - CPO lette
9. Adverse Event Reporting	 Template AE_Immunisation Coc

5. GOVERNANCE

This process will be overseen by:

COVID-19 Vaccine PMO
COVID-19 Vaccination Population Delivery Group
COVID-19 Vaccination Programme Board