



SOP Number 1.3 Covid-19 Vaccine AstraZeneca

SOP Title Housebound Patients / Care Home Residents who have not yet received vaccination

	NAME	TITLE	SIGNATURE	DATE
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Effective Date:	
Review Date:	

READ BY			
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1. PURPOSE

This is the standard operating procedure for Trust District Nursing Teams and/ or Mobile Vaccination Teams to support Primary Care in the delivery of the Covid-19 vaccination programme to housebound patients and to residents in care homes who have not yet received their vaccination through the care home vaccination programme, including new residents

2. INTRODUCTION

The purpose of this guidance is to support Primary Care with planning and delivery of the AstraZeneca COVID-19 vaccine to house bound patients as per the priority groups and any resident who did not receive their vaccination through the care homes vaccination programme including new residents, by Trust District Nursing Teams and/ or Mobile Vaccination Teams.

The guidance primarily focuses on clinical considerations for planning these visits, including vaccine storage, handling, administration, and documentation.

Secondly the operational arrangement for the visits:

- Infection Control Procedures
- Ability to respond appropriately to any adverse reactions,
- Have contingency measures in place in the event of IT failure to allow administration to be recorded and entered retrospectively

3. SCOPE

This SOP covers the trust district nursing/mobile vaccination teams that will deliver the service to this group.

4. DEFINITIONS

COVID-19 – Coronavirus

PPE – Personal Protection Equipment

PGD- Patient Group Directions

PSD – Patient Specific Direction

PIL- Patient Information Leaflet



5. RESPONSIBILITIES

All GPs affiliated with the District Nursing Teams will be asked to identify all patients who require administration of AstraZeneca vaccine by DN Team /Mobile Vaccination Team. The following must be provided;

- The supply of the vaccine AstraZeneca and necessary supplies from their allocation of product. Supplies include needles, syringes, PIL and vaccination record card.
- **A LIST OF THE HOUSEBOUND PATIENTS/CARE HOME RESIDENTS REQUIRING VACCINATION AT HOME/IN THEIR CARE HOME.** Information required includes patient/resident name, address, HSC number, and contact details. The list should be given to the respective HSC Trust District Nursing Team where the patients live so they can administer the vaccine.
- Provide an opinion on each patient's capacity to give consent and complete the PSD /best interests paperwork as required. Where an individual does not have capacity to give consent the views of families must be obtained by the GP
- Following a review of their health, wellbeing, contra indications and allergy status prescribe appropriately.

These arrangements and advice will allow the Trust District Nurses to act in the patients/ residents best interests and will allow the vaccine to be administered by the Trust District Nurses under a Patient Group Directive (PGD) or Patient Specific Direction (PSD).

- Trust District Nursing Teams/ Mobile Vaccination Teams will have completed the required vaccination training and will be responsible for the safe delivery of the COVID-19 vaccination to the Patients/ Care Home Residents.

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- District Nurses / Mobile Vaccination Team Lead will have overall day to day clinical responsibility for managing and planning of visits for vaccine administration



- District Nursing/Mobile Vaccination Teams will deliver the vaccine programme in patient homes/care homes

6. SPECIFIC PROCEDURE

6.1 VACCINE REQUIREMENTS - TRANSPORT, STORAGE AND HANDLING

The COVID-19 vaccine is a vaccine used for active immunisation to prevent COVID-19 disease caused by sars-cov-2 virus. The vaccine triggers the body's natural production of antibodies and stimulates immune cells to protect against COVID-19 disease.

Refer to DoH Guidance On The Use Of The COVID-19 Vaccine AstraZeneca To Vaccinate Housebound Patients



- Vaccinators administering this vaccine under a PGD MUST have signed the Trust PGD for the COVID-19 vaccine to be administered and for management of adverse events (whilst having access to individual copies)
- All nursing staff should also review relevant vaccine package Summary of Product Characteristics and Patient Information Leaflet (PIL) before commencing visits.
- The vaccination sessions should be pre- planned around the number of patients with appointments requiring vaccination during the District Nursing/Mobile Vaccination Team planned day.
- Only the required number of vials should be removed from the practice fridge and transported using a validated cool box. These should be “unopened” vials. The vial could be stored overnight in a HSC Trust fridge, e.g. for use over the weekend, however the cold chain must be maintained during transport from the GP fridge to the HSCT fridge, and then out to the housebound patients.
- If individual vials are selected place them in a suitable container that will keep them from moving and securely hold them during transportation. They should be



protected from light. An example of a locally sourced suitable container could be a small plastic box

- There are no concerns from a movement stability perspective of transporting the AstraZeneca vaccine from house to house or care home to support vaccination of housebound patients. The vaccine should be stored at 2 to 8°C until first use (The travel time should be no more than 2 hours) . 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.
- All efforts should be made to minimise wastage with the COVID-19 vaccine and as part of this district nursing teams should consider the feasibility of vaccinating patients from multiple practices in a locality as part of the same vaccination session, in order to ensure that all doses are administered.

6.2 Contraindications (as per PGD)

- For patients who are less than 18 years of age
- No valid consent/ Best Interest decision
- Have had a previous systemic allergic reaction (including immediate-onset anaphylaxis) to a previous dose of the COVID-19 vaccine AstraZeneca. A second dose of the COVID-19 vaccine AstraZeneca should not be given.
- Any person with a previous systemic allergic reaction (including immediate-onset anaphylaxis) to any component of the vaccine or residues from the manufacturing process
- Are known to be pregnant
- Are suffering from acute severe febrile illness (the presence of a minor infection in not a contraindication for immunisation)
- Individuals who have tested COVID-19 Positive within the last 4 weeks should not receive the vaccine.
- With evidence of current deterioration of COVID-19 symptoms deferral of vaccination may be considered
- If the Individual has been participating in COVID Vaccine trial , they should not receive COVID 19 Vaccine



- If the individual has evolving Neurological condition consider postponing immunisation until stabilised
- have received another vaccination in the previous 7 days
- Advised by Medicines & Healthcare Regulatory Agency (MHRA) not to receive COVID-19 vaccine AstraZeneca

6.3 Vaccine Administration

Complete Pre Vaccination Check list re

- Patient/Resident screening for vaccine history, contraindications and precautions
- Accept a Patient/Resident's verbal report as proof of vaccination Review written guidance from GP in event no capacity
- Check the Patient/Resident's status re Pregnancy, Postnatal or Breastfeeding, Allergies and previous Covid positive testing.

See Appendix 1 for Vaccine Safety Checklist

6.4 Cautions including any relevant action to be taken

- 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 haematoma may occur following intramuscular administration to these individuals. (**REFER TO PGD Route of Administration**).
- According to the **Green Book** individuals with bleeding disorders may be vaccinated intramuscularly if, in the opinion of a doctor familiar with the individuals bleeding risk, vaccines or similar small volume intramuscular injections can be administered with reasonable safety by this route.
- Refer anyone back to their GP, for whom vaccine is deferred because of a contraindication or precaution in order for a record to be completed on the daily situation report, which will be generated by the COVID-19 vaccine management system.



6.5 Patient/ Resident Information

- Provide the patient/resident with a Patient Information Leaflet (PIL) every time a dose of vaccine is administered.
- Allow time for questions and after-care instructions before administering vaccines.
- Provide patient/resident with COVID 19 after Care Leaflet and information

Make every contact count

Reiterate Public Health advice

Keep your distance - Wash your hands - Wear a face covering.

6.6 Patient/Resident Care during Vaccine Administration

- Prepare Patient/Resident for vaccination
- When determining Patient/Resident positioning consider their comfort, safety, age, activity level, and the site of administration.

6.7 Infection Control

Refer to PHA: Infection Prevention Control Guidance for Adult COVID-19 vaccination clinics (Dec 2020)

https://www.publichealth.hscni.net/sites/default/files/2020-12/Infection%20control%20guidance%20for%20adult%20COVID-19%20vaccination%20clinics_0.pdf

Risk assess each COVID-19 administration environment to ensure COVID Secure Compliance with 2 metre distancing and face coverings

- Perform hand hygiene before vaccine preparation, between Patient/Residents, and any time hands become soiled.
- Use an alcohol-based hand rub. If hands are visibly dirty or contaminated with body fluids, wash with soap and water.
- On a risk assessed basis wear single use gloves, apron and eye protection if there is a risk of contact with blood and bodily fluids. All staff should wear a fluid shield mask.
- Never recap, cut, or detach needles from syringes before disposal



- Place used syringe, needle devices and vials in biohazard containers (Yellow Sharps Box- Purple cytotoxic lid) immediately after use. Biohazard containers must be closable, puncture-resistant, leak-proof, and labelled with vaccine waste sticker and must be returned to the trust for disposal., If there are any unused dosages, agree with the GP practice how they should be used within the 6 hour period .

7. VACCINE PREPARATION

- COVID-19 Vaccine AstraZeneca does not require reconstitution
- Before drawing up a dose of vaccine from the multidose vial, clean hands with alcohol-based gel or soap and water and don PPE
- Each multidose vial should be clearly labelled with initials and date and time;
 - it was first punctured
 - it can no longer be used
- Do not use the vaccine if the time of first puncture was more than 6 hours previously
- Check the appearance of the vaccine. It should be colourless to slightly brown, clear to slightly opaque and free of any particles. Discard the vaccine if particulates or discolouration are present
- Do not shake the vaccine vial
- The vial bung should be wiped with an alcohol swab and allowed to air-dry fully
- A 1 ml dose-sparing syringe with a 23 g or 25 g, 25 mm fixed needle should be used to draw up and administer the COVID-19 Vaccine AstraZeneca
- Separate longer-length (38mm) needles and syringes are available to order for morbidly obese patients to ensure the vaccine can be injected into the muscle
- **WITHDRAW A DOSE OF 0.5 ML FOR EACH VACCINATION. Take particular care to ensure the correct dose is drawn up as a partial dose may not provide protection**
- Any air bubbles should be removed before removing the needle from the vial in order to avoid losing any of the vaccine dose
- Use standard aseptic technique with all preparation and administration of vaccine



7.1 Patient/Resident Administration

- Have supplies available, including hand hygiene supplies (e.g. bottles of alcohol-based hand rub), individually packaged sterile antiseptic wipes, syringes, gauze
- Always have patients sitting or lying down during vaccine administration.
- Use a new needle and new syringe for each patient. *Never use needles and syringes to administer vaccine to more than one patient.*
- Immediately place the needle and syringe in a sharps container following administration. *Do not recap the needle.*

7.2 Documentation

Document vaccination in the Spreadsheet/ Individual record including:

- Name of vaccine
- Date & time of administration
- Vaccine manufacturer
- Vaccine lot number
- Expiration date & time
- Dose, site, and route of administration
- Name/title/initials of person administering the vaccine

Provide Patient/Resident with their own immunisation record that includes vaccine(s) administered and date administered and advise that they will be contacted in approximately 10 weeks to schedule a 2nd appointment.

In a Care Home setting, you should also notify Care Home provider about immunisations given.

The District Nurse /Mobile Vaccination Team will return all Vaccine Records to the GP Practice and the GP Practice will record on the Electronic Vaccine System.

7.3 Preventing and Managing Adverse Events

- Screen Patient/Resident for contraindications and precautions before vaccination every time.
- Always have patients sitting down when being vaccinated.



- Vaccinator must have access to an Anaphylaxis kit and telephone to summons help. If possible a family member should be asked to be present for vaccination.

7.4 Post Vaccination

- Observe for signs of anaphylaxis, which usually begin within minutes of vaccination. These signs and symptoms include:
 - Skin reactions:
 - Pruritus (itching)
 - Erythema (redness)
 - Urticaria (hives)
 - Angioedema (facial swelling)
 - Respiratory compromise:
 - Dyspnoea (difficulty breathing)
 - Wheezing
 - Bronchospasms
 - Stridor (high-pitched breathing)
 - Hypoxia
 - Low blood pressure
 - Gastrointestinal tract involvement
 - Persistent crampy abdominal pain
 - Vomiting

Follow standing orders for Medical Management of Vaccine Reactions

- Have anaphylaxis kit available and follow anaphylaxis algorithm



- Record the patient's reaction (e.g. hives, anaphylaxis) to the vaccine, all vital signs, medications administered to the patient, including the time, dosage, response, and the name of the staff who administered the medication, and other relevant clinical information on the adverse incident form and Yellow card notification system



7.5 Medications and Supplies for Managing Vaccine Reactions

First-line medication

- Adrenaline ampoules 1:1000 dilution.

Supplies required for a community vaccination setting

- Syringes (1ml and 5ml) and needles (22g and 25 g, 1", 1½", and 2") for Adrenaline.
- Antiseptic wipes
- Cell phone or access to onsite phone to contact emergency services

8. POST VACCINATION - REPORTING ADVERSE EVENTS AND VACCINE ADMINISTRATION ERRORS

- Recipients of COVID-19 vaccine should be observed for any immediate reactions during the period they are receiving any post-immunisation information and subsequent appointment if required.
- Ask Patient/Residents (**Relatives/Care Home Staff**) to monitor for reactions for an extended period of 6 weeks following vaccination and to report any adverse reactions/complications to their GP and the Medicines and Healthcare products Regulatory Agency (MHRA) via the Yellow card notification system- an online process available on the Department of Health Website within this 6 week period.(<https://coronavirus-yellowcard.mhra.gov.uk/>)

FORMS/TEMPLATES TO BE USED

See Appendix 2 - Recording Sheet Template – complete one sheet for each vial per GP Practice, e.g If there were only 7 patients from one practice and another 3 from a different practice then that would be 2 sheets 1-7 and then 1-3.

The completed template needs to be returned to the GP practice on the same day or first thing the next day after the vaccine is administered.



9. INTERNAL AND EXTERNAL REFERENCES

9.1 Internal References

<https://www.publichealth.hscni.net/covid-19-coronavirus/northern-ireland-covid-19-vaccination-programme/infection-prevention-control>

[COVID-19 Vaccination Programme information materials | HSC Public Health Agency \(hscni.net\)](#)

PHA Specification for Large Clinics (Dec 2020)

Include all relevant local trust policies

9.2 External References

COVID-19: vaccination programme guidance for healthcare practitioners

<https://www.gov.uk/government/publications/covid-19-vaccination-programme-guidance-for-healthcare-practitioners>

Training slideset:

<https://khub.net/documents/135939561/390853656/COVID+Core+training+slideset.pptx/99fdae1f-18fa-d245-10eb-7acf59e836ad?t=1606474747025>

E-learning programme:

<https://www.e-lfh.org.uk/programmes/covid-19-vaccination/>

COVID-19: vaccinator training recommendations

<https://www.gov.uk/government/publications/covid-19-vaccinator-training-recommendations>

COVID-19: vaccinator competency assessment tool

<https://www.gov.uk/government/publications/covid-19-vaccinator-competency-assessment-tool>

<https://www.gov.uk/government/publications/regulatory-approval-of-covid-19-vaccine-astrazeneca>

[Regulatory approval of COVID-19 Vaccine AstraZeneca - GOV.UK \(www.gov.uk\)](#)

Green book chapter:



<https://www.gov.uk/government/publications/covid-19-the-green-book-chapter-14a>

ALL THE DOCUMENTS AND LINKS ABOVE ARE AVAILABLE ON THE
COVID-19 vaccination programme page:

<https://www.gov.uk/government/collections/covid-19-vaccination-programme>

9.3 CHANGE HISTORY

SOP no.	Effective Date	Significant Changes	Previous SOP no.



Appendix 1 Vaccine Safety Check

Vaccine Safety Check

*Have you had a positive test for COVID – 19 in the last 28 days?

No

Yes advise patient vaccine cannot proceed

*Have you had any vaccine (including for flu) in the last 7 days?

No

Yes advise patient vaccine cannot proceed

*Have you had a serious allergic reaction to any medicine?

No

Yes please seek medical advice to proceed

*Have you had a serious allergic reaction to any vaccine?

No

Yes please seek medical advice to proceed

Proceed to vaccinate Yes

No

Reason for not vaccinating

Deferred due to family refusal

Deferred due to illness

Deferred due to patient refusal

Advised by GP

COVID-19 VACCINE AstraZeneca

SOP Title: Housebound patients/
Care Home residents who have not
yet received a vaccination



Appendix 2 Recording Sheet

2	(INSERT) HSC TRUST COMMUNITY NURSING COVID VACCINATION TEAM - HOUSEBOUND PATIENTS/RESIDENTS IN CARE HOME WHO HAVE NOT YET RECEIVED A VACCINATION															
3	DATE OF VACCINATION					Vaccine	Vaccine Dosage	Vaccine Batch number	Vaccine Expiry date (DD/MM/YYYY)							
4	NAME OF NURSE					COVID-19 Vaccine AstraZeneca 0.5ML										
5	GP PRACTICE	THE PATIENTS BELOW ARE ALL RECEIVING THE VACCINATION FROM THE SAME VIAL														
6	Patient meets eligibility criteria	Patient past significant reaction to any vaccine or medicine?	First name	Last name	HCN Number	Date of birth (DDMMYYYY)	Sex at birth	Ethnic background	Postcode	Mobile Number	Email address	Vaccine administration site	Consent Given	GP advice received	Reason given if vaccination does NOT proceed	[If reason given is other]
7	1															
8	2															
9	3															
10	4															
11	5															
12	6															
13	7															
14	8															
15	9															
16	10															
17																
18	RESERVE															
19								White				Left Arm	Yes		Appointment no longer required	
20								Irish Traveller				Right Arm	No - in best interest of patient		Deferred due to NOK refusal	
21								White and Black Caribbean				Other	No		Deferred due to illness	
22								White and Black African							Deferred due to patient refusal	
23								White and Asian							Did not attend	
24								Any Other Mixed/Multiple Ethnic Background							Inappropriate age	
25								Indian							No cancellation reason specified	
26								Pakistani							Pregnancy	
27								Bangladeshi							Duplicate	
28								Any Other Asian Background							Location	
29								African							Other (describe in next column)	
30								Caribbean								
31								Any Other Black/African/Caribbean Background								
32								Chinese								
33								Arab								
34								Other Ethnic Group								
35								Refused to provide an answer								
36																