



SOP Number 1 PFIZER BIONTECH COVID-19 VACCINE

SOP Title Mobile teams for Care Homes

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Effective Date:	
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## 1. PURPOSE

This Standard Operating Procedure for the Trust Vaccination Teams attending the Care Homes and Supported Living facilities to ensure the safe delivery of the COVID19 Vaccine to Residents / tenants and Staff . The reference to Care Homes throughout this document includes all Supported Living facilities.

## 2. INTRODUCTION

The Joint Committee on Vaccination and Immunisation (JCVI) have recommended that Residents, tenants and Staff in Care Homes & supported Living facilities are the top priority group for the administration of the COVID19 Vaccine. There are approx. 14,000 residents and 28,000 Staff in Care Home Settings alone. The programme will commence December 2020.

This SOP covers the Trust Vaccination teams that will deliver the service to the Staff and Residents / tenants in Care Homes and Supported Living facilities.

## 3. DEFINITIONS

COVID19 – Coronavirus  
HCN – Health & Care Number  
PPE – Personal Protection Equipment  
PGD- Patient Group Directions  
PIL- Patient Information Leaflet

## 4. RESPONSIBILITIES

Trusts and Homes will ensure that all current PPE guidance is adhered to at all times to ensure a safe working environment and minimise associated risk. All Resident and Staff information will comply with and be managed in accordance with GDPR principals.

All GPs have been asked, to provide:

- a list of their patients who live in each care home
- Provide an opinion on the residents capacity to give consent
- for patients unable to consent the likely best interests of the patient in receiving the vaccine.



These arrangements and advice will allow the Trust to act in the residents best interests and will allow the vaccine to be administered by the Trust mobile team under a Patient Group Directive (PGD).

GPs are not giving permission or consent but are providing information for such best interest decisions to be made

Please note:

Where the GP expresses a view that the vaccination is **NOT** likely to be in the best interest of the resident - the vaccination should **NOT** be given.

Where the relative expresses a view that they do **NOT** wish their relative to receive the vaccination - the vaccination should **NOT** be given.

Where relatives do not have the right to provide or withhold consent on behalf of a family member, consideration will be given consider to what further processes is needed to further explore best interests.

Each Care Home will ensure that

- All Residents, Staff & Care partners are informed of the planned visit
- Care Home staff will discuss arrangements with the identified NOK /nominated individual and residents to inform them of the process and provide written information / accessible information as required. If relatives express concerns that the vaccination may not be in the resident's best interests, these concerns should be recorded and shared with the residents GP.
- Care homes should invite staff not rostered on the day of the mobile team visit, to attend the home to receive their vaccination on that day.
- Provide an appropriate area that can be used as a clinical work station. This should consider the environment in which residents and staff can receive their vaccine to ensure it provides privacy and dignity. Homes should consider the number of residents & staff receiving their vaccination and provide adequate space; we recommend that more than one area may be required to ensure a safe working environment.

Each Trust will establish mobile Vaccination teams consisting of 3-5 Registered Health Professionals and one admin support.



- Health Professionals will have completed the required vaccination training and will be responsible for the safe delivery of the COVID-19 vaccination to all Staff and Residents.
- Admin Support will manage the COVID-19 Vaccine Management System and ensure the upload of all resident's details, including those not receiving the vaccine, and all staff who wishes to receive the vaccine. This will provide health intelligence to support further planning and ensure residents can be re considered when alternative vaccines become available.
- Provide a point of contact to facilitate communication with Care Homes

## 5. 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.

Contraindications (as per PGD)

- Any person with a history of immediate-onset anaphylaxis to a vaccine, medicine or food should not receive the Pfizer BioNTech vaccine. A second dose of the Pfizer BioNTech vaccine should not be given to those who have experienced anaphylaxis to the first dose of Pfizer BioNTech vaccination.
- a severe illness with high fever. However, a mild fever or upper airway infection, like a cold, are not reasons to delay vaccination.
- Pregnancy or breast feeding, or planning to get pregnant in the next three
- have received another vaccination in the previous 7 days
- Individuals receiving anticoagulant therapy or those with a bleeding disorder that would contraindicate intramuscular injection, should not be given the vaccine unless the potential benefit clearly outweighs the risk of administration.

The Trust Teams will

- Ensure that all Vaccinators are aware of the transport, storage & handling requirements of the vaccine
- Ensure plans are in place for maintaining vaccine at appropriate temperatures while it is stored and throughout the clinic day.



- Limit the amount of vaccine transported to only what will be needed that workday.
- Use a calibrated temperature monitoring device with continuous monitoring and recording capabilities during transport.
- Ensure vaccines are in an appropriate storage unit(s) at the recommended temperature range(s) immediately upon arrival at the facility.
- Read and record storage unit temperature at off-site/satellite facility a minimum of 2 times during the work day.
- Ensure that teams only prepare the number of vaccines required for each home.
- Vaccines should be prepared in a clean sterile area of the Care Home
- All Vaccines should be disposed of in line with Trust policy at the end of the 2nd vaccine session with a record of the number of vaccines disposed.

## 6. SPECIFIC PROCEDURE

### Preparations in advance of Home visit

The Trust Teams will

- Identify Care Homes within their Trust to be vaccinated
- Ensure that contact details for care home lead are available- address/name of manager/senior on duty /contact number etc
- Provide Trust contact details with Care Home.
- Check care home outbreak status and liaise with PHA, for those homes currently in an outbreak to discuss scheduling of home visit. Consideration will be given to length of outbreak and personnel involved.
- Contact Home in advance of visit to collate information required and confirm date of planned visit. The final number of recipients should be confirmed no less than 48 hrs prior to visit.
- Only transport to Care Homes vaccine sufficient for the number of recipients identified by the Care Home in advance of the visit
- Ensure facilities, personnel, emergency medications and equipment are available to treat immediate hypersensitivity reactions



Each Care Home will

- Accept the 1<sup>st</sup> date offered. Only homes currently in an outbreak will be considered for an alternative date. Advice will be sought from PHA if an alternative date is requested. The team will return 21 days later to administer the 2nd dose of the vaccine.
- Ensure that consent or a best interest's decision has been sought for all residents receiving the vaccine. This information should be shared with the Trust & mobile team, in advance of the visit, who can then vaccinate under a Patient Group Directive (PGD).
- Compile a list of all Residents currently in the home, confirming the consent or best interest decision for each resident, and a list of staff wishing to be vaccinated. This should include a HCN for all residents & staff and will ensure that only required vaccine is transported to the home. Staff from ROI will need to have their hospital number available.
- Please ensure that recipients will still be present in the Care Home in 21 days for receipt of 2<sup>nd</sup> dose of vaccine. Those residents who are on a short term or temporary placement may need to be considered for an alternative vaccination pathway.

### **Vaccine Administration**

The Trust Teams will

- Facilitate a safety briefing with the Care Home. All staff should be orientated to their working environment. This must include
  - Location of emergency equipment including the anaphylaxis kit
  - Location of facilities including emergency exits & evacuation procedures
- Complete a risk assessment to ensure the environment is COVID-19 secure
- Prepare the Vaccine for administration aseptically in line with the vaccine requirements
- Consult with the Care Home Senior Nurse in Charge about clients with a potential contraindication or precaution: ie recent Covid History & flu vaccination
- Screen Staff / residents vaccine history, and identify any contraindications and precautions
- Ensure consent or best interest decision has been attained for all recipients



On the day of vaccination each Care Home will:

- Facilitate a safety briefing for the visiting team. All staff should be orientated to their working environment. This must include
  - Location of emergency equipment including the anaphylaxis kit
  - Location of facilities including emergency exits & evacuation procedures
- Provide Resident and Staff lists as detailed above.
- Ensure that all staff has their HCN number available. Staff from ROI will need to have their hospital number available.
- Assist Trust teams with the identification of residents and assistance as required to facilitate administration of the vaccine. Care Homes are requested to ensure staff present are suitability qualified.

### **Resident Care during Vaccine Administration**

- Prepare resident for vaccination considering their age and stage of health /cognitive development.
- When determining resident positioning consider their comfort, safety, age, activity level, and the site of administration.
- Always have the residents sitting or lying down during vaccine administration.
- Use an appropriate sized needle for each resident, depending on age, weight, and gender

### **Resident Information**

- Each of the recipients of the vaccine will be provide with a Patient Information Leaflet (PIL)
- Allow time for questions and after-care instructions before administering vaccines.
- Provide recipients and Home with COVID 19 After Care Leaflet

### **Infection Control**

- All staff, Trust & Care Home will adhere to Current IPC guidelines.
- Perform hand hygiene before vaccine preparation, between 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.

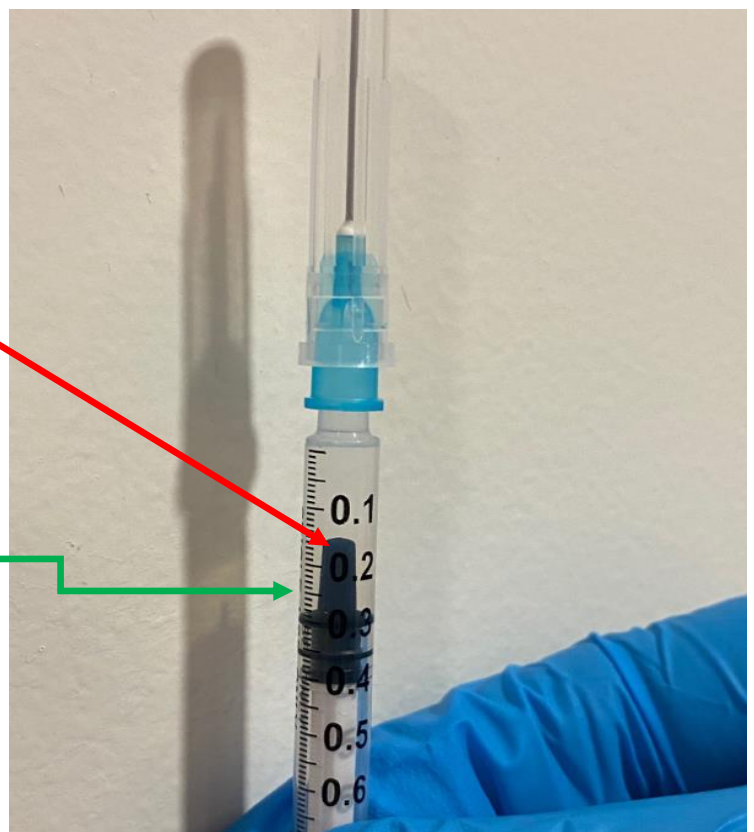


- A Fluid Resistant Mask, Plastic Gloves and Apron and Goggles/Visor must be worn for each client. Change PPE between residents and staff vaccinations and perform hand hygiene between each individual .
- The need for additional PPE should be for risk assessed as per IPC guidelines
- Place used syringe and needle devices in biohazard containers (Purple lid Sharps Box) immediately after use. Biohazard containers must be closable, puncture-resistant, leak-proof, and labelled.
- Never recap, cut, or detach needles from syringes before disposal.
- Clean the vaccine station after each client's use

### Vaccine Preparation

- Reconstitute vaccines according to manufacturer guidelines  
[https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/940565/Information\\_for\\_Healthcare\\_Professionals\\_on\\_Pfizer\\_BioNTech\\_COVID-19\\_vaccine.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/940565/Information_for_Healthcare_Professionals_on_Pfizer_BioNTech_COVID-19_vaccine.pdf)
- Vaccinators should follow any Trust SOP which have been created to facilitate this preparation

- Please note it is not the tip of the bung that is used for measuring purposes
- Administration syringe picture showing the amount the plunger should be withdrawn for measuring 0.3ml.







### Key Principle Requirements

- Have facilities, personnel, emergency medications and equipment available to treat immediate hypersensitivity reactions regardless of the clinic setting.
- Draw up vaccines in a designated clean clinical area.
- Ensure Vaccines are securely stored and not left unattended by Trust Teams.
- Equipment selection should be as per Vaccine requirements
- Select a separate sterile syringe and needle for each injection.
- Visually inspect the vaccine. The diluted vaccine should present as an off white solution with no particulates visible. Discard the diluted vaccine if particulates or discoloration are present
- Use *ONLY* the manufacturer-supplied diluent for that vaccine. Unpreserved sodium chloride 9 mg/mL (0.9%) solution for injection is the only diluent that should be used.
- Check the expiration dates on the vaccine AND diluent vials.
- When removed from the freezer, the undiluted vaccine has a maximum shelf life of up to 5 days (120 hours) at 2 °C to 8 °C and an additional 2 hours at temperatures up to 25 °C in
- The diluted vials should be marked with the dilution date and time and stored between 2 °C to 25 °C. This should be used within 6 hours from dilution.
- Diluted vaccine should **NOT** be transported from the home for administration to any recipient. Vaccine must be administered at the location dilution occurred.
- Do not change the needle between drawing up and administering the vaccine, unless the needle is contaminated.
- Disinfect the rubber septum of the vaccine vial with alcohol prior to piercing. Ensure vaccine is labelled with the Name, Dose, Batch No
- Discard all unused reconstituted vaccine at the end of the day, or sooner if indicated in the package insert.
- All unused & used vials and syringes must be returned to Trust pharmacies for disposal.

### Documentation

Document vaccination on the COVID-19 Vaccine Management System electronic record, including:

- Name of vaccine
- Date of administration
- Vaccine manufacturer
- Vaccine lot number
- Expiry date



- Dose, site, and route
- Name/title/signature of person administering the vaccine

Provide resident with their own immunization record that includes vaccine(s) administered and date administered. In addition, you should also notify client's provider about immunizations given.

### **Preventing and Managing Adverse Events •**

- A protocol for the management of anaphylaxis and an anaphylaxis pack must always be available whenever the Pfizer BioNTech vaccine is given. Immediate treatment should include early treatment with 0.5mg intramuscular adrenaline (0.5ml of 1:1000 or 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.
- Screen resident for contraindications and precautions before vaccination every time.
- Always have residents sitting or lying down when being vaccinated.
- Vaccine recipients should be monitored for 15 mins after vaccination, with a longer observation period when indicated after clinical assessment. This can be done in a separate waiting area to keep the flow moving.
- Observe for signs of anaphylaxis, which can begin within minutes of vaccination. These signs and symptoms include:
  - Skin reactions:
    - Pruritus (itching)
    - Erythema (redness)
    - Urticaria (hives)
    - Angioedema (facial swelling)
  - Respiratory compromise:
    - Dyspnea (difficulty breathing)
    - Wheezing
    - Bronchospasms
    - Stridor (high-pitched breathing)
  - Hypoxia
  - Low blood pressure
  - Gastrointestinal tract involvement
  - Persistent crampy abdominal pain
  - Vomiting



- Have facilities, personnel, emergency medications and equipment available to treat immediate hypersensitivity reactions regardless of the clinic setting.
- Following completion of the final vaccination two members of the mobile team will remain on site for 15 mins to ensure observations complete.
- 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. Inform GP.

## **Medications and Supplies for Managing Vaccine Reactions**

### **First-line medication**

- A protocol for the management of anaphylaxis and an anaphylaxis pack must always be available whenever the Pfizer BioNTech vaccine is given.
- Immediate treatment should include early treatment with 0.5mg intramuscular adrenaline (0.5ml of 1:1000 or 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.
- Adhere to Trust Anaphylaxis protocol/policy
- Access to the Care Home Emergency Equipment
- Have facilities, personnel, emergency medications and equipment available to treat immediate hypersensitivity reactions regardless of the clinic setting.
- 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 medical personnel who administered the medication, and other relevant clinical information on your agency's clinical incident form.
- Follow standing orders for Medical Management of Vaccine Reactions.

### **Post vaccination - Reporting Adverse events and Vaccine administration Errors**

- The vaccination team must monitor the residents both immediately post vaccine for any mild local reactions and treat accordingly.
- Ask care home staff to observe 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.( E-mail [coronavirus-yellowcard.mhra.gov.uk](mailto:coronavirus-yellowcard.mhra.gov.uk))

To make a report or find out more about the Yellow Card COVID-19 reporting site please visit: [Coronavirus Yellow Card reporting site](#)

## 7. FORMS/TEMPLATES TO BE USED

Insert Electronic Record

## 8. INTERNAL AND EXTERNAL REFERENCES

### 8.1 Internal References

PHA Infection Control Guidance 2020

- Where possible all staff as part of the vaccinator team should travel in their own transport as per covid-19 regulations
- Mobile Team will ensure collection or delivery of the vaccine and supplies need that days planned visits. This will include needles, syringes, diluents, sharps container, waste bags and PPE for vaccinators for that day.

Vaccinators may arrive in advance of the vaccine along with their admin support to meet with staff and discuss the process- they will set up clinical area, check PGD complete, and check all patient consent complete. Check the health status of the clients/care home staff. The admin support will ensure that all Residents & Recipients details are available on the COVID-19 Vaccine Management System



## 8.2 External References

### **GUIDANCE FOR HEALTHCARE PRACTITIONERS**

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

### **TRAINING SLIDASET:**

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

### **PFIZER VACCINE INFORMATION:**

[https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/940565/Information\\_for\\_Healthcare\\_Professionals\\_on\\_Pfizer\\_BioNTech\\_COVID-19\\_vaccine.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/940565/Information_for_Healthcare_Professionals_on_Pfizer_BioNTech_COVID-19_vaccine.pdf)

### **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>

### **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. CHANGE HISTORY

SOP no.	Effective Date	Significant Changes	Previous SOP no.