

STANDARD OPERATING PROCEDURE



SOP No: V2
SOP Title: COVID-19 Vaccine

SOP Number V4
SOP Title SOP for Large Vaccine Clinics

	NAME	TITLE	SIGNATURE	DATE
Author	Deirdre Webb	Assistant Director of Nursing		6th Dec 2020
Reviewer		Band 8a		
Authoriser		Band 8a		

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Review Date:	

READ BY			
NAME	TITLE	SIGNATURE	DATE



1. PURPOSE

This is the SOP for the Large Fixed COVID-19 Vaccination Clinics which Trusts should adapt for their local trust locations.

2. INTRODUCTION

The purpose of this guidance is to assist with planning and implementation of large COVID-19 vaccination clinics by Trusts.

The guidance primarily focuses on clinical considerations for planning a vaccination clinic, including vaccine storage, handling, administration, and documentation.

Secondly the operational arrangement for the session:

- The floor plan of the building,
- The Emergency Exits & Fire Safety procedures
- IPC Procedures
- Telephones,
- Emergency Equipment,
- Drinking water.
- Have contingency measures in place in the event of ICT failure to allow administration to be recorded and entered retrospectively
- A one way system should be in place to allow clients to check in proceed to vaccination station and onward to the observation area before exiting the clinic

3. SCOPE

This SOP covers the provision of a COVID19 Vaccine Service in a large fixed clinic within the Trust area

4. DEFINITIONS

COVID-19 – Coronavirus

PPE – Personal Protection Equipment

PGD- Patient Group Directions

PIL- Patient Information Leaflet



5. RESPONSIBILITIES

At each large clinic there will be:

- Senior Nurse Lead: Overall day to day clinical responsibility for the Large Clinics
- Site/ location manager: Overall responsibility for the running of the building.
- Supervising Pharmacists: Supervise the Management of the vaccines and have oversight of the preparation of the same
- Band 6 Co-ordinators: Supervise the preparation and administration of the vaccines and Support vaccinators
- The Vaccinators Registered Health Professionals deliver the vaccine programme
- Health Care Assistants Assist vaccinators, assist clients and observe post vaccine
- Admin support staff Book clients in and assist with imputing the data and improving the quality of the vaccine data

6. SPECIFIC PROCEDURE

6.1 Preparation before the Clinic

A safety briefing must be carried out at the commencement of each shift. 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.
- Purpose of the clinic
- Supervision structure
- Vaccine(s) being administered
- Indications, contraindications, and precautions
- Correct dose and route of administration
- Preparation of the vaccine, including any special conditions for preparation, expiry timings of the prepared product and pharmacy procedure for accessing the vaccine



- Vaccinators to have signed one central copy of the PGD for the COVID-19 vaccine to be administered and for management of managing adverse events (whilst having access to individual copies)
- All clinic screening and documentation forms and their location
- All clinic staff should also review relevant vaccine package Summary of Product Characteristics and Patient Information Leaflet (PIL) before the clinic begins.
- All personnel, including staff who administer vaccines, must receive training and demonstrate competency in Basic life support, anaphylaxis training, vaccine storage, handling, preparation, administration, and management of adverse events.
- Validate staff knowledge and skills - Knowledge of Trust policies and procedures
- Use PGD signed by appropriate Trust authorisation for each vaccine type
- Ensure access to the Electronic System for recording the administration of the vaccine given.

Vaccines should be stored Between 2°C and 8°C unless otherwise stated in the relevant Summary of Product Characteristics or equivalent document.

6.2 Vaccine Transport, Storage and Handling

- 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 tracking capabilities during transport.
- Place vaccines 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.

Transporting diluents:

- Transport diluents with the corresponding vaccines at the storage temperatures specified in the summary of product characteristics and store as such.
- Only use diluents as guided by the SPC for the particular products



6.3 Vaccine Administration

- Client screening for vaccine history, contraindications and precautions
- Assess client's vaccine history.

MHRH state- Any person with a history of immediate-onset anaphylaxis to a vaccine, medicine or food should not receive the Pfizer BioNTech vaccine (9th Dec 2020) Link attached

- Accept a client's verbal report as proof of vaccination
- Check the client's status re Pregnancy, Postnatal or Breastfeeding, Allergies and previous Covid positive testing.
- **Cautions including any relevant action to be taken**
- Individuals with a bleeding disorder may develop a haematoma at the injection site (see PGD Route of Administration).
- 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.
- Consult with the Senior Nurse in Charge on site about potential vaccinees with a contraindication or precaution.
- Refer anyone to GP, for whom vaccine is deferred because of a contraindication or precaution, a record should be completed on a daily situation report which will be generated by the COVID-19 vaccine management system.

6.4 Client Information

- Provide the client 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 client with COVID 19 after Care Leaflet- link attached

Make every contact count

Reiterate Public Health advice

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



6.5 Client Care during Vaccine Administration

- Prepare client for vaccination
- When determining client positioning consider the client's comfort, safety, age, activity level, and the site of administration.

6.6 Infection Control

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

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

- Perform hand hygiene before vaccine preparation, between clients, 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.
- All staff should wear a fluid shield mask and all individuals attending the COVID-19 clinics should wear a face covering.

On a risk assessed basis, wear single use gloves, an apron and eye protection if there is a risk of contact with blood and bodily fluids.

- The need for PPE should be Risk Assessed. A Fluid Resistant Mask should be worn for each session
- If wearing gloves, change them and perform hand hygiene between each patient.
- Never recap, cut, or detach needles from syringes before disposal
- Place used syringe and needle devices 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.
- All unused & used vials and syringes must be returned to Trust pharmacies for disposal.
- Clean the vaccine station after each client's use as per trust protocol



7. VACCINE PREPARATION

- In Vaccine Clinic settings: Prepare vaccines in a designated clean clinical area. Follow summary of product characteristics for each vaccine
- Equipment selection: Use a separate sterile syringe for each injection.
- Check expiration date of needle and/or syringe, if there is one.
- Visually inspect the vaccine for discoloration, precipitation or if it cannot be re-suspended prior to administration. If problems are noted, the vaccine should not be administered.
- Vaccines requiring reconstitution or dilution: Reconstitute or dilute vaccines according to manufacturer guidelines just before administration.

Use *ONLY* the manufacturer-supplied diluent for that vaccine.
Check the expiration dates on the vaccine and diluent vials.

- **Multi-dose vial** - use as per summary of product characteristics-
- **NB: Pfizer BioNTech vaccine directs to gently invert 10 times prior to dilution/ gently invert the diluted solution 10 times. Do not shake.**
- Draw up approved dose record date & time of reconstitution on the vial (Link attached)
- Discard all unused reconstituted vaccine at the end of the day, or sooner as per summary of product characteristics.
- **Note:** Some reconstituted vaccines must be discarded if not used immediately. Check summary of product characteristics.
- Check expiry dates of all products As per Summary of Products Characteristics

Label the vaccine with the correct beyond use date/time and your initials.

- Use standard aseptic technique with all preparation and administration of vaccine
- Ensure vaccine is labelled with the Name, Dose & Batch No



7.1 Client 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 electronic 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 client with their own immunisation record that includes vaccine(s) administered and date administered with an appointment for their 2nd dose. In addition, you should also notify client's provider about immunisations given.

7.3 Preventing and Managing Adverse Events

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

7.4 Post Vaccination

- Observe patients for 15 minutes after vaccination. This can be done in a separate waiting area to keep the flow moving.



- 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 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 staff who administered the medication, and other relevant clinical information on the adverse incident form.

7.5 Medications and Supplies for Managing Vaccine Reactions

First-line medication

- Adrenaline ampoules 1:1000 dilution.

Supplies required for a community immunisation clinic

- Syringes (1 and 5ml) and needles (22 and 25 g, 1", 1½", and 2") for Adrenaline.
- Antiseptic wipes
- Airways (small, medium, and large)
- 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.
- COVID-19 mRNA Vaccine BNT162b2 (Pfizer BioNtech) COVID-19 vaccine recipients should be monitored for 15 mins after vaccination, with a longer observation period when indicated after clinical assessment.
- 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.
- Ask clients 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

Insert link to Electronic Record

8. 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>

Confirmation of guidance to vaccination centres on managing allergic reactions following COVID-19 vaccination with the Pfizer BioNTech vaccine

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

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>

CMO letter on PFIZER BIONTECH COVID-19 VACCINE - UPDATED GUIDANCE ON MANAGING ALLERGIC REACTIONS



9.3 CHANGE HISTORY

SOP no.	Effective Date	Significant Changes	Previous SOP no.