

Cold Chain Management in Community Vaccination Clinics

SOP number	PPH009	Version	2.0
Title	Standard Operating Procedure for Fridge Temperature Monitoring, and Vaccine Stock Maintenance		

Prepared by	Aileen Begley	Date	June 2024
Approved by	Elaine Paton	Date	12/6/2024

Team	PPH Health Protection for Vaccination clinics
------	---

Purpose

This document replaces all previous (Covid-19) vaccination SOPs. The vaccination clinics now offer different vaccinations types of vaccine for various programmes including seasonal flu, Covid-19, routine and non-routine.

Each vaccine type should be stored in a separate fridge or on a separate shelf whenever possible.

Regardless of the vaccine programme being offered, the following steps must be adhered to on days in which the clinic is operating.

This SOP and associated guidance should be used in any setting where vaccines are stored and administered,

Temperature monitoring

Clinic lead should identify responsible person(s) for monitoring the fridge temperatures and removing vaccines from the fridge for that vaccination session (a session is defined as a 4 hour period for the purpose of this document).

- Fridges containing vaccines in use at clinic - temperatures should be recorded first thing in the morning on arrival, at end of the clinic and throughout the day on each occasion when the fridge is opened.
- Fridges containing vaccines not in use at clinic e.g. when an alternate vaccine is being administered during clinic or on days clinic is not operational, temperatures should be recorded at start and end of day.
- Ensure data logger in each fridge is located in the centre of the middle shelf.
- Separate temperature record sheets should be kept for each fridge. There is no requirement to have separate record sheets for different vaccines within each fridge.
- Monitor fridge temperature and record actual, maximum and minimum temperatures on fridge temperature record sheets stored on top of or near the fridge.
 - Record of the clinic name, month and year, fridge number and data logger number should be written clearly in spaces provided at the top of the temperature record sheets.
 - Record of the date and time, signature of person recording temperature and comment, when applicable e.g. vaccine delivery, should be written clearly in the spaces provided on the temperature record sheet.

- Record the temperature on each occasion when the fridge has been opened.
- Record actual temperature first, then maximum and minimum temperature.
- **It is vital that the fridge thermometer is reset after temperatures have been recorded.**
- Record correction of error(s) or other relevant information including signature of person who identified the error, on next available line(s) on the temperature record sheet. Do not overwrite or score out.
- Observe the fridge to ensure that the temperature has returned to the usual range after opening to identify any transient fluctuation below 2 °C or above 8°C degrees.
- Record actual, maximum and minimum temperature approx. 15 minutes after fridge is closed and maximum/minimum temperatures are reset.
- Report any excursions (below 2°C or above 8°C) to clinic lead for advice (see temperature fluctuations below).
- Record detail of temperature excursion and signature on temperature recording sheet.
- Clinic lead is responsible for ensuring all staff carrying out fridge temperature checks are aware of how to respond to temperature variation including recording, reporting and undertaking any necessary remedial action.
- Clinic lead should review temperature record sheets at the end of each vaccination session, or more frequently when necessary, to identify any temperature breaches not already reported and to identify any temperature drift.

Temperature fluctuations

A temperature which returns to normal range within 20 minutes is not classed as an excursion, and does **NOT** need reported to Pharmaceutical Public Health (PPH), but should be recorded in comments column of temperature record sheet.

In the event of a fridge showing a temperature of concern, put stock into quarantine in an alternative working, monitored by data-logger, Kelsius or other temperature recording device if applicable, fridge and contact PPH for advice. Put stock into a plastic bag clearly marked to show stock is quarantined. PPH phone number and e-mail address is on fridge magnet. Phone: 0141 201 4424 / 201 4824 pharmacypublichealth@ggc.scot.nhs.uk

Storage, distribution and disposal of vaccines: the green book recommend aiming for +5°C, the midpoint in the +2°C to +8°C range. Avoid opening the fridge if the temperature shown is above 6°C as this could cause the temperature to go above 8°C (once opened) and not have the time to cool properly afterwards.

Arrival of vaccine from supplier (Unit C) or other vaccination clinic

- Prior to delivery of vaccine, ensure previous fridge temperatures were recorded as being between 2°C and 8°C on temperature record sheets.
- Vaccine will be supplied by the local vaccine holding centre (VHC). For NHSGGC, this is Unit C within the Pharmacy Distribution Centre, Phone 0141 201 3488 vaccines@ggc.scot.nhs.uk

- Vaccine delivered from VHC will come in the Helapet or refrigerated van. The Helapet requires to be emptied and returned to the driver immediately.
- Vaccine deliveries must be refrigerated immediately on receipt.
- On receipt of stock, record actual, maximum and minimum temperature fridge temperatures prior to placing vaccine in designated fridge. Ensure vaccine is placed in fridge so packaging is not touching side walls or rear of fridge.
- Record batch number(s), expiry details on comments section of fridge temperature record pad. Check batch number and expiry details of each package as a mix of batches may have been supplied. Ensure expiry date recorded is shortest expiry date shown on product such as the expiry date given when vaccines were defrosted, not manufacturer's original expiry date.
- Record quantity of vials received in the balance section of Vaccine running total log for vaccines delivered. Maintain a total running balance e.g. add the quantities received to remaining stock and record the total.
- Ensure fridges are never packed to more than 60% capacity to allow air circulation between products.
- Pack vaccine into fridge(s) according to expiry date to ensure short dated stock is used first. Place each daily delivery on separate shelf to allow stock rotation, when possible.
- Record actual temperature first, then maximum and minimum temperature.
- Record actual, maximum and minimum temperature approx. 15 minutes after fridge is closed and maximum/minimum temperatures are reset after recording.

Advice for removal from fridge to prepare for administration

- Ensure temperature monitoring is being undertaken and records maintained.
- Document on temperature log how many vials e.g. Covid-19 or individual pre-filled syringes e.g. seasonal flu are removed.
- Complete the vaccine stock running total log with quantity of vials removed. Ensure expiry rotation system is followed.
- Remove only the minimum of vaccine required and aim that all stock is used within 4 hours.
- If the vial is not being used immediately then annotate the vial with time removed from fridge. Move vaccine to designated area. Ensure area clear and ready for preparation of vaccine by vaccinating team.
- Minimise number of openings for removing vaccine from fridge to avoid temperature fluctuation.
- Ensure fridge always closed securely and locked.
- Check with clinical lead when on site to determine which vaccine is being used as this may change on a daily basis depending on vaccination service needs.
- Reallocate vaccine amongst vaccinators towards end of the clinic to avoid wastage.

- Ensure correct waste management procedures are followed and recorded correctly.

Medicine Defects

- In the event of any vaccine being deemed defective, the clinic lead must be informed by the vaccinator. HCSW should be aware of the process for reporting, though it is the responsibility of the clinic lead to complete the documentation.
- Clinic lead must complete the medicine defect form including photograph if possible, carefully quarantine the vaccine marked DO NOT USE and report promptly to pharmacy public health.
- Completed and return medicines defect form promptly to PharmacyPublicHealth@ggc.scot.nhs.uk ideally the same day.
- Clinic lead must complete a Datix reporting form

Contacts

- In first instance, contact clinic lead for advice.
- If the query is more complex, clinic lead should contact Pharmaceutical Public Health, pharmacypublichealth@ggc.scot.nhs.uk, telephone: 0141 201 4424 / 0141 201 201 4824.
- In the event of vaccines requiring quarantine and replacement stock is required to complete the clinic, please advise your clinic lead who will contact VHC. Please note that the Unit C opening hours are Monday to Friday (7am-4pm) vaccine department on 0141 201 3488.

Training

- See checklist in Appendix 1.

Documentation

- Relevant documentation and LearnPro module GGC: 097 Cold Chain Management must be completed to gain an understanding of current practice for the safe and secure handling and storage of vaccines for the vaccine clinic.
- Staff member must sign to confirm that they have read and understood the documents listed in Appendix 1.

Version Control

Version	Date	Description
2.0	12 th June 2024	Updated SOP from 2021. Expanded to include training checklist applicable for any vaccination location.

Training Checklist for Staff undertaking Fridge Temperature Monitoring, and Vaccine Stock Maintenance

Appendix 1 Training Record and Checklist

DOCUMENT TITLE	DATE	STAFF SIGNATURE	COMMENTS
SOP for cold chain (this document)			
Cold Chain Management-LearnPro GGC:097 Cold Chain Management			
Watch YouTube training video			

ROLE AT CLINIC – HEALTHCARE SUPPORT WORKERS ARE TRAINED IN BELOW TASKS		
TASK	STAFF SIGNATURE	COMMENTS
Responsible person to be established for removing vials from fridge and record fridge temperature readings for clinic duration		
Provide each vaccinator with sufficient vaccine for initial 2 hours		
Assessing quantity to be provided every 2 hours. Share vaccine amongst vaccinators towards end 90 min blocks.		
Ensure each station have enough sundries/leaflets and top up throughout the day.		
Communicate with lead nurse - vials required at stations.		
End of day communicate with immunisers re: vaccine in use prior to removing more from fridge.		
Ensure each vaccinator records expiry time of vaccine on removal from fridge.		
Reallocate vaccine amongst vaccinators towards end of 90 minutes blocks.		
Prior to last 2 hours minimise stock removed, share amongst vaccinators		
Ensure no unused diluted vaccine. Vaccinators to record any waste vials/reason for waste and report to lead nurse.		

Appendix 2 Training Declaration

Names of person(s) trained: _____

Declaration: The individuals named above have been trained in essential aspects of cold chain management.

Name of trainer: _____

Job title: _____

Signature of trainer: _____

Date of training: _____

For permanent staff please return completed sheet to ggc.adultimmunisationadmin@nhs.scot
For all Bank staff please return completed sheet to ggc.staffbankservicedelivery@nhs.scot