NHS
Greater Glasgow and Clyde

CLINICAL GUIDELINE

Vaccine Ordering, Storage and Handling

A guideline is intended to assist healthcare professionals in the choice of disease-specific treatments.

Clinical judgement should be exercised on the applicability of any guideline, influenced by individual patient characteristics. Clinicians should be mindful of the potential for harmful polypharmacy and increased susceptibility to adverse drug reactions in patients with multiple morbidities or frailty.

If, after discussion with the patient or carer, there are good reasons for not following a guideline, it is good practice to record these and communicate them to others involved in the care of the patient.

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Important Note:

The online version of this document is the only version that is maintained.
Any printed copies should therefore be viewed as 'Uncontrolled' and as such, may not necessarily contain the latest updates and amendments.

Contents

1. Introduction

1.1. Purpose of Guidelines

The aim of these guidelines is to provide detailed information to support NHS GGC staff involved in vaccination clinic activities in the storage and handling of vaccines. This guideline supplements the recommendations made in Chapter 3 of Immunisation against Infectious Disease (the Green Book).

1.2. Background

Vaccines naturally biodegrade over time and storage outside the recommended temperature range at any time will speed up loss of potency which cannot be reversed, resulting in failure of the vaccine efficacy and vaccine wastage.

The terms of medicines marketing authorisations (product licences) cover storage requirements. Vaccines that have not been properly distributed or stored are therefore no longer within the terms of the marketing authorisation and, following risk assessment, require confirmation using manufacturer stability data on whether they can still be used.

It is essential that all those handling vaccines follow policies to ensure cold chain compliance.

1.3. Guidance and Policies

- The Department of Health Publication "Immunisation against Infectious Diseases" ('The Green Book') provides guidelines and information on vaccination including storage and handling of vaccines. Always refer to the online version as regular updates are only published electronically. https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book

- NHSGGC have produced these guidelines which provide the local governance and policy/process. They have been produced in line with Public Health Scotland March 2023 guidance which can be accessed for further information:

Guidance on vaccine storage and handling - Guidance on vaccine storage and handling - Publications - Public Health Scotland

2. Recommendations

2.1. Summary of Recommendations

A summary of the NHSGGC Guidelines are available in a fridge magnet form and should be displayed prominently (preferably on the fridge door) within every immunisation area (see Section 11.1).

2.2. Main Recommendations

- Specific member(s) of staff should be identified to monitor the pharmaceutical supplies fridge. Any temperature readings outside 2-8˚C should be investigated immediately and discussed with Pharmaceutical Public Health.
- The correct maintenance temperature of the vaccine fridge is 2-8˚C.
- Check and record the fridge temperature (maximum, minimum and current) at least twice a day. Suitable sheets are available from Pharmacy Public Health (ggc.pharmacypublichealth@nhs.scot).
- The thermometer should be reset after each reading.
- Store vaccines in the middle of the fridge away from walls. Do not fill fridge more than two thirds full and do not obstruct fan.
- Always check the expiry date (or thawed expiry) of a vaccine following removal from the fridge and before dispensing or administration.
- Rotate stock to ensure shortest shelf life is used first.
- Refrigerate vaccine deliveries immediately. (This should be the responsibility of the member of staff accepting delivery).
- Do not keep excess stock.
- Clean and defrost vaccine fridges if required on a regular basis (3 monthly) including self-defrost models. Place vaccines in another fridge or in a validated cool box while this takes place and until the fridge temperature is restored to 2-8˚C.
- Recalibrate or check the calibration of the thermometer annually or as otherwise specified according to the Green Book or manufacturer recommendations.
- Protect the power supply to the fridge ideally with a spurred connection or a fixed unit over the plug and socket to ensure the plug cannot be pulled out. Mark the electrical socket with a cautionary notice advising staff not to switch off power.
- Do not store foodstuffs in the vaccine fridge at any time.
- Any vaccine unsuitable for use (e.g. expired stock or heat/cold damaged vaccines) should be quarantined in a clearly marked bag pending further advice, or destroyed as appropriate.
- Vaccines should only be transported outside established clinics using validated cool boxes.
- Only remove from the fridge at any one time the minimum quantity required.
- Reconstituted vaccines and opened multi-dose vials should be disposed of and recorded in line with local guidelines at the end of a session (4 hours).
- Any surplus vaccine not used during a clinic session (4 hours) should be returned to the fridge as quickly as possible, marked, and used first for a subsequent session. Discard any vaccine not used during second session.

3. Ordering

3.1. Vaccine Supplies

All vaccines available on the NHS are supplied by the Pharmacy Distribution Centre (PDC) Unit C. Vaccine requests for all sites should be ordered from the PDC Unit C using up-to-date order forms provided by the PDC.

The contact details for the PDC Unit C are as follows:

Unit C Pharmacy Distribution Centre
Dava Street
Moorpark Central
Govan
Glasgow
G51 2JA
Contact number- 0141 201 3488

Email address: ggc.pdc.vaccines@nhs.scot

3.2. Ordering Vaccines

3.2.1. Order form

Clinics providing vaccinations should order vaccines for scheduled and ad hoc clinics using the order form with their pharmacy code/location on them. Clinics may obtain a copy of their form by e-mail from the PDC Unit C (ggc.pdc.vaccines@nhs.scot). Orders must be submitted prior to the delivery date as listed on the individual clinic location form.

3.2.2. Calculating the order Quantity

Clinics calculate order quantities required and enter on form.

When placing orders for vaccines from the PDC Unit C ensure that:

- The order form with clinic details is used and that all details are completed.
- The order form is sent to ggc.pdc.vaccines@nhs.scot using the appropriate mechanism as directed by PDC Unit C's ordering processes.
- Arrangements for high volume clinics (or unscheduled/ad hoc catch-up) should be discussed with the PDC Unit C prior to making appointments to ensure sufficient vaccine can be made available for the required date. These may require up to 2 weeks' notice.
- Vaccines can come in boxes of multiple doses per pack rather than individually, such as a box of 10. Ensure when ordering these that "1" is written on the relevant form if 10 are required.

3.2.3. Monitoring stock

Vaccine stocks must be monitored to avoid over-ordering or stockpiling, ideally by a designated person. Clinics should have sufficient vaccines to cover maximum two weeks of expected clinic activity. Where cold chain capacity is limited or during significant peaks of immunisation activity, clinics are advised to hold sufficient stock plus a small buffer (e.g. no more than two weeks) to meet expected demand until the next scheduled delivery from PDC Unit C.

3.2.4. Delivery

To guarantee delivery, a vaccine order must be with the PDC Unit C as per order form cut off time/day. Out of schedule deliveries may not be accommodated and should be discussed with PDC Unit C.

Queries regarding individual vaccine orders should be made to the PDC Unit C which is open from 8am to 4pm Monday to Friday. The best way to contact the PDC Unit C is via email ggc.pdc.vaccines@nhs.scot, or alternatively call 0141 201 3488.

For non-vaccine enquiries, the PDC general customer service department is available from 9am to 5pm Monday to Friday and can be contacted via email support@ggcpdc.zendesk.com or by calling 0141 347 8974.

4. Receipt

All staff likely to take receipt of vaccine deliveries should:

- Ensure that vaccines must be placed in the vaccines fridge(s) IMMEDIATELY upon delivery.
- Know where the keys for vaccine fridges are kept and have access to them to prevent delay in vaccines being stored at the appropriate temperature.
- Be aware of usual vaccine delivery days and any expected ad hoc deliveries.

It is good practice to check the received vaccines against the order for discrepancies and for leakage or damage before signing for them and to record the fridge temperature after a vaccine delivery has been placed in the fridge and again 15 minutes later (See Section 5.2. for stock rotation and temperature monitoring advice).

5. Storage and Equipment

5.1. Storage

5.1.1. Correct Temperatures

Vaccines should be stored in the original packaging at +2°C to +8°C and protected from light as exposure to ultraviolet light may cause loss of potency. This is relevant to consider where glass-fronted fridges are in use. Repeated warming and cooling of vaccines may also result in reduced potency.

It is generally recommended that vaccine fridges should be maintained as close as possible to 5°C, as this gives a safety margin of +/- 3°C.

5.1.2. Content of Fridges

It is important that the fridge is not overfilled. This can restrict the circulation of air causing some parts of the fridge to become warmer than others. It can also result in vaccines being pushed against cooling plates in the back or sides of the fridge.

It is recommended that the fridge is only partially filled with a maximum stock level no more than two thirds (66%) filled to allow circulation of air and achieve the correct temperature gradients. During periods of high activity, fridges may need to be filled beyond this level but these situations should be kept to a minimum where possible.

Vaccines should not be stored directly on the floor of the fridge or in 'salad drawers' with a lid as this can restrict airflow circulation and cause temperature variations. Occasionally, pharmaceutical fridges may have supplied baskets/storage that is elevated from the floor of the fridge, which can be used.

Food, drink and clinical specimens must never be stored in the same fridge as vaccines. This may also cause the door to be opened frequently for access resulting in a raised temperature.

5.1.3. High Temperatures

Heat speeds up the decline in potency of most vaccines and reduces their shelf life. Therefore, the effectiveness of the vaccine cannot be guaranteed unless it has been stored at the correct temperature.

Vaccines should not be stored in a fridge door as they will be exposed to the full ambient room temperature every time the door is opened. Pharmaceutical fridges will not have door storage built in for this reason.

5.1.4. Low Temperatures

Vaccines must not be kept at temperatures below 0°C. Freezing may cause increased reactogenicity and loss of potency for some vaccines. It can cause hairline cracks in the container, invisible to the naked eye, which could lead to contamination of the contents. It is important that vaccines are not stored close to any freezing/cooling component in the fridge (usually the back wall and sides).

5.1.5. Recording on the Temperature Chart

The temperature of the fridge should be recorded on the temperature monitoring chart and an appropriate note made next to these readings when:

- A new delivery has been placed in the fridge.
- Expiry dates have been checked and stock rotated.
- Stock has been taken out or stock check has been done e.g. for ordering.
- Any other reason involving the fridge door being open longer than usual.

This will explain any transient elevated temperatures when the chart undergoes a monthly 'sense' check. The temperature should be checked and recorded again 15 minutes after any of the above activities to ensure that the running temperature is satisfactory.

Care should be taken to ensure that the thermometer is reset on each occasion to prevent the persistence of elevated readings which may subsequently reduce confidence in the storage history of the vaccines.

See section 6.2.1 for the review of records.

5.2. Stock Management and Rotation of Stock

5.2.1. On Receipt

Shortly after receipt, all deliveries and existing stock should be routinely date checked and rotated within the fridge to ensure that those vaccines with the earliest expiry date are at the front and used first. Ideally, any vaccines with a short shelf life should be marked for example with the words "use first" or with an indicative sticky dot. It is good practice to have this process as part of written procedures.

5.2.2. Batch Numbers and Expiry Dates

Care should be taken when recording batch numbers. Where vaccines are presented as two components the batch number printed on the outer package of vaccines is the number which should be recorded.

Companies differ in the format they use for expiry dates. Care should be taken when checking expiry dates, note the following very different examples.

Batch: 2585H EXP: 10/2027	Batch: 68689Y EXP BY: 10/2027	Batch: 2299J EXP BEFORE: 10/2027
Expiry would be 31/10/2027	Expiry would be 30/9/2027	Expiry would be 30/9/2027

Thawed expiry dates must be adhered to and supersede printed expiry dates otherwise listed or printed on the original vaccine packaging. Staff must be aware of vaccines (e.g. Jynneos®) where thawed expiry dates are shorter than the expiry dates listed on the original vaccine packaging. Jynneos®, which has a short thawed shelf-life, may show a thawed expiry date of "13/05/25" whereas the package itself may show "Use by: 06/2028".

5.2.3. Out of date stock

Any out of date stock should be removed, recorded, and destroyed as soon as possible. Records must be kept as per local process and waste recorded in the appropriate database/spreadsheet/log. If it is not possible to remove, record, and destroy expired stock, or it is being held in quarantine, the expired stock must be labelled clearly to prevent inadvertent usage. See section 8 for disposal instructions.

5.3. Fridge Use and Specifications

5.3.1. Fridge Specifications

Specialised fridges are available for the storage of pharmaceutical products and must be used for vaccines and diluents. Ordinary domestic fridges must not be used. The following features are considered essential when purchasing a pharmaceutical fridge for storage of vaccines:

- Operational temperature +2°C to +8°C
- Forced air cooling – interior fan for temperature stability and rapid temperature recovery after door openings
- Door lock (e.g. key or digital lock)
- CFC, HCFC and ammonia free
- Auto-defrost function
- Wire shelves/baskets or shelves capable of allowing air ventilation
- Integral thermometer which has a digital display recording actual and maximum/minimum temperatures

- Thermometer has an integral high/low temperature alarm (audio/visual) and operates independently from the mains electric supply

Where a clinic or area has a fridge which does not have the essential features listed above, a replacement should be considered, unless the missing specifications can be addressed by an alteration to the equipment or environment e.g. if fridge is not lockable it should be kept in a lockable room, or if a fridge does not have an integral thermometer, a recommended stand- alone digital thermometer could be purchased.

Glass fronted fridges are preferable where available as they can minimise door openings. They allow an easier visual check to aid in stock ordering, location of stock in the fridge and can help to demonstrate that they are pharmaceutical fridges.

5.3.2. Age of Fridge

Where a vaccine fridge is over 6 years old, it should be considered for replacement within the following 12 months and before it is 7 years old. Daily temperature monitoring, appropriate annual servicing, regular audit and routine maintenance should be used to ensure ongoing satisfactory performance.

5.3.3. Manufacturers and Fridge Purchase Guidance

There are a number of manufacturers of fridges such as Lec®, Labcold®, Swan® and Sanyo®, or thermometers such as Fisher Price (Healthcare Logistics US).

See section 11.2 for further information on fridge purchase and cold chain equipment.

5.3.4. Installing a new Fridge or Moving a Fridge

When a new fridge is installed, refer to the manufacturer's guidelines before switching the appliance on. Generally after relocating a fridge, if it has not been tilted or placed on its side it may be turned on immediately. If it has been significantly disturbed or there is any dubiety it should be allowed to settle for 24 hours.

In either instance, the fridge temperature should be allowed to stabilise before it is used to store vaccines. The time for this may vary according to the make of the fridge and ambient temperatures. Best practice would suggest a period of 48 hours for installation of a new fridge but an existing fridge may be used after a minor relocation as soon the temperature is in the 2-8°C range.

A note should be made in the temperature log book of the date a new fridge is used for the first time or the date an existing fridge is relocated or recommissioned.

Fridges may require to be checked by Quality Assurance and Pharmacy Public Health prior to use.

5.3.5. Fridge Location/ Environment

Ideally a switchless electrical (spurred) supply should be installed to a fridge. If this is not possible sockets for fridges should be fitted with a cover. At the very least a fridge plug should be marked with a cautionary notice advising staff not to switch off power.

A fridge should not be situated near a radiator or any other heat source (including direct sunlight) and positioned to ensure adequate ventilation e.g. adequate space for air circulation between the compressor and the wall. It should be kept in a well ventilated room with no extremes of temperature (<16°C or > 32°C and ideally at 20-24°C maximum) to ensure performance at maximum efficiency. The manufacturer's user guide will provide specific information relating to this and should be consulted.

5.3.6. Securing the Fridge

Ideally a pharmaceutical fridge should be lockable as vaccines are prescription only medicines. Locking the fridge ensures that it is properly closed and can help to maintain the correct temperature. In addition to maintaining security of the vaccines, locking the fridge also helps to ensure or avoid the following:

- When the door is slammed shut quickly there is a potential for 'bounce back' resulting in the door being left very slightly ajar. This must be avoided.
- Equipment leads, paperwork and miscellaneous items can fall or be displaced, jamming the fridge door open.
- The door can be accidentally knocked open e.g. by a cleaner's equipment.

Unnecessary vaccine wastage can be prevented by ensuring that all individuals accessing the fridge understand their responsibilities, keeping the area around the fridge tidy and most importantly by keeping the fridge locked.

5.3.7. Routine Maintenance

Routine maintenance should be carried out by clinic staff. The manufacturer's user guide for the fridge will provide specific information on this and should be consulted.

Fridges should be cleaned and if necessary defrosted at least quarterly. Even self-defrost models may demonstrate icing, or a build-up of ice, particularly in warm humid conditions, see below. If this occurs regularly for no obvious reason then a fridge service should be considered.

When a fridge is to be cleaned/defrosted observe the following:

- Ensure that vaccine stock levels are at a minimum.
- Remove/transfer the vaccine to another monitored fridge (which is also maintained in accordance with NHSGGC Guidelines).
- Record "vaccine removal/transfer" on both sets of temperature recording sheets (in the comments section).
- Replace the vaccines in the fridge only once it has returned to the correct temperature after cleaning/defrosting.
- If an alternative fridge is not available an appropriately prepared validated cool box e.g. Vaccine Porter® may be used.
- Clean/defrost the fridge ensuring that:
    - An appropriate/compatible cleaning agent is used (check manufacturer's instructions but generally a dilute solution of sodium bicarbonate and water or detergent and water for routine cleaning).
    - The drainage hole for self-defrosting models is wiped well and not blocked.
    - The door seal is washed to remove all dust/debris and is checked that it is intact and free from any punctures.
    - The door hinges are checked and are dust free.

- The element at the back of the fridge is regularly dusted and remains dust free.

Note: There should be **no ice build-up** in the cabinet of self-defrosting models. This should be investigated if it occurs regularly as it may be an indication that there is moisture in the cabinet and the fridge will not be working at full efficiency. Causes include:

- The room is too warm or humid.
- The fridge thermostat/temperature is set too low.
- Cardboard packaging may have come in contact with the back wall at some point and is wet.
- Open Tupperware® style containers are being used and are attracting moisture.

5.3.8. Planned and Preventative Maintenance

All vaccine fridges should have an annual electrical check undertaken as part of the practice/clinics routine approach/contract for checking electrical equipment i.e. Portable Appliance Testing (PAT) inspection.

There are a range of providers who can be contracted to undertake this work, including NHSGGC Medical Physics Department (based at Stobhill Hospital, contact 0141 355 1019). A PAT inspection may be applied to electrical equipment which is not always portable, doesn't need to be conducted when a new fridge is installed as this is covered by the manufacturer's warranty and is not the same as servicing of the equipment.

Clinics may wish to have regular (e.g. annual) servicing in place to provide independent reassurance on their fridges' performance. For vaccine fridges to be used for longer than 5 years, there should be an annual service undertaken at the end of year 5 and year 6 to ensure appropriate functionality.

In addition, a service should be carried out if:

- It appears that 'drift' is occurring to determine whether the fridge is working within desired parameters.
- Where the fridge temperatures appear to be fluctuating or the fridge is operating outside of the 2-8°C range with no clear and fixable explanation.

Servicing of fridges can be arranged via contractors such as McMillan or Bellfrost. Contact ggc.pharmacypublichealth@nhs.scot for signposting to contractors if required.

5.3.9. Disposal of Old Equipment

Old fridges must be disposed of appropriately in line with Waste Electrical and Electronic Equipment (WEEE) regulations. When supplying a new fridge, manufacturers must (by law) provide the opportunity for the old equipment to be picked up and disposed of. A small cost may be applied for the service or may be free of charge for some manufacturers/suppliers if the new fridge is replacing one of their own models.

5.4. Thermometer Specifications

5.4.1. Thermometers

Digital thermometers or temperature monitoring devices are recommended to record the minimum, maximum and actual temperatures, since these are more reliable. This is the most frequent type of device used as an integral thermometer in modern pharmaceutical fridges.

If standalone thermometers are required, a digital thermometer with a min/max reading which has an inbuilt alarm (such as the 'Traceable Memory Monitoring Thermometer 17988') is recommended. Such a device will record the time that the alarm is triggered, providing a useful audit trail for breaks in the cold chain. The thermometer typically has a probe that is sealed in a small bottle of non-toxic glycol solution simulating a vial of vaccine. This provides a more accurate reading reflecting the temperature of stored vaccine rather than the air temperature of the Fridge. See section 11.2.

5.4.2. Air and Simulated Vaccine Temperature

Devices which only measure air temperature will respond immediately to any rise in the fridge air temperature. If the fridge air temperature is increased for a few seconds e.g. the door is opened briefly, a maximum temperature of >8˚C may be recorded which will remain until the next time the thermometer is re-set. However, it is likely that this will not reflect the actual temperature history of the stored vaccines because the actual temperature of a vial of vaccine will not change as quickly as air temperature. Devices simulating vaccine temperature provide a more accurate reading of the actual vaccine temperature and provide greater assurance of the actual maximum and minimum temperature of the vaccine.

5.4.3. Thermometer use and Resetting

Maximum and minimum temperatures recorded will remain until the next time the thermometer is reset. It is important that they are reset after every reading.

Guidance on the use of the type of digital thermometer suggested above is included in section 11.2. For guidance on the use and resetting of all other thermometers, please refer to the manufacturer's instructions.

5.4.4. Thermometer Calibration

Recalibration of temperature monitoring equipment by an appropriate contractor in accordance with manufacturer's recommendations can be expensive. In many instances it is cheaper to replace a stand-alone thermometer or logging device with a new model.

It is acceptable to verify the calibration of the thermometer. This may be done simply by comparing the temperatures registered by the thermometer with a logging device or ideally as part of a 'temperature mapping' exercise (see section 5.3) Verification of the calibration of the thermometer should be undertaken annually. Contact Pharmacy Public Health for further advice Tel. 0141 201 4824/4424.

5.5. Logging Devices

5.5.1. Loggers

Temperature "loggers" are available to monitor fridges continuously. Temperature information is downloaded into tailored software to allow preparation of a temperature history graph. They should not be used to monitor the fridge temperature alone as they will usually only measure air temperature rather than the simulated vaccine temperature. Two types of logging systems are in use – those requiring download (standard) and those that are connected to the internet for continual monitoring. Both fridge temperatures and logger temperatures should be collected. See Section 6.

	Standard loggers	**Connected loggers**
Example	ICESPY, LogTag	Kelsius

Data access	On download	Realtime
Alarm functionality	No	Yes
Requires internet	No	Yes
Power supply	Battery powered	1 per network controller

Loggers can be useful as they give an indication of how long a fridge has run out with the approved temperature range but variations between logger and thermometer readings can raise uncertainties around the temperature audit trail.

Prices for these vary widely and may require the purchase of software to download and analyse data onto a laptop or PC or ongoing support costs. The most widely used continual/connected temperature monitoring system within NHSGGC immunisation programme is Kelsius though other systems are also available for purchase.

Contact Pharmacy Public Health for further advice Tel. 0141 201 4824/4424

6. Temperature Monitoring

In line with national guidelines all staff managing vaccines should observe the '4 Rs':

- Read…fridge temperatures, at least twice daily.
- Record…these on an appropriate temperature chart.
- Reset…the thermometer every time a reading is recorded.
- React…to any temperatures outside the recommended range of 2-8˚C.

6.1. Roles and Responsibilities

As a minimum, designated members of staff should be identified as responsible for monitoring the fridge temperatures every day. There should be clear arrangements with regards to who should deputise in the event of holidays, sickness, absences etc. These staff must be trained to use the equipment and respond to any abnormal readings.

However, it is good practice that all staff on premises where vaccine is routinely stored e.g. Clinic leads, Health Care Support Workers, reception staff and administrative staff, complete basic cold chain training such as LearnPro 097 Cold Chain Management, and know how to respond in the event of an emergency e.g. fridge alarm sounding, protracted power cut.

It should be made clear to all staff involved with immunisation that the existence of designated members of staff to monitor temperatures does not devolve them from responsibility in ensuring that the vaccines they administer have been stored within the correct range of 2-8˚C.

6.2. Monitoring and Recording Temperatures

Fridge temperature readings (maximum, minimum and current) must be read and recorded at least TWICE every working day, at the start of clinical activity and at the end.

Recording pharmacy fridge temperature readings in this way provides the best audit trail if a temperature deviation occurs outside business hours. Even if continuous monitoring devices or

systems e.g. loggers, Kelsius are in place, a fridge temperature check at these times might highlight temperature excursions in a timely fashion and prevent delays to a subsequent clinic while quarantined vaccine is risk assessed.

In periods of high activity (e.g. vaccination clinics, stock checks, vaccine deliveries) temperature readings should be recorded after the specific event has finished and a note made on the recording sheet of the activity. If the temperature has exceeded 8˚C for a short time during the work (<20 minutes) annotate the temperature recording pads with the fridge temperatures, then reset it after it has returned within range (see section 5.2).

Pharmacy Public Health (0141 201 4424/4824) must be contacted if there is doubt about any temperature variations outside acceptable levels and care must be taken to ensure that the thermometer is reset after each reading. This approach provides the most accurate audit trail of vaccine storage temperatures in the event of an incident.

6.2.1. Monthly Review of Records

Monthly review of fridge temperature charts should be undertaken. This can highlight temperature 'drift' which may indicate that a fridges temperature control is becoming less reliable or is under stress e.g. increased ambient temperatures. This is important for all fridges but particularly for ageing models (over 5 years). Check for at least twice daily records and no excursions beyond 2-8˚C without adequate documentation or explanation. Check also for variation in minimum and maximum temperatures to ensure that the thermometer is being reset each time the temperatures are read.

The temperature chart should be signed and annotated as such after monthly review has been completed to audit compliance. Investigation into the cause of any 'drift' should be undertaken. Contact Pharmacy Public Health for further advice Tel. 0141 201 4824/4424.

Pads of temperature recording sheets are available to order from Pharmacy Public Health ggc.pharmacypublichealth@nhs.scot (see section 11.1).

6.2.2. Retaining Temperature Records

The Scottish Government Records Management NHS Code of Practice states under Pharmacy Records: Quality Assurance 'it is recommended that fridge temperature records should be retained for the life of any vaccine stored therein with a minimum of a one year retention period'. As a vaccine's shelf life can be up to four years or longer, retaining records for five years will generally enable the full storage history of vaccines to be accounted for.

6.3. Resetting the Thermometer

It is vital that staff monitoring and recording temperatures understand how to reset maximum and minimum temperatures. If these are not reset, elevated readings which may occur transiently during a clinic or after putting away a delivery, may not be cleared. Refer to manufacturer's instructions carefully. After a successful reset the actual, minimum and maximum temperatures should be the same. Contact Pharmacy Public Health for advice if required.

6.4. Setting Temperature Alarm Parameters

Where a fridge has an integral alarm to alert high and low temperatures it is important to ensure that the appropriate parameters for the alarm are set. It is recommended that the alarm should be set to sound after the temperature has been below 2°C or higher than 8°C for more than 15 minutes.

6.5. Action in the event of Abnormal Temperatures

Abnormal temperatures are those which are outside the recommended vaccine storage range of 2-8°C. If vaccines have been stored outside the recommended temperature range, the cold chain may have been broken and the vaccine may be unsuitable for use.

Action taken in the event of abnormal temperatures or reasons for abnormal temperatures should be clearly recorded on the temperature monitoring sheets e.g. “Delivery Received”.

Any temperature outside the recommended range which cannot be attributed to the putting away of an order or vaccine being removed (e.g. for a clinic, stock check) should be dealt with according to the following:

- In the event of an incident Pharmacy Public Health (PPH) will require full details to provide the best possible advice.
- A ‘Vaccine Incident Form’ must be sent to PPH (and can be requested from ggc.pharmacypublichealth@nhs.scot).

Once a response is received PPH will follow the relevant NHSGGC Pharmacy Public Health Standard Operating Procedures to risk assess the vaccine stock affected and give advice on onward use or destruction. If the quarantined vaccines are deemed unsuitable for further use, they should be disposed of as per information in section 8.

If the affected vaccines are deemed suitable to be used, they should be clearly marked. Wording such as “Subject to Cold Chain Breach. Use First” and any other supporting information as detailed in the Cold Chain Incident letter may be useful. If a second exposure occurs the vaccine must be re-assessed.

6.6. Assessment and Response to Incidents

An incident may be identified by clinic staff when thermometer readings outside 2-8˚C have occurred for >20 minutes with no reasonable explanation or as a result of a power cut. In this instance clinic staff must contact Pharmacy Public Health who will advise them how to proceed. The following will be factored in:

- Analysis of temperature record charts or continuous monitoring system (i.e. Kelsius) for adequacy of recordings, temperature drift and explanation for any >8°C temperatures recorded e.g. constant minimum and maximum readings may indicate that thermometer is not being re-set or temperature may have increased temporarily as the result of a stock check but this has not been recorded.
- Analysis of temperature logger results in comparison to fridge thermometer recordings and temperature ‘swing’ which might indicate failing fridge performance.
- Responses to reported self-audit data.

6.6.1. Response to Incidents

The response to incidents will be made following the relevant NHSGGC Pharmacy Public Health Standard Operating Procedures (SOP). PPH will provide as soon as possible:

- A ‘vaccine risk assessment report’ detailing how vaccines may be used. This advice will state that vaccines may be used as normal or need to be destroyed and waste logged for clinic/area records.

- An individualised report for the clinic/area detailing any recent previous incidents, potential reasons for the incident, recommendations to prevent future similar incidents and an invitation to undertake a self-audit of clinic/area vaccine storage arrangements. Copies of this report are also sent to Clinic Leads or service management for the area as appropriate.

While answering the immediate question regarding the continued use of vaccine, professional review undertaken by PPH enables an assessment of contributory factors and provides recommendations to improve practice and prevent future repeat occurrences.

6.7. Contingency Arrangements

Clinics should consider the practicality of alternative pharmaceutical fridge storage arrangements and ensure that they have suitable contingency plans in place which are clearly outlined to all staff in the event of a fridge failure. **Where there is a power cut keep fridges closed for as long as possible**.

If the power supply has been interrupted for a period of four hours or less, it may be enough to ensure that the fridge door is kept closed and close monitoring of temperatures is undertaken until either the supply is reinstated or alternative arrangements for vaccine storage can be made.

However if a power failure is persistent, vaccines should be moved to a suitable back- up or an alternative fridge which has been maintained in accordance with NHSGGC Guidelines.

N.B. the vaccines should not be removed from the fridge until alternative storage has been identified. When vaccines are transferred, record “vaccine removal/transfer” on both sets of fridge temperature recording sheets (in the comments section). Remove vaccines only when it is safe to do so, i.e. temperatures are in-range and the power is available (follow internal SOPs where present).

7. Transportation

7.1. From Holding Centres to Practices/Clinics

The World Health Organisation (WHO) has undertaken studies on vaccine storage and transportation and recommends that an efficient ‘cold chain’ is established for vaccine distribution to ensure that the correct temperatures are maintained throughout, as any breaks in the cold chain, may reduce the potency of vaccines and contribute to primary vaccine failure.

Within NHSGGC, vaccines are distributed from Unit C, Pharmacy Distribution Centre (PDC) to health areas using a refrigerated van or vaccine porters. These are containers that maintain cold chain which are usually validated for a maximum of eight hours (except Mini Vaccine Porter®) with a minimum number of openings to maintain the cold chain (check product specific information). Once received by the clinic/area, immediate transfer of vaccines to the vaccine fridge will ensure that the cold chain is fully maintained.

Cool packs (Medicool® 28 and other approved products) must be used as per manufacturer instructions.

With time and use, cool boxes and packs may become damaged and no longer maintain the required temperature range. Periodic validation may not be necessary but good practice is to visually inspect boxes for damage and packs for leakage.

For further information about preparing Vaccine Porters® and the Vaccine Mini Porter® please go to www.helapet.co.uk/catalog/index.php

7.2. From Clinic/Area to Another Location

Vaccines may require to be transferred from the vaccine fridge to another clinic or for domiciliary visits. Where this occurs, validated cool boxes e.g. Vaccine Porters® or Vaccine MiniPorters® – should be used following product-specific instructions. Cool packs (Medicool® 28 and other approved products) should be refrigerated according to instructions provided by the manufacturer. Packs usually require the same storage conditions for at least 24 hours as vaccines are stored (spaced out allowing airflow and kept away from walls/back/floor of fridges).

Mini Vaccine Porters® are available for transport of up to 10 vials of vaccine and are normally suitable for practices/clinics. They require the insertion of a Medicool® 11 pack, which must be frozen in advance, validated for a maximum of eighteen hours with a minimum number of openings to maintain the cold chain. See Section 11.2 for further information.

If a vaccine porter is not available small quantities of vaccine may be transported over a short distance and duration of time not exceeding 20 minutes.

Follow local SOP where present.

7.2.1. Domiciliary/Home Visiting teams

Transporting vaccines in motor vehicles in particular may expose vaccine to temperatures well above estimated room temperature or below freezing. Use of a vaccine porter is recommended especially if multiple visits to housebound patients are involved.

Vaccine porters are to be used to help maintain vaccines in the cold chain when conducting multiple visits to the housebound or delivering mass vaccination to care homes. Large vaccine porters, which use chilled Medicool® 11 packs, are used in care home mass vaccination programmes but are large and are only validated for 4 openings - these are not practical for domiciliary visiting. They may require 2 persons to move – follow manual handling guidance.

The Helapet Vaccine MiniPorter® is a practical choice. It can transport up to 10 vaccines and uses a Medicool® 11 pack which must be prepared by freezing. If the Medicool® 11 pack is prepared according to the instructions the Helapet Vaccine MiniPorter® is validated for multiple openings over 18 hours. Access to a freezer may be difficult in a healthcare setting. However, it should be noted that a domestic freezer may be used as long as the Medicool® 28 pack achieves a temperature of -18˚C for 24 hours. Instructions for full preparation of the Vaccine MiniPorter® are contained in manufacturer information.

Any vaccines maintained within equipment used as per manufacturer instructions may be returned to a pharmaceutical fridge for first use at the next suitable clinic. This minimises how often vaccines are exposed to movement and vibration which can cause degradation while avoiding waste. Leaving vaccines overnight in the Mini Vaccine Porter® should be avoided.

7.3. During Vaccination Clinic

When running a clinic in a room that does not have a fridge, it is can be unnecessary to store the vaccines in a validated cool box during the clinic session. Only remove the minimum vaccine required for a session (4 hours) from the fridge and do not remove it from the fridge any earlier than necessary.

Vaccines which are presented as solutions in multi-dose vials should be discarded as per manufacturer or local processes after the specified period of time. The individual Summary of

Product Characteristics (SPC) should be consulted. SPCs are available at http://emc.medicines.org.uk/.

Expiry dates and batch numbers of each vaccine must be recorded in patient records. This is necessary to provide an audit trail in the incidence of product withdrawal or adverse reaction, which may be attributable to the vaccine.

8. Disposal

Dispose of opened or prepared vials of vaccine unused during a clinic session in a yellow sharps bin with blue lid as per waste management guidance.

Retain and contact Pharmacy Public Health (0141 201 4424/4824) to report vaccines and devices which have malfunctioned or appear faulty.

Do not flush vaccines down the sink or toilet or transport vaccines with attached exposed sharps without prior discussion with Pharmacy Public Health.

9. Spillage

Spilt vaccines should be treated according to NHS GGC Infection Prevention and Control Policies as 'Other body fluid spillages'.

Gloves and protective apron should be worn while the vaccine is soaked up with paper towels. Dispose of the paper towels as clinical waste and clean the area with a disinfectant providing 1000ppm available chlorine.

Where live vaccines are used staff should exercise due care and attention to eliminate any risk of their hands being contaminated.

In the event of eyes being splashed with vaccine, the eyes should be rinsed with copious amounts of Sodium Chloride 0.9% and immediate medical advice sought. (Refer to the relevant policy on the HR website https://www.nhsggc.scot/staff-recruitment/hrconnect/health-and-safety/policies-guidance-documents-and-forms/ and those concerned with sharps https://www.nhsggc.scot/staff-recruitment/hrconnect/health-and-safety/policies-guidance-documents-and-forms/sharps/)

10. Recall

In the event of vaccines being recalled, all ordering sites will be notified in line with NHSGGC policy.

The clinic lead responsible for vaccine storage and handling must check all stock as soon as possible. Any affected vaccines should be placed in refrigerated quarantine clearly marked 'NOT TO BE USED'.

The responsible person/clinic lead should notify the PDC that stock requires to be returned as outlined by the initial recall notification. The clinic must keep records of all stocks returned as per the notification and on the temperature recording sheet where removed stock quantity should be annotated.

Appendix 1 shows an example of the returns form which will be provided by PDC in the event of product recall.

11. Support Materials

11.1. Fridge Magnets and Temperature Charts

Fridge magnets with a summary of the NHS NHSGGC Guidelines and contact numbers for advice and temperature charts have been prepared. The magnets should be placed on all vaccine fridges.

Recommended temperature charts for use in NHS NHSGGC premises are available. In addition to a full list of the guidelines the charts have a copy of the incident checklist.

An initial distribution of the magnets and temperature chart pads is made when a clinic is set up.

Extra magnets and replacement temperature chart pads may be obtained from Pharmacy Public Health.

11.2. Equipment Guidance

11.2.1. Fridges

When commissioning a pharmaceutical fridge or a temperature recording device, the advice of the Pharmacy Public Health Team must be sought for areas affected post-Vaccine Transformation Programme (Tel. 0141 201 4824/4424). This includes adult vaccinations, seasonal programmes, and non-routine programmes. Prisons, sexual health, addictions and other services can be provided with advice.

National procurement has negotiated a national framework for cold chain solutions and their email is nss.e-fcategory@nhs.scot

11.2.2. Thermometers

See Section 5.4.

11.2.3. Temperature Monitoring Apparatus (Loggers)

Temperatures “loggers” are available to support cold chain maintenance. See section 5.5.1. for full details.

Contact Pharmacy Public Health Team Tel. 0141 201 4824/4424) for further advice.

11.2.4. Vaccine Transport Equipment

See section 7.2 and Appendix 2 for full detail. Follow local SOPs.

Contact Pharmacy Public Health Team (Tel. 0141 201 4824/4424) for further advice.

11.3. Vaccine Fridge Incident Checklist

Ensure vaccines affected by a cold chain excursion are kept in quarantine (in a monitored, working fridge) until a risk assessment has been conducted. A vaccine incident form (available from ggc.pharmacypublichealth@nhs.scot) should be completed along with a corresponding DATIX/error record. Please do not close the DATIX until PPH team has completed an investigation.

An incident may highlight the need to review current procedures and undertake a self-audit. Further information and support is available from the Pharmacy Public Health Team Tel. 0141 201 4824/4424

11.4. Training

- LearnPro module ‘Cold Chain Management’ has been developed by PPH which should be completed by all staff. The online course can be accessed anywhere at any time and takes less than 30 minutes to complete. Enter 097 Cold Chain Management into the search box. (Any comments on the module can be forwarded to ggc.pharmacypublichealth@nhs.scot)
- Healthcare staff not directly employed by the NHS working in other areas should register for LearnPro by visiting

https://community.learnprouk.com/lms/login.aspx?ReturnUrl=%2flms%2fuser_level%%202fwelcome.aspx

12. References

Department of Health (2006). Immunisation against Infectious Diseases (The Green Book) accessed January 2025 at https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book

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Public Health Scotland (2023). Guidance on Vaccine Storage and Handling Version 1. Accessed January 2025 at https://rightdecisions.scot.nhs.uk/media/kfmdi1fe/vaccine-storage-and-handling-guidance-march-2023.pdf

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Appendix 1. Vaccine Return Form

NHS Greater Glasgow and Clyde

Appendix 1
Vaccine Return Form

Enclose hard copy of form with returned vaccines and e mail completed form to ggc.pdc.vaccines@nhs.scot to arrange uplift.

GP/ Clinic name/ ward name :
Address:
Date of Return:
Reason for Return : RECALL ☐
Details:
Processed By: Name & Designation:
Signature:

Vaccine Name	Batch Number and expiry date	Quantity

Appendix 2. Preparation of Vaccine MiniPorter®

The Vaccine MiniPorter® is comprised of, a Medicool® 11 cool pack (to be frozen), a spacer/protection mat (to be chilled), an inner polystyrene insulated box and lid, and an outer carrying case (see manufacturers' guidance - Instructions_for_Use_-_Vaccine_MiniPorter.pdf)

Preparing the Mini Vaccine Porter®:

1. Freeze the MC11 Medicool® Cool pack for at least 24 hours at -18° C. This temperature can be achieved in the freezer or freezer compartment of a domestic fridge (temperature can be confirmed by placing a maximum/minimum thermometer in the freezer compartment).
2. Chill the Medimat at +5°C for at least 24 hours in the main storage area of a fridge.
3. Remove the MC11 Medicool® unit from the freezer 20 minutes before needed. It is important that this unit is placed in the insulated box directly from the freezer.

Packing vaccines:

4. Place the vaccine to be transported in the bottom of the insulated box.
5. Place the Medimat directly on top of the vaccine.
6. Place the Medicool® 11 pack on top of the spacer/protection mat.
7. Finally, replace the insulated lid and close the flap of the outer carrying case. The porter is now ready for use and is validated for 18 hours with multiple openings.

Note:

- It takes 24 hours to prepare the Medicool® 11 (frozen) and Medimat (refrigerated). If vaccine transport is required daily then it will be necessary to purchase additional Medicool® 11 and Medimats, and consideration given to more than one Vaccine MiniPorter®.
- If more than one Vaccine MiniPorter® is being operated from a fridge it is good practice to mark the time that each cooling unit is returned to the fridge to ensure properly prepared mats and cool packs are being used.
- Detail in this section relates to the Medicool® 11 for the Vaccine MiniPorter®, cooling and preparation requirements may vary according to the type and size of porter used – it is therefore important to read the manufacturers' instructions carefully to ascertain which system is being used. Follow local SOPs where available.

Please direct any enquires to Pharmacy Public Health

Email ggc.pharmacypublichealth@nhs.scot Telephone 0141 201 4824