



CLINICAL GUIDELINE

Vaccine Ordering Storage and Handling Guideline

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 Intranet 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.

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1. Introduction

1.1. Purpose of Guidelines

The aim of these guidelines is to provide detailed information which will support NHS GGC primary care staff in the storage and handling of vaccines. It is also hoped that GP practices and community clinics (practice/clinics) in particular will find the information a valuable tool in delivering and supporting training to relevant staff at a local level.

1.2. Background

Vaccines naturally biodegrade over time and storage out with 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 require confirmation using manufacturer's 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 on-line version as regular updates are only published electronically. <https://www.gov.uk/government/organisations/public-health- england/series/immunisation-against-infectious-disease-the-green-book>
- The NHS (General Medical Services Contracts) (Scotland) Regulations 2004 set out detailed requirements for GP practices regarding the proper storage of vaccines. Specifically, these regulations, at paragraph 8 of Schedule 5, require the contractor to ensure that:
 - a) *all vaccines are stored in accordance with the manufacturer's instructions.*
 - b) *all fridges in which vaccines are stored have a maximum/minimum thermometer.*
 - c) *Refrigerator (fridge) temperature readings are taken on all working days*
- NHSGGC have produced these guidelines and Health Protection Scotland has produced National Guidelines available at <http://www.hps.scot.nhs.uk/resourcedocument.aspx?id=6330>

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 or a Prescribing Support Pharmacist if necessary. [Section 6.](#)
- The correct maintenance temperature of the vaccine fridge is 2-8°C. [Section 5.](#)
- Check and record the fridge temperature (maximum, minimum and current) twice daily. Suitable sheets are available from Primary Care Distribution Centres. The thermometer should be re-set after each reading. [Section 6.](#)
- Store vaccines in the middle of the fridge away from walls. Do not fill fridge more than two thirds full. [Section 5.](#)
- Always check the “Expiry Date” of a vaccine following removal from the fridge and before dispensing or administration. Check expiry dates and rotate stock to ensure shortest shelf life is used first. Do not keep excess stocks. [Section 5.](#)
- Refrigerate vaccine deliveries immediately. (This should be the responsibility of the member of staff accepting delivery). [Section 4](#)
- 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. [Section 5.](#)
- Recalibrate or check the calibration of the thermometer regularly according to the manufacturer’s recommendations. [Section 5.](#)
- 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. [Section 5.](#)
- Do not store foodstuffs in the vaccine fridge at any time. [Section 5.](#)
- Any vaccine unsuitable for use (e.g. expired stock or heat/cold damaged vaccines) should be clearly identified and returned for disposal. Telephone the Pharmacy Distribution Centre to arrange. [Section 6.](#)
- Vaccines should only be transported to peripheral clinics using validated cool boxes. [Section 7.](#)
- Only remove from the fridge at any one time the minimum quantity required. Reconstituted vaccines and opened multidose vials should be disposed of in line with local guidelines at the end of a session. [Section 8.](#)
- Any surplus vaccine not used during a clinic session should be returned to the fridge as quickly as possible and used first for a subsequent session. Discard any vaccine not used during second session. [Section 7.](#)

3. Ordering

3.1. Who Supplies Vaccine

Childhood vaccines for use in the Scottish Immunisation Recall System (SIRS), selective immunisation for Hepatitis B for at risk babies and any additional childhood vaccines for ad hoc vaccination clinics should be ordered from the Pharmacy Distribution Centre (PDC) using the pre-prepared order form provided by PPH, please contact 0141 201 4424/4824 or email Pharmacy Public Health if you don't have one.

The table below highlights information for different vaccines.

Order From	Vaccine Type	Order Method	Contact
Pharmacy Distribution Centre	Childhood Vaccines (Baby, Pre-School and missed School Programme) National Immunisation Programme (e.g. Zostavax) Flu vaccine for <18 years old (IM and intra nasal)	Vaccine Order Form. Each practice or community clinic has an individualised electronic copy (Appendix 1)	Pharmacy Distribution Centre, Dava Street, Moorpark Central, Govan, Glasgow, G51 2JA Tel 0141 347 8981
Movianto	Seasonal variations apply to influenza vaccine ordering arrangements ¹	Web based ordering system Each practice and site has individual sign on details	Phone: 01234 48632 Email: flu.scotland@movianto.com
Local Community Pharmacy	Travel Vaccines and Adult Booster Vaccines (e.g. Revaxis) PPV23 for patients with underlying health conditions ²	Individual Prescriptions (GP10)	n/a

1. Arrangements for distribution of seasonal flu vaccine particularly for Fluenz and injectable vaccine for children may vary from season to season. Clinics and practices will be updated on an annual basis.
2. Pneumococcal Polysaccharide Vaccine (PPV23) is provided to individuals who have underlying health conditions and those 65 years and older. Vaccine for the 65 years and older cohort is sourced nationally and will be supplied on contract.

3.2. How to Order

Order form

GP practices and community clinics should order vaccines for both scheduled and ad hoc clinics using their designated pre-prepared vaccine order form. There is space on the form to write the name of any vaccine not listed. Clinics may obtain a copy of their pre-prepared form by e-mail from [Pharmacy Public Health](#) (or Telephone 0141 201 4424/4824).

Calculating the order quantity

Community clinics and GP practices calculate order quantities required and enter on form. When placing orders for vaccines from the Pharmacy Distribution Centre (PDC), ensure that:

- The pre-prepared order form with practice/clinic details is used and that all details are completed.
- The order form is signed before scanning and emailing to vaccines@ggc.scot.nhs.uk. (If a scanner is not available the unsigned order may be emailed to the PDC from the approved NHS email address e.g. @nhs.net or @ggc.scot.nhs.uk of a suitably qualified member of staff).
- The date of the clinic is added to the subject line of the e-mail.
- Arrangements for large clinics (or unscheduled/ ad hoc catch-up) should be discussed with the Pharmacy Distribution Centre prior to making appointments to ensure sufficient vaccine can be made available for the required date.
- Care is taken in counting the vaccines, especially as certain vaccines e.g. Fluenz Tetra® and Prevenar 13® are packaged in multiple quantities e.g. packs of 10. So 1 pack of ten Prevenar 13® should be recorded as 10 vaccines on the order form.

Monitoring stock

Vaccine stocks must be monitored to avoid over-ordering or stockpiling, ideally by a designated person. GP practices and community clinics should have no more than two to four weeks' supply of vaccines at any time.

Delivery

To guarantee delivery, a vaccine order must be with the PDC 48 hours before the expected delivery day. If a practice/clinic misses this deadline but needs the vaccine before the following scheduled delivery day, they should contact the PDC to arrange an alternative. This may for example involve someone from the practice/clinic uplifting the vaccine.

Queries regarding individual orders should be made to the PDC vaccine section which is open from 8am to 4pm Monday to Friday. The best way to contact the PDC vaccine section is to email vaccines@ggc.scot.nhs.uk alternatively tel. 0141 347 8981. (The PDC general customer service section is available from 9am to 5pm Monday to Friday tel. 0141 347 8974).

The Pharmacy Distribution Centre has different delivery times for vaccines depending upon a surgeries' geographical position. Vaccine orders should be placed with this in mind. The table below illustrates the schedule.

Glasgow Practices/Clinics	Routine Delivery Day	Vaccine requisition must be submitted by
South West and Dunbartonshire	Monday	Thursday 12 noon
East	Tuesday	Friday 12 noon
West	Wednesday	Monday 12 noon
South East and Inverclyde direct deliveries	Thursday	Tuesday 12 noon
North	Friday	Wednesday 12 noon
Renfrewshire		
<i>Dispatched from PDC on Monday to RAH for onward delivery</i>	Tuesday pm or Wednesday am	Friday 12 noon
<i>Inverclyde</i>		
<i>Dispatched from PDC on Wednesday to IRH for onward delivery</i>	Thursday	Monday 12 noon

4. Receipt

All staff likely to take receipt of deliveries should:

- Understand 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 30 minutes later (See Section 5.2. for stock rotation and temperature monitoring advice).

5. Storage and Equipment

5.1. Storage

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. 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.

Too warm

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.

It's 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.

So it's recommended that the fridge is only partially filled (around 50%) and even at maximum stock level is not more than two thirds (66%) filled to allow circulation of air and achieve the correct temperature gradients.

Some pharmaceutical fridges have wire baskets on feet situated on the floor of the fridge in which vaccine may be stored. Otherwise, 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.

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.

Too cold

Vaccines must not be kept at temperatures below 0°C. Freezing may cause increased reactogenicity and loss of potency for some vaccines.

Moreover it can cause hairline cracks in the container, invisible to the naked eye, which could lead to contamination of the contents. So it's important that vaccines are not stored close to any freezing/cooling component in the fridge (usually the back wall)

Non-pharmaceutical items

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

Use of temperature recording charts

Review temperature records at the end of the month. 'Sense check' them, for example if the temperatures are showing no variation this may indicate that the thermometer is not being reset or are there any unexplained wide variations in temperature. Any temperature deviances should have a clear explanation in the comments section and the additional temperature recordings taken should be recorded on the sheet

Temperature recording charts are available to order from Primary Care Distribution centres. Further advice about their use is in Section 11.1.

5.2. Stock Management and Rotation of Stock

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 “use first”. It is good practice to have this process as part of written procedures.

Checking batch numbers

Take care 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. This number incorporates details of all components of the final reconstituted vaccine. For example, Priorix[®], manufactured by Glaxo Smith Kline, has one batch number which includes C (representing the combined product) while the component freeze-dried vaccine component has a batch number containing the letter F and diluent containing the letter D.

Checking expiry dates

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

<p>Batch: 2585H</p> <p>EXP: 10/2007</p>

Expiry would be 31/10/2007

<p>Batch: 68689Y</p> <p>EXP BY: 10/2007</p>

Expiry would be 30/9/2007

<p>Batch: 2299J</p> <p>EXP BEFORE: 10/2007</p>
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Expiry would be 30/9/2007

Annotating 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 counted 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 30 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.

Dealing with out of date stock

Any out of date stock should be labelled clearly, removed from the fridge and returned for destruction as soon as possible according to local procedure (See Section 8. Disposal).

5.3. Fridge Use and Specifications

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 since they are not designed to maintain the rigorous temperature range and internal cabinet temperature gradients required for storage of vaccines.

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
- 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 practice/clinic 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.

Age of Fridge

Where a fridge is over 5 years old, it should be considered for replacement. Fridges are likely to operate satisfactorily for at least 5 years. Beyond this age the fridge function may deteriorate e.g. door seals can harden and crack, leaking cold air. Daily temperature monitoring and routine maintenance should be used to ensure ongoing satisfactory performance.

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). There is a list of manufacturers and suppliers with contact details and an approximate dimension and price list in Section 11.2.

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. If the oil in the fridge compressor has been displaced in a move and has not settled back, the fridge motor may become damaged.

Generally after relocating a fridge, if it hasn't been tilted or placed on its side it may be turned on immediately. If it has been significantly disturbed or there is any doubt 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.

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. Details of socket covers are given in section 11.2.

At the very least a fridge plug should be marked with a cautionary notice advising staff not to switch off power.

Generally, 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.

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 maintain the correct temperature. An open door will cause the fridge motor to work harder to maintain the temperature reducing the life of the fridge and potentially posing a fire risk.

If a fridge door isn't always locked shut:

- When the door is slammed shut quickly, there is the potential for 'bounce back' resulting in the door being left very slightly ajar. This often happens at the end of the day when health care practitioners are rushing to finish clinics.
- 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, keep the area around the fridge tidy and most importantly by keeping the fridge locked.

Routine Maintenance

Routine maintenance should be carried out by practice/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 even damp
- 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

Additional/ Annual 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).

N.B. 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.

Practice/clinics may wish to have regular (e.g. annual) servicing in place, to provide independent reassurance on their fridges' performance.

If regular temperature monitoring, in-house maintenance and annual audit are being carried out in accordance with NHSGGC guidelines, specialist annual servicing by a contractor may not be necessary i.e.

- Temperature monitoring is carried out in accordance with NHSGGC Guidelines
- Temperature charts are reviewed on a monthly basis to determine that temperature 'drift' (a widening range of maximum minimum temperatures and steadily increasing or decreasing mean temperatures) is not occurring

However have a service carried out

- If it appears that 'drift' is occurring to determine whether the fridge is working within desired parameters
- The fridge is more than ten years old
- 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 refrigeration, www.mcmillanrefrigeration.co.uk. Tel: 0845 293 0823, E-mail sales@mcmillanrefrigeration.co.uk or Bellfrost Tel: 01698 834344.

Disposal of old equipment

Old fridges must be disposed of appropriately. 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

Digital thermometers or temperature monitoring devices are recommended to record the minimum, maximum and actual temperatures, since these are more reliable. This is often the type of device used as an integral thermometer in modern pharmaceutical fridges. Where a digital thermometer is not fitted as integral to the fridge, or if a practice/clinic is using a manual thermometer, a stand-alone digital thermometer should be purchased and situated centrally within the cabinet, in the middle of stored vaccines.

Type of stand-alone thermometer

A digital thermometer with a min/max reading which has an inbuilt alarm (such as the 'Traceable Memory Monitoring Thermometer 17988') is a good choice. 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. for details of thermometer manufacturers and suppliers.

Air versus simulated vaccine temperature

Devices which only measure air temperature will respond immediately to any rise in the fridge air temperature. So even if the fridge air temperature is increased for a few seconds e.g. the door is opened briefly, a maximum temperature of $>8^{\circ}\text{C}$ 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. So 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.

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.

Thermometer Calibration

Recalibration of temperature monitoring equipment by an appropriate contractor in accordance with manufacturer's recommendations can be expensive. In many instances it's probably 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

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.

They 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.

In particular those which monitor simulated vaccine temperature may be very expensive. Contact Pharmacy Public Health for further advice Tel. 0141 201 4824/4424.

6. Temperature Monitoring

As a general principle 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 out with recommended range of 2^oC to 8^oC

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 regard 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 e.g. GPs, reception staff and administrative staff complete basic cold chain training (see section 11.4) 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 °C to +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 and near the close of business. Additionally if work has been undertaken in the fridge (e.g. vaccination clinic, stock check, delivery), the temperature should be recorded after this has finished and a note made on the recording sheet of the activity that has taken place (see section 5.2).

A designated person should be responsible for taking these readings. This person should also be trained and confident in using the thermometer and be aware of the actions to be taken if the temperature is out with the recommended 2°C to 8°C range. Records of daily temperature readings should then be reviewed on a monthly basis to check for 'drift' (see below) in temperatures. This may highlight failing equipment or the need to reset thermostats.

Pharmacy Public Health (0141 201 4424/4824) must be contacted if there is doubt about any temperature variations out with 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.

Recording pharmacy fridge temperature readings TWICE daily may not seem to be of much importance at the time, but, when a fridge incident occurs, this information is the deciding factor as to whether a vaccine can safely be used or whether revaccination might be required.

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.

The temperature chart should be signed 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 Primary Care Distribution Centres (see section 11.1.).

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 in doubt.

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

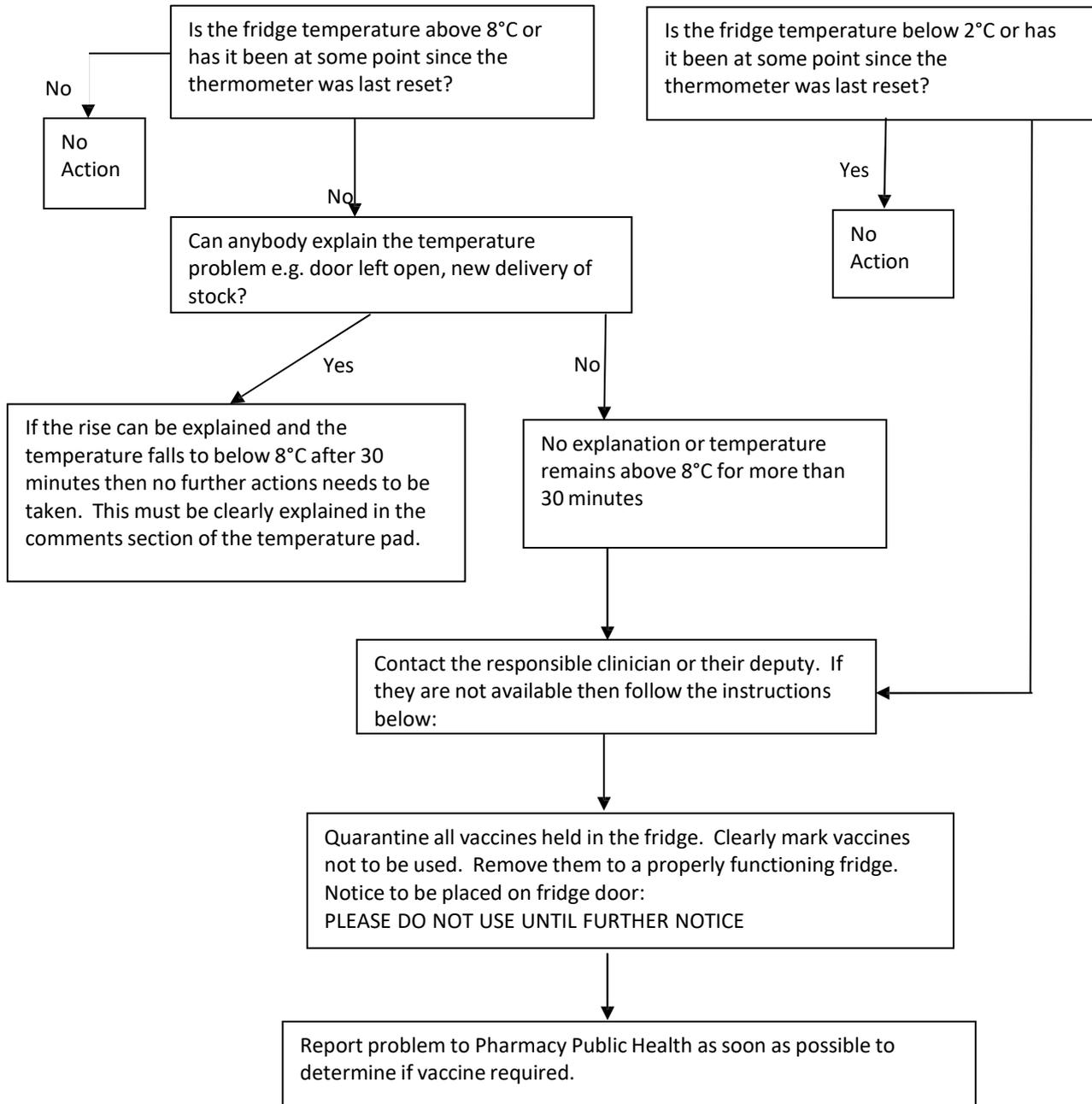
Abnormal temperatures are those which are out with the recommended vaccine storage range of 2-8°C. If vaccines have been stored out with the recommended temperature range, the cold chain may have been broken and the vaccine may be unsuitable for use.

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 out with the recommended range which cannot be attributed to the putting away of an order or vaccine being removed for a clinic, should be dealt with according to the NHSGGC guidance. See Figure 1. 'Management of Fridge Temperature Problems for clinic staff' below.

Figure 1

Management of Fridge Temperature Problems for Primary Care



N.B. Regular review at end of month should identify any temperature drift, temperature records maintained satisfactorily and explanations provided for any temperature outside 2°C - 8°C.

FURTHER ADVICE AVAILABLE FROM The HSCP Pharmacist, refer to your local directory or Pharmacy Public Health, PH Pharmacist (Health Protection) Telephone: 0141 201 4424 / 4824.

To provide the best possible advice Pharmacy Public Health (PPH) will require details of the incident. They will e-mail a Vaccine Incident Form to the practice/clinic to collect information. A “Vaccine Incident Checklist” is included in Section 11.3 to give a guide to the types of information that will be required.

Once a response is received PPH will follow the NHSGGC Pharmacy Public Health Standard Operating Procedure. See Figure 2. Pharmacy Public Health Risk Assessment of Vaccines.

If the quarantined vaccines are deemed unsuitable for further use, they should be disposed of. See Section 8. Disposal

If the quarantined vaccines are deemed suitable to be used, they should be clearly marked with “Subject to Cold Chain Breach. Use First”. If a second exposure occurs, then the vaccine will have to be re-assessed.

6.6. Assessment and Response to Incidents

An incident may be identified in 2 ways:

- When a clinic reports an incident after failure of cold chain storage
- After analysis of audit data undertaken routinely or at the request of PPH.
 - Analysis of temperature record charts for adequacy of recordings, temperature drift and explanation for any $>8^{\circ}\text{C}$ 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.

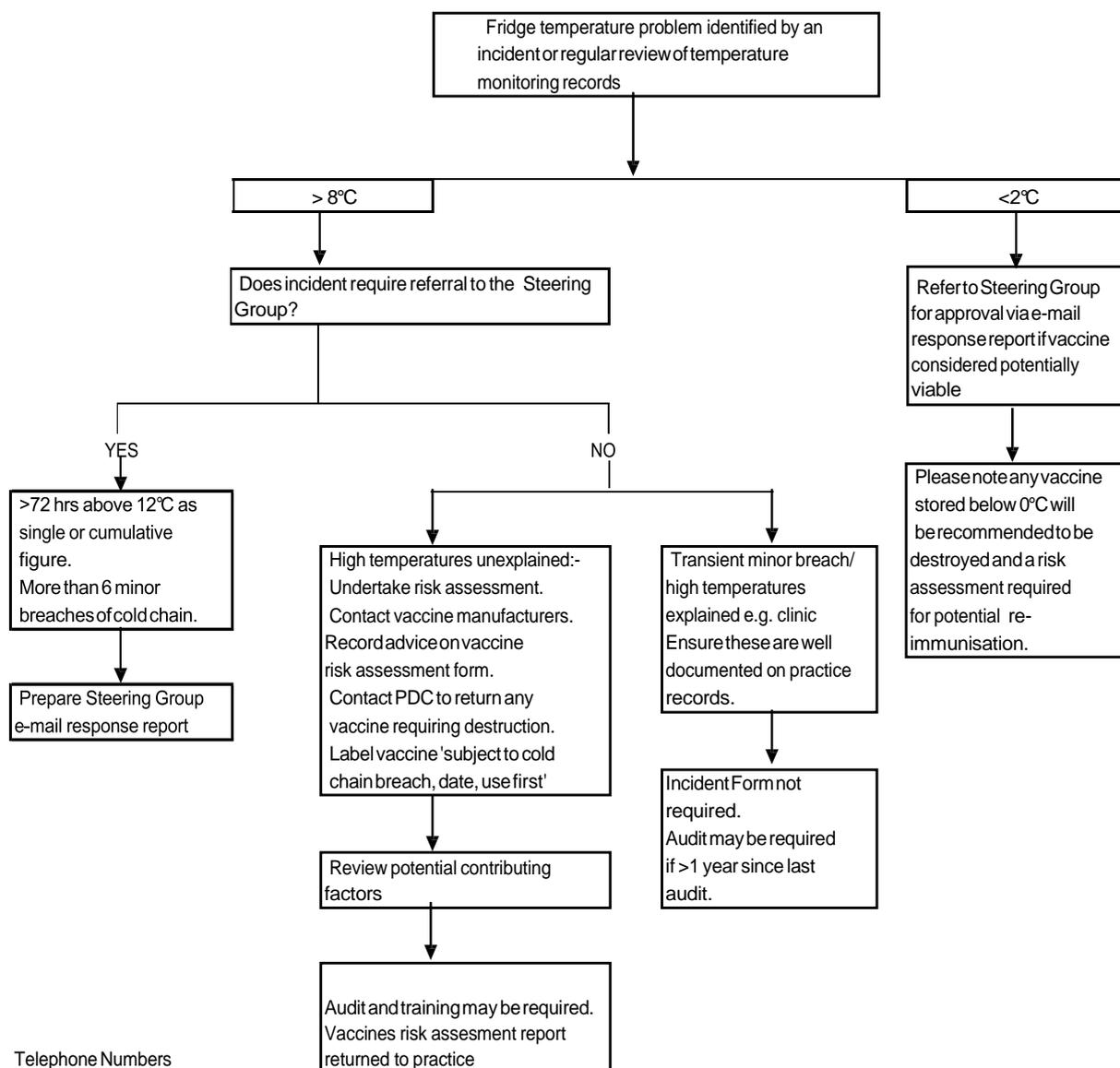
The process to be followed for all incidents is;

GP practice/community clinic responsible clinician or their deputy contacts PPH to report the incident and arrange new vaccine supply if required see Figure 1.

PPH will provide advice depending on the scale of the incident see Figure 2. ‘Pharmacy Public Health Risk Assessment of Vaccines Process’ below.

Figure 2

Pharmacy Public Health Risk Assessment of Vaccines Process



Telephone Numbers
PDC 0141-347-8981
PPH 0141-201-4824

All incidents will require completion of a Vaccine Incident Form to be returned promptly to Pharmacy Public Health (PPH).

Response to incidents

The response to incidents will be made following the NHS GG& C Pharmacy Public Health Standard Operating Procedure (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, used 'off license' or need to be destroyed and should be retained for practice/clinic records.
- an individualised report for the practice/clinic 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 practice/clinic vaccine storage arrangements. Copies of this report are also sent to the Sector Clinical Director and Lead Clinical Pharmacist.

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

Practices and 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.

Pharmaceutical fridges might normally be expected to maintain the fridge temperature for up to 4 hours in the event of a power failure.

So 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 failure lasts longer than four hours 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 shouldn't 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).

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 the Pharmacy Distribution Centre (PDC) to health centres, clinics and surgeries using a refrigerated van or cool boxes. These are special containers which are validated to maintain the cold chain for eight hours, including allowance for multiple openings. Once received by the surgery/clinic, immediate transfer of vaccines to the vaccine fridge will ensure that the cold chain is fully maintained.

7.2. From Practice/Clinic to another Location

Occasionally vaccines may have to be transferred from the practices vaccine fridge to another clinic or for domiciliary visits. Where this occurs, validated cool boxes e.g. Vaccine Porters® or Mini Vaccine Porters® – should be used if available. Large Vaccine Porters® are not normally practical for practices/clinics since they take up a lot of space and require several shelves of fridge space to store the cool packs prior to their use.

Smaller cool boxes (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 cool pack, which must be frozen in advance, for accredited use and are validated for up to 18 hours. See Section 11.2. for further information.

If a vaccine porter is not available small quantities of vaccine may be transported over a short period of time amounting to no more than an excursion during a vaccination clinic as described below e.g. a 10 minute journey to a housebound patient for immediate administration of vaccine.

7.3. During vaccination clinic

When running a clinic in a room that does not have a fridge, it is not necessary to store the vaccines in a cool box during the clinic session. Only remove the minimum vaccine required for a session from the fridge and don't remove it from the fridge any earlier than necessary.

Unused vaccines removed from the fridge for one clinic session in unopened packs, should be returned to the fridge clearly labelled "Use First" and should be selected immediately for the subsequent session requirement. They should **not** be returned for refrigeration more than once.

Vaccines which are presented as solutions in multi-dose vials should usually be discarded after four hours, or at the end of the session, whichever is sooner. The individual Summary of Product Characteristics (SPC) should be consulted for exceptions e.g. some coronavirus vaccines may allow a 6 hour period of use up to 25°C.

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 not used during a clinic session in a blue topped sharps bin.

Contact Pharmacy Public Health (0141 201 4424/4824) to report and arrange uplift of:

- Vaccines syringes and devices which have malfunctioned or appear faulty

Contact the PDC by telephone (0141 347 8981) to arrange uplift of:

- Large quantities of vaccine which are unfit for use e.g. past expiry date or subject to cold chain excursion. A returns form will be provided by the PDC and should be completed ensuring that the date, batch number, expiry, quantity returned and reason for return is provided. Please clearly mark the items for disposal. Small quantities of vaccine <10 vials may be disposed of in a blue topped sharps bin after removal from packaging.

Do not:

- Flush vaccines down the sink or toilet
- Return vaccines with attached 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 GGNHSB Management of Occupational and non-Occupational exposure to blood borne viruses <https://www.nhsggc.org.uk/working-with-us/hr-connect/occupational-health/needlestick-similar-injuries/#>)

10. Recall

In the event of vaccines being recalled, all ordering sites will be notified by the Pharmacy Distribution Centre.

The person in the practice/clinic 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 should notify the Pharmacy Distribution Centre that stock requires to be returned as outlined in Section 8. Disposal, or as directed by the initial recall notification. The practice/clinic must keep records of all stocks returned, (as per returns sheet).

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 has been made to all practices/clinics.

Extra magnets for second or back up fridges or replacements for lost or damaged magnets and replacement temperature chart pads may be obtained from the Primary Care Distribution Centres.

For Greater Glasgow Practices and clinics: Primary Care Distribution Centre, Clutha House, 120 Cornwall Street South, Glasgow, G41 1AD.

Tel: 0141 427 8246

For Clyde Practices and clinics: Argyle and Clyde Primary Care Supplies, NHS NHSGGC Depot, 21 Dava Street, Govan, Glasgow, G51 2JA.

Tel: 0141 201 3062

11.2. NHSGGC Equipment Guidance

Fridges

When purchasing a pharmaceutical fridge or a temperature recording device, it is strongly recommended that the advice of the Pharmacy Public Health Team is sought (Tel. 0141 201 4824/4424). Often medical suppliers/wholesalers are unable to offer technical advice on such equipment and apparatus.

National procurement has negotiated discounted prices on fridge equipment, details available from pharmacy public health on request.

The dimensions, prices and specifications of equipment offered by suppliers can vary quite widely. As a rough guide, however, NHSGGC and PPSU have studied the evidence and believe that Labcold®, LEC®, Sanyo® and Swan® manufactured pharmacy fridges generally fulfill the guidelines for storage of vaccines.

Labcold® now offer an IntelliCold® range of fridges incorporating a logging device which may be used to determine when and for how long a cold chain breach has occurred.

The Scottish National procurement has secured discounted prices for certain models of Lec and Labcold fridges. Contact Pharmacy Public Health for details.

The chart overleaf gives a rough guide to the size and price of fridges and where they may be sited.

Typical Pharmacy Fridge sizes and prices (N.B. these are for guidance only)

Typical Location-size	Dimensions W/D/H (mm)	Capacity litres	Number of shelves	Price range <i>*Approximation only</i>
Table top - small	380/500/660	35-60	2	£400-£500
Under bench - medium	560/600/865	135-150	2-3	£650-£800
Tall - large	595/ 910/1850	300-500	5-7	£1000-£3000

Thermometers

Modern pharmaceutical fridges will have an integral thermometer, however, for various reasons a standalone thermometer may need to be purchased separately.

N.B. In the event of a second thermometer being purchased for a fridge it is strongly recommended that only one thermometer is used to monitor the cold chain.

A Traceable® Memory Monitoring Fridge/Freezer Thermometer is the recommended device because:

- It records minimum, maximum and actual temperatures
- Has an alarm
- Records the time whenever the alarm is triggered providing a useful audit trail for breaks in the cold chain.
- The thermometer probe is sealed in a small bottle of non-toxic glycol solution allowing the thermometer to record the product temp.

Please note these thermometers include a 2 year calibration certificate which indicates an expiry date at which point the accuracy will no longer be guaranteed. Recalibration of the thermometer is expensive and in practical terms it is usually cheaper to replace the thermometer.

Newer thermometers such as the FisherBrand Traceable® Excursion Trac™ Thermometer also provide a continuous logging function but are more expensive and can be quite complicated to read.

Temperature monitoring apparatus (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.

They 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.

It is particularly important to ensure that a logging device is secured in the centre of the fridge. Small logging devices can be easily displace leading to false readings e.g. if pushed against the cooling plate on a fridge wall.

Prices for these vary widely and may require the purchase of software to download and analyse data onto a laptop or PC. In particular those which monitor simulated vaccine temperature may be very expensive. Contact Pharmacy Public Health Team Tel. 0141 201 4824/4424) for further advice.

Socket covers

There are a number of socket covers readily available on the market. They can be inexpensive and easy to fit. Fitting one over a fridge socket and plug can prevent the loss of vaccine due to accidental removal of the plug for example by a cleaner when hoovering the room.

Vaccine transport equipment

Cool boxes must be of the required certificated standard to maintain the cold chain and manufacturers can advise on the validation and appropriate use of these. Vicarey Davidson & Co Surgical Instrument Makers, 12A Carron Place, Kelvin Industrial Estate, East Kilbride, G75 0YL. Tel: 01355 570034 can advise on models currently available. The manufacturer of the Vaccine Porter's® website is at www.helapet.co.uk/catalog/index.php?CG_ID=4

Large cool boxes (e.g. Vaccine Porters®) are not normally practical for practice/clinics since they take up a lot of space and require several shelves of fridge space to store the cool packs prior to their use. Health and Safety Regulations require two persons to carry the Vaccine Porter 24.

However, Mini Vaccine Porters® are suitable for transport of up to 10 vials of vaccine and correctly prepared, are validated to maintain the interior temperature at 2° to 8°C for 18 hours with multiple openings.

Because the cold chain has been maintained any unused vaccine stored in a properly prepared Mini Vaccine Porter® within the defined time parameters can be returned to the fridge and used again without constraint, So it's good practice to use a Mini Vaccine Porter® or similarly accredited cool box to transport vaccines from a surgery to a domiciliary situation, especially when it's likely that some vaccine may have to be returned unused. Contact Pharmacy Public Health Team (Tel. 0141 201 4824/4424) for further advice.

Guidance and Procedures for Use of Mini Vaccine Porters®

Access to a fridge with a full freezer compartment is required for the preparation of a Mini Vaccine Porter as the MC11 MEDICOOL® COOLPACK pack used to ensure temperature maintenance must be frozen and not simply chilled.

Although the Mini Vaccine Porter® can maintain the interior temperature at 2° to 8°C for up to 18 hours, it is good practice to return all vaccines, thus transported, back to the main holding fridge on the same day as they were issued.

Leaving vaccines overnight in the Mini Vaccine Porter® should be avoided.

Preparing a Mini Vaccine Porter®:-

The Mini Vaccine Porter® is comprised of, a MEDICOOL® MC11 coolpack (to be frozen), a spacer/protection mat (to be chilled), an inner polystyrene, insulated box and lid,) and an outer carrying case.

Freeze the MC11 Medicool® Cool pack for at least 24 hours at -18° C. This temperature can be achieved in the freezer or 'ice cube' compartment of a domestic fridge and may be confirmed by placing a maximum/minimum thermometer in the freezer compartment for a few hours.

1. Chill the spacer/protection mat at +5° for at least 24 hours. This can be achieved in the main storage area of a fridge.
2. Remove the Medicool® unit from the freezer 20 minutes before needed. It is important that this unit is not taken directly from the freezer and placed in the insulated box.
3. First, place the vaccine to be transported in the bottom of the insulated box.
4. Secondly, place the spacer/protection mat directly on top of the vaccine.
5. Thirdly, place the Medicool® Cool pack on top of the spacer/protection mat.
6. 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.

N.B.

- As it takes 24 hours to prepare the cool pack and the mat, if vaccine transport is required daily then it will be necessary to purchase additional cool packs and mats or two porters.
- If more than one Mini Porter® is being operated from one fridge it is good practice to mark the time that each cooling unit is returned to the fridge thus ensuring that properly prepared mats and cool packs are being used.
- While the MC11 MEDICOOL® COOLPACK for the Mini Vaccine Porter® requires to be frozen prior to use, larger vaccine porters use different cool packs which only require refrigeration prior to use. It is important to read the manufacturers instructions carefully before use to ascertain which system is being used.

Maintenance of porters

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?CG_ID=4

11.3. Vaccine Fridge Incident Checklist

Ensure affected vaccines are kept in quarantine, in a monitored fridge, until a risk assessment has been conducted and the Vaccine Fridge Incident Form has been completed.

Important details required include:

- Clinic/Practice Name and Address
- Contact Name and Phone Number
- Fridge affected (ID and Location)
- Background to the incident
- Maximum (or Minimum) Temperature Vaccine Reached
- Length of time vaccines exposed
- When were the correct temperatures last recorded
- Copy of Temperature Recording sheets for preceding month
- Details of any affected vaccines used for immunisation during period of malfunctioning:
- Details of affected vaccines (type, manufacturer, batch number, quantity, expiry dates)
- Potential to recoup cost of lost vaccine via insurance

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

11.4. Training

- A LearnPro course, 'Cold Chain Management' has been developed by the Pharmaceutical Public Health team which is suitable for all staff involved in the delivery of immunisation and vaccination services. Like all LearnPro programmes, the online course can be accessed anywhere, any time and takes less than 30 minutes to complete. Enter 097 Cold Chain Management into the search box. (Please forward any comments you have on this module to liz.mcgovern@ggc.scot.nhs.uk)
- Staff directly employed by the NHS may access the course by visiting <http://nhs.learnprouk.com/>
- Healthcare staff not directly employed by the NHS working in GP practices should register for LearnPro by visiting https://community.learnprouk.com/lms/login.aspx?ReturnUrl=%2flms%2fuser_level%2fwelcome.aspx

12. References

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A guide to the required standards of practice in the management of records for those who work within or under contract to NHS organisations in Scotland.

<http://www.scotland.gov.uk/Publications/2012/01/10143104/0>



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Please direct any enquires to Pharmacy Public Health
Telephone 0141 201 4824