

## Maintaining the cold-chain in your pharmacy

With the adoption of Clinical Governance into the pharmacy contract came the requirement to monitor and record fridge temperatures, in order to create confidence that the cold-chain is preserved and that products are stored under the correct conditions. Pharmacy staff are now well used to checking fridge temperatures on a daily basis and taking action if temperatures go outside of the range of 2°C to 8°C. This CPD module will review the best practice guidance in order to help pharmacists and technicians maintain the dispensary cold-chain.

### A note on digital thermometers

Temperatures must be monitored with maximum/minimum thermometers, which traditionally were mercury or alcohol based, but increasingly digital thermometers are becoming the norm.

When a digital thermometer comes off the production line there must be a Quality Control process to ensure it is measuring correctly and that it is calibrated to a referent control. This means that when you buy it you can be confident the device is fit for purpose and will accurately record your fridge temperature. Once the thermometer is in use however, there can be no guarantees that it remains accurate, for example if dropped or otherwise tampered with.

This raises the question of how confident we can be in the accuracy and performance of the thermometer over time and whether there is a need to recalibrate it on a regular basis. The MHRA has issued guidance on the circumstances when recalibration is required:

#### *Wholesale dealers*

Wholesalers and distributors of medicines are expected to comply with the principles of Good Distribution Practice (GDP) and this requirement is enshrined in an EC directive (European Directive 92/25/EEC). This is of particular importance when dealing with medicines that require cold storage so as to maintain the cold-chain at all stages of distribution. As part of GDP any recording devices used for monitoring fridge temperatures should be **calibrated annually against a certificated standard**. This therefore applies to pharmacies which hold a Wholesale Dealer's Licence (WDL).

#### *Non-wholesaling pharmacies*

Pharmacies that do not hold a WDL and hence do not redistribute cold-chain products except directly to patients do not need to comply with GDP. There is therefore no requirement for fridge thermometers to be annually recalibrated. Pharmacists may *choose* to pay for evidence of calibration as part of their Clinical Governance procedures, however there is no statutory requirement to do so. Alternatively, the fridge thermometer could be replaced on an annual basis.

### Monitoring fridge temperatures

The Clinical Governance lead is responsible for maintaining the cold-chain within the pharmacy but responsibility for monitoring of fridge temperatures can be delegated to an appropriate, trained member of staff. The member of staff taking and recording the readings must be trained in the use of the thermometer, including how to reset it, and understand how to take action if readings are outside of the range.

Fridge temperature readings must be taken daily (when trading), ideally at around the same time each day. The minimum and maximum temperature, along with the time and date, must be recorded on an appropriate chart (see SOP for a copy) or on the PMR.

If the fridge temperature is outside the range on a single occasion the pharmacist or clinical governance lead must be informed. The possible cause, for instance putting stock away, date checking or an incorrectly set thermostat should be determined and rectified if possible. The fridge temperature should then be taken 30-60 minutes later to ensure it is now in range.

Fridge temperature records should be reviewed on a monthly basis, checking that the fridge temperature has been recorded every day. If readings have gone outside the normal range has the necessary remedial action been taken and recorded? The review should be signed and dated by the clinical governance lead.

### **Best Practice for maintaining fridge temperatures**

It is one thing to monitor the fridge temperature and record it, but what actions are necessary to actually ensure that the temperature does remain within range? The following procedures are taken from our Cold Chain Medicines SOP which can be downloaded in full from <http://www.numarknet.com/download/397>

On receipt of a cold-chain medicine it should be checked against the invoice and checked for any damage to the packaging or product. If the product appears damaged or warmed it should not be accepted. In addition, the product must not have come into direct contact with any cold/ice packs as this could result in freezing of the medicine.

Cold-chain medicines must be stored in a refrigerator reserved solely for that purpose. They must not be stored along with any food, drink or non-medicinal items. The fridge should only be filled to around 60% capacity to allow air to freely circulate and care should be taken to ensure air vents are not blocked by products and that products do not touch the refrigeration plate.

Opening the door for prolonged periods of time whilst loading or checking medicines must be avoided if at all possible. If this does occur it should be recorded on your temperature record chart as an explanation for any discrepancy. Stock should be rotated so that the shortest dated items are at the front of the fridge and used first to ensure expiry dates are not exceeded. However, you must be conscious of the time spent with the fridge door open and again, record it on the temperature chart.

### **What to do if your fridge fails or the temperature remains outside of the required range**

A plan of action should be prepared and followed in the event of the fridge temperature being regularly or continually outside of the necessary range. The following advice can help you prepare a plan which should be recorded as part of an SOP.

Arrangements should be made for a back-up refrigerator to be available in case of break-down. In the interests of maintaining the cold-chain any available refrigerator can be used, provided food or drink is removed first. If attached to a surgery or health centre, consider requesting temporary use of their medicine fridge. Once in use, the temperature of the replacement fridge should be monitored and maintained within range as if it was the usual medicine fridge.

If the fridge temperature has fallen below 0°C and medicines have been frozen they should be removed from the fridge and quarantined before appropriate disposal. Any medicines that have been frozen or suspected frozen must not be supplied to a patient.

Make attempts to correct the temperature by resetting the thermostat and checking air vents or call an engineer to make repairs. The fridge temperature should continue to be monitored for any consistent improvement. Stock must not be stored in the fridge until the temperature is shown to be consistently within range.

If the fridge temperature is shown to be regularly outside of the range (but above 0°C), or the fridge breaks down, all stock should be marked as quarantined and moved to a replacement refrigerator as soon as possible.

Compile a list of all the products affected so that the manufacturers can be contacted for stability data. The manufacturer will advise on whether a product remains stable at ambient temperatures and for how long. Numark's Information Service is also available for guidance on 0800 7835709.

If you determine that a product can safely be dispensed to patients then it can be removed from quarantine. The batch numbers of each item should be recorded and the products dispensed ahead of any newly received stock. It is good practice to make a record on the patient's PMR when an affected product is dispensed. Any products that cannot be safely dispensed to patients must be disposed of in the appropriate manner.

### **Home delivery of fridge lines**

Fridge lines that are due for delivery can be dispensed in advance, packaged, labeled and stored in the dispensary refrigerator. Alternatively they can be dispensed immediately prior to leaving the premises. In either case, medicines must remain refrigerated until they leave the premises.

Delivery routes should be planned so as to ensure fridge lines are delivered as soon as possible and the cold chain is maintained. If possible, a cool box should be used to maintain low temperatures during transit. The recipient should be reminded to follow the manufacturer's instructions on domestic storage of the medicine – which may not involve continued refrigeration.

If a fridge line cannot be successfully delivered for any reason then it must be returned to the pharmacy as soon as reasonably possible. The pharmacist must be satisfied that the cold chain has been maintained, giving further grounds for the use of a cool box.

### **Actions to take now**

1. Download and implement the Cold Chain Medicines SOP
2. Ensure all staff are trained as to the correct use of the fridge and thermometer
3. Ensure all staff follow best practice for maintaining fridge temperatures
4. Implement a contingency plan in case of fridge breakdown and ensure all staff are aware of the procedures to follow
5. Check with your commercial insurance provider to see if you are covered for stock damaged by mechanical breakdown. Numark's commercial insurance provides a £1000 contingency for spoiled medicines.
6. If you hold a Wholesale Dealer's Licence ensure that you comply with GDP by arranging annual calibration of your fridge thermometer(s)
7. Non-wholesaling pharmacies should also consider replacing fridge thermometers on a yearly basis to ensure consistent and reliable readings

### **References**

1. Refrigerated medicinal products: what pharmacists need to know; Steve Todd GDP Medicines Inspector for MHRA, The Pharmaceutical Journal Volume 281, 18th October 2008.
2. Numark Cold Chain Medicines SOP <http://www.numarknet.com/download/397>