NHS
Dorset
Clinical Commissioning Group

MEDICINES STANDARD E1:
STORAGE & SAFE CUSTODY OF MEDICINES
(INCLUDING TEMPERATURE MONITORING)

GENERAL BACKGROUND

All medicines must be stored in the manufacturer's original packaging/container. Medicines should not be transferred from one container to another or left loose.

Failure to store the medicine in the original container can affect the integrity of the medicine, for example:

- Cartons can protect the product from light, which can degrade the product
- Some containers include a desiccant, which protects the product from moisture

Medicine cupboards should generally be sited in a room to which the general public does not have access. The design and location of all drug storage cupboards should allow maximum security against unauthorised entry.

Cupboards should not be sited where they may be subjected to higher than average humidity or temperature.

Where the term 'cupboard' is used, the word drawer may be substituted provided that the storage space is adequate and is not used to store controlled drugs.

Controlled Drug and medicines cupboard keys should be kept on separate key rings (e.g. 1 x CD Keys and 1 x general medicines keys) and should not include keys to other storage cupboards that do not contain medicinal products.

STORAGE LOCATIONS AND ASSOCIATED MONITORING

Any medicine stock must be stored in a dedicated locked cupboard or locked refrigerator. No other substances or articles may be stored in these places. Unless stated otherwise in product literature and labels, the majority of medicinal products that do not require refrigeration can be stored under conditions of controlled room temperature without compromise to their stability and recommended shelf life. These products are usually labelled 'do not store above 25°C'.

A maximum/minimum thermometer should be placed in all rooms where medicines are stored and the temperature of the room monitored on a daily basis (preferably at the same

time each day) to ensure that medicines stored in the room are stored within the recommended limit.

Room temperature monitoring must take place on a daily basis (preferably at the same time each day) and the actual, maximum and minimum temperature should be recorded on the 'Daily Room Temperature Monitoring Form' (see Appendix 2) and the thermometer should always be reset.

If the temperature reaches above 25°C for more than seven consecutive days then a significant event form should be completed.

INTERNAL AND INJECTABLE MEDICINES

A lockable medicines cupboard, of adequate size, attached to a solid wall is to be used for the storage of internal and injectable medicines or named patient items.

REFRIGERATED PRODUCTS AND ASSOCIATED STANDARDS

A lockable, dedicated medicines refrigerator in which the minimum and maximum temperature is monitored and recorded on a daily basis (when operational) is required.

A **digital** minimum/maximum thermometer is recommended, as use of mercury thermometers is not recommended.

Only medicinal products are to be kept in the refrigerator/freezer, alternative storage should be found for pathological/ food items.

The medicines refrigerator must maintain temperatures between 2°C and 8°C.

All refrigerators used for storing medicines should be of pharmaceutical grade and meet the Medicines and Health Regulatory Agency (MHRA) guidelines on 'Control and monitoring of storage and transportation temperatures of medicinal products'.

The following criteria should be followed:

- The medicines refrigerator should be stored in a locked room to allow maximum security against unauthorised entry.

- Refrigerators to store medicines should maintain an air temperature of 2-8°C with the minimum of intervention, and the fridge must be lockable.

- The fridge should not be sited in an environment where extremes of temperature (< 10 °C or > 32 °C) will affect their performance.

- The fridge should allow sufficient space to be maintained between the goods held in them and the internal surfaces to allow adequate airflow (i.e. is the fridge large enough for the needs of the practice/dispensary?)

- Pharmaceutical grade refrigerators must only be used for the storage of medicinal products. Medicines must not to be stored together with food or pathological specimens.

- Refrigerated products should be stored in an orderly fashion on shelves - not on the floor of the unit - to ensure air circulation and consistent temperatures throughout.

- The power supply to the refrigerator must be clearly identified to avoid accidental interruption of electrical power. Ideally, the supply of electricity to the refrigerator should be via a hard-wired fuse.

- Refrigerators must be maintained and defrosted in line with manufacturers' guidelines. The refrigerator should be cleaned regularly (as part of a general cleaning rota) and serviced at least annually. If fitted with an audible or visual alarm this should routinely tested to confirm correct operation.

- Temperature monitoring must take place on a daily basis (preferably at the same time each day) and the actual, maximum and minimum temperature should be recorded on the 'Daily Medicines Refrigerator Monitoring Form' (see Appendix 1.) and the thermometer should always be reset.

- Temperature records should identify any temperature deviations and give details of corrective actions taken as a result. For instances where there has been a temperature deviation, best practice would be to take a further reading later the same day, to ensure that it was a transient deviation and show that the temperature was now back within prescribed parameters.

- Temperature monitoring should be by an electronic maximum/minimum thermometer, with an accuracy of + 0.5 °C, which should be readable from the outside of the refrigerator.

- It is advised that the thermometer has a battery back-up (if mains powered) so that it will continue to function for 48 hours in the event of a power failure.

- Temperature monitoring probes should be sited in a central location within the refrigerator and, preferably, between the products. They should not be placed in the door.

ACCIDENTAL DISCONNECTION OF ELECTRICAL SUPPLY / FRIDGE BREAKDOWN

If the refrigerator temperature has remained inside the range of 2 – 8°C, reconnect the power supply and no further action is required.

If the refrigerator temperature is outside the range of 2 – 8°C:

- Place the medicines in a bag marked "DO NOT USE" and transfer to another refrigerator (preferably another medicines refrigerator, if available) ensuring they are quarantined and kept separate from unaffected stock.

- If no alternative refrigerator is available, reconnect the power supply to the malfunctioning fridge and keep the door of the refrigerator closed.

- Note the refrigerator current maximum and minimum temperatures.

- Check the monitoring form for when the refrigerator was last working properly. Try and establish how long the drugs have been stored outside the required range of temperatures.

- Record the drugs and manufacturers name. Attempt to find out if the medicines are safe to use. This may be done via several mechanisms:

- Record the drugs and manufacturers name. Contact the manufacturer of the drug. The name and contact details of the manufacturer can be found in the product packaging or via the electronic medicines compendium (eMC) at www.emc.medicines.org.uk

- Contact the medicines information service at Southampton General Hospital (Telephone: 023 8120 6908 or 023 8120 6909 or e-mail medicinesinformation@uhs.nhs.uk)

- As advice changes continually, seek advice about whether the medicines are still safe to use after every incident.

- If (after seeking advice) you are advised that it is safe to use the drugs which have been exposed to higher than storage temperatures, these stocks must be marked 'use first' and mark with a new expiry date if applicable.

- Complete adverse incident form via the 'Safeguard' online portal as a record of the incident.

- If there is vaccine wastage as a result of the incident, report the incident to Public Health England via Immform.

CYTOTOXIC MEDICATION (e.g. METHOTREXATE)

Cytotoxic drugs requiring refrigeration (e.g. methotrexate pre-filled syringes) should be stored in a medicines refrigerator, and should be segregated from other stock, ideally on a dedicated shelf within the refrigerator.

Cytotoxic drugs requiring room temperature storage should be stored in a dedicated section of the medicine cupboard.

MEDICINES FOR USE IN AN EMERGENCY

Medicines for use in an emergency are exempt from the above storage guidelines although attention should be paid to the safe storage and security of these items.

LOSS OF A DRUG CUPBOARD / FRIDGE KEY

Every effort should be made to find a missing key. If the cupboard / fridge key is not found then a new lock must be fitted to the cupboard / fridge, even if there are other keys in existence, to prevent unauthorised access to the drugs. If there is no duplicate key, the lock is to be broken open and a new lock fitted at once (or the drugs stored in another lockable cupboard / fridge whilst the lock is broken).

STORAGE OF DRUGS DURING TRANSPORTATION

All drugs should be kept out of sight during transportation and must not be stored in any vehicle overnight or for any length of time that may compromise the stability (or security) of the medicinal product. Consideration must be given to cold chain requirements and environmental temperatures.

When transporting medicines it is essential the medicine is stored in line with the product license, as per summary of product characteristics (sPC). The sPC can be found at www.emc.medicines.org.uk

Medicines should not be routinely transported by practitioners to patients' homes except in exceptional circumstances and at the practitioner's discretion, e.g. influenza vaccines. Where this is necessary, appropriate measures should be followed to maintain the cold chain etc.

DUTIES/RESPONSIBILITES AND ACCOUNTABILITY

All healthcare practitioners are responsible for ensuring medicinal products are stored in accordance with the patient information leaflet, summary of product characteristics and in accordance with instructions on the label. The patient information leaflet and/or summary of product characteristics document for UK licensed medicinal products may be found at www.emc.medicines.org.uk.

The healthcare professional with overall responsibility for the area in which the drugs are stored is responsible for the safekeeping (including access) of medicines.

The person who receives a delivery of medicines is responsible for checking the contents of delivery against the order and signing to authorise receipt of the delivery. This person is also responsible for unpacking any refrigerated items immediately, putting them away in the medicines refrigerator and ensuring the fridge is closed correctly and locked for safety and security

A nominated member of staff in the practice is responsible for monitoring and recording the medicines refrigerator temperature, the temperature treatment room(s) and ensuring appropriate actions are taken if temperatures fall/ exceed safe parameters or in the event of a refrigerator breakdown.

The GP in charge is responsible for the safe keeping of the keys. It is not always practical for the keys to be returned to the GP in charge each time they are used, however, every effort should be made to do this, and to communicate who has the keys at any given point during the day.

'Authorised personnel' are staff who may hold a set of keys and includes any member of staff who legitimately needs access to the medicines in order to fulfil their role. This will generally be registered nursing staff, but could also include medical staff and allied health professionals. It is the responsibility of the authorised personnel to ensure that the storage area is left tidy and locked were appropriate and the keys are returned to the GP in charge.

REFERENCES

Safe and Secure Handling of Medicines, Royal Pharmaceutical Society of Great Britain (December 2019).

Controls Assurance Standard - Medicines Management (Safe and Secure Handling),

Department of Health (Oct 2001).

Medicines Code Chapter on Temperature Monitoring of Medicinal Products

Medicines and Health Regulatory Agency (MHRA) guidelines on 'Control and monitoring of storage and transportation temperatures of medicinal products'

'The safe and secure handling of medicines, A team approach; Royal Pharmaceutical Society of Great Britain', March 2005

Electronic Medicines Compendium (for Summary of product characteristics for UK medicines)

National Patient Safety Agency Alert on Vaccine Cold Storage (January 2010)

Refrigerated medicinal products: what pharmacists need to know (Pharmaceutical Journal, October 2008)

Public Health England guidance on responding to vaccine errors (March 2012)

Cold chain information resource - includes a cold chain protocol, self-audit, cold chain breach investigation form and template daily temperature log (Dorset CCG, February 2017)

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APPENDIX 1 DAILY MEDICINES REFRIGERATOR MONITORING FORM

MONTH _____ YEAR _____

Date	Time	Temperature °C			Checked by (Initials)	Thermometer Reset (Tick)
		Actual	Maximum	Minimum		
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APPENDIX 2 DAILY ROOM TEMPERATURE MONITORING FORM

MONTH _____ YEAR _____

Date	Time	Room Temperature °C	Checked by Initials
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APPENDIX 3 STANDARD OPERATING PROCEDURE FOR MEDICINES REFRIGERATOR TEMPERATURE MONITORING

Objectives

- To ensure the security, safe handling, quality and integrity of medicines within GP practices in NHS Dorset Clinical Commissioning Group
- To ensure there is an effective system in place to monitor the temperatures of all refrigerators that are used to store medicines
- To ensure that medicines that require refrigeration are stored under conditions that allows their quality to be maintained

Scope

To be used in all GP practices across NHS Dorset Clinical Commissioning Group that store medicines in a refrigerator.

The Stages of the Process

- A nominated member of staff in the practice is responsible for monitoring the medicines refrigerator temperature, and ensuring appropriate actions are taken if temperatures fall/ exceed safe parameters.
- The nominated member of practice staff also has responsibility for ensuring that the temperatures are monitored and recorded using the appropriate documentation on a daily basis.
- The monitoring should take place at the same time each day in order to give an accurate audit trail.
- The nominated person should read the actual temperature shown on the screen of the digital thermometer and record on the 'medicines refrigerator temperature monitoring form.
- Next he/she should press the appropriate button on the device to show the maximum and minimum temperature from the digital refrigerator thermometer and then record these details on the medicines refrigerator-monitoring sheet.
- The 'Daily Medicines Refrigerator Monitoring Form' should be attached in a plastic wallet to the outside of the medicines refrigerator door.
- The sheet should be completed in full each day and the nominated person should ensure all sections are complete and initial to indicate he/she has checked the temperature and recorded the requirements accurately.
- The refrigerator temperature should not be greater than 8°C or fall below 2°C. If this occurs then please refer to the SOP for the 'Process to follow when temperatures exceed/fall below safe parameters' for further instructions.
- The thermometer must then be reset by pressing the appropriate button on the device.

- Temperature monitoring forms should be kept for one year before destruction.

Responsibility

It is the responsibility of the nominated person to check and record the temperatures of the refrigerator and complete all relevant documentation.

Review

This SOP should be reviewed annually unless new guidance or legislation dictates a review any sooner.

I have read and understood the SOP for temperature monitoring of medicinal products in *<insert the name of your Surgery/Practice/Unit here>.*

Name	Sign	Date

APPENDIX 4 **STANDARD OPERATING PROCEDURE FOR TEMPERATURE MONITORING OF TREATMENT ROOMS**

Objectives

- To ensure the security, safe handling, quality and integrity of medicines is not compromised during storage at Dorset Primary Care Trust managed services/locations.
- To ensure there is an effective system in place in which the temperature of all treatment/clinic rooms that are used to store medicines are checked and monitored on a daily basis.
- To ensure that medicines are stored under conditions that allows their quality to be maintained

Scope

- To be used in all clinical areas across the CCG that store medicines in clinical areas.
- All healthcare staff that work in clinical areas of the CCG that store medicines in treatment/clinic rooms should follow the Procedure.

The Stages of the Process

- A nominated member of staff in the practice is responsible for monitoring the treatment room temperature, and ensuring appropriate actions are taken if temperatures fall/ exceed safe parameters.
- The nominated member of practice staff also has responsibility for ensuring that the temperatures are monitored and recorded using the appropriate documentation on a daily basis.
- The monitoring should take place at the same time each day in order to give an accurate audit trail.
- The nominated person should read the actual temperature shown on the screen of the digital thermometer and record on the 'Daily Room Temperature Monitoring Form'.
- Next he/she should press the appropriate button on the device to show the maximum and minimum temperature from the digital refrigerator thermometer and then record these details on the 'Daily Room Temperature Monitoring Form'.
- The 'Daily Room Temperature Monitoring Form' should be attached in a plastic wallet to a wall or cupboard in the treatment room.
- The sheet should be completed in full each day and the nominated person should ensure all sections are complete and initial to indicate he/she has checked the temperature and recorded the requirements accurately.
- The temperature of the room should not exceed 25°C for more than seven consecutive days. If this occurs please refer to the standard operating procedure 'Process to follow if the temperature exceeds/falls below safe parameters' for further instructions.

- Temperature monitoring forms should be kept for one year before destruction.

Responsibility

- It is the responsibility of the nurse in charge of the ward/unit to nominate a member of healthcare staff to monitor the temperature of the clinic room where medicines are stored each day.
- It is the responsibility of the nominated monitoring person to check and record the temperature of the treatment/clinic room and complete all relevant documentation.

Review

This SOP should be reviewed annually unless new guidance or legislation dictates a review any sooner.

I have read and understood the SOP for temperature monitoring of medicinal products in <*insert the name of your Surgery/Practice/Unit here>.*

Name	Sign	Date

APPENDIX 5 STANDARD OPERATING PROCEDURE FOR THE PROCESS TO BE FOLLOWED WHEN MEDICINE STORAGE TEMPERATURES FALL OUTSIDE SAFE PARAMETERS

Objectives

- To outline the procedure to be followed if medicines storage temperatures exceed/fall below safe parameters.

Scope

- To be used in all clinical areas across Dorset community health services that store medicines
- All nursing staff that work in clinical areas Dorset Community Health Services that store medicines in treatment/clinic rooms and medicines refrigerators

The Stages of the Process

Medicines Refrigerator – Refrigerator Breakdown

- If the temperature exceeds/falls below the safe temperature stated in the temperature monitoring policy (2-8°C) the nominated person should record the findings on the 'Medicines refrigerator monitoring form' as normal.
- Next he/she should check that the refrigerator door is closed and locked securely. If the door of the refrigerator is not locked, it should be closed immediately and the thermometer reset. And a further reading should be taken after 30 minutes and recorded on the sheet.
- If the door is closed and the temperature still exceeds/falls below safe parameters the monitoring staff nurse should contact the estates department to arrange a maintenance technician to come and service the refrigerator.
- In this instance transfer the medicines held in the refrigerator (in a bag marked DO NOT USE) to another refrigerator if possible, keeping them separate from other contents.
- If this is not possible keep the door to the malfunctioning refrigerator closed.
- Note the current refrigerator maximum and minimum temperatures.
- Check the monitoring form for when the refrigerator was last working properly. Try and establish how long the drugs have been stored outside the required range of temperatures.
- Record the drugs and manufacturers name.
- As manufacturer's advice changes continually, the pharmacy should be contacted for advice after every incident.
- If you are advised to use the drugs, which have been exposed to higher than storage temperatures, these stocks must be marked 'use first' and mark with a new expiry date if applicable.

- Complete a significant event form as a record of the incident. If there is vaccine wastage as a result of the incident, report the incident to Public Health England via Immform.

Medicines Refrigerator – Accidental Disconnection Of Electrical Supply

- If the refrigerator temperature has remained inside the range of 2-8 °c, reconnect the power supply and no further action is required.

If the Refrigerator Temperature Is Outside The Range Of 2-8 °C

- Place the medicines in a bag marked "DO NOT USE" and transfer to another refrigerator (preferably a medicines refrigerator, if available).
- Ensure the drugs are quarantined and kept separate from unaffected stock. If it is not possible to move the medicines to a working refrigerator, reconnect the power supply to the malfunctioning fridge, quarantine the medicines as described and keep the door of the refrigerator closed.
- Note the current maximum and minimum temperatures recorded on the thermometer.
- Check the monitoring form for when the refrigerator was last working properly. Try and establish how long the drugs have been stored outside the required range of temperatures.
- Record the drugs and manufacturers name. Contact the supplying pharmacies medicines information team for advice. As manufacturers' advice changes continually, the pharmacy should be contacted for advice after every incident.
- If (after seeking advice) you are advised that it is safe to use the drugs which have been exposed to higher than storage temperatures, these stocks must be marked 'use first' and mark with a new expiry date if applicable.
- Complete a significant event form as a record of the incident. If there is vaccine wastage as a result of the incident, report the incident to Public Health England via Immform.

Temperature Of Treatment Room

- If the temperature of the treatment/clinic room exceeds 30 °C for more than seven consecutive days, complete a significant event form as a record of the incident. If there is vaccine wastage as a result of the incident, report the incident to Public Health England via Immform.

Responsibility

- It is the responsibility of the healthcare worker who notices the refrigerator/room temperature has exceeded/fallen outside safe parameters to take appropriate action as mentioned above.
- It is the responsibility of the practice to promptly arrange repair of a malfunctioning medicines refrigerator.
- It is the responsibility of the practice to seek advice on actions required in relation to use

of medicines that have been stored outside the recommended temperatures, and to follow the advice received (e.g. shorten expiry or destroy stock)

- It is the responsibility of the risk team to act on significant event forms that show treatment room temperatures reaching unsafe temperature ranges.

Review

This SOP should be reviewed annually unless new guidance or legislation dictates a review any sooner.

I have read and understood the SOP for temperature monitoring of medicinal products in <*insert the name of your Surgery/Practice/Unit here>.*

Name	Sign	Date