MI Q&A

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HOW DO I MANAGE A MEDICINE TEMPERATURE EXCURSION?

Background

Medicines should be stored under conditions which assure the quality of the medicine until administration to the patient.

The chemical and physical properties of a medicine and the product formulation determine the product stability and shelf life. Exposure to hazards may impact the quality, efficacy, safety and aesthetics of a medicine. Temperature is one of the primary hazards that affects medicine stability and shelf life.

A temperature excursion is a deviation from the approved storage conditions. A temperature excursion can include exposure to higher or lower temperatures (including freezing). In the hospital setting they can occur in various places/stages including the pharmacy, at the ward level or after medicines have been dispensed to a patient.

There can be many consequences of a medicine temperature excursion including:

- Degradation and loss of potency
- Toxicity or harmful degradation products
- Reduced microbial integrity
- Cost implications
- Treatment delays

Temperature excursions should be addressed systematically to prevent a further adverse impact on the quality of the product.

Immediate management

On notification of a temperature excursion, the following steps should be immediately taken:

- Access the temperature log and/or confirm details of the temperature excursion
- Correct the problem if possible (e.g., close the fridge door, ensure the fridge is plugged in)
- If fridge is malfunctioning, contact maintenance
- Notify appropriate management staff in the area
- Label the stock “Quarantined - Do not use” and move the stock to another storage area that meets temperature requirements
- Assess the stock for suitability of use
- Ensure replacement medicines are made available especially those due for patient administration or required as a life saving medicine.

Further information required

When investigating a temperature excursion, the following information is required:

- Where the excursion occurred and what happened
- Which medicine/s were involved (including brands)
- Batch and expiry data
- Quantities of medicines involved
- Whether the medicine has undergone a prior temperature excursion
- Temperature range
- Duration of temperature excursion
- The need for replacement stock and logistics of obtaining replacement stock
- Estimated cost of replacing stock

Assessment of risk to the medicines

After obtaining the required excursion information, assessment of the risks can commence. Information about the stability of medicines potentially affected by temperature excursions can be difficult to locate. Useful resources and considerations may include:

- Review the stability data and storage information in the Australian Approved Product Information and Consumer Medicines Information
- Contact the manufacturer to check for any in-house extended stability data (*if data exists, request in writing*)
- Review any data obtained from previous temperature excursions (*consider brands, formulation changes, batch specific data*). Note that companies often only provide information on a case-by-case basis, and that recommendations may change over time.
- Consider exposure to previous temperature excursions (*there is sometimes data on cumulative temperature excursions*)
- Consider cost and availability of replacement stock (*decision may be made to discard low cost and/or readily available medicines if information is not readily available*)
- Conduct a literature search if required (*there can be published information*)
- Ensure currency of information (*formulations and excipients of products may change over time*)

Decision

Analysis of the data obtained should occur to assess whether the medicine/s can be used or should be destroyed. When a decision has been made, the following should be done:

- Provide information about the appropriateness of use of the medicine/s
- Advise of any changes to expiry date and ensure this is annotated on the medicine
- Mark the medicine (e.g., with a sticker) to indicate the medicine has undergone a temperature excursion (in case a subsequent excursion occurs)

Documentation

Details of the event should be clearly documented and include information regarding:

- Data obtained
- Decisions made
- What happened to the affected medicines and when
- Who the details of the temperature excursion were communicated to

Follow up

- Ensure the cause of the temperature excursion has been investigated and addressed (e.g., faulty fridge, power failure, human error)
- Consider any actions that can be taken to prevent a similar event (e.g., update of standard operating procedures, training of staff)
- Consider an insurance claim if appropriate

Further reading and resources

- The most recent Australian approved Product Information and Consumer Medicines Information
- Medical Information department of manufacturer
- SHPA Medicines Information Discussion forum / Medicines Information colleagues
- Davis SR, Anderson EA. Creation of a Temperature Stability Database for Refrigerated Medications. JPPR 2010; 40(1): 31-35
- Morais EM, Salgado TM, Gomez IV, Duarte AM, Fernandez-Llimos F. Differences in the information about procedures after cold chain disruption provided by pharmaceutical industry to hospital and community pharmacies. Eur J Hosp Pharm 2016; 23:96-99.
- NHS Pharmaceutical Quality Assurance Committee. Risk Management of Medicines Stored in Clinical Areas: Temperature Control. June 2015.
- UK Medicines Information (UKMi). Guidelines for safe management of products requiring refrigerator storage between 2 and 8°C when these products have been found stored above and below these temperatures. Accessed from https://www.sps.nhs.uk/articles/ukmi-enquiry-answering/ 6th May 2020.

MI Q&A is an initiative of the Medicines Information Leadership Committee of the Society of Hospital Pharmacists of Australia.
MI Q&A aims to present concise, factual information on issues of current interest in therapeutics, drug safety and cost-effective use of medications. The topics presented are based on frequently encountered medicines information requests made to Medicines Information centres and/or matters of current clinical importance. Note that any treatment decisions should be made with careful consideration of the individual clinical circumstances of each patient. Comments, contributions or suggestions are welcome. Please join the SHPA Medicines Information stream at: https://www.shpa.org.au/join-interest-group or email specialtypractice@shpa.org.au