Managing storage temperature excursions for medicines

The first stop for professional medicines advice
Storage of medicines

- The supply chain between the manufacturer and the pharmacy department is usually well managed and controlled.

- Once the medicines have left the pharmacy strict temperature control cannot always be achieved.

- Other considerations apply e.g.:
  - Security and control has to prevent unauthorised access but enable appropriate access.
Storage of medicines

• Nonetheless, medicines should be stored under conditions which assure the quality of the medicine until the end of administration to the patient.

• Any decision to store a medicine outside the recommended temperature range must be informed by a robust risk management approach to safeguard medicines, patients and public health.

• A pharmacist who makes such a decision must be able to defend it if challenged
“Medicines are safely and securely distributed from a pharmacy and stored in a secure and suitable environment prior to administration. SOPs and systems, informed and monitored by the pharmacy team, underpin the legal, secure and appropriate handling of medicines wherever they are stored (wards, outpatient clinics, patients’ lockers etc.)”

Professional Standards for Pharmacy Services (Royal Pharmaceutical Society 2012)

“the lack of effective temperature monitoring of medication storage areas on some wards had the potential to impact on the safety of relevant medicines to patients”

Care Quality Commission report (2013)
How does storage temperature relate to shelf-life?

\[ S_{(T_2)} = \frac{T^{(S_{T1})}}{Q_{10}^{(T_2-T_1/10)}} \]

where

- \( T_1 \) = max storage temp allowed by manufacturer
- \( T_2 \) = actual storage temp
- \( S(T_1) \) = shelf-life at \( T_1 \)
- \( S(T_2) \) = reduced shelf life
- \( Q_{10} \) = reaction rate
“……………you can’t make as recipe for something as complicated (as surgery). Instead, you can make a recipe for how to have a team that’s prepared for the unexpected…….”

Atul Gawande
Identification of risks

Out of range storage?
- Higher temperatures
- Lower temperatures
- Humidity
- Freezing
- Time
- Physico-chemical stability
- Microbiological integrity

Risks to patients
- Degradation of medicines
- Loss of potency
- Toxicity/harmful degradation products
- Microbial proliferation

Consequences of loss of stock
- Treatment delay/interruption
- Costs
Prevention is better than cure: Trust Medicines Policy

- Standards
- Appropriate facilities
- Accountability and responsibility
- Understanding and awareness
- Monitoring & audit
- Action to be taken if……& possible outcomes
- Reporting, monitoring and review
- Risk Register
  - Clinical & £
“……………you can’t make a recipe for something as complicated as accurately quantifying all the possible consequences for patients if a medicine is incorrectly stored for an unknown length of time in unknown conditions. Instead, you can make a recipe for how to have a team that’s prepared for the unexpected.”

Tim Root
What if?
Take action to prevent further damage

• correct the problem (close the fridge door!)
• move the stock elsewhere
And then?
What do you need to know?

- What happened
- Medicine
  - Many can now be stored up to 30C
- Brand/manufacturer
- Max Temp & time
- What patients
- Need for medicine
- Available alternatives
- Time to replace
- (Cost)
Assess the risk to the medicines

• Check the SmPC
• Ask the manufacturer
• UKMi Fridge Database
• Q10 calculations
What next with at-risk stock?

• Mark & reduce expiry?
• Quarantine?
• Destroy?
• Use the manufacturer’s original expiry?

• Document the decision
• Post incident risk assessment - learning points?
Summary:
• Assess the risks locally
• Develop robust systems to control the risks
• Document everything
  • Trust-endorsed medicines policy
    • Including how to respond to an incident
  • Trust Risk Register
If it happens
• Data & information
• Simple decision support tool
• Documented decision

Professional judgement
Next steps?

• Decision support tool?
• Duthie 3 (RPS – October 2017)
References

1. Risk management of Medicines Stored in Clinical Areas Edition 1 June 2015 NPQAC

2. Guidelines for safe management of products requiring refrigerator storage between 2 and 8°C when these products have been found stored above or below these temperatures