

Keeping it cool! A systematic approach to cold chain management

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Background

It is essential to have effective processes to ensure that refrigerated medicines are maintained between 2-8°C to preserve their safety and efficacy.

Issues with cold chain breaches (temperature excursions outside of 2-8°C) include:

- **Therapeutic failure** – loss of medicine potency
- **Cost** – medicine discarded due to unclear stability
- **Accountability** – processes are required to ensure the safety of affected medicines and investigate potential system failures in the event of a cold chain breach

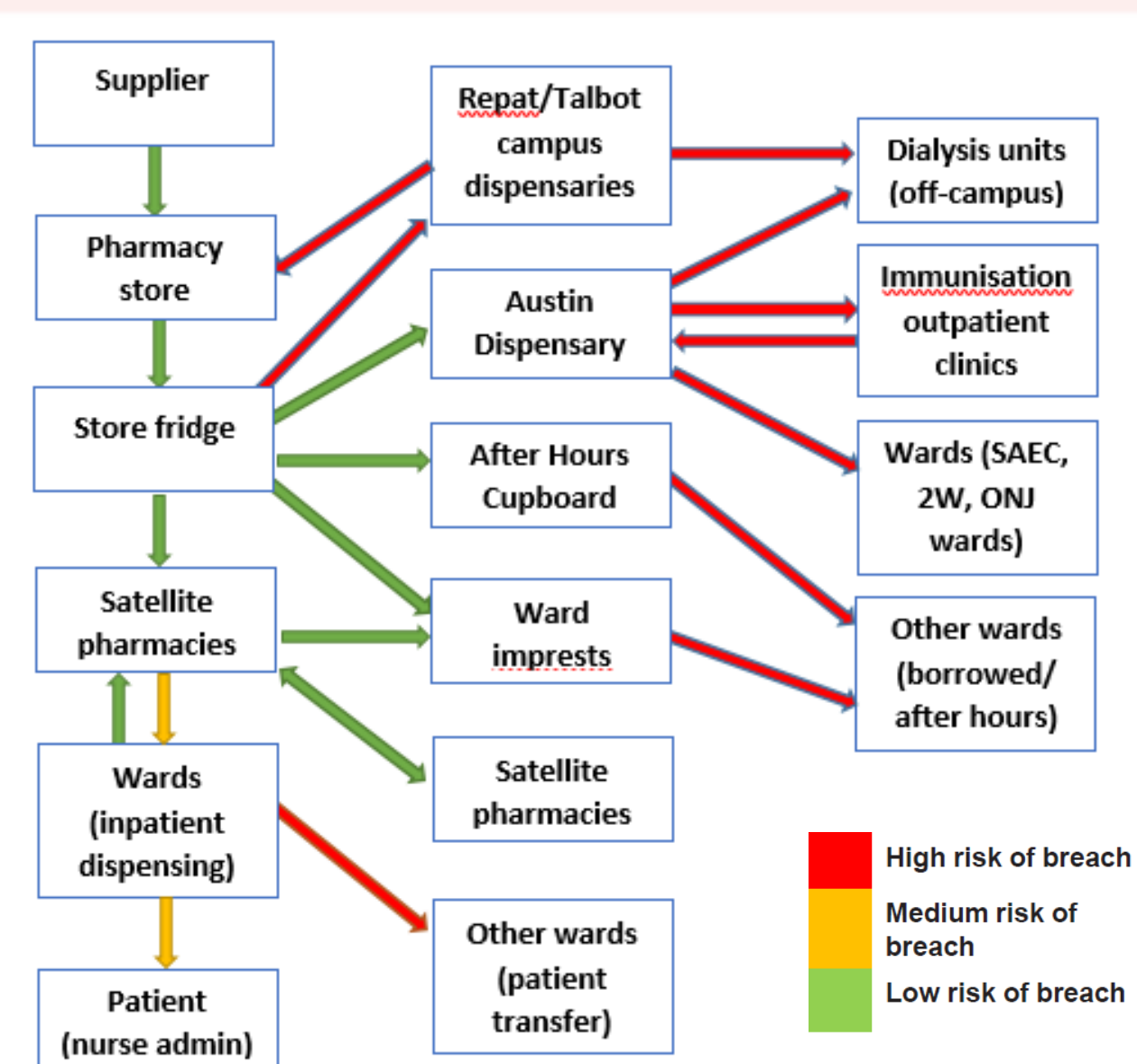
Aims

- To systematically identify processes or areas where there is risk of cold chain breach
- To implement preventative measures to address areas identified as higher risk for cold chain breach
- To set up a management process to consistently report and investigate cold chain breach events
- To create labels that can clearly identify medicines exposed to temperature excursions to ensure medication safety
- To raise pharmacy staff awareness of cold chain breach events and preventative actions

Methods

1. Identify areas of cold chain breach risk

All transfer processes for refrigerated medicines at our organisation were mapped out to identify key areas where are risks of cold chain breach.

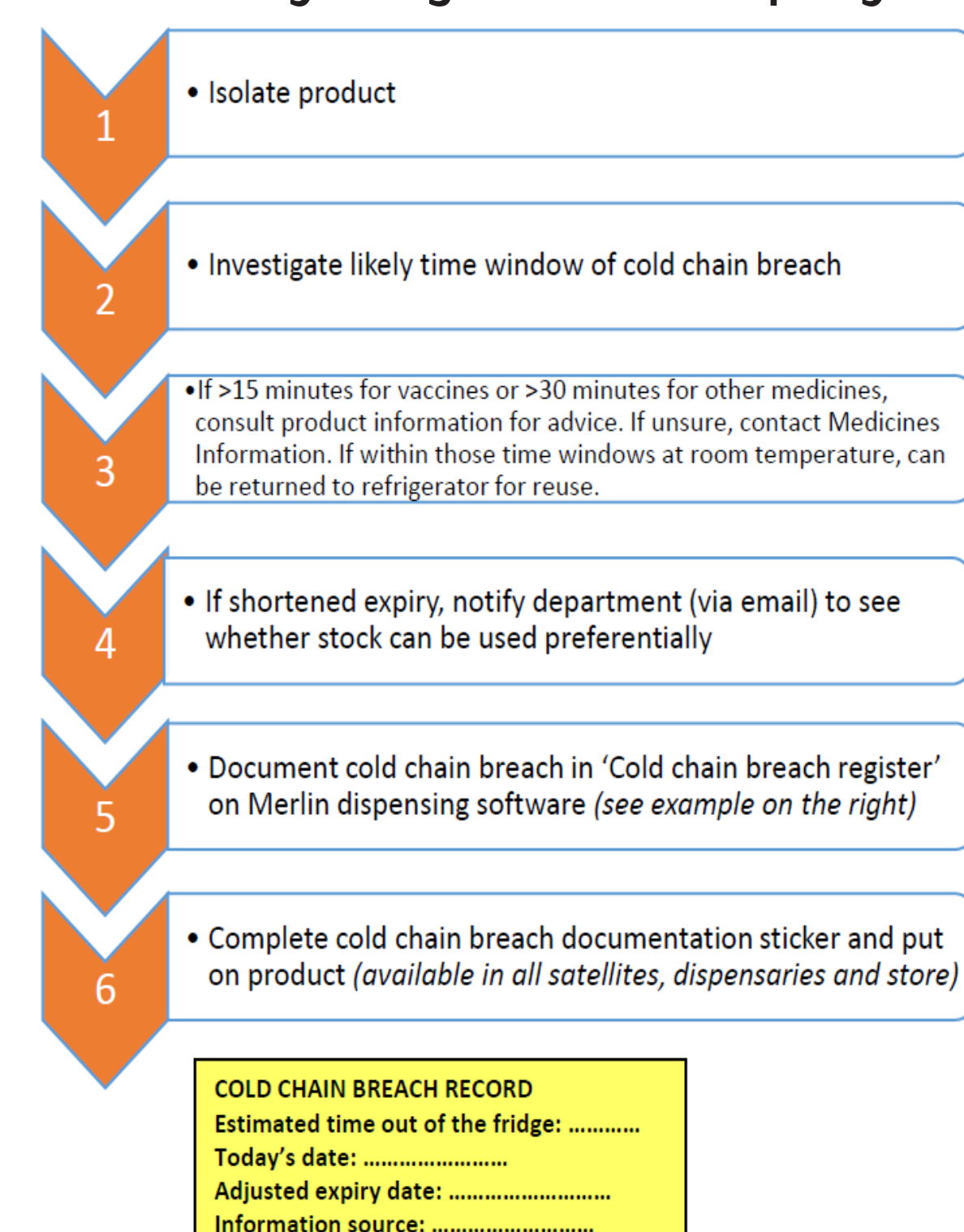


2. Implement proactive measures to address areas of cold chain breach risk

- New pharmacy store system of unpacking cold chain deliveries into fridges within 30 minutes of arrival
- Standardised cooler box packing procedures
- Changed pharmacy dispensing workflows to improve labelling and storage of temperature-sensitive medicines
- Improved labelling of refrigerated medicines in After Hours area
- Calibrated cooler box to maintain 2-8°C during courier transport within the hospital
- Temperature-monitored vaccine cooler box in outpatient clinics

3. Set up cold chain breach management processes

- A cold chain breach management flowchart outlines the procedures to be followed in the event of a cold chain breach.
- An electronic pharmacy record was set up to document cold chain breach events. The record can send automatic emails to trigger appropriate follow-up and investigation, as well as raise pharmacy staff awareness of cold chain breach events.
- Cold chain breach stickers were produced to clearly label medicines with temperature excursions and identify adjusted expiry dates.



The screenshot shows the 'Cold chain breach register - Merlin' interface. It includes instructions for all refrigerated products that have been stored outside the recommended range of +2°C to +8°C. The steps are: 1. ZOOM cold (Cold) and 2. Fill out prompts provided: Location where breach detected (e.g. ward, satellite), Product and number of units exposed, Expiry (if new expiry given to product based on product information and/or discussion with Medicines Information. If Medicines Information not available to give advice, proceed with documentation in Merlin and add comment in remarks. If expiry unchanged, enter in expiry from product label), and Remarks: document nature of cold chain breach; where product was found and outcome. Below the instructions is a screenshot of the software interface showing a table with columns for Date, Location, Product, and Expiry.

Results

Interventions to address cold chain breach risks have minimised the time that refrigerated medicines may be exposed to temperatures outside 2-8°C.

Since its implementation, our cold chain breach management process has identified ten cold chain breach events, leading to raised staff awareness of risks and prompting preventative actions.

Conclusion

Our model for identifying and documenting cold chain breach events allows for systematic investigation and risk minimisation, and may be replicated by other institutions.

Contact

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