

# Immunisation:

## Vaccine Management & Cold Chain



# Learning Outcomes

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- describe the current NHMRC guidelines for transport, storage and temperature monitoring of vaccines
- identify vaccines which are affected by extreme temperatures
- describe the management systems for vaccine wastage and cold chain monitoring in your state/territory
- apply knowledge to clinical practice

# Brief Overview

- What is 'cold chain'?
- Vaccine Storage Management (process, equipment and people)
- Refrigerators for vaccine storage
- Guidelines on vaccine storage
- Maintenance of Refrigerators
- Monitors
- Ordering, unpacking and transporting vaccines
- Management of Cold Chain problems
- Risk management

# What is the Cold Chain?

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The system of transporting and storing vaccines within the safe temperature range of 2°C to 8°C from the place of manufacture to the point of administration.

# Vaccine Cold Chain



**Vaccine  
Manufacturers**



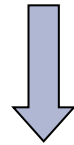
**International Air  
freight**



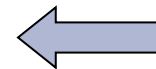
**Australian  
Supplier**



**National road or air  
freight**



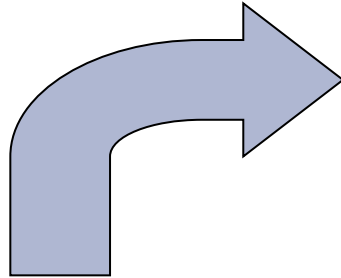
**State Distribution  
Centre**



**State road or air  
freight**



**Hospitals, medical  
centres, community  
health centres, nursing  
homes, aboriginal  
health services**



# How sensitive are vaccines to heat and cold?

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Vaccines are delicate biological substances that can become less effective or destroyed if they are:

- Frozen; (0 C and below)
- Allowed to get too hot; and
- Exposed to direct sunlight or fluorescent light.

# Vaccine Storage - Process

- **Strive for 5**
- **Simple routine processes**
- **Establish written protocols**
  - Monitoring and recording
  - Ordering and receiving vaccines.
  - Rotating stock
  - How to calculate vaccine requirements
  - Storage of vaccines
  - Monitoring and adjusting of equipment
  - Equipment maintenance

# Vaccine Storage - Process

- **Written Protocols** continued
- **Action** to take if the refrigerator temperature goes outside the recommended range
  - Communication channels with other staff
  - Ongoing education of staff
  - How to manage a power failure.
  - How to pack a cooler
- **Annual self audit**
- **Retain documentation**

# Vaccine Storage - Equipment

- Fridge capacity
- Regular maintenance
- Know your fridge
- Check thermometer accuracy
- Change battery
- Temperature monitoring card
- Power sticker
- Reduce opening fridge door
- Do not store food
- Check that alterations do not affect warranty

# Vaccine Storage - People

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- Education of all staff
- Trained, designated person responsible for vaccine storage and implementation of protocols.
- Trained nominated backup person(s) available to relieve the designated person when required

# Refrigerators For Vaccine Storage

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- Domestic refrigerators are not recommended for vaccine storage
- Vaccine Purpose built fridges are recommended
- **Bar refrigerators should not be used**

# Guidelines for Vaccine Storage

## **For all types of fridges:**

- Place out of sunlight
- Ensure the power source is marked clearly
- Stabilise temperature before ordering vaccine
- Ensure Celsius digital minimum/maximum thermometer and a temperature recording chart
- Read and record temperatures, and reset digital thermometer, twice daily

# Guidelines for Vaccine Storage

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- Keep door closed as much as possible
- Key trained person responsible and back up staff
- Establish and document protocols for response to cold chain breaches
- Vaccine storage self-audit

# Domestic Refrigerators

- **Cyclic defrost** (see p 48 Strive for 5) and **bar refrigerators are not recommended** because they produce wide fluctuations in the internal temperatures, with regular internal heating.
- **Frost-free refrigerators** (see p 47) do not have heating cycles but have low level warming cycles.
- **Bar refrigerators, in particular, are strongly not recommended** because of the risk of freezing, temperature instability and susceptibility to ambient temperatures.

# Guidelines for Vaccine Storage

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## **Domestic Fridges only:**

- Place water bottles or ice packs in freezer
- Fill the lower drawers and the door with plastic bottles/containers filled with salt water
- Record temperatures throughout fridge
- Store the vaccines in enclosed plastic containers

# Guidelines for Vaccine Storage

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- Store vaccines in plastic containers
- Keep all components of the vaccine together ie.  
Vaccine and diluent

# Guidelines for Vaccine Storage

- Place freeze-tolerant vaccines in the shelves identified as being the coldest
- Do not store in door and lower drawers
- Place temperature probe:
  - inside vaccine packaging which has not had components separated (box and leaflet)
  - inside and near the back of an enclosed plastic container

# Guidelines for Vaccine Storage

## **Purpose Built Vaccine Fridges:**

- Management less demanding
- Reduced risk of freezing
- Good temperature recovery
- Nearly all internal space can be used
- Other pharmaceuticals can be stored
- How to choose - page 20 of 'Strive for 5'

# Guidelines for Vaccine Storage

## **Purpose Built Vaccine Fridges:**

- Do not overstock
- Only small amount of vaccines? Cold mass
- Situate fridge as per company's advice
- Plastic baskets or trays
- Monitor & record temperature readings
- Store vaccines in original packaging

# Fridge Maintenance

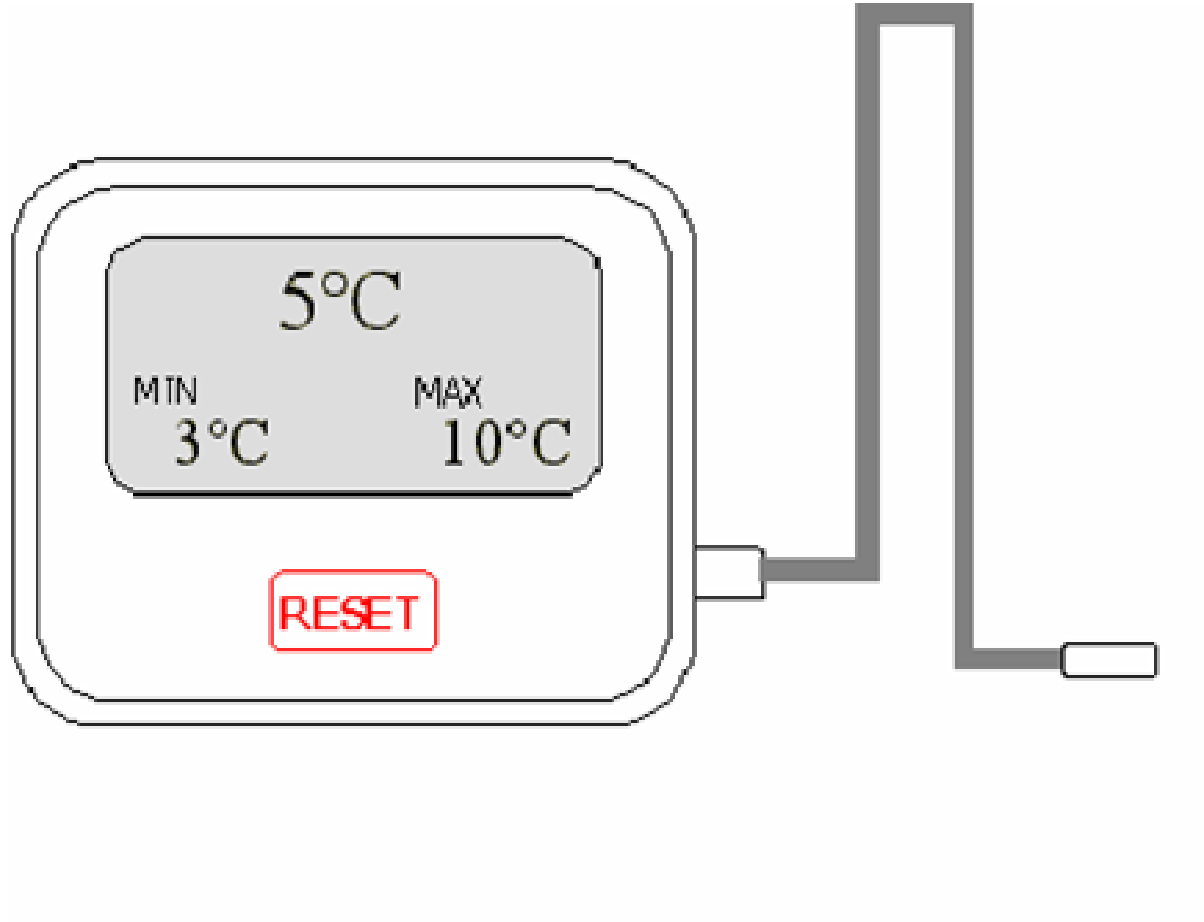
- Report breakdowns immediately
- Regularly check the refrigerator seals
- Defrost refrigerator regularly, if required
- Keep coils clean
- 6 monthly audits
- Defrost regularly if not 'frost-free' (**frost-free refrigerators still require regular monitoring**)
- During defrosting or cleaning move vaccines to:
  - second monitored fridge
  - pre-cooled insulated container

# Monitors

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- Min /max thermometer
- Temperature Chart Recording Systems
- Data loggers
- Cold Chain Monitors

# Digital Thermometer



# Cold Mark Indicator



# Ordering Vaccines

- Keep stock to a minimum (monthly orders)
- Rotate stock
- Use formula to order

Quantity required (quantity used in last period) ***minus*** the amount left over from last period ***plus*** 10% of quantity used in the last period (buffer).

# Unpacking Vaccines

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- check cold chain monitors are included
- check number of vaccines matches order
- refrigerate vaccines immediately
- do not remove individual vaccines from their packaging
- rotate stock according to expiry dates

# Cooler (esky)

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- Minimum size is 10L
- Experiment to know how many ice packs
- Secure packing so no movement
- Keep cooler out of direct sunlight
- Remove vaccines only as required

# Transporting Vaccines

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## Golden Rules:

- remove ice bricks from freezer to 'condition' for at least 60 minutes prior to packing with vaccines
- place CCM card and thermometer with packed vaccines
- ensure a barrier between ice bricks and vaccines
- secure the lid of transporting container

# Packing For Vaccine Transport

## Option 1 (eg: GP to ACF)

- pre cool the cooler
- place shredded paper in bottom of cooler
- place vaccines in centre of cooler
- place thermometer and freeze indicator at centre of vaccine stock
- surround vaccines with more shredded paper or bubble wrap or polystyrene foam
- place 'conditioned' ice-bricks on top of paper/bubble wrap/foam

# Packing For Vaccine Transport

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## Option 2 (mostly used for mobile clinics)

- place vaccines, thermometer and freeze indicator in a chilled styrofoam container
- place the styrofoam container into a larger cooler
- surround the styrofoam container with 'conditioned' ice-bricks

# Management of Cold Chain Problems

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## Power Failure

- Up to 4 hours - keep vaccines in fridge (door closed) and monitor temperature
- 4 hours and over - move vaccine to prepared monitored coolers with conditioned ice packs and monitor temperature by placing thermometer probe inside a vaccine box in the cooler

# Management of Cold Chain Problems

**Cold Chain Breach** is when refrigerator temperatures go outside 2 - 8 Celsius

- Isolate vaccines
- Label 'Do not use'
- Review why the temperature has gone outside range
- Contact Communicable Disease Prevention Unit (CDPU) at DHHS - 1 800 671 738
- Do not discard until advised to by the CDPU

# Risk Management

- delegate one person to be responsible for cold chain management
- person responsible must be trained
- immediately report to DHHS - CDPU any vaccines exposed to temperatures outside of the 2°C-8°C range
- do not discard any vaccines unless directed to do so by the DHHS - CDPU
- aim to keep current fridge temp at 5°C
- make use of fridge stickers

# Risk Management

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## Risks of injecting 'frozen' vaccines:

- sterile abscess at injection site
- decreased or no antibody response
- decrease in herd immunity = potential for disease outbreak
- potential for litigation

# Risk Management

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For private vaccines advise clients to:

- collect the vaccine from the pharmacist and bring immediately to the practice (explain temperature storage issues).
- or have the pharmacist deliver the vaccine to the practice
- and store in monitored fridge until required

# How To Reduce Wastage

Order what you need plus 10% (buffer)

Eg 30 DTPa (quantity used in last period) minus 5 DTPa  
(the amount left over from the last period) plus 3 DTPa  
(10% of quantity used in the last period , buffer stock).

Quantity required is 28 DTPa

# How To Reduce Wastage

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- do not stockpile
- one trained person to be responsible for cold chain management
- do not dispose of vaccines unless directed to by DHHS
  - CDPU

# Contacts

- Communicable Disease Prevent Unit – Department of Health and Human Services
  - Phone: 1800 671 738 or 6222 7724
  - Fax: 6222 7668 or 1800 723 256
  - Address: GPO Box 125, Hobart Tas 7001
    - Ordering
    - Cold chain breaches
    - Questions

# Summary

- vaccines are delicate biological substances
- quality cold chain management = vaccine efficacy = herd immunity = disease control
- take action if vaccines exposed outside temperature range of 2°C - 8°C (not related to opening the fridge door)
- order vaccine stock wisely

# Workshop: Vaccine Cold Chain Management



# Workshop Questions

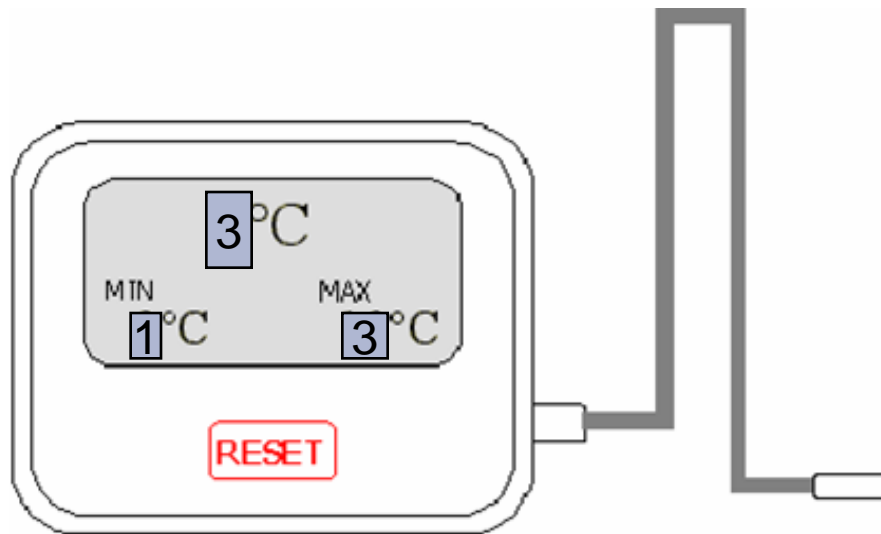
1. Which is the best type of domestic refrigerator to store vaccines in?

Cylic, frost free or multiflow

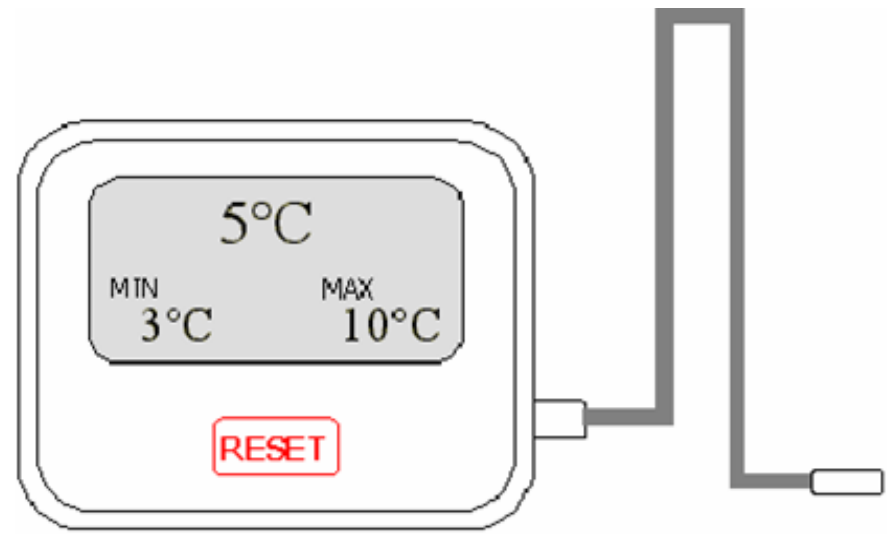
2. Which one of the following minimum/maximum thermometer readings is most likely to be associated with a vaccine cold chain failure? Give reason.
  - a) Current temp 3, min 1 and max 3
  - b) Current temp 5, min 3 and max 10

# Workshop Questions

a)



b)



# Workshop Questions

3. The correct way to store vaccines in a single cooler when defrosting your fridge is to place the vaccines in the cooler, then a layer of shredded paper or bubble wrap or polystyrene foam followed by 1 or 2 frozen cold packs straight from the freezer.

True/false

4. To accurately record the temperature of vaccines in your fridge, the thermometer probe should be placed: in a small container of water/saline inside a vaccine box on the middle shelf

True/false

# References

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- National Vaccine Storage Guidelines ‘Strive for 5’, Department of Health & Ageing, Australian Government.
- [www.immunise.health.gov.au](http://www.immunise.health.gov.au)
- NHMRC(2003) ‘Transport, storage and handling of vaccines’ Australian Immunisation Handbook 8th edn.

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**Thank you**

**Any Questions?**