

This fact sheet summarises the most important requirements for maintenance of the vaccine cold chain. Please refer to the documents listed in the *Resources* section for in-depth information.

## What is the cold chain?

The cold chain is the process that ensures vaccines are continuously stored at temperatures between +2°C to +8°C from the time of manufacture to the point of administration.

## Why is maintaining the cold chain important?

Vaccines are delicate biological substances. If exposed to temperatures above or below those recommended, vaccines may be irreversibly damaged and cannot be relied upon to provide the expected level of protection against the disease/s that they were designed to prevent.

## Cold chain accreditation (CCA)

Completion of cold chain accreditation ensures that all immunisation providers' cold chain management practices and processes meet the required *National Standards for Immunisation Storage and Transportation for Immunisation Providers 2017 (2nd Edition)*.

All immunisation providers are required to achieve CCA (or cold chain compliance if appropriate). CCA documents can be found on the *Ministry of Health National Immunisation Programme cold chain management* webpage [www.health.govt.nz/coldchain](http://www.health.govt.nz/coldchain).

## Essentials for effective cold chain management

### People

- Ensure a designated cold chain person and a second back-up person are identified.
  - The designated cold chain lead should be an authorised vaccinator, general practitioner or a pharmacist vaccinator.
- All staff understand and ensure continuity of the cold chain and can operate the cold chain equipment including the data logger (an electronic recording device).
- Staff have access to, and are familiar with, all relevant reference information and the provider's cold chain management policy (template available from the *Ministry of Health National Immunisation Programme cold chain management* webpage [www.health.govt.nz/coldchain](http://www.health.govt.nz/coldchain)).
- Know how to contact your Immunisation or Cold Chain Coordinator. Refer to the *Regional advisors and local coordinators* page on our website [www.immune.org.nz/health-professionals/regional-advisors-local-coordinators](http://www.immune.org.nz/health-professionals/regional-advisors-local-coordinators) for contact details.

### Cold chain management policy

- All immunisation providers storing and/or transporting vaccines must have a written, current cold chain management policy.
  - Refer to the policy template on the [Ministry of Health and IMAC](http://www.health.govt.nz) websites for guidance.
  - Review and update this policy annually or when there are changes to cold chain staff, equipment or processes.

## Resources

- The *National Standards for Vaccine Storage and Transportation for Immunisation Providers 2017 (2nd Edition)*.
- *Annual Cold Chain Management Record (ACCMR)*.
- *Current Immunisation Handbook*.
- The provider's cold chain management policy.

## Vaccine refrigerator

- Store vaccines between +2°C to +8°C in a pharmaceutical refrigerator with a digital temperature monitoring display/device.
- The vaccine refrigerator must:
  - Be continuously monitored by a data logger.
  - Be sited against an internal wall in a well-ventilated room.
  - Be protected from direct sunlight.
  - Have at least 4 cm but preferably 10 cm clearance from surrounding surfaces to allow adequate air circulation.
  - Be positioned in such a way that the door closes automatically.
  - Be connected to an independent power point that:
    - is power surge protected,
    - has a notice that clearly states 'Do not turn off or disconnect this refrigerator',
    - has the power plug taped over to prevent accidental removal/dislodgement.
  - Be used to store medicines and vaccines only.
  - Have regular maintenance carried out and documented in the cold chain records/ACCMR by provider staff.
    - This includes regular checks for any build-up of ice on the back plate. If this occurs, ensure the refrigerator is adequately defrosted.
    - Be serviced annually by an approved/licensed technician.
- The top of the refrigerator must be kept clear, except for the temperature records.
- Have a plan to replace the refrigerator before it reaches 10 years of age.

## Vaccine stock management

- Maintain a current vaccine register.
- Ensure a minimum level of 2 weeks and a maximum level of 4 weeks supply of vaccines is maintained.
- Have a process for receiving vaccines and recording their arrival date.
- Rotate the stock to ensure the vaccines with the closest expiry dates are used first.
- Store vaccines:
  - in their original packaging, all transport packaging should be removed,
  - a minimum gap of 25mm between the vaccine boxes and the refrigerator walls and back plate,
  - boxes stacked in columns (not blocks) to allow optimum air circulation,
  - vaccines may be placed in containers or on trays providing they are fully ventilated to allow free flow of air around all sides of the vaccine boxes.
- Vaccines must not be stored on solid shelves, on the floor of the refrigerator, in plastic bags or in solid containers.
- Do not overstock the refrigerator, i.e. do not exceed 90% of the available storage space.

## Temperature monitoring

- The refrigerator must be monitored by a digital device (usually the refrigerator display) that records minimum and maximum temperatures and displays the current temperature.
- The minimum and maximum temperatures must be documented in the provider's cold chain records (ideally using the ACCMR) every day the provider is open, preferably at the same time of day. Clear and reset the memory after every daily reading.
- The refrigerator must also be monitored by a data logger (or other electronic continuous monitoring device) and the temperature data accessed and reviewed at least weekly and in response to any temperature breaches. The electronic data must be saved/stored for retrospective access.
- Spatial monitoring of refrigerators must be completed at least every 3 years (this is completed by your Immunisation or Cold Chain Coordinator).
- The data logger must be configured to record the current temperature at least every 5 minutes.
- Compare the daily minimum/maximum temperatures and data logger readings weekly. Be aware that these will not be the same because they monitor different areas in the refrigerator.
- It is recommended to move the data logger to a different shelf every month to allow monitoring of the whole interior space. Note in your records what shelf the logger is monitoring.
- Write a monthly refrigerator performance summary in the cold chain records.
- Electronic temperature monitoring equipment should be calibrated/validated every 12 months or as per the manufacturer's recommendations.
- Change the batteries every 12 months or as per the manufacturer's recommendation and document in the cold chain records that this has been done.
- When transporting/storing vaccines in an insulated container, the cold chain must always be maintained.
  - Ensure the insulated container's temperature is within the recommended range of +2°C to +8°C prior to packing vaccines into it.
  - Data loggers should be set to record temperatures at 5-minute intervals.
  - Constantly monitor the temperature with a data logger with a display, a remote probe and an alarm.
  - Check and document the temperatures at least every 30 minutes.
  - Download, review and save the recorded temperatures once transportation is completed.

## Record keeping

- Use the Annual Cold Chain Management Record or another record to document temperature data and details of cold chain management. Keep this close to the refrigerator to allow access by all staff.
- Document all servicing and maintenance done.
- Document all actions taken by staff if the temperature goes outside the recommended range.
- Save/store all cold chain documents and records for 10 years. This includes ensuring all electronic data is backed up and able to be accessed.

## Managing cold chain problems

- Quarantine the vaccines
  - Maintain the vaccines within the cold chain and label them 'Not for use' while advice is obtained.
- Check the digital thermometer, other monitors if available, and download the data logger.
- Contact your Immunisation/Cold Chain Coordinator for advice.
- Do not dispose of any vaccines until advised to do so by your Immunisation or Cold Chain Coordinator.
- Ensure all the advice received and actions taken are documented.
- Your Immunisation or Cold Chain Coordinator is required to inform the Ministry of Health Immunisation Team directly or by email, [immunisation@moh.govt.nz](mailto:immunisation@moh.govt.nz), if any patients require recall or reimmunisation.
- Providers are required to ensure an appropriate emergency plan and equipment are always available for use, e.g. chilly bin, packing/insulation materials, ice packs, refrigerator at an alternate location, and monitoring equipment.

## References

Refer to the documents listed in the *Resources* section on page one.