

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 more 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.

All immunisation providers are required to achieve cold chain accreditation (or cold chain compliance if appropriate).

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 management lead should be an authorised vaccinator, general practitioner or a pharmacist vaccinator.
- All staff understand and ensure continuity of the cold chain and are able to operate the cold chain equipment including the data logger.
- Staff have access to, and are familiar with, all relevant reference information and the practice cold chain policy (template available from the Ministry of Health National Immunisation Programme cold chain management webpage www.health.govt.nz/coldchain).
- Know how to contact your Immunisation or Cold Chain Coordinator.

Cold chain policy

- All immunisation providers must have a current and appropriate cold chain policy.
 - Refer to the policy template on the [Ministry of Health](#) and [IMAC](#) websites for guidance.
 - Review and update this policy annually.

Resources

- The National Standards for Vaccine Storage and Transportation for Immunisation Providers 2017.
- Annual Cold Chain Management Record (ACCMR).
- Current Immunisation Handbook.
- *The essential data logger*, Immunisation Advisory Centre fact sheet.
- The provider's cold chain 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 which clearly states 'Do not turn off or disconnect this fridge',
 - 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 by provider staff.
 - This includes regular checks for any build-up of ice on the back plate. If this occurs, ensure the fridge is adequately defrosted.
 - Be serviced annually by an approved/licensed fridge 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 record the date of arrival on each vaccine box.
- Rotate the stock to ensure the vaccines with the closest expiry dates are used first.
- Store vaccines in their original packaging with the lids closed with:
 - 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 **must not** be stored on solid shelves, on the floor of the fridge, in plastic bags or in solid containers.
 - 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.
- Do not overstock the fridge, i.e. do not exceed 90% of the available storage space.

Temperature monitoring

- The fridge must be monitored by a digital device (usually the fridge display) that records minimum and maximum temperatures and displays the current temperature.
- The minimum and maximum temperatures must be documented in the Annual Cold Chain Management Record every day the provider is open, preferably at the same time of day. Clear and reset the memory after every daily reading.

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Temperature monitoring *continued*

- The fridge must also be monitored by a data logger that is downloaded at least weekly and in response to any temperature breaches.
- The data logger must be configured to record the current temperature at least every 10 minutes (ideally every 5 minutes).
- Compare the ACCMR and data logger readings. Be aware that these will not be exactly the same because they monitor different areas in the fridge.
- If you have a large fridge, it is recommended to move your data logger to a different shelf every month to allow monitoring of the whole interior space. Remember to note in your records which shelf the logger is monitoring.
- Write a monthly fridge performance summary in the provider's 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 that this has been done.
- When transporting/storing vaccines in an insulated container, the cold chain must be maintained at all times.
 - Ensure the insulated container's temperature is within the recommended range of +2°C to +8°C prior to packing vaccines into it.
 - 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 and review the recorded temperatures once transportation is completed.

National Cold Chain Audit (NCCA)

10% of National Schedule vaccine orders will contain a NCCA logger.

- A yellow sticker on the outside of a vaccine order alerts providers to the presence of a NCCA logger before the order is unpacked.
 - A yellow instruction sheet explaining how to check the logger will be inside the order on top of the vaccines.
 - These instructions should be followed before unpacking the vaccines into the refrigerator.
- The logger stays with the box of vaccine it is allocated to until either the last dose of vaccine is used or two weeks have passed, whichever occurs first.
- An addressed, prepaid courier envelope is provided for return of the logger to IMAC.
 - The logger is downloaded by IMAC once it is returned to us.
- For more information, refer to the National Standards for Vaccine Storage and Transportation for Immunisation Providers 2017.

Record keeping

- Use the Annual Cold Chain Management Record to document temperature data and details of cold chain management. Keep this close to the fridge 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.
- Store all cold chain documents and records for 10 years.

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 in the Annual Cold Chain Management Record.
- Inform the Ministry of Health Immunisation Team directly or by email, immunisation@moh.govt.nz, if any patients require recall or reimmunisation.
- Ensure an appropriate emergency plan and equipment are available for use at all times, e.g. chilly bin, packing/insulation materials, ice packs and monitoring equipment.

References

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