The essential data logger

The Immunisation Advisory Centre

This fact sheet provides an introduction to the use of data loggers to ensure optimal monitoring of the vaccine cold chain. For more information, please refer to the resources listed below, contact your Immunisation or Cold Chain Coordinator, and refer to the manufacturer's information supplied with the equipment.

Resources

- National Standards for Vaccine Storage and Transportation for Immunisation Providers 2017.
- Annual Cold Chain Management Record.
- Your organisation's current Cold Chain Management Policy.
- *The essential cold chain*, an IMAC fact sheet, available from www.immune.org.nz.
- The current Immunisation Handbook.

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. A cold chain breach occurs when the vaccines have been stored outside the required +2°C to +8°C temperature range.

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 breaches can occur even in well designed and well managed systems. However, if there are effective monitoring processes in place, problems will be detected and managed before a cold chain failure occurs, i.e. administration of damaged vaccine.

Why are data loggers essential to cold chain monitoring?

Data loggers record vaccine refrigerator temperatures temperatures at set intervals (5 minute intervals are recommended). Regular downloads of the recorded temperature information provide an enduring record of the temperatures that vaccines have been exposed to. Data logger information is invaluable when assessing vaccine viability after a cold chain breach as it shows the duration of exposure to temperatures outside the recommended range of +2°C to +8°C.

Cold Chain Accreditation or Compliance

All immunisation providers require current Cold Chain Accreditation (CCA) (or Cold Chain Compliance (CCC)) that may be valid for up to 3 years. To achieve CCA/CCC, every vaccine refrigerator must be monitored by both a digital minimum/maximum thermometer (usually the in-built refrigerator display) and a data logger.

Evidence of weekly data downloads and review against the daily minimum and maximum temperature recordings to check for any unexplained temperature variations, is required.

What is a data logger?

A data logger is a self-contained recording device that measures and records the refrigerator temperature at pre-set intervals and stores the data until it is downloaded to a computer. Data loggers must be configured prior to use and data downloaded using the software supplied with the logger. Most data loggers have a visual and/or audible alarm to alert staff if a cold chain breach occurs.

Data loggers with 24 hour external 'real time' monitoring are available and can be set up to alert nominated staff to cold chain breaches that occur during and outside working hours. Data is downloaded via a web portal. These systems usually have the capability to securely store data off site long term.

Downloaded data can be organised into various report formats, including graphs, and used to validate the accuracy of the daily digital minimum/maximum thermometer recordings and any other monitoring equipment used over the same period. Data from the logger will also provide more accurate information about the duration of a cold chain breach.

Data loggers with a display that shows the current and minimum/maximum temperatures can be used daily to confirm the accuracy of the refrigerator temperature display, monitor the refrigerator temperature during a power outage, and monitor vaccines whilst they are being transported.

Data loggers that do not have a visible display cannot be used to monitor the refrigerator temperature during a power outage or monitor vaccines during transportation. Therefore, an additional battery powered digital minimum/maximum thermometer with a display, remote probe (i.e. a probe on a cable) and audible alarm will be required for emergency use.

NOTE: The use of a data logger does not replace the requirement to check and document the daily minimum/maximum refrigerator temperatures recorded by the refrigerator display/digital thermometer.

How is a digital thermometer different to a data logger?

Digital thermometers display the current refrigerator temperature and store the minimum and maximum temperatures reached since the thermometer was last reset. They do not record the duration of these temperatures. Some brands have an alarm that can be set to alert staff if a cold chain breach occurs.

Digital thermometers cannot be used to determine how long vaccines have been exposed to temperatures outside the recommended range of +2°C to +8°C after a cold chain breach. Digital thermometers are the secondary monitoring device in the vaccine refrigerator/offsite chilly bin and are generally only used to monitor vaccines during emergency transportation.

Key points

- All vaccine refrigerators must be monitored by a digital minimum/maximum thermometer with a display and audible alarm (usually the inbuilt refrigerator display), and a data logger.
- Minimum and maximum refrigerator temperatures must be checked and recorded daily (preferably first thing in the morning), and the digital thermometer reset daily.
- Data loggers must be configured to record the current temperature at least every 10 minutes in refrigerators (ideally every 5 minutes) and every 5 minutes in a chilly bin.

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Key points continued

- Data from the logger must be downloaded and reviewed every week or in the event of the daily minimum/maximum temperature being out the required +2°C to +8°C temperature range.
  - After the weekly download, compare the data with the daily minimum/maximum refrigerator temperature recordings. The temperatures should be consistent but will not be exactly the same because different areas of the refrigerator are being monitored. Ensure all recorded temperatures are within 2–8°C.
- The downloaded data must be backed up and stored securely for a minimum of 10 years.
- Set up the data logger graph so that temperature deviations outside 2–8°C are clearly demonstrated. This will help ensure that any cold chain breaches are easily detected and not accidentally overlooked. For assistance with this, contact your Immunisation or Cold Chain coordinator or the data logger supplier.

NOTE: A one-off cold chain breach up to 12˚C for less than 30 minutes that occurred for a known reason, e.g. during a vaccine stocktake, does not need to be notified to the Immunisation or Cold Chain Coordinator. However, it must be documented in the cold chain records. Repeated breaches, even when the reason is known, require action and must be reported.

- Data loggers should have the 'rollover function' activated to ensure the most recent data is always available.
- Data loggers should be placed in the centre of a shelf, away from the walls, vents or floor of the refrigerator and in close proximity to the vaccines being monitored. They may be hung beneath a shelf or placed directly on the shelf.
  - It is recommended to move the data logger to a different shelf every month to allow monitoring of the whole interior space as warm/cold spots can occur. Remember to note which shelf the logger is monitoring.
- At the end of every month, write a summary of the refrigerator performance in your cold chain records.
- Change equipment batteries every 12–24 months as per the manufacturer's recommendations and document that this has been done.
- Electronic temperature monitoring equipment, including data loggers, should be validated/calibrated every 12 months or as per the manufacturer's recommendations.
  - Refer to the National Standards for Vaccine Storage and Transportation for Immunisation Providers 2017 Appendix 4 for information about checking the accuracy of a digital thermometer or data logger.
- Contact your Immunisation or Cold Chain Coordinator to arrange annual independent validation of the refrigerator's temperature and cold chain monitoring equipment.
- **Ensure all relevant clinical staff members are able to operate the data logger, access the data when required, and effectively manage a cold chain breach.**

Temporary vaccine storage

- When storing or transporting vaccines in an insulated container such as a chilly bin, it is important to maintain and monitor the cold chain at all times.
- Ensure the temperature of the insulated container is within the recommended range of +2°C to +8°C prior to packing vaccines into it.
- Constantly monitor the temperature using a data logger with a display, a remote probe and an audible alarm. Configure the data logger to record the current temperature every 5 minutes.
  - The minimum, maximum and current temperatures must be checked and documented every 20–30 minutes (if possible) whilst the vaccines are in the chilly bin.
- Download the logger data and review the recorded temperatures once transportation is complete.

Temporary vaccine storage in chilly bins ONSITE

- Providers who temporarily store vaccines onsite in a chilly bin, e.g. a supply of influenza vaccines is kept in a clinical room to facilitate access, must maintain the cold chain at all times and may use either a digital minimum/maximum thermometer (or ideally a data logger) with a display, remote probe and audible alarm to monitor the temperature of the vaccines throughout the time they are stored in a chilly bin. The display must be visible without opening the chilly bin and the minimum, maximum and current temperatures must be checked and documented every 20–30 minutes.

Temporary vaccine storage in chilly bins OFFSITE

- Providers who offer an offsite immunisation service must use a data logger with a visible display, remote probe and alarm to monitor vaccine temperatures. The data logger must be set to record the temperature every 5 minutes The display must be visible without opening the chilly bin or refrigerator door, and the minimum, maximum and current temperatures must be checked and documented every 20–30 minutes (including during transportation, whenever possible and safe to do so). Data must be downloaded, reviewed and saved after returning to the clinic.

NOTE: While checking and documenting temperatures during temporary storage, the data logger/digital thermometer does not need to be reset. If temperatures are noted to be outside the recommended range, adjust the storage conditions as appropriate, e.g. add or remove ice packs, and ensure the current temperature is then within range. Contact your Immunisation or Cold Chain Coordinator for advice as required.

References

- Ministry of Health. National Standards for Vaccine Storage and Transportation for Immunisation providers 2017. Wellington: Ministry of Health; 2017. Available from: http://www.health.govt.nz/publication/national-standards-vaccine-storage-and-transportation-immunisation-providers-2017.
- Ministry of Health. Annual Cold Chain Management Guide and Record. Wellington: Ministry of Health; 2012. Available from: http://www.health.govt.nz/publication/annual-cold-chain-management-guide-and-record.