# Divisions of General Practice
# DATA LOGGING GUIDELINES

**PREAMBLE**

Divisions of General Practice play a key role in promoting and providing data logging of vaccine fridges for general practice. Considering the significant level of uptake within general practice of this service, the opportunity exists to develop guidelines for Divisions of General Practice who provide and undertake data logging services.

Data logging is recommended for domestic fridges being used for vaccine storage. It is not recommended for purpose built vaccine fridges or those fridges with an inbuilt temperature controlling device. However, data logging in these fridges can be undertaken to verify the accuracy of their temperature recording devices.

The NHMRC *National Vaccine Storage Guidelines, Strive for 5* recommend that fridges storing vaccines should be kept at a temperature between +2°C and +8°C to maintain optimum vaccine potency. Data logging allows the recording of patterns of temperature over time and in conjunction with a min/max thermometer support vaccine service providers to ensure this standard is met.

## 1. WHAT IS A DATA LOGGER

Temperature data loggers are small, electronic devices that measure fridge temperatures and keep a record of the results over a period of time.

Each logger is a self-contained miniature computer. They come in a range of shapes and sizes. Once programmed via a standard computer, loggers are disconnected from the computer and placed in the vaccine fridge in close proximity to the temperature probe. The logger then operates independently on its own battery until the recording is downloaded on to the computer. Once you have saved this information the previous data is overridden as the logger is relaunched.

A data logger can be used for routine temperature monitoring however it must have a visual display of min/max temperatures so twice daily recording can occur. If the fridge does not have this function then a min /max thermometer (either independent or in built into the fridge) is also required to allow the twice daily recording of min/max temperature as a timely alert to any cold chain breach (refer to *Section 2.1* for definition of a cold chain breach).

Many data loggers can be programmed to alarm when the temperature is recorded outside the NHMRC recommended temperature range of +2°C to +8°C. Data loggers have a replaceable battery which has a typical life of 1 to 2 years (*see manufacturers guidelines*) although advances in technology are producing more features in data loggers, including automatic programming of results, off site alarming systems and the inclusion of min/max thermometers in combination with the data logger.

## 2. DATA LOGGING PROCESS (external logger)

- Install data logging software onto your computer and program the logger to be able to download results (*refer to manufactures instructions for setting up your data logger*)

- If using a single data logger, place it in the centre of the refrigerator, away from the rear back plate of fridge. If using multiple loggers, place one in the centre, one on top shelf (below freezer plate) & one on the bottom shelf. The data logger must remain in the same position in the refrigerator for the entire placement time.

- Ensure logger is next to (or if possible, attached to) the min/max thermometer probe for comparison readings.

- If the data logger has a temperature probe, this should not be in contact with any fridge surface. Refer to the *manufactures instructions* for correct placement of the probe. In the absence of any other available information, the data logger probe should be placed in an empty vaccine box (ideally with the min/max thermometer probe) as per NHMRC recommendation for positioning of a thermometer probe.

- Set data logger to commence at least 12 hours after you have placed in the fridge. This will allow the temperature detector to cool down and align with the fridges regular temperature.

- The data logger will record the date, time and temperature of the fridge in increments as programmed by the operator (e.g. the division or the practice staff member). These are usually 10-15 minutes duration. Check the manufactures instructions for recommendations on ideal increment settings for your data logger.

- The data logger should ideally remain in the vaccine refrigerator no longer than 7 days and include a weekend.

- After the defined period of logging (usually weekly) results are downloaded to a computer and a printed out for record keeping and analysis.

- Once results are downloaded:
  - Record in the software the time the log was checked and your initial (this may log automatically, in which case initial the automatic record)
  - If unable to edit computer software, print the data log and sign before filing
  - Check and record the min/max temperature either using this function on the data logger or separate min/max thermometer

### 2.1 Cold Chain Breaches

A cold chain breach occurs when vaccine storage temperatures have been outside the NHMRC recommended range of +2°C to +8°C. This does not include deviations or excursions of up to +12°C lasting no longer than 15 minutes when stocking or restocking the fridge.

Cold chain breaches are required to be reported to the local public health authority. Each State Health Department have their own process for this to occur. Divisions have a role in the promotion of State Health guidelines for cold chain reporting and should work with their local public health unit immunisation staff to ensure this is implemented at a local level and communicated effectively to practices.

Data logging involves temperature mapping and therefore has the potential to detect a cold chain breach. The practice may or may not be aware of if this if the data logger had not detected it. Guidelines for reporting and dealing with a cold chain breach detected as a result of data logging by divisions are further outlined in Section 5.

## 3. TYPES OF LOGGING

### 3.1 Periodic Logging

This activity is usually undertaken by the division, local state health unit or practice to verify cold chain efficacy and provide verifying documentation to support accreditation and cold chain breach investigation. Most divisions who undertake data logging provide the logger to practices for one week duration (either the practice self installs or division representative installs it). After the data logging period, divisions return to the practice to download the results. The division provides the practice with a hard copy of the results and may offer support services to implement any remedial activity that may be required. (Refer to *Section 5*)

** Note: Divisions may not provide data logging records to third parties without prior consent of the vaccine service provider.*

Data logging is an excellent quality improvement activity to up skill GPs and practice staff on the guidelines for maintaining the cold chain effectively. The graph and information printouts quantify the temperature recordings in easily readable format and are able to be filed for later reference and comparison.

### 3.2 Permanent Logging

Where a practice has its own data logger which permanently logs the fridge temperature, it is recommended that weekly downloading occurs as a permanent record of temperature. This may be more frequent under the following circumstances:

- When a cold chain breach is detected and is being followed up;
- Suspicious temperature fluctuations which could lead to a cold chain breach;
- Upon reconnection of the fridge following a power failure; and/or
- Installation of a new fridge, particularly a purpose built fridge.
  **Note: These fridges may have inbuilt data loggers however external data loggers are often used to get a comparator indicator of temperature.*

If undertaking permanent data logging it is recommended that:

- The practice has a data logging policy and procedure and a dedicated staff member responsible for data logging
- **All** staff understand the reason for data logging and are trained to recognise the alarm and what to do when it is activated
- Data loggers have their alarm systems activated to alarm outside +2°C and +8°C
- Immediate downloading and recording of information occurs when an alarm is activated.
- Regular calibration (minimum annually) and battery change occurs as per the manufacturer recommendation. NATA is the regulatory body which certifies the calibration of data loggers to Australian standards. They can be contacted on (02) 9736 8227.
  NATA recommends the following accredited calibration labs:
  - Australian Calibrating Services ph. (03) 9417 5688.
  - Testing and Certification Australia ph. (02) 9410 5176
  - VMS International ph. (02) 9771 9300
  - Thales Australia ph. (03) 9319 4444
  - ECE Fast ph. (02)9338 8188
  - Energex ph. (07) 3407 5460

- The minimum/maximum temperature is recorded daily

- All data logging activities are documented by the practice. These may include; weekly logging results, change of battery, any change to the process recorded in the policy & procedure, calibration and the reasons for deviations of temperature outside +2°C and +8°C

## 3. BENEFITS OF DATA LOGGING

- Confirms cold chain maintenance inside the NHMRC recommended range of +2°C and + 8°C and provides accurate knowledge of the patterns of vaccine fridge temperature. For this reason, if conducted correctly, data logging is currently the most accurate and reliable method of temperature monitoring for vaccine fridges.

- Identifies times where vaccines are at risk of being frozen (0°C or below). This most commonly occurs when the practice is left unattended for periods of time e.g. overnight or long weekends.

- It supplements a cold chain audit and assists the practice to understand the functioning of refrigerators.

- Creates a temperature map of the fridge. This identifies which shelves of the fridge are more likely to freeze vaccine.

- Provides feedback to the practice on fridge temperatures following the implementation of changes as a result of cold chain breach, power failure or installation of new fridge.

- Confirms efficacy of modifications made to domestic fridges such as addition of bottles of saline to doors and bottom drawers, ice/gel packs in the freezer, 4 cm spacing around the internal wall and the placement of plastic containers for storage of vaccine vials. A full list of these modifications can be found in *National Vaccine Storage Guidelines, Strive for 5*(2005) (page 9-15).

- Provides documentation required to meet standards for accreditation (refer to the *RACGP Standards for General Practice, 3rd Edition* for current requirements).

- Confirms the fridge thermometer accuracy. Many thermometers have a ±1°C of accuracy. Data loggers when stored in the exact location of the thermometer have a degree of accuracy of 0.1°C to 0.5°C.

## 4. LIMITATIONS OF DATA LOGGING

- Data logging adds another layer of work to vaccine management for the practice. This requires an increased knowledge, skill and time requirement of both division and practice staff.

- If undertaking permanent data logging at the practice, **ALL** staff should be trained in the purpose of data logging and their responsibility in managing the data logger when it is in the fridge. This can be time consuming, especially when part time staff are involved.

- The division is offering a service to the practice if it undertakes periodic logging. Therefore, the division staff member needs to be trained in the purpose of data logging, the process, troubleshooting, division's policy on reporting and storage of practice logging results and their

responsibility in the event of a cold chain breach. Divisions must also calibrate the data logger annually and keep up to date with new models to ensure the most accurate reading is produced.

- When the data logger and the thermometer are not co-located in the fridge different recordings can occur, resulting in competing and false data on the efficacy of the cold chain.

- All data logger manufacturers identify a degree of error in the recordings. This should be known by the data logger operator otherwise a breach may be falsely detected and reported. This may lead to vaccines being discarded when they may still be viable for use.

## 5. ROLES & RESPONSIBILITES

With the provision of periodic data logging by the division, the practice and State Health have a role to play to ensure effective results are obtained and any cold chain breaches detected are dealt with correctly as stipulated by the relevant State Health Department.

### 5.1 Division

The provision of a data logging service to practices is a voluntary role of local Divisions of General Practice. Each division will decide how they wish to provide this service to their local general practices. There is usually no charge for this service. Data logging by divisions can be performed in two ways:

1. Division routinely data logs all practices that have requested this service. This is done routinely (e.g. rotational basis) by the division staff using data loggers purchased by the division.

2. Division provides data loggers to practices on demand. This may be due to a recent change in the fridge, suspected cold chain breach, restoration process following a cold chain breach or practice accreditation. Practices may either undertake the logging themselves or the division will do so as a one off service.

In undertaking data logging it is important for the division to be clear about the service they are providing. This should include:

- How the data logging service is provided to practices (as per the above two examples)

- Who is responsible for the purchase and maintenance of the data logger. This includes knowledge and understanding of the manufacturers recommendations and acceptable degree of error

- Role of the division staff undertaking the data logging (what they do and don't do). This should be clearly communicated to practices preferably prior to undertaking the data logging.

- Provision of a written report analyzing results. This should be provided no later than 48hrs following the downloading of results from the practice. If the recordings are within the NHMRC guidelines for vaccines of +2°C and +8°C, the report confirms this and the practice files it for future reference.

- Confidentiality of results
  ** Note: Divisions may not provide data logging records to third parties without prior consent of the vaccine service provider provider.*

- The procedure for dealing with a cold chain breach detected from the logging undertaken by the division.

** Note: The division should consult with their local public health unit immunisation staff as to the correct procedure for reporting a cold chain breach in their local area. The Division staff should advise the practice of this procedure and strongly advise that they contact the relevant authority to report the beach.*

- Process for documentation of data logging activities undertaken at the practice and the secure storage of any results taken back to the division.

- Inform the practice that it is their responsibility to contact relevant local pubic health unit if a cold chain breach is detected from the data logging results.

**5.2 Practice**

The practice is responsible for implementing activities to ensure the viability of vaccines according to *National Vaccine Storage Guidelines, Strive for Five*. It is recommended that the practice document all action taken as a result of the logging and keep these with the data logging records. Current RACGP Standards for General Practice 3rd Edition requires patient records to be kept for 7yrs. Data logging records are currently recommended to be kept for the same time however please consult with your local public health unit to determine if there are any additional requirements.

The role of the general practice during the logging process undertaken by the division should include:

- Notify practice staff when and why data logging is occurring at the practice and their responsibilities during this time (e.g. not to move the data logger).
- Take all necessary precautions to ensure data logger remains in the same position in the fridge and if positioned as such, remains attached to the thermometer probe
- Continue monitoring and recording of daily minimum/maximum temperatures
- Undertake a cold chain audit
- Record all actions taken as a result of the data logging and set up an appropriate document storage system so that records can be stored and accessed as required.

If a cold chain breach is detected from results of the division's data logging, the practice has the responsibility to report this to the relevant local authority as advised by their division.

As soon as a breach is detected, it is important that the practice be aware of the following:

- Do not to delay contacting the local authority as advised by the division as the practice may be using vaccine that is no longer viable.

- Inform all GPs and staff of the cold chain breach (staff meeting is often used). Also advise of the outcome and changes to the practice vaccine management procedures that need to be implemented.

- Do not discard any vaccines until notified to do so by your local public health unit.

- When reporting the cold chain breach it is necessary to provide information on the temperature and time recorded outside the guidelines as well as the vaccines currently stored in the fridge.

- There is the potential need to recall patients for revaccination. This should be done in conjunction with local public health units.

- Advise practice to check insurance policy to ensure that accidental loss of vaccines is covered under this policy. Both publicly funded vaccines and private vaccines may be covered.

- If patient's private vaccines are stored in the fridge, contact the private supplier. If the vaccines need to be discarded, the practice will need to replace at their own cost.

- State Health Department may place a temporary suspension of vaccine supply until the cold chain is restored and effective vaccine management procedures are in place. This will be managed in conjunction with the local AHS.

- Record all actions taken as a result of the cold chain breach. This may include alterations in fridge set up, quantity and type of discarded vaccines and documentation in clinical notes if patients are recalled for vaccination.

- File all documentation occurring as a result of the cold chain breach.

When undertaking permanent data logging, the practice should also consider the above points plus education for all practice staff on principles of vaccine management in order for effective monitoring to occur.

### 5.3 Local Public Health Units

- Work with local divisions to ensure all practices are aware of the State health guidelines for reporting of cold chain breaches and the process for local implementation of these guidelines.
- Follow up on any reported cold chain breaches as reported by the local general practices including provision of written advice to the practice on actions to be taken. This should include recommendations for discarding vaccines, patient revaccination if required, cost of vaccine wastage and any recommendations for modifications to vaccine management procedures.

## REFERENCES

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