

## Data Logging Guidelines for Divisions of General Practice

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 routinely undertaken 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 display (either separate or inbuilt into the data logger) 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 min/max temperature probe (if contained in a separate device) and operates independently on its own battery. The recording is then downloaded on to the computer and saved, this overrides the previous data and the logger is relaunched. Alternatively the logger can be set to record continuously and when the memory is full it overwrites the oldest data. By selecting the interval you may, for example, always record the last 3 months of fridge history.

A data logger can be used for routine temperature monitoring however it must have a visual display of min/max temperatures for twice daily temperature recording to 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).

A purpose built vaccine fridge will have a built-in controller with a min/max display. In this case the data logger needs to only act as an auditing tool. It does not require a min/max temperature or alarm LED but this may provide additional peace of mind. A domestic fridge must have a thermometer with a min/max display. Some temperature loggers will also display the current temperature as well as display the min/max.

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 may have a life of up to 10years (*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.

It is important that staff periodically check the temperature via the min/max display, either on the logger or separate thermometer. The data logger acts as an independent auditor to ensure the fridge and staff are doing their job.

## **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.

- Loggers should be placed:
  1. Close to the temperature probe of the vaccine fridge IF you are trying to validate the vaccine fridge's thermometer.
  2. Any where in the fridge if you are trying to audit every location within the fridge. The best place normally for a temperature logger is where the fridge's temperature sensor is NOT. In a heavily loaded fridge there will be a temperature difference between the front and back, top and bottom.
  3. The logger/probe should not be in direct contact with the back plate, metal trays, or in the air return.
- 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 a max of 30 mins after you have placed in the fridge. There may be one high reading at the start as the fridge cools down. A well-functioning fridge should quickly return to its pre-set temperature. If possible allow the logger to record over a weekend as this will provide information on the temperature when the fridge is closed for a longer period and when there may be changes in the room 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 at intervals of 10-20 minutes duration. A basic logger can store around 2,000 readings which means the logger will last 3 to 4 weeks before readings must be downloaded. The sample rate will determine how often READINGS must be downloaded to the computer. Faster sampling is possible, but should not be set any more than 30 minute increments. Check the manufacturer's instructions for recommendations on ideal increment settings for your data logger.
- Ideally the data logger should remain in the refrigerator forever, however if Division loggers are used by a number of practices the data logger should ideally remain in the vaccine refrigerator for approximately 7 days and include a weekend.
- Logging results should be downloaded at least weekly, or after the defined period of logging. Results should be printed out for record keeping and analysis However, in the event of a cold chain breach logging should be stopped and results immediately downloaded.
- 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**

Resources for divisions and practices:

*National Vaccine Storage Guidelines – Strive for 5* at

<http://www.immunise.health.gov.au/internet/immunise/publishing.nsf/Content/provider-store>

KISS Guide to vaccine management at

[http://www.gpqld.com.au/page/Programs/Immunisation/Vaccine\\_Management/](http://www.gpqld.com.au/page/Programs/Immunisation/Vaccine_Management/)

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 Queensland Health Immunisation Program. Divisions have a role in the promotion of Queensland Health guidelines for cold chain reporting and should work with their local Population Health Unit 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 the breach until the data logger detects 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 or practice to verify cold chain efficacy and provide documentation to support accreditation and/or cold chain breach investigation. Divisions who undertake data logging provide the logger to practices for one week duration. 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 if 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, practice nurses 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 can 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
- 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 comparative indicator of temperature.*

Data logging does not replace daily temperature monitoring, however 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 when the temperature goes outside +2°C and +8°C
- Immediate downloading and recording of information occurs when an alarm is activated.
- Regular calibration (annually) and battery change occurs as per the manufacturer's recommendation.

- 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.

National Association of Testing Authorities (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 laboratories:

- 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
- ECEFast ph. 1800 811 818
- Energex ph. (07) 3407 5460

#### **4. 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 'cold spots' in the fridge which 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  $\pm 1^\circ\text{C}$  of accuracy. Data loggers when stored in the exact location of the thermometer have a degree of accuracy of approximately 0.5°C.

#### **5. LIMITATIONS OF DATA LOGGING**

- Data logging adds another layer of work to vaccine management for the practice as it does not replace daily temperature monitoring. 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 staffs 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. There will be uncertainty about which is accurate.
- 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.

## **6. ROLES & RESPONSIBILITIES**

With the provision of periodic data logging by divisions of general practice, practices and Queensland Health have a role to play to ensure any cold chain breaches that are detected are dealt with quickly and effectively.

### **6.1 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 or if they want to provide this service for their local general practices. There is usually no charge for this service. Divisions may choose to use the *data logging consent form* that accompanies these guidelines. 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 analysing results. This should be provided as soon as possible following the downloading of results from the practice. This is of utmost importance if the report suggests a cold chain breach. 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.*
- The procedure for dealing with a cold chain breach detected by the logging undertaken by the division. It is not the role or responsibility of the division to report any cold chain breaches. Their role is to strongly encourage practices to report any cold chain breach as practices have a duty of care regarding the administration of viable vaccines to their patients and to ensure the effectiveness of immunisation.
- NOTE: The Division should be aware of Queensland Health guidelines on reporting a cold chain breach. Division staff should advise the practice of this procedure and strongly advise that they contact Queensland Health to make a report.
- 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 Queensland Health Immunisation Program if a cold chain breach is detected from the data logging results.

## 6.2 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 3<sup>rd</sup> Edition requires patient records to be kept for 7yrs.

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

1. 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).
2. Take all necessary precautions to ensure data logger remains stable in the fridge and if positioned as such, remains attached to the thermometer probe
3. Continue monitoring and recording of daily minimum/maximum temperatures
4. Undertake a cold chain audit
5. 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, it is the practice's responsibility to report this as soon as possible to Queensland Health on (07) 3234 1500, Monday to Friday during business hours.

Once a breach is detected, it is important that the practice be aware of the following:

- The vaccines in the fridge should not be used until given clearance by Queensland Health (funded vaccines) or by the vaccine manufacturer (privately purchased vaccines.) Follow usual cold chain breach procedures.
- Immediately download the results from the data logger and save/print. Contact Queensland Health Immunisation Program on (07) 3234 1500 to discuss the results and any action required.
- Do not delay in contacting Queensland Health as the practice may be using vaccine that is no longer viable. There is the potential for recall of patients for revaccination. This will be done in conjunction with the local Population 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.
- Inform all GPs and staff of the cold chain breach (staff meeting is often used). Also advise 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 Queensland Health or your local Population Health Unit.
- Advise the 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.
- Queensland Health may temporarily suspend vaccine supply until the cold chain is restored and effective vaccine management procedures are in place. This will be managed in conjunction with Queensland Health and/or your local Population Health Unit.
- 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.

### 6.3 Local Population Health Units

- Work with local divisions to ensure all practices are aware of the 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 to Queensland Health Immunisation Program by general practices, including 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.

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