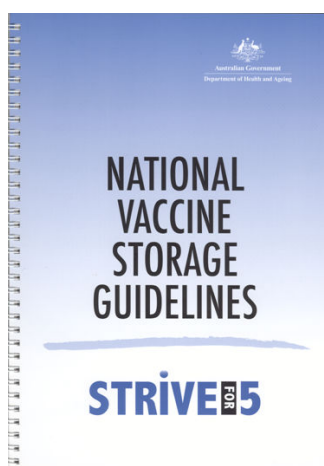


Western Australia General Practice Vaccine Management Policy and Protocol Template



March 2008

NOTE: Ensure your healthcare service has a written Vaccine Management policy and protocol
Reference: The Australian Immunisation Handbook 9th Edition

Acknowledgments

The information contained in this document has been modified to suit Western Australia vaccine management from the original KISS (Keep it Simple and Safe) Guide to vaccine management developed as a joint initiative between General Practice Queensland and Queensland Health to support service Providers in effective vaccine management.



Vaccine Management Policy and Protocol Template

March 2008

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INTRODUCTION TO VACCINE MANAGEMENT

About cold chain

The National Vaccine Storage Guidelines: Strive for Five define the cold chain as the system of transporting and storing vaccines within the safe temperature range of +2°C and +8°C. The cold chain begins from the time the vaccine is manufactured, moves through to the State or Territory vaccine distribution centres and ends when the vaccine is administered. The success of the system involves three key elements: people, processes and equipment.

Why it is important

Vaccines are delicate biological substances that can become less effective or destroyed if they are frozen, allowed to get too hot and/or exposed to direct sunlight or fluorescent light. The outcome following exposure to any or all of these conditions is dependent on the vaccine itself. For example, for vaccines that are cold or freeze-sensitive such as Pneumococcal and Influenza vaccines, the loss of potency following freezing is immediate and these vaccines must not be administered. When vaccines are exposed to repeated episodes of heat, the loss of vaccine potency is cumulative and cannot be reversed.

STRIVE^{FOR FIVE} See pages 2-6

OUR VACCINE MANAGEMENT PROFILE

Our people

Policy

In our practice/clinic, the following staff members are responsible for these activities: [\[customise this section\]](#)

Activity	Staff details
Primary person responsible for vaccine management	
Secondary person responsible for vaccine management	
Recording the temperature in the morning	
Recording the temperature in the evening	
Ordering vaccines	
Receiving vaccines	
Checking vaccine expiry dates and rotating stock	

All new staff members who are involved in some or all elements of vaccine management are provided with a comprehensive orientation program when they start to ensure that they are well-versed in their role and responsibilities.

All key staff members also receive regular updates on immunisation and vaccine management via attendance at education sessions, newsletter articles or receiving practice visits and other methods of support offered by our local Division of General Practice, Department of Health, professional association (e.g. APNA, AAPM, RACGP, ACRRM), accreditation bodies (e.g. GPA, QIP/AGPAL) and other like organisations.

STRIVE^{FOR FIVE} See pages 2-6

Our processes

Policy

It is essential that the practice/clinic establish simple, routine cold chain processes and systems for their particular immunisation service that are easily maintained. The practice/clinic should also establish written protocols on effective vaccine management which reflect the way their systems operate.

In our practice/clinic, we have implemented the following protocols to safely and effectively manage our vaccines:

- About cold chain and why it is important.
- Key staff members responsible for vaccine management.
- Vaccine refrigerator and monitoring equipment.
- Ordering vaccines.
- Receiving vaccines.
- Appropriate disposal of vaccines.
- Packing the vaccine refrigerator.
- Daily monitoring and recording of the vaccine refrigerator temperature.
- Managing a power failure.
- Action in the event of a cold chain breach.
- Packing a portable cooler.
- Maintenance of the vaccine refrigerator and monitoring equipment.

STRIVE^{FOR}**5** See pages 2-6

Our vaccine refrigerator

Policy

In our practice/clinic, we use the following dedicated refrigerator to store vaccines: [\[choose your refrigerator and delete the other options\]](#)

- Purpose-built vaccine refrigerator.
- Modified domestic refrigerator.
- Bar refrigerator (**NOTE:** Bar refrigerators and cyclic defrost refrigerators are not recommended because of the risk of freezing, temperature instability and susceptibility to ambient temperatures. Refer to **page 7** in the National Vaccine Storage Guidelines: Strive for Five for further information).

Details of our vaccine refrigerator are as follows: [\[customise this section\]](#)

Refrigerator model:	
Name of supplier:	
Contact details of supplier:	
Warranty expiry date:	
Name of maintenance service:	
Contact details of maintenance service:	
Next service due:	

Our vaccine refrigerator offers the following features to help us achieve effective vaccine management: [\[customise this section\]](#)

- Door open/ajar alarm that activates after 30 seconds.
- Abnormal temperature alarm system for low and high temperatures.
- Refrigerator door closes automatically.
- Built-in power filter to protect from power surges.
- Refrigerator is linked into our security/alarm system which activates if the refrigerator experiences a power failure or is outside the recommended temperature range of +2°C and +8°C.
- Audible alarm activates during power failure.
- Domestic refrigerator has been modified to make it safer for vaccine storage.

STRIVE¹⁰³5 See pages 2-6, 7-18 and 19-21

Our monitoring equipment

Policy

In our practice/clinic, we use the following equipment to monitor the temperature of our vaccine refrigerator: [\[choose your monitoring equipment and delete the other options\]](#)

- Minimum and maximum digital thermometer.
- Data logger.
- Temperature chart recorder (also called temperature graph recorder).

We record the temperature of our vaccine refrigerator using the procedure listed under Checking and recording the vaccine refrigerator temperature in this document.

We maintain our equipment using the procedure listed under Maintaining our monitoring equipment in this document.

STRIVE¹⁰³5 See pages 22-23

ORDERING, RECEIVING AND DISPOSAL OF VACCINES

Ordering vaccines

Policy

At our practice/clinic, we keep vaccine stock to a minimum by regularly monitoring the vaccine stored in the vaccine refrigerator.

We order our publicly funded vaccine through the Western Australia Department of Health Immunisation Program allocated distribution centre on a weekly basis using the procedure listed below.

We order our private vaccine on a [\[insert frequency of ordering private vaccines, e.g. weekly\]](#) basis through the following suppliers: [\[customise this section\]](#)

Vaccine	Supplier	Contact details

Procedure

In our practice/clinic, we follow this procedure for ordering publicly funded vaccine:
Metropolitan:

1. Order from the Western Australia Department of Health Immunisation Program distribution contractor – CSL via fax: **9227 6196** or phone: **9328 7322**.
2. Orders can be placed weekly.
3. A contracted distributor will deliver vaccine to our practice/clinic

Rural / Remote:

1. Order from the Western Australia Department of Health Immunisation Program distribution contractor for your region.
[customise this section with name of distributor, fax and phone numbers]
2. Orders can be placed weekly.
3. A contracted distributor will deliver vaccine to our practice/clinic

NOTE: Delays in delivery may occur because of remoteness, weekends, public holidays and adverse weather conditions.

Receiving vaccines

Procedure

In our practice/clinic, we follow this procedure for receiving vaccines:

1. Vaccines must only be received by the practice/clinic staff.
2. Sign the delivery docket and return to the courier.
3. Check that the consignment is correct against the delivery invoice and that the vaccines are packed appropriately.
4. Unpack the vaccine immediately. All staff need to be familiarised with the urgency of this process particularly in the metropolitan area.
 - If applicable check temperature indicators to ensure vaccines have maintained safe temperature ranges,
5. Transfer vaccines to the refrigerator immediately, minimising the time that the refrigerator door is open. Fresh vaccines should be placed to the rear of the current stock.
6. If you have any concerns about your vaccine delivery, isolate the vaccines in the vaccine refrigerator and contact the supplier as soon as possible after receiving your delivery.

Disposal of vaccines

Policy

Publicly funded vaccine should only be discarded on advice from your Regional Immunisation Coordinator (RIC) or the Central Immunisation Clinic – 9321 1312. Discarding vaccine may be as a result of expiration or cold chain breach.

Note:

Pharmaceutical class waste is all waste generated by the breakage, expiring dates and rejection of Pharmaceutical or Bioplasma related product.

Pharmaceutical class waste is classed as prescribed waste under the authority of the Environmental Protection Authority (EPA).

PACKING OUR VACCINE REFRIGERATOR

Principles of packing our vaccine refrigerator

Policy

Correct packing of our vaccine refrigerator is essential if vaccines are to remain safe and effective. The vaccine refrigerator needs to have capacity to accommodate the maximum vaccine storage needs including during the influenza vaccination period.

Domestic refrigerators are designed for food storage and not the specialised needs of vaccines therefore modification of domestic refrigerators is necessary to reduce the risk of adverse storage events. Frost-free refrigerators are suitable following modification, however cyclic defrost and bar refrigerators are not recommended.

Careful monitoring and knowledge of our refrigerator is essential to minimise risk to the vaccine, so it is important that we 'know our vaccine refrigerator' by monitoring and recording temperatures throughout (also called 'mapping') and pack the refrigerator accordingly. The National Vaccine Storage Guidelines: Strive for Five provide clear instructions on how to record temperatures throughout the vaccine refrigerator under **Step 5** on **page 11**.

Once the temperatures have been 'mapped', it is important that we pack the refrigerator accordingly or make modifications. The National Vaccine Storage Guidelines: Strive for Five provides a case study on modifying a domestic refrigerator on **pages 41 to 43**.

STRIVE^{FOR FIVE} See pages 9-15

Packing a purpose-built vaccine refrigerator

Procedure

In our practice/clinic, we follow these principles when packing our purpose-built vaccine refrigerator:

- Vaccines can be stored in shallow plastic baskets/trays clearly labelled with the name(s) of vaccine(s).
- Allow space between baskets/trays for air circulation.
- Some purpose-built vaccine refrigerators have a cooling plate. If this is the case, ensure there is a gap of at least 4cm between the vaccines and the back of the refrigerator.
- Keep the door closed as much as practical.
- Place a sticker on the refrigerator door reminding GPs and staff to only open the door when required.
- Always leave vaccines in their original packaging – do not remove from box to fit more in the refrigerator.
- If the refrigerator is new, wait until it is between +2°C and +8°C before stocking with vaccine.
- Don't overstock the refrigerator with vaccines – allow air to circulate. It is suggested that practices/clinics also check with the vaccine refrigerator manufacturer regarding air circulation requirements as this may vary between brands. For example, recommendations gaps between vaccine packaging, gaps from the sides and back of the refrigerator and stock on the bottom of the refrigerator.

- If there is a small amount of stock in the refrigerator, place cooled bottles of water or refrigerated ice packs/gel packs to help stabilise the temperature.
- The refrigerator is used exclusively for the storage of vaccines. Medications requiring refrigeration may also be stored providing there is sufficient space. It is not used to store food or drink.
- Place a warning sticker above the refrigerator power source stating “DO NOT TURN POWER OFF”. If the power source is exposed, a switch cover may be necessary.

STRIVE⁵ See pages 19-21

Packing a modified domestic refrigerator

Procedure

In our practice/clinic, we follow these principles when packing our modified domestic refrigerator:

- Know the refrigerator by:
 - recording temperatures throughout the refrigerator (this will help you find the “cold spots”),
 - locating the air vents which return cold air from the freezer, and
 - being trained in the adjustment of the thermostat.
- Store vaccines in their original packaging in a set of sliding plastic drawers or enclosed plastic containers. Label drawers/containers clearly with the name(s) of vaccine(s).
- Ensure there is a gap of at least 4cm between the plastic container and all refrigerator walls including the back.
- Do not use any shelf in the refrigerator where the temperature is known to have been unstable or not between +2°C and +8°C. Fill any shelves inappropriate for storing vaccine with cooled water bottles/containers. Leave a small gap between the bottles/containers to allow air circulation.
- Fill the lower drawers and the door with cooled water bottles/containers. Leave a small gap between the bottles/containers to allow air circulation.
- Place water bottles or ice packs/gel packs in the freezer compartment.
- Keep the door closed as much as practical.
- If the refrigerator is new, wait until it is between +2°C and +8°C before stocking with vaccine.
- Don't overstock the refrigerator with vaccines – allow air to circulate.
- If there is a small amount of stock in the refrigerator, place cooled bottles of water or refrigerated ice packs/gel packs to help stabilise the temperature.
- Place a sticker on the refrigerator door reminding GPs and staff to only open the door when required.
- Place a sticker on or near the thermostat advising staff that only authorised personnel are permitted to adjust.
- The refrigerator is used exclusively for the storage of vaccines. It is not used to store food or drink.
- Place a warning sticker above the refrigerator power source stating “DO NOT TURN POWER OFF”. If the power source is exposed, a switch cover may be necessary.

STRIVE⁵ See pages 9-18 and 41-43

Location of the external thermometer probe in a modified domestic refrigerator

Policy

If a practice/clinic uses an external thermometer, the thermometer probe should be placed inside vaccine packaging (including the box and product information leaflet) so that the probe is able to measure the air temperature closest to where a vaccine vial would be and therefore simulates vaccine temperature. The box and product information leaflet provide some further protection from very short term fluctuations, e.g. after the door is opened and closed.

An empty box with the product information should be used so that the probe does not get misplaced when vials are used. The box should be labelled as "EMPTY" so that the probe isn't inadvertently moved.

Procedure

In our practice/clinic, we use an external thermometer and follow this procedure in terms of placement of the probe in the vaccine refrigerator:

1. Locate the probe inside an empty vaccine package with retained product information.
2. Label the vaccine package "EMPTY".
3. Place package containing the probe inside and near the back of an enclosed plastic drawer or container.

STRIVE⁵ See page 14

CHECKING AND RECORDING THE VACCINE REFRIGERATOR TEMPERATURE

Principles of monitoring our vaccine refrigerator

Policy

Checking and recording the minimum and maximum temperature of the vaccine refrigerator is an essential element of ensuring that vaccines remain safe and effective. Checking and recording temperatures before using vaccine enables the identification of problems before vaccine (which may be damaged) is given.

Twice daily checks give a better indication of any problems in the refrigerator's function and temperature fluctuations over the course of the day. However, the temperature needs to be viewed and considered every time the refrigerator is opened.

Procedure

In addition to daily monitoring and recording the temperature of the vaccine refrigerator, our practice/clinic ensures safe and effective vaccines by completing the following:

1. Check minimum/maximum temperatures:
 - on receipt of vaccines,
 - every day before vaccination commences and at the end of the working day,
 - last thing Friday afternoon and first thing Monday, if the centre closes over the weekend,
 - hourly during outreach clinics, and
 - every time you open the refrigerator.
2. Plus record comments and any action taken in the temperature chart/log every time the minimum and maximum temperature exceeds the recommended range of +2°C and +8°C, e.g. if restocking or defrosting the refrigerator.

3. Never reset the thermometer unless the temperatures have been recorded.
4. Have a separate temperature chart/log for each vaccine refrigerator in the practice/clinic.

STRIVE¹⁰⁰⁵ See page 14

Monitoring vaccines using an external thermometer

Procedure

In our practice/clinic, we follow this procedure for checking and recording the temperature of our vaccine refrigerator:

At the beginning of the first session (at start of business)...

1. Check the vaccine refrigerator thermometer.
2. Record the date, time, minimum and maximum temperature and your initials on the temperature chart or log. (Every vaccine refrigerator needs to have its own temperature chart or log book.)
3. **RESET** to clear the temperature memory after recording the temperature (**NOTE:** Resetting depends on the type of monitoring equipment. Refer to Our monitoring equipment for details.)

At the end of the last session (at close of business)...

1. Check the vaccine refrigerator thermometer.
2. Record the date, time, minimum and maximum temperature and initials of the person in the vaccine refrigerator temperature chart or log book. (Every vaccine refrigerator needs to have its own temperature chart or log book.)
3. **RESET** to clear the temperature memory after recording the temperature (**NOTE:** Resetting depends on the type of monitoring equipment. Refer to Our monitoring equipment for details.)

NOTE: If vaccine storage temperatures have been outside the recommended range of +2°C and +8°C, isolate the vaccines, notify other staff not to use until further notice and review the Cold Chain Breakdown Action Plan and ring your Regional Immunisation Coordinator (RIC) or the Central Immunisation Clinic (9321 1312) during business hours as soon as possible to inform them of the breach and to seek advice. See Action in the event of a cold chain breach for further information.

STRIVE¹⁰⁰⁵ See pages 14 and 22

Monitoring vaccines using a data logger

Procedure

In our practice/clinic, we follow this procedure for checking and recording the temperature of our vaccine refrigerator:

At the beginning of the first session (at start of business)...

1. Download the readings of the data logger.
2. Check both the minimum (MIN) and maximum (MAX) temperatures.

3. If using computer software, record in the software the time checked (if not logged automatically) and your initials.
4. If unable to edit computer software:
 - Print the log, circle the minimum and maximum temperatures and sign.
OR
 - Record the date, time, the minimum and maximum temperature and your initials on the temperature chart or log.

At the end of the last session (at close of business)...

1. Download the readings of the data logger.
2. Check both the minimum (MIN) and maximum (MAX) temperatures.
3. If using computer software, record in the software the time checked (if not logged automatically) and your initials.
4. If unable to edit computer software:
 - Print the log, circle the minimum and maximum temperatures and sign.
OR
 - Record the date, time, the minimum and maximum temperature and your initials on the temperature chart or log.

NOTE: If vaccine storage temperatures have been outside the recommended range of +2°C and +8°C, isolate the vaccines, notify other staff not to use until further notice and review the Cold Chain Breakdown Action Plan and ring your Regional Immunisation Coordinator (RIC) or the Central Immunisation Clinic (9321 1312) during business hours as soon as possible to inform them of the breach and to seek advice. See Action in the event of a cold chain breach for further information.

STRIVE¹⁵ See pages 14 and 22

MANAGEMENT OF COLD CHAIN PROBLEMS

Planning and prevention

Policy

Cold chain problems can take many shapes and forms such as inadequate equipment and processes, incorrect packing of the vaccine refrigerator, staff involved in vaccine management not provided with training, vaccine accidentally left out of the refrigerator, refrigerator accidentally turned off or unplugged, power failure, load shedding of electricity and natural disasters including cyclones and floods. All of these events can lead to a cold chain breach.

Procedure

In our practice/clinic, we have put the following measures in place to prevent wherever possible a cold chain breach:

- Simple, routine processes established.
- Written protocols developed on safe and effective vaccine management.
- Staff involved in vaccine management have received training in vaccine management and understand the cold chain and its importance.
- Appropriate vaccine refrigerator and monitoring equipment are utilised.
- Processes are in place for ordering and receiving vaccines.
- Processes are in place for safe disposal of vaccines.
- The vaccine refrigerator is packed in accordance with best practice guidelines.

- The temperature of vaccines is monitored and recorded in accordance with best practice guidelines.
- Processes in place for managing a power failure.
- Equipment and process for packing a portable cooler.
- Processes in place for maintenance of the vaccine refrigerator and monitoring equipment.
- Conduct a vaccine management audit on an annual basis.
- Conduct cold chain risk management planning.
- Conduct quality review processes in the event that a cold chain problem occurs.

We also have processes in place to appropriately manage a cold chain breach. For further information, refer to Action in the event of a cold chain breach.

Managing a power failure in a purpose-built vaccine refrigerator

Policy

Purpose-built vaccine refrigerators (particularly those with glass doors) may lose their chill quicker than a domestic refrigerator, often as a little as 20-30 minutes. Vaccine service providers should know how long their brand of purpose-built vaccine refrigerator will hold a temperature of +2°C and +8°C in the event of a power failure by contacting the refrigerator's manufacturer.

According to the manufacturer, our practice's purpose-built vaccine refrigerator is able to maintain a temperature of +2°C and +8°C in the event of a power failure for [\[insert length of time\]](#).

Procedure (during business hours)

In our practice/clinic, we follow this procedure in the event of a power failure during business hours:

1. Investigate the reason for the power failure:
 - If it is a power cut, phone the utility company to ascertain approximately how long the power will be interrupted.
 - If the practice/clinic is part of a shopping centre or other complex, ensure that management is aware of the need to keep the power cut to a minimum.
 - If a safety switch (Residual Current Device) has tripped, reset it. If it trips again, contact an electrician.
2. Frequently monitor the temperature of the refrigerator.
3. Some purpose-built vaccine fridges warm quickly during a power failure. If the area is prone to power failures, consider adding cooled water bottles or refrigerated ice packs/gel packs to the vaccine refrigerator to help keep it cool during these periods.
4. Always have an alternative means of vaccine storage available such as a cooler, frozen ice packs/gel packs and insulating material.
5. If the vaccines are transferred to a portable cooler, continue to monitor the temperature of the vaccines by placing the thermometer probe inside a vaccine box inside the cooler. It is recommended that monitoring occurs every 15 minutes for the first 2 hours as freezing is most likely to occur during this period. Following the 2 hour period, monitor the cooler every hour. For further information, refer to Packing a portable cooler.

IMPORTANT: Depending on the circumstances of a power failure, ice packs/gel packs may not be given adequate conditioning time prior to packing a portable cooler. In these instances, use additional insulating material to protect the vaccine and monitor the portable cooler closely.

STRIVE⁵ See pages 26-27

Managing a power failure in a modified domestic refrigerator

Procedure (during business hours)

In our practice/clinic, we follow this procedure in the event of a power failure during business hours:

1. Investigate the reason for the power failure:
 - If it is a power cut, phone the utility company to ascertain approximately how long the power will be interrupted.
 - If the practice/clinic is part of a shopping centre or other complex, ensure that management is aware of the need to keep the power cut to a minimum.
 - If a safety switch (Residual Current Device) has tripped, reset it. If it trips again, contact an electrician.
2. Frequently monitor the temperature of the refrigerator.
3. During a power failure of **4 hours or less**, the refrigerator door should be kept closed.
4. For power failures of **more than 4 hours**, or if the refrigerator temperature reaches 14°C, transfer the vaccines to a portable cooler.
5. Always have an alternative means of vaccine storage available such as a cooler, frozen ice packs/gel packs and insulating material.
6. If the vaccines are transferred to a portable cooler, continue to monitor the temperature of the vaccines by placing the thermometer probe inside a vaccine box inside the cooler. It is recommended that monitoring occurs every 15 minutes for the first 2 hours as freezing is most likely to occur during this period. Following the 2 hour period, monitor the cooler every hour. For further information, refer to Packing a portable cooler.

IMPORTANT: Depending on the circumstances of a power failure, ice packs/gel packs may not be given adequate conditioning time prior to packing a portable cooler. In these instances, use additional insulating material to protect the vaccine and monitor the portable cooler closely.

STRIVE₅ See pages 26-27

Action in the event of a cold chain breach

Policy

According to the National Vaccine Storage Guidelines: Strive for Five, a cold chain breach is when vaccine storage temperatures have been outside the recommended range of +2°C and +8°C. This does not however include temperature deviations or excursions up to +15°C lasting no longer than 15 minutes when stocktaking or restocking.

Cold chain breaches left unidentified and untreated can have serious implications – especially when it involves informing people that they or their child may have received an ineffective vaccine and will require revaccination.

STRIVE₅ See pages iii and 26-27

Procedure

In our practice/clinic, we follow this procedure in the event of a cold chain breach:

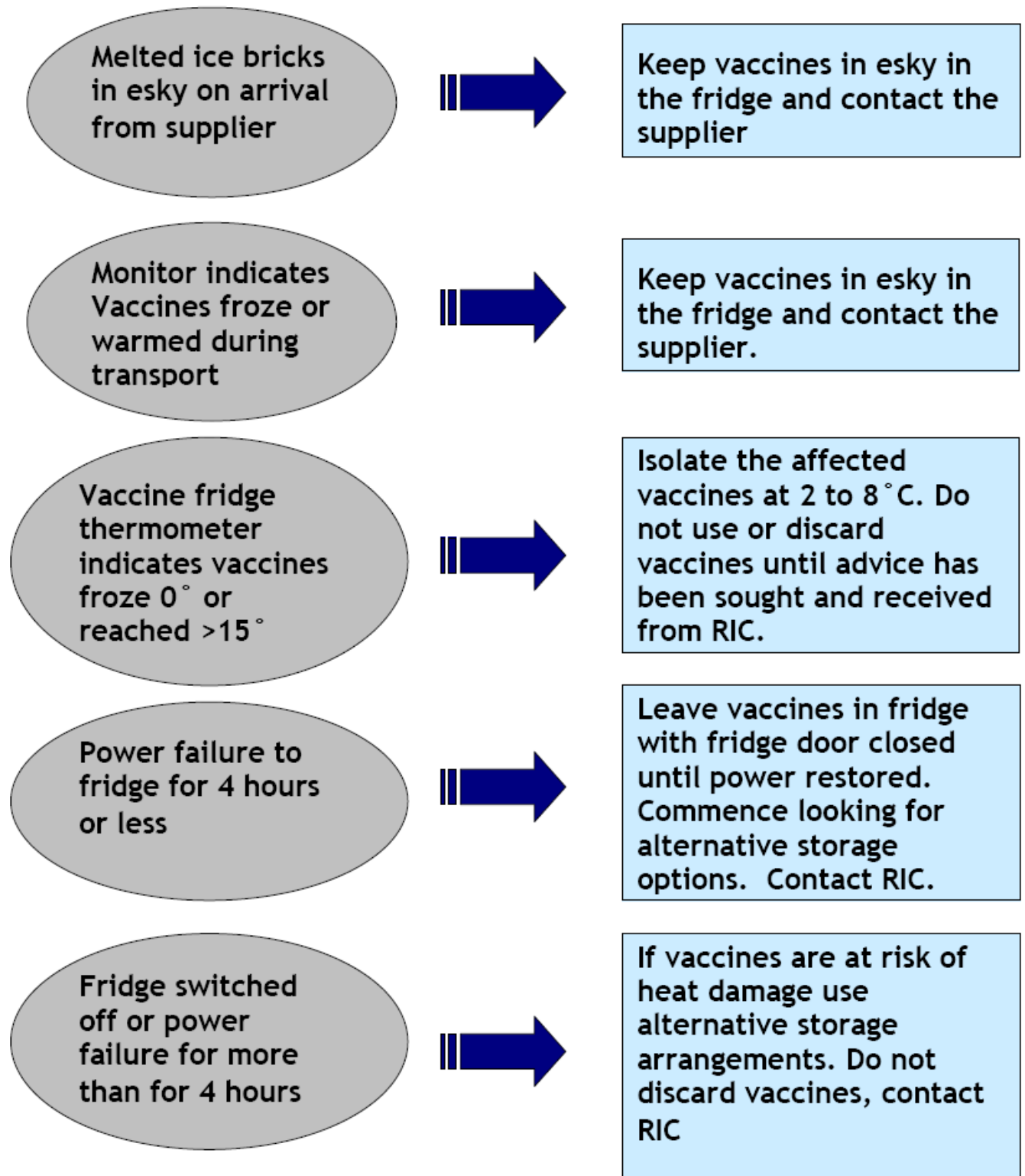
1. Isolate the vaccines immediately to prevent further use (e.g. sign on the refrigerator door) and notify relevant staff.

2. Keep vaccines refrigerated between +2°C and +8°C.
3. Refer to Cold Chain Breakdown Action plan immediately and take appropriate action.
4. Have important details on hand when contacting the RIC or Central Immunisation Clinic including:
 - the vaccine service provider number,
 - date of the breach,
 - the minimum and maximum temperature reading,
 - when the thermometer was last reset,
 - how long you think the temperature was outside +2°C and +8°C, and
 - what you think was the cause of the cold chain breach.
5. Publicly funded vaccine should only be discarded on advice from your Regional Immunisation Coordinator (RIC) or the Central Immunisation Clinic – 9321 1312..
6. Take active steps to correct the problem and prevent the problem from recurring.
7. For privately purchased vaccines, contact the manufacturer for advice.
8. Record notes on the temperature log or chart regarding what happened and how the problem was corrected.

STRIVE FOR **5** See pages 26-27

COLD CHAIN BREAKDOWN ACTION PLAN

For advice on all Cold Chain incidents contact your
Regional Immunisation Coordinator (RIC) or the Central Immunisation Clinic (9321 1312)



ABOUT PORTABLE COOLERS

Policy

A cooler, also known by names such as Esky™ or Willow™, is a solid-walled insulated container with a tight fitting lid with the temperature inside maintained by ice packs or gel packs.

Although generally associated with outreach immunisation clinics, practices/clinics will generally need a portable cooler in the following circumstances:

- Transport of vaccines.
- Defrosting a domestic vaccine refrigerator.
- During a power failure.
- Vaccine refrigerator breakdown.
- Vaccine refrigerator not maintaining the correct temperatures of between +2°C and +8°C.
- Other circumstances requiring the practice/clinic to remove vaccines from the refrigerator (e.g. cyclone).

It is important to note that freezing happens very easily in all coolers, usually in the first 2 hours after packing. A practice/clinic should therefore select a cooler that is large enough to store their vaccine as well as sufficient insulating material to ensure that the vaccine is protected. It is encouraged that practices/clinics experiment with their cooler to maintain a stable temperature which includes knowing how many ice packs/gel packs are required.

IMPORTANT: In the event of a natural disaster such as a cyclone or depending on the circumstances of a power failure, ice packs/gel packs may not be given adequate conditioning time prior to packing a portable cooler. In these instances, use additional insulating material to protect the vaccine and monitor the portable cooler closely.

STRIVE₅ See pages 28-31

Monitoring a cooler

Procedure

In our practice/clinic, we check the temperature of the cooler:

- after packing,
- every 15 minutes for the first 2 hours, and then every hour following the 2 hour period (freezing is most likely to occur within the first 2 hours after packing),
- regularly but at least hourly,
- prior to administering vaccine, and
- before returning vaccine to the vaccine refrigerator.

STRIVE₅ See pages 14 and 29

Equipment for a portable cooler

Procedure

In our practice/clinic, we have the following equipment available to pack a portable cooler:

- Cooler (such as an Esky™ or Willow™) at a size that meets the practice/clinic needs. It is recommended that a cooler for storing vaccines be a minimum size of 10 litres.
- Ice packs and/or gel packs.
- Insulating material such as polystyrene sheets (width 12-20mm), polystyrene chips, plastic bubble-wrap and/or shredded paper.
- Minimum/maximum thermometer with probe.

NOTE: Practices/clinics with a purpose-built vaccine refrigerator will need to add ice packs/gel packs to the freezer of their domestic refrigerator which stocks lunches, refreshments, etc.

STRIVE FOR **5** See pages 28-31

Packing a portable cooler

Procedure

In our practice/clinic, we follow this procedure to pack a portable cooler:

1. Chill the inside of the cooler prior to use by placing ice packs/gel packs in it for a few hours.
2. Place insulating material at the bottom of the container.
3. Use a minimum/maximum thermometer to monitor the temperature inside the cooler. Place the probe placed inside an empty vaccine box with product information leaflet.
4. Surround the vaccines with more insulating material.
5. If using a small cooler, place the conditioned ice packs/gel packs on top, close and seal the lid of the cooler.
6. If using a large portable cooler, place conditioned ice packs/gel packs around the sides of the cooler as well as on top. Experiment to find the correct combination for the practice/clinic needs.
7. Ensure vaccine is not in direct contact with the ice packs/gel packs to minimise risk of freezing.

STRIVE FOR **5** See pages 28-31

Conditioning ice packs/gel packs

Policy

Conditioning means leaving the ice packs/gel packs at room temperature to allow the ice or gel at the core to rise to about 0°C. This is also known as 'sweating'.

Ice packs/gel packs must be conditioned correctly before use as the risk of freezing vaccines increases if the ice packs/gel packs are not conditioned correctly. It is noted however that in the event of a natural disaster such as a cyclone or depending on the circumstances of a power failure, ice packs/gel packs may not be given adequate conditioning time prior to packing a portable cooler. In these instances, use additional insulating material to protect the vaccine and monitor the portable cooler closely.

Procedure

In our practice/clinic, we follow this procedure for conditioning ice packs/gel packs:

1. Remove ice packs/gel packs from the freezer.
2. Lay out in a single row on their sides (where possible).

3. Leave a 5cm space around each ice pack/gel pack to allow maximum air exposure to reduce conditioning time.
4. Conditioning time depends on the ambient temperature, type of ice pack/gel pack and size/weight of ice pack/gel pack.
5. Always follow the manufacturer's instructions on correct conditioning of gel packs.

STRIVE^{FOR}**5** See pages 32-34

OUTREACH IMMUNISATION CLINIC

Policy

An outreach immunisation clinic involves careful preparation and selecting the correct equipment to ensure that the cold chain is maintained. Correct equipment for storing and transporting vaccine is dependent on type of conditions (such as ambient temperature) and period of time they will be transported.

Portable coolers are adequate for the transport of vaccines for 8 hours or less however for longer periods of time and in extreme conditions, a specialised vaccine cold box would be recommended.

STRIVE^{FOR}**5** See pages 24, 28-31, 35

Preparing for an outreach immunisation clinic

Procedure

In our practice/clinic, we follow these procedures to prepare for an outreach immunisation clinic:

1. Choose an adequately sized portable cooler or specialised vaccine cold box according to length of storage and transport time and type of conditions.
2. Ensure sufficient stock of vaccine, diluents and adrenaline are taken.
3. Ensure sufficient stock of ice packs/gel packs according to:
 - ambient temperature,
 - type and size of cooler,
 - number of vaccines,
 - cooler capacity, and
 - size and type of ice packs/gel packs.
4. Condition the ice packs/gel packs.
5. Pack the portable cooler according to cold chain requirements, immediately prior to leaving for the clinic.
6. Monitor the temperature of the vaccines.
7. Ensure the contents of the cooler are packed securely so that they cannot move around during transport.

STRIVE^{FOR}**5** See pages 24, 28-31, 35

Monitoring the cooler during the clinic

Procedure

During an outreach immunisation clinic, check the temperature of the cooler:

- before you leave,
- every 15 minutes for the first 2 hours, and then every hour following the 2 hour period (freezing is most likely to occur within the first 2 hours after packing),
- when you arrive,
- prior to administering vaccine, and
- regularly throughout the immunisation session (at least hourly).

STRIVE 5 See pages 24, 28-31

Maintaining the cold chain at the clinic

Procedure

In our practice/clinic, we follow this procedure to ensure the cold chain is maintained during an outreach clinic:

1. On arrival at the facility, place the portable cooler in the coolest place and out of the sun.
2. Keep vaccines in the portable cooler with the lid tightly closed until all other preparation for the clinic has been completed.
3. In a best practice clinic, vaccines should only be drawn-up immediately prior to use. MMR, for instance, quickly loses potency once reconstituted and exposed to high temperatures and light.
4. Should you choose to pre-draw vaccines, then strict cold chain conditions **MUST** be maintained:
 - do not pre-draw more vaccines than will be used within 15 minutes,
 - place pre-drawn vaccines on top of an ice brick/freezer block wrapped in bubble plastic or newspaper in portable cooler,
 - place minimum/maximum thermometer probe on top of the vaccines and another wrapped ice brick/freezer block on top of vaccines and close lid of esky, and
 - monitor temperature of pre-drawn vaccines.
5. For all day clinics carry an esky that contains only ice packs/gel packs and use these to replace those ice packs/gel packs in contact with vaccines as they melt.

MAINTAINING OUR EQUIPMENT

Policy

A well maintained vaccine refrigerator and monitoring equipment is essential if vaccines are to remain safe and effective.

For vaccine refrigerators, it involves having a maintenance program in place, positioning the refrigerator in a suitable location and defrosting a domestic refrigerator (if not frost-free).

Ensuring monitoring equipment is effective involves changing the battery every year plus an annual check to know the degree of accuracy and to identify potentially faulty equipment, flat batteries or a damaged probe or cable which can affect readings.

Maintaining our vaccine refrigerator

Procedure

In our practice/clinic, we maintain our vaccine refrigerator via the following ways:

- Conduct a vaccine management audit (including people, processes and equipment) at least every 12 months.
- Report refrigerator problems immediately to the nominated person in the practice/clinic (such as the Practice Manager) so that repairs can be made.
- Check the rubber seal around the door. If brittle or torn, arrange for replacement.
- Refrigerators requiring defrosting are not recommended. However if the refrigerator is not frost-free, defrosting should be done on a monthly basis. Transfer the vaccines to a portable cooler and monitor the temperature. Refer to About portable coolers for more information.
- If there are exposed coils on the back of the refrigerator, keep them clean and dust free to improve operating efficiency.

STRIVE¹⁵ See pages 16-18

Location of our vaccine refrigerator

Procedure

In our practice/clinic, we have positioned our vaccine refrigerator according to these principles:

- Place the vaccine refrigerator away from warm external walls and out of direct sunlight.
- Ensure that the refrigerator is in a secure area only accessible to staff.
- Follow the manufacturer's instructions about positioning the refrigerator to enable sufficient air circulation around the back and sides.
- Ensure the power source is labelled clearly to prevent the refrigerator from being accidentally unplugged or turned off. If the power source is exposed, a switch cover may be necessary.

STRIVE¹⁵ See pages 9-10

Defrosting a domestic refrigerator

Policy

A refrigerator works well only if it is properly installed, cleaned and defrosted regularly. Thick ice in the freezer compartment does not keep a refrigerator cool. Instead, it makes the refrigerator work harder and uses more power.

Refrigerators requiring defrosting are not recommended. However if the refrigerator is not a frost-free, the World Health Organization recommends defrosting the refrigerator when ice becomes more than 0.5cm thick, or once a month, whichever comes first.

Procedure

In our practice/clinic, we follow this procedure to defrost and clean the vaccine refrigerator which is not a frost-free unit:

1. Take out all vaccines and transfer them to:
 - a second refrigerator which must be monitored during this time, OR
 - a correctly packed portable cooler (refer to About portable coolers for further information about packing and monitoring a portable cooler).
2. Turn off the power supply to the refrigerator.

3. Leave the door open and wait for the ice to melt. Do not try to remove the ice with a knife or ice pick, since doing so can permanently damage the refrigerator. You can place a pan of boiling water inside and close the door.
4. Clean the inside of the refrigerator and door seal with a clean wet cloth.
5. Turn the refrigerator on again.
6. When the temperature in the main section falls to +8°C or lower (but not less than +2°C), pack the refrigerator according to best practice guidelines.

STRIVE⁵ See page 17

Maintaining our monitoring equipment

Procedure

In our practice/clinic, we maintain our monitoring equipment by doing the following:

- Conduct an accuracy check of the external thermometer (also called “slush” test). An accuracy check should be conducted after receiving a new thermometer, after changing the battery and at least every 12 months or sooner if having thermometer or cold chain problems. Record the results on the temperature chart or log for future reference.
- Replace the battery of the thermometer or data logger at least every 12 months or sooner if having thermometer or data logger problems.

STRIVE⁵ See page 22

Knowing the accuracy of the external thermometer (“slush” test)

Procedure

In our practice/clinic, we follow this procedure to know the accuracy of the external thermometer:

1. Two-thirds fill a polystyrene or plastic cup with cold water.
2. Place cup in the refrigerator freezer until a fine layer of ice forms on the top and small sections of ice form within the fluid. This may take up to 2 ½ hours.
3. Using this method, the mixture is 0°C if ice is present.
4. Place the temperature probe into the middle of the container. Be careful not to let the probe touch the container.
5. Observe the temperature on the display screen at 2 minutes.
6. The temperature will drop quickly at first and then more slowly, however the temperature should drop to 0°C within 2 minutes.

Interpreting the results

- The results should be within one degree above or below 0°C, therefore the display screen may show three possible readings: +1°C, 0°C, -1°C.
- If the temperature reading is more than one degree above or below 0°C at 2 minutes, replace the battery and test again.
- If still not within range, contact for RIC or the Central Immunisation Clinic for further advice.
- If the temperature reading is 0°C this demonstrates that the thermometer is accurate and can be used as normal.
- If the temperature reading is either +1°C or -1°C this demonstrates that the accuracy is within acceptable limits and can continue to be used HOWEVER this needs to be:
 - recorded on the temperature chart,

- taken into account should the thermometer record temperatures outside the +2°C to +8°C range, and
- included in the details given to your RIC or the Central Immunisation Clinic when reporting a cold chain breach.

STRIVE^{FOR}**5** See page 22