

Section 4: Vaccine management

All SIP VSPs must store SIP vaccines in a purpose-built vaccine refrigerator. A current vaccine management protocol must be in place for all SIP VSPs. Please refer to the current *National Vaccine Storage Guidelines: Strive for 5* available at www.health.gov.au/internet/immunise/publishing.nsf/content/IMM77-cnt

4.1 Vaccine supply

Vaccines listed on the recommended National Immunisation Program Schedule are available to registered VSPs free of charge for the purposes of implementing the SIP.

Principles of safe vaccine storage management

- Store vaccines in a purpose-built vaccine refrigerator.
- Nominate a staff member to be responsible for vaccine management, and a back-up staff member to take responsibility in their absence.
- Ensure policies, procedures and protocols are in place for vaccine management in each facility.
- Ensure all people involved in vaccine transport, storage and administration are trained in vaccine management to ensure the vaccines remain effective and potent.
- Perform vaccine storage self-audits at least annually.
- Perform temperature monitoring of vaccine refrigerators twice daily.
- Ensure plans are in place for responses to cold chain breaches and power failures in each facility.
- Report temperatures outside the +2 degrees Celsius to +8 degrees Celsius range to Queensland Health. Do not use or discard vaccine until advice is given.
- Follow the guidelines for using ice packs/gel packs and monitoring vaccines in coolers and cold boxes.

Why is vaccine storage management important?

- Health professionals have a responsibility to ensure that clients receive effective health products (i.e. vaccines that have not been adversely affected by heat or cold).
- Vaccines are expensive and can be in short supply. The total financial value of the vaccines contained within one vaccine refrigerator can be significant.
- Good vaccine management precludes the need to revaccinate clients who may, under circumstances of poor vaccine management, receive an ineffective vaccine.
- Cold chain breaches can occur due to technical malfunctions, even in well-designed and well-managed systems. If there are effective procedures in place, problems will be detected and managed *before* an ineffective vaccine is used.
- Efficient vaccine storage management is a good quality assurance measure of an immunisation service provider.
- Exposure to heat or freezing temperatures has a cumulative effect on vaccine viability.

Tips

- A current vaccine management protocol must be in place for all SIP providers.
- Vaccines must be stored and transported within the recommended temperature range of +2 degrees Celsius to +8 degrees Celsius at all times. Most vaccines are destroyed by freezing and some vaccines are also particularly heat sensitive.
- The vaccines must be stored in their original packaging from the manufacturer as this helps protect them from temperature fluctuations and ultraviolet (UV) light until they are ready for use at the school clinic.
- Some vaccines are destroyed if exposed to light.

Equipment

VSPs participating in the SIP are required to use a purpose-built vaccine refrigerator in which to store their SIP vaccines, unless otherwise negotiated with the Immunisation Program. The purpose-built vaccine refrigerator should have the ability to:

- alarm when temperatures outside +2 degrees Celsius to +8 degrees Celsius are reached
- either display a digital minimum and maximum temperature that can be reset, **or** a data logger that continually monitors the temperature of the fridge and can be downloaded twice daily
- store the quantity of vaccines required by the VSP to administer during School Immunisation Program sessions as well as other vaccination programs that the VSP may be involved with throughout the year.

Ordering vaccine

Prior to commencing your school vaccination clinics, two forms need to be completed:

Clinic dates and student numbers form (Appendix 4).

- This form needs to be submitted to your PHU contact at the beginning of each semester.
 - Please note: The *Clinic dates and student numbers for the semester* form does not generate a vaccine order.
- SIP vaccine request form (Appendix 5).
 - An up-to-date SIP vaccine request form is to be used to order vaccines.
 - Your PHU contact will be able to provide the latest SIP vaccine order form to order vaccines. This form should include stock on hand (if applicable), expiry date of vaccines and vaccine requirements.
 - The form must be completed and emailed to QHIP.Sbvp@health.qld.gov.au or faxed to the Immunisation Program on 3328 9720 **at least a fortnight prior to the date supply is required.**
 - Once the Immunisation Program has received the form, an order confirmation will be emailed or faxed back to the VSP. This form will contain the following:
 - a) *Order Date* – the date you provided the quantity on hand
 - b) *Dispatch Date* – the date vaccines are packed by the vaccine distributor
 - c) *Estimated Date of Arrival (EDA)* – the date you require your vaccines delivered (this date must be prior to your clinic date and NOT the date of the clinic).

Keep a hard copy of your order confirmation to refer to at a later date and ensure there is a responsible person available to accept delivery of vaccines on the nominated EDA.

Please note: No deliveries are made on Monday or Friday.

Tips

- Submit the *Clinic dates and student numbers for the school year* to your SIP Coordinator at the beginning of the year.
- If clinic dates change please advise your SIP Coordinator.
- The most up to date *School Immunisation Program vaccine order* form must be used to order vaccines.
- Orders should be based on the number of expected eligible students, plus an additional 10 per cent to cover unexpected demand or wastage.
- **Place your SIP order with the Immunisation Program at least a fortnight prior to the date the vaccine is required.**
- The VSP must identify and organise consumables, vaccines, equipment and alternative transport arrangements to be readily available prior to the commencement of the program.

Follow-up of School Immunisation Program vaccine orders

Immunisation Program staff may need to contact the VSP to clarify information provided for SIP orders. If there are any issues about the vaccine order or delivery of the order, you may be contacted by email or telephone.

Orders outside of the Brisbane metropolitan area are dispatched on Mondays, Tuesdays or Wednesdays to minimise the risk of vaccine loss due to a cold chain breach over the weekend.

Please note:

- It is important to notify the Immunisation Program and your SIP Coordinator immediately should your contact details change.
- **Refrigerated trucks deliver vaccines in southeast Queensland. Therefore, packaging does not contain ice packs (a heat sensitive monitor will be included and must be checked as soon as the vaccines are unpacked) so the vaccines need to be placed in a purpose-built vaccine fridge IMMEDIATELY upon arrival to your clinic. Staff receiving vaccines should be trained in handling vaccines and know the importance of storing vaccines appropriately.**

Check expiry dates of vaccines on hand and rotate vaccine stock using the shortest expiry date first. Keep an accurate vaccine audit of your stock, including recording the number of vials of each type of vaccine taken to each clinic.

Vaccines that may need to be discarded must continue to be refrigerated between +2 degrees Celsius and +8 degrees Celsius until the issue is reported to the Immunisation Program and discussed with your PHU. At the time of discard, vaccines must be recorded on the *Vaccines to be discarded or transferred form*, which is available at www.health.qld.gov.au/publications/clinical-practice/guidelines-procedures/vaccine-discard-transfer-form.pdf Please also refer to 'Unused Vaccines' in Section 2.2.

Receiving vaccines

Tips

- Queensland Health uses a distribution contractor to deliver vaccines to VSPs.
- It is the responsibility of the VSP to ensure vaccines are accepted and received by a responsible nominated staff member trained in vaccine management

Vaccines must be checked immediately on arrival to ensure:

- vaccines arrive in good condition

- that vaccine containers arrive intact with lids well sealed
- that the cold mark monitor (if included) and heat monitor are checked at the time of delivery.
- any variations from the recommendations should be reported by calling the Immunisation Program on 3328 9888.
- there is ice still present in the ice packs/gel packs (if applicable)
- vaccines are within their expiry date
- the number of vaccines received is the same as the number on the SIP *vaccine order form* contained in the order.

If there are any discrepancies between the consignment and the packing slip, notify the Immunisation Program by calling 3328 9888 immediately following delivery of the vaccines.

4.2 Purpose-built vaccine refrigerator

Purpose-built vaccine refrigerators are specifically designed to store vaccines and are the best practice storage option.

Using your purpose-built vaccine refrigerator

- Ensure the refrigerator is placed out of direct sunlight and follow the manufacturer's instructions for air circulation around the back and sides.
- Ensure the refrigerator is in a secure area accessible to staff only.
- Ensure the power source is marked clearly in a way to prevent the refrigerator from being accidentally unplugged or turned off.
- Check and record the minimum and maximum temperature:
 - Check and record the vaccine refrigerator temperature (minimum and maximum) twice daily: before the refrigerator is used for the first time and at the end of each day.
- Use the red *Daily Temperature Log Book* to record the temperatures.
- Note: To order more books contact the Immunisation Program on 3328 9888. Be aware there are some purpose-built vaccine refrigerators that require twice daily data logger downloads to monitor minimum and maximum temperatures.
- Purpose-built vaccine refrigerators should alarm if temperatures outside +2 degrees Celsius and +8 degrees Celsius are reached. This alarm should be tested once a week.
- **Do not overstock** or crowd the vaccines by overfilling the shelves. Allow space between vaccine boxes 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 four centimetres between the vaccines and the back of the refrigerator.
- If there is a small amount of vaccine in a purpose-built vaccine refrigerator, place bottles of water or refrigerated ice packs/gel packs to help stabilise the temperature.
- Keep door openings to a minimum and ensure the refrigerator door is not left open for long periods.
- If you are using a chart recorder, the chart recorder paper must be changed and stored every seven days.
- **All vaccines must be kept in their original packaging until administered.**

Managing a power failure in a purpose-built vaccine refrigerator

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

In the event of a power failure, refer to your vaccine management protocol:

- Immediately isolate the vaccines and label 'DO NOT USE'.
- Keep vaccines refrigerated between +2 degrees Celsius and +8 degrees Celsius. Investigate the reason for the power failure.
- Phone the utility company to ascertain approximately how long the power will be interrupted.
- Check if safety switch has tripped and reset it. If it trips again contact an electrician.
- Frequently monitor the temperature of the refrigerator.
- 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.
- Always have a backup plan and an alternative means of vaccine storage available (refer to the current *National Vaccine Storage Guidelines for Power Failure Procedure*).
- If you do not have a digital minimum/maximum thermometer to monitor your vaccines during a cold chain breach/power failure, contact the Immunisation Program on 3328 9888 who will supply one thermometer for this purpose.
- 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 two hours as freezing is most likely to occur during this period. Following the two-hour period, monitor the cooler every hour.

For further information on packing a portable cooler refer to the current *National Vaccine Storage Guidelines: Strive for 5*.

Tips

- 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.
- It is important to have your vaccine management protocol and a plan in place to move vaccines in the event of a power failure.
- Have equipment readily available and a check list in place.
- Organise an appropriate venue to move your vaccines where they are monitored and can be stored between +2 degrees Celsius and +8 degrees Celsius, e.g. hospital pharmacy refrigerator.

4.3 Vaccine storage and handling

Portable coolers

The type of coolers used by VSPs will depend on the type of clinics to be conducted, the length of time the vaccines will be stored in the box and the ambient temperatures to which the cooler is likely to be exposed. When selecting a cooler, please refer to the current *National Vaccine Storage Guidelines: Strive for 5* and the manufacturer for technical specifications and performance of the cooler.

Portable coolers (such as an Esky™, Willow™ or Coleman) are a solid-wall insulated container with a tight fitting lid where a stable inside temperature can be maintained by ice packs or gel packs.

VSPs should be aware that freezing episodes happen very easily in all coolers (often soon after packing) and they are generally not appropriate for prolonged storage of vaccines (more than eight hours).

Equipment for a portable cooler

Equipment required for outreach clinics includes:

- solid-walled insulated container/s with a tight fitting lid (adequate size for transport and storage of vaccines)
- the number of ice packs or gel packs needed to maintain required temperature

- insulation material to ensure vaccines do not come in contact with ice/gel packs
- digital minimum/maximum thermometer to monitor the vaccines during transport and at the outreach clinics, and
- *Temperature Log Book for Outreach Clinics* (blue book).

Packing a portable cooler

There are two options for how to pack a cooler. Please also refer to the current *National Vaccine Storage Guidelines: Strive for 5*.

- Chill the inside of the cooler prior to use by placing ice/gel packs in it for a few hours.
- Place insulating material such as bubble wrap or polystyrene chips at the bottom of the container. However, if using bubble wrap avoid wrapping the vaccines tightly.
- Use a minimum/maximum thermometer to monitor the temperature inside the cooler. Place the temperature probe inside an empty vaccine box with product information leaflet.
- Surround the vaccines with more insulating material.
- If using a small cooler, place the conditioned ice/gel packs on top, close and seal the lid of the cooler.
- If using a large portable cooler, place conditioned ice/gel packs around the sides of the cooler as well as on top. Experiment to find the correct combination for the practice/clinic needs.
- Ensure vaccine is not in direct contact with the ice/gel packs to minimise risk of freezing.
- Ensure the cooler is secured and will not move around during transportation.

Tip

- Have you considered using a purpose-built portable vaccine refrigerator for your school immunisation clinics?

Conditioning ice/gel packs

Conditioning means leaving the ice/gel packs at room temperature to allow the ice or gel at the core to rise to about 0 degrees Celsius. This is also known as 'sweating'. Please refer to the current *National Vaccine Storage Guidelines: Strive for 5*.

Ice/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. Please refer to the manufacturer's instruction on conditioning ice and gel packs.

- Remove ice/gel packs from the freezer.
- Lay out in a single row on their sides (where possible) leaving five centimetres of space around each ice/gel pack to allow maximum air exposure to reduce conditioning time.
- Wait until ice packs begin to sweat. This will take up to one hour at +20 degrees Celsius.
- The ice pack is conditioned as soon as water begins to 'slosh' about slightly inside the ice pack.
- Conditioning time depends on the ambient temperature, type, size and weight of ice/gel pack.

However, in the event of a natural disaster, such as a cyclone, or a power failure ice/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.

Tips

- **Danger: Incorrect conditioning of ice/gel packs may cause vaccines to freeze easily because they may be too cold for safe vaccine storage.**
- Ensure vaccines are not in direct contact with ice/gel packs.
- Coolers should not contain any other pharmaceuticals and must not contain food.
- Consider the ambient temperatures the cooler is exposed to, particularly in the summer months.
- Remember to place left-over vaccines transported for outreach clinics back into the vaccine refrigerator on return from the clinic.
- Vaccines returned after an outreach clinic should be used first at the next clinic.

Temperature monitoring at school immunisation clinics

School immunisation clinics involve careful preparation and selection of the correct equipment to ensure that the cold chain is maintained. Correct equipment for storing and transporting vaccine is dependent on the 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 eight hours or less. For longer periods of time and in extreme conditions, a specialised vaccine cold box is recommended.

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

Monitor the minimum and maximum temperature of your vaccines:

- before you leave
- during transport
- when you arrive
- prior to administering
- regularly throughout the vaccination session (at least hourly)
- when you return to base.

On arrival at the facility, place the portable cooler in the coolest place and out of the sun.

- Keep vaccines in the portable cooler with the lid tightly closed until all other preparation for the clinic has been completed.
- In a best practice clinic, vaccines should only be drawn up immediately prior to use.

- For all day clinics carry an extra portable cooler that contains only ice packs/gel packs and use these to replace those ice packs/gel packs as they melt.

Tips

- *Temperature Log Books for Outreach Clinics* are required for school immunisation clinics. Replacement log books can be obtained from the Immunisation Program by calling 3328 9888.
- Each portable cooler of vaccines must have its own thermometer and *Temperature Log Book for Outreach Clinics* (blue book).

4.4 Cold chain breach

Vaccines are affected by temperatures below +2 degrees Celsius and above +8 degrees Celsius. This does, however, not include temperature deviations or excursions up to +12 degrees Celsius lasting no longer than 15 minutes when stocktaking or restocking. Unexplained temperature deviations should be reported to the Immunisation Program by calling 3328 9888 between 9.00am and 3.00pm from Monday to Friday.

Cold chain breaches left unidentified and untreated can have serious implications, especially when it involves informing parents/legal guardians/authorised carers that their child may have received an ineffective vaccine and requires revaccination.

If there is any doubt about breaches of the cold chain, contact the Immunisation Program during office hours by calling 3328 9888 for further advice, and take following steps:

- Isolate the vaccines immediately to prevent further use (e.g. sign on the refrigerator door) and notify relevant staff.
- Keep vaccines refrigerated between +2 degrees Celsius and +8 degrees Celsius.
- Have important details on hand including:
 - your vaccine service provider number
 - date of the breach
 - the minimum and maximum temperature readings
 - when the thermometer/temperature recording was last reset
 - how long you think the temperature was outside +2 degrees Celsius and +8 degrees Celsius
 - the cause of the cold chain breach
 - circumstances surrounding the breach.
- Do not discard any vaccine unless advised by the PHU.
- Take active steps to correct the problem and prevent the problem from recurring.
- For privately purchased vaccines, contact the manufacturer for advice.
- Record notes on the temperature log or chart regarding what happened and how the problem was corrected.

References

Australian Government Department of Health and Ageing 2013. (current *National Vaccine Storage Guidelines: Strive for Five, 2nd Ed.*). Canberra: Department of Health and Ageing.