Template Policies and Procedures   
for Addressing Vaccine Potency and Cold Chain in General Practice

Date

RACGP Standards for General Practices

Established in the 1990’s, the Royal Australian College of General Practitioners (RACGP) Standards for general practices (the Standards) and the associated accreditation processes were developed to encourage general practice quality improvement and the meeting of best practice standards.

A general practice can self-assess against the Standards for practice quality improvement, or seek independent accreditation by one of the four national approved agencies.

Currently, these are:

* Australian General Practice Accreditation Limited (AGPAL)
* Quality Practice Accreditation
* Global Mark Propriety Limited
* The Australian Council on Healthcare Standards

**Table: Comparison of the RACGP Standards for general practices, fourth and fifth edition criterion relating the vaccine storage and maintaining cold chain.**

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| --- | --- | --- |
|  | **RACGP Standards for General Practices overview** | |
| Fourth edition  Released in October 2010 | Fifth edition  Released in October 2017 |
| **Standard** | **Standard 5.3**  Our practice maintains the potency of vaccines. | **GP Standard 6**  Our practice maintains the potency of vaccines. |
| **Criterion** | Criterion 5.3.2 Vaccine potency. | Criterion GP6.1 Maintaining vaccine potency. |
| **Indicators** | **A.** Our practice team can identify the person with primary responsibility for cold chain management within the practice. | **GP6.1 A** Our practice has at least one team member who has primary responsibility for cold chain management in the practice. |
| **B.** The person with primary responsibility for cold chain management has this responsibility defined in their position description and can describe how the process used for cold chain management complies with the current edition of the *National Vaccine Storage Guidelines*. | **GP6.1 B** The team member who has primary responsibility for cold chain management ensures that the process used complies with the current edition of the *National vaccine storage guidelines: Strive for 5*. |
| **C.** Our practice can demonstrate how we review the following processes to ensure potency of our vaccine stock:   * Ordering and stock rotation protocols * Maintenance of equipment * Annual audit of our vaccine storage procedures * Continuum of cold chain management, including the handover process between designated members of the practice team * Accuracy of our digital vaccine refrigerator thermometer. | **GP6.1 C** The team member who has primary responsibility for cold chain management reviews the following processes to ensure potency of our vaccine stock:   * Ordering and stock rotation protocols * Maintenance of equipment * Annual audit of our vaccine storage procedures * Continuity of the cold chain, including the handover process between designated members of the practice team * Accuracy of our digital vaccine refrigerator thermometer |
|  | **GP6.1 D** Our practice has a written, practice-specific policy that outlines our cold chain processes. |

Introduction

The following is an example of a cold chain management procedure, vaccine coordinator and cold chain job description, and self-audit for general practice. The document is typed in Word format for easy modification to adapt to each practice’s specific requirements.

Essential reading

National Vaccine Storage Guideline – Strive for 5

Provides health professionals on the most effective clinical guidelines on vaccine storage and includes free posters, stickers and temperature log for downloading, visit the Department of Health Immunise Australia Program website:

<http://www.immunise.health.gov.au/internet/immunise/publishing.nsf/content/IMM77-cnt>

Australian Immunisation Handbook, 10th Edition

Provides clinical guidelines for health professionals on the safest and most effective use of vaccines in their practice.

Available on the Immunise Australia website at:

<http://www.immunise.health.gov.au/internet/immunise/publishing.nsf/Content/Handbook10-home>

Instructions

Practice details

Throughout this template policy and procedure, there are sections where the practice will be required to insert particular personal information. These areas are identified as bold magenta italic underlined text.

For example: ***<location of pharmaceuticals and medical consumables>***

Location of a related policy and procedure

In some cases, a policy and procedure may have very similar characteristics to another, or there may be additional related information available. In these cases, related policies and procedures will be referred to in blue-grey bold italics.

For example: ***Practice services, Chapter 1.2 - Triage***

Templates, forms and checklists

Various templates and checklists are referred to throughout the policies and procedures. Where we have created or recommend a version for your use, these are made elsewhere in the Practice Assist Tool Kit and Library.

Where a policy or procedure has a related template form, checklist or letter, this will be referred to in capital letters, apple-green, underlined, italic letters.

For example: *MEDICAL SUPPLIES REVIEW LOGBOOK*

Vaccine potency

Policy

Vaccines are delicate biological substances, they can become less effective or destroyed if they are not kept within an optimal temperature range or are exposed to direct ultraviolet (UV) light. Practices must therefore maintain the potency of vaccines in order to ensure they are effective in improving immunity against disease (RACGP Standards for General Practices, 5th edition, p. 161).

Our practice ensures the continuing potency of vaccines by adhering to best practice guidelines found in the *National vaccine storage guidelines: Strive for 5* and through the application of the following procedures.

Procedures

Nominating a person with primary responsibility for cold chain and vaccine storage

* Our practice has nominated a member of the clinical team to take responsibility for the cold chain management and compliance with cold chain management guidelines for our practice.
* The nominated staff member with primary responsibility for our vaccines, including the monitoring and maintenance of the vaccine refrigerator and cold chain management is <insert name>.
* When <insert name> is away from the practice or no longer employed, the secondary nominated staff member <insert name>, has primary responsibility for our vaccines, including the monitoring and maintenance of the vaccine refrigerator and cold chain management.
* Both <insert name> and <insert name> have received appropriate training in the current *National Vaccine Storage Guidelines: Strive for 5* as required for this role, and this role is defined in their position descriptions.
* The nominated person/s will conduct regular reviews of the following processes to ensure potency of our vaccine stock:
  + Ordering and stock rotation protocols
  + Maintenance of equipment
  + Annual audit of our vaccine storage procedures
  + Continuity of the cold chain, including the handover process between designated members of the practice team
  + Accuracy of our digital vaccine refrigerator thermometer

All practice staff have been made aware of the nominated staff members through orientation/induction and staff meetings and are encouraged to ask the nominated person/s for advice and support to ensure vaccine potency.

National vaccine storage guidelines

* Vaccines are delicate biological products and if not stored appropriately they will become ineffective.
* In addition, many consumables, drugs and vaccines may be toxic or harmful if swallowed.
* To protect our staff, patients and visitors these will be stored in a manner that minimises risk, hazards and avoidable events.
* All medical supplies, including but not exclusive of, consumables, drugs and vaccines, are stored in conditions that are in accordance with the manufacturer instructions to maintain efficacy.
* Our practice maintains the ‘cold chain’ system of transporting and storing vaccines within the safe temperature range of between 2oC – 8o Celsius (C), preferably stabilising at 5oC.
* It is the responsibility of <insert name> to maintain our practice’s medical supplies.
* All vaccines will be stored in a dedicated vaccine refrigerator.
* Food and drink will not be stored in vaccine refrigerators. (The *National Vaccine Storage Guidelines* advise against using bar refrigerators or cyclic defrost domestic refrigerators as they are not suitable for vaccines.)
* Opening the vaccine refrigerator door will be kept to a minimum. There is a sticker on the refrigerator door near the handle instructing staff to consider whether or not they need to open it. (*Stickers are available from Strive for 5*)
* Vaccines are stored on middle and upper shelves. Lower shelves, drawers and door of the refrigerator become too warm (above 10oC) if the refrigerator is opened frequently.
* We maintain a space between vaccine packages (such as by using an open-weave plastic container) and the evaporation plate to prevent the vaccines from freezing through contact with the plate.
* Vaccines are stored with earlier expiry dates to front. This will ensure that stock is rotated regularly.

Gaps are left around the vaccines to allow the cool air to circulate. A gap of at least 4cm from all walls and between large packages of vaccine vials is recommended.

* Expired vaccines are discarded immediately upon expiry and recorded on the VACCINATION RECORD FORM.
  + Our practice will contact the Western Australian Department of Health before discarding any government vaccines.

Other vaccines are discarded in the hazardous waste bin or taken to a pharmacy for disposal.

Packing a vaccine refrigerator

When stocking the refrigerator, the nominated person will:

* Put new stock to the rear (with a longer expiration period) and move existing stock (with a shorter expiration period) forward to be used first.
* Store emergency drugs on the lower shelves.
* Store the vaccines in their original packaging from the manufacturer as this helps to protect them from temperature fluctuations and ultraviolet (UV) light.
* Label containers clearly with names of vaccines.
* Not crowd the vaccines by overfilling the shelves. If not using open weave baskets, allow space between containers for air circulation.
* When storing influenza vaccines, separate and clearly label vaccines for adults and children less than five years of age and store them in separate areas of the refrigerator.
* Ensure privately purchased vaccines are clearly marked with the patient name and separated from the National Immunisation Program or Western Australian Department of Health vaccines.
* For a solid door refrigerator, place a guide on the outside of the refrigerator indicating where each type of vaccine is stored, for example a picture or map of the packed refrigerator. This allows quick open and shut of the door.
* Not store food and other goods in the refrigerator. This would increase the likelihood of a cold chain breach by:
  + Overcrowding the vaccines.

Increasing the number of door openings.

Use of salt water bottles

* Salt water bottles help stabilise the temperature in the vaccine refrigerator.
* Add enough salt to make water undrinkable (approx. 1-2 tablespoons of salt per litre of water).
* Line the lower drawers and doors of the vaccine refrigerator with bottles of salt water.
* Allow space between the bottles for air circulation.
* Label salt water bottles accordingly.

The vaccine refrigerator will not be over-filled to ensure that air is able to circulate around the vaccines.

Cold chain failure (suspected or confirmed)

In the event of a known or suspected cold chain failure we will:

* Not use the vaccines. We will refrigerate them immediately and contact the supplier for advice.
* Isolate the suspect vaccines in the refrigerator in a labelled container and do not use them until advised otherwise.
* Fill out the COLD CHAIN BREACH AND VACCINE WASTAGE FORM found on the Government of Western Australia Department of Health website at: <http://ww2.health.wa.gov.au/Articles/A_E/Cold-chain-management>
* Contact the Communicable Disease Control Directorate (CDCD), Western Australian Department of Health (<http://www.healthywa.wa.gov.au/publichealthunits>) and alert them to the suspected cold chain failure. Follow all instructions provided by CDCD.
* If requested, fax through the completed COLD CHAIN BREACH AND VACCINE WASTAGE FORM.

Do not discard any vaccine unless directed to so by CDCD.

Delivery of vaccines

* Vaccines are delivered by the supplier in refrigerated containers.
* Upon delivery of vaccines, the receiver (ie receptionist) will check the consignment and transfer to the nominated person <insert name> immediately.
* The nominated person <insert name> will:
  + ensure the freezer blocks in the consignment are still partly frozen on arrival.
  + check the temperature monitor is included and of a satisfactory temperature.
  + ensure that the quantities of the vaccines delivered are correct.
  + transfer the vaccines to the refrigerator immediately.
  + check the expiry dates of stock.

Vaccines are stored in the refrigerator in their original packaging. Removal from original packaging exposes vaccines to room temperature and/or lighting.

Transport of vaccines

When transporting vaccines, the nominated person will:

* Pack vaccines in an insulated esky.
* Wrap the vaccines and thermometer probe in bubble wrap, and place at the bottom of the esky.
* Place a polystyrene separator on top of the bubble wrap.
* Remove freezer blocks from freezer and allow to ‘sweat’ for 5-10 minutes.
* Place freezer blocks on top of the polystyrene separator.
* Close lid of esky and seal with tape.

Organise for the esky to be transported as soon as possible.

Vaccine temperature monitoring

* The vaccine refrigerator has a minimum/maximum digital-type thermometer.
* The thermometer probe is in a vaccine box labelled ‘thermometer’, next to a vaccine vial and placed in a plastic perforated basket on the middle shelf of the refrigerator. This allows the probe to measure the air temperature closest to a vaccine vial.
* The vaccine refrigerator thermometer minimum and maximum temperature is recorded twice daily (preferably at the beginning and at the end of the working day) in the *VACCINE REFRIGERATOR LOGBOOK*.
* The vaccine refrigerator temperature is maintained at 5oC but not less than 2oC and not greater than 8oC.
* An adhesive sticker has been placed over the temperature adjusting dial instructing staff that only an nominated person is able to modify the temperature.

Our practice will regularly audit our vaccine refrigerator to ensure the potency of vaccines.

To check the accuracy of a thermometer

* Fill a polystyrene or plastic cup with cold tap water.
* Place the cup in the vaccine refrigerator and monitor regularly until a fine layer of ice forms on the top and small sections of ice form within the liquid (this may take up to 2½ hours).
* The presence of ice is an indication that the temperature of the water has reached 0ºC.
* Place the temperature probe into the middle of the container (be careful not to let the probe touch the container).
* Observe the temperature on the display screen after two minutes.
* The temperature will drop quickly at first and then more slowly.

The temperature should drop to 0ºC within two minutes.

An ‘acceptable’ degree of accuracy of a thermometer can vary eg to within ±1ºC; check with the organisation that supplied the thermometer for the expected accuracy. Even if the thermometer is considered accurate within ±1º, this check could result in the display screen showing three possible readings: +1ºC, 0ºC, -1ºC.

Record the results of the accuracy check on the temperature chart. The information becomes important, particularly if the vaccine refrigerator temperature goes outside the recommended range of +2ºC to +8ºC.

The thermometer must be accurate to ±1ºC or better. If the temperature reading is more than one degree above or below 0ºC at two minutes, replace the battery and test again. If still within range, replace the thermometer.

Monitoring the cold chain process

A cold chain is a series of temperature-controlled storage and distribution activities (also called a ‘supply chain’). An unbroken cold chain is a supply chain that never exceeds or drops below a given temperature range. A cold chain helps to maintain the shelf life and potency of vaccines (RACGP Standards for General Practices, 5th edition, p. 161).

* At the beginning of the working day, check the thermometer of the vaccine refrigerator.
* Record the date, time and minimum and maximum temperature on the vaccine refrigerator logbook.
* Reset the thermometer.
* At the end of the working day, check the thermometer of the vaccine refrigerator.
* Record the date, time and minimum and maximum temperature on the vaccine refrigerator logbook.
* Reset the thermometer.

If the thermometer indicates that the minimum and/or maximum temperature has exceeded the recommended range, refer to Refrigerator power failure and to Cold chain failure.

Refrigerator power failure

* During a power failure of four hours or less, and the refrigerator temperature is below 8ºC, keep the vaccine refrigerator door closed. Place sign on the refrigerator door stating ‘Power out. Do not use vaccines. Keep refrigerator door closed’.
* If the power failure lasts for more than four hours, or the temperature of the refrigerator rises above 8ºC, store vaccines in an insulated esky:
  + Wrap the vaccines and thermometer probe in bubble wrap, and place at the bottom of the esky.
  + Place a polystyrene separator on top of the bubble wrap.
  + Remove freezer blocks from freezer and allow to ‘sweat’ for 5-10 minutes.
  + Place freezer blocks on top of the polystyrene separator.
  + Ensure that the esky is packed in such a way that the freezer blocks do not come into direct contact with the vaccines.

Close lid of esky and seal with tape.

* Monitor the esky hourly to ensure vaccines are stored between 2oC-8oC.

Take into consideration that the esky would be unlikely to preserve the vaccines for longer than 8 hours, and less in extreme heat.

Vaccine refrigerator maintenance

* The vaccine refrigerator is a ‘frost free’ model (but not cyclic or multi-flow defrost) model.
* The vaccine refrigerator is large enough to accommodate the vaccines stored in our practice through the year (please take into account busy periods such as the influenza vaccination period).
* Vaccines are stored in an alternative refrigerator or insulated container with freezer blocks when defrosting the vaccine refrigerator.
* The refrigerator is in an area where it does not receive direct sunlight.
* There is a 10cm space around the refrigerator to allow ventilation.
* The vaccine refrigerator has a secure power source. For example, an uninterruptible power supply (UPS) in case of electricity failure.

There is a sticker placed above the power source warning people to not unplug or turn the power off, or the electricity plug is taped to the socket and is switched to the ‘on’ position.

Maintenance of the vaccine refrigerator

* Our vaccine refrigerator is maintained according to manufacturer instructions and undergoes regular calibration. Inspections may need to occur more frequently as the refrigerator ages.
* Suspicion of, or known breakdowns are to the nominated staff member, <insert name>, immediately so that cold chain can be maintained and repairs can be made.
* We check refrigerator seals to ensure cold air cannot leak out. If the seals are brittle or torn, arrange for replacement.
* We ensure the area around the vaccine refrigerator (including behind and under) is clean and dust free.

See also

* Practice staff meeting policies and procedures

Position description: Nominated person responsible for cold chain management and vaccine storage

Responsible for:

* Monitoring cold chain practises as per the practice polices, procedures and the *National vaccine storage guidelines: Strive for 5.*
* Ensuring all vaccines and biologics are handled correctly and procedures are documented.
* Ensuring that vaccines and biologics storage and handling protocols are up-to-date, in a binder near or attached to the refrigerator.
* Ensuring rescue and transport supplies (coolers, freezer packs, flashlight, protocols, etc) are in close vicinity of the refrigerator.
* Keeping and maintaining a contact list of suppliers, manufactures and government departments relating to vaccines and cold chain processes updated.
* Reviewing and recording the temperature of the refrigerator in the *VACCINE REFRIGERATOR LOGBOOK* and biologics twice daily.
* Following up on recommended actions following a cold chain failure.
* Ordering vaccines and biologics stock.
* Receiving and checking expiry dates of the vaccines and biologics deliveries.
* Recording date, numbers of vaccines received, vaccine types and batch numbers in the Vaccine Log.
* Rotating stock.
* Completing monthly inventory counts and checks.
* Arranging maintenance as per refrigerator’s recommended guidelines (at least every 12 months).
* Changing the logger and thermometer batteries (at least every 12 months).
* Cleaning the vaccine refrigerator.
* Conducting an annual check on the thermometers/data logger.
* Conducting annual self-audit of cold chain management processes and vaccine storage procedures.
* Keeping up-to-date with changes to the West Australian Immunisation Schedule and the *National Vaccine Storage Guidelines: Strive for 5*.
* Undertaking ongoing education that is relevant to the job description (subject to prior approval from the practice manager).
* Providing an information session on vaccines and cold chain policies and procedures to all new staff; reporting any updates at staff meetings and providing annual refresher sessions on cold chain processes.

Vaccine storage annual self-audit

Our practice will conduct a self-audit at least once every 12 months, and more frequently where there have been problems with equipment and where there has been a suspected, near miss or actual cold chain breach.

Self-auditing is important because:

* It is part of routine quality assurance and risk management processes

It enables staff to have confidence that they are providing safe and effective vaccines.

Our practice will use the National Vaccine Storage Guidelines: Strive for 5 templates for Vaccine storage self-audit (page 42).

Direct link: <http://www.immunise.health.gov.au/internet/immunise/publishing.nsf/content/D7EDA378F0B97134CA257D4D0081E4BB/$File/strive-for-5-guidelines.pdf>

Related contacts

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| --- | --- | --- |
| Organisation | Contact for | Contact details |
| Central Immunisation Clinic | Adverse event following immunisation (AEFI) | Phone: 9321 1312  Contact your local [Public/Population Health Unit](http://ww2.health.wa.gov.au/sitecore/content/Healthy-WA/Articles/A_E/Contact-details-for-population-public-health-units)  See the [WA surveillance reports](http://www.public.health.wa.gov.au/2/484/2/infectious_disease_data.pm)  See [the Australian Immunisation Handbook 10th Edition](http://www.health.gov.au/internet/immunise/publishing.nsf/Content/Handbook10-home) |
| **Prevention and Control Program – Communicable Disease Control Directorate** | Vaccine ordering of government funded vaccines | http://ww2.health.wa.gov.au/Articles/U\_Z/Vaccine-ordering  Phone: 9388 4835  Fax: 9388 4877 Email: [vaccineorders@health.wa.gov.au](mailto:vaccineorders@health.wa.gov.au) |
| **Prevention and Control Program – Communicable Disease Control Directorate** | **Cold chain breach** | <http://ww2.health.wa.gov.au/Articles/A_E/Cold-chain-management> |
| **Quality Improvement and Change Management Unit** | Safe storage of medications | <http://ww2.health.wa.gov.au/Articles/S_T/Safe-storage-of-medications> |