



KISS GUIDE TO VACCINE MANAGEMENT



Vaccine management audit

April 2007

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Keep it Simple and Safe!

INTRODUCTION TO THE VACCINE MANAGEMENT AUDIT

About the audit

This Vaccine Management Audit can be conducted by the practice/clinic or by an external person such as your local Division of General Practice or Population Health Unit.

It is designed to provide a rigorous evaluation of how your practice/clinic performs against best practice standards as stated in the [National Vaccine Storage Guidelines: Strive for Five](#). It involves reviewing your policies and procedures, vaccine refrigerator, monitoring equipment and minimum/maximum temperature records to ensure that your practice/clinic continues to administer safe and effective vaccine to patients.

Conducting the audit

Review each question or statement in the audit and consider how your practice/clinic operates. Record as to whether your practice/clinic meets the requirements (tick 'yes') or doesn't meet the requirements (tick 'no'). If a section or question is not applicable to your practice/clinic, mark it not applicable (or 'N/A').

At the end of the audit, record the item number where you have answered 'No' in the table under [Outcomes of the audit](#). Plan what changes need to be made, implement the changes, inform staff and review to ensure that they are working effectively. Record comments as necessary in the table regarding the outcome.

The [National Vaccine Storage Guidelines: Strive for Five](#) recommend that an audit is conducted every 12 months as part of a quality assurance and risk management routine. Keep a copy of the audit so you can maintain a history of the results and compare to future audits.

Helpful information sources

There are many resources and other materials available if you need to make any changes to your practice/clinic resulting from the audit.

For tools and templates including a **policy and procedure document**, **orientation checklist**, **choosing a purpose-built vaccine refrigerator** and **education modules** visit <http://www.qdgp.org.au/vaccinemanagement>.

For more detailed information about best practice standards and guidelines, please refer to the current editions of the [National Vaccine Storage Guidelines: Strive for Five](#) and [The Australian Immunisation Handbook](#).

For assistance in conducting the audit or reviewing the outcomes of the audit, please contact your local Division of General Practice or Population Health Unit. For contact details, visit www.qdgp.org.au/vaccinemanagement.

Source of material

QDGP has sourced material from the following documents to compile this audit:

1. [National Vaccine Storage Guidelines: Strive for Five](#), Australian Government: Department of Health and Ageing, 2005, copyright Commonwealth of Australia reproduced by permission.
2. [Proceedings of the National Vaccine Storage Workshop](#), Queensland Government: Queensland Health, 2004.
3. [The Australian Immunisation Handbook](#), 8th Edition, National Health and Medical Research Council, 2003.

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Disclaimer

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Practice/clinic details

Name of practice/clinic: _____

Contact person: _____

Audit details

Date of audit: _____/_____/_____

Audit conducted by: _____

Audit reviewed by: _____

Date last audited conducted: _____/_____/_____

PEOPLE

- Does the practice/clinic have a primary person assigned to oversee vaccine management? Yes No
- Does the practice/clinic have a secondary person assigned to oversee vaccine management in the absence of the primary person? Yes No
- Are new staff members involved in vaccine management [oriented](#) to the practice/clinic policies and procedures? Yes No
- Do staff members who handle vaccines receive training in correct vaccine storage and handling according to the current [National Vaccine Storage Guidelines: Strive for Five](#)? Yes No

PROCESSES

- Is every effort made to store vaccines within the safe temperature range of +2°C and +8°C? Yes No
- Is every effort made to protect light sensitive vaccines from sunlight and/or fluorescent light? Yes No
- Does the practice/clinic have customised and documented policies and procedures for vaccine management that meet the requirements of the [National Vaccine Storage Guidelines: Strive for Five](#)? Yes No
- If yes, does the policy and procedure document include details on:
 - Key staff members responsible for vaccine management
 - Vaccine refrigerator and monitoring equipment
 - Ordering vaccines
 - Receiving vaccines Yes No
(only tick 'yes' if all the policies and procedures have been ticked)

- 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
 - Conducting a Vaccine Management Audit on an annual basis
 - Quality review process for cold chain problems
 - Cold chain risk management planning
- Does the practice/clinic have the current editions of the following reference material?
 - National Vaccine Storage Guidelines: Strive for Five
 - The Australian Immunisation Handbook
- Yes No
(only tick 'yes' if all areas have been ticked)
- Do all staff members know where the reference material is located?

Yes No

ORDERING, RECEIVING AND DISPOSAL OF VACCINES

- Do staff members follow the process in the policy and procedure manual for ordering and receiving vaccine?

Yes No
- On delivery, are publicly funded vaccines only accepted by practice/clinic staff?

Yes No
- Are all staff members familiar with the urgency of unpacking and refrigerating vaccine, particularly in metropolitan areas?

Yes No
- Do staff members know how to check and read the cold chain monitors when unpacking vaccine (e.g. freeze indicator and/or dual time-temperature indicator)?

Yes No
- When an order is received, is fresh vaccine placed to the rear of the current stock?

Yes No
- Does the practice/clinic have procedures in place to ensure that there is no expired vaccine in the vaccine refrigerator?

Yes No
- Does the practice/clinic have appropriate procedures and facilities for discarding vaccine in accordance with State/Territory legislation?

Yes No

PACKING THE VACCINE REFRIGERATOR

Packing a purpose-built vaccine refrigerator

- Has the practice/clinic checked with the purpose-built vaccine refrigerator manufacturer as to the following:
 - If there is a small quantity of vaccine being stored, do cooled water bottles or refrigerated ice packs/gel packs need to be added to empty space to add thermal mass
 - If vaccines can be stored in their packaging in trays or containers
 - If vaccines can be stored on the floor of the refrigerator
 - If vaccines can be stored next to the sides and back of the refrigerator
- Have the above recommendations from the purpose-built vaccine refrigerator manufacturer been implemented?
- Is the refrigerator of sufficient size to store the maximum amount of vaccine taking into consideration new vaccines to be included in the schedule and including influenza vaccine?
- Are vaccines stored in their original packaging including box and product information leaflet?
- Is there a sticker on the refrigerator door reminding GPs and staff to only open the door when required?
- Is the refrigerator not overstocked so that air is able to circulate?
- Is the refrigerator used exclusively for the storage of vaccines?

Packing a modified domestic vaccine refrigerator

- What type of domestic refrigerator does the practice/clinic have:
 - Frost-free refrigerator
 - Cyclic defrost refrigerator (**NOTE:** Cyclic defrost refrigerators are not recommended because they produce wide fluctuations in the internal temperatures with regular internal heating. Refer to **page 7** in the [National Vaccine Storage Guidelines: Strive for Five](#) for further information)
 - Bar refrigerator (**NOTE:** Bar 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)
- Does the practice/clinic “know the refrigerator” by completing the following:
 - Recorded temperatures throughout the refrigerator to identify “cold spots”
 - Located the air vents which return cold air from the freezer
- Has the refrigerator been modified to make it suitable for storing vaccine? (Refer to **pages 12-13** and **41-43** of the [National Vaccine Storage Guidelines](#) for further information)

- | | |
|--|--|
| <ul style="list-style-type: none"> • Is the refrigerator of sufficient size to store the maximum amount of vaccine taking into consideration new vaccines to be included in the schedule and including influenza vaccine? | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| <ul style="list-style-type: none"> • Are vaccines stored in the following manner: <ul style="list-style-type: none"> <input type="checkbox"/> In their original packaging <input type="checkbox"/> In a set of sliding plastic drawers or enclosed plastic containers <input type="checkbox"/> On shelves in the refrigerator that are stable and maintain the +2°C to +8°C temperature range | <input type="checkbox"/> Yes <input type="checkbox"/> No
<i>(only tick 'yes' if all areas have been ticked)</i> |
| <ul style="list-style-type: none"> • Have staff members been trained in adjusting the thermostat? | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| <ul style="list-style-type: none"> • Is there is a gap of at least 4cm between the plastic container and all refrigerator walls including the back? | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| <ul style="list-style-type: none"> • Are the lower drawers and the door filled with cooled water bottles/containers? | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| <ul style="list-style-type: none"> • If there is a small amount of stock in the refrigerator, are cooled water bottles or refrigerated ice packs/gel packs placed on empty shelves to help stabilise the temperature? | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| <ul style="list-style-type: none"> • If there are shelves in the refrigerator where the temperature is known to have been unstable or not between +2°C and +8°C, have they been filled with cooled water bottles or refrigerated ice packs/gel packs? | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| <ul style="list-style-type: none"> • Are there small gaps between the water bottles or refrigerated ice packs/gel packs to allow air circulation? | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| <ul style="list-style-type: none"> • Have water bottles or ice packs/gel packs been placed in the freezer compartment? | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| <ul style="list-style-type: none"> • Is there a sticker on the refrigerator door reminding GPs and staff to only open the door when required? | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| <ul style="list-style-type: none"> • Are vaccines stored in their original packaging including box and product information leaflet? | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| <ul style="list-style-type: none"> • Is the refrigerator not overstocked so that air is able to circulate? | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| <ul style="list-style-type: none"> • Is the refrigerator used exclusively for the storage of vaccines? | <input type="checkbox"/> Yes <input type="checkbox"/> No |

Location of the external thermometer probe in a modified domestic refrigerator

- | | |
|--|--|
| <ul style="list-style-type: none"> • Is the probe of the external thermometer placed using the following process: <ul style="list-style-type: none"> <input type="checkbox"/> Locate the probe inside an empty vaccine package with retained product information <input type="checkbox"/> Label the vaccine package "EMPTY" <input type="checkbox"/> Place package containing the probe inside and near the back of an enclosed plastic drawer or container | <input type="checkbox"/> Yes <input type="checkbox"/> No
<i>(only tick 'yes' if all areas have been ticked)</i> |
|--|--|

CHECKING AND RECORDING THE VACCINE REFRIGERATOR TEMPERATURE

- | | |
|--|--|
| <ul style="list-style-type: none"> • Do staff members follow the process in the policy and procedure manual for checking and recording the vaccine refrigerator temperature? | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| <ul style="list-style-type: none"> • Are the minimum/maximum temperatures <u>checked</u>? <ul style="list-style-type: none"> <input type="checkbox"/> On receipt of vaccines <input type="checkbox"/> Every day before vaccination commences <input type="checkbox"/> At the end of the working day <input type="checkbox"/> Last thing Friday afternoon and first thing Monday, if the centre closes over the weekend <input type="checkbox"/> Hourly during outreach clinics <input type="checkbox"/> Every time the refrigerator door is opened | <input type="checkbox"/> Yes <input type="checkbox"/> No
<i>(only tick 'yes' if all areas have been ticked)</i> |
| <ul style="list-style-type: none"> • Are the minimum/maximum temperatures <u>recorded</u>? <ul style="list-style-type: none"> <input type="checkbox"/> Every day before vaccination commences <input type="checkbox"/> At the end of the working day | <input type="checkbox"/> Yes <input type="checkbox"/> No
<i>(only tick 'yes' if all areas have been ticked)</i> |
| <ul style="list-style-type: none"> • Does each vaccine refrigerator in the practice/clinic have its own temperature chart? | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| <ul style="list-style-type: none"> • Are comments and any action in the temperature chart/log recorded 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? | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| <ul style="list-style-type: none"> • Is the thermometer only reset <u>after</u> the temperatures have been recorded? | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| <ul style="list-style-type: none"> • Does the practice/clinic have a policy for retaining temperature records? (NOTE: Practices/clinics may wish to contact their medical defence organisation for advice on this matter) | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| <ul style="list-style-type: none"> • Do the temperature records from the last 12 months indicate that the minimum/maximum temperatures have been recorded at least at the beginning of every working day? | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| <ul style="list-style-type: none"> • If the temperatures haven't been recorded, is there a valid documented reason if monitoring has been missed? | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| <ul style="list-style-type: none"> • Were all deviations outside +2°C and +8°C reported to the Queensland Health Immunisation Program? | <input type="checkbox"/> Yes <input type="checkbox"/> No |
| <ul style="list-style-type: none"> • Have the responses to all deviations outside +2°C and +8°C been documented and recommended actions taken? | <input type="checkbox"/> Yes <input type="checkbox"/> No |

MANAGEMENT OF COLD CHAIN PROBLEMS

- Has the practice/clinic conducted [cold chain risk management planning](#) including the following:
 - Identify potential vaccine management problems and their causes
 - Identify strategies to prevent or reduce the likelihood of the problem occurring
 - Identify strategies to reduce the impact of the problem should it occur
 - Identify strategies to manage the problem if it occurred

Yes No
(only tick 'yes' if all areas have been ticked)
- Has the practice/clinic implemented the above cold chain risk management strategies?

Yes No
- If cold chain problems occur, does the practice/clinic have a documented process in place including the 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°C and +8°C
 - Contact the Queensland Health Immunisation Program on **3234 1500** during business hours as soon as possible to inform them of the breach and to seek advice
 - Do not discard any vaccine unless advised by the Queensland Health Immunisation Program
 - 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

Yes No
(only tick 'yes' if all areas have been ticked)
- Are there quality review processes in place after cold chain problems have occurred including consideration to:
 - What happened?
 - Why it happened?
 - How was it handled?
 - How could it have been handled better?
 - What needs to be done to fix it?
 - What can be done to prevent it or reduce the likelihood of it happening again?

Yes No
(only tick 'yes' if all areas have been ticked)
- Does the practice/clinic have the following in place for managing power failures:
 - Documented processes according to the vaccine refrigerator type
 - Suitable equipment (such as portable cooler) and processes to store vaccines if they need to be transferred and/or transported

Yes No
(only tick 'yes' if all areas have been ticked)

Further information on cold chain problems can be found in **Education Module 2: Cold chain risk management planning** available on www.qdgp.org.au/vaccinemanagement.

PORTABLE COOLERS

- Does the practice/clinic have a documented process in place for packing a portable cooler including the following steps:
 - Chill the inside of the cooler prior to use by placing ice packs/gel packs in it for a few hours
 - Place insulating material at the bottom of the container
 - Place a minimum/maximum thermometer in the centre of the vaccine stock
 - Surround the vaccines with more insulating material
 - If using a small cooler, place the conditioned ice packs/gel packs on top, close and seal the lid of the cooler
 - 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
 - Ensure vaccine is not in direct contact with the ice packs/gel packs to minimise risk of freezing
 - Does the practice/clinic 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
 - 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
 - Are ice packs/gel packs correctly conditioned prior to packing the portable cooler? (Refer to **pages 32-34** of the [National Vaccine Storage Guidelines: Strive for Five](#) for further information)
 - After packing, is the temperature of the portable cooler checked:
 - 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
 - Before returning vaccine to the vaccine refrigerator
- Yes No
(only tick 'yes' if all areas have been ticked)
- Yes No
(only tick 'yes' if all areas have been ticked)
- Yes No
- Yes No
(only tick 'yes' if all areas have been ticked)

OUTREACH CLINICS

- Does the practice/clinic have a documented process in place for preparing for an outreach clinic including the following steps:
 - 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 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
 - Condition the ice packs/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
- During an outreach clinic, is the temperature of the portable cooler checked:
 - 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
 - Regularly throughout the immunisation session (at least hourly)
 - On return to the clinic
 - Before returning vaccine to the refrigerator

Yes No
(only tick 'yes' if all areas have been ticked)

Yes No
(only tick 'yes' if all areas have been ticked)

MAINTAINING THE EQUIPMENT

Maintaining the vaccine refrigerator

- Does the practice/clinic maintain the vaccine refrigerator by:
 - Immediately reporting refrigerator problems to the nominated person
 - Regularly checking the rubber seals around the door to ensure they are intact and not brittle
 - Defrosting monthly or sooner if required (if the refrigerator is not purpose-built or frost-free domestic)
 - Regularly cleaning exposed coils on the back of the refrigerator

Yes No
(only tick 'yes' if all areas have been ticked)

- Is the practice/clinic vaccine refrigerator:
 - Away from external walls
 - Out of direct sunlight
 - In a secure area only accessible to staff
 - Positioned to allow sufficient air circulation around the back and sides
- Is the power source labelled clearly or protected with a switch cover to protect the refrigerator from being accidentally unplugged or switched off?

Yes No
(only tick 'yes' if all areas have been ticked)

Yes No

Maintaining monitoring equipment

- Is an accuracy check of the external thermometer (also called “slush” test) conducted:
 - After receiving a new thermometer
 - After changing the battery
 - At least every 12 months
 - If having thermometer or cold chain problems

Refer to **page 22** in the [National Vaccine Storage Guidelines: Strive for Five](#) for instructions on conducting an accuracy check.
- Have the results of the accuracy check been recorded on the temperature chart or log for future reference?
- Is the battery of the thermometer or data logger replaced:
 - At least every 12 months
 - If having thermometer or cold chain problems

Yes No
(only tick 'yes' if all areas have been ticked)

Yes No

Yes No
(only tick 'yes' if all areas have been ticked)

OUTCOMES OF THE AUDIT

Areas to be addressed by the practice/clinic:

Item	Description of follow-up	Changes made	Staff informed	Changes reviewed	Comments
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

Item	Description of follow-up	Changes made	Staff informed	Changes reviewed	Comments
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

Any other vaccine management support required by the practice/clinic?

Other comments:
