

Cold Chain Management Policy for Immunisation Services

Name of provider/clinic/department:	Maternity Assessment Unit (MAU)
Date:	29/8/17
Name of our local immunisation coordinator and/or cold chain coordinator:	Liz Grinlinton
Contact number(s):	570 9798 or 027 5577 241
Name of our IMAC Regional Advisor:	Bernadette Heaphy
Contact number(s):	027 292 4174

Designated staff with overall responsibility for cold chain management

First person: Natasha Jelbert	MAU Registered Nurse
Second person: Abi Prescott	Maternity Department / MAU Midwife

All staff are responsible for ensuring that the vaccines they administer are stored correctly and are expected to receive cold chain orientation.

Vaccine documents

The vaccine documents listed below provide detailed information to support our cold chain management and inform the development of this policy. The following documents are available or there is online access to:

- The current *Immunisation Handbook*
- Access to the online versions of the Immunisation Handbook as this version is the most up-to-date information – available on the Ministry's website at: www.health.govt.nz
- Current *National Standards for Vaccine Storage and Transportation for Immunisation Providers 2017* – available on the Ministry's website at www.health.govt.nz/coldchain
- *Annual Cold Chain Management Record* available on the Ministry's website at: www.health.govt.nz/coldchain
- Medsafe vaccine data sheets (available from the Medsafe website at: www.medsafe.govt.nz/Medicines/infoSearch.asp)

These documents are located in the Cold Chain Folder and are available online..

Cold Chain Accreditation

All immunisation providers, clinics and departments storing vaccines must achieve Cold Chain Accreditation (CCA) or Cold Chain Compliance (CCC) if appropriate. The documentation from our CCA visit is located in our Cold Chain Folder. MAU CCA is valid until 1st May 2018

Vaccine requirements

All staff are aware of how much vaccine stock is required at any one time, based on the size of our vaccinating population, including both casual and enrolled patients/clients. To avoid overstocking and to ensure stock rotation, a minimum stock of National Immunisation Schedule vaccines of two weeks, and no more than four weeks worth of stock should be held at any given time.

Our stock requirements

The number of:

30 Boostrix	Boostrix to pregnant women 28-38 weeks pregnant
30 Influenza Vaccines	Influenza vaccine to all pregnant women regardless of gestation Influenza vaccine to Staff members. Numbers will vary according to clinics and seasonal influenza vaccination.

The minimum and maximum vaccine stock levels are:

	Boostrix® DTaP	Influenza as Vaccine
Minimum	10	10
Maximum	40	40

Vaccine ordering and stock keeping

We undertake a stock count twice a month on the 1st and 3rd Wednesday of the month and order vaccines as appropriate.

All vaccines are logged in the vaccine register (or inwards goods process in the case of a pharmacy), including their arrival date, name, batch number, expiry date and total number in stock.

Boostrix will be ordered from ProPharma twice monthly – these are delivered directly to MAU for storage in the MAU fridge. Influenza Vaccine is ordered via the Pharmacy Department as required – these vaccines are delivered directly to Pharmacy and are sent down to MAU via a pharmacist or orderly.

Receiving and storing vaccines

All staff must complete a cold chain orientation and know what to do when a vaccine order arrives from the distributor or hospital pharmacy.

- Vaccines are checked to ensure they have arrived within the indicated timeframe on the packaging.
- Vaccines are left in their original packaging, as this acts as insulation and protects vaccines sensitive to light.
- Vaccines are unpacked as quickly as is practical on arrival.
- Vaccine stock is rotated so that those with earlier expiry dates are used first.
- Vaccines are placed in the refrigerator in such a way as to allow for air circulation.

National cold chain audit logger

All staff are aware they need to check each vaccine delivery for any national cold chain audit loggers and are aware that they will need to follow the instructions supplied. See Appendix 1

Cold chain equipment – operation and maintenance

This service uses a pharmaceutical refrigerator to store vaccines (details on page 4 of the Cold Chain Policy document).

All vaccinators are responsible for ensuring that the pharmaceutical refrigerator:

- is not used to store non-medical materials (eg, food or lab specimens)
- is positioned in a well-ventilated room
- is away from direct sunlight or a heat source
- is at least 4 to 10 centimetres away from surrounding surfaces to allow air to circulate around the condenser
- has nothing placed on the top of it, except the daily minimum/maximum recording charts
- has an independent power point

- is either hard wired into the wall and/or has a large bright notice advising to not unplug.
- has a surge protector if required by the refrigerator manufacturer.

We will contact our immunisation coordinator when purchasing new equipment or if we have any questions about cold chain equipment.

Refrigerator temperature monitoring

The minimum and maximum vaccine refrigerator temperature is recorded daily from the inbuilt temperature monitor. The minimum and maximum temperatures are reset after they have been recorded.

The minimum and maximum temperature is recorded at the same time of each working day in the morning. The current temperature records are kept on the bench above the refrigerator and archived as with other medical records for at least 10 years. The *Annual Cold Chain Management Record* is used to document the clinics daily readings. MAU will document daily recordings onto the hospital CFR fridge temperature monitoring form which is found on the hospital intranet under FORMS/CLINICAL/PHARMACY. At the end of each month this is sent to Pharmacy for archiving.

The data logger is set to record the refrigerator temperature every 5–10 minutes. This is downloaded weekly and reviewed alongside the daily minimum/maximum temperature for that week and any unusual variations are discussed promptly with the immunisation/cold chain coordinator. The data logger must also be downloaded in response to temperatures outside the +2°C to +8°C temperature range.

The immunisation/cold chain coordinator will be contacted if the temperature goes below 2°C, is between 8°C and 12°C for more than 30 minutes or is more than 12°C. The data is regularly backed up and is stored for a minimum of 10 years.

The following staff are able to download the data logger:

Name	Designation	Date
Natasha Jelbert	Registered Nurse	August 2018
Abi Prescott	Midwife	August 2018

Monitoring chilly bins for transport and temporary storage

- a minimum/maximum digital thermometer with audible alarm is used to measure the temperature of vaccines when using chilly bins to transport or temporarily store vaccines.
- Staff will check and record the minimum, maximum and current temperatures of the vaccines:
 - before transporting the vaccines
 - before unpacking them at the alternative storage area
 - every 20–30 minutes while transporting or temporarily storing them.

Monitoring chilly bins for storage in offsite immunisation clinics

MAU does not have offsite immunisation clinics.

Maintenance and replacement plan and schedule

This covers all cold chain equipment, including:

Equipment		Location in clinic	Maintenance and replacement plan
Refrigerator:	Rollex	MAU in the Early Pregnancy Assessment room	Annual service due annually in December. Annual check of refrigerator performance and temperature ranges by your local immunisation/cold chain coordinator or refrigerator manufacturer. Refrigerator replacement plan. Mark at Rollex – 0508 765 539
Date purchased:	April 2016		
Model:	LEG PG207 4070002844		
Minimum and maximum monitoring device		Vaccine refrigerator	Inbuilt
Electronic temperature monitoring device – Rolleg e-logger Date purchased: April 2016		Vaccine refrigerator	This device is set to record the internal refrigerator temperature every 5–10minutes. It is separate from the unit that is used to record the daily minimum and maximum temperature readings. It does not require calibration.
Chilly bin/s: For transporting vaccines in the event of a power or equipment failure, Please note MAU does not hold offsite vaccination clinics.	This equipment is used for storing vaccines when transporting them, defrosting your vaccine refrigerator, in the event of a power or equipment failure or for offsite vaccination clinics.	In bottom drawer of small filing cabinet next to the vaccination fridge in MAU – Early Pregnancy Assessment room	In the event of a power failure, vaccines will be transferred to the chilly bin and taken to the Occupational Health or Regional Public Health fridge. Packing material is in the chilly bin. Ice packs can be obtained from the Maternity Department Fridge on the 2 nd Floor (Postnatal end) Refer to section 7.3 in the <i>National Standards for Vaccine Storage and Transportation for Immunisation Provider 2017</i> for the minimum requirements.
Ice packs for use when: <ul style="list-style-type: none"> transporting vaccines in the event of a power or equipment failure 	Refer to section 7.3 in the <i>National Standards for Vaccine Storage and Transportation for Immunisation Provider 2017</i> for the	The Maternity Department Fridge on the 2 nd Floor (Postnatal end)	Ice packs are kept frozen, in the Maternity Department Fridge on the 2 nd Floor (Postnatal end) 6 icepacks are required for the size of the MAU chilly bin
Insulation material			Located in the Chilly bin

Equipment		Location in clinic	Maintenance and replacement plan
Digital thermometer/s or data loggers with visible display	minimum requirements		<p>This is yet to be purchased. Please note that MAU does not have off-site vaccination clinics. The hospital has back-up generators.</p> <p>If vaccines need to be transferred to another hospital fridge (CCA accredited) this can be done within a 5-10 minute period.</p> <p>Calibration and ice pointing undertaken if required or recommended by manufacture.</p>

Process for vaccine stored outside +2°C to +8°C temperature range

This process is taken from the *National Standards for Vaccine Storage and Transportation 2017*.

Vaccine temperatures are recorded outside required temperature range (below +2°C or above +8°C)*

*When one-off temperature variations of up to 12°C for less than 30 minutes occur for known reasons (eg, stocktake), you do not need to notify the immunisation/cold chain coordinator; however, you must document the variations in your records.



Quarantine the vaccines.

- Label and quarantine all the vaccines involved.
- Ensure the vaccines are kept within the required temperature range of +2°C to +8°C. Seek alternative storage arrangements, if required, as per your cold chain policy.
- Communicate with colleagues to ensure the vaccines are not used until further notice.
- Document the incident.



Confirm and define the incident.

- Review the refrigerator temperature records and download information from the data logger to clarify the cold chain before this event.
- Confirm current refrigerator temperatures.
- Check the refrigerator's service history to date.



Collect as much information as possible.

- What monitoring has taken place (maximum, minimum and/or current thermometer readings)?
- For how long were the vaccines stored outside the required +2°C to +8°C range (minutes, hours or days)?
- Identify all vaccines stored in the refrigerator, the length of time they were stored, usual stock turnover and expiry dates.
- Identify any previous events involving these vaccines where the temperature has gone outside the required +2°C to +8°C range.
- Is it likely that any individuals received a compromised vaccine?



Contact your local immunisation/cold chain coordinator with all the available information and work with them through to resolution. Ensure that you fully document the incident and outcomes.

Emergency plan for dealing with equipment and power failures

In the event of a power failure and/or equipment failure, the refrigerator will be monitored using an independent digital thermometer or data logger with a visible display and the kept door closed. If the power failure extends beyond 4 hours or the internal refrigerator temperature is above +8°C seek alternative refrigeration.

	Event	Action	Who responsible
Power failure or refrigerator failure	1. If failure is less than 4 hours and temperature remains between +2°C and +8°C.	<ul style="list-style-type: none"> Keep refrigerator door closed and monitor refrigerator temperature. Do not remove any vaccines from the refrigerator unless temperature range is below +2°C degrees or above +8°C degrees. 	Natasha / Abi
	2. If temperature remains stable between +2°C and +8°C but power failure is continuing beyond 4 hours.	<ul style="list-style-type: none"> Contact immunisation/cold chain coordinator. Pack vaccines for transport in accordance with the <i>National Standards for Vaccine Storage and Transportation for Immunisation Providers 2017</i> and take to Occupational Health or Regional Public Health fridges 	Natasha / Abi
	3. If the refrigerator temperature is below +2°C degrees	<ul style="list-style-type: none"> Quarantine vaccines in the refrigerator, download the data logger. Move your vaccines to your alternative refrigeration site. Contact immunisation/cold chain coordinator for further advice. 	Natasha / Abi
	4. If the refrigerator temperature is above +8°C	<ul style="list-style-type: none"> Quarantine the vaccines. Download the data logger. Discuss with immunisation/cold chain coordinator. Pack vaccines for transport in accordance with the <i>National Standards for Vaccine Storage and Transportation for Immunisation Providers 2017</i>, and take to Occupational Health or Regional Public Health fridges 	Natasha / Abi
Location for alternative refrigeration - Occupational Health or Regional Public Health fridges			
Contact details for alternative refrigeration – Janet Heads ext 9942 or Liz Grinlinton ext 9798 Before transporting vaccines, check the alternative facility has storage capacity for the vaccines.			
Contact the local immunisation coordinator to inform them of the breach and for further advice.			

Vaccine disposal

Before disposing of vaccines (other than for expiry reasons), we will contact the local immunisation/cold chain coordinator. Refer to *National Standards for Vaccine Storage and Transportation for Immunisation Providers 2017* for more information on vaccine disposal and returning vaccines for destruction.

All vaccines for disposal will be returned to your local ProPharma 576 1830 or Hutt DHB pharmacy.

Policy review

All new staff will be orientated to this cold chain management policy and our cold chain process. Staff will sign the back page to acknowledge that they have received cold chain specific training and information.

Our cold chain policy is reviewed and updated annually and when changes are made to designated cold chain staff or the vaccine documents.

The immunisation/cold chain coordinator will be contacted:

- when there is a significant change in staff responsible for cold chain management
- before purchasing a new pharmaceutical refrigerator or cold chain equipment, including chilly bins and temperature monitoring equipment
- in the event of a cold chain breach* before disposing of vaccines
- for cold chain management advice.

*One-off vaccine temperature variations of up to 12°C for less than 30 minutes that occur for known reasons (eg stock take) do not need to be notified to the immunisation coordinator, however it must be documented in the your records.

The undersigned accept this document as this services cold chain management policy.

Signature of 1st designated staff member:	Signature of 2nd designated staff member:
Position: Registered Nurse	Position: Midwife
Name: Natasha Jelbert	Name: Abi Prescott
Date policy approved:	31 st August 2017
Date of next cold chain policy review:	31 st August 2018

Clinical staff who have been orientated to the cold chain process and policy for this service

Name	Designation	Date
Natasha Jelbert	Registered Nurse	31 st August 2017
Abi Prescott	Midwife	1 st September 2017

By signing this, I acknowledge that I have received training and information in relation to MAU cold chain policy and processes.

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