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| **Standard Operating Procedure (SOP)****Document name:** SOP 1 - Receiving and storing vaccines**Document category:** Vaccinations**Document heading:** Vaccinations**Internal ID:** IM01 / F01**Review Frequency:** Every 2 years**Reviewed by:** xx**Next Review:** xx/xx/xxxx |
| **Purpose**To ensure that vaccines are correctly received and stored, and appropriate action is taken and appropriate documentation is kept should a temperature deviation occur. **Personnel**Pharmacy Manager. |
| **Procedure*** All staff who may receive a delivery of vaccines, including part-time staff, must be aware of the need for prompt action on vaccine receipt. The pharmacist vaccinator is responsible for ensuring this occurs. Authorised pharmacist vaccinators and staff members given the responsibility to manage vaccine stock need to read and understand this SOP and record that they have done so.
* Clinical staff must ensure continuity of the cold chain. They must be competent in all aspects of vaccine storage and transportation to ensure that vaccines are kept within 2°C to 8°C at all times. Staff must take appropriate action when the cold chain is not maintained. They must take responsibility for ensuring the vaccines they administer have been correctly stored. They must read and understand the pharmacy’s cold chain policy.
* All procedures and requirements in the Ministry of Health National Standards for Vaccine Storage and Transportation for Immunisation Providers 2017 are complied with.
* At least two people are given the overall responsibility for the pharmacy’s vaccine storage and temperature monitoring, as recorded in the Temperature Monitoring Records in the Dispensary Refrigerator Temperature Monitoring Record that is kept by the pharmacy [state where the pharmacy keeps this document]. The template for this document is found on the Pharmacy Guild here: <https://www.pgnz.org.nz/members1/audit-tools/quality-improvement-tools>. delete one] or see Appendix 2.
* At least two people are given the overall responsibility for the pharmacy’s vaccine storage and temperature monitoring, as recorded in the Clinic Cold Chain History in the Annual Cold Chain Management Guide and Record that is kept by the pharmacy [state where the pharmacy keeps this document]. The template for this document is found at <http://www.health.govt.nz/publication/annual-cold-chain-management-guide-and-record>. [delete one]
* Both responsible persons need to know exactly what needs to be done and liaise with each other to cover different days and absences. Changes in personnel responsible for cold chain are recorded in the Temperature Monitoring Records or Clinic Cold Chain History [delete one].
* All relevant staff (see Personnel) need to know where the following documents are kept, have read them, and adhere to the standards (including record keeping) at the time specified:
	+ National Standards for Vaccine Storage and Transportation for Immunisation Providers 2017
	+ Dispensary Refrigerator Temperature Monitoring Record or Annual Cold Chain Management Guide and Record [delete one]
	+ Cold Chain Management policy

**Vaccinator Training and Assessments*** A pharmacist vaccinator is a New Zealand registered pharmacist with a current Annual Practising Certificate who has completed the vaccinator training course and passed the clinical assessment.
* Following the completion of the initial vaccinator training course, each pharmacist vaccinator must complete the pharmacist vaccinator update course every two years.
* Copies of all certification for completion of the vaccinator training course, pharmacist vaccinator update course and clinical assessment for each pharmacist vaccinator needs to be kept at the pharmacy (including all previous certificates and assessments).
* These documents are kept [state where the pharmacy keeps this document].
* All pharmacist vaccinators must advise the Pharmaceutical Society when they have completed any vaccinator training or vaccinator update courses.

**First Aid Requirements*** Pharmacists who are vaccinators must undertake resuscitation training that includes the following resuscitation skills:
	+ Infant, children and adult CPR, including mouth to mouth, mouth-to-mask and the management of choking
	+ Administration of IM adrenaline for treatment of anaphylaxis
	+ Use of an automated external defibrillator
	+ One- and two-person bag valve mask ventilation and mouth-to-mask technique
	+ Resuscitation training updates required at least once every two years
* When providing vaccination services, a minimum of two staff must be present, one being a pharmacist vaccinator and the other being at a minimum, a competent staff member who is able to call for emergency support and has a basic life support first aid certificate.
* The second staff member does not have to be a pharmacist or a pharmacist vaccinator.
* For non-pharmacist staff, basic life support first aid training should be refreshed every two years.
* Copies of all first aid certificates must be kept at the pharmacy.
* These are kept [state where the pharmacy keeps this document].

**Vaccine arrival*** Delivered vaccines must be dealt with promptly.
* Check that the vaccine delivery is within the stated delivery window (check the packing label for time dispatched and timeframe).
* Check whether any vaccines have monitoring devices included e.g an NCCA or distributor data logger. Follow any instructions provided on using those devices. See notes at end of SOP for further information.
* Check that the ice packs are still cool and the vaccines feel cool but are not frozen. If the vaccines feel warm to touch, contact the distributor.
* Check that the contents are in good order and match the order form.
* Check all vaccines are at least one month from their expiry date.
* Record vaccine details (date received, batch number, expiry) in a vaccine register/log or stock management system.

*See below, Appendix 1 – Pharmacy Vaccine Register** Document the arrival date in the pharmacy on the vaccine box.
* Leave the vaccines in their original boxes but always remove the vaccines from the cold chain packaging before being refrigerated – never store in the fridge in the cold chain packaging.
* Immediately store vaccines in the refrigerator.
* Place new vaccines behind current stock to ensure rotation with batch number and expiry dates within easy view (where possible).
* Enter new stock into your dispensary computer system.

**Storage of vaccines*** Do not exceed the manufacturer’s recommended capacity for the fridge.
* Air must be able to circulate in the refrigerator. There should be 20 to 30mm between vaccine boxes, and walls and the back of the refrigerator, and between the vaccines and the shelf above. Do not stack vaccines against the walls of the refrigerator.
* Store vaccines in their individual boxes.
* DO NOT store vaccines in plastic bags, in solid containers, in the fridge door, in the drawer at the bottom of the fridge, or on the floor of the fridge.
* Keep the top of the fridge clear.
* Minimise opening and closing the refrigerator door.
* Document fridge temperatures daily (as per SOP D02 Fridge Temperature recording and cleaning), preferably at the same time of day. Record these in the Dispensary Refrigerator Temperature Monitoring Record or Annual Cold Chain Management Guide and Record [delete one].
* A vaccine refrigerator must have TWO forms of temperature monitoring equipment:
* **A daily check using a max/min thermometer with an externally visible display** (eg the inbuilt fridge temperature recording device or an external digital max/min thermometer with an audible alarm. Record the max and min temperatures daily, ideally, first thing in the morning then reset the device.
* **A weekly check using a data logger or an online temperature monitoring and alerting device.** It should be pre-set to record the current temperature at least every 10 minutes (5 minutes if it has capacity). The weekly check does not override the need to check and record the daily max/min temperatures. Download the information every week and compare it with the daily max/min recordings to check for any unexplained temperature recordings, with appropriate action then taken, including informing the immunisation coordinator.
* Ensure all areas of your fridge are within the correct temperature range – move your data logger around the fridge and record where it is positioned as it is moved around. All areas used for stock must be 2–8°C. Putting the data logger in a dispensing skillet will replicate the conditions of stock in packaging.
* Tape over the plug and clearly mark not to unplug the refrigerator to avoid inadvertent unplugging. Use a surge protector for the plug.
* The fridge should be levelled so the door shuts automatically if left ajar.

**Cold chain breach** * Vaccines must remain between 2° and 8°C. If they move out of that range during storage, transport, or off-site vaccinations, this is considered a cold chain breach and action is required immediately.
* It is recommended that a solid chilly bin with a clip-on lid and frozen ice packs needs to be ready in case of a power failure.
* Leave the vaccines in the fridge, but quarantine with clear instructions “not for use” to ensure they are not used in the interim.
* Ensure all staff know not to use the vaccines until further notice.
* Download the data logger and review the record.
* Confirm current refrigerator temperature.
* Check the refrigerator’s service history to date.
* Refer to the Temperature Control Flow Chart in the Dispensary Refrigerator Temperature Monitoring Record (p18) delete one] **OR**
* Refer to the Temperature Control Flow Chart in the Annual Cold Chain Management Guide and Record (p9) [delete one]
* Collect as much information as possible eg what monitoring has taken place, how long were the vaccines stored outside of the required range, identify all vaccines in the fridge, the length of time stored, usual stock turnover and expiry dates. Identify any previous out of range events involving these vaccines. Determine if any individuals received a compromised vaccine.
* CONTACT YOUR LOCAL IMMUNISATION COORDINATOR WITH ALL OF THE AVAILABLE INFORMATION AND WORK WITH THEM THROUGH TO RESOLUTION.

Our local immunisation coordinator is [enter name and contact details of local one here]. *A list of local immunisation coordinators can be found:* <https://www.immune.org.nz/resources/regional-advisors-and-local-coordinators> *.* * In a power failure, vaccines can remain in the fridge for up to 4 hours – open the fridge as little as possible during this time. At 4 hours or before, transfer the vaccines to the chilly bin with a layer of frozen ice packs on the bottom (warmed until there is no frost on the outside), cover with shredded paper or a 10mm thick polystyrene sheet then the most heat-sensitive vaccines, then place the least heat sensitive vaccines (or most freeze-sensitive) furthest from the ice packs.
* Include a minimum/maximum thermometer or data logger with the transferred stock. Transfer the stock to [insert name, address and phone number of back-up fridge for power failure, e.g. another pharmacy, medical centre – have alternatives in case a nearby pharmacy is also affected by a power failure].
* In case of fridge failure contact [name and phone number of fridge supplier or service provider].
* When one-off temperature variations of up to 12°C for less than 30 minutes occur for known reasons (eg stocktake), the pharmacy does not need to notify the immunisation coordinator, but it must document the reason for the variation in the records.

**Routine actions*** Refer to the Dispensary Refrigerator Temperature Monitoring Record or Annual Cold Chain Management Guide and Record [delete one] for monthly, six-monthly and annual actions.
* Download the data logger weekly and compare with the daily max/min recordings to check any unexplained temperature variations. Save the information in a file on the computer, or print it. If any discrepancies are found, take appropriate action and inform the immunisation coordinator.
* Ensure this data is backed up in case of computer failure.
* The data logger needs to be calibrated at least annually, e.g. by checking against another data logger when the annual service and refrigeration temperature check occurs.
* Ice-pointing should be used to check accuracy of all max/min thermometers and data loggers after buying them, after the battery is changed and every 12 months (see the [National Standards for Vaccine Storage and Transportation for Immunisation Providers 2017](http://www.health.govt.nz/publication/national-standards-vaccine-storage-and-transportation-immunisation-providers-2017) for details).
* The annual service of the fridge is conducted by an approved/licensed refrigerator technician [name of company and phone number] every [enter month]. The fridge temperature measurement also needs to be measured independently every year (this may occur with the service). This annual temperature measurement should use three areas of the fridge. Servicing, calibrations and any change in the refrigerator are recorded in the Dispensary Refrigerator Temperature Monitoring Record or Annual Cold Chain Management Guide and Record [delete one].
* For maintenance – see the Dispensary Refrigerator Temperature Monitoring Record or Annual Cold Chain Management Guide and Record [delete one].

The fridge must be cleaned every 6 months and documentation made of the cleaning. **NOTES*** If vaccines are supplied from ProPharma check for a data logger, which may be packed with your vaccine order. If it has a green light, the order can be received and used. If it has a red light, follow the instructions in the order including ringing the provided number to inform of the order status, putting the stock in the fridge in quarantine (clearly mark “Not for Use”). Return the data logger the same day as the delivery, and you will hear back in 24 hours with what action to take. This action includes: that the vaccine can be used (remove from quarantine, and check stock against invoice); or that the stock cannot be used. If it cannot be used, the distributor will arrange a pick-up of this stock and replacement delivery.
* Check for National Cold Chain Audit (NCCA) temperature loggers on arrival. These are which are used to monitor up to 10% of vaccines. The loggers stay with the box of vaccines they are allocated to, until either the last dose of vaccine is used or two weeks have passed, whichever occurs first. The loggers are yellow ECONOLOGGERS. When the vaccine arrives in the pharmacy, one of two lights will be flashing. This is the only time the pharmacy is required to check the logger. Follow the instructions provided with the logger. For further information on what to do if you receive vaccines containing an ECONOLOGGER check Appendix 1 of the Standards.

*See Vaccination SOP 8 - Chilly bin validation* |
| **Created by** | **Date** |
| **Approved by** | **Date** |

**Appendix 1: Pharmacy vaccine register**

On receipt of vaccines, enter the details in this vaccine register. This is a requirement of the National Standards for Vaccine Storage and Transportation for Immunisation Providers 2017.

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| Vaccine | Date received | Batch # | Expiry | Quantity  | Signature |
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**NOTE:**

* Document the arrival date on the vaccine box in bold pen
* Store the vaccines in their original boxes
* Store in the pharmaceutical refrigerator with the expiry dates visible to ensure that those with the shortest expiry date are used first

Appendix 2



