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| **Standard Operating Procedure (SOP)****Document name:** SOP 8 -Chilly bin validation**Document category:** Vaccinations**Document heading:** Vaccinations **Internal ID:** IM08/F08**Review Frequency:** Every 2 years**Reviewed by:** xx**Next Review:** xx/xx/xxxx |
| **Purpose**To ensure that all equipment used for storing, transporting and monitoring vaccines is fit for purpose and appropriately maintained and tested. Part of this maintenance and testing is to trial and test the capacity of the pharmacy’s portable storage equipment.**Personnel**Pharmacy Manager **Pharmacy Quality Audit Requirements***To meet the National Standards for Vaccine Storage and Transportation for Immunisation Providers 2017 requirements.*   |
| **Objectives**Immunisation providers must consider the following factors when transporting or storing vaccines in chilly bins, to ensure the vaccines are kept at +2°C to +8°C. Providers will need a datalogger(s), ice packs, insulation sheets and a chilly bin to transport the vaccines, or any other trialled system (eg, Cryopaks).**Procedure*** The amount of vaccine to be transported or stored will determine the size of the chilly bin required.
* In hotter weather, additional ice packs may be needed for precooling to reach the acceptable temperature within 30 minutes. Alternatively, precooling ice packs can be left in the chilly bin overnight.
* Trial any alternative equipment and show that they can maintain a temperature of between +2°C to +8°C at all times.
* Packing requires two pieces of insulation mat: one for below the vaccine and one for above. The bottom mat should fit the chilly bin; the top mat should be cut larger to allow for 1–2 cm to go up the sides of the chilly bin. A full packing and monitoring protocol can be found in the COOL Project stakeholder summary on the IMAC website: [www.immune.org.nz/health-professionals/cold-chain](file:///%5C%5Cmoh.govt.nz%5Cdfs-userdata%5Cuserstate%5Cdmurfitt%5CDocuments%5Cwww.immune.org.nz%5Chealth-professionals%5Ccold-chain).
* Pre-Freeze ice packs for at least 2 days
* Use empty vaccine outer boxes or boxes of a similar size.
* Ensure the volume of vaccine is no more than one-third of the chilly bin capacity.
* Prepare chilly bin as you would for vaccines ie. begin cooling at least 30 minutes before using.
* Pack as you would usually with the appropriate insulation

*See Vaccination SOP 1 - Receiving and storing vaccines** Use the data logger (set to record the temperature every 5 minutes) to record max/min and current temperatures, every 20 to 30 min for eg four hours or as long as you would expect to be away for an off-site vaccination.
* Record this information on the chilly bin validation sheet

*See below, Appendix 1 chilly bin validation* * It is important that the environmental conditions are recorded. Record the room temperature every 20 to 30 minutes as well.
* Take note of the time and outside temperature at which the chilly bin can no longer keep a stable temperature i.e exceeds 8°C.
* Undertake this process a minimum of two times to ensure results are consistent.
* It is advisable that the process is undertaken in summer temperatures as well as winter conditions to ensure that a full range of environmental conditions that can influence temperature, are covered.
* Save the information recorded as proof of the chilly bin validation.
* This process would have to be undertaken again at any time any part of the equipment changes or is replaced.

Equipment* 1 x chilly bin with clip lid (state dimensions)
* 1 x spare chilly bin with clip lid (state dimensions)
* XX x flat bottle ice packs/large gel packs (state which)
* 1 x data logger with external probe
* insulation material (state what this is)
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| **Created by** | **Date** |
| **Approved by** | **Date** |

**Appendix 1: Chilly bin validation sheet**

Date:

Equipment tested:

Temperature log: record every 20 to 30 minutes

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| **Environment** | **Chilly bin** |
| **Maximum** | **Minimum** | **Current** |
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Time and environmental temperature when chilly bin temperature exceeds 8 °C:

Pharmacist signature verifying validation: