

# **COLD CHAIN MANAGEMENT**

Medical department MSF OCBA

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# **INTRODUCTION: DEFINITION and OBJECTIVE**

The "cold chain" is a continuous system of conservation and distribution of thermo-sensitive products (vaccines, as well as some drugs and diagnostic test) at a defined temperature, from manufacturing to administration, ensuring their effectiveness.

It means all the means used to keep the temperature of thermo-sensitive products between +2 ° C to +8 ° C.

The respect of procedures for cold chain is under the joint responsibility of medical and logistics teams.

Stock management of temperature of thermo-sensitive products, as well as the rest of the pharmaceutical stock is the responsibility of the medical team. By contrast, supply, equipment installation, servicing and maintenance are the responsibilities of the logistics team. Therefore, working in collaboration at all levels is essential to insure the conservation, transportation and adequate management of temperature sensitive products.

These procedures take over the key responsibilities of the medical team and are coming from various documents listed in the reference list.

Neither the technical logistics related to the cold chain, nor the cold chain applied to a campaign of vaccination are discussed in this document.

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## **I- CONSERVATION**

Vaccines as well as some drugs and diagnostic tests are very sensitive products which lose quickly their potency if they are exposed to heat (Temperature >8°C) and/or freezing. In the MSF catalogues and on the order lists, these products are indicated by "Keep cool" and associated to a cold chain code:

*	The product MUST be kept refrigerated					
*F	The product CAN NOT be frozen					
*0(F)	The product MUST be kept refrigerated and					
*A(F)	transported by cold chain with the following					
*B(F)	indicators:					
*C(F)	Transport :					
	- Cold chain monitor card (3M)					
	<ul> <li>Freezing indicator (Freeze-tag)</li> </ul>					
	<ul> <li>Temperature recorder (LogTag)</li> </ul>					

Those products must be transported and stored between +2 $^{\circ}$ C and +8 $^{\circ}$ C

#### VACCINES:

• In accordance with WHO recommendations :

« All vaccines must be maintained between +2ºC and +8ºC from production to their administration.»

- Freezing of vaccines :
  - WHO no longer recommends freezing of vaccines, except for oral polio vaccine at regional and national level. This does not apply to MSF projects.
  - BCG, Measles, Yellow fever, Meningitis and Hib vaccines should be maintained between +2°C and +8°C and must not be frozen.
  - Diluents should be at the same temperature of the vaccines (between +2°C and +8°C) at the time of reconstitution. It's not necessary to store them in the refrigerator, but the required amount of diluents must be put in the refrigerator or in a cold box 12 hours before use.

# **II- TRACEABILITY, MONITORING AND CONTROL**

The refrigerator is normally locked since it's a pharmaceutical stock. The pharmaceutical stock manager holds the key and is responsible of stock management just like the rest of the pharmacy stock (IN/OUT, inventory, temperature and indicators monitoring)

He will supervise in collaboration with logistics energy supply<sup>1</sup>, maintenance of the refrigerators.

For more information, technical sheets are available in the MSF logistic catalogue.

## **TOOLS FOR TEMPERATURE MONITORING:**

• **Temperature monitoring sheet** = Code : PCOLCONT4CT (Annex 1)

It should be stuck on each refrigerator.

The temperature must be reported each morning and each afternoon (including day off) by the pharmacy management team.

Some fridges are equipped with a thermometer outside but we will prefer always to check the real temperature (thermometer placed inside the fridge)

#### • Instantaneous and recorder thermometers

A thermometer must be placed in each refrigerator, each freezer, each cold box, and each vaccine carrier

INSTANTANEOUS THERMOMETERS



Alcohol thermometer (Moëller® 104614) = PCOLTHER1A-Temperature range: -40°C to +40°C



Liquid crystal thermometer LCD = PCOLTHER3C-Temperature range: 0°C to +20°C

RECORDER THERMOMETERS OR Fridge Tag® = PCOLCONT5--



Indicate instantaneous temperature, alarms (< +2°C and > +8°C during more than 1 hour) and provides access to the history of the past 30 days. With this thermometer, it is unnecessary to add an alcohol thermometer.

<sup>&</sup>lt;sup>1</sup> We should prefer plan gas and/or petrol supply on fixed dates: Do not wait cold chain rupture to replace gas bottle for example. As average, we will consider 10-15 days for gas bottle and 2-3 days for petrol supply.

• Freezing indicator: Freeze Tag® = PCOLCONT3FT



Irreversible freezing indicator. Alarm when the device has been exposed for at least one hour to a temperature  $\leq 0$  °C (uncertainty  $\pm 0.3$  °C)

#### • Monitor card 3M® = PCOLCONT1C-



Irreversible and cumulative temperature indicator. It shows exposure to temperature > +10 °C according to the duration.

Place the card in the refrigerator for at least 1h before activating it. To activate the indicator, pull on the strip on the left.

To read the card, consider the colour modification of the windows A, B, C and D, which change from white to blue depending on the exposure temperature and the duration of this exposure. Explanatory note at the back of the card.

Stop-Watch® card =PCOLCONT2R-



Combination of the cumulative indicator and freezing indicator. Indicates if temperature  $\geq$  +10°C and/or temperature  $\leq$  0°C for at least one hour.

#### • Temperature recorder LogTag® = PCOLZBD0069



Temperature recorder programmable and reusable. Used by supply centres (MSF Log and MSF Supply) Reading with hardware and software (computer) to extract history of temperature recorded. Although its primary indication is the transport, le LogTag® can still be used in addition with 3M® card and Freeze tag® to help managing the cold chain at field level. It serves to document in case of cold chain shortage.

#### Vaccine Vial Monitor (VVM)



Cumulative temperature integrator. Most vaccines are fitted with. It indicates temperature exposure > +8°C according to the duration.

LECTURE DES PCV:





### **IN SUMMARY:**

• All cold chain equipments must be equipped with a thermometer and both indicators (3M® card and Freeze Tag®)

	Temperature	Moëller	LCD	FreezeTag	3M card	LogTag
	sheet	(or Fridge Tag)	Thermometer	Stop Watch card		LOGIOG
Vaccine carrier		(X)		х	х	х
Cold box RCW25			Х	х	х	х
Refrigerator	х	Х		х	Х	(X)
lsothermal box				х	х	х

X Mandatory (X) Recommended

The Log Tag can be added in each refrigerator to document cases of cold chain breakdown. In any case, it does not replace the other indicators

- Temperature must be checked and reported twice a day, including days off, on a monitoring sheet stuck on each refrigerator's door.
- In case of rupture, the products must be kept in cold chain and the coordinators (medical and logistic) immediately informed (See Part V «What to do in case of cold chain breakdown")

## **III- RECEPTION and EXPEDITION**

The logistics team is responsible for the reception and the transportation of the cold chain. As soon as the products are part of the pharmaceutical stock, the medical team is responsible to receive / store / manage them adequately and eventually, prepare packaging for a new expedition.

#### RECEPTION

- These products must be transported by air in cold boxes coated with frozen icepacks. These boxes maintain a correct temperature for 96 hours after leaving the supplier. This time may be prolonged if they are stored in cold rooms during the transit.
- The field is informed about date and time of arrival.
- In order not to interrupt the cold chain, it is recommended to transport the cold boxes until their final destination and to place the products immediately in the fridge. If this is not possible (waiting period at the airport, too long distances or roads of bad quality), 2 solutions are suggested:
  - Replace the icepacks by frozen ones (either brought in a cold box, or obtained by the national/regional vaccine store at the airport)
  - Transfer the products in a cold box containing newly frozen ice packs.

Be careful; see below procedures to prevent freezing risk!

• On arrival, the temperatures indicators (3M® card, Freeze Tag® and temperature recorder LogTag®) must be checked (press once the button "start / mark" of the LogTag®, to indicate the exit time of the isothermal box) and the products must be placed in refrigerator.

### EXPEDITION

• Follow procedures for transportation of thermo-sensitive products (preparation, monitoring tool, labelling and shipping documentation)

See Annex 2 for loading of RCW25 cold box.

The technical sheet for loading the isothermal box is available inside each isothermal box and accessible through MSF logistique website (www.maflogistique.org)

- In order to prevent freezing risk during transportation :
  - Use only icepacks filled with water!<sup>2</sup>
  - Wait for the frozen icepacks to rise to 0°C before placing them in the cold box (keep them at the room temperature for minimum 30 minutes until water is visible inside)
  - o Dry the icepacks and place them in the cold box.
  - o Place cardboard between thermo-sensitive products and icepacks to prevent them touching.

 $<sup>^2</sup>$  Icepacks pre-filled with eutectic product (coloured gel) are not suitable since they have a freezing point below 0°C.

# **IV- STORAGE and MANAGEMENT**

Each project must have a cold chain for pharmaceutical products with sufficient volume for the conservation of these thermo-sensitive products.

The logistics team is responsible to install and maintain the cold chain equipment.

The cold chain consists of:

• Active cold, composed by freezers and refrigerators.

• Passive cold, composed by RCW25 / Vaccine carriers / Ice packs. These devices do not produce cold but can maintain temperature below +8°C for some time.

MSF provides only materials pre-qualified by WHO. For further specifications, refer to technical sheets in MSF logistic catalogue.

## 1) Characteristics of refrigerators

Each equipment must be clearly identified; the contents will be mentioned outside: identification sheets in Annex 3.

#### **COMPRESSION REFRIGERATOR**

The Vestfrost<sup>®</sup> refrigerator are compression fridges with double wall. An internal icelining (icepacks) surrounds the vaccine storage area and the frozen icepacks provide cooling during power failures. The so-called « icelined » maintain the temperature below +8°C with only 8 hours of electricity supply per 24 hours. In order to freeze the icepack of the icelining system, at the first switching on, you have to adjust the thermostat on "8" and let the fridge run empty for at least 24 hours (see operating instructions manual)

Compression refrigerators are powered by electricity. The cooling capacity of a compression refrigerator is significantly higher than the one of an absorption fridge. Compression models are the most reliable, the safest and the easiest to maintain. Therefore they are the best choice when electricity is available.

#### ABSORPTION REFRIGERATOR

The Sibir® refrigerator are absorption fridges. There are 2 models: electricity/oil and electricity/gas. They do not perform as well as the compressor-driven equivalents. They require constant attention to ensure correct and stable internal temperatures and more maintenance is needed.

These models are potentially dangerous (fire and explosion hazard) Make sure to follow the safety instructions. If you can choose, prefer a gas operated model since its maintenance will be easier.

#### DOMESTIC REFRIGERATOR

The use of domestic refrigerators to store thermo-sensitive pharmaceutical products is not recommended for the following reasons:

- Lighter insulation
- Imprecise regulation of the temperature
- Heterogeneity of the temperatures
- Variations in temperatures in case of automatic defrosting
- Difficult location of the cold and warm areas because of the diversity of the models and technologies.

## 2) Refrigerator location

The refrigerator should be installed:

- Protected from sunlight, source of heat. If possible, in the coldest room.
- In a room ventilated but without draft-free for absorption fridge.
- At a distance of 50 cm from the other equipment, the walls and ceiling.
- Protected from dust.
- On blocks or pallets to avoid direct contact with the ground and increase heat evacuation.

## 3) Storage

- No product should be stored in doors of vertical refrigerators.
- Do not store food and drinks in refrigerators used for thermo-sensitive products storage.
- Do not append the boxes together: leave a space between them to allow cold air to circulate.
- Products should be identified quickly. Names and expiry dates must be located on the front and be readable as soon you open the fridge.
- To facilitate handling and reduce the time opening the door, apply the rule: expiration date closest to the left of the shelf and the farthest to the right. Products with expiry dates closest leave first, then date more distant (stock rotation)
- If there is enough place, the diluents may be stored in the refrigerator also.
- Be careful, not to store freeze-sensitive products in the coldest part of the fridge /in contact with the evaporator): downstairs for horizontal fridge (door at the top) and on the top for horizontal fridges (front door)
- Reminder : Each refrigerator must be equiped with a thermometer and mandatory indicators (Stop-Watch card®) +/- Logtag®)





## 4) Stock management

Stock in the cold chain is part of pharmacy stock.

- As for the rest of the stock, it is necessary to ensure traceability of these products. For this, we use stock card, stating expiration date and eventually batch number. We apply same rules and monitoring process for these products : regular inventory, FEFO method (First Expired First Out)
- Record the temperature and check indicators twice a day. See part II « Traceability-Monitoring and Control »
- Design a rescue plan of the products in case of cold chain break :
  - Provide enough cold boxes to store products temporarily
  - o Always have the required number of frozen icepacks available for the cold boxes
  - Post up the way to proceed and train the staff
- Note carefully any cold chain rupture (duration, reached temperatures and exposed products) and contact immediately the pharmacist in headquarter or in supply centre to know the line to take. Refer to Annex 4.

## V- WHAT TO DO IN CASE OF COLD CHAIN BREAKDOWN

In case of doubt on the integrity of the cold chain or in case of indicators alarms:

- Clearly identify the products and place them in quarantine under cold chain between +2°C and +8°C (refrigerator running properly or cold box equipped with icepacks and temperatures indicators)
- Inform the logistician.
- Write a cold chain breakdown report<sup>3</sup> and send it to medical and logistical coordinators. It must be submitted as soon as possible :
  - To the supply centre if the breakdown occurs during transportation
  - To headquarter (Medical responsible, logistical responsible and pharmacist)

Information to be provided:

- Products: name, manufacturer, code, batch number, expire date and quantity.
- Cold chain rupture: temperature range, exposure time, reading of 3M® card and Freeze-tag®, Logtag® file if available, reading of VVM.
- Wait for pharmacist recommendations.

<sup>&</sup>lt;sup>3</sup> Cold chain breakdown report available in MSF catalogues, in supply centre website and here, in annex 4.

# **Appendices list**

- Annex 1: Temperature monitoring chart
- Annex 2: RCW25 loading
- Annex 3: Identification sheet for cold chain equipment
- Annex 4: Cold chain breakdown report

# **References list**

- MSF catalogues
- Cold Chain support EN V2011.03 MSF logistique
- Supply of drugs and medical supplies and pharmacy management MSF 2<sup>nd</sup> edition 2008
- Gestion de la chaîne de froid Mémo guide MSF 2010
- Part 3 Immunization in practise A practical guideline for health staff WHO 2004
- WHO/V&B/02.35 Getting started with Vaccine Vial Monitor WHO 2003
- <a href="http://www.who.int/topics/immunization/en/">http://www.who.int/topics/immunization/en/</a>
- WHO/GPV/98.07 Thermostability of the vaccines WHO 1998
- Opened Vial Policy WHO