



<b>Subject : Cold Chain Protocol</b>		
<b>Document no : SOP-HSE-005</b>	<b>Date of effect : 05-April-2011</b>	
<b>Prepared by : Dr.Sumaya Alghassan</b>	<b>Revision number : 000</b>	
<b>Approved by : Sameer AlZayani</b>	<b>Controlled by : Zahra AlHammadi</b>	

# Cold Chain Protocol

Revision History			
Revision No	Date	Description of Changes	By
000	15-07-10	Original created based on ISO 9001:2008 requirements	ZHA009

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## Introduction

Cold Chain is defined as the system of people and equipment which ensure that the correct quantity of potent vaccine reach those who need it, as per MOH Circular # 16 released November 10, 2003.

This protocol should guide anybody in the practice of monitoring and maintaining an effective and safe vaccine available in the medical clinic; moreover, by adhering to it we are in turn, improving the lives of all the employees.

## Goals and objectives

To maintain a cold chain system in APM Terminals that is safe, effective and conforming to Government standards.

To guide the clinic staffs a clear cold chain guidelines and effective vaccination schedule and monitoring.


To minimize wastage and vaccine cost due to improper vaccine storage and handling.

### General Guidelines

- **There should be separate refrigerator for vaccines and medicines.**
- **No vaccine is to be put in the refrigerator door.**
- **Vaccine labels should always be readable and kept dry.**
- **The refrigerator should be kept in a cold place away from light.**
- **The thermometer should be inside the refrigerator not freezer.**
- **No food, drinks or culture media in the vaccine refrigerator.**
- **Ice packs for transportation of vaccines loosely packed in the freezer compartment.**
- **Ice box should be used in transportation of vaccine with one index monitor**
- **Sealed water bottles and cold packs should be kept in the door shelf of the refrigerator to minimize temperature fluctuations.**
- **As per MOH, the clinic should maintain a file of the following Cold Chain Manual, Monthly temperature graph, and Expiry dates list and evaluation form.**
- **Incase of brown-out (No electrical supply), the fridge should not be open for the duration of brown-out unless instructed by Doctor.**
- **Disposable syringes should be used for the injection of vaccines.**

### Equipments and Expiry monitoring

A check sheet (Cold Chain Refrigerator graph form) should be kept in the door of the refrigerator to be used in the monitoring the refrigerator temperature, at the beginning and end of the shift. The monitoring for APM terminals clinic vaccine refrigerator will be done by the nurses, B = for 1<sup>st</sup> shift incoming nurse (7am-7pm); E = for 2<sup>nd</sup> shift incoming nurse (7pm-7am). A copy should be submitted or faxed to MOH monthly.

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### Proper Storage in the refrigerator

Inside the refrigerator vaccines should always be arranged properly.

Freezing compartment - ice packs and ice cubes.

Main compartment vials should be found in:

Top part - oral polio and measles, MMR vaccines

Middle part – BCG, DPT, TT, TD, diluents and the thermometer

Lower part – water bottles or cold packs

Door shelves – sealed water bottles

### Vaccine vial monitoring

The form (EPI vaccine monitoring) should be kept in the door of refrigerator for monitoring of Batch number and Expiry date of vaccines. A copy should be submitted or faxed to MOH monthly. If the expiry date shows month and year only (January 2008) Vaccines will expire on the 1<sup>st</sup> day of the month. Expired vaccines should be recorded and disposed in the biohazard container immediately.

Another monitor is the COLD CHAIN Index monitor. Index monitor will change color in the event of exposure of the vials to temperature 10 degrees Celsius (A, B, C) and 34degrees Celsius (D). The index indicator B is for Measles, yellow fever; index indicator C for BCG; and index indicator D for Hepatitis B and Tetanus Diphtheria and all other. This monitor will be activated upon the receipt of the vaccine from the MOH PHD immunization unit. In the event that any window changes to blue, the monitor should be change to new one and the affected batch/lot should be labeled and the time limit for there use which is 3 months should be clearly marked in each vial.


If available, Polio vaccine vials color of the viability indicator should be monitored daily.

### Vaccine wastage monitoring

Strictly no opened vials will be kept inside the refrigerator at all times. If a multi-dose vial will be open to use, write the date and time in the label. Unused opened vaccine vials should be discarded at the end of the same day. A form (PPD materials and vaccine wastage sheet) should be filled-up in case of unconsumed vaccine disposal. After logging the details, vials should be disposed in the biohazard/sharps container.

### Vaccination record

The medical clinic should have a comprehensive employee's vaccination record for easy monitoring and follow-up. A form (Monthly Immunization Statistics) should used and copy should be submitted or faxed to MOH monthly.

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## Incident reporting

### A. Refrigerator failure report

When the temperature is below 0 or above 8 degrees Celsius, adjust the thermostat to “colder” or “warmer” on case to case bases. Check the vials and cold chain index monitor for any changes. Then inform Doctor of the incident.

### B. Adverse reaction from the vaccine

In case of a patient presenting an adverse reaction to the vaccine injection a report should be made immediately.

2 type of forms

**Annex 2 and 4** – Surveillance of adverse events following immunization **should be sent or faxed immediately to MOH.**

**Annex 1-** Line listing for adverse events following immunization **should be sent or faxed monthly to MOH.**

### **Scheduling/Appointments for employees**

A comprehensive yearly plan of immunization will be formulated. The schedule will be based on the world weather trends (Influenza, MMR), W.H.O. programs and advisory (Birds flu), and immerging need of employee (punctured wounds –Anti-tetanus).

Three months before the schedule of immunization, coordinate with MOH immunization unit the availability of vaccines for reservation and purchase. This is to be assured that the vaccine is available.

On the month of vaccination schedule, the medical staff will get the roster schedule of all employees per department to be immunized.

Two weeks before the scheduled date for mass immunization, the medical staff should give the list and email the department manager or shift manager with the date, name, and specific time of appointment of each employee for vaccination.

Reporting to MOH will be done monthly using the provided form (Monthly immunization statistics).