



HEALTH HOLDING

HAFER ALBATIN HEALTH
CLUSTER
MATERNITY AND
CHILDREN HOSPITAL

Department:	Pharmaceutical Care Department		
Document:	Multidisciplinary Policy And Procedure (MPP)		
Title:	Storage Of Refrigerator, Biologics And Vaccines		
Applies To:	Pharmacists, Physicians & Nurses		
Preparation Date:	December 15, 2024	Index No:	MM- MPP-010
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1. PURPOSE:

- 1.1 To describe the process by which Frozen Medications, Biologics and Vaccines are stored safely and according to the manufacturer's temperature requirement.
- 1.2 To describe the monitoring and recording process for all refrigerators and freezers located within the department, store room, and patient care areas
- 1.3 To ensure proper storage of Frozen Medications, Biologics and Vaccines in the warehouse, main pharmacy and hospital storage facilities.
- 1.4 To maintain the potency & stability of Frozen Medications, Biologics And Vaccines stored in the hospital for effective and safe medications.

2. DEFINITONS:

- 2.1 Refrigerate (2 – 8 °Centigrade / 35 – 46 degrees Fahrenheit).
- 2.2 Digital Data Logger Thermometer: Refrigeration thermometer that monitors temperatures twenty-four hours a day.

3. POLICY:

- 3.1 All Refrigerator and Frozen Medications, Biologics and Vaccines are well stored, separated and properly labelled.
- 3.2 All refrigerators and freezers located within the department will be routinely monitored to assure that the correct temperature range is maintained with respect to the items being stored in each respective refrigerator or freezer. Documentation of the monitoring activity will be maintained.
- 3.3 All medications are stored according to manufacturer's recommendations (temperature, light, humidity, sanitation).
- 3.4 No food or drinks will be allowed inside medication refrigerators.
- 3.5 The pharmacy department will keep temperature records for at least Two years

4. PROCEDURE:

- 4.1 General principles:
 - 4.1.1 Upon receipt of medications from MOH, Medical Supplies / or venders (purchase), Drug Store supervisor shall place all Refrigerator And Frozen Medications, Biologics And Vaccines into the appropriate storage areas based on the manufacturer's requirements for temperature, light, moisture, ventilation, sanitation, segregation, if any, and security.
 - 4.1.2 Medications are stored by scientific names (alphabetical), if possible, well separated, properly labelled.
 - 4.1.3 Light sensitive vaccines: Should be kept in packed in dark bottles away from light.
 - 4.1.4 Refrigerated and Freezing Items:
 - 4.1.4.1 Refrigerated items should be stored in temperature of (20°C to 80°C) inside a refrigerator across Hospital.

- 4.1.4.2 Temperature record should be done every shift for all medication refrigerators across Hospital and once daily for OPD pharmacy, day surgery unit and endoscopy unit.
- 4.1.4.3 Food, drinks, biological samples and culture media are not allowed in medication refrigerators across Hospital.
- 4.1.5 High alert medications stored in refrigerator:
 - 4.1.1.1 High alert medications should be stored in separate properly labeled shelves and labeled individually on each item.
- 4.1.6 Look-alike/sound-alike medications: Should be stored in separate places and properly labeled.
- 4.1.7 Pharmacy administration shall call maintenance, to handle problems with refrigerators and freezers. And arrange for immediate maintenance.
- 4.1.8 Nutritional Products: All parenteral nutrition bags must be stored in the drug fridge or fridge designated for PN at temperature between "2 to 8 °C". The expiry date is stated on the labels. Pharmacy should be notified of any unused bags. Discard in clinical waste. Parenteral nutrition bags should be removed from the fridge at least 1/2 hour prior to use, to allow fluid to reach room temperature. If the bag is in any way damaged or leaking please notify the Pharmacy Department immediately and send the bag to the pharmacy so that the cause can be determined. The compounded products of PN are good for 24 hours only.
- 4.1.9 The Medication Reconciliation Form content shall be subjected to an initial immediate review by a pharmacist before dispensing of any patient medication (except in emergency situations). This reconciliation should compare the Medication Reconciliation Form to existing therapy.
- 4.1.10 Medications will not be dispensed or distributed beyond the expiration date, First expiry/First out" (FEFO) principle will be followed.
- 4.1.11 Any expired, discolored, damaged, or inappropriately labeled medication shall be returned to the pharmacy store for proper disposal. Unused or not needed medications for a specific patient (or not intended for stock) are also returned to the pharmacy for processing or disposal by the pharmacy store.
- 4.1.12 Any notification of a drug quality issue (e.g. discoloration, precipitation, etc.), the medication will be recalled and reported to the MOH Medical Supply and the Saudi FDA, as required.
- 4.1.13 Drugs for external use are stored separately from injectable. This applies to the pharmacy store, Inpatient and outpatient pharmacies, and the wards.

5.2 At Transfer

- 5.2.1 Refrigerated medications must be stored at appropriate temperatures according to the following:
 - 5.2.1.1 Room temperature: between 18-25 °C
 - 5.2.1.2 Cool place: between 8-15 °C
 - 5.2.1.3 Refrigerator: between 2-8 °C
- 5.2.2 Pharmacy staff in Inpatient, OPD, ER and store room, and Head Nurses in patient care areas is responsible for recording daily and maintaining a log sheet for temperature of refrigerators in the pharmacy and wards.
- 5.2.3 Medication refrigerators should have a working thermometer ensuring the proper temperature range.
- 5.2.4 Notify the maintenance department of any problem, which will in turn evaluate the situation and contact the respective supervisor for repair if required.
- 5.2.5 Corrective action for units displaying temperature outside desired range should be taken immediately by first calling the maintenance department for repair within 30 minutes. If not repaired then transfer all contents to a similar unit within the department, attach an inventory list to the broken unit, listing all items removed, quantity and new location. Attach a copy of the inventory list to the temporary new location. Inform the maintenance manager of the refrigeration problem and the transfer of the inventory. During normal hours the maintenance supervisor is responsible to call physical plant to repair the malfunction. For after hour's refrigeration problems, the charge nurse is responsible for calling maintenance.
- 5.2.6 Medication refrigerators should not be used to store food, drinks, biological samples, or culture media.

5.2.7 A temperature log must be maintained for each medication refrigerator and will be checked at least once daily.

5.2.8 The documentation must indicate that the temperature is monitored on a daily basis.

5.3 Refrigerators:

5.3.1 Large units (room size) refrigerators:

5.3.1.1 Used for storing large quantities of refrigerated drug items such as vaccines, insulin, heparins, and other drugs, these refrigerators are found in the Pharmacy Store and the Main Pharmacy

5.3.1.2 Equipped with a temperature monitoring device which is connected to the maintenance department who will in turn evaluate the situation and contact the respective area supervisor if required.

5.3.2 Small and medium size refrigerators:

5.3.2.1 Used to store small stocks of refrigerated drug items and is available in inpatient, outpatient, and ER pharmacies and also in patient care areas.

5.3.2.2 Some of these refrigerators are equipped with a portable temperature monitoring device (thermometer) in the pharmacy areas, while other refrigerators have the device (thermometer) mounted on the unit itself as in patient care areas

5.3.3 The small units' refrigerators are checked daily. If any problem, the maintenance department will be contacted to evaluate the situation and correct the problem or contact the respective area supervisor if required.

5.4 Storage of Vaccines, Human Plasma Fractions & Insulin:

5.4.1 Delivery from Medical Supply Stores:

5.4.1.1 The Drug store pharmacist ensures that the supplied vaccines, human plasma fractions and insulin were in good conditions during delivery from Medical Supply Stores.

5.4.1.2 If the Drug store pharmacist verified that the supplied vaccines, human plasma fractions and insulin were broken, he/she must inform the Medical Supply immediately by a written notification (a copy to Head of Pharmacy Dept.) to be returned or replaced.

5.4.1.3 The Drug store pharmacist ensures to keep all the vaccines, human plasma fractions and insulin in a suitable temperature. These products should be kept under specified storage temperature during and after supply from company, until it reaches the Drug Store Refrigerator and then, being transferred to In-patient, Out-Patient Pharmacies and Nursing Units.

5.4.2 Vaccines, and insulin are kept in a temperature between +2°C & +8 °C.

5.4.3 As a general rule, multi-dose vaccines should be kept for one hour after opening if there is no preservative. Vaccines which contained a preservative should be discarded after THREE HOURS from the opening time. Insulin vials should be kept in the refrigerator for ONE MONTH after opening. Unused human plasma derivatives should be discarded immediately after opening.

5.4.5 Specific rules:

5.4.4.1 Tetra-act HIB vaccine stable for 24 hours in the refrigerator.

5.4.4.2 BCG vaccine stable for four hours after opening in the refrigerator.

5.4.4.3 Insulin Flexpen stable for one month after first use and can be kept at room temperature.

5.4.6 In-Charge Nurses are instructed to give particular attention to the importance of shaking vaccine containers after the addition of diluents immediately before use.

5.4.7 The Head of Pharmacy and/or designee monthly checks the hospital staff clinic for:

5.4.7.1 Availability of the vaccines.

5.4.7.2 Proper storage at proper temperature.

5.4.7.3 The Staff Nurse daily checks the refrigerators temperature of the staff clinic.

5.4.7.4 No food stuff is allowed to be kept inside medicine refrigerators.

5.4.8 Various medication stores in hospital is as follows:

- 5.4.8.1 Drug store
- 5.4.8.2 Inpatient nursing unit
- 5.4.8.3 Outpatient clinics
- 5.4.8.4 Emergency Room
- 5.4.8.5 In-patient Pharmacy
- 5.4.8.6 Out-patient Pharmacy

5.4.9 Table below provides a list of available vaccines and required temperature for storage:

Vaccine Names	Storage Temperature	Stability
1.Chloromphenicol eye drop	+ 2 °C to + 8 °C	1 Month
2. BCG Vaccine	+ 2 °C to + 8 °C	
3. Proparacain HCL drop	+ 2 °C to + 8 °C	1 Month
4. Pneumococcal Polysaccharide Conjugate Vaccine	+ 2 °C to + 8 °C	Single dose
5. Hepatitis B vaccine	+ 2 °C to + 8 °C	Single dose
6. Inactivated hepatitis A virus vaccine	+ 2 °C to + 8 °C	Single dose
7. Inactivated influenza vaccine	+ 2 °C to + 8 °C	Single dose
8. Tuberculin Purified protein derivative	+ 2 °C to + 8 °C	1 Month
9. Meningococcal vaccines.. Protect from light.	+ 2 °C to + 8 °C	Single dose
10. MMR (Mumps, Measles, Rubella vaccine)	+ 2 °C to + 8 °C	Single dose
11. Scorpion venom antitoxin	+ 2 °C to + 8 °C	Single dose
12. Snake venom antitoxin	+ 2 °C to + 8 °C	Single dose
13. Clindamycin Inj	+ 2 °C to + 8 °C	24 hours
14. Novoseven Inj	+ 2 °C to + 8 °C	6 hr at 25 °C 24 hr at 5 °C
15. filgrastim	+ 2 °C to + 8 °C	Single dose
16. Verorab Vaccine	+ 2 °C to + 8 °C	Single dose
17. Human normal Immunoglobine	+ 2 °C to + 8 °C	Single dose
18. Alprostadil	+ 2 °C to + 8 °C	24 hr
19. Human tetanus Immunglobin	+ 2 °C to + 8 °C	Single dose
20. syngis	+ 2 °C to + 8 °C	Single dose
21. Human HB Immunoglobin	+ 2 °C to + 8 °C	Single dose
22. Teatanus Vaccine	+ 2 °C to + 8 °C	Single dose
23. Gonal F	+ 2 °C to + 8 °C	28 days Below 25 °C 3 Months at 25 °C
24. survanta	+ 2 °C to + 8 °C	Single dose
25. Methergine	+ 2 °C to + 8 °C	14 days out of refrigerator but not more than 25 °C
26. Insulin	+ 2 °C to + 8 °C	28 days
27. Minirin	+ 2 °C to + 8 °C	4 weeks
29. Tractocille	+ 2 °C to + 8 °C	Single dose
30. Pediatric multivitamin infusion	+ 2 °C to + 8 °C	Single dose
31. One alpha Injection	+ 2 °C to + 8 °C	Single dose
32. Syntocinon Inj	+ 2 °C to + 8 °C	Single dose
33. carbprost Inj	+ 2 °C to + 8 °C	
34. Anti D	+ 2 °C to + 8 °C	
35. Human Varicella globin	+ 2 °C to + 8 °C	
36. Antihemophilic Factor VIII	+ 2 °C to + 8 °C	

5.4.10 Table below provides a beyond-use date of medications after opening:

Formulation type	Expiry details	Comments
Tablets & capsules in original blister strips or container with printed expiry date	Manufacturer's expiry date as printed on original box or individual foils (check patient information leaflet)	
Tablets & capsules stored in dispensing bottles from pharmacy	6 months from date of dispensing unless otherwise informed by pharmacist	Write the DATE when opened on the Label
Tablets/Capsules stored in pharmacy packed blisters - Monitored Dosage System (MDS)	8 weeks from date of dispensing	Write the DATE when opened on the Label
Oral liquids (in original manufacturer's packaging or amber bottles)	6 months from date of opening or follow manufacturer's guidance e.g. for specially manufactured items or expiry date on packaging. For antibiotics, check with pharmacist if not clear from label.	Write the DATE when opened on the Label
External liquids (e.g. Lotions, shampoos & bath oils)	6 months from opening or manufacturer's recommendation where shorter	Write the DATE when opened on the Label
Creams in tubes or pump dispensers	3 months from date of opening or manufacturer's recommendations if shorter	Write the DATE when opened on the Label
Creams in pots, tubs or jars.	1 months from date of opening	Write the DATE when opened on the Label
Ointments in tubes or pump dispensers	6 months from date of opening or manufacturer's recommendations if shorter	Write the DATE when opened on the Label
Ointments in pots, tubs or jars.	3 months from date of opening or manufacturers recommendations if shorter	Write the DATE when opened on the Label
Sterile Eye/Ear/Nose drops/Ointments	28 days from date of opening	Write the DATE when opened on the Label
Inhalers	Manufacturer's expiry date	
Insulin	Unopened: Manufacturer's expiry date when stored in a fridge at temperature between 2°C and 8°C. Once opened: 4 weeks for insulin vials and pens unless otherwise stated. When in use can be kept at normal room temperature (i.e. less than 25°C).	Write the DATE when opened on the Label

5. MATERIAL AND EQUIPMENT:

- 5.1 Temperature Monitoring Log Sheet.
- 5.2 Drug recall form.
- 5.3 Drug quality form.

6. RESPONSIBILITIES:

- 6.1 Pharmacist: is responsible for performing monthly audits of patient care areas to ensure patient safety regarding the storage of medications.
- 6.2 Pharmacy staff and Head Nurses: are responsible for recording daily and maintaining a log sheet, for temperature of refrigerators in patient care areas, in the pharmacy and wards.
- 6.3 Maintenance supervisor: is responsible for repair the malfunction, when a refrigeration problem occurs.
- 6.4 The charge nurse: is responsible for calling maintenance, for after duty hour's refrigeration problems, and other role in storing medications in the ward.
- 6.5 Medical supply: is responsible for maintained all refrigerated medication from 2-8 degree during supply.

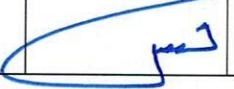
7. APPENDICES:

- 7.1 Refrigerator Temperature Checklist

8. REFERENCES:

- 8.1 General Pharmaceutical Care Administration policies and procedures.

9. APPROVALS:

	Name	Title	Signature	Date
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REFRIGERATOR TEMPERATURE CHECK LIST

YEAR: REFRIGERATOR NUMBER:

*Please, inform maintenance when temperature exceeds the range (2-8°C)

Days	JAN	FEB	MAR	APR	MAY	JUNE	JULY	AUG	SEPT	OCT	NOV	DEC
	INITIAL	SIGN										
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