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	Document Title:	PROPER HANDLING, STORAGE, SECURITY, INVENTORY AND CONTROL OF VACCINE

PURPOSE:

1. To ensure safe and effective handling of vaccine and provide guidance for storage and temperature monitoring of refrigerators.
2. To provide guidance to all staff who handle and/or administer vaccines on the storage and distribution of vaccines.
3. To ensure that cold chain is maintained for vaccines transported and handled within RMCI.

LEVEL:

All Physicians, Nurse and Pharmacists of Riverside Medical Center Incorporated


DEFINITION OF TERMS:

Vaccines are preparations containing antigenic substances that induce a specific and active immunity against an infective agent. They may contain:

- a) Live microorganisms attenuated by treatments designed to reduce their virulence but retain their immunogenicity.
- b) Microorganisms inactivated by chemical or physical means.
- c) Antigens produced by microorganism (as is or after detoxification) or biotechnological.

Shelf life is the length of time that food, drink, chemicals and many other perishable items are given before they are considered unsuitable for sale, use or consumption. It is the recommendation of time that products can be stored, during which the defined quality of a specified proportion of the goods remains acceptable under expected (or specified) conditions of distribution, storage and display.

Vaccine Cold Chain is a temperature-controlled environment used to maintain and distribute vaccines in optimal condition. It begins with the cold storage unit at the manufacturing plant, extends through transport of vaccine(s) to the

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distributor, then delivery and storage at the provider facility and ends with administration of vaccine to the patient. Appropriate storage conditions must be maintained at every link in the cold chain.


Thermometer/thermostat is a device that adjusts the amount of heating and cooling produced and/or distributed by automatically responding to the temperature in the environment.

Temperature Log Sheet is the written record that enables the staff to monitor and take action if temperatures go outside the required range.

Diluent is a liquid substances used to reconstitute vaccines prior to administration.


POLICY:

1. All refrigerators or freezers located within the department shall 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.
 - 1.1 The drug fridge temperature shall be monitored by the unit manager or designee and documented every 8 hours shift.
2. Vaccines shall only be removed from the fridge as necessary prior to administration to the patient.
3. Bar or dormitory style refrigerators shall not be used in the pharmacy or clinics unless it cannot be avoided.
4. Each practice, clinic or pharmacy shall have one trained individual responsible for the receipt, storage, rotation, checking of expiry dates of vaccines and the recording of refrigerator temperatures. There must be at least one staff assigned


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to cover times of absence. Any other staff who may be involved with vaccines shall also be trained appropriately.

5. All equipment shall have an accurate and functional thermometer inside as part of the equipment.
6. All refrigerators located within the department shall be routinely monitored to assure that the correct temperature range is maintained with respect to the items.
7. Temperature of the refrigerator shall be maintained at 2°C to 8°C. Refer to *Storage of Medication* policy and procedure.
8. Temperature monitoring log sheet shall be kept for 2 years.
9. Post temperature log on the door of the storage unit.
10. Vaccines shall not be placed in storage compartments of the refrigerator door, as the temperature is warmer than in the main body.
11. Out of range temperatures (outside the 2°C to 8°C for clinics shall be reported to the Engineering Department as soon as possible. Vaccines shall be removed from the refrigerator and taken to pharmacy for holding until the unit is repaired or replaced.
 - 11.1. Temperature fluctuations can occur for the following reasons:
 - 11.1.1 Restoring the fridge or after a busy immunization where the fridge door has been opened frequently.
 - 11.1.2 Fridge malfunctions or power failure.
 - 11.2. Advice shall be sought when:
 - 11.2.1 The thermometer is reading a current temperature above 8 degrees centigrade which has not corrected within an hour.

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- 11.2.2 The thermometer is reading a maximum temperature above 8 degrees centigrade when the fridge has not been opened.
- 11.2.3 Any temperature reading below 2 degrees centigrade.
- 11.2.4 A temperature reading greater than 8 degrees centigrade at the end or start of a day.
- 11.3. All cold chain incidents shall be reported and documented using the Incident Report Form.
- 11.4. Refrigerators shall be serviced and cleaned on a regular basis. Records shall be kept of any servicing or cleaning. It is recommended that refrigerators used for storing vaccines shall have automatic defrost cycles. This will maintain proper storage of the vaccine.
- 11.5. Vaccines shall not be tightly packed; room shall be left for the circulation of cold air. Stock shall not be placed in trays unless they have a mesh construction that allows the passage of air.
- 11.6. Vials or ampoules shall not be removed from their original packaging so as to retain information on batch numbers and expiry dates and protection from light.
- 11.7. Any vaccine that has reached their expiry date shall be disposed of as pharmaceutical waste and shall be sent to the main pharmacy.
- 11.8. Lockable doors should be kept locked, especially after office hours. Alternatively, the vaccine refrigerator shall be stored in a restricted area with lockable doors.
- 11.9. Always store vaccines in their original packaging with lids closed until ready for administration.
- 11.10. Do not leave vaccine in a storage unit that does not maintain temperature within the recommended range.
- 11.11. Do not use dry ice, even for temporary storage. Dry ice might expose the vaccines to temperature colder than -50°C (-58°F).

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DOCUMENTATION:


New Policy

DISSEMINATION:








1. RMC Hospital Communicator
2. Conducting hospital wide continuing education to all healthcare professionals.


REFERENCES:

1. CBAHI Standards
2. Public health England, protocol for Ordering, Storing and Handling Vaccines; March 2014
3. WHO Standards
4. USP Guidelines
5. Southern Health NHS; Temperature Management of Medicines Storage and Transport
6. Policies Procedures Guidelines, Clinical Medicine documents Medicine Management of Refrigerated Storage of Medicines and Vaccinations in Clinical Areas.
7. NHS North of Tyne "Storage, Distribution, Handling and Disposal of Vaccines".

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	Document Title:	PROPER HANDLING, STORAGE, SECURITY, INVENTORY AND CONTROL OF VACCINE

PURPOSE:


To ensure safe and effective handling of vaccine and provide guidance for storage and temperature monitoring of refrigerators.

SCOPE:

Applies to Inpatient Pharmacy Department and Nursing Service Department staff of Dr. Pablo O. Torre Memorial Hospital

PERSON RESPONSIBLE:

Nurses and Pharmacists and other Healthcare Staff, Clinical Department Heads, Managers, Supervisors and Clinical Facilitators, Engineering and Maintenance Service Staff, Pharmacy and Therapeutics Committee

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PROCEDURE:

1 Ordering

1.1 Pharmacy


- 1.1.1 The pharmacy inventory supervisor and his/her designee is responsible for stock control and ordering.
- 1.1.2 It is recommended that only one-month supply is ordered at any time. This will ensure that stock does not become outdated, and is less at risk of damage due to disruption of the cold chain. It will ensure that fridges are not overfilled.

1.2 Outpatient Clinics/OPD complex/ER

- 1.2.1 Requesting units will order on a regular basis to maintain appropriate stock levels in order to avoid over/under stocking and vaccines expiring before use.

2 Receipt of Vaccines in Pharmacy

- 2.1 Deliveries will be clearly labeled "Vaccines-Refrigerate Immediately" and will be signed for on receipt.
- 2.2 Deliveries will be inspected for leakages and damage. Affected vaccines should be returned to the supplier.
 - 2.2.1 Goods receive will be checked against the order and/or delivery note and any discrepancies reported to the supplier.
 - 2.2.2 Deliveries should be refrigerated immediately.
- 2.3 Never leave a vaccine delivery container unpacked and unattended.
- 2.4 Records will be kept for five (5) years. This will allow information to be readily available in the event of any batch recalls or if any vaccine becomes out date. Refer to *Drug Recall* policy and procedure. Vaccine on stock record includes:

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- 2.4.1 Date of delivery (and initials of the person who unpacked the delivery)
- 2.4.2 Vaccine and Diluent name and manufacturer
- 2.4.3 Number and expiration date lot (including expiration dates based on beyond use date guidance in the product information).
- 2.4.4 Number of doses received
- 2.4.5 Condition of each vaccine and Diluent upon arrival (e.i., did vaccine arrive in good condition at the proper temperature?).
- 2.4.6 Cold monitor reading is included in the shipping container and actions taken if the monitor was triggered, signaling a possible temperature excursion.
- 2.4.7 Number of doses used (i.e., administered, wasted, compromised, expired, or transferred).

2.5 Vaccines should be date-checked and rotated to ensure that the oldest stock is used first. First to Expire – First Out (FEFO).

3 Storage

3.1 Pharmacy

- 3.1.1 The refrigerator will be dedicated to the storage of pharmaceuticals or vaccines only.
- 3.1.2 The temperature of the refrigerator compartment will be maintained at 34°C to 46° Fahrenheit (2°C to 8°C). The temperature will be recorded twice daily and temperature monitoring log sheet will be available.
- 3.1.3 The refrigerators should be large enough to hold the necessary stock and allow sufficient space around the individual vaccine packages for air to circulate, thus enabling the temperature to remain constant.
- 3.1.4 If large quantities of vaccine are required, (i.e. during flu season), it may be necessary to increase the frequency of ordering, rather than

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the quantity ordered, to avoid receiving more than can be stored safely.

- 3.1.5 Vaccines will not be stored near the bottom of the compartment but on the middle shelves away from the freezer compartment. Freezing may inactivate the liquid vaccines and can cause the glass ampule to crack. Any vaccine subjected to temperature of 0°C and below must be discarded.
- 3.1.6 Ensure that space is left between the vaccine and the refrigerator wall, and that there is a space between each box or tray of vaccine in the refrigerator to allow for adequate air circulation around the vaccine.
- 3.1.7 Group vaccines by vaccine type in the refrigerator.
- 3.1.8 Refer to the product monograph or package insert to determine the required storage conditions for the vaccine diluent (e.g., refrigeration or room temperature).
- 3.1.9 Never leave vaccines on the counter or on the floor.
- 3.1.10 Protect all vaccines from light (either sunlight or fluorescent light) by not removing the box.

3.2 Nursing Units/Wards. Vaccines shall not be stored in all patient care units.

3.3 Clinics/OPD Complex/ ER


- 3.3.1 Upon receipt of the order from the pharmacy, vaccines must be kept in the original packaging and should only be packed immediately prior to dispatch. Cool box with cool packs should be used as recommended by the manufacturer's instruction. Vaccines must remain in the closed cool box until they are required for use or place in an appropriate refrigerator.

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- 3.3.2 A temperature monitoring device will be used. Temperature in the refrigerator will be monitored and written on the temperature monitoring log sheet twice daily.
- 3.3.3 Vaccines will not be stored near the bottom of the compartment but on the middle shelves away from the freezer compartment.
- 3.3.4 Whenever there is doubt about the integrity of a vaccine, it should be clearly marked "DO NOT USE" and send to pharmacy for appropriate disposal.

4 Vaccination Session

- 4.1 Vaccines should be prepared in a designated area away from any space where potentially contaminated items are placed.
- 4.2 **Only prepare vaccines when the staff in-charge is ready to administer them. Always check expiration dates and confirmation that you have selected the correct vaccine.**
- 4.3 **Only administer vaccines you have prepared. This is a quality control and patient safety issue and best practice standard of medication administration.**
- 4.4 **Never** use partial doses from two or more vials to obtain a dose of vaccine.
- 4.5 **Never** administer vaccine reconstituted with the wrong diluent(s).
- 4.6 **Never** use a stock vial of sterile water or normal saline to reconstitute vaccines. Diluent(s) are not interchangeable unless specified by the manufacturer.
- 4.7 **Vaccines will only be removed from the refrigerator at the beginning of the session when they will be used.**
- 4.8 All vaccines required for session will be removed from refrigerator at the same time to avoid frequent opening and closing of the refrigerator door.
- 4.9 Vaccines should be out of a refrigerator for as short a time as possible and certainly for no longer than two hours. Therefore, only the required number of doses should be taken.

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- 4.10 Freeze-dried vaccines should be reconstituted immediately prior to use and used within the manufacturers recommended period.
- 4.11 Once opened, vials must be disposed of at the end of the session, or if the manufacturer's recommended period has expired, return to the pharmacy store. Yellow sharp container should be used for disposal of all vaccines.

5 Spillage


- 5.1 Spillages must be cleared up quickly. PPE should be worn. The spillage should be soaked up with paper towels or underpads, taking care to avoid skin puncture from glass or needles. The area should be cleaned according to the Environmental health Services disinfection policy for infectious waste. Refer to *Infections Waste* policy and procedure.
- 5.2 Spillage on the skin should be washed with soap and water. If the vaccine is splashed in the eyes, they should be washed with sterile 0.9% sodium chloride solution and medical advice from Emergency should be sought.
- 5.3 Any spillage or incident that has resulted in a member of staff, patient or visitor being exposed to risk in RMCi premises, must be reported. Incident report must be recorded and documented.

6 Diluent Storage

- 6.1 Diluent is shipped with the corresponding vaccine.
- 6.2 Store diluent as directed in manufacturer's product information.
- 6.3 Store refrigerated diluent with corresponding vaccine (these diluent may contain vaccine antigen).
- 6.4 Do not freeze diluent; not even during transport.
- 6.5 Label diluent to avoid inadvertent use of the wrong diluent when reconstituting a vaccine.

7 Vaccine Placement and Labeling

- 7.1 Store vaccine away from unit walls, coils and vents.

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- 7.2 Keep vaccines in original packaging.
- 7.3 Stack in rows with same type of vaccine.
- 7.4 Use labels with vaccine names and age indicators or color coding.
- 7.5 Protect vaccine from light.

8 Security

- 8.1 Install a security/alarm system that will give a warning if the temperature rises or fall outside temperature.
- 8.2 Invest in a back-up generator that automatically provides to maintain the temperature in the refrigerator/freezer, should there be a power outage.
- 8.3 Prepare a written plan of action in the event of a power outage.
- 8.4 Install a lock on the refrigerator/freezer plug to ensure that it does not accidentally get unplugged.
- 8.5 Place a warning sign at the plug and another at the circuit breaker to ensure that the refrigerator/freezer power is not turned off.

9 Control and Inventory

- 9.1 Conduct a monthly vaccine and diluent inventory in all covered areas.
- 9.2 Avoid stocking excessive vaccine supplies minimum 30 days/maximum 120 days' supply (depends on the demand of certain vaccines).
- 9.3 Monitor vaccine(s) and diluent(s) expiration dates closely, contact pharmacy when they are 3 months away from the expiration date.
- 9.4 Rotate stock, so that vaccine and diluent with shortest expiration dates are used first (FEFO).
- 9.5 Never use expired vaccine or diluent.
- 9.6 Order vaccine responsibly based on: projected demand, storage capacity and current supply.
- 9.7 Request delivery during office hours.


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10 Preventive Measure

- 10.1 Use a guard or safety-lock plug
- 10.2 Post a warning sign above the plug and on the refrigerator.
- 10.3 Label fuses and circuit breakers.
- 10.4 Install temperature alarms.
- 10.5 Do not store vaccine in vegetable/fruit bins, deli drawers or doors
- 10.6 Perform daily inspection of storage unit(s).
- 10.7 If other biologic must be stored in the same unit, store them BELOW the vaccines to avoid contamination.
- 10.8 Use water bottles in the refrigerator and ice packs in the freezer to maintain temperature.
- 10.9 Containers of water labeled "DO NOT DRINK".

REFERENCES:

1. CBAHI Standards
2. Public health England, protocol for Ordering, Storing and Handling Vaccines; March 2014
3. WHO Standards
4. USP Guidelines
5. Southern Health NHS; Temperature Management of Medicines Storage and Transport
6. Policies Procedures Guidelines, Clinical Medicine documents Medicine Management of Refrigerated Storage of Medicines and Vaccinations in Clinical Areas.
7. NHS North of Tyne "Storage, Distribution, Handling and Disposal of Vaccines

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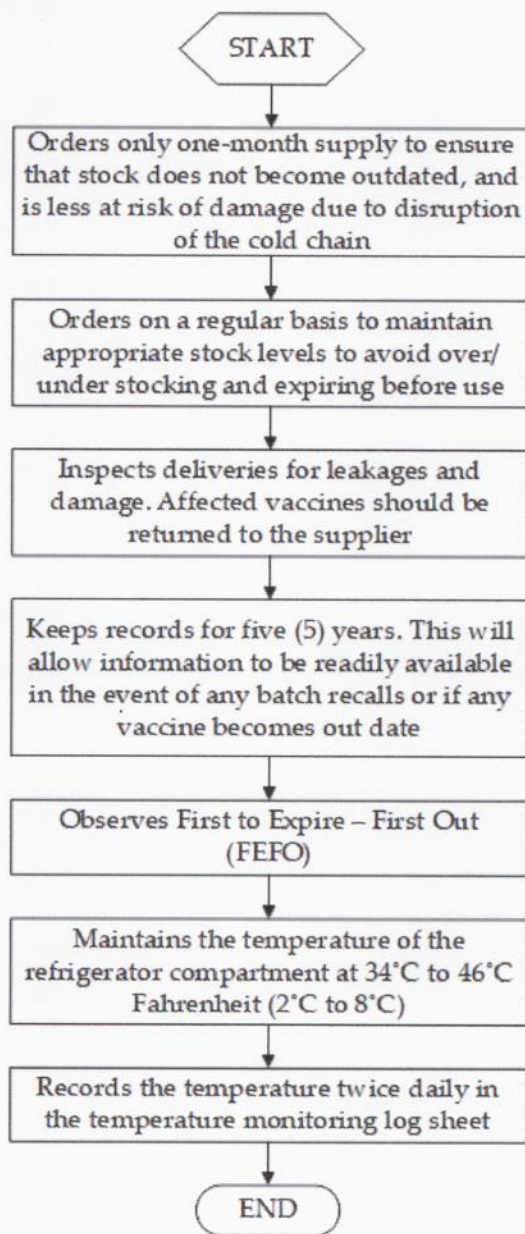



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FLOWCHART




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KEY TASKS	PERSON RESPONSIBLE
1. Orders only one-month supply to ensure that stock does not become outdated, and is less at risk of damage due to disruption of the cold chain.	Pharmacy Inventory Supervisor and his/her designee
2. Orders on a regular basis to maintain appropriate stock levels to avoid over/under stocking and expiring before use.	Requesting Units
3. Inspects deliveries for leakages and damage. Affected vaccines should be returned to the supplier.	Pharmacy Inventory Supervisor and his/her designee
4. Keeps records for five (5) years. This will allow information to be readily available in the event of any batch recalls or if any vaccine becomes out date.	
5. Observes First to Expire – First Out (FEFO).	
6. Maintains the temperature of the refrigerator compartment at 34°C to 46° Fahrenheit (2°C to 8°C).	
7. Records the temperature twice daily in the temperature monitoring log sheet.	

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