Texas Children's Hospital®

SOP Standard Operating Procedure

TITLE	**Global HOPE Pharmacy Medication Delivery, Storage, and Cold Chain Procedure**
SOP #	10767
DOCUMENT OWNER	Kristina Wilson-Lewis - Director, Global **H**ematology **O**ncology **P**ediatric **E**xcellence **(HOPE)**
THIS PROCEDURE APPLIES TO:	All Global HOPE Operations, Faculty & Staff at Baylor International Pediatric AIDS Initiative **(BIPAI)** Non-Governmental Organizations (NGO)
CATEGORIES	Subcategories of Clinical not selected. →Subcategories of Clinical not selected.

STATEMENT:

This standard operating procedure **(SOP)** explains the procedure for the receipt, storage, and handing of pharmaceutical products to ensure product integrity through maintenance of proper conditions of temperature.

Standard Operating Procedure

1. **Products will stored and handled based on the manufacturer's guidelines for the product in its original packaging.**
    - 1.1. All products should be stored in a manner such that drug stability, potency, integrity, and proper temperature are maintained.
        - 1.1.1. Liquid products must be placed on the lower shelves or on bottom of stacks.
        - 1.1.2. High security/high value products, including controlled substances, must be stored separately in appropriately monitored/restricted security areas.
        - 1.1.3. Remove damaged and/or expired products from the usable stock promptly, and dispose using established procedures.
        - 1.1.4. Arrangement of storage area should facilitate first-to-expire, first-out (FEFO) policy
    - 1.2. Temperature guidelines for each product are to be maintained throughout the duration of the shipping and receiving process as well as subsequent storage to ensure integrity of the product.
    - 1.3. Temperature and storage guidelines may change when products are removed from the original container and manipulated/compounded for patient use (e.g., the addition of a

medication to a diluent bag for intravenous administration). Storage and handling of this final product must follow published data and best practice recommendations.

2. Receipt of products at the site

2.1. All medication shipments should be delivered/shipped directly to the local site. The Global HOPE pharmacist, Program Director, or trained designee on site must receive the delivery in person. All shipments must be documented by in-person signature during normal business hours.

2.2. When receiving health products:

2.2.1. Ensure sufficient storage space.

2.2.2. Areas used for receiving and storing products must be prepared and cleaned.

2.2.3. Packages must be inspected for any damage or expiration.

2.3. If products are expired or have been damaged:

2.3.1. Separate damaged and/ or expired products separate from the usable stock.

2.3.2. If damage/expiration is observed while delivery personnel is still on-site, refuse the products and make notes of the problem(s) on the delivery note.

2.3.3. If damage or expiration is observed after delivery personnel has left site, follow facility procedures on the handling of damaged/expired products.

2.4. If products are not expired or have not been damaged:

2.4.1. Count number of units received for each product and compare to document of issue.

2.4.2. Make a record of the date and quantity received.

2.4.3. Ensure expiration date for every package or unit is marked visibly on the product.

2.4.4. Products must be arranged in the storage area to facilitate the FEFO procedure.

2.5. Hazardous drugs must be appropriately packaged and labeled to assure safe handling during delivery and unpacking.

2.6. Cold chain products should be unboxed immediately and transferred to appropriate storage conditions.

3. Any required temperature documentation must be completed immediately as per guidance included in the packaging or provided upon shipment by a distributor or partner (e.g., manual or electronic documentation of temperature tracker data). Products should be stored in an orderly manner.

3.1. Hazardous drugs should be stored separately from non-hazardous drugs

3.1.1. All medications should be stored in alphabetical order by generic name

3.1.2. Medications should be separated by route of administration, with separate areas for the following: parenteral preparations (i.e., IV, IM, subQ), oral solid dosing forms, oral suspension/solutions, topical creams/ointments/sprays, ophthalmic preparations (including drops, gels, ointments, etc.), intranasal products, and otic preparations.

4. The following guidelines should be used for determining how a medication should be stored:

4.1. Temperature excursions (i.e., exposure of drug products to temperatures outside the recommended storage range) can negatively affect product stability. Pharmaceutical grade thermometers should be used to monitor temperature in the pharmacy storeroom, freezers, and refrigerators.

4.2. Freezer: A place in which the temperature is maintained thermostatically between -25° C and -15° C (-13° F and 5° F). To ensure continuous storage of all frozen medications at the manufacturer recommendations, pharmacy area freezers should be maintained at a temperature range of -25° C and -15° C (-13° F and 5° F).

4.3. Refrigerator: A cold place in which the temperature is maintained between 2°C and 8°C (35.6°F and 46.4°F).

4.4. Keep cool: Store between 8°-15°C (45°-59°F).

4.5. Room temperature (controlled room temperature): A temperature held between 15°C and 25°C (59°F and 77°F). NOTE: the temperature range for alarm settings is 15°C to 25°C.

4.6. Ambient temperature: Items can be stored at the surrounding temperature. This temperature can be “room temperature” or under normal storage conditions, which is defined as storage in a dry, clean, well ventilated area at room temperatures between 15° to 25°C (59°-77°F) or up to 30°C, varying based on the climatic conditions.

4.7. Relative humidity [RH], or the humidity in pharmacy area, will also be monitored and logged. Product labels stating “protect from moisture,” should be stored in a space with no more 60% relative humidity.

4.8. Flammable products (e.g., acetone, alcohols, and kerosene): It is very important to stores the items in the coolest location possible and never in direct sunlight to avoid pressure build-up and to control evaporation rate.

4.8.1. Large supplies should be stored in a different location away from the main storage area, on the premises but it should be more than 20m away from other buildings. Equipment for firefighting should be easily available and large supplies should never be stored in the same area as medications.

4.8.2. Small supplies may be placed in a steel cabinet in a well-ventilated area, away from any electrical appliances and open flames. Cabinets should be marked to signify they contain highly flammable liquids, and the international hazard symbol must be displayed. Additionally, cabinet shelves shall be designed to contain and isolate spills. Flammables must always be stored in their original container.

4.9. Corrosive/ oxidant products (e.g., acetic acid, concentrated ammonia solutions, silver nitrate, sodium nitrate, and sodium hydroxide pellets) should always be stored away from flammables, in a separate steel cabinet to prevent leaks. Personnel must use appropriate industrial-type protective gloves and eyeglasses when handling the products.

5. Refrigerators and freezers

5.1. Each medication refrigerator or freezer should have two labels on the door:

5.1.1. Medication Refrigerator (or Medication Freezer)

5.1.2. Not for Storage of Flammables, Food, or Biohazardous Materials

5.2. Thermometers and alarms:

5.2.1. The temperature of each medication refrigerator or freezer should be checked daily (every business day staffed by pharmacy) and the temperature recorded on the Temperature Documentation Log.

5.2.2. If the temperature is not within range:

5.2.2.1. Contact the local Baylor COE Facilities Manager and the Hospital Biomedical Manager to inspect the refrigerator/freezer immediately.

5.2.2.2. Move the medications to another secure storage location with the appropriate temperature range (e.g., another pharmacy refrigerator).

5.2.2.3. Document the out of range temperature, duration of the temperature excursion (if known), and any follow up actions on the Daily Activity Checklist.

5.2.2.4. Email the Global HOPE Pharmacy Director and Program Manager with a brief description of the situation, mitigation plan, and any recommendations to prevent additional temperature excursions.

5.2.2.5. Is this a random event with unknown cause (or due to extremely hot weather etc.) and the temperature has since fallen back into range?

5.2.2.5.1. If yes, medications can be moved back from the temporary storage location and Global HOPE Pharmacy Director and Program Manager should be e-mailed with a brief description of the situation, mitigation plan, and any recommendations to prevent additional temperature excursions.

5.2.2.6. Can the refrigerator be repaired?

5.2.2.6.1. If yes, a service request must be submitted to repair the refrigerator. The request will be examined and if deemed necessary, refrigerator will

be sent back to the manufacturer to be repaired. Once the refrigerator has been repaired and is back on site, medications can be moved back from the temporary storage location. The Global HOPE Pharmacy Director and Program Manager should be e-mailed with a brief description of the situation, mitigation plan, and any recommendations to prevent additional temperature excursions.

5.2.2.6.2. If the refrigerator cannot be repaired, the refrigerator replacement process should be initiated by submitting a service request to replace the existing refrigerator. The Facility Budget will be examined, and if in budget, funding will be approved. The procurement team will place an order for a new refrigerator. Once the new refrigerator arrives on site, medications can be moved back from the temporary storage location. The Global HOPE Pharmacy Director and Program Manager should be e-mailed with a brief description of the situation, mitigation plan, and any recommendations to prevent additional temperature excursions.

5.3. Products that are sensitive to freezing or very low temperatures should be stored on the upper shelves as the coldest part of a refrigerator is at the bottom.

5.4. Maintain an adequate number of frozen icepacks (only those filled with water) to transport items requiring cold storage in cold boxes and/or vaccine carriers.

6. Storage of food and other non-pharmaceuticals in medication refrigerators or freezers is strictly prohibited.

7. Keeping Track of Items in the Storeroom: Refer to relevant SOP on Inventory Management.

8. Maintenance of Product Quality

8.1. Preventing damage and contamination

8.1.1. Physical damage: Crushing of products that are stored in bulk must be avoided. Products should be stacked to no more than 8 feet (2.5m) high. Fragile or heavy items should be placed in smaller stacks.

8.1.2. Contamination: Pharmacy areas should be cleaned regularly. Refer to relevant SOPs on Cleaning and Maintenance.

9. Cold Chain Processes

9.1. When determined that a cold chain process is required for additional distribution (e.g., from a Global HOPE storage facility to the dispensing pharmacy on site), Global HOPE will use a Cold Chain shipping system product approved by Supply Chain Management to ensure that the temperature level is maintained at all times.

9.2. Reference documents and qualifications of packaging guaranteeing 2°C and 8°C for different times based on the shipping solution should be maintained on file locally and in Houston.

9.3. Pharmacy staff must be trained on appropriate packing and storage conditions for cold chain products to ensure the integrity of the cold chain process. Packing instructions for each product used should be available in the pharmacy or saved on record for review by pharmacy staff.

9.4. Cold chain shipments will be packed to consider the longest duration for the cooler to reach the site. When scheduling for delivery of refrigerated medication, the time-in-transit should not be greater than 24 hours, unless under exigent circumstances.

10. Delays in delivery

10.1. When it is determined that product delivery may be impacted due to extreme weather, delivery delays, or breakdown in distribution process, alternative methods will be leveraged to support on-time delivery for patient to avoid missed doses, ensure integrity of the product, and avoid potential loss of adulterated product if appropriate temperature storage is broken.

10.2. Alternative delivery options include, but are not limited to:

10.2.1. Earlier or delayed shipment depending on timing of expected weather.

10.2.2. Alternative routes or modes of transit.

10.2.3. Re-sending product if original delivery time is sufficiently delayed to cause concern for product integrity.

REFERENCES:

Guidelines for the Storage of Essential Medicines and Other Health Commodities. World Health Organization. https://apps.who.int/medicinedocs/en/d/Js4885e/9.html. Published 2003. Accessed February 28, 2020.

SOP Administrator Use Only:

Original Creation Date: 10/16/2020	Version Creation Date: 10/16/2020	Effective Date: 10/16/2020

INSPECTION LOG

Refrigeration Temperatures

Date	______ Unit # Location ______						______ Walk-in # Location ______					
	A.M.			P.M.			A.M.			P.M.		
	Time	Temp.	Init.	Time	Temp.	Init.	Time	Temp.	Init.	Time	Temp.	Init.