VolkswagenStiftung

MARTIN-LUTHER-UNIVERSITÄT HALLE-WITTENBERG

MUHAS

UFZ

Workshop

Drug lifecycle control in Subsaharan Africa

From production to responsible safe disposal and elimination in wastewater treatment plants

(Med4Africa)

ALGORITHM AND ROLE OF STORAGE IN DRUG MANAGEMENT CYCLE

A Presentation by Adiukwu Paul

School of Pharmacy

University of Botswana

INTRODUCTION

- SDG 2030 Agenda has set a new horizon for response to improve access to essential medicines and health care products: **Influence Responsible Consumption and Production**

- This has generated the required need for the World Health Organisation (WHO) to adjust and strengthen all three levels of the organisation [WHO, 2012].

- In addressing the present need for access to health care products, a fundamental reflection at the state of medicine and health care products' supply chain is crucial in charting a pathway.

- At the fore front of possible collateral damage, if the present status quo remains, are the low and mid-income countries (LMICs) who bear the major brunt of poor access to healthcare.

- Noted that these countries are poorly equipped with necessary healthcare infrastructure. The lack in necessary capacity to manufacture health care products has further impeded previous efforts at improving access.

- In recent time, improving storage and store facilities for health care products has attracted the concerted attention from major stakeholders with the intent to ensure availability of affordable quality essential medicines and health care products.

- The perspective review of the drug management system will provide the stopgap arrangements and the role of storage in ameliorating the effect of stock outs in a challenged economy [Kebede *et al*., 2021].

INTRODUCTION: *Storage*

- Storage can be the act of stowing, retaining, holding, safe-keeping, conserving, preserving or storing an item temporarily or permanently as maybe suitable.
- In order to ensure a proper and adequate storage for health care products, the WHO has made available guidelines for good storage practices (GSP) [WHO, 2019]: proper action and arrangements for retaining goods in their defined properties and qualities throughout their shelf life or until the need for their use, application or disposal.
- Clear description of store spaces, and facility for holding or safe-keeping these items has been made crucial in the equation to achieve good storage. Some of these facilities include storeroom, warehouses etc.
- In view of the connotations of storage, there are tangible and intangible inventory in commerce.
- Storage facilities for tangible inventory are basically designed to hold and manage products with the sole purpose of controlling price fluctuations, addressing demands and improving accessibility.
- The act of storage cannot meet these ultimate goals without appropriate inventory management.
- Therefore, the aim is to critically review the contemporary drug management system, vis-à-vis the process and role of good storage in the management of health care products.

Health care product (HCP) storage

- Storage amenity for HCPs may range from small enclosures like a cupboard, storeroom to bigger facilities like warehouses which are designated for holding large business inventories.

- Health care inventory usually consists of products awaiting purchase or dispensing. How a business manage this inventory will depend on the
  - ✓ Type and Volume of the inventory,
  - ✓ Extent of activities taking place in the storage facility (indicative of size of business)
  - ✓ Available store space,
  - ✓ Cost of store space,
  - ✓ Spoilage concerns, as well as,
  - ✓ Future plans and/or needs for better efficiency.

Health care product (HCP) storage…..continues

- **Good storage** is a product of proper inventory management which can
  - ✓ optimize efficiency in the store activities,
  - ✓ minimize costs to inventory storage, and
  - ✓ save time spent both in cleaning, searching for items, responding to requests and receiving orders.

- As such, inventory storage method for any facility depends on its
  - ✓ business size,
  - ✓ business activities and
  - ✓ the applied inventory movement: first-in-first-out (FIFO), or last-in-first-out (LIFO) system.
  - ✓ .

- Whichever method used, it should ensure
  - ✓ the prevention or minimizing of inventory loss or spoilage,
  - ✓ adequate inventory tracking and
  - ✓ efficiency

Health care product (HCP) storage: *Inventory storage methods*

- Inventory storage is a necessity for almost all business models.
- The right storage method can bring efficiency and visibility to the business and product (inventory).
- Generally, businesses rely on 3 main storage methods. These methods can be broadly divided into
  - ✓ Self-storage (compartmentalized storage)
  - ✓ Warehouse storage (central storage)
  - ✓ Subcontracting storage: One innovation of this method is the point-of-use storage system (Dealers?)

Health care product (HCP) storage: *Inventory storage methods*

- 1. Self-storage: many small businesses may choose to manage the storage of their inventory. In this regard, they often opt for self-storage options and use existing spaces to store their stock (inventory). This method which can also be referred to as compartmentalized storage is cost-effective as it utilizes small storage facility either alone or in combination with one or more of the followings: drawers, cabinets, cupboards, refrigerators, mini-shelves, car garage, or converted small rooms within a building to store products. This can work well with small volume inventory which will always be on hand and easy to access.

- 2. Warehouse storage: Warehouse storage is the most traditional of all inventory storage methods. Because of its central nature to many other stores, it can also be called central storage. It is designed for bigger businesses and more accommodating to large volumes of inventory. An established warehouse can handle all inventory, receive shipments and supply products to smaller store locations or customers. In this storage method, inventory is better organized and managed by trained personnel.

- 3. Subcontracting storage: This can be another approach to manage large stock volumes. This will relieve the company from the burden and potential risks associated with managing the inventory storage. Usually in this method, a third-party storage provider will handle the receiving, packing and shipment of orders for the company. It is a costly approach to storage. However, the advent of e-commerce has provided opportunity for this method. The point-of-use storage system to reach costumers is an innovation of this method.

Health care product (HCP) storage: *Warehouse*

- Warehouse is a large storage facility (building) where materials or products can be retained before their distribution to required locations.
- It plays significant role in the smooth functioning of the supply chain system either for a country, manufacturer, importer, exporter, wholesaler, transport businesses, etc.
- It ensures the accomplishing of the essential functions of storage along with the services that allow for maximum inventory control.
- It acts as a centralised store or location for easier pick and transport of goods to desired consumption centres.
- Warehousing provides businesses with economic benefits, efficient storage, and also, operational logistics to reduce costs.
- It is indispensable in the supply chain in order to maintain a balance between demand and supply, as well as, provide fair stability to pricing.

Health care product (HCP) storage: *Types of warehouse*

- There are different types of warehouses:
  - ✓ General Warehouse:
  - ✓ Bonded Warehouse:
  - ✓ Fulfilment Centres:

- **General Warehouse**: General warehouse storage is the traditional commercial type big storage facility which provides accumulation of goods at one place and brings efficiency to the overall logistic management. It employs various storage systems, ranging from floor (stacking) storage, semi-automatic and automatic shelf-racking to manual/robotic storage systems and more.

- **Bonded Warehouse**: Bonded warehouses are Customs Controlled Warehouses for the retention of imported goods until duty clearance. It can be government or private owned. The primary function of bonded warehouses is to store bonded goods until customs duty is paid. It allow importers to handle temporary liquidity crunch until clearance and release of goods.

- **Fulfilment Centres**: Are order processing warehouses that are usually located closer to the customers or end users. These centres are third party storage operators who received contract (as in subcontracting storage method) to manage the storage of products. With the rise of e-commerce, fulfilment centres have become a vital part of the supply chain and aid activities such as order management, picking, packing, returns, control and more.

Health care product (HCP) storage: *Storage Systems*

- Storage system is the physical structure(s) and arrangement employed for optimal and effective use of space, as well as, ease of access to products.
- There are different storage systems which can be used either alone, or in combination.
- Basically in warehousing, there are three basic types of storage systems:
  - ✓ shelving,
  - ✓ racking and
  - ✓ stacking.
- The ultimate target of any system employed will be to ensure accessibility of inventory and efficiency of operations.
- The type of inventory and how fast it moves will determine the type of storage system that will work best for the facility and business.

Health care product (HCP) storage: *types of Storage Systems*

Common types of the storage systems are:

- Shelving (and bin) storage system
- Racking storage System:
  - ✓ Pallet Racking:
  - ✓ Pallet-less Racking:
- Stacking Storage System:
  - ✓ Pallet-Stacking:
  - ✓ Pallet-less Stacking:
- Some Special storage systems:
  - ✓ Dry storage system:
  - ✓ Cold (chain) storage system:
  - ✓ Point-of-Use storage system:
  - ✓ Access–controlled storage system:

- ***Shelving (and bin) storage system***: This approach employs shelves, sometimes in combination with bins, in the arrangement of stored inventory. It is a good and flexible manner to hold small inventory. It allows for good visibility and access to unit items. The system can be automated for easy retrieval of inventory.

- ***Racking storage System***: This system uses racks in the arrangement of products (inventory). Usually, inventories managed in this type of system are bulky. It is an approach utilised by warehouses and big storage facilities to allow for better space management and ease of access. Its sub-types which depends on whether or not the inventory is loaded on pallet are
  - ✓ *Pallet Racking*: is the most common storage system implemented at warehouses. In this case, loaded pallets are arranged on racks both in horizontal and/or vertical rows in multiple levels. It is commonly used due to the ease and cost effectiveness of installation.
  - ✓ *Pallet-less Racking*: is a system where products, not loaded on pallet are arranged on racks. The goods may be contained (or not) in cartons.

- ***Stacking Storage System***: This is an inventory storage system where products are loaded over each other on the floor. It is the predominant storage system at the grassroots and do not require any installation. Globally, it's a system which can be utilised by warehouses due to its low setup costs, flexibility, and the ability to exploit vertical space. However, efficiency is only realisable if the same type of products are placed in the same stack. Stacking can be categorized, depending on the number and arrangement of stacks in proximity, into
  - ✓ *single,*
  - ✓ *double* or
  - ✓ *block stacking*.

- ***Special storage systems***: There are some storage systems that are designed because of the peculiarity of the inventory or storage product. The uniqueness of each special storage system is usually aimed at maintaining security and quality of product to ensure quality service to end users. Some of these storage systems include

  - ✓ *Dry storage system*: Some inventory or goods like health care and agricultural products use dry storage to store shelf-stable items. The products may require a cool temperature with proper ventilation and adequate cleaning measures. The ideal temperatures for dry storage system range from 50 to 70° F (i.e. not exceeding 21° C) at a relative humidity not more than 60 %.

  - ✓ *Cold (chain) storage system*: Another type of inventory storage system used in pharmaceutical and agricultural sectors is the cold storage, referred to as cold chain in the pharmaceutical supply chain. It include the use of refrigerators and freezers to preserve the quality of products and prevent spoilage. Typical products managed in this manner are vaccines and products that are susceptible to denature due to high temperature.

  - ✓ *Point-of-Use storage system*: A point-of-use storage system delivers inventory directly to store locations or point-of-use locations. If a business supplies (or orders) inventory based on "when and as needed", storing inventory at the point-of-use will lower operational costs and reduce inventory errors.

  - ✓ *Access–controlled storage system*: This is common with controlled drugs, and sometimes, expensive frequently dispensed (or sold) items that are prone to theft. Using lockable systems will greatly control ease of access.

Health care product (HCP) storage: *types of Storage Systems*

- To optimize efficiency in inventory management, the choice or combination of choices of the type of storage system should be able to
  - ✓ Provide a robust management system to track inventory. There are software which can show all the inventory at a glance, provide accurate inventory reports and analyse trends for inventory forecasts. With a click of a button, reorder points can be set and new stock can be ordered.
  - ✓ Ease determination of reorder points for each inventory item. Avoid over or under-ordering by setting item thresholds to ensure good inventory management. As such, fast selling items will have more frequent reorders due to the higher frequency of the reordering points.
  - ✓ Allow for inventory checks and stock taking on a daily, weekly or more intervals to ensure reconciliation. Inventory checks are essential to monitor product volumes, reduce loss and prevent spoilage and theft.
  - ✓ Allow ease of upgrading the inventory storage system. If the storage system can no longer support the business sufficiently due to growth then, upgrading may be inevitable in order to improve management and sustain growth. When deciding what type of inventory storage system to use, the current and future plan should be in focus.

- It is not atypical to refer to a storage facilities either as medical, agricultural, mechanical or equipment store. Usually, this is borne out of the type of inventory in store.

- Most HCP storage facilities at the status of a warehouse are commonly referred to as Central Medical Stores.

- Such medical stores can utilize any or a combination of the different storage systems, depending on the size and extent of activities.

- The performance of any of these facility is greatly anchored on
  - ✓ Proper use of space
  - ✓ Provision of good layout or arrangement to enable unhindered activities
  - ✓ Minimal damages during storage.

Health care products storage: *Storage facility*

- Storage facilities where the inventory are health related (medicines, medical devices, etc.), cardinal requirements for good storage must include among others

  - ✓ Good Security
  - ✓ Space
  - ✓ Climate-Control
  - ✓ Pickup and Delivery Services (if central or warehouse)
  - ✓ Cleanliness (No Pests)
  - ✓ Insurance for Inventories

- Good Security

If pilferage of essential medicines must be arrested, this is one thing that must be addressed from the onset. Without doubt, it is assuring to know that your goods will be there when you return the next day. The storage facility should be well-lit with an access gate which is monitored around the clock. Good lighting will limit intruders and permit entrance only through the access gate.

Space

- A good storage facility should have enough space for everything you intend stocking with the flexibility to expand your stock in future. More and diverse space options offers the comfort to make changes to the arrangement and/or layout as may be necessary.

- Climate-Control

The best HCP storage facilities must provide climate-controlled storage units. In this perspective, there should be a system in place to control the facility temperature, humidity, and in some instances, lighting within the acceptable condition appropriate for storage. Without such, it is expected that the inventory will be subjected to constantly changing storage climatic conditions. The humidity is especially important because it determines how much moisture your inventories are exposed to. Sometimes, this can be devastating. Unregulated temperatures can also be as damaging as well. The consequence is very severe for products that requires cold chain storage system. If a facility is not climate-controlled, the storage units will not guarantee any required protection against rapid deterioration of inventories.

- Pickup and Delivery Services (if central or warehouse)

This service is common with most central and big storage facilities. It is related to distribution. Today, smaller businesses are beginning to do similar services for end users. A typical example is the home delivery of medications to the elderly, disabled or highly restrained individuals. This service can also, be subcontracted to a third party at a cost.

- Cleanliness (No Pests)

This is a major requirement for GSP. It is necessary to keep the storage facility clean regularly. This will keep away destructive pests and ensure that the integrity of the product packs are not compromised.

- Insurance for Inventories

This is one of the most neglected aspect in HCP inventory management. Unfortunately, it is one of the most important qualities of good storage particularly, for the commercial facilities. You want to have your product in the store and ready for use or application when needed. Unfortunately, with the best security and climate-controlled units, accidents may occur. In this kind of circumstance, what separates a regular and conventional storage from a good storage is the ability to ensure the protection of, not just the inventory, but also their value.

THE ALGORITHM OF GOOD STORAGE

- Good storage is basically
  - ✓ knowing what to store (or stock),
  - ✓ where to store it and
  - ✓ how to store it for the appropriate safe application or use at the right time.
- In essence, it is knowing what, where and how to retain an item till the right time for its rational use or application.
- In an ideal situation, good storage do not give room to
  - ✓ expiration,
  - ✓ deterioration or
  - ✓ damages of inventory (product).
- Good storage is required to ensure that products remain in good state and quality throughout the storage period or shelf life while in holding before use.
- Therefore in good storage, it is required that a clearly defined use of an item be established in order to make a decision for retention.
- It should be noted that good storage of a product extends beyond the shelf-life or expiration date. It includes the storage (services) before disposal.

THE ALGORITHM OF GOOD STORAGE: steps to guide processes

- Suitable steps or processes necessary to effect good storage can be broadly separated into two.

1. Requirements for good storage
   - ✓ Storage facility (physical infrastructure or building)
   - ✓ Store space arrangement (layout) and security

2. Maintenance or practices for good storage
   - ✓ Store logistics and personnel (administration)
   - ✓ Good storage practices (GSP)

THE ALGORITHM OF GOOD STORAGE: Storage facility (physical infrastructure or building)

- Location of facility
  - The potential site for a storage facility is mostly guided by existing laws and policies (on town planning).
  - Essentially, the decision for a site should consider the environmental impact assessment of increased
    - ✓ traffic,
    - ✓ noise,
    - ✓ air pollution and
    - ✓ other similar factors.

- Design of facility:
  - There are standard designs guided by existing policy requirements for storage facilities in most countries.
  - This is particularly true for warehouses and other buildings intended for central storage to hold large inventories.
  - The required specifications which varies, depending on the type of storage facility, may indicate
    - ✓ total floor space,
    - ✓ dimensions,
    - ✓ stress and strength.

THE ALGORITHM OF GOOD STORAGE: Storage facility (physical infrastructure or building)

- Design of facility:
  - The design must consider the
    - total volume of all the products or commodities (based on a maximum stock level), as well as,
    - required space for intended activities:
      - storage space,
      - operational logistics (offices) and aisle distances etc.
      - specific ancillary (sanitary, recreation, offices, receiving and packing, loading bays, cold room, quarantine and isolation) spaces
  - Such physical structures are also designed to allow access for good and regular cleaning.
  - Acceptably, smaller storage or storeroom may not be exposed to such terms or rigidity. Such facilities may only require a room fitted with either
    - cupboards,
    - shelves,
    - refrigerator, or
    - a combination or all the mentioned items with
    - a fitted climate control unit and a lockable cupboard for controlled drugs.

THE ALGORITHM OF GOOD STORAGE: Storage facility (physical infrastructure or building)

- Building fixtures and fittings:
  - fixtures for warehouses and central (big) medical stores should be incorporated with the view to allow for flexibility and future expansion of the business.
  - The use of widely placed columns or column free physical infrastructure can give sufficient flexibility to future space use.
  - Orientating the physical structure, and integrating fixtures that enhances the internal energy modulation of the structure is very beneficial for passive internal temperature control. This may be crucial in
    - ✓ hot and dry zones where good construction and night time ventilation can maintain temperatures below ambient temperature.
    - ✓ In hot and humid climate like the Sub-Sahara Africa (WHO, 2018), cross ventilation can provide a passive control of humidity while
    - ✓ in temperate regions, structures should be well insulated.

THE ALGORITHM OF GOOD STORAGE: Storage facility (physical infrastructure or building)

- Building fixtures and fittings:
  - Store fittings, like climate regulator units, can further enhance the viability of the physical structure in protecting products from deteriorating during storage.
    - ✓ Climate regulators are particularly necessary for the cold chain room. It is worthy to note that the shelf life for essential medicines may come in varying durations depending on the propensity to deteriorate. As such, their storage will require different climatic conditions.
    - ✓ Other fittings suitable for storage facility include smoke and fire detector, fire protection, firefighting equipment, etc.

- Insurance cover:
  - Contemporary practices in storage business is becoming highly demanding and of great risk.
  - The changing global climate and escalation of natural disaster has put paid to the dare need of insurance for warehouses and big storage facilities.
  - This current position is in consistence with the policy of increasing number of countries.
  - A suitable insurance cover for the entire physical infrastructure (including fixtures and fittings) may be necessary in some countries, though this may not be a matter of policy.

THE ALGORITHM OF GOOD STORAGE: Store space, arrangement (layout) and security

- **Space:**
  - Effective use of space is important for good storage practice.
  - A storeroom is under-utilized if too much space is vacant.
    - ✓ In this instance, adequate account of floor space cannot be given in terms of time and available stock during space under-utilization
  - A storeroom over-utilized when products are crammed up together.
    - ✓ Over subscription of space leads to damages and lost time and difficulty to practice GSP due to limited space.
  - In both instances money is lost.
- It is important to note that too much inventory (stock or assets) which may be in the form of "excess inventory", can be a major physical liability, just like too little stock will lead to loss of time and money.
- Thus, it is important to estimate the size of the required floor space for the maximum stock level for each product.

THE ALGORITHM OF GOOD STORAGE: Store space, arrangement (layout) and security

- Space:
  - The challenges warehouse managers usually struggle with is space maximization.
  - Improper space management may carry grave consequences which may include
    - ✓ blocked aisles,
    - ✓ lost stocks, and
    - ✓ low productivity
  - While moving to a larger facility might be a quick-fix solution, but it may not be a practical choice for most investors.
  - Other managers may consider resolving the challenge using Economic Order Quantity (EOQ): the ideal quantity a company may require (in terms of space based on previous demand) which will be purchased to minimize inventory costs, carrying costs or holding cost and shortages. Though this may decrease spending, it will not address the concern for space.
  - In addressing challenges with holding space and future shipment concerns, the adequacy of space for stocks and shipments can be determined by considering the space and quantity simultaneously.
  - Considering the space and quantity simultaneously can help in reliable decision making that will save time and money.

THE ALGORITHM OF GOOD STORAGE: Store space, arrangement (layout) and security

- Space:
  - Example of space calculation:
    - ✓ The amount of floor space requirement to store any product can be estimated using formal techniques [USAID, 2011]. For instance, the store space for 1,000,000 syringes of chloroquine phosphate injection can be determined by
    - ✓ Divide by 100 syringes per carton to give 10,000 cartons.
    - ✓ Multiply by the unit volume (Lx W x H) of each carton: 0.004307 m^3 per carton. It gives the total volume of 43.07 m3 for all the carton consignment.
    - ✓ Divide by 2.5 m (8ft) the maximum carton stack height (allowed in GSP) to determine the floor space required. This gives a total floor space of 17.23 m^2.
    - ✓ The total floor space can be multiplied by 2 to allow 100 percent extra for handling space. This gives a total of 34.46 m^2 floor space required for consignment.
    - ✓ For required dimension, determine the square root of 34.46 m^2 (5.87 m). In this sense, the floor area can be determined using suitable dimensions since the required floor space is approximately 35 m^2: 7 m by 5 m or 5 m by 7 m, depending on the design of the physical infrastructure (building).
  - Subsequent shipment (of the same product and same packaging) to replenish stock to the maximum stock level can easily be determined by simple arithmetic using

$$Y=(TS \times MSS)/(MSL)$$

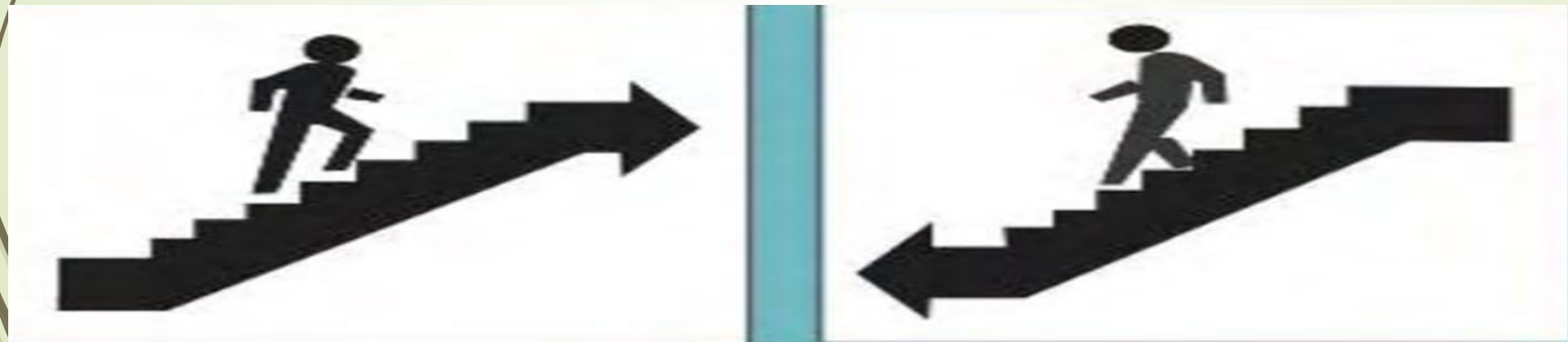
y: space required for shipment; TS: transit stock or shipment; MSS: maximum stock level space i.e. space for maximum stock level; MSL: maximum stock level

THE ALGORITHM OF GOOD STORAGE: Store space, arrangement (layout) and security

- Space:
  - Other techniques can also be adopted to determine storage space requirement in the warehouses and central storage facilities.
- Layout and arrangement:
  - To develop a workable layout for a storage facility, it may be important to identify the various activities that will be undertaken in the facility.
  - Space and activities can be reconciled to come up with a suitable layout.
  - To maximize the use of space pallets, racks, shelves and other equipment can be employed, depending on the activities and size of the facility.
  - Irrespective of the activities and size of the storage facility, layout must
    - ✓ allow adequate traffic flow and
    - ✓ unhindered store activities.
  - For many big storage facilities (warehouse), a number of sections or spaces which typifies store activities can be considered when arranging the spaces. Some of these sections include
    - ✓ Space for receiving, inspecting, and quarantine (if need be) of supplies
    - ✓ Space for picking, packing, and shipping of requisitions
    - ✓ Office space for store personnel
    - ✓ Space for security and/or vigilance activities

THE ALGORITHM OF GOOD STORAGE: Store space, arrangement (layout) and security

- Layout and arrangement:
  - Arrangement in the facility is supported by using shelves, racks, pallets, forklifts and other equipment.
  - The arrangement of the items (stocks) on these supporting equipment is usually executed, bearing in mind efficiency and comfort in the work place (ergonomic pattern).
  - The principle for arranging the items (layout) along the aisles in the storage space must be spelt out and understood by personnel right from the onset. There are several aisle layout options for inventory arrangement.
  - Whichever arrangement or combination of arrangements adopted, the aim is to
    - ✓ reduce time of accessing inventory, as well as,
    - ✓ optimize the use of space

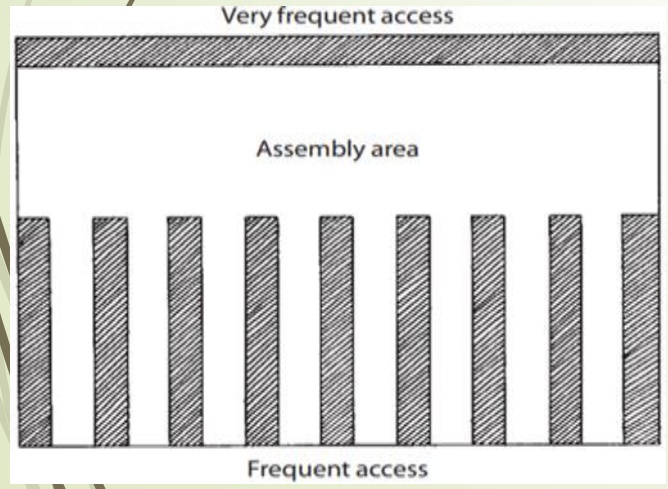


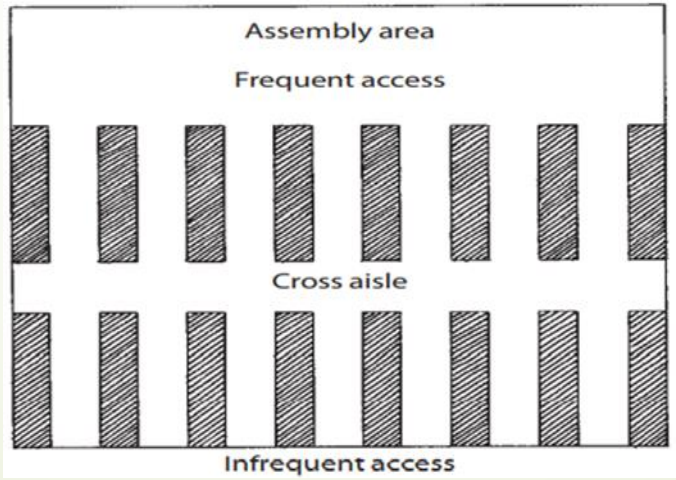
THE ALGORITHM OF GOOD STORAGE: Store space, arrangement (layout) and security

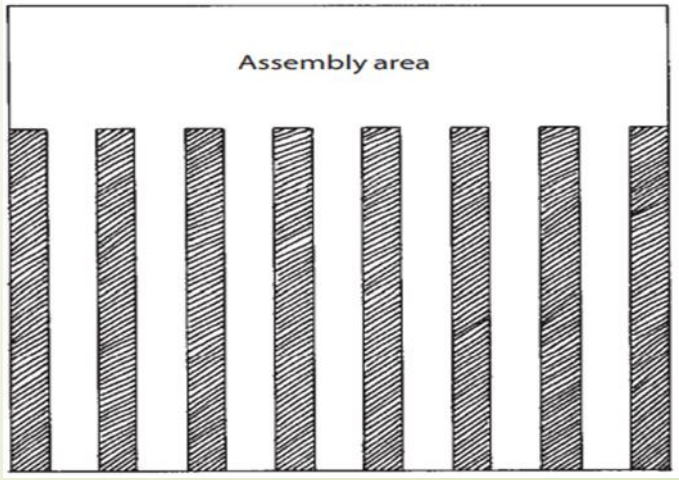
- Layout and arrangement:
  - Some of the arrangement options for inventory include
    - Option based on expiration or date of receiving date
      - ✓ First to expire first out (FEFO): Sometimes this arrangement can be referred to as first in first out (FIFO) if supplies are received in batches of recently/latest manufactured products (from same manufacturer); or
      - ✓ First in last out/Last in first out (FILO/LIFO) if the incoming products are closer to expiration than prior products in the store . It is a good arrangement for the medical store and can minimize wastages from expiry. It is important to issue products that will expire first, however, it is critical to ensure that received product is in good quality before shelving. Caution demands that the quality of the product under your control is that in the store you manage. As such, the remaining shelf life must be sufficient to allow the product to be used before the expiry date.
    - Option based on Alphabetical arrangement: This is an arrangement option commonly used by many medical storage facilities. It employs the generic names of medicines and it is suitable in the operation of the essential drug list (EDL).

THE ALGORITHM OF GOOD STORAGE: Store space, arrangement (layout) and security

- Layout and arrangement:
  - Option based on pharmacologic arrangement: This can also be called therapeutic arrangement. It is most useful in smaller storage facilities, storerooms or dispensaries. It is expected that the operator should have a level of knowledge in the pharmacological nature of medicinal products.
  - Option based on dosage form arrangement: There are various dosage forms of medicines: liquid, solid, semi-solid and gaseous. As such, tablets (solid), syrups (liquid) and inhalers (aerosol) will be arranged separate from each other. The application of this technique is usually supported by the ergonomic pattern to ensure precision.
  - Option based on frequency of movement (sales or dispensed or supplied) arrangement: In this option, frequently used products that move quickly through the store should be placed in front of the aisle or room. If shelved, they shelf should be in front of the aisle room or store space entrance. There are various patterns as suggested by the diagrams below.







THE ALGORITHM OF GOOD STORAGE: Store space, arrangement (layout) and security

- Layout and arrangement:
  - Commodity coding arrangement: This option uses the categorising of goods by a common identity such as cost or volume. Each category is given a code and arranged according to its code allocation.
    - ✓ This a flexible approach and works well in a computerized inventory control system.
    - ✓ It does not require significant knowledge in medical products.

THE ALGORITHM OF GOOD STORAGE: Store space, arrangement (layout) and security

- Security:
  - This is an integral aspect of stock management that should not be neglected in good storage.
  - Usually, investors will prefer to sleep with both eyes closed, knowing that their inventories or stock will be there when they return the next day.
  - It could be heart wrenching to notice that your stock is not there when needed.
  - Therefore, security must be a component part in the planning and execution of good storage.
  - Commonly used today are
    - ✓ surveillance (CCTV) cameras
    - ✓ alarm systems
    - ✓ Private security agencies are particularly engaged, to ensure adequate security for most central storage facilities.

THE ALGORITHM OF GOOD STORAGE: logistics and personnel (administration)

- Skilled and knowledgeable personnel, as well as, appropriate logistic management is indispensable to good storage.

- A clear and vision driven organisation which provides an efficient **inventory management** is a product of an appropriate and efficient logistic flow.

- For an efficient logistic flow, there must be appropriate personnel with the right skill and knowledge to drive the management.

- INVENTORY MANAGEMENT
  - Inventory is asset. It may refer to a list of assets which are components or raw materials which can be utilise
    - in daily operations,
    - production or
    - sells.

THE ALGORITHM OF GOOD STORAGE: logistics and personnel (administration)

- **INVENTORY MANAGEMENT**
  - As a verb, "inventory" refers to the act of counting or listing assets. As such, it is a current asset in accounting.
  - When the business of an organisation revolves around the selling of inventories (assets) then, the continuity and fiscal status of the business is directly dependent on the management of these inventories.
  - In this case, good inventory management will be core to good storage of the inventory.
  - The type of inventory, to a large extent, determines how it can be controlled or managed.
  - There are several types of inventory, but of particular interest in this study is the finished product inventory which are the HCPs.

THE ALGORITHM OF GOOD STORAGE: logistics and personnel (administration)

- **Inventory management:**
  - The management of health care products (HCP) as inventory is fundamentally focused on the
    - utilisation/use,
    - control and
    - Accounting
  - These 3 lines of actions guides the management in order to ensure that there is enough stock (inventory) at hand for the intended future application or use, at every point during patients' management.
  - Proper management of inventory will assist a business organisation to
    - ✓ Acquire the right quantity of stock and ensure optimization of inventory levels (maximum stock),
    - ✓ Maximize the use of space
    - ✓ Minimize wastes (damages, deterioration, expiration)
    - ✓ Reduce storage costs and
    - ✓ Prevent or minimize stock-outs.

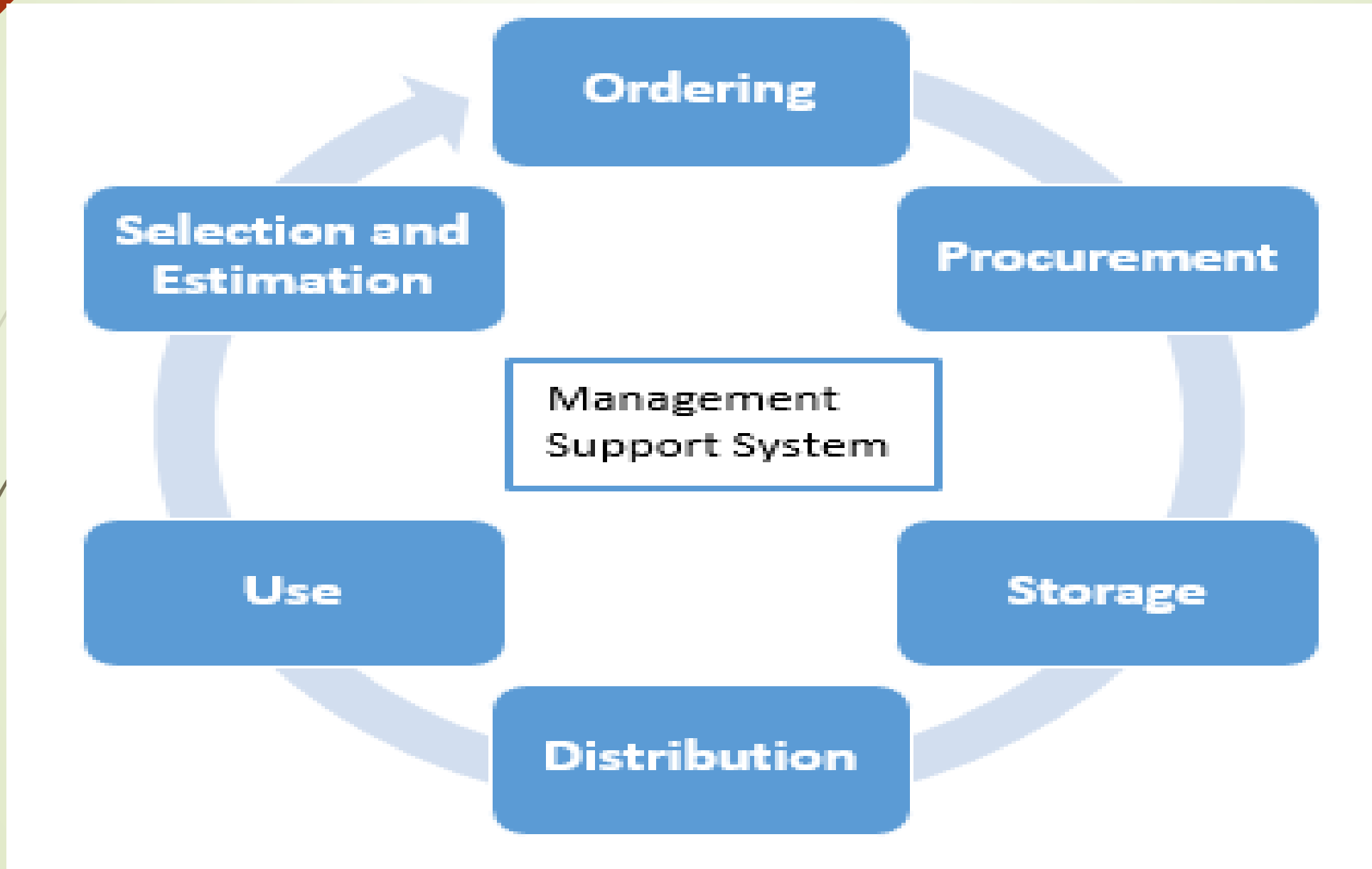
THE ALGORITHM OF GOOD STORAGE: logistics and personnel (administration)

- **Inventory management**:
  - Effective inventory (HCP) management has limitations and one of the major limitations is that it may detect, but not prevent theft.
  - Therefore, to achieve an effective implementation of inventory management, it is imperative to consider
    - ✓ Store space,
    - ✓ Efficient stock (inventory) analysis and control,
    - ✓ Accurate tracking and
    - ✓ Security.
- Inventory management is the key to the information on the product (HCP) procurement, distribution, consumption or usage and disposal.

THE ALGORITHM OF GOOD STORAGE: logistics and personnel (administration)

- **Drug (inventory: HCP) management cycle (DMC):**
  - DMC is a cycle that provides the practical steps required in inventory management.
  - It includes the required steps followed to ensure that good quality essential drugs at affordable prices are available for rational use.
  - Each of the components of the DMC builds on the previous component which leads logically to the next component, and held in place by the management support system (MSS).
  - The oversight function of the MSS framework is basically logistic to ensure a common goal for all the components of DMC and other activities:
    - ✓ Items' (drugs/HCP) selection, ordering and procurement,
    - ✓ Analysis and control of usage,
    - ✓ Storage
    - ✓ Distribution and
    - ✓ Waste handling.

THE ALGORITHM OF GOOD STORAGE: logistics and personnel (administration): **Drug (HCP) management cycle (DMC)**



THE ALGORITHM OF GOOD STORAGE: logistics and personnel (administration)

- **DMC: Management support system (MSS)**

  - The MSS is the framework that holds together, and provides the logistics for the functionality of the cycle. The functions include:

    - ✓ Organization of the structural support.
    - ✓ Financial management for sustainability.
    - ✓ Information management.
    - ✓ Human resources or personnel management.
    - ✓ Operationalising and monitoring of the (entire framework) and implementation of the drug policies, laws and regulations.

THE ALGORITHM OF GOOD STORAGE: logistics and personnel (administration)

- **DMC: Selection**
  - Appropriate selection is essential in generating a suitable list of quality essential products
    - ✓ that can be procured on time for use and
    - ✓ at a cost effective manner.
  - In developing countries, pharmaceuticals constitute up to 40% of the health care budget and up to 90% of the household budget (Ref).
  - In other words, acquiring medicines is an expensive venture and procuring all the medicines in commerce is not feasible.
  - Therefore, every organisation require an essential list, like the essential drug list (EDL), that is carefully selected to meet its needs.
  - A carefully selected list is usually a product of rational use; guided by the essential list (EDL) and treatment guidelines.

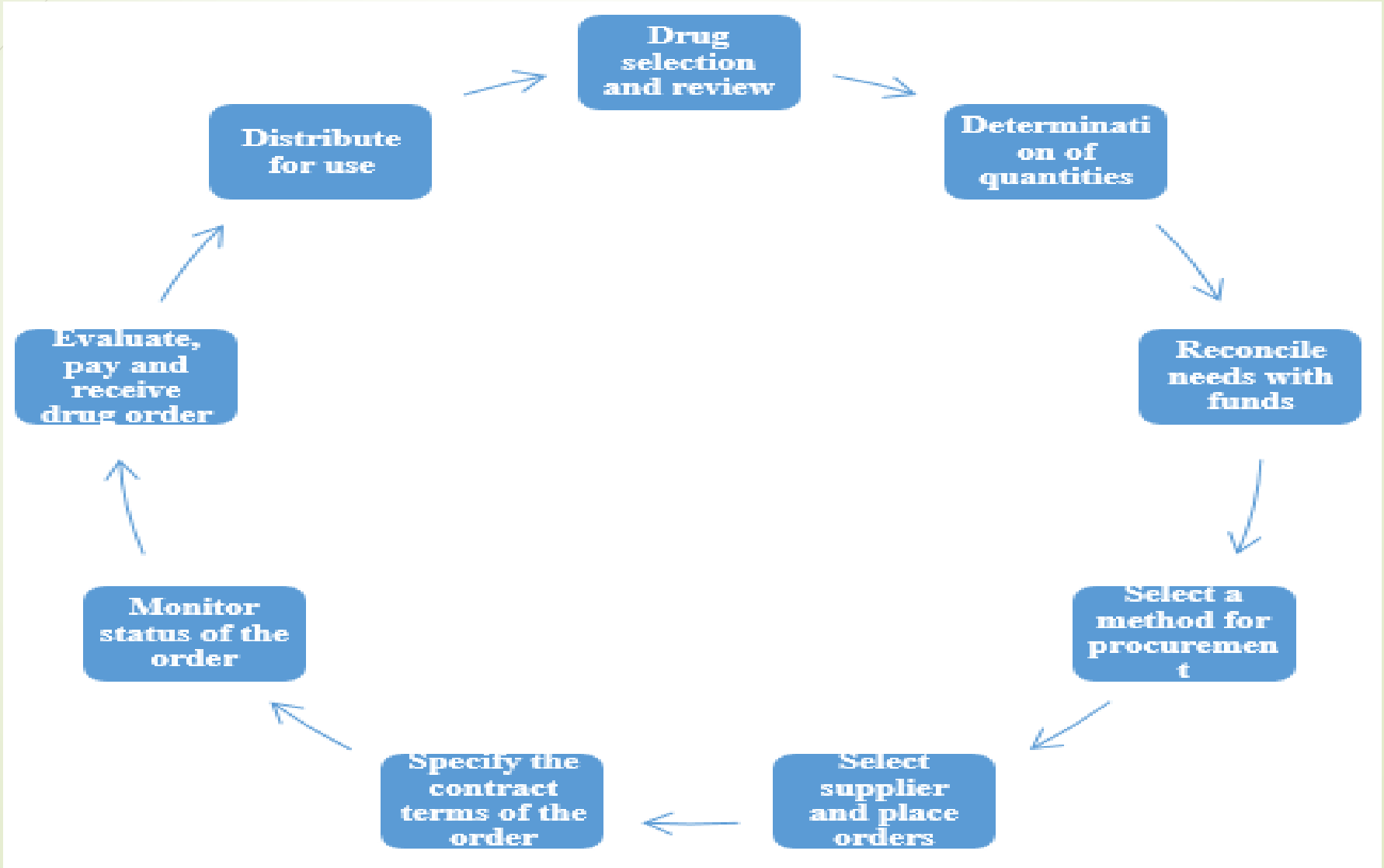
THE ALGORITHM OF GOOD STORAGE: logistics and personnel (administration)

- **DMC: Procurement**
  - Drug procurement procedure may vary depending on the organisation or country, however, the components of an effective procurement scheme is essentially the same. The efficiency of such scheme should be able to address
    - ✓ Selection of the most cost-effective essential drugs to treat commonly encountered diseases
    - ✓ Accurate quantification of the needs
    - ✓ Properly pre-select potential suppliers: for the order of supplies
    - ✓ Manage procurement and delivery (receive supplies and financial settlements)
    - ✓ Ensure good quality products are received
    - ✓ Monitor the performance of suppliers and the procurement system.

- Failure in any of these areas will ultimately lead to lack of access to (or stock out of)appropriate drugs with increase in wastage.

THE ALGORITHM OF GOOD STORAGE: logistics and personnel (administration)

- **Typical Procurement cycle**



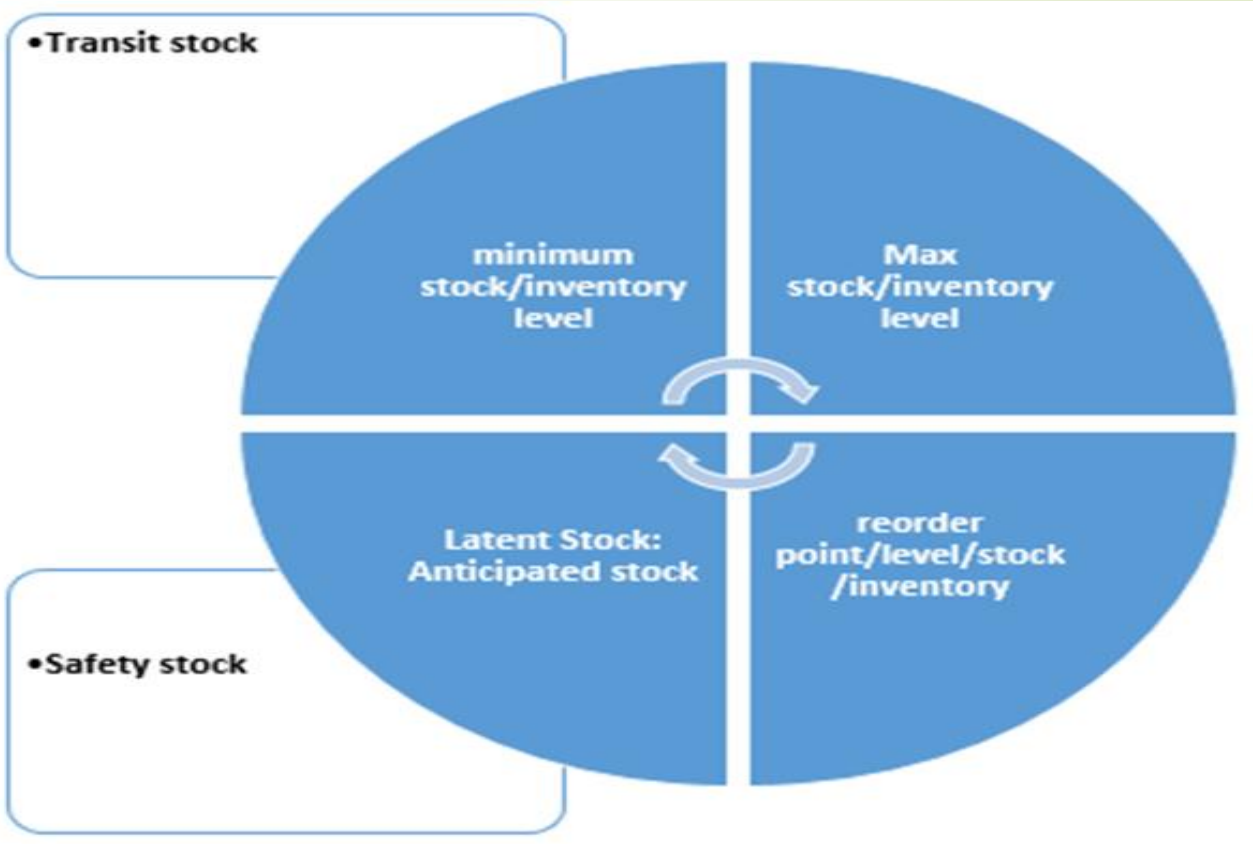
THE ALGORITHM OF GOOD STORAGE: logistics and personnel (administration)

- **DMC: Drug (inventory: HCPs) analysis and control**
  - Also known as stock control, it is the process of ensuring that the right quantity of good quality stock are available at the right time and price, in order to satisfy demand while maintaining the costs associated with storage at a minimum.
  - The act of inventory control involves the indulgence of knowledgeable and skilled personnel. It encompasses activities to
    - ✓ Determine quantity of stock to procure (transit stock/inventory) for the right space;
    - ✓ Monitoring of stock levels: minimum, maximum, and reorder stock levels;
    - ✓ Ordering stock by using the ordering point or stock level
    - ✓ receiving stock
    - ✓ Responding to sudden change to demand and supply: safety stock;
    - ✓ Physical stock monitoring (tracking and balancing of stock), as well as,
    - ✓ Monitoring business turnover.

THE ALGORITHM OF GOOD STORAGE: logistics and personnel (administration)

DMC: Drug (inventory: HCPs) analysis and control

- In some instances, it may require the application of the Just-in-time (JIT) inventory control technique. Particularly as may be related to space or in-process/intermediate products
- JIT inventory control allows the receiving of ordered stock particularly, raw materials required for production schedules, to coincide with the time for use. Utilizing the JIT technique is a great way to reduce costs.



A typical Inventory (analysis and) Control Cycle:

NB: safety and anticipatory (smothering) inventory is equal to the buffering stock/inventory. This is to prevent under-stocking or over-stock from occurring as a consequence of any unexpected event.

THE ALGORITHM OF GOOD STORAGE: logistics and personnel (administration)

- **DMC: Drug (inventory: HCPs) analysis and control**

  - There are 2 methods of inventory analysis and control.
    - Manual
    - Automated

  - manual inventory analysis and control system (**MICS**):
    - ✓ can also be called periodic inventory control system (**PICS**).
    - ✓ It keeps up to date with the total stock by a physical count of goods on hand at specific intervals.
    - ✓ As such, the stock at hand cannot be known until after the interval, and also, after the physical count is completed.
    - ✓ This is time and manpower consuming and will not be effective for large inventory management.
    - ✓ In MICS basically, stock books, tally or bin cards, ledgers, or spreadsheets can be employed in a manual system to effect the analysis and control of stock.
    - ✓ The manual system may be suitable for small, and new enterprises however, it may not be sustainable as the enterprise grows.
    - ✓ The above reason is why the automated stock analysis and control systems are gaining momentum in contemporary inventory management, particularly the cloud based software

THE ALGORITHM OF GOOD STORAGE: logistics and personnel (administration)

- **DMC: Drug (inventory: HCPs) analysis and control**
  - Automated inventory analysis and control system (**AICS**):
    - ✓ Also called continuous inventory analysis and control system (**CICS**),
    - ✓ The automated system is efficient in tracking inventory in real-time.
    - ✓ It utilizes the barcode of the items which is scanned and removed from a global inventory database when sold.
    - ✓ When received, it is scanned and added to the inventory database.
    - ✓ Both ends of the system can access the same global database and information to provide a detailed overview of the inventory level, as well as, changes at all times.
    - ✓ It is suitable for all volumes of inventory.
    - ✓ Other technologies that have found use in this system are the Automatic Identification and Data Capture (AIDC) software like radiofrequency identification (RFID), and also, the Global Positioning System (GPS).
  - Regardless of the approach: JIT inventory control, MICS or AICS, it is pertinent to ensure periodic review of the stock control system employed, vis-a-vis the performance of the inventory management.

THE ALGORITHM OF GOOD STORAGE: logistics and personnel (administration)

- **DMC: Distribution**

  - This is the movement (or spread) of an item or product from a central location, usually the manufacturer or the wholesaler, down the supply chain network to different locations/point of use or the end users.

  - Usually, it is a routine logistic activity in response to placed orders or requests.

  - In some logistic systems, the quantity to be supplied is determined by persons placing the order. This is called a Requisition or Pull System.

  - In other systems, the quantity to be supplied is determined by the persons filling the order. This is called Allocation or Push system.

  - The requisition (pull) system gives room for persons placing the order to determine the required store space and make adequate arrangement to receive stock. This may not be exactly the same for the allocation (push) system.

THE ALGORITHM OF GOOD STORAGE: logistics and personnel (administration)

- **DMC: Distribution**
  - Because most of the product manufacturers are based internationally, the most common in-country distribution system is a system where products flow from central medical stores to districts and regions; and ultimately to service delivery points and end users.
  - In the utilization of health care products, distribution play an essential role in the logistics system. However, to maintain a functional distribution system, you must consider some salient factors in transportation planning and execution:
    - ✓ Operations management
    - ✓ Fleet management
    - ✓ Human resources
    - ✓ Performance monitoring and costs
    - ✓ Insurance (for businesses).
  - However, not all distribution concepts may potent transportation. Distribution by a health facility storeroom to its networks or units may not incur expense akin to such distributions between facilities.
  - Whichever case this maybe, it is important to monitor the operational and human management.

THE ALGORITHM OF GOOD STORAGE: logistics and personnel (administration)

- **Health care waste product (HCWP) storage and handling**:

  - HCWPs are generated at
    - ✓ health care facilities,
    - ✓ laboratories, and
    - ✓ research facilities.

  - Examples includes
    - ✓ Sharps (including used needles),
    - ✓ used gauze,
    - ✓ blood/IV lines,
    - ✓ gloves, infusion sets, scalpels, blades, and broken glass are of HCW.
    - ✓ Also it includes expired drugs, laboratory reagents, and cleaning solvents.

THE ALGORITHM OF GOOD STORAGE: logistics and personnel (administration)

- **Health care waste product (HCWP) storage and handling**:
  - HCWP is a major health and environmental concern.
  - The primary objective to properly manage HCWP is to protect health workers and facility staff, the community and the environment.
  - A well-functioning logistics system is fundamental to the proper management of HCWP at various levels which include
    - ✓ Adequate waste storage away from active and viable stock
    - ✓ Proper waste handling and
    - ✓ Appropriate and immediate transportation from the originating facility to the final HCW disposal

THE ALGORITHM OF GOOD STORAGE: logistics and personnel (administration)

- **Health care waste product (HCWP) storage and handling**:
  - To store HCW properly and safely, it is recommend that existing standard operational procedures (SOPs) be followed (blue book).
  - As such, chemical wastes like expired and damaged pharmaceuticals should be stored separately from in-use products.
  - It is proper to separate HCWPs based on the main categories (represented with colours):
    - ✓ Infectious hazardous waste
    - ✓ Non-infectious hazardous waste
    - ✓ Non-hazardous waste and
    - ✓ General waste.
- People handling wastes should have access to protective equipment that will enable them to safely carry out their duties.
- HCWPs and disposal transportation involves movement internally, and also from the point where the waste is created (sometimes via an intermediate facility) to a final storage at the eventual disposal site.
- To avoid contamination during transport, hazardous waste should be separate from regular or general wastes.

THE ALGORITHM OF GOOD STORAGE: Good storage practices (GSP)

- **GSP** is that part of quality assurance in the DMC that ensures that the quality of products are maintained by means of adequate controls during storage.
- It is the day to day activities carried out to ensure that products or items retain their ascribed qualities throughout the storage period and before expiration.
- It can be considered rightly, as good store maintenance culture. It requires an SOP for every facility.
- It is expected that the storage facility management will engage responsible personnel with the right skills and knowledge for the sole purpose of ensuring GSP.
- GSP include:
  - ✓ Regular clean-up and disinfection of storage space or storerooms.
  - ✓ Store supplies in a dry, well-lit and well-ventilated storeroom, out of direct sunlight.
  - ✓ Secure the storeroom from water penetration.
  - ✓ Ensure fire safety equipment is available and accessible. Personnel should be trained to use it.
  - ✓ Store latex products away from electric motors and fluorescent lights.

THE ALGORITHM OF GOOD STORAGE: Good storage practices (GSP)

- ✓ Maintain and monitor climate controlled (cold) storage facility, including cold chain for required commodities
- ✓ Keep narcotics and other controlled substances in a locked and regulated area.
- ✓ Store flammable products separately, using appropriate safety precautions.
- ✓ Stack cartons at least
  - 10 cm (4 in) off the floor,
  - 30 cm (1 ft) away from the walls and other stacks, and
  - Not more than 250 cm (8 ft) high.
  - Store medical supplies separately, away from insecticides, chemicals, old files, office supplies, and other materials.
- ✓ Arrange cartons so that arrows point up; ensure that identification labels, expiry, retest and manufacturing dates are visible.
- ✓ Store supplies in a manner accessible for FEFO, counting, and general management.

ROLES AND BENEFITS OF GOOD STORAGE

Benefits of good storage revolves around the appropriate execution of the inventory management which is essential for planning and provision of the required services.

- As such, the role of good storage which is delivered through the logistics of the MSS, provides that part of the products' quality assurance required after manufacture, during holding and before disposal.

- In perspective, it will assist to:
  - ✓ Reduce or eliminate "out of stocks".
  - ✓ Improve product access.
  - ✓ Reduce or eliminate excess or overstocks which also has cost implication.
  - ✓ Eliminate understocking or under subscription of space
  - ✓ Optimize stock to enable identification of frequent and infrequent moving items.
  - ✓ Ensure adequate tracking
  - ✓ Provide product value protection and business continuity.
  - ✓ Optimize space utilization
  - ✓ Minimize holding cost
  - ✓ Monitor and eliminate or reduce losses due to damages, expiration and deterioration
  - ✓ Monitor expired, damaged and deteriorated items for proper handling and disposal.
  - ✓ Ensures adequate economic returns for business solvency

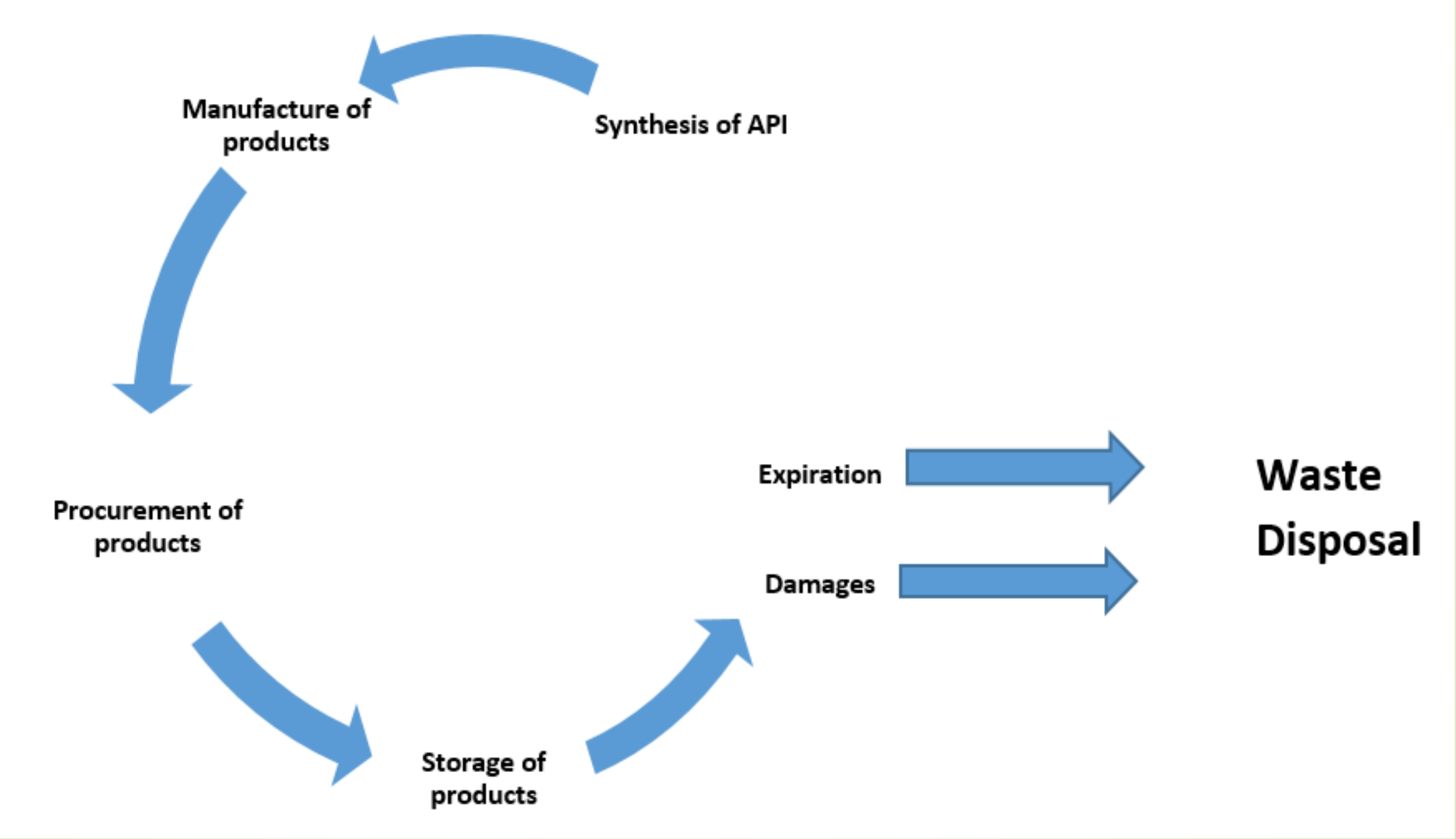
ROLES AND BENEFITS OF GOOD STORAGE

- Increase returns on stock (investment) through inventory flow.
- ✓ Improve efficiency and sales through time and space management
- ✓ Improve items retrieval time from the warehouse or storeroom.
- ✓ Mitigate theft and abuse. Note that uncontrolled raw materials and goods can easily go missing.
- ✓ Prevent or eliminate redundancies (items remaining too long in the stock), or excess of the same items.
- ✓ Maintain fair stability in pricing of items, despite slight market price fluctuations.
- ✓ Overcome variability in the supply chain (delays in supply) in order to prevent "out of stock" and maintain the provision of services.
- ✓ Allows proper traffic and product distribution.
- ✓ Provides good handling of damaged and/or expired products.
- ✓ May supports appropriate disposal of products requiring recycle

EMERGING ROLE OF GOOD STORAGE IN THE ACTIVE PHARMACEUTICAL INGREDIENT (API) MANAGEMENT (APIM), LIFE CYCLE AND DISPOSAL

- As a standard practice, API can be assigned a retest date and/or expiry date at the point of release.
- A retest date portents a period after which the API can only be used after valid tests or approved quantitative and qualitative evaluation.
- This is contrary to the expiration date which indicates the shelf life and last day (date) the API is guaranteed for use, if stored according to the stipulated conditions (ICH, 2006).
- APIM and Life Cycle: The APIM cycle provides practical steps for the management of API as an inventory. This management is typical of any inventory management as explained (above).
- The uniqueness in APIM is premised in the retests after set period of storage, as stipulated for good manufacturing procedure (GMP) (ICH, 2006).
- However, the utilization cycle of API is as designated by the approximate trail for production of health products and eventual disposal.

EMERGING ROLE OF GOOD STORAGE .....



EMERGING ROLE OF GOOD STORAGE ……..

Mythology about expiry date among patients and the healthcare community is associated with the toxicity and dangers of using expired drugs [Mohit *et al*., 2019].

- This fable has made a lucrative business out of the destruction and disposal of expired health care products along with possibly and potentially useful APIs.
- The principle of expiry date for health care products is occasioned by the allocated shelf period (shelf-life) for guaranteed efficacy and safety by the manufacturer.
- It is considered to be the period taken for a product's API to depreciate or degrade to 90 % of its original content in the product.
- Such period is premeditated based on stability studies: accelerated and/or real time stability studies.
- Although prior studies have shown that the degradation product of some health care products are toxic (Ellepola *et al*., 2020; Melo *et al*., 2014], the extent of toxicity vis-à-vis the safety of many of these health care products after expiry date, have remained largely speculative than concrete data.

EMERGING ROLE OF GOOD STORAGE ……..

- Most of the known degradation products are organic, and considered to be by-products from the API synthetic process and its degradation (and possibly excipients) during the transient time between its use in production, storage and consumption or expiration of the product [Melo *et al*., 2014].

- Such secondary products or agents, commonly referred to as organic impurities, are not unexpected or uncommon with health care products.

- The International Conference on Harmonisation (ICH), for the sake of product registration, suggests that the amount of degradation product permissible in a product be defined along the fine lines of notification, identification, reporting and qualification threshold [ICH, 2006].

- Basically, contemporary expiration date determination do not necessarily incorporate these thresholds in the eventual shelf-life estimation.

- However, some regulatory concerns are based on the fact that the presence of some chemicals, even in small amounts, can influence the quality and safety of pharmaceutical (health care) products (Roy, 2002].

EMERGING ROLE OF GOOD STORAGE ……..

- This is not in any way to demean or undermine the expiry caution by the manufacturer.
- Perhaps, it is a prompt for a quest to probe the possible prospects of the expired medicine or health care product.
- Such stance may provide a standard API recycling procedure for expired medicines in order to
  - Address the recurrence of “stock outs” and
  - Manage the adverse effects of disposing the increasing volumes of health care waste products to the environment.

Health care waste product management

The need to ensure adequate and proper disposal of health care wastes (HCW) has become a global concern.

- This is the genesis behind the emergence of the World Health Organization (WHO) handbook on the safe, sustainable and affordable management of health-care wastes, commonly known as "the Blue Book" [Chartier *et al*., 2014].

- Fifteen to 25 % of wastes generated by health care activities have been reported to be hazardous and possess the potential to be detrimental to health and the environment [Padmanabhan *et al*., 2018].

- These wastes which include expired drugs, laboratory reagents, and cleaning solvents are mainly generated at health care, laboratory, and research facilities.

Health care waste product management

- The primary objective for proper waste management is targeted at preventing associated occupational hazards and the eventual impact on the environment.

- To guarantee this objective, it is paramount to have a functional logistic which will require among others
  - ✓ Adequate waste storage space
  - ✓ Trained personnel in waste management
  - ✓ Equipment for proper waste handling
  - ✓ Adequate funding and
  - ✓ Appropriate and immediate transportation from the originating facility to the final HCW disposal.

Health care waste product management

- For the low and middle income countries (LIMCs), it is an enormous task managing the increasing waste products.

- In the United States of America (USA), available record shows that the hospitals alone, discard over $800 million worth of drug products annually. This do not include the costs of expired drugs at long-term-care, retail pharmacies and consumer medicine cabinets [Allen, 2017].

- A study in India showed that almost 92.6 % of households noted to have expired medicinal products discarded the products after few days in house hold trash cans [Manocha *et al*., 2020]. While in Mwanza, Tanzania 96 % of household in a study, withheld unused medications which were supposed to be disposed [Marwa *et al*., 2021].

- These data are evidences of inherent challenges involved in dealing with the increasing volume of waste products.

Reset advocacy concept for stock-out and disposal resolution

- Addressing the enormous challenge posed by the health care waste products especially, in the LMICs will require concerted effort from all the stakeholders.

- Currently, some of the techniques employed in the disposal of wastes include
  - ✓ Recycling.
  - ✓ Plasma Gasification.
  - ✓ Composting.
  - ✓ Incineration.
  - ✓ Sanitary Landfill

Reset advocacy for expired HCPs, stock-out and disposal

- Although the techniques may not be satisfactory or applicable to all known waste products, more programmes have been introduced with the view to ameliorate the effects of the increasing volume.
- An instance is the "National Prescription Drug Take Back Day" sponsored by the USA Drug Enforcement Administration (DEA).
- One other proposed approach is "Recycling of Expensive Medicines" [Pomerantz, 2004]. The list is inexhaustible.
- However, waste management measures will be greatly beneficial when executed with the commitment to provide a profound viable economic, and environmental friendly outcomes.
- This brings ashore the potentials of exploring the concept of waste recycling for expired health care products.

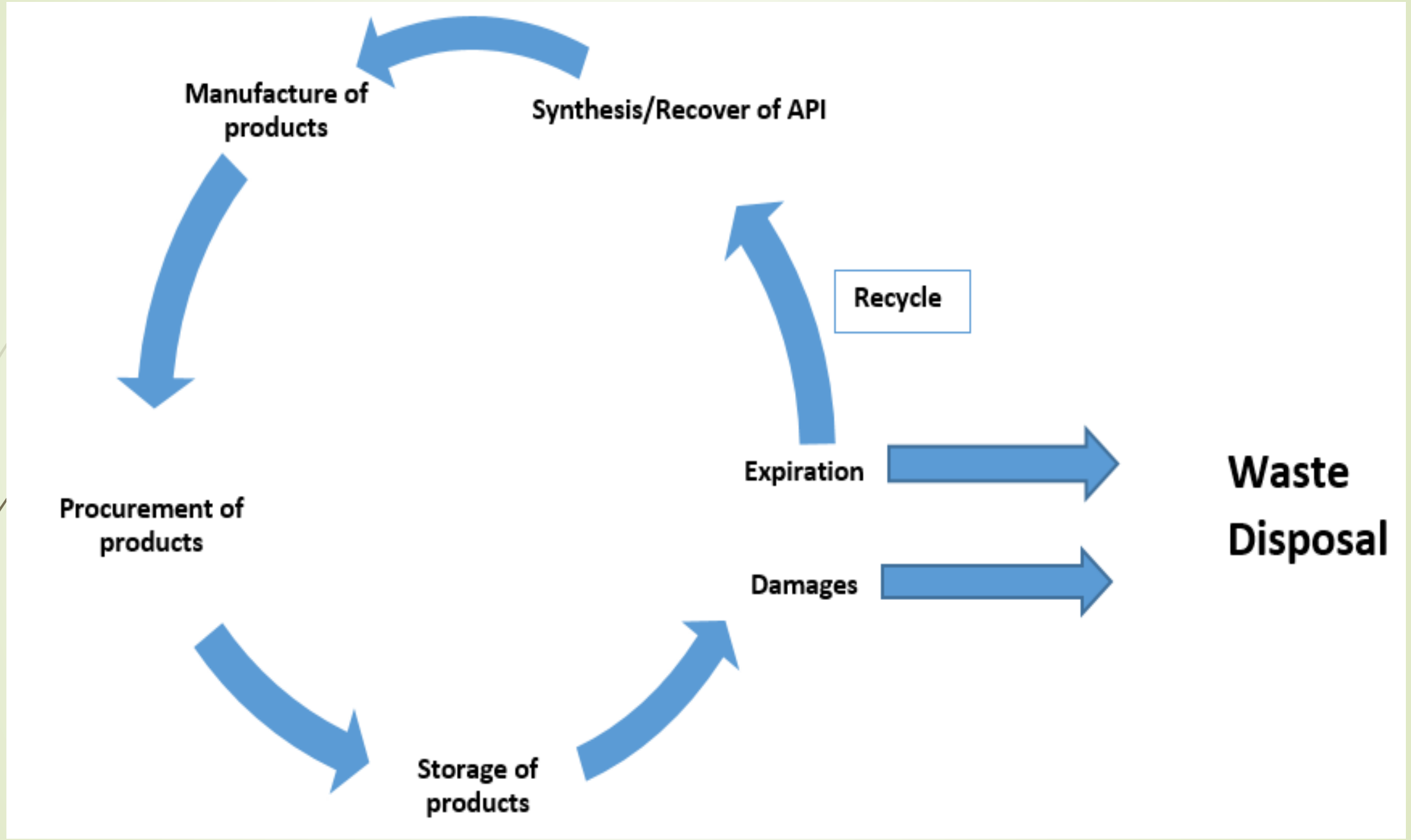
Conclusion: Prospects of a modified API life cycle

- Following the evidences that health care products could still retain substantive safety and efficacy after expiry date, data have emerged indicating techniques to recover the pure API from expired products.

- The qualitative and quantitative evaluations of such recovered API has been shown to be of good quality, and can serve another phase of manufacturing, as may be akin to recycling [Basha, *et al*., 2015].

- One of the studies showed that reuse for the manufacture of other products, or as chemicals for educational purpose is possible [Mohit *et al*., 2019].

- If these applications are to be explored with the intent to address the current stock outs and disposal challenge then, a different prospect for API utilization cycle may emerge as represented below.


Manufacture of products
Synthesis/Recover of API
Recycle
Procurement of products
Expiration
Waste Disposal
Damages
Storage of products