

Estimating the capacity of storage facilities

Technical supplement to
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Annex 9: Model guidance for the storage and transport of time and temperature-sensitive pharmaceutical products

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ECSP/ECBS version

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Abbreviations

EEFO	Earliest-Expiry-First-Out
FIFO	First-In-First-Out
IFRC	International Federation of Red Cross and Red Crescent Societies
ISO	International Standards Organization
MSF	Médecins Sans Frontières
SIA	Supplementary Immunization Activity
SKU	Stock-keeping unit
TTSP	Time and Temperature-Sensitive Pharmaceutical Product
UPC	Universal Product Code
VEN	Vial, Essential, Nonessential

Glossary

ABC analysis: Tool for reviewing stock movement, which categorizes items by the volume and value of consumption during a specific period of time, usually one year. Class A items—10 to 20 percent of items, representing 75 to 80 percent of expenditures—are mostly high-volume, fast-moving medicines. Class B items are usually 10 to 20 percent of items, and 15 to 20 percent of expenditures. Class C items often represent 60 to 80 percent of the items but only about 5 to 10 percent of the total expenditures; these are the low-volume, slow-moving items. Thus, class C is a good place to look for items that might not be needed in stock at all times. See also *VEN analysis*.

Controlled or hazardous products: TTSPPs and other products with high illicit value: poisons, narcotics, psychotropic products, inflammable or explosive substances and radioactive materials.

Gross storage capacity: The gross free volume of a load support system available for storing SKUs. This volume is measured between the shelves of a shelving unit, or between the support beams of a racking system.

Insulated shipper: A single-use insulated passive container, containing coolant, typically used to distribute TTSPPs by road or air transport.

Inventory turnover: A measure of the number of times inventory is sold or used in a time period such as a year. The equation for inventory turnover equals the cost of goods sold divided by the average inventory. Inventory turnover is also known as inventory turns, stockturn, stock turns, turns, and stock turnover.

Net storage capacity: The total volume available for storing TTSPPs, taking account of the type of load support system employed (floor-standing pallets, adjustable pallet racking, shelving units or cabinet). Net storage capacity is calculated by multiplying the gross storage capacity of the load support system by the utilization factor (less than one) that can be achieved for the chosen SKU type.

Pallet: Wooden or plastic platform designed to be lifted by pallet jack or forklift truck. Typically used for storing and handling tertiary cartons.

Pharmaceutical product: Any product intended for human use or veterinary product intended for administration to food producing animals, presented in its finished dosage form, that is subject to control by pharmaceutical legislation in either the exporting or the importing state and includes products for which a prescription is required, products which may be sold to patients without a prescription, biologicals and vaccines. Medical devices are not included¹.

Primary container: Bag, blister pack, strip, bottle, cartridge, vial, ampoule, prefilled device, plastic dispenser, tube, single dose container or the like containing tablet(s), capsule(s), liquid preparation or the like.

Refrigeration equipment: The term 'refrigeration' or 'refrigeration equipment' means any equipment whose purpose is to lower air and product temperatures and/or to control relative humidity.

¹ Definition from WHO/QAS/08.252 Rev 1 Sept 2009. *Proposal for revision of WHO good distribution practices for pharmaceutical products – Draft for comments.*

Secondary pack or carton or market package: The package presentation intended for the end user (e.g. bottle + cap liner + dose cap + leaflets + carton) but not including packaging used solely for transport purposes (e.g. *Tertiary carton* or *Insulated shipper*). The secondary pack may contain multiple units of product.

Standard Operating Procedure (SOP): A set of instructions having the force of a directive, covering those features of operations that lend themselves to a definite or standardized procedure without loss of effectiveness. Standard operating policies and procedures can be effective catalysts to drive performance improvement and improve organizational results.

Stock-keeping unit (SKU): In the field of inventory management, a code number, typically used as a machine-readable bar code, assigned to a single item of inventory. As part of a system for inventory control, the SKU represents the smallest unit of a product that can be sold from inventory, purchased, or added to inventory. Applied to wholesale, retail, or production operations, the SKU can assist in monitoring transactions, tracking customer spending patterns, controlling inventory and purchasing, and providing information about pricing², for example via its Universal Product Code (UPC). In the context of this Technical Supplement, and depending on the level in the supply chain, an SKU may be a complete pallet, a tertiary carton, a secondary carton or a primary container.

Temperature-controlled: Includes any environment in which the temperature is actively or passively controlled at a level different from that of the surrounding environment within precise predefined limits.

Temperature-modified: Includes any environment in which the temperature is predictably maintained at a level different from that of the surrounding environment, but is not actively or passively controlled within precise predefined limits.

Tertiary pack or carton: The pack/carton that contains a number of secondary cartons; usually constructed of corrugated fibreboard. *Note:* the tertiary carton is not the same as the insulated shipper used for international air shipment of TTSPPs, although the insulated shipper may contain one or more of these cartons.

Time and temperature sensitive pharmaceutical product (TTSP): Any pharmaceutical good or product which, when not stored or transported within pre-defined environmental conditions and/or within pre-defined time limits, is degraded to the extent that it no longer performs as originally intended.

Utilization factor: The percentage of the total volume available for storing TTSPPs that can reliably be achieved in practice, taking account of the types of stock-keeping unit (SKU), the types of load support system and the stock management systems used in the store.

VEN analysis: Method for categorizing stock as vital (V), essential (E), or nonessential (N). This system is sometimes modified to two categories—V and N. VEN analysis is often used to prioritize procurement when not enough funds exist to purchase all items requested. The system can also help determine which items should be kept in stock and which can be ordered when needed. See also *ABC analysis*.

² Source: <http://www.britannica.com/EBchecked/topic/1242199/SKU>

1. Introduction

This technical supplement has been written to amplify the recommendations given in Section 3.1 to 3.4 of WHO Technical Report Series No. 961, 2011, Annex 9: *Model guidance for the storage and transport of time- and temperature-sensitive pharmaceutical products*³.

Related topics are covered in the following Technical Supplements:

- *Design of storage facilities.*
- *Maintenance of storage facilities.*
- *Qualification of temperature-controlled storage areas.*
- *Security and fire protection in storage facilities.*

1.1 Requirements

Pharmaceutical warehouses and other related storage facilities need to be of an appropriate size to store sufficient TTSPPs and other products to meet demand, taking account of the following factors:

- a. The frequency of supply from product manufacturers and/or from higher level warehouses or storage facilities;
- b. Levels of safety stock to be held for each product line stored;
- c. Frequency of onward delivery to lower level stores or health facilities;
- d. Patient demand for each product line, taking account of seasonal and other fluctuations in consumption.
- e. Seasonal re-supply factors, such as road closures caused by flooding and the like.

In the case of an existing storage facility, decisions regarding factors a, b and c are in turn affected by the actual storage capacity of the building and the opportunities available for reorganization or expansion.

1.2 Objectives

The objective of the Technical Supplement is to provide guidance on how to meet the above requirements. The document only covers the process of determining the *net storage capacity* required; it does not cover the related process of determining the gross capacity of the storage area and the size of loading bays, packing areas, administrative areas and the like. This is part of the subsequent building design process, described in the companion supplement: *Design of storage facilities*.

The supplement borrows from, and updates, the methodology described in a 1993 WHO document, *How to estimate warehouse space for drugs*⁴. It describes a way of establishing the minimum net capacity of a store and for calculating the net capacity of sub-stores within such a store; for example, cold rooms.

On a continuing basis, the methodology may be used to assist with the planning of forthcoming purchases and deliveries so as to ensure that they do not exceed available

³ <http://apps.who.int/medicinedocs/documents/s18683en/s18683en.pdf>

⁴ WHO/DAP/93.3

warehouse capacity. This on-going review process is particularly important for health programmes undergoing rapid growth. The collected data may also be used to check the capacity of existing stores when supply circumstances change. Finally, the data may also be used to assess transport volumes and to check that adequate temporary storage space is available at ports and airports when deliveries arrive.

1.3 Target readership

The supplement provides guidance aimed at more senior operations staff. Principally these will be the owners and operators of warehouses, pharmacies and other buildings used to store TTSP's and those responsible for property development and property acquisition on behalf of owners and operators. It will also be of value to those responsible for preparing a brief for the medical warehouse design team when designing or procuring storage facilities.

2. Guidance

Correct estimation of the net volume of TTSPPs, general pharmaceuticals and other related supplies is the critically important first step in designing or procuring a warehouse. It is also essential information for estimating the volume of goods flowing into and out of the facility so that transport requirements can also be calculated. Without these data it is impossible to determine how large a building is required, or to estimate the associated TTSPP cold storage capacity needed within the warehouse. Similar net volume data are also needed to calculate realistic storage requirements for smaller facilities, such as hospital pharmacies or health centres, and also to determine the capacity of refrigerators and freezers in these facilities.

This supplement provides an introduction to some of the concepts involved, outlines the key decisions that should be made and identifies the data that need to be collected. The basic questions that have to be answered in order to size a pharmaceutical warehouse or store can be summarized as follows:

- Which products are to be stored?
- How many units of each product must be stored?
- What is the product's unit volume in the SKU type applicable to this particular storage level (e.g. carton, case, pallet, etc.)?
- What is its ABC and/or VEN rating?
- At what temperature must it be stored?
- Under what security regime must it be stored (e.g. normal security, controlled or hazardous)?
- Does it have an expiry date?

The ABC or VEN rating of the product needs to be recorded because this will affect the final physical layout of the building and the sub-areas within the store – for example 'A' or 'V' rated products tend to be fast-moving lines and some or all of the stock must be readily accessible for efficient order picking. Similarly, products without an expiry date do not necessarily have to be stored in First-In-First-Out (FIFO) order, but could be block stacked or stored on double-deep or drive-in racking to make the most efficient use of storage space. See companion technical supplement: *Design of storage facilities*. This is in contrast to products with an expiry date which have to be stored in Earliest-Expiry-First-Out (EEFO) order.

2.1 Associated materials and equipment

None required.

2.2 Inventory management concepts

There is a great deal of excellent information available on the subject of inventory management. See for example MDS-3. *Managing access to medicines and health technologies, Chapter 23: Inventory management*⁵. A good understanding of this topic is a

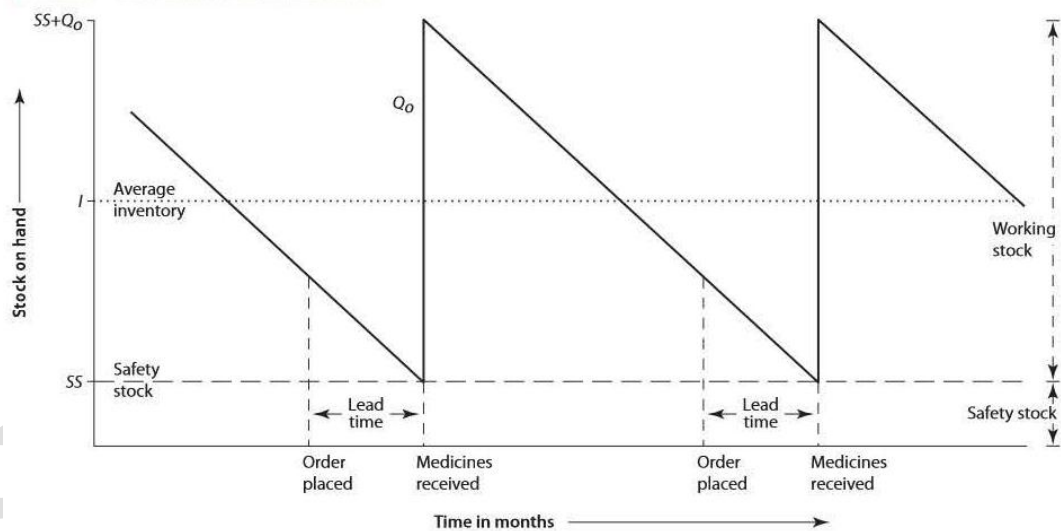
⁵ <http://www.msh.org/sites/msh.org/files/mds3-ch23-inventorymgmt-mar2012.pdf>

necessary precondition for sizing a pharmaceutical store⁶; decisions and assumptions have to be made about the frequency with which the store will be resupplied with goods, the frequency with which these goods will be distributed from the store, or, in the case of a pharmacy or health facility, the rate at which they will be dispensed. Combined with ABC and/or VEN analysis and related policy decisions on the desired service level – the probability that the store will be able to satisfy a medical request involving a particular product⁷ – these decisions in turn affect the levels of safety stock to be held in the store. Use and distribution of products is also categorized by the level of care (e.g. hospital, health centre, health post); storage volume estimates also have to take this factor into account.

Whenever an inventory management system is designed or restructured, safety stock policy is an important consideration. The policy on safety stock may differ at each level of the system, between products, or between different facilities at the same level (depending on VEN and ABC classification systems, lead times, and consumption patterns). The objective is to provide maximum service levels throughout the supply system with minimum necessary total safety stock.

Figure 1 illustrates the principles of the ‘ideal’ inventory control model. In this ideal model, pharmaceuticals are issued in response to demand, but stockouts are not permitted; the stock on hand steadily declines until the point at which an order must be placed.

Figure 1 – The ideal inventory control model



Source: MDS-3: Figure 23-3

The stock on hand consists of two components: the working stock (WS) and the safety stock (SS). In the ideal model, the supplier performs according to plan, the shipments arrive on time, the quantity ordered (Q_0) is received, and the inventory level returns back to its starting maximum point ($Q_0 + SS$). Working stock varies from zero to the quantity

⁶ The material in the remainder of section is a slightly adapted quotation from MDS-3.

⁷ 100 percent service level is desirable, at least for vital items; setting lower goals might be reasonable for nonessential medicines and supplies.

ordered and represents the stock used to satisfy demand between deliveries. Note that in the ideal model, the average working stock is half of the order quantity:

$$\text{Average working stock (WS)} = \frac{1}{2} Q_o$$

The average inventory (I) or average stock on hand is the safety stock plus the average working stock:

$$I = SS + \frac{1}{2} Q_o$$

When medicines are used at a constant rate, the line in Figure 1 representing stock on hand declines with a constant slope.

In order to reduce the average inventory and thereby reduce the inventory-holding costs – and by extension the size of the required storage facility – the working stock, the safety stock, or both can be lowered. Large, infrequent orders lead to high average inventory levels. The average working stock can be reduced by placing smaller orders more frequently. The average inventory can also be reduced by cutting the safety stock, but this method increases the chance of stockouts. Alternatively, inventory-holding costs may be reduced through improved storekeeping practices and by better financial management – for example by bulk purchasing.

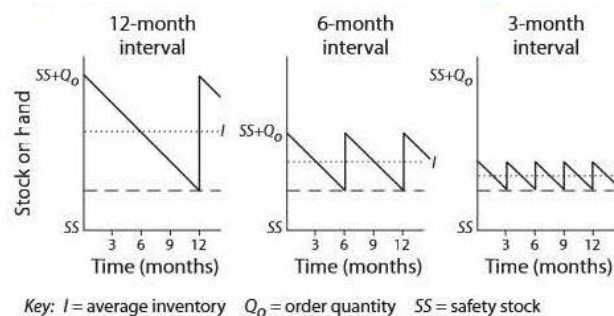
As illustrated in Figure 1, any inventory control model used to manage purchasing must address the following issues—

1. *Safety stock*—how much stock will be kept in reserve to prevent stockouts;
2. *Reorder frequency*—the period of time between each order for an item (also known as the procurement period);
3. *Reorder quantity*—the number of units specified when an order is placed.

In addition, *storage capacity*—the amount of space available for storage—needs to be considered when determining target stock levels and ordering and replenishment frequency.

The policy on reorder frequency has a major influence on average stock levels and inventory-holding costs, as well as on service level. Figure 2 shows how a simple change in reorder interval has a dramatic effect on the average inventory held in a store. The ability to control the reorder interval is one of the key levers available to a warehouse manager in the complex process of balancing incoming and outgoing stock and fluctuating demand levels.

Figure 2 – The ideal inventory control model and the effect of reorder interval



Source: MDS-3: Figure 23-4

Clearly the ideal model shown above is not an accurate depiction of reality. The actual flow of product into and out of a store is likely to be much lumpier. Some of the reasons for this are as follows:

- Staggered reorder deliveries for different products and/or suppliers;
- Fluctuating demand leading to unequal distributions;
- Seasonal factors;
- Disease outbreaks.

More sophisticated procurement and reordering strategies can be used to help resolve some of these problems, to the extent that the local context allows.

For all the reasons described above, an essential first step in sizing any pharmaceutical store is a clear understanding of current inventory management policies. A failure to appreciate the implications of these policies may radically affect the ability of the store to operate efficiently and may lead to the procurement of a building which is either too small or unnecessarily large. Equally, a systematic analysis and review of current practices can generate substantial cost savings. For example, the increased procurement costs associated with shortening the supply interval might be outweighed by lower building construction or warehouse rental costs, reduced inventory holding costs and reduced expiry due to faster inventory turnover.

Do not attempt to finalize the sizing of a pharmaceutical warehouse until all parties involved have agreed and understood the physical and operational implications of the following:

- The procurement and supply context;
- The applicable inventory management policies;
- The way in which both of these are likely to change over the foreseeable future.

2.3 Collecting product data

Although good data are available on the volume-per-dose and weight of individual vaccine products and associated injection and waste management equipment, collecting similarly detailed information for general pharmaceutical products and related supplies remains a challenge. It is highly unlikely that data on all products will be available. Accordingly the most effective strategy is to concentrate on collecting information on those products that represent a large physical volume and are the fastest moving items – using the principle of ABC analysis, these 'A' classified products will typically represent about 80% of throughput.

2.3.1 Vaccines

In countries where vaccines are stored and distributed as part of an integrated pharmaceutical supply chain these products can represent a significant proportion of total TTSP volumes⁸. In the field of vaccine logistics, extensive information is available on the volume-per-dose of individual products⁹. These data are used by a number of related tools,

⁸ Many countries still operate a separate vaccine supply chain.

⁹ See the WHO vaccine database at:

http://www.who.int/immunization_standards/vaccine_quality/PQ_vaccine_list_en/en/index.html

enabling logisticians to estimate the required volume per recipient for any specific vaccine schedule¹⁰. Vaccine volume calculation and the associated sizing of cold chain equipment requirements is now a relatively straightforward task. For both routine and supplementary (campaign) immunization the schedule is fixed at national level, and the target populations, coverage and wastage rates are known to a reasonable approximation. In addition there is only a limited range of products. The WHO prequalified vaccine list contains some 35 vaccines in 213 product/presentation combinations¹¹; only a proportion of these combinations are widely used. The list for immunization syringes and safety boxes is also short and data on these products are similarly held on a WHO website¹². An alternative data source is the UNICEF *Cold Chain Weight and Volume Calculator*¹³. This is restricted to vaccine products supplied by UNICEF Supply Division. However it has the advantage that it includes data on the volume of insulated shipping containers.

2.3.2 General pharmaceuticals, including non-vaccine TTSPs

Demand for general pharmaceuticals, including non-vaccine TTSPs, is not as predictable as the demand for vaccines. Quantification of requirements is a specialised topic on which much guidance is available – see for example MDS-3. *Managing access to medicines and health technologies, Chapter 20: Quantifying pharmaceutical requirements*¹⁴.

Estimation is typically based on consumption or morbidity data. Order quantities can then be calculated based on the use classification and stock management principles outlined in Section 2.1. Unfortunately current quantification methodologies and tools only concentrate on estimating the number of doses – or physical units – required for each product; they do not specifically capture physical characteristics (package dimensions and weight) as an aid to logistics planning.

The 2013 WHO Model List of Essential Medicines (adults and children) contains well over 300 generic products, themselves available from multiple manufacturers and in multiple formats¹⁵. The UNICEF Supply Catalogue likewise lists a large number of pharmaceutical products, as does MSF. None of these sources provides any data on physical packed volumes. However, the IFRC catalogue does list shipping weights and volumes for many products and the catalogue entries are cross-referenced to the WHO list – see Figure 3.

¹⁰ See for example the EVM Assistant tool and user guide at:

http://www.who.int/immunization/programmes_systems/supply_chain/evm/en/index3.html

¹¹ WHO vaccine database, accessed January 2014.

¹² See the WHO PQS database and catalogue at:

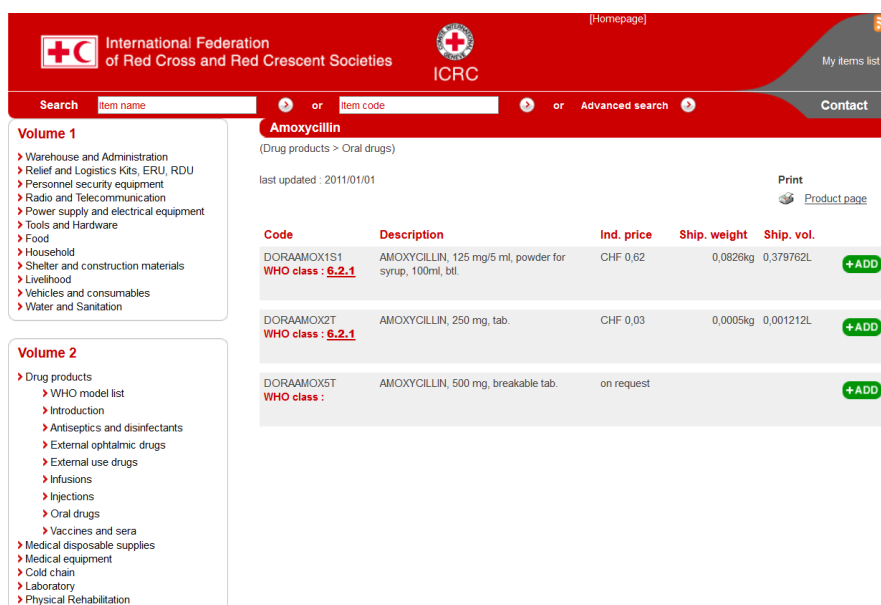
http://apps.who.int/immunization_standards/vaccine_quality/pqs_catalogue/

¹³ http://www.unicef.org/supply/files/Cold_Chain_Weight_and_Volume_Calculator.xlsm

¹⁴ <http://www.msh.org/sites/msh.org/files/mds3-ch20-quantifying-mar2012.pdf>

¹⁵ In 1977 WHO listed 220 essential medicines; this had risen to 340 by 2010. Source: WHO.




Figure 3 – IFRC catalogue page






Source: <http://procurement.ifrc.org/catalogue/detail.aspx?productcode=DORAACSA>

In addition, the UNICEF Catalogue uses an icon classification system which is helpful in allocating products to specific storage zones based on temperature and/or security and/or safety considerations. Table 1 shows a sample.

Table 1 – UNICEF catalogue icons

Icons	Category	Detailed description
	Temperature considerations	<p>Cold Chain temperature requirements: Constant temperature between +2 to +8°C at all levels from manufacturer to the end user.</p> <p>Cool Chain temperature requirements: Constant temperature between +8 and 15°C at all levels from manufacturer to the end user.</p> <p>Controlled Room Temperature¹⁶: Temperature between +15°C and +25°C.</p> <p>Pharmaceutical products: Unless specified as having cold chain or cool chain requirements, should be kept at controlled room temperature and not above 25°C or in a freezer during transport and storage; unless otherwise specified on the label.</p> <p>Vaccines: Sent directly from manufacturers.</p> <p>Polio vaccines should be stored between -15 to -25°C at primary cold chain stores. At the lower service delivery point, they should be stored between +2 to +8°C.</p> <p>All other vaccines should be stored between +2 to +8°C at all levels.</p> <p>Diagnostics: Should be kept at controlled room temperature and not above 25°C or in a freezer during transport and storage; unless otherwise specified on the label.</p>
	Narcotic/psychotropic substance	Narcotic and or psychotropic substances, which require import authorisation. i.e. Diazepam, Phenobarbital, Morphine, Ketamin, as well as related kits (IEHK kit, suppl.1a-drugs, Midwifery kits, suppl.1a-drugs, Obstetric, surgical kit, suppl.1a-drugs).
	Hazardous materials	Items that are classified as hazardous materials (dangerous goods) are subject to transport restrictions i.e. requiring special labelling and packaging in accordance

¹⁶ The UNICEF catalogue defines controlled room temperature as: *Temperature between 20°C and 25°C. Excursions between 15°C and 30°C and spikes up to 40°C are permitted, as long as they do not exceed 24 hours.* However +15°C to +25°C is generally available in most third party warehouses.

Icons	Category	Detailed description
		with international rules on handling and transportation of hazardous materials. Depending on the danger classification, some hazardous materials must be shipped by sea.
	Air only	Items requiring cold chain transportation/storage must be sent only by air. Items include vaccines and Oxytocin, and related kits (IEHK kit, suppl.1a-drugs, Midwifery kits, suppl.1a-drugs, Obstetric, surgical kit, suppl.1a-drugs).
	Shelf life	Items with a shelf life.
	Storage considerations	Some items require specific storage conditions.

In the absence of a comprehensive central database of product volumes and weights, the analyst has to rely on those sources that are available. This includes data collected locally from on-site measurement and from the shipping documentation provided by supply agencies, manufacturers and distributors.

For an alternative approach to data collection, refer to the 'Layout planning' section of the JSI document: *Guidelines for Warehousing Health Commodities*.

2.3.3 Volume data and SKU types

It is important to be clear about the type of Stock-keeping Unit (SKU) to which the collected volumetric data applies. In the case of vaccines, there are three 'levels' of SKU that are relevant to warehouse sizing:

- Secondary carton:* The first level is the secondary carton¹⁷ which contains the vaccine vials or 'primary containers'.
- Tertiary carton:* Some vaccines are supplied in tertiary cartons or cases, each containing a number of secondary cartons; the additional layer means that the volume-per-dose for this SKU type is slightly increased.
- Insulated shipping container:* Finally, when vaccines are shipped by air, they are generally packed with coolant in insulated shipping cartons. For ease of bulk handling, some countries choose to store their vaccines at the central warehouse level in these containers. The thickness of the insulation and the space occupied by coolant means that the volume-per-dose for this SKU type can be several times greater than the product's listed volume-per-dose in a secondary carton SKU¹⁸.

If these volumetric differences are not recognized in the process of estimating net storage volume, the size of a cold room calculated on the basis of the published WHO figures will be far too small. Similar volume-per-dose ranges apply to other TTSPs, especially those that are air-freighted in insulated containers¹⁹.

When carrying out a net volume calculation, do ensure that the dimensional and weight data that are used are correct for the SKU type which will be held in the store.

¹⁷ The WHO vaccine database publishes the volume-per-dose in a secondary carton SKU. The database is gradually being extended to include data on tertiary cartons and insulated shipping containers.

¹⁸ For information on shipping container volumes, see also the UNICEF *Cold Chain Weight and Volume Calculator*.

¹⁹ It is possible to ship TTSPs in actively cooled sea or air containers. In this case, insulated packaging might be unnecessary.

Larger and bulkier SKUs with greater unit volumes are typically stored and transported at higher levels in the supply chain. When bulk is broken for distribution to peripheral facilities, SKU dimensions and unit volumes will generally be smaller.

2.4 Calculating maximum inventory volumes

Once the relevant SKU volume data have been collected, as described in the previous section, inventory volume calculations for each product can be carried out.

Do make allowances for fluctuations in demand and resupply for individual products. In addition, do make sure that you take account of future programme expansion plans and include an adequate allowance for new product lines, including new vaccine introductions.

2.4.1 Vaccines and related supplies

Vaccine volume requirements can be calculated using one of the WHO Excel tools that have been designed for this purpose – see **Tools** section. The general principle on which these tools work is described by the formulae below.

Maximum stored volume of each vaccine used for routine immunization:

$$IV_{max} = (P_{tot} \times \frac{T}{100} \times \frac{1}{R_f} \times \frac{100}{(100-W)} \times \frac{(100+SS)}{100} \times V_{dose} \times D_{series}) / 1,000,000$$

Maximum stored vaccine volume for supplementary immunization activities (SIA):

$$IV_{max} = (P_{tot} \times \frac{T}{100} \times \frac{100}{(100-W)} * V_{dose}) / 1,000,000$$

Where:

- IV_{max} Maximum inventory volume for the specific vaccine, in cubic metres;
- P_{tot} Total population: This is used as the basis for standardising a population target for each vaccine;
- T Target population percent: This is the percentage of the total population targeted to receive a specific vaccine for a specific immunization purpose. For example, the target population percentage for birth-dose hepatitis B is different from the target population for the same vaccine given to health workers.
- R_f Reorder frequency: the number of times that vaccine is scheduled to be received by a store or facility in one year;
- W Percentage of vaccine wasted during distribution and delivery: the formula for this term converts the percentage *wastage rate* for the vaccine into the *wastage factor*;
- SS Safety stock: Expressed as a percentage of the working stock;
- V_{dose} Vaccine volume-per-dose in cm³ is measured at the level of the type of SKU applicable to the store (secondary carton, tertiary carton of shipping container);
- D_{series} Number of doses per series as set out in the immunization schedule. When this figure is multiplied by the vaccine volume-per-dose, it gives the volume of packed vaccine for a completed series of immunizations.

Note: When using formula B, review the planning data for future supplementary activities to estimate the worst-case total vaccine volume. This depends on both target population

and vaccine volume-per-dose. If deliveries for parallel SIAs coincide, the maximum volumes for each activity must be summed.

The data needed for the storage volume calculations for syringes and sharps safety boxes relate closely to the formulae described above and are calculated within the tools referenced below. The calculation method takes account of the following factors:

- *Vaccine formulation*: oral or injectable; liquid or lyophilized (and requiring a separate reconstitution syringe);
- *Vaccine presentation*: single or multi-dose vials or pre-filled injection device;
- *Safety box capacity*: Number of used syringes or pre-filled devices that can be accommodated into the chosen size of safety box;
- *Syringe wastage*: A small proportion of syringes will be wasted due to breakage or mishandling.

Similar calculations can be carried out for the injection device and waste management needs of other injectable products.

2.4.2 General pharmaceuticals and supplies, including non-vaccine TTSPPs

To calculate maximum net inventory volumes for general pharmaceuticals, use the following formula:

Maximum stored volume for general pharmaceuticals and supplies:

$$IV_{max} = (AD \times \frac{1}{R_f} \times \frac{(100+SS)}{100} \times V_{unit}) / U$$

Where:

IV_{max} Maximum inventory volume for the specific product line;

AD Annual demand: This is the estimated number of units of the product required per year obtained from the requirements quantification process;

R_f Reorder frequency: The number of times that the product is scheduled to be received by a store or facility in one year;

SS Safety stock percent: Stores must be sized to allow for an appropriate reserve stock; this may vary from product to product depending on its ABC or VEN classification;

V_{unit} Volume-per-unit: Measured in at the level of the type of SKU applicable to the store (primary container, carton, pallet or other SKU); this may be expressed in cm^3 (divisor = 1,000,000), litres (divisor = 1,000) or m^3 (divisor = 1).

U Volume conversion unit: The divisor needed to convert the result into cubic metres.

2.5 Calculating net storage capacity requirements

By the end of the procedure described in Section 2.6, the maximum inventory volume for each product line will have been calculated. However, a figure for maximum inventory volume on its own does not tell you where in the store each product line should be kept, or how much actual space it will actually occupy in the store. In order to establish this it is necessary to classify every product by storage temperature and security category and then

to establish the most suitable type of load support system within each of these storage zones.

2.5.1 Classifying products by storage temperature and security category

The first step in the sizing process is to group products in 'families' according to their labelled storage temperature and security regime. Table 2 shows a matrix for establishing the possible combinations, based on the UNICEF catalogue classifications shown in Table 1²⁰ – not all of these will be relevant in any particular situation. This allocation process has significant implications for the final design of the store. For example, should TTSPP narcotics be stored in a locked or caged off area of the main cold room, or should they be located in a separate secure cold room or in a refrigerator in a separate locked room? The decision will depend partly on the relative volumes involved and partly on a detailed risk assessment of the individual products in the context of the actual operating environment.

In the classification shown below, space has been allowed for products that require a 'normal' level of security, controlled products such as narcotics or poisons which have a high illicit value or are dangerous and must be kept in a secure locked compound, and hazardous products which are inflammable, explosive or radioactive and require special storage conditions, such as an explosion-proof refrigerator or a room with an explosion hatch. Some products may be both 'controlled' and 'hazardous'.

Table 2 – Temperature and storage regime 'families'

Temperature	Normal security	Controlled	Hazardous	Controlled and hazardous
Below -25.0°C				
-15.0 to -25.0°C				
+2.0 to +8.0°C				
+8.0 to +15.0°C				
+15.0°C to +25.0°C				
Uncontrolled ambient				

When the applicable combinations have been identified, the total net storage volume for each category can be entered in the table above by sorting the cumulative volume data into the relevant categories.

2.5.2 Load support systems

The most common load support systems are shelves (open or closed), floor standing pallets and multi-level pallet racking systems. In addition, secure cupboards may be used for narcotics and hazardous substances and drawers may be used for smaller items. There are also a number of other more sophisticated systems such as flow racking and carousels which can be used to increase picking efficiency. Finally, in smaller facilities, TTSPPs are likely to be kept in refrigerators or freezers rather than in cold stores with bulk storage on

²⁰ Other classifications are used. For example, MSF lists five temperature regimes: -15 to 0°C, +2 to +8°C, +5 to +25°C, +5 to +35°C and +5 to +40°C (unpublished draft warehouse design guideline).

shelving or racking. Refrigerators and freezers may be front opening or top opening, so the product may be stored on shelves or in baskets.

Comprehensive guidance on the use and limitations of most types of load support system is given in the JSI document: *Guidelines for Warehousing Health Commodities*.

2.5.3 The utilization factor concept

A refrigerator, a drawer, a shelving bay or a pallet racking bay has a certain gross storage capacity available for storing goods – defined by the length, width and height of the free storage volume, measured inside the cabinet, between shelves, or between racking support members and the like. Only in exceptional cases can this volume be fully occupied by stored product. In practice the available volume has to be modified by a *utilization factor* which will always be less than one. How much less than one depends on a number of additional factors, including:

- *Storage method*: The two basic methods are *fixed* and *fluid*. In fixed-location storage, each (SKU) is always kept in a specific location. No other SKU can be stored in that location, even if the location is empty. In fluid-location storage, any SKU can be assigned to any free location. It is possible to have both fixed and fluid systems operating in a warehouse simultaneously. In fact, this arrangement is sometimes preferable. A typical arrangement would call for most bulk supplies to be stored on pallets and loose items to be stored on shelves. A fixed-location system is used for items stored on shelves; a fluid-location system is used for the pallets stored on the pallet racks. Table 3 indicates the appropriate use of the two methods²¹.

Table 3 – Storage method by commodity type

Type of commodity	Storage method	Example types
Low inventory items stored and issued in smaller packs	Fixed (entire stock kept on shelves)	Specialized medicines
Bulky items stored and issued in complete pallets	Fluid (entire stock kept on pallets)	Equipment
Items contained in large cartons stored on pallets but issued in smaller packs	Fixed (stock to be issued kept on shelves) and fluid (bulk stock kept on pallets)	Essential drugs that are issued by bottles or small packs; condoms

Source: JSI | DELIVER: *Guidelines for Warehousing Health Commodities*. Table 5.

- *Dimensional compatibility*: The way in which the product fits the available storage space. For example a carton that is 35 cm high will make poor use of a shelving bay if the shelves are fixed at 60 cm apart;
- *Space occupied by additional elements*: For example, the volume of the supporting pallet in a pallet racking bay uses a proportion of the available storage volume.
- *Ventilation around the product*: This is a particular requirement in cold rooms where it is necessary to maintain a good airflow to ensure even temperature distribution.
- *Unsuitable zones*: Some parts of the load support system may be unsuitable for storing particular products due to temperature deviations or temperature

²¹ Adapted from JSI | DELIVER: *Guidelines for Warehousing Health Commodities*.

stratification – see the companion Technical Supplement: *Qualification of temperature-controlled storage areas*.

- *Ease of access*: For example, a health facility refrigerator containing a mix of products may be packed quite loosely so that the health worker can easily access individual products. This reduces effective volume utilization.

2.5.4 Pallet bay calculation

Table 4 shows the six ISO pallet sizes; of these, the EUR-EPAL and the US 40" x 48" are widely encountered. The latter makes particularly efficient use of the space in standard ISO shipping containers. Other non-ISO sizes are also used, including the EURO pallet range.

Table 4 – Standard ISO pallets

Dimensions, mm (W × L)	Wasted floor in ISO container	Region where most used
1016 × 1219 (40" x 48")	3.7% (20 pallets in 40 ft ISO)	North America
1000 × 1200	6.7%	Europe, Asia; similar to 40" × 48".
1165 × 1165	8.1%	Australia
1067 × 1067	11.5%	North America, Europe, Asia
1100 × 1100	14%	Asia
800 × 1200 (EUR-EPAL)	15.2%	Europe; fits many doorways

Source: <http://en.wikipedia.org/wiki/Pallet>

The volume of product that can be stacked on a pallet depends on the size of the pallet, the extent to which the product cartons coordinate with the pallet footprint, and the stacking height. In practice, a reasonable assumption is that a EUR-EPAL can hold an average of about 0.8 m³ and a US 40" x 48", or ISO 1000mm x 1200mm pallet, can hold about 1.0 m³. On this basis²² the following formula can be used to estimate the number of pallet bays required for each of the product lines which will be allocated for pallet storage.

$$N_{pallet} = \frac{IV_{max}}{V_{pallet}}$$

Where:

N_{pallet} Number of pallets required to store the product line;

IV_{max} Maximum inventory volume for product line, in cubic metres;

V_{pallet} Average volume of product per pallet, in cubic metres.

2.5.5 Shelving unit calculation

A reasonable rule is that only half to two thirds of the gross storage capacity of shelving units²³ can actually be occupied by product – a utilization factor between 0.5 and 0.65. When planning a store layout it is safer to adopt the lower figure, although the use of an adjustable shelving system may allow more efficient use of the available volume.

²² Source: JSI | DELIVER and MSF.

²³ The volume measured between shelves.

In warehouses, especially those that include pallet racking, the top shelf is often much lower than the ceiling so that storing product at this level is not restricted by ceiling height; instead, the maximum stacking height is restricted by the need to be able to access the product on the upper shelves. If access is from floor level, the height of the top shelf should be no more than 1.7 to 1.8 metres above the floor, and no more than 1.6 to 1.7 metres if the shelves are wider than 600 mm. If access is from a mobile ladder, the maximum shelf height can be increased to about 2.7 metres.

In smaller stores and in walk-in cold rooms and freezer rooms, ceiling height is often restricted and product on the top shelf has to be arranged so that there is space for air circulation above the load.

The following two formulae can be used to assess the length of shelving unit required, in metres, to store a given net volume of product, expressed in cubic metres²⁴. The first version is used where ceiling height is restricted; the formula assumes a clearance of 10 cm between the top of the load and the ceiling for air circulation. The second version is used where ceiling height is not restricted; in this case the height of the load placed on the top shelf is assumed to be 40 cm – this figure can be changed.

Shelf unit length (restricted ceiling height):

$$L_{shelf} = \frac{IV_{max}}{(H_{room} - (b + (n \times t) + 0.1)) \times w \times UF}$$

Shelf unit length (unrestricted ceiling height):

$$L_{shelf} = \frac{IV_{max}}{(H_{unit} + 0.4 - (b + (n \times t))) \times w \times UF}$$

Where:

L_{shelf} Length of shelving unit required to store the product line, in metres;

IV_{max} Maximum inventory volume for the product to be stored, in m³;

H_{room} Room height, in metres;

H_{unit} Height of shelving unit from floor to top shelf, in metres;

b Height of underside of bottom shelf from floor, in metres;

n Number of shelves;

t Shelf thickness, in metres;

w Shelf width, in metres;

UF Utilization factor (from 0.5 to 0.65).

If standard sized shelving unit bays with a known gross storage capacity are used (including the gross storage volume above the top shelf), an alternative and simpler approach is to use the following formula:

$$N_{bay} = \frac{IV_{max}}{V_{bay} \times UF}$$

Where:

²⁴ The first two calculation methods described below can be found in the WHO *EVM Assistant tool*.

- N_{bay} Number of shelving bays required to store the product line;
- IV_{max} Maximum inventory volume for the product to be stored, in m^3 ;
- V_{bay} Gross capacity of one shelving bay, in cubic metres;
- UF Utilization factor (from 0.5 to 0.65).

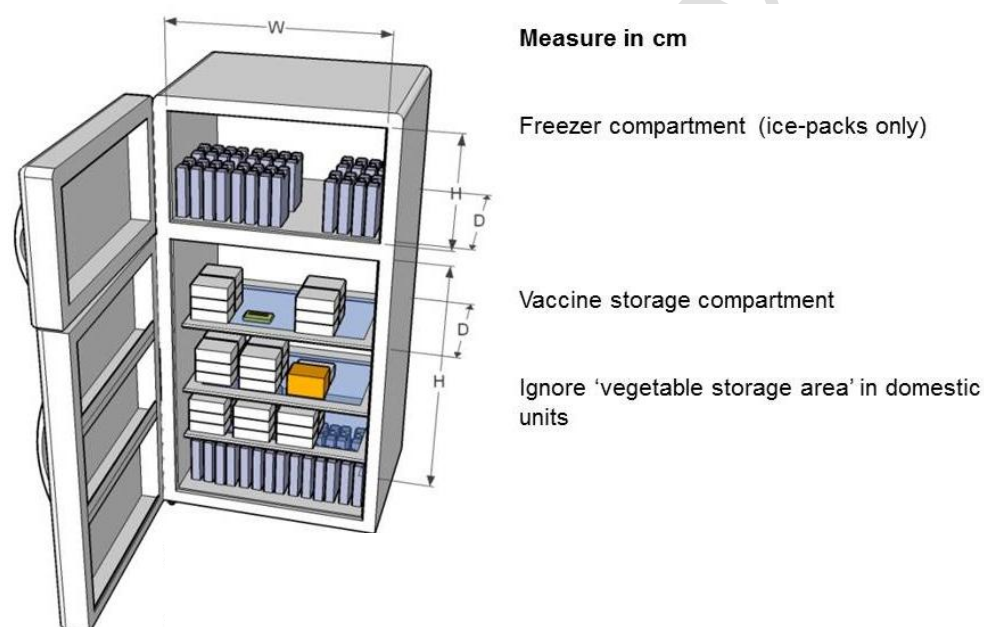
2.5.6 Closed shelving units and safety cabinets

These units are used to store controlled and hazardous products. It is reasonable to apply a utilization factor of 0.5 to the rated capacity of the unit.

2.5.7 Refrigerators and freezers

Data on gross and net storage capacity for WHO prequalified vaccine refrigerators and freezers are published in the WHO *PQS catalogue*. For non-prequalified products, and where manufacturer's data are not available, the method described in Figure 1 can be used.

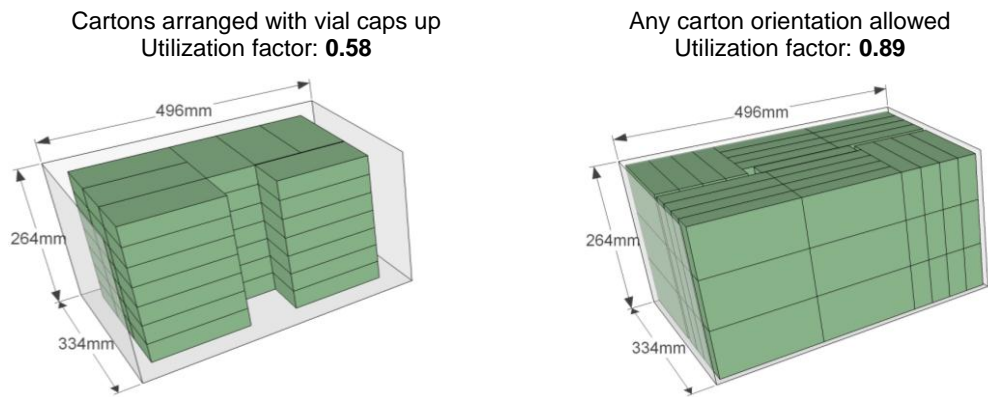
Figure 1 – Measuring capacity of a front opening refrigerator



2.5.8 Load optimization tools

Numerous software tools are available, designed to optimize available storage volume on load support systems and in transport vehicles. These tools can also be used to make efficient use of the storage space when stacking pallets, packing shipping cartons, cold boxes and the like – see **Tools** section. Figure 2 illustrates an example of a cold box packing problem, solved by using one of these packages. The calculation produces an image of each packing arrangement, together with the relevant utilization factor.

Figure 2 – Cartons of vaccine packed in a prequalified cold box



Many of these tools can handle the optimization of mixed loads – the most sophisticated versions are used to drive robotic pallet stackers.

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<http://www.who.int/medicines/publications/essentialmedicines/en/index.html>
- *WHO List of Prequalified Medicinal Products*
<http://apps.who.int/prequal/query/ProductRegistry.aspx>
- *WHO PQS catalogue*
http://apps.who.int/immunization_standards/vaccine_quality/pqs_catalogue/categorylist.aspx
- *WHO Technical Report Series, No. 902, 2002. Annex 9. Guidelines on packaging for pharmaceutical products*
http://www.who.int/medicines/areas/quality_safety/quality_assurance/GuidelinesPackagingPharmaceuticalProductsTRS902Annex9.pdf
- *WHO Technical Report Series No. 961, 2011, Annex 9: Model guidance for the storage and transport of time- and temperature-sensitive pharmaceutical*
<http://apps.who.int/medicinedocs/documents/s18683en/s18683en.pdf>

Tools

Load optimization tools:

- Cape Systems. <http://www.capesystems.com/index.htm>
- CubeIQ. <http://www.magiclogic.com/>
- CubeMaster Online. <http://www.cubemaster.net/Subscription/home.asp>
- Iris Pallet. <http://www.iris-it.com/en/products/robotics/palletization-software.html>
- Logen. <http://www.logensolutions.com/default.html>
- PLMPack Stackbuilder (freeware). <http://stackbuilder.codeplex.com/>
- QuickPallet Maker. <http://www.koona.com/qpm/>
- TOPS Pro and Maxload Pro. <http://www.topseng.com/index.html>

Quantification tools:

- Center for Pharmaceutical Management, Management Sciences for Health.
Quantimed: Pharmaceutical Quantification and Cost Estimation Tool. Arlington, VA. 2011.
<http://www.emtct-iatt.org/wp-content/uploads/2013/02/Quantimed-Pharmaceutical-Quantification-and-Cost-Estimation-Tool.pdf>

Vaccine volume calculation tools:

- UNICEF *Cold Chain Weight and Volume Calculator and User Guide*.
http://www.unicef.org/supply/files/Cold_Chain_Weight_and_Volume_Calculator.xls
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Revision history

Date	Change summary	Reason for change	Approved